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1factory QMS User Manual

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Introduction

Welcome to 1factory's QMS! This guide is designed to ensure a smooth transition from your current Quality Management System (QMS) to our electronic Quality Management System (eQMS). By following the steps outlined in this user manual, you will be able to efficiently configure, populate, and utilize 1factory's QMS to meet your organization's unique needs.

1factory's eQMS is designed to help organizations streamline their quality management processes, ensuring accuracy, compliance, and efficiency. With features such as automated document control, real-time traceability, and robust user management, 1factory eQMS empowers your organization to maintain high standards of quality while simplifying the management of complex documentation and processes.

0.0 Preface

0.1 Definitions

Automated Training: Training assignments automatically generated during QMS document creation and assigned to designated QMS roles.

Business Function: Departments or functional areas within your organization (e.g., Human Resources, Engineering, Quality) used to categorize and organize QMS documents.

Document No Prefix: The alphanumeric prefix used before sequential numbering in document identification (e.g., PRO- for Procedures, WI- for Work Instructions).

Document Sub-Type: An optional classification tag applied to a document within its document type, configured through the List of Values. Sub-Types allow organizations to further organize documents (e.g., classifying a Procedure as a Manual, Policy, or SOP) without changing the document type itself.

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Course: A QMS document type used to deliver training content, such as a video, PDF, or slide deck, to assigned personnel. Courses are external documents only and do not support native content authoring.

Effective Date: The date on which a QMS document transitions from Pending Release to Released status and becomes active in production. When Document Effectivity is enabled, this date is set when moving a document to Pending Release and must be the current date or a future date.

External Certificate: Training documentation completed outside the 1factory system that can be uploaded as proof of competency.

Federated QMS: A quality management system structure that allows multiple organizations within an enterprise to maintain separate but connected QMS instances.

Forms: Controlled document templates that serve as the foundation for creating Records (objective evidence of quality activities).

Legacy No: A label field used to trace back to document numbers from before the transition to 1factory, providing traceability during QMS migration.

List of Values (LOV): Configurable dropdown lists that standardize data entry across the system (e.g., Business Functions, Roles, Standards Organizations, Document Sub-Types).

Manage Courses Permission: A permission that controls access to the Courses tile and list. Users without this permission cannot author or manage Courses, and only interact with them through their assigned training.

Mandatory Approver Role: A QMS role required as an approver for all changes to controlled documents within the QMS.

Mandatory Course Approver Role: The QMS role required to approve all Courses before release, configured separately from the Mandatory Approver Role used for regular documents. Organizations can assign the same role to both if they choose.

Minor Update: A document revision process that allows quick release while bypassing the standard approval workflow and Pending Release status, indicated by decimal revision numbers (e.g., A.1). The Effective Date is automatically set to the date of release.

Pending Release: A document lifecycle status between Approved and Released, available when Document Effectivity is enabled. A document in Pending Release is distributed for training but is not visible to general users as a released document and carries a **PENDING - UNRELEASED** watermark. The document moves to Released automatically when both the Effective Date has been reached and the Training Completion Threshold has been met.

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Records: Completed documents containing actual data and results, providing objective evidence that activities were performed and requirements met.

Redline Mode: A viewing mode that tracks and visualizes changes during document revisions with color-coded highlighting.

Related Documentation: The network of cross-referenced documents linked within the QMS system.

Retraining Interval: Automatic retraining schedules triggered if a document is not revised within a specified timeframe.

Role: Organizational roles within your QMS that align with job descriptions or positions (e.g., HR Manager, Machinist) used for assigning responsibilities, approvals, and training.

Standards Organization: External parties whose requirements your QMS needs to meet (e.g., ISO, SAE, FDA, customers).

Training Completion Threshold: The percentage of assigned personnel who must complete training on a document before it can be automatically released to production. Configured in QMS Settings and only active when Document Effectivity is enabled. A value of 0 means no training completion is required before the document becomes effective on its Effective Date.

0.2 QMS Document Types Overview

All QMS document types are accessed from the **QMS tab** via the **Documents tile**. Documents are organized by type and can be further classified using **Sub-Type** tags configured in your List of Values.

Document Type	Purpose	Examples	Storage Location
Standards	Houses external regulatory or customer requirements that establish the foundation of your QMS. Standards can be cross-referenced within your Quality Manual and support direct linking from clause numbers to internal Procedures.	ISO 9001:2015, AS9100D, ISO 13485:2018, FDA 21 CFR Part 820, Customer Quality Manuals, Supplier Requirements, Code of Conduct	QMS Tab > Documents tile > Standards

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Mfg. Standards	Technical reference documents that define specifications, requirements, and acceptance criteria for production operations. These documents establish standardized methods for manufacturing processes, material requirements, and quality characteristics.	ASTM B580, ASTM B841, Customer-specific packaging requirements, Plating specifications, Heat treating standards	QMS Tab > Documents tile > Mfg. Standards
Procedures	Stores internal documents that outline the operation of your QMS, such as SOPs, policies, and manuals. Procedures define high-level processes and demonstrate compliance with external standards.	Internal Audit Procedure, Supplier Qualification Procedure, Risk Management Procedure, Design and Development Procedure, Employee Development Procedure	QMS Tab > Documents tile > Procedures
Work Instructions	Provide detailed, step-by-step guidance on how to perform specific tasks within your QMS. Work Instructions focus on the "how" and may be cross-referenced within Procedures. Work Instructions can also be linked directly to Manufacturing and Receiving Plans when manufacturing-level guidance is required.	How to Calibrate a Multimeter, How to Perform Gage R&R, How to Enter a New Supplier, Assembly Steps for a Specific Part, Ultrasonic Wash Process, Anodizing Instructions	QMS Tab > Documents tile > Work Instructions
Forms	Controlled document templates that serve as the foundation for creating Records (the objective evidence of your quality activities). Think of a Form as a blank template that, when completed with actual data, becomes a permanent quality Record.	Weekly Maintenance Sheet, Machine Set-up Sheet, Surveys, Design Review Meeting Minutes, Validation Plans and Reports	QMS Tab > Documents tile > Forms

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Courses	Delivers training content to personnel outside of standard document training. Courses are external documents only and support PDF, PowerPoint, and video formats. Restricted to users with the Manage Courses permission.	Lock Out Tag Out Training, New Hire Safety Orientation, Annual Ethics Training	QMS Tab > Courses tile
----------------	---	--	-------------------------------

0.2.1 Key Differences to Note

Standards and **Mfg. Standards** are external documents; all others are internal.

Procedures explain "what" and "why"; **Work Instructions** explain "how."

Forms become **Records** once completed.

Work Instructions can serve both general QMS and manufacturing-level purposes. When linked to a Manufacturing or Receiving Plan, they function as process-level or part-specific instructions. Sub-Types can be used to distinguish these within the Work Instructions list.

The **Documents tile** is the single location for all QMS document types. **Tags** and **Sub-Types** are used to filter and organize documents within each type.

Courses are training content, not process documentation. They carry their own approval role, permission, and tile, separate from Standards, Procedures, and other document types.

0.2.2 Where to Store Customer Documents:

0.2.2.1 Store in Standards when:

- The document defines quality system requirements (e.g., Customer Quality Manual, Supplier Requirements)
- It establishes policies or principles your QMS must comply with (e.g., Code of Conduct, Ethics Policies)
- It requires systemic compliance across your organization
- You need to demonstrate compliance through your Procedures

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0.2.2.2 Store in Mfg. Standards when:

- The document provides manufacturing specifications or methods (e.g., customer-specific packaging requirements, marking requirements, plating specifications)
- It defines technical requirements for a manufacturing process
- It will be referenced in conjunction with Manufacturing or Receiving Plans
- Multiple parts or processes will reference the same specification

0.2.2.3 Store in Work Instructions when:

- The document provides step-by-step guidance on how to perform a task, whether in the quality system or on the shop floor
- It defines how to perform a manufacturing process that will be linked to Manufacturing or Receiving Plans
- It is part-specific and needs to be tied to a specific part number via plan linkage

0.2.2.4 Store in Spec Libraries when:

- The document contains dimensional data or specifications that need to be entered into plans
- It includes measurable requirements (e.g., SAE Port Specs with critical dimensions)
- Data from the document will be transcribed into inspection plans
- The document serves as a reference for data entry rather than a process to follow

0.2.3 Document Type Feature Matrix

This matrix shows which features are available for each document type:

Feature	Standards	Mfg. Standards	Procedures	Work Instructions	Forms	Courses
Built-in Rich-Text Editor	Yes	Yes	Yes	Yes	Yes	No
Training Assignment	Yes	Optional (off by default)	Yes	Optional (off by default)	No	Yes

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Quiz Creation	Yes	Yes	Yes	Yes	No	Yes
External Certificate	Yes	Yes	Yes	Yes	No	Yes
Document Approvers	Yes	Yes	Yes	Yes	Yes	Yes
Access Control	Yes	Yes	Yes	Yes	Yes	Yes
Upload Native Document File	Yes	Yes	Yes	Yes	Yes	Yes
Attachments	Yes	Yes	Yes	Yes	No	Yes
Document History	Yes	Yes	Yes	Yes	Yes	Yes
PDF Export	Yes	Yes	Yes	Yes	No	No
Link to Procedures	Yes	No	No	No	No	No
Quality Matrix	Yes	No	Yes	No	No	No

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Impact Assessment	No	No	Yes	No	No	No
Record Creation	No	No	No	No	Yes	No
Form Download	No	No	No	No	Yes	No
Links to Mfg./Rec. Plans	No	No	No	Yes	No	No
Document Sub-Types	Yes	Yes	Yes	Yes	Yes	Yes

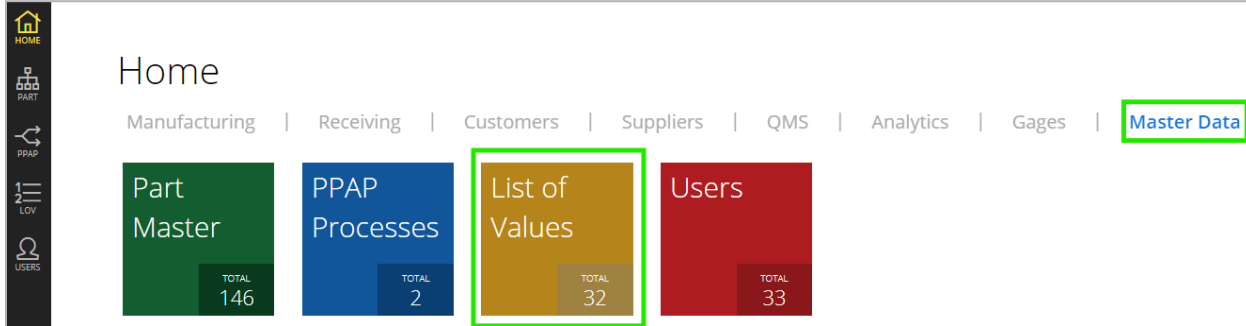
1.0 Quick Start Guide

Before your organization begins utilizing 1factory's QMS modules, there are a few steps to ensure a smooth transition from your current system to the new QMS within 1factory. In the section below, we have detailed these steps for your convenience.

1.1 Setting up the List of Values (LOV)

1factory allows users to configure their accounts to better match their organizational structure. To achieve this, 1factory has developed what we call the "List of Values". You can find the List of Values by navigating to the **Master Data tab** and clicking on the yellow **List of Values** tile.

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Once you are in the List of Values tile, you will find three QMS-related Lists of Values to fill out before uploading any documents into the QMS. We have explained how each is intended to be used within 1factory. To simplify this process, we have provided a pre-formatted file that you can complete and automatically import into your 1factory account. You can find the link to the file here: [QMS Lov's](#).

1.1.1 Standards Organization

The Standards Organization List should be configured to reflect any external party whose requirements your organization must comply with. This list is used across two document types:

- **Standards** are external documents that drive requirements into your QMS, such as ISO 9001:2015, AS9100D, or a customer's Supplier Quality Manual. These define the compliance framework your QMS is built around.
- **Manufacturing Standards** are external documents that drive requirements into your manufacturing processes specifically, such as customer-specific packaging requirements, industry plating specifications, or heat treating standards. These may not apply to your QMS directly but must be controlled and traceable at the manufacturing level.

In both cases, this list identifies the *organization* issuing the document, NOT the standard itself. For example, the list should state "ISO" and NOT "ISO 9001:2015."

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Proc. CAPAs

Proc. CAPAs

Approved Vendor List

Approved Vendor List

Approved Vendor List

Customers

Inspection Types

Inspection Types

Mfg. Resources

Proj. Ident.

Gages

Gages

Gages

Gages

Gages

PPAPs

PPAPs

PPAPs

Specification

Specification

Specification

Specification

Specification

Specification

QMS

QMS

QMS

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Commod. Codes

Org Codes

Cert. Codes

Customers

Manufacturing

Receiving

Machines

Part Master

Types

Makes

Locations

Cal. Vendors

Storage Locations

Reason Codes

Requirements/Documents

Levels

Characteristic

Unit

Insp. Method

Sampling

Operation

Label

Standards Organizations

Business Functions

QMS Roles

Manage List of Values

Group: QMS

List: Standards Organizations

Changes are effective for current objects. To add, use blank row at bottom of grid. To delete, clear the value of a cell. Click SAVE to save changes.

	Value	Occurs
1	FDA	0
2	Ford	0
3	IATF	0
4	ISO	2
5	Raytheon	1
6	SAE	1
7	Zimmer Biomet	2
8		

SAVE

1.1.2 Business Function

The **Business Function** List should be established to accurately reflect the business processes that comprise your QMS. These are usually departments within your organization, such as "Human Resources" or "Engineering." This list will later be used to identify which business function each QMS document is associated with.

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Proc. CAPAs

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Approved Vendor List

Approved Vendor List

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Mfg. Resources

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Gages

Gages

Gages

Gages

PPAPs

PPAPs

PPAPs

Specification

Specification

Specification

Specification

Specification

Specification

QMS

QMS

QMS

Standards

Agencies

Commod. Codes

Org Codes

Cert. Codes

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Storage Locations

Reason Codes

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Levels

Characteristic

Unit

Insp. Method

Sampling

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Label

Standards Organizations

Business Functions

QMS Roles

Manage List of Values

Group: QMS

List: Business Functions

Changes are effective for current objects. To add, use blank row at bottom of grid. To delete, clear the value of a cell. Click SAVE to save changes.

	Value	Occurs
1	Human Resources	4
2	Leadership	4
3	Maintenance	2
4	Manufacturing Operations	3
5	Purchasing	0
6	Quality	24
7	Research & Development	1
8	Sales	2
9	Supplier Quality	2
10	Warehouse and Shipping	0
11		

SAVE

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1.1.3 QMS Roles

The **Roles** List should be created to accurately reflect the organizational roles within your QMS. These roles typically align with job descriptions or positions in your organization, such as "HR Manager" or "Machinist." This list will be utilized for assigning roles to users, facilitating the document approval process, assigning training responsibilities, and demonstrating ownership of QMS documents. Users may hold multiple roles as needed.

You can find the **Roles** list at the top of the **List of Values** page under the **Users** group. Navigate to the **Master Data** tab, click the **List of Values** tile, and select **Roles** from the top of the list.

The screenshot displays the 'Manage Lists of Values' interface. On the left, a sidebar lists various groups: HOME, PART, PROD, LOW, MACHINE, USERS, MCH PROD, CONTROL, TABLES, and MAP/STATUS. The main area is titled 'Manage Lists of Values' and includes a sub-header 'First, select a list of values, then work with its values in the slide out.' Below this is a table with two columns: 'Group' and 'List Name'. The 'Users' group is selected, and the 'Roles' list is highlighted. The right pane shows the 'Manage List of Values' for the 'Roles' list. It includes a 'Group' dropdown set to 'Users' and a 'List' dropdown set to 'Roles'. Below these is a text box explaining that changes are effective for current and new objects and that values are automatically sorted alphabetically. A table lists 11 roles with columns for 'Value', 'Active' (checkbox), and 'Occurs' (count). A 'SAVE' button is at the bottom.

	Group	List Name
	Users	Roles
	CAPA / SCAR / NCR / Complaint	Problem Type
	CAPA / SCAR / NCR / Complaint	Root Cause
	CAPA / SCAR / NCR / Complaint	Caused By
	CAPA / SCAR / NCR	Detected At
	CAPA / SCAR / Complaint	CAPA/SCAR Cost Category
	CAPA / SCAR / Complaint	Complaint Cost Category
	CAPA	CAPA type
	Complaint	Complaint type
	Proc. CAPAs	Audit Standards
	Proc. CAPAs	Audit Agencies
	Approved Vendor List	Commod. Codes
	Approved Vendor List	Org Codes
	Approved Vendor List	Cert. Codes
	Customers	Customers
	Inspection Types	Manufacturing
	Inspection Types	Receiving

	Value	Active	Occurs
1	Design Engineer	☒	1
2	General Manager	☒	45
3	HR	☒	48
4	Manufacturing Engineer	☒	1
5	PROD_Cable: Production Supervisor	☒	3
6	PROD_Cable_C/P: Cell Leader	☒	3
7	QE I	☒	37
8	QE II	☒	8
9	QMS Coordinator	☒	104
10	Quality Manager	☒	275
11	RD&D management	☒	131

1.1.4 Document Sub-Types

Document Sub-Types allow your organization to further classify documents within each major document type, in addition to the **Business Function** already assigned to each document. Where Business Function identifies the department or functional area that owns a document, **Sub-Type** describes the nature or category of the document itself. Together they give your team flexible ways to filter and report across your QMS library as it grows. For example, a quality team managing both regulatory and customer-specific standards can quickly filter the Standards list to view only one category at a time, reducing noise during audits or document reviews.

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Inspection Types	Receiving
Mfg. Resources	Machines
Proj. Ident.	Part Master
Gages	Types
Gages	Makes
Gages	Locations
Gages	Calibration Vendor
Gages	Storage Location
Gages	Inactive/Re-active Reason
PPAPs	Reason Codes
PPAPs	Requirements/Documents
PPAPs	Levels
NCR	Inventory Location
NCR	MRB Disposition
NCR	NCR type
Specification	Characteristic
Specification	Unit
Specification	Insp. Method
Specification	Sampling
Specification	Operation
Specification	Label
QMS	Standards Organizations
QMS	Business Functions
QMS	QMS Roles
QMS	QMS Standard Types
QMS	Manufacturing Standard Types
QMS	Procedure Types
QMS	Work Instruction Types
QMS	Form Types

✕ Manage List of Values

Group:
List:

Changes are effective for current and new objects. To add a new value, use the blank row at bottom of grid. To delete, clear the value of a cell. To reorder the list, select and drag rows or use the sort button.

Click **SAVE** to save changes.

	Value	Active	Occurs
▣	Regulatory	☒	32
▣	Customer	☒	2
▣		☐	
▣		☐	
▣		☐	

A separate Sub-Type List of Values exists for each of the following document types. The examples below are provided as a starting point and should be adjusted to reflect your organization's terminology and document categories.

Document Type	Example Sub-Types
<i>Standards</i>	Regulatory, Customer, Industry Guideline
<i>Manufacturing Standards</i>	Customer, Industry Guideline
<i>Procedures</i>	Manual, Policy, SOP's
<i>Work Instructions</i>	QMS, Process, Assembly
<i>Forms</i>	Calibration, Audit, Finance

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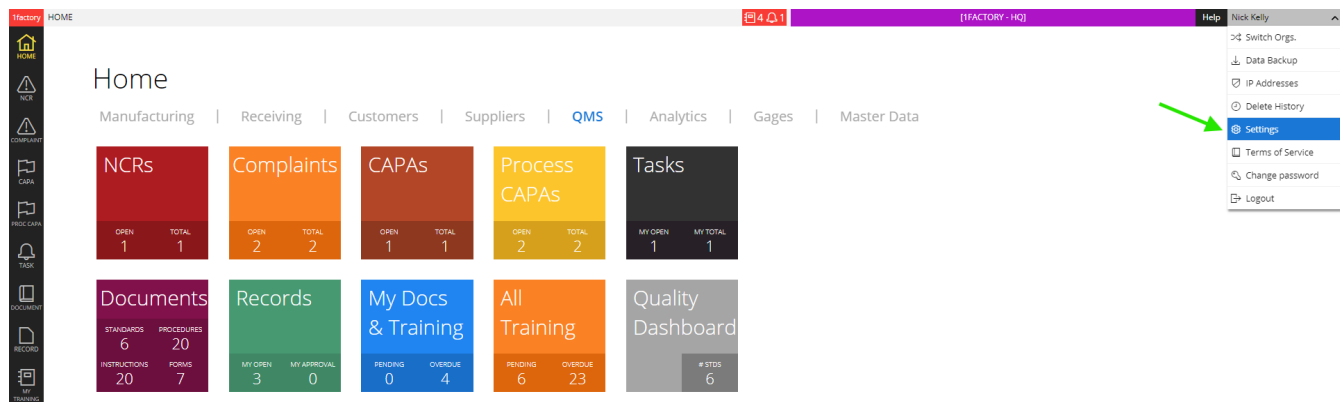
Once a Sub-Type List is configured, the **sub-type** field becomes available when creating a new document of that type. Sub-type is optional and can also be assigned or updated from the document detail page while the document is in **Draft** status. The sub-type column appears in each document list and supports filtering and Excel export, making it easy to sort and report across large document libraries.

To add, remove, or rename sub-type values, navigate to the **List of Values** page under the **Master Data** tab. Sub-type values *cannot* be edited from within the document itself. Once your sub-type values are defined in the LOV, you can assign or change a document's sub-type to any value in the list directly from the document detail page, provided the document is in **Draft** status.

Note: We have included a file with default QMS Lists of Values for your reference. Once you have determined your organization's List of Values, simply paste the values from this sheet into the List of Values. See the link to the file here: [QMS_LOV](#)

1.2 QMS Settings

To access QMS Settings, click your name in the top-right corner of the screen and select **Settings**. Navigate to the **QMS** section.



The settings below should be configured before you begin creating or importing documents, as several of them affect document numbering, approval behavior, and revision formatting in ways that are difficult to change after documents have been created.

- **Enable QMS Onboarding:** Set this to **Yes** to enable the document migration features described in Section 1.3, including metadata import, bulk ZIP file import, bulk release, and baseline training setup. Organizations building a new QMS from scratch may leave this set to **No**.
- **Quality Manual:** This setting allows you to designate a specific procedure as your organization's Quality Manual. The selected document will be surfaced in areas of the platform

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where the Quality Manual is referenced. This is optional and can be configured after documents have been created.

- **Mandatory Approver Role:** The selected QMS role is required as an approver on all controlled documents routed for approval, regardless of the approver roles configured on individual documents. This role is typically assigned to a Quality Manager or QMS Coordinator and serves as the final approval gate for all document changes. For organizations operating under ISO 13485, AS9100, or FDA 21 CFR Part 820, this setting is the primary mechanism for enforcing approval authority at the organizational level.
- **Mandatory Course Approver Role:** The selected QMS role is required as an approver on all Courses routed for approval, regardless of the approver roles configured on individual Courses. This setting is configured separately from Mandatory Approver Role so that training content can be reviewed by a different function, such as HR, rather than the roles who approve process documentation. Any QMS role can be selected, including the same role used as your Mandatory Approver Role, if a single approval authority is preferred.
- **Mandatory Approver Controls Release:** When set to **Yes**, only users assigned to the Mandatory Approver Role can release documents to production. Additionally, the Mandatory Approver must approve the document before any other configured approvers can submit their review. This enforces a sequential approval structure where the Mandatory Approver acts as both the first gatekeeper and the exclusive release authority. When set to **No**, any user with Manage Document privileges can release documents once all required approvals are obtained.
- **Documents are Immediately Effective:** This optional setting controls whether documents become effective immediately upon release or follow a defined effectivity workflow. It defaults to **Yes**, which preserves standard release behavior. When set to **No**, a Pending Release status is introduced into the document lifecycle between Approved and Released, and an **Effective Date** field becomes available on each document. Organizations that need to formally separate "released for training" from "active in production" should set this to **No**. See **Section 2.1.10** for full details on how Document Effectivity works.
- **Training Completion Threshold:** This setting is only available when **Documents are Immediately Effective** is set to **No**. It defines the percentage of assigned personnel who must complete training on a document before it can be automatically released to production. The value can be set anywhere from **0 to 100**. Setting this to **0** means no training completion is required before the document becomes effective on its Effective Date, which is useful for organizations that want to use the Effective Date scheduling feature without gating release on training. Any value above 0 requires that percentage of trainees to complete their assignment before the document moves from Pending Release to Released, as long as the Effective Date has also been reached.
- **Use Alphabetic Revisions:** Controls the revision sequence format applied to all QMS documents. When set to **No** (default), documents follow a numeric sequence (0, 1, 2...). When set to **Yes**, documents follow an alphabetic sequence (A, B, C...). Select the format that matches your organization's existing revision convention before creating or importing any documents.

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- **Document Numbers:** This setting determines how document numbers are assigned across all document types. Select the option that fits your organization before importing or creating documents, as changing this setting after documents have been created is not recommended.
 - **1factory numbers:** Documents are assigned numbers in 1factory's default format, with a document type prefix followed by a sequential number (for example, PRO-1, WI-1, FRM-1). Best suited for organizations building a new QMS from scratch.
 - **1factory with legacy numbers:** Documents are assigned 1factory format numbers and also include a legacy number label for traceability back to the document number used in your previous system. This option supports organizations that want to adopt 1factory's numbering convention while preserving a reference to the original document number at the time of migration.
 - **Your own numbers:** Documents follow your organization's existing numbering convention. You can define your document number prefixes per document type in the fields that appear below the selector, separated by commas. Any document created using a defined prefix will automatically receive the next sequential number for that prefix.
- **Allow External Files as Documents:** When set to **Yes**, users can upload a PDF or Microsoft Office file as the controlled document body when creating QMS documents, rather than authoring content natively in 1factory. This is the primary enabler for the bulk migration workflow described in Section 1.3. Organizations migrating an existing document library should set this to **Yes** before beginning the import process. Users retain the option to author documents natively in 1factory regardless of this setting.
- **Periodic Document Reviews:** When set to **Yes**, document owners can configure a review interval on each controlled document. When a review comes due, the document owner is prompted to confirm whether the document remains accurate or requires revision. This feature supports certification cycle requirements under standards such as ISO 9001 and AS9100, which require organizations to periodically reaffirm the adequacy of their documented information.
- **Document Review Period:** Defines how many days before a document's scheduled review due date the review process is initiated. Available options are **30, 60, or 90 days**. This gives document owners advance notice so reviews are not missed ahead of audit cycles or certification renewals.

1.3 Importing Documents

Migrating your existing QMS documents into 1factory is a structured process that preserves traceability while establishing the foundation for controlled document management. The migration workflow consists of three stages:

1. **Metadata Import:** Create document placeholders by importing a structured Excel file for each document type

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2. **File Import:** Upload the actual document files (PDFs and attachments) via bulk ZIP import
3. **Bulk Release:** Release all migrated documents in a single action once files are uploaded

Documents in 1factory are organized into several lists accessible from the QMS tab via the Documents or Mfg. Documents tile.

Note: If your organization is building a new QMS from scratch within 1factory, skip this section and proceed to Section 2.0.

1.3.1 Metadata Import

The metadata import creates placeholder documents for each of your QMS documents, establishing document numbers, titles, ownership, and workflow configuration before any file content is uploaded. A pre-formatted Excel template is available for each document type.

For each document type, complete the template and import it using the **Excel Import** button at the bottom of the left-hand sidebar in the respective document list. The supported document types, their core fields, and available configuration columns are described below.

A	B	C	D	E	F
No	Standard No	Title	Owner Org	Applicable Orgs	Revision
STD-0025	0036	Business Document Review	1factory - HQ	1factory - HQ	A
STD-0026	0037	Mandatory Training Requirements	Apex Aerospace Components	Apex Aerospace Components	B
STD-0027	0038	Receiving Inspection Procedure	NorCal Machining Division	NorCal Machining Division	C
STD-0028	0039	Logistics and Shipping Change Control	Apex Aerospace Components	Apex Aerospace Components	A
STD-0029	0040	Calibration and Measurement System Anal	Gulf Coast Fabrication	Gulf Coast Fabrication	D
STD-0030	0041	Corrective and Preventive Action (CAPA) P	Apex Aerospace Components	Apex Aerospace Components	B
STD-0031	0042	Non-Conforming Material Control	Triton Medical Devices	Triton Medical Devices	C
STD-0032	0043	Supplier Qualification and Approval	Apex Aerospace Components	Apex Aerospace Components	A
STD-0033	0044	Document and Record Control	Triton Medical Devices	Triton Medical Devices	E

Note: All data input into the template **must** be aligned with your QMS configurations and settings established in Sections 1.1 and 1.2.

1.3.1 Metadata Import

The metadata import creates placeholder documents for each of your QMS documents, establishing document numbers, titles, ownership, and workflow configuration before any file content is uploaded. A pre-formatted Excel template is available for each document type.

For each document type, complete the template and import it using the **Excel Import** button at the bottom of the left-hand sidebar in the respective document list. The supported document types, their core fields, and available configuration columns are described below.

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Note: All data input into the template must be aligned with your QMS configurations and settings established in Sections 1.1 and 1.2.

QMS Standards (Template: Standard_upload.xlsx)

Stores all external standards and customer requirements your QMS must comply with, such as ISO 9001:2015, AS9100D, or a customer's Supplier Quality Manual.

- **No.:** Auto-assigned in 1factory format (STD-1, STD-2...) or your own prefix based on organization settings.
- **Standard No. & Rev.:** The document number and revision as issued by the standards body.
- **Title:** Name of the external document.
- **Issuing Org.:** Organization that owns the standard (e.g., SAE for AS9100D).
- **Owner:** QMS Role responsible for ensuring requirements are met.
- **Revision:** Current revision at time of migration.
- **Type:** Categorization of the standard using your configured List of Values (e.g., Regulatory, Customer).
- **Applicable Orgs:** Specifies which organizations within a multi-org or federated QMS hierarchy this document is applicable to.
- **Approver Roles:** Defines the QMS roles required to approve a document revision before it can be officially released.
- **Access Roles:** Restricts document visibility to designated QMS roles, ensuring only authorized personnel can view or interact with the document.
- **Training Roles:** Identifies the QMS roles that must complete training upon document release or revision.
- **Training Interval:** Sets the recurring period (in months) at which assigned roles must complete retraining on this document.
- **Training Completion Time:** Number of days allowed for personnel to complete their assigned training after the document is released or a retraining cycle is triggered.
- **Training Type:** Defines the method used to complete training: Self Assessment, Quiz, or External Certificate.
- **Release Notes:** Free-text field to summarize the changes made in the current revision compared to the previous version.
- **Review Period:** Sets the interval (in months) at which the document owner must review and reaffirm the document remains accurate and current.
- **Last Review Date:** Records the most recent date the document was reviewed or reaffirmed, used to calculate the next scheduled review.

Mfg. Standards (Template: Mfg_Standard_upload.xlsx)

Stores manufacturing-level external standards and customer requirements applicable to production operations. Mfg. Standards support the same fields as QMS Standards above, including **Type** for categorizing the standard using your configured List of Values (e.g., Regulatory, Customer).

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Procedures (Template: Procedure_upload.xlsx)

Stores internal SOPs, policies, and manuals that define how your QMS operates and demonstrate compliance with external standards.

- **No.:** 1factory format (QA-PR-1, MFG-PR-2...) or your own prefix.
- **Title:** Name of the procedure.
- **Owner Org:** The organization within the QMS that owns this procedure.
- **Applicable Orgs:** Specifies which organizations within a multi-org or federated QMS hierarchy this document is applicable to.
- **Revision:** Current revision at time of migration.
- **Business Function:** Department or functional area. Must match the LOV.
- **Type:** Categorization of the procedure using your configured List of Values.
- **Owner:** QMS Role responsible for the procedure. Must match the LOV.
- **Approver Roles:** Defines the QMS roles required to approve a document revision before it can be officially released.
- **Access Roles:** Restricts document visibility to designated QMS roles, ensuring only authorized personnel can view or interact with the document.
- **Training Roles:** Identifies the QMS roles that must complete training upon document release or revision.
- **Training Interval:** Sets the recurring period (in months) at which assigned roles must complete retraining on this document.
- **Training Completion Time:** Number of days allowed for personnel to complete their assigned training after the document is released or a retraining cycle is triggered.
- **Training Type:** Defines the method used to complete training: Self Assessment, Quiz, or External Certificate.
- **Release Notes:** Free-text field to summarize the changes made in the current revision compared to the previous version.
- **Review Period:** Sets the interval (in months) at which the document owner must review and reaffirm the document remains accurate and current.
- **Last Review Date:** Records the most recent date the document was reviewed or reaffirmed, used to calculate the next scheduled review.

Work Instructions (Template: Work_Instruction_upload.xlsx)

Stores all work-level instructions in a single unified list, including general work instructions, process-level instructions applicable across multiple parts or plans, and part-specific instructions tied to a single part number. Work Instructions can be cross-referenced within Procedures, creating automatic links between documents.

- **No.:** 1factory format or your own prefix. All work instruction types share a single prefix set.
- **Title:** Name of the work instruction.

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- **Part Number:** The part number this document is associated with. Required for part-specific work instructions; leave blank for general or process-level instructions.
- **Owner Org:** The organization within the QMS that owns this work instruction.
- **Applicable Orgs:** Specifies which organizations within a multi-org or federated QMS hierarchy this document is applicable to.
- **Revision:** Current revision at time of migration.
- **Business Function:** Department or functional area. Must match the LOV.
- **Type:** Categorizes the work instruction using your configured List of Values (e.g., QMS, Process, Part-Specific).
- **Owner:** QMS Role responsible for the work instruction. Must match the LOV.
- **Has Training:** Indicates whether this work instruction has a training requirement. When set to Yes, training plan controls are enabled and the document appears in training assignment selectors. Defaults to No.
- **Approver Roles:** Defines the QMS roles required to approve a document revision before it can be officially released.
- **Access Roles:** Restricts document visibility to designated QMS roles, ensuring only authorized personnel can view or interact with the document.
- **Training Roles:** Identifies the QMS roles that must complete training upon document release or revision. Only applicable when Has Training is set to Yes.
- **Training Interval:** Sets the recurring period (in months) at which assigned roles must complete retraining on this document.
- **Training Completion Time:** Number of days allowed for personnel to complete their assigned training after the document is released or a retraining cycle is triggered.
- **Training Type:** Defines the method used to complete training: Self Assessment, Quiz, or External Certificate.
- **Release Notes:** Free-text field to summarize the changes made in the current revision compared to the previous version.
- **Review Period:** Sets the interval (in months) at which the document owner must review and reaffirm the document remains accurate and current.
- **Last Review Date:** Records the most recent date the document was reviewed or reaffirmed, used to calculate the next scheduled review.

Forms (Template: Form_upload.xlsx)

Stores controlled form templates that serve as the foundation for creating Records. For example, a "New Supplier Audit Form" referenced by a Work Instruction becomes a Form that quality personnel fill out to generate Records.

- **No.:** 1factory format (FRM-1, FRM-2...) or your own prefix.
- **Title:** Name of the form.
- **Owner Org:** The organization within the QMS that owns this form.
- **Applicable Orgs:** Specifies which organizations within a multi-org or federated QMS hierarchy this document is applicable to.

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- **Revision:** Current revision at time of migration.
- **Business Function:** Department or functional area. Must match the LOV.
- **Type:** Categorization of the form using your configured List of Values.
- **Owner:** QMS Role responsible for the form. Must match the LOV.
- **Approver Roles:** Defines the QMS roles required to approve a document revision before it can be officially released.
- **Access Roles:** Restricts document visibility to designated QMS roles, ensuring only authorized personnel can view or interact with the document.
- **Release Notes:** Free-text field to summarize the changes made in the current revision compared to the previous version.
- **Review Period:** Sets the interval (in months) at which the document owner must review and reaffirm the document remains accurate and current.
- **Last Review Date:** Records the most recent date the document was reviewed or reaffirmed, used to calculate the next scheduled review.
- **Records Prefix:** Defines the prefix used when numbering individual records created under this form (e.g., CAL-, NCR-, AUDIT-).
- **Records Creator Roles:** Identifies the QMS roles permitted to create new records under this form.
- **Records Viewer Roles:** Restricts which QMS roles can view records created under this form.
- **Records Approver Roles:** Defines the QMS roles required to approve individual records created under this form.

Additional Configuration Columns

All templates support additional columns that allow you to pre-configure approvals, access control, training, and review schedules as part of the import, eliminating the need to set these up manually for each document afterward. These columns apply across all document types unless otherwise noted. Multiple roles are entered as **pipe-separated** values, meaning each role is separated by a vertical bar character, for example: **Quality Manager|Engineering Lead|QMS Coordinator**.

- **Approver Roles:** List of QMS role names required to approve this document. If not set, only the Mandatory Approver Role applies.
- **Access Roles:** List of QMS roles that can view the document. Leave blank for unrestricted access within the organization.
- **Training Roles:** List of QMS roles required to complete training when this document is released or revised. Not applicable to Forms.
- **Training Interval:** Retraining interval in months. If not set, no automatic retraining is scheduled.
- **Training Completion Time:** Number of days users have to complete training after document release. If not set, no due date is applied.
- **Training Type:** One of: Self Assessment (default), Quiz, or External Certificate. Note: quiz questions must be configured manually after import.
- **Release Notes:** Release notes for the initial revision of the document.

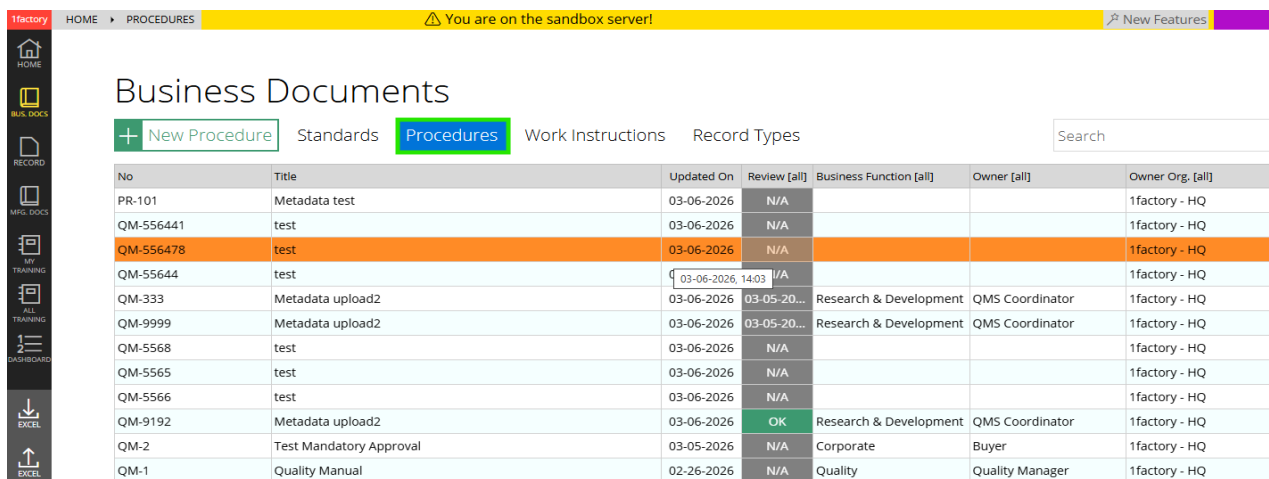
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- **Review Period:** Number of months from release before a document review is due.
- **Last Review Date:** Date the document was last reviewed in your previous QMS. When set, the next review date is calculated from this date rather than the 1factory release date, ensuring review schedules carry over accurately. If a document was never formally reviewed, use its release date from the legacy system.
- **Type:** Optional categorization field available on all document types. Values are drawn from the List of Values configured for each document type. Leave blank if no categorization is needed.
- **Records Prefix** (Forms only): Prefix used to number Records created from this form (e.g., "STA"). Required to enable Record creation.
- **Records Creator Roles** (Forms only): List of roles authorized to create Records from this form.
- **Records Viewer Roles** (Forms only): List of roles authorized to view Records created from this form.
- **Records Approver Roles** (Forms only): List of roles required to approve Records created from this form.

Note: For organizations using Federated QMS, role names can be suffixed with the organization name in square brackets (e.g., QC Manager [1Factory Austin]) to assign roles from a specific entity within the federation.

Importing the File

Navigate to the QMS tab and open the **QMS Documents** tile, then select the tab for the document type you are importing (e.g., Procedures).

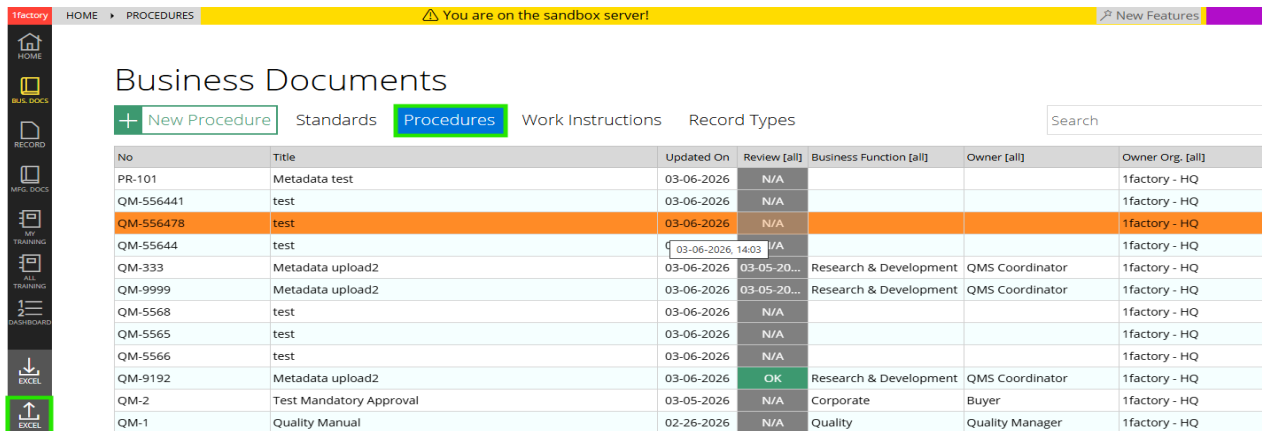


The screenshot shows the 1factory QMS interface. The top navigation bar includes 'HOME', 'PROCEDURES', and a status message 'You are on the sandbox server!'. The left sidebar contains icons for 'HOME', 'BUS. DOCS', 'RECORD', 'MFG. DOCS', 'MY TRAINING', 'ALL TRAINING', 'SCHEDULED', 'EXCEL', and 'EXCEL'. The main content area is titled 'Business Documents' and features a tabbed interface with 'New Procedure', 'Standards', 'Procedures' (selected), 'Work Instructions', and 'Record Types'. A search bar is located to the right of the tabs. Below the tabs is a table with the following data:

No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Owner Org. [all]
PR-101	Metadata test	03-06-2026	N/A			1factory - HQ
QM-556441	test	03-06-2026	N/A			1factory - HQ
QM-556478	test	03-06-2026	N/A			1factory - HQ
QM-55644	test	03-06-2026, 14:03	N/A			1factory - HQ
QM-333	Metadata upload2	03-06-2026	03-05-20...	Research & Development	QMS Coordinator	1factory - HQ
QM-9999	Metadata upload2	03-06-2026	03-05-20...	Research & Development	QMS Coordinator	1factory - HQ
QM-5568	test	03-06-2026	N/A			1factory - HQ
QM-5565	test	03-06-2026	N/A			1factory - HQ
QM-5566	test	03-06-2026	N/A			1factory - HQ
QM-9192	Metadata upload2	03-06-2026	OK	Research & Development	QMS Coordinator	1factory - HQ
QM-2	Test Mandatory Approval	03-05-2026	N/A	Corporate	Buyer	1factory - HQ
QM-1	Quality Manual	02-26-2026	N/A	Quality	Quality Manager	1factory - HQ

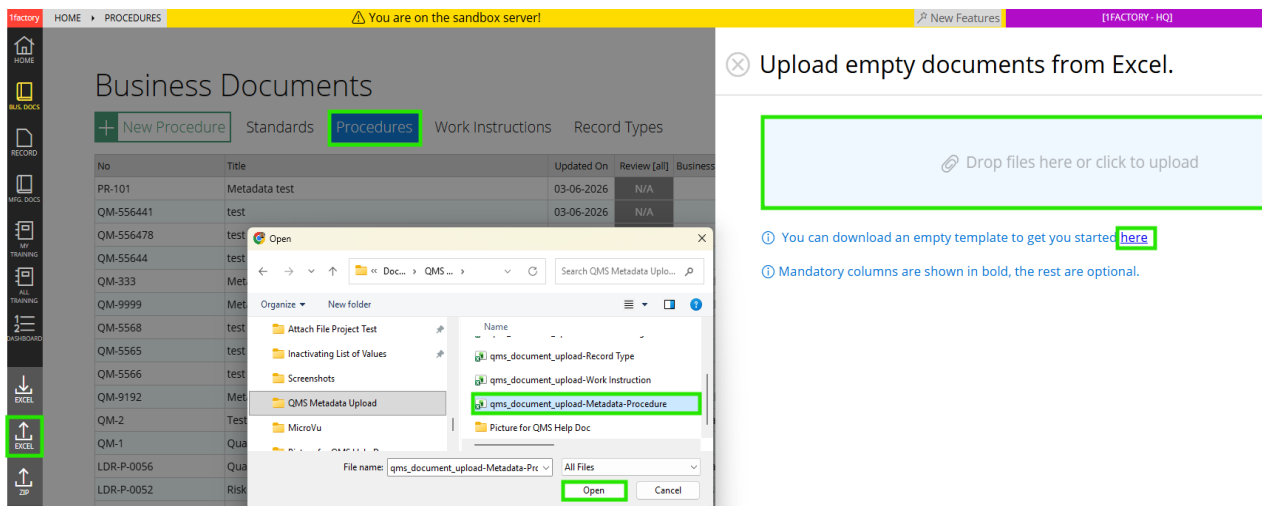
Click the **Excel Import** button at the bottom of the left-hand sidebar.

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No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Owner Org. [all]
PR-101	Metadata test	03-06-2026	N/A			1factory - HQ
QM-556441	test	03-06-2026	N/A			1factory - HQ
QM-556478	test	03-06-2026	N/A			1factory - HQ
QM-55644	test	03-06-2026, 14:03	N/A			1factory - HQ
QM-333	Metadata upload2	03-06-2026	03-05-20...	Research & Development	QMS Coordinator	1factory - HQ
QM-9999	Metadata upload2	03-06-2026	03-05-20...	Research & Development	QMS Coordinator	1factory - HQ
QM-5568	test	03-06-2026	N/A			1factory - HQ
QM-5565	test	03-06-2026	N/A			1factory - HQ
QM-5566	test	03-06-2026	N/A			1factory - HQ
QM-9192	Metadata upload2	03-06-2026	OK	Research & Development	QMS Coordinator	1factory - HQ
QM-2	Test Mandatory Approval	03-05-2026	N/A	Corporate	Buyer	1factory - HQ
QM-1	Quality Manual	02-26-2026	N/A	Quality	Quality Manager	1factory - HQ

In the slideout that opens, click the green paper clip icon to attach your completed template file.



Upload empty documents from Excel.

Drop files here or click to upload

You can download an empty template to get you started [here](#)

Mandatory columns are shown in bold, the rest are optional.

Repeat for each document type. After import, each document will appear in the list in Draft status as a placeholder, ready to receive its document file.

Note: For organizations using Federated QMS, role names can be suffixed with the organization name in square brackets (e.g., QC Manager [1Factory Austin]) to assign roles from a specific entity within the federation.

1.3.2 Bulk File Import (ZIP)

Once placeholder documents have been created via metadata import, the next step is uploading the actual document files. Rather than uploading files one at a time, 1factory supports bulk file upload via a single ZIP archive, significantly reducing the effort required to migrate large document sets.

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Preparing the ZIP File

The ZIP file may contain a mix of primary document files and supporting attachments. Follow these naming conventions:

- **Primary document** files must be named using the document's reference number (e.g., PRO-1.pdf, WI-15.pdf).
- **Attachment files** must be named with the document reference number, followed by a space, followed by the desired attachment name (e.g., PRO-1 Source Drawing.pdf, WI-15 Reference Table.xlsx).
- Only one primary file per document is permitted.
- For all document types except **Forms**, primary files must be in PDF format.
- For Forms, primary files may be PDF, Word (.doc, .docx), Excel (.xls, .xlsx, .xslm), or PowerPoint (.ppt, .pptx, .ppsx, .potx, .pub).
- Multiple attachment files per document are supported in any file format.

Important: Placeholder documents must already exist in 1factory in Draft status and must never have been previously released. The reference number in the filename must exactly match the document number in the system.

Uploading the ZIP File

1. Navigate to the QMS Documents or Mfg. Documents list page.

HOME ⚠ You are on the sandbox server!

Home

Manufacturing | Receiving | Customers | Suppliers | **QMS** | Analytics | Gages | Master Data

NCRs		Complaints		CAPAs		Process CAPAs		Tasks	
OPEN	TOTAL	OPEN	TOTAL	OPEN	TOTAL	OPEN	TOTAL	MY OPEN	MY TOTAL
2392	2471	37	37	713	739	57	62	13	23

Business Documents		Records		Mfg. Documents		My Training		All Training		Quality Dashboard	
PROCEDURES	INSTRUCTIONS	MY OPEN	MY APPROVAL	PROCESS	PART	PENDING	OVERDUE	PENDING	OVERDUE	# STDS	
24	6	2	0	6	5	1	1	3	1	5	

2. Click the **Bulk File Import** button in the command bar.

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The screenshot shows the 1factory QMS interface. On the left, a sidebar contains icons for various functions, with the 'ZIP' icon highlighted in green. The main area displays the 'Business Documents' slideout, which includes a table of documents and a right-hand panel with instructions for uploading a zip file.

No	Title	Updated On	Review [all]	Business
MFG-PR-353550	Test	03-12-2026	N/A	Distribu
MFG-PR-353549	Ticket 524	03-11-2026	N/A	Custom
MFG-PR-353548	[PR #2089] [Bug #798]	03-05-2026	N/A	Custom
MFG-PR-353547	[PR #2083][QMS] [Ticket#475] [Align]	03-05-2026	N/A	Custom
PR-0022	Baseline Upload1	03-04-2026	N/A	Custom
PR-0022	Baseline Upload1	02-20-2026	N/A	Custom
MFG-PR-353546	Business Document Review	02-18-2026	N/A	Product
MFG-PR-353545	Test Mandatory Role(INACTIVE)	02-12-2026	N/A	Custom
MFG-PR-22234	Test Upload	02-02-2026	N/A	Human
MFG-PR-222	Test Upload	01-26-2026	N/A	Human
MFG-PR-353544	Bug479	12-18-2025	N/A	Custom
MFG-PR-222	Test Upload	01-26-2026	N/A	Human
MFG-PR-353543	Bug 3457	01-31-2026	N/A	Custom
MFG-PR-353539	Test link	11-17-2025	N/A	Distribu
PRO-111325	test	03-06-2026	N/A	
MFG-PR-353542	test	01-31-2026	N/A	Custom
MFG-PR-353542	test	01-31-2026	N/A	Custom
MFG-PR-353541	0025	01-31-2026	N/A	Custom
MFG-PR-353540	Receiving Procedure	01-31-2026	N/A	Quality
MFG-PR-353539	Test link	11-17-2025	N/A	Distribu

Upload a zip file.

To upload a zip file, click paper clip to select a file.

Import instructions

- Bulk-import primary pdf documents and supporting attachments into existing QMS Documents from a zip file.
- Placeholder QMS documents must have already been created in 1Factory, and must be unreleased (they must have a single, draft revision).
- Imported files must have a file-name that matches the document number of a 1Factory QMS document.
- Primary files must be a pdf (unless document is a Form, which allow non-pdf files)
- Attachments can be any file type.
- Reference and attachment file name formats:
[refNo].pdf - for reference QMS document
[refNo] [attachmentFile] - for attachment document
- Examples of a .zip file with reference and attachment files:
PRO-22 Attach A.pdf
PRO-22 Attach B.xlsx
PRO-22.pdf

Go

3. In the slideout, attach your ZIP file using the paper clip icon and click **Go**.

This screenshot is identical to the one above, showing the 1factory QMS interface with the 'Business Documents' slideout. The 'ZIP' icon in the sidebar is highlighted in green, and the right-hand panel displays the 'Upload a zip file' instructions and the 'Go' button.

4. Upon completion, the slideout will display a summary of successfully uploaded files and any errors encountered.

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⊗ Upload a zip file.

① To upload a zip file, click paper clip to select a file.



> Import instructions

Previously uploaded by Thach Nguyen(Supplier) at Thu Mar 12 21:29:31 GMT 2026

Total number of files: 2
Number of reference documents successfully processed: 1
Number of attachments successfully processed: 1



Note: Only one bulk file import may run at a time per organization. If an import is already in progress, the slideout will display its status and provide an option to cancel. If your total file size exceeds the system limit, split your documents into multiple ZIP files and import them in batches.

1.3.3 Bulk Release

After uploading document files, the final migration step is releasing the imported documents to production. Rather than releasing each document individually, 1factory provides a Bulk Release tool that publishes all eligible migrated documents in a single action. This is appropriate for documents being brought over from a legacy system where they were already active, approved records and do not require re-approval to become controlled in 1factory.

Eligibility Criteria

The Bulk Release tool will only release documents that meet all of the following conditions:

- The document type matches the currently selected tab (e.g., Procedures, Work Instructions).
- The document is in Draft status and has never been previously released in 1factory.

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- The document has an external PDF file uploaded. Documents being authored natively in 1factory are excluded and should be released individually as they are completed.

Documents in Pending Approval status or without an uploaded PDF will be skipped.

Performing a Bulk Release

- Navigate to the document list tab for the type you wish to release (e.g., **QMS** tab > Documents > **Procedures**).

Business Documents

+ New Procedure Standards Procedures Work Instructions Record Types

Search 1-31 of 31

No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Owner Org. [all]	Applicable ...	Created By [all]	App. [all]	Rev. [all]	
PRO-101	Test	03-12-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353550	Test	03-12-2026	N/A	Distribution and Logistics	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353549	Ticket 524	03-11-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353548	[PR #2089] [Bug #798]	03-05-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353547	[PR #2083][QMS] [Ticket#475] [Avalign]	03-05-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
PR-0022	Baseline Upload1	03-04-2026	N/A	Customer Service	Quality Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	B	!
PR-0022	Baseline Upload1	02-20-2026	N/A	Customer Service	Quality Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
MFG-PR-353546	Business Document Review	02-18-2026	N/A	Production	General Manager	1factory, Inc	✓	Mike Corrales	N/A	A	!
MFG-PR-353545	Test Mandatory Role(INACTIVE)	02-12-2026	N/A	Customer Service	General Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
MFG-PR-22234	Test Upload	02-02-2026	N/A	Human Resources	QMS Coordinator	1factory, Inc	✓	Nick Kelly	N/A	B.1	!
MFG-PR-222	Test Upload	01-26-2026	N/A	Human Resources	QMS Coordinator	1factory, Inc	✓	Nick Kelly	N/A	B	!
MFG-PR-353544	Bug479	12-18-2025	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
MFG-PR-222	Test Upload	01-26-2026	N/A	Human Resources	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353543	Bug 3457	01-31-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353539	Test link	11-17-2025	N/A	Distribution and Logistics	HR	1factory, Inc	✓	Thach Nguyen(Supplier)	ASSIGNED	C	!
PRO-111325	test	03-06-2026	N/A			1factory, Inc	✓	Nick Kelly	APPROVED	A	!

- Click the **Bulk Release** button in the command bar.

Business Documents

+ New Procedure Standards Procedures Work Instructions Record Types

Search 1-31 of 31

No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Owner Org. [all]	Applicable ...	Created By [all]	App. [all]	Rev. [all]	
PRO-101	Test	03-12-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353550	Test	03-12-2026	N/A	Distribution and Logistics	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353549	Ticket 524	03-11-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353548	[PR #2089] [Bug #798]	03-05-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353547	[PR #2083][QMS] [Ticket#475] [Avalign]	03-05-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
PR-0022	Baseline Upload1	03-04-2026	N/A	Customer Service	Quality Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	B	!
PR-0022	Baseline Upload1	02-20-2026	N/A	Customer Service	Quality Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
MFG-PR-353546	Business Document Review	02-18-2026	N/A	Production	General Manager	1factory, Inc	✓	Mike Corrales	N/A	A	!
MFG-PR-353545	Test Mandatory Role(INACTIVE)	02-12-2026	N/A	Customer Service	General Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
MFG-PR-22234	Test Upload	02-02-2026	N/A	Human Resources	QMS Coordinator	1factory, Inc	✓	Nick Kelly	N/A	B.1	!
MFG-PR-222	Test Upload	01-26-2026	N/A	Human Resources	QMS Coordinator	1factory, Inc	✓	Nick Kelly	N/A	B	!
MFG-PR-353544	Bug479	12-18-2025	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	!
MFG-PR-222	Test Upload	01-26-2026	N/A	Human Resources	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353543	Bug 3457	01-31-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	!
MFG-PR-353539	Test link	11-17-2025	N/A	Distribution and Logistics	HR	1factory, Inc	✓	Thach Nguyen(Supplier)	ASSIGNED	C	!
PRO-111325	test	03-06-2026	N/A			1factory, Inc	✓	Nick Kelly	APPROVED	A	!
MFG-PR-353542	test	01-31-2026	N/A	Customer Service	General Manager	1factory, Inc	✓	Nick Kelly	ASSIGNED	B	!

- The slideout will display the count of documents eligible for release.

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⊗ Bulk release procedures

Release all procedure documents in Draft state, that have never been previously released in 1Factory and that have pdf documents uploaded.

① 1 procedure(s) to be released

Release notes

Required

SHF G	GO
----------	----

4. Enter release notes (required).

⊗ Bulk release procedures

Release all procedure documents in Draft state, that have never been previously released in 1Factory and that have pdf documents uploaded.

① 1 procedure(s) to be released

Release notes

Release 1

SHF G	GO
----------	----

5. If eSignatures are enabled for your organization, complete the attestation: *I hereby certify that by conducting this bulk release of documents, all change requirements have been fulfilled.*

1factory QMS User Manual

⊗ Bulk release procedures

Release all procedure documents in Draft state, that have never been previously released in 1Factory and that have pdf documents uploaded.

① 1 procedure(s) to be released

<i>I hereby certify that by conducting this bulk release of documents, all change requirements have been fulfilled</i>	
--	-------

Release notes

Release 1

SHF G	GO
----------	----

6. Click the **Go** button to **Release**, then confirm in the modal that appears.

⊗ Bulk release procedures

Release all procedure documents in Draft state, that have never been previously released in 1Factory and that have pdf documents uploaded.

① 1 procedure(s) to be released

<i>I hereby certify that by conducting this bulk release of documents, all change requirements have been fulfilled</i>	
--	-------

Release notes

Release 1

SHF G	GO
----------	----

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Bulk release 1 procedure(s)?

This will release procedures in Draft state.

Would you like to continue?

YES

NO

All documents uploaded by 1.3.2 Bulk File Import the status will be changed to Green

Owner [all]	Owner Org. [all]	Applicable ...	Created By [all]	App. [all]	Rev. [all]	
QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	⋮
QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	⋮
QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	⋮
QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A	⋮
QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	⋮
Quality Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	B	⋮
Quality Manager	1factory, Inc	✓	Thach Nguyen(Supplier)	APPROVED	A	⋮
General Manager	1factory, Inc	✓	Mike Corrales	N/A	A	⋮

Note: Bulk Release can be run multiple times, for example, once per document type, or in batches as PDFs are uploaded. Re-running the tool will only release newly eligible documents; already-released documents are automatically skipped.

Important: Bulk Release is available only to users assigned to the Mandatory Approver Role (or any user with Manage Document privileges if no Mandatory Approver Role is configured). Approval workflows are bypassed for bulk-released documents under the assumption that they were previously approved in the legacy system. Bulk-released documents will display an Approved status in the document list. The Approval section will not appear in the Manage slideout for the initial revision, though configured approvers will be applied to all future revisions.

1.3.4 Baseline Training Setup

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When migrating into 1factory, your users likely have existing training records on many of the documents being imported. Without establishing a training baseline, 1factory would generate new training assignments for all personnel on every migrated document at the point of release, creating an unnecessary retraining burden and inaccurate compliance records.

The Baseline Training Import resolves this by allowing you to upload a record of completed training from your legacy system before documents are released. This establishes each user's current training status in 1factory, ensuring continuity of compliance records and preventing duplicate assignments.

Prerequisites

- All users must already be imported into 1factory and assigned their QMS Roles. To assign roles, navigate to the Master Data tab, click the Users tile, select a user, and assign the appropriate role(s) from the QMS Roles tab in the slide-out panel.
- Placeholder documents must exist in Draft status and must not yet have been released.
- Training metadata (roles, intervals) must already be configured on each document, either manually or via the training columns described in Section 1.3.1.

Preparing the Training Import File

The training baseline import uses an Excel file with the following three columns:

- User Email: Email address identifying the 1factory user belonging to the organization performing the import.
- Document No.: Reference number of the document the user is trained on (e.g., PRO-34). Must be a document that supports training (not a Form) and must not yet have been released in 1factory.
- Completed Date: Date on which training was completed in the legacy system. Interpreted in the timezone of the user performing the import.

Performing the Import

1. Navigate to **QMS tab > All Training tile > Training Log** tab.
2. Click the Import button in the command bar.
3. Attach your completed Excel file and click Open.

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1factory HOME ALL TRAINING You are on the sandbox server New Features Help

All Training

+ New Training Training Log By Document By User

Created on	Created by [all]	Type [all]	Document	Role	User
03-12-2026	Thach Nguyen(Supplier)	Baseline	MFG-PR-353548 (PR #2...		Thach
03-12-2026	Thach Nguyen(Supplier)	New to Role	MFG-PR-353547 (PR #2...		Test_B
03-12-2026	Thach Nguyen(Supplier)	Ad-hoc	MFG-PR-222 Test Upload	HR	Thach
03-05-2026	Thach Nguyen(Supplier)	New to Role	MFG-PR-353547 (PR #2...	QMS Coordinator	
01-12-2026	Oleg Nickolayev	New to Role	MFG-PR-353539 Test link		Danh
12-16-2025	Thach Nguyen(Supplier)	New to Role	MFG-PR-353539 Test link		Thach
11-12-2025	Nick Kelly	New to Role	MFG-PR-353539 Test link		Sara R
11-05-2025	Matthew Stanley	New to Role	MFG-PR-353539 Test link		Matth
10-30-2025	Thach Nguyen(Supplier)	New to Role	MFG-PR-353539 Test link		Jolie N
10-29-2025	Thach Nguyen(Supplier)	New to Role	MFG-PR-353539 Test link		Thach
10-27-2025	Nick Kelly	New to Role	MFG-PR-353539 Test link	Quality Manager	

Upload baseline training records from Excel.

① Upload existing, baseline training records for training previously completed in an external system.
① Records must be for documents already in 1Factory, but not yet released.

Drop files here or click to upload

You can download an empty template to get you started [here](#)

① Mandatory columns are shown in bold, the rest are optional.

The system validates each row and returns errors for unrecognized users, unrecognized document numbers, released documents, or future-dated completion entries. If valid, baseline training records are created for each user, with retraining due dates calculated from the completed date and the document's configured retraining interval.

Note: Baseline training records are classified as type "Baseline" in the training log. Re-running the import will update existing baseline records. If a user's training record for a given document already exists, it will be overwritten with the values from the new file.

Important: Baseline training records establish the starting state of training compliance but do not include training certificates or assessment results. When documents are released, users with an active baseline record will not receive duplicate training assignments. Retraining will be automatically generated when their baseline records expire per the configured retraining interval.

1.4 Go Live Release

With your legacy documentation migrated and bulk released into 1factory, your QMS is now live! From here, your team can begin creating new documents, revising existing ones, and assigning training as your QMS grows and evolves. The following sections detail how documents are created, revised, and released to production within 1factory.

2.0 Creating & Revising Documentation

This section provides a step-by-step guide to creating, editing, and managing QMS documents in 1factory. It covers the core features shared across all document types such as version control, approvals, training, access permissions, and attachments, while also detailing the unique capabilities of **Standards**, **Procedures**, **Work Instructions**, **Forms**, and **Manufacturing Standards**. Together, these tools ensure consistent document control, regulatory compliance, and efficient knowledge sharing across your organization.

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2.1 Common Document Features

All QMS document types share core functionality that ensures consistent document control, compliance tracking, and quality management across your organization.

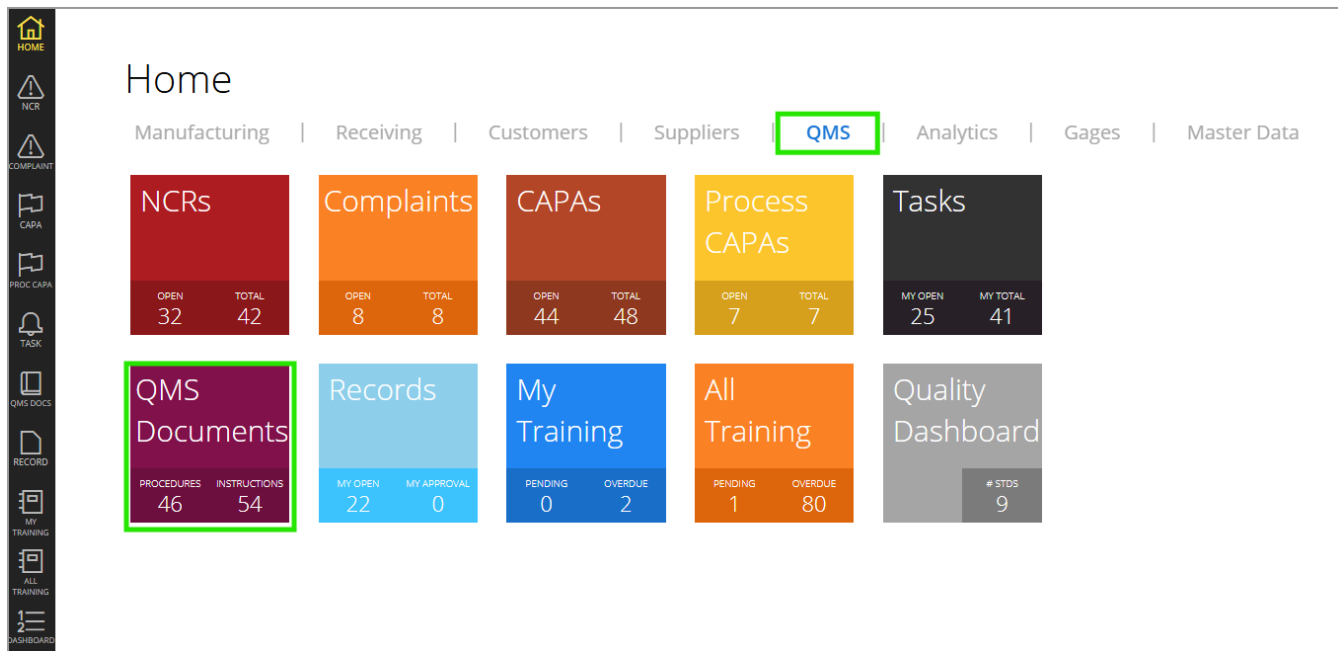
2.1.1 Creating Documents

The document creation process follows a consistent pattern across all document types, with minor variations in required fields.

The document creation process follows a consistent pattern across all document types, with minor variations in required fields.

Step 1: Navigate to Document Type

All document types are accessed through the QMS Documents tile: *QMS Tab > QMS Documents tile > select the appropriate tab (QMS Standards, Mfg. Standards, Procedures, Work Instructions, Forms)*



Step 2: Create New Document

Click the appropriate **New [Document Type]** button to initiate the document creation process.

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QMS Procedures												
New Procedure StandardsMfg StandardsProceduresWork InstructionsForms Search 1-24 of 24												
No	Title	Updated On	Review (all)	Business Function (all)	Type (all)	Owner (all)	Owner Org. (all)	Applicable ...	Created By (all)	App. (all)	Rev. (filter...)	
QA-P-6162028	Demo procedure	Mar-30-20...	OK	Quality		Quality Manager	1factory - HQ	✓	Emily Anderson	APPROVED	B	
LDR-P-0052	Risk Management	Mar-26-20...	OK	Leadership		C.E.O	1factory - HQ	✓	Emily Anderson	N/A	E.3	
LDR-P-0056	Quality Policy	Feb-26-2026	OK	Corporate		Corp. Quality Manager	1factory - HQ	✓	Autumn Repetto	N/A	D.1	
QA-P-0062	Control of Non-conforming Material	Feb-20-2026	OK	Quality		Quality Manager	1factory - HQ	✓	Autumn Repetto	N/A	M.1	
QM-1	Quality Manual	Feb-26-2026	OK	Quality		Quality Manager	1factory - HQ	✓	Michael Corrales	APPROVED	F	
QA-PRO1	Control of Records	Jan-31-2026	N/A	Quality		QMS Coordinator	1factory - Austin	✓	Autumn Repetto	N/A	A.1	
QA-P-6162027	Preservation of Products	Mar-26-20...	OK	Quality		Quality Manager	1factory - HQ	✓	Autumn Repetto	N/A	A.1	
lst-3	Prevention of NCR	Mar-26-20...	N/A	Warehouse & Shipping			1factory - Little Rock	✓	Michael Corrales	N/A	A	
SQA-P-0087	Supplier Development	Mar-26-20...	OK	Supplier Quality		Supplier Quality Engineer	1factory - HQ	✓	Emily Anderson	APPROVED	E	
QA-P-0055	Control of Documented Information	Mar-26-20...	OK	Quality		QMS Coordinator	1factory - HQ	✓	Emily Anderson	APPROVED	D	
ENG-P-0054	Product Design and Development	Oct-23-2025	OK	Research & Development		Engineering Manager	1factory - HQ	✓	Emily Anderson	N/A	D.1	
QA-P-0052	Corrective and Preventive Action	Jan-15-2026	OK	Quality		Quality Manager	1factory - HQ	✓	Emily Anderson	N/A	E.1	
SQA-P-88	Counterfeit Parts Prevention	Feb-18-2026	OK	Supplier Quality		Supplier Quality Engineer	1factory - HQ	✓	Emily Anderson	APPROVED	B	
SAL-P-0063	Complaint Handling	Jan-13-2026	OVERDUE	Sales		Sales Manager	1factory - HQ	✓	Thach Nguyen	APPROVED	F	
QA-P-0053	Change Management	Mar-26-20...	OK	Quality		QMS Coordinator	1factory - HQ	✓	Thach Nguyen	APPROVED	F	

Step 3: Define Document Properties

Configure the required fields based on your document type:

Common Fields (All Document Types):

- **Document No/Document No Prefix:** Select or confirm the document numbering format
- **Title:** Enter a descriptive title for your document
- **Business Function:** Choose from the dropdown (must match LOV)
- **Owner:** Assign the QMS role responsible for this document
- **Sub-type:** Optional. Select from your organization's configured List of Values to classify the document. Sub-type can be assigned or changed while a document is in Draft status and all changes are tracked in the document's audit history.

Document-Specific Fields:

- **Standards Additional Fields:**
 - **Standard Number:** Standard number used within organization
 - **Standard Revision:** The revision of this document and is free text
 - **Issuing Org:** Choose the standards organization from dropdown
- **Forms Additional Fields:**
 - **Upload:** To upload the template file for this Form
 - **Record Number Prefix:** Required if creating Records from this Form
- **Work Instructions Additional Fields:**
 - **Part Number:** Optional. Select a Part Master if this Work Instruction is specific to a particular part number. This association is set at creation and cannot be changed afterward.

After completing all required fields, click the **Save** button to begin creating the document body content.

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No	Title	Updated On	Review (all)	Business Function (all)
QA-P-6162028	Demo procedure	Mar-30-20...	OK	Quality
LDR-P-0052	Risk Management	Mar-26-20...	OK	Leadership
LDR-P-0056	Quality Policy	Feb-26-2026	OK	Corporate
QA-P-0062	Control of Non-conforming Material	Feb-20-2026	OK	Quality
QM-1	Quality Manual	Feb-26-2026	OK	Quality
QA-PRO1	Control of Records	Jan-31-2026	N/A	Quality
QA-P-6162027	Preservation of Products	Mar-26-20...	OK	Quality
tst-3	Prevention of NCR	Mar-26-20...	N/A	Warehouse & Shipp
SQA-P-0087	Supplier Development	Mar-26-20...	OK	Supplier Quality
QA-P-0055	Control of Documented information	Mar-26-20...	OK	Quality
ENG-P-0054	Product Design and Development	Oct-23-2025	OK	Research & Develop
QA-P-0052	Corrective and Preventive Action	Jan-15-2026	OK	Quality
SQA-P-88	Counterfeit Parts Prevention	Feb-18-2026	OK	Supplier Quality
SAL-P-0063	Complaint Handling	Jan-13-2026	OVERDUE	Sales
QA-P-0053	Change Management	Mar-26-20...	OK	Quality
SAL-P-0089	Customer Satisfaction	Mar-26-20...	OK	Sales
MFG-P-0036	Production and Services Provisions	Mar-26-20...	OK	Manufacturing Oper

2.1.2 Editing Documents

Once your document is created, you can draft and refine content using 1factory's built-in rich-text editor. This editing environment provides the tools needed to create clear, compliant documentation that meets ISO standards and regulatory requirements.

Core Editing Features

- **Rich-Text Formatting:** Style content using bold, italic, underline, text color, and highlighting directly in the editor toolbar. No special syntax or markdown is required. Simply just use the tool bar at the top of each content section.
- **Structural Formatting:** Organize content using bullet lists, numbered lists, and indentation controls.
- **Tables:** Insert tables directly into any section and manipulate rows and columns as needed. When exporting to PDF, tables are appended to a Table Glossary at the end of the document, with inline links from each section pointing to the corresponding table in the glossary.
- **Images and Video:** Insert media by clicking the image icon in the toolbar, by dragging and dropping a file directly into a section, or by pasting an image from your clipboard.
- **Cross-References:** Type a document number (for example, PRO-1 or WI-4) anywhere in the document body. When viewed in Reading Mode, correctly entered document numbers automatically become clickable hyperlinks to the referenced document.
- **Section Management:** Add, modify, or delete sections using the Add New Section Before, Add New Section After, Section Number and Heading, Inline Section, and Delete Section controls.
- **Mode Switching:** Toggle between Editing Mode, Reading Mode, and Redline Mode.
- **Auto-Save:** All changes are automatically saved to prevent data loss.

Step 1: Use 1factory Built-in Editor

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Begin drafting your document with headings and content. During your document drafting process, use 1factory's built-in editor to help you create documents quicker. This is particularly valuable when documenting complex requirements that require precise step-by-step instructions and clear formatting.

4.2 Documentation and Records

Each non-conformance must be documented using a standardized **Non-Conformance Report (NCR)** that captures essential details within the Quality Management software per QA-WI-0085.

The NCR must include, at minimum, the following information:

- Unique identification number
- Date of identification
- Detailed description
- Affected batch/lot information
- Estimated quantity impacted
- Initial risk
- Supporting evidence (photos, measurements, certificates) — as applicable

The table below summarizes each required NCR field, its purpose, and whether it is mandatory:

NCR Field	Description	Required?
Unique Identification Number	System-generated number for traceability	Yes
Date of Identification	Date nonconformance was detected	Yes
Detailed Description	Nature of the nonconformance; actual vs. required	Yes
Affected Batch/Lot Information	Lot number, serial number, or work order reference	Yes
Estimated Quantity Impacted	Number of units or weight of affected material	Yes
Initial Risk	Preliminary assessment: Low / Medium / High	Yes
Supporting Evidence	Photos, measurement data, certificates, inspection records	As applicable

Critical: NCRs must be opened in the QMS system within **24 hours** of detection. Delays in documentation may result in uncontrolled release of nonconforming material and are considered a process nonconformance in their own right.

Record Retention: All NCRs and associated records must be retained for a minimum of **10 years** in the QMS document control system, or as otherwise required by the applicable regulatory standard (ISO 13485, AS9100D, IATF 16949).

External Document ONLY: Content appears in the window on the right side of the interface, with form preview on the left. The right hand content field is typically used to reference other QMS documents in the system to the form itself.

1. PURPOSE
This work instruction provides detailed steps for conducting employee training programs and competency assessments at 1factory to ensure personnel possess the necessary skills and knowledge to perform their assigned duties in accordance with ISO 9001, ISO 13485, and AS9100 requirements for precision machined components in the Aerospace and Medical device industries.

2. SCOPE
This instruction applies to all 1factory personnel including full-time employees, temporary workers, and contractors who perform activities affecting product quality, regulatory compliance, or operational safety.

3. REFERENCES
-HR-WI-0021 Employee Training and Competency Assessment
-LDR-WI-0041 Continuous Improvement and Corrective Actions
-MFG-WI-0049 Production Scheduling and Planning
-MFG-WI-0050 Machine Setup
-MFG-WI-0051 Operating Procedures for CNC Machines
-MFG-WI-0052 Process Validation and Verification
-MTN-WI-0005 Preventive Maintenance for Manufacturing Equipment
-PUR-WI-0012 Inventory Management and Stock Control

4.5 Heading not active
4.6 Load data manual

Step 2: Switch Between Editing Modes

1factory provides three viewing modes to support different stages of document development:

- **Editing Mode:** Allows you to edit and draft the content of the document. Access by default when creating new documents. Use when drafting new content or making revisions.
- **Reading Mode:** Displays document in read-only format as it appears to end users. Hyperlinks become active and clickable. Use to review document flow and verify cross-references.

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Important: Document numbers must be typed correctly. In Reading Mode, correctly linked documents appear blue and underlined. Incorrect references appear in red and black.

- **Redline Mode:** View content changes highlighted in different colors. Green indicates additions or modifications compared to the previous revision. Essential for maintaining compliance with quality management standards. Provides clear documentation of modifications between versions.

The screenshot displays the 1factory QMS interface. At the top, the document title is 'Control of Non-Conforming Material' and the status is 'DRAFT'. The document content is organized into sections. Section 4.1, 'Identification of Non-Conforming Material', describes the inspection process and includes a note about reporting non-conformances. To the right of this section is an image of a 'Red Reject tag' with fields for job number, part name, serial number, and inspection details. Below section 4.1 is section 4.2, 'Documentation and Records', which explains the Non-Conformance Report (NCR) process. A table summarizes the required NCR fields:

NCR Field	Description	Required?
Unique Identification Number	System-generated number for traceability	Yes
Date of Identification	Date nonconformance was detected	Yes
Detailed Description	Nature of the nonconformance: actual vs. required	Yes

Step 3: Section Modification

Within Editing Mode, use these features to structure your document:

- **Add New Section Before:** Inserts an empty section before the current section. Useful when adding preliminary instructions or safety warnings.
- **Add New Section After:** Inserts an empty section after the current section. Ideal for adding clarifications that follow the current content.
- **Section Number and Heading:** Creates a section with both a number and heading. Ensures consistent formatting throughout documentation and makes it easier for users to navigate complex procedures.
- **Inline Section:** Creates inline content without a formal heading. Useful for adding supporting information, notes, or brief clarifications.
- **Delete Section:** Removes the current section. A warning message appears before deletion. Note: Deleted content cannot be recovered after confirmation.

Note: Deleted content cannot be recovered after confirmation

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The screenshot displays the 1factory QMS interface for a document titled 'Control of Non-conforming Material'. The top menu bar includes icons for various functions, with the 'Image' icon highlighted by a green arrow. The document content is organized into sections: 4.1 Identification of Non-Conforming Material, 4.2 Documentation and Records, and a Red Reject tag. A video player is visible on the right side of the page.

4.1 Identification of Non-Conforming Material

Non-conforming materials can be identified at several stages throughout the production process, including during **incoming inspection, in-process inspection, final inspection or shipping**. Incoming inspection involves checking materials as they are received from suppliers to ensure they meet specified quality standards. In-process inspection is conducted at various stages of production to catch any issues early and prevent further processing of defective materials. Final inspection is the last checkpoint before the product is released to the customer.

Non-conformances can manifest in various forms, including but not limited to deviations from established specifications, which may involve incorrect dimensions, materials, or tolerances. Other common issues include physical damage to materials, incorrect or incomplete labeling, or improper packaging that fails to meet safety or regulatory requirements. These non-conformances must be identified and addressed immediately, per QA-WI-0085, to maintain the integrity of the final product and ensure customer satisfaction.

Note: Any employee who identifies a potential non-conformance must stop the affected process immediately and notify Quality before continuing production. a Red Reject tag must be filled out in its entirety and place on the material in question and be easily identifiable.

4.2 Documentation and Records

Each non-conformance must be documented using a standardized **Non-Conformance Report (NCR)** that captures essential details within the Quality Management software per QA-WI-0085.

The NCR must include, at minimum, the following information:

- Unique identification number
- Date of identification
- Detailed description
- Affected batch/lot information
- Estimated quantity impacted
- Initial risk
- Supporting evidence (photos, measurements, certificates) — as applicable

The table below summarizes each required NCR field, its purpose, and whether it is mandatory:

NCR Field	Description	Required?
Unique Identification Number	System-generated number for traceability	Yes

Step 4: Insert Images and Videos

Visual aids are crucial for process instructions, showing equipment setup, safety procedures, or quality checkpoints.

To Insert:

1. Click the **Image** icon in the top menu bar
2. Click the **Paper Clip** icon to select your file, then choose a placement option.
3. **Place Image At Right** (default) wraps text around the image.
4. **Place Image At Bottom** positions the image at full width below the text.

To Delete:

1. Select the image or video.
2. Click the **Delete** icon in the top menu.

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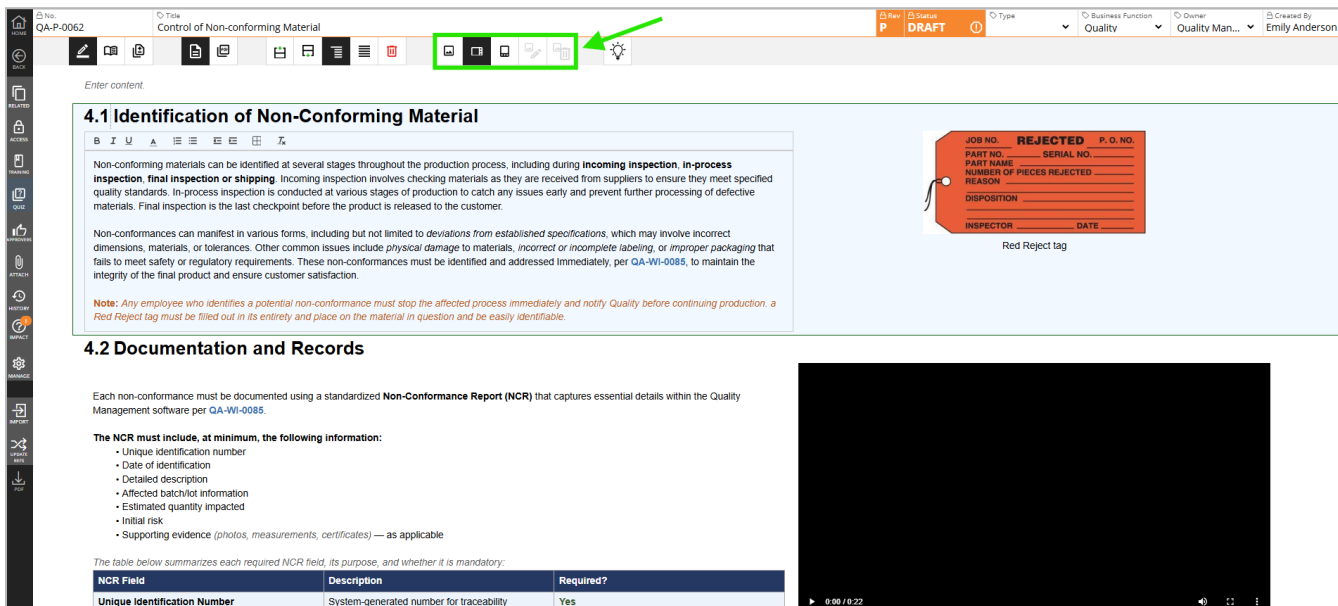
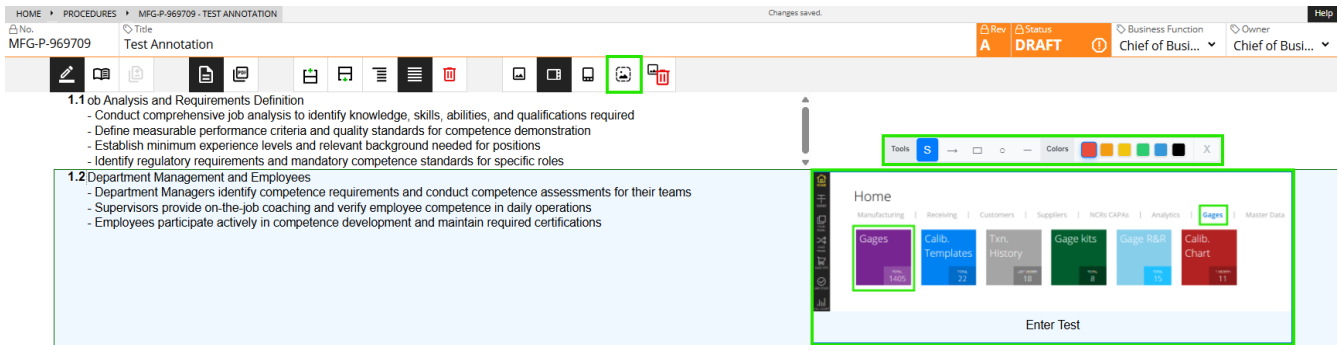


Image Annotation for Document Drafting

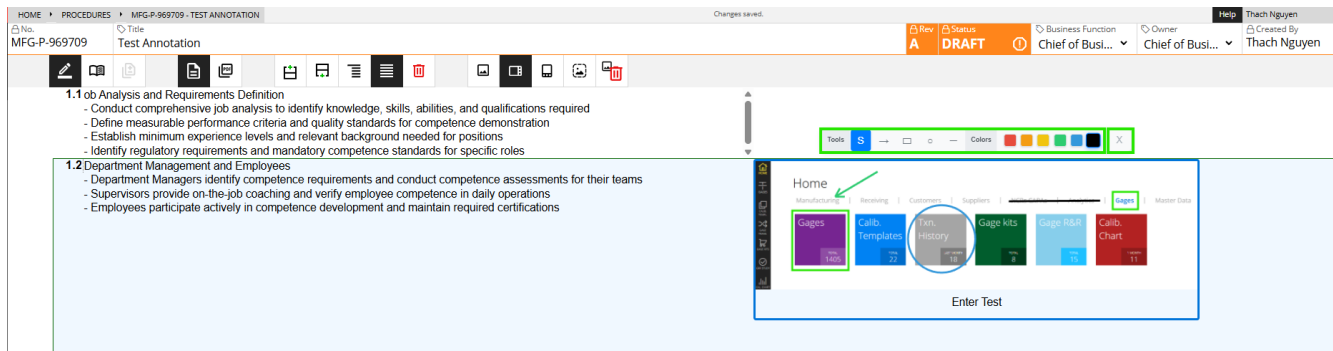
The Image Annotation feature allows users to insert images and add annotations directly onto uploaded images during the document drafting process. This supports comprehensive quality management documentation by enabling users to mark up, highlight, and annotate visual content within controlled documents.

After you insert an image into your document, navigate to the **Markup Image** icon to annotate your image. This feature is located in the top menu where the Add Image and Video features are found. Click on your image and navigate to the **Markup Image** button.

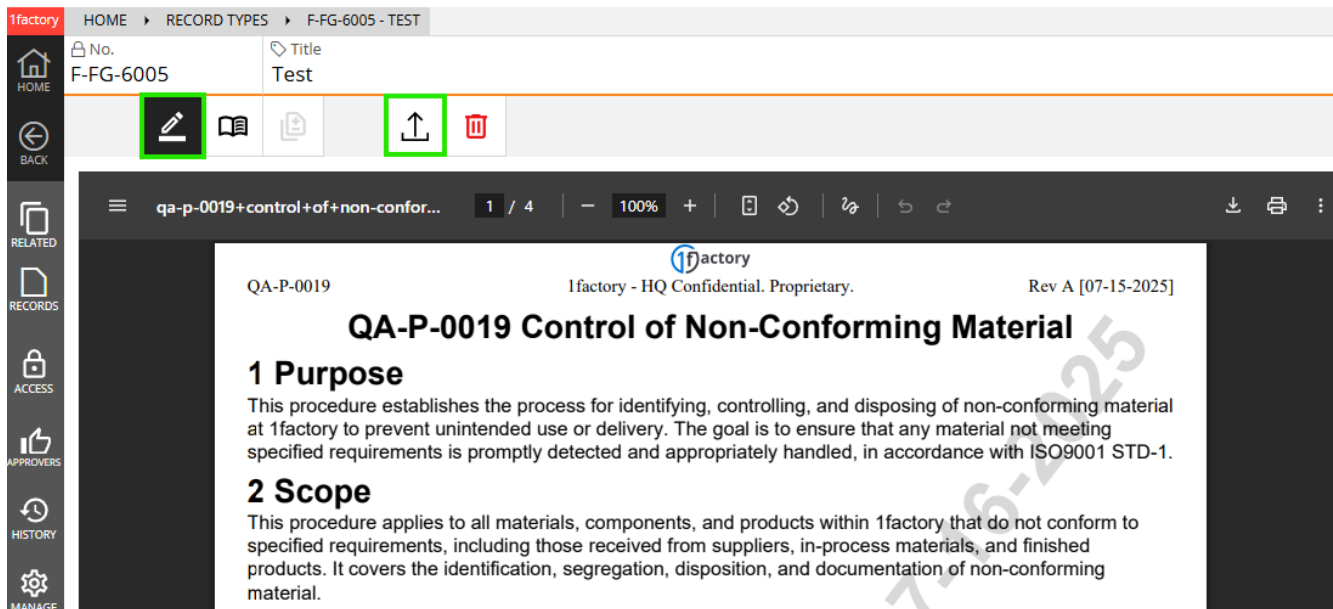


1factory offers 5 annotation tools: **Select**, **Arrow**, **Rectangle**, **Circle**, and **Line**, combined with 6 colors (**Red**, **Orange**, **Yellow**, **Green**, **Blue**, **Black**) to help you mark up your document. With each annotation you insert, you can change size, move, rotate, and specify the color. Click the **(X)** icon in the top right corner of the toolbar to cancel an annotation.

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Forms: Unlike other document types, Forms do not support native rich-text content authoring. Instead, the controlled document is an uploaded file. In Editing Mode, click the Upload Form Document icon, click the paper clip icon to select your file, and click Go. Supported file types include PDF, Word (.doc, .docx), Excel (.xls, .xlsx, .xlsm), and PowerPoint (.ppt, .pptx, .ppsx). Uploaded PDFs display in read-only mode within 1factory. All other file types appear as a downloadable link. To replace the file with a newer version, simply upload a new file following the same steps.



2.1.3 Related Documentation

The Related Documentation feature creates a comprehensive network of cross-referenced documents, making it easier for operators and auditors to navigate between related documents.

Step 1: Input documents into content

Place the reference document number and into your document body during drafting.

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QA-P-0062 Control of Non-conforming Material

Rev: P Status: DRAFT Type: Quality Business Function: Quality Owner: Quality Man... Created By: Emily Anderson

Enter content.

4.1 Identification of Non-Conforming Material

Non-conforming materials can be identified at several stages throughout the production process, including during **incoming inspection**, **in-process inspection**, **final inspection** or **shipping**. Incoming inspection involves checking materials as they are received from suppliers to ensure they meet specified quality standards. In-process inspection is conducted at various stages of production to catch any issues early and prevent further processing of defective materials. Final inspection is the last checkpoint before the product is released to the customer.

Non-conformances can manifest in various forms, including but not limited to deviations from established specifications, which may involve incorrect dimensions, materials, or tolerances. Other common issues include physical damage to materials, incorrect or incomplete labeling, or improper packaging that fails to meet safety or regulatory requirements. These non-conformances must be identified and addressed immediately, per QA-WI-0085, to maintain the integrity of the final product and ensure customer satisfaction.

Note: Any employee who identifies a potential non-conformance must stop the affected process immediately and notify Quality before continuing production. A Red Reject tag must be filled out in its entirety and place on the material in question and be easily identifiable.

Red Reject tag

JOB NO. **REJECTED** P. O. NO.
PART NO. SERIAL NO.
PART NAME
NUMBER OF PIECES REJECTED
REASON
DISPOSITION
INSPECTOR DATE

Step 2: Activate the hyperlink

Switch between **Edit Mode** and **Reading Mode** to activate the hyperlink. The document number will become blue and underlined when correctly linked.

QA-P-0062 Control of Non-conforming Material

Rev: P Status: DRAFT Type: Quality Business Function: Quality Owner: Quality Man... Created By: Emily Anderson

4 Procedure

4.1 Identification of Non-Conforming Material

Non-conforming materials can be identified at several stages throughout the production process, including during **incoming inspection**, **in-process inspection**, **final inspection** or **shipping**. Incoming inspection involves checking materials as they are received from suppliers to ensure they meet specified quality standards. In-process inspection is conducted at various stages of production to catch any issues early and prevent further processing of defective materials. Final inspection is the last checkpoint before the product is released to the customer.

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Red Reject tag

JOB NO. **REJECTED** P. O. NO.
PART NO. SERIAL NO.
PART NAME
NUMBER OF PIECES REJECTED
REASON
DISPOSITION
INSPECTOR DATE

Note: If you input the wrong document number, the hyperlink cannot be activated.

Step 3: View related documents

Click the **Related** button on the left menu bar to view all documents linked to the current document.

QA-P-0062 Control of Non-conforming Material

Rev: P Status: DRAFT Type: Quality Business Function: Quality Owner: Quality Man... Created By: Emily Anderson

4 Procedure

4.1 Identification of Non-Conforming Material

Non-conforming materials can be identified at several stages throughout the production process, including during **incoming inspection**, **in-process inspection**, **final inspection** or **shipping**. Incoming inspection involves checking materials as they are received from suppliers to ensure they meet specified quality standards. In-process inspection is conducted at various stages of production to catch any issues early and prevent further processing of defective materials. Final inspection is the last checkpoint before the product is released to the customer.

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Note: Any employee who identifies a potential non-conformance must stop the affected process immediately and notify Quality before continuing production. A Red Reject tag must be filled out in its entirety and place on the material in question and be easily identifiable.

4.2 Documentation and Records

Related Documents

Other documents that are related to this document.

[This Procedure does not implement any Standard Requirements.](#)

[This Procedure refers to the following documents:](#)

No.	Title	Updated On	Owner	Ver.
EXT-P-0012	ISO 9001:2015:1 Quality management systems - Requirements	Feb-09-2026	Corp. Quality Manag...	2015.1
STD-1	13485 1.0 medical device	Feb-11-2026	Quality Manager	1.0
QA-P-0052	Corrective and Preventive Action	Jan-15-2026	Quality Manager	E
MTN-P-0011	Total Productive Maintenance (TPM)	Mar-26-20...	Maintenance Manag...	E
LDR-P-0061	Management Review	Mar-26-20...	Quality Manager	F
QA-P-0489	Control of Records	Feb-11-2026	QMS Coordinator	C
QA-WI-0085	Creating an NCR	Mar-26-20...	Quality Inspector	C
MFG-WI-0048	Clean Point Sorting	Mar-26-20...	Production Manager	B

[No released documents refer to this Procedure.](#)

The Related Documentation feature creates a comprehensive network of cross-referenced documents, making it easier for operators and auditors to navigate between related documents.

1factory QMS User Manual

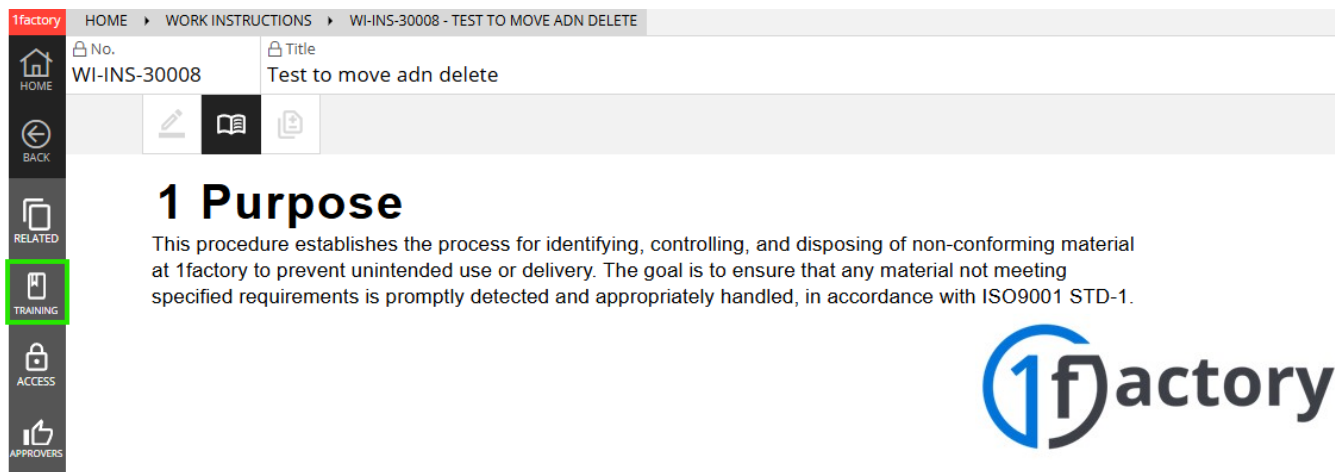
2.1.4 Assigning Training

Not Available For: Record Types

The Training feature ensures personnel receive proper instruction before executing quality processes. Training records are maintained automatically, providing audit trails for regulatory requirements.

Step 1: Assign the training

On the left vertical menu, click the **Training** tile to start assigning training for users.



The screenshot displays the 1factory QMS user interface. On the left is a vertical sidebar with icons for HOME, BACK, RELATED, TRAINING (highlighted with a green border), ACCESS, and APPROVERS. The main content area shows a breadcrumb trail: HOME > WORK INSTRUCTIONS > WI-INS-30008 - TEST TO MOVE ADN DELETE. Below this, there are fields for 'No.' (WI-INS-30008) and 'Title' (Test to move adn delete). A row of three icons (pencil, book, document) is visible. The section is titled '1 Purpose' and contains the text: 'This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with ISO9001 STD-1.' The 1factory logo is positioned on the right side of the page.

Step 2: Configure training parameters

- **Select Roles:** Choose which QMS roles require training
- **Time to Complete:** Set deadline for training completion after document release
- **Retraining Interval:** Define automatic retraining schedules if document isn't revised within time frame
- **Assessment Method:** Select Self Assessment, Quiz, or External Certificate

1factory QMS User Manual

⊗ Training Plan

Select roles that need to be trained on this document, and how often they need to be retrained

Click names to add role

Select roles ...

Selected roles

Director of Marketing

Time to complete (days)

15

Retraining interval (months)

1

① No "Time to complete" indicates there is no deadline to complete training.

① No "Retraining interval" indicates that regularly scheduled retraining is not required.

Assessment Method

Quiz

① Users must successfully answer multiple choice questions in order to complete the training.

SHF
G

GO

After completing all fields, click the **Go** button.

Step 3: Design Quiz training (if applicable) If using Quiz assessment:

1. Click the **Quiz** tile on left vertical menu
2. Design questions and answers for the training
3. Click **Go** button after completing all questions

HOME > WORK INSTRUCTIONS > WI-INS-30010 - HOW TO INSTALL THE PLUNGER

WI-INS-30010 How To install the plunger

1 PURPOSE AND SCOPE

This work instruction provides detailed step-by-step procedures for the assembly of Plunger Assembly part number 12-5039 ensures consistent assembly processes that meet aerospace (AS9100) and medical device (ISO 13485) quality requirements machined components.

Applicable Standards:

- MFG-P-2 - Cleaning burr process
- MR-WI-S-08062025 - Assembly process part master
- MR-WI-S-8062025 - Safety working area instruction

2 RESPONSIBILITIES

Assembly Operator: Execute assembly procedures according to this work instruction and maintain quality records.
Manufacturing Engineer: Provide technical support and approve any process deviations.
Quality Inspector: Verify dimensional conformance and approve completed assemblies.
Production Supervisor: Ensure proper training and resource availability for assembly operations.

3 REQUIRED MATERIALS AND TOOLS

Materials Required:

- Plunger Body (P/N 12-5039-001)
- Spring Assembly (P/N 12-5039-002)
- Retaining Ring (P/N 12-5039-003)
- O-Ring Seal (P/N 12-5039-004)
- Threaded Cap (P/N 12-5039-005)

Tools and Equipment:

Training Assessment Quiz

Define multiple choice questions and answers that users must successfully complete in order to complete training on this document.

Question
Need to clean the burr before assembly?

Correct Answer
Yes

Wrong Answer
No

Wrong Answer

Question
Enter a question

Correct Answer

Wrong Answer

Wrong Answer

Wrong Answer

SHF
G

GO

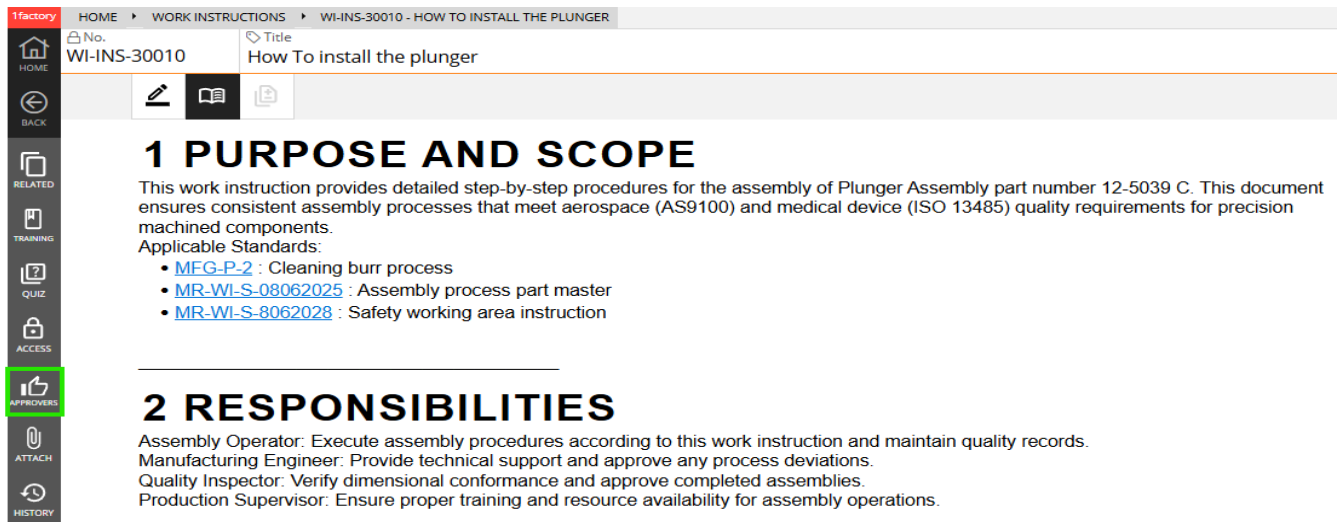
2.1.5 Assigning Document Approvers

1factory QMS User Manual

Define the approval workflow before documents become active in the QMS, ensuring proper review and authorization.

Step 1: Assign Approvers

On the left vertical menu, click the **Approvers** tile.



The screenshot displays the 1factory QMS user interface. On the left is a vertical sidebar with icons for HOME, BACK, RELATED, TRAINING, QUIZ, ACCESS, **APPROVERS** (highlighted with a green box), ATTACH, and HISTORY. The main content area shows a breadcrumb trail: HOME > WORK INSTRUCTIONS > WI-INS-30010 - HOW TO INSTALL THE PLUNGER. Below this, there are fields for 'No.' (WI-INS-30010) and 'Title' (How To install the plunger). The document content is titled '1 PURPOSE AND SCOPE' and describes the assembly procedure for Plunger Assembly part number 12-5039 C. It lists applicable standards: MFG-P-2 (Cleaning burr process), MR-WI-S-08062025 (Assembly process part master), and MR-WI-S-8062028 (Safety working area instruction). Below this is a section titled '2 RESPONSIBILITIES' which lists roles: Assembly Operator, Manufacturing Engineer, Quality Inspector, and Production Supervisor, each with a brief description of their duties.

Step 2: Select approver roles

- Choose QMS roles required to approve the document
- System automatically includes mandatory approver role from organization settings
- After completing selections, click **Go** button

1factory QMS User Manual

⊗ Approvers

Select roles that must approve new revisions of this document.

Click names to add role

Select roles ...	▼	Chief of Business Integration
------------------	---	-------------------------------

ⓘ Approver roles will also include mandatory approver role: QMS Coordinator

ⓘ Document must be approved by one user from each Approver role before it can be released.

SHF G	GO
----------	----

Note: If your document requires more than two roles with multiple approvers, select a different approver name for each role.

2.1.6 Document Access Control

Configure viewing permissions based on roles and responsibilities, ensuring only authorized personnel can access documents.

Step 1: Initialize Access Controls

On the left vertical menu, click the **Access** tile.

1factory

HOME ▶ WORK INSTRUCTIONS ▶ WI-INS-30010 - HOW TO INSTALL THE PLUNGER

WI-INS-30010

How To install the plunger

BACK

RELATED

TRAINING

ACCESS

APPROVERS

ATTACH

HISTORY

MANAGE

1 PURPOSE AND SCOPE

This work instruction provides detailed step-by-step procedures for the assembly of Plunger Assembly part number 12-5039 C. This document ensures consistent assembly processes that meet aerospace (AS9100) and medical device (ISO 13485) quality requirements for precision machined components.

Applicable Standards:

- [MEG-P-2](#) : Cleaning burr process
- [MR-WI-S-08062025](#) : Assembly process part master
- [MR-WI-S-8062028](#) : Safety working area instruction

2 RESPONSIBILITIES

Assembly Operator: Execute assembly procedures according to this work instruction and maintain quality records.
Manufacturing Engineer: Provide technical support and approve any process deviations.
Quality Inspector: Verify dimensional conformance and approve completed assemblies.
Production Supervisor: Ensure proper training and resource availability for assembly operations.

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Step 2: Configure Access Restrictions

- **Viewer Roles:** Define which QMS roles can view the document
- **Applicable Organizations:** For Federated QMS, specify which organizations can access documents

Access

Restrict access to this document.

Click names to restrict to roles

Select role ...		Restricted to roles
		Chief of People and Development

- ① Document is accessible only by the selected roles.
- ① If no roles are selected, then the document is accessible by all roles.
- ① Document is always accessible by the mandatory approver role: QMS Coordinator

SHF G	GO
----------	----

After completing selections, click the **Go** button.

2.1.7 Document Attachments

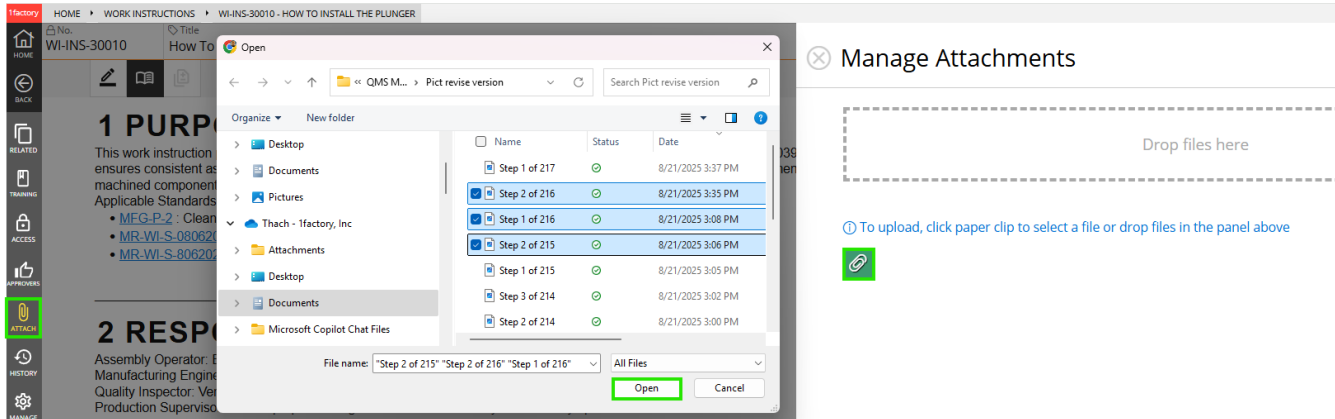
Not Available For: Record Types

Attach supporting files to provide additional resources and reference materials.

Step 1: Attach document

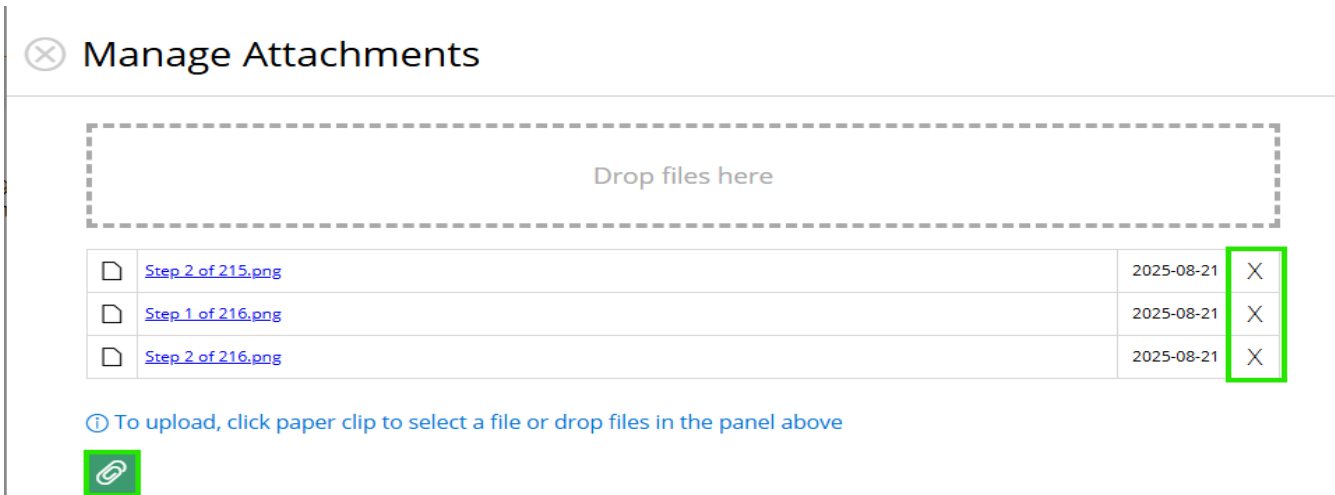
Click the **Attach** tile on the left vertical menu.

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Step 2: Select and manage files

- Click paper clip icon to add files
- Use Shift + left click for multiple files
- Click (x) icon to remove files
- Click (x) at Manage Attachments to exit



Supported capabilities:

- Various file formats (PDF, Word, Excel, images)
- Version control for attached files
- Attachments inherit parent document access controls
- Full audit trail of attachment changes

2.1.8 Document History

1factory QMS User Manual

Provides a complete audit trail of all changes and activities, maintaining compliance with regulatory requirements.

The screenshot displays the 1factory QMS interface. On the left, a sidebar contains icons for various functions, with the 'History' icon highlighted. The main content area shows a work instruction document titled 'How To install the plunger' (WI-INS-30010). The document includes sections for '1 PURPOSE AND SCOPE' and '2 RESPONSIBILITIES'. On the right, a 'Change History' table is visible, detailing revisions to the document.

ID	Field - Value	Revised on	Revised by
0	VERSION 1: CREATED	2025-08-21, 20:10	Thach Nguyen
1	DOCUMENT NUMBER: WI-INS-30010	2025-08-21, 20:10	Thach Nguyen
2	TITLE: How To install the plunger	2025-08-21, 20:10	Thach Nguyen
3	BUSINESS FUNCTION: Production	2025-08-21, 20:10	Thach Nguyen
4	OWNER: QA Manager	2025-08-21, 20:10	Thach Nguyen
5	SECTION 1: IMPORTED	2025-08-21, 20:11	Thach Nguyen
6	SECTION 2: IMPORTED	2025-08-21, 20:11	Thach Nguyen
7	SECTION 3: IMPORTED	2025-08-21, 20:11	Thach Nguyen
8	SECTION 4: IMPORTED	2025-08-21, 20:11	Thach Nguyen
9	SECTION 5: IMPORTED	2025-08-21, 20:11	Thach Nguyen
10	SECTION 6: IMPORTED	2025-08-21, 20:11	Thach Nguyen
11	SECTION 7: IMPORTED	2025-08-21, 20:11	Thach Nguyen
12	SECTION 8: IMPORTED	2025-08-21, 20:11	Thach Nguyen

Access by clicking the **History** icon on left menu bar to view:

- Revision history with all document versions
- User activity tracking
- Status change log
- Approval records and comments
- Training assignment history
- Access logs
- Upload/Download activity (Record Types only)

2.1.9 Routing Documents for Approval

Manage the document lifecycle from creation to release through proper workflow management.

Step 1: Access Management

Click the **Manage** tile on the left vertical menu.

1factory QMS User Manual

1 Purpose

This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with EXT-P-0012, AS

2 Definitions

Enter content.

2.1

Non-Conforming Material: Material, component, or product that does not meet established specifications, quality standards, or customer requirements.

2.2

Non-Conformance Report (NCR): A formal document used to record and track instances of nonconforming material, including details of the issue, root cause analysis, and corrective actions.

2.3

Complaint Management: This is owned by customer service and they are responsible for reporting to the Quality Engineer

2.4

Manage

Minor Update?
YES NO

Approval

Status	Role	Approver	Signed on
N/A	QMS Coordinator		
N/A	Operations Manager		

Versioning
DRAFT PENDING APPROVAL RELEASED

Release notes
Optional

Retraining required? YES NO Status ACTIVE INACTIVE

Review interval (months)
24

Save

Step 2: Route for Approval

Select the **Approver(s)** from the dropdown menu, click the **Pending Approval** button to start the approval process, and click **Save**. The approver receives an email notification.

1 Purpose

This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with EXT-P-0012, AS

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2.3

Complaint Management: This is owned by customer service and they are responsible for reporting to the Quality Engineer

Manage

Minor Update?
YES NO

Approval

Status	Role	Approver	Signed on
N/A	QMS Coordinator	Emily Anderson	
N/A	Operations Manager	Anthony Clark	

Versioning
DRAFT PENDING APPROVAL RELEASED

Release notes
Updated to include reference shipping process.

Retraining required? YES NO Status ACTIVE INACTIVE

Review interval (months)
24

Save

Step 3: Approve or Reject the Document

Each assigned approver navigates to the document, opens the **Manage** tab, and selects either **Approved** or **Rejected**. An optional approval note can be entered to provide context for the decision. Click **Save** to record the decision.

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The screenshot displays the 1factory QMS interface. On the left, a document titled "Control of Non-conforming Material" (QA-P-0062) is open, showing sections 1 through 3. On the right, the "Manage" sidebar is visible, containing various controls for the document.

1 Purpose
This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with [EXT-P-0012, AS9100](#).

2 Definitions

- 2.1 **Non-Conforming Material:** Material, component, or product that does not meet established specifications, quality standards, or customer requirements.
- 2.2 **Non-Conformance Report (NCR):** A formal document used to record and track instances of nonconforming material, including details of the issue, root cause analysis, and corrective actions.
- 2.3 **Complaint Management:** This is owned by customer service and they are responsible for reporting the issues to the customer.
- 2.4 **Corrective Action:** A process implemented to eliminate the root cause of a detected non-conformance to prevent recurrence.

3 Responsibilities

- 3.1 **Quality Control (QC) Team:** The QC team is responsible for identifying non-conforming materials during inspections, documenting non-conformances in detail, and initiating Corrective Action Preventive Action (CAPA) processes. They maintain comprehensive records of all non-conformance investigations and ensure thorough tracking of quality-related issues in all process and division.

Manage

Minor Update?

Approval

Status	Role	Approver	Signed on
APPROVED	QMS Coordinator	Emily Anderson	Apr-03-2026
PENDING	Operations Manager	Anthony Clark	

By signing off and approving this document, I hereby certify that I have fulfilled all responsibilities associated with my role in the release of this document into the QMS. **Emily Anderson** - Apr-03-2026, 10:34

Review Notes
Enter a review note (optional)

Versioning

Release notes
Updated to include reference shipping process.

Retraining required? Status

Review interval (months)
24

If the document is **rejected**, the document author receives an email notification. The author can then either return the document to **Draft** status to make the requested changes and re-route for approval, or discuss the reason for rejection directly with the approver before taking further action. Once any changes are made in Draft, the document must be re-routed through the full approval process.

Step 4: Release Document

Once all required approvers have approved the document, return to the **Manage** tab. If Document Effectivity is enabled in QMS Settings, you will see a **Pending Release** option between Approved and Released. See **Section 2.1.10** for details on that workflow. Otherwise, switch the status from **Approved** to **Released**, add **Release Notes** (required), and click **Save**.

1factory QMS User Manual

QA-P-0062

Control of Non-conforming Material

1 Purpose

This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with [EXT-P-0012](#), AS9100.

2 Definitions

2.1

Non-Conforming Material: Material, component, or product that does not meet established specifications, quality standards, or customer requirements.

2.2

Non-Conformance Report (NCR): A formal document used to record and track instances of nonconforming material, including details of the issue, root cause analysis, and corrective actions.

2.3

Complaint Management: This is owned by customer service and they are responsible for reporting the issues to the customer.

2.4

Corrective Action: A process implemented to eliminate the root cause of a detected non-conformance to prevent recurrence.

3 Responsibilities

3.1

Quality Control (QC) Team: The QC team is responsible for identifying non-conforming materials during inspections, documenting non-conformances in detail, and initiating Corrective Action Preventive Action (CAPA) processes. They maintain comprehensive records of all non-conformance investigations and ensure thorough tracking of quality-related issues in all process and division.

Manage

Minor Update?

YESNO

Approval

Status	Role	Approver	Signed on
APPROVED	QMS Coordinator	Emily Anderson	Apr-03-2026
APPROVED	Operations Manager	Anthony Clark	Apr-03-2026

Review Notes

Apr-03-2026, 10:36Anthony Clarkverified.

Versioning

DRAFTAPPROVEDRELEASED

By signing off and releasing this document, I hereby certify all requirements associated with the release of this document into the QMS have been fulfilled.**Anthony Clark** - Apr-03-2026, 10:36

Release notes

Updated to include reference shipping process.

Retraining required?

NOYES

Status

ACTIVEINACTIVE

Review of this document is due by Apr-03-2028.

SAVE

Minor Update Process

For released documents requiring minor edits without full approval, open the document and click **Manage**, click **Draft** to create a new revision, make edits in the new revision, return to Manage and select **Yes** for Minor Update, select **AMENDED** status, add Release Notes (required), and click **Save**.

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931

⊗ Manage

Minor Update?

YES	NO
-----	----

ⓘ Minor updates do not require approval or retraining. They should be used only for small amendments that do not materially affect the document.

Versioning

DRAFT	AMENDED
-------	---------

By signing off and releasing this document, I certify that this update qualifies as a minor change and does not impact the intent, scope, or requirements of the original document.

Enter password to sign

Release notes

Optional

Status

ACTIVE	INACTIVE
--------	----------

SHF G	SAVE
----------	------

Note: Minor updates use a decimal revision format (for example, A becomes A.1). Minor updates can be completed by any user holding the **Mandatory Approver Role**.

Multi-Stage Approval with Mandatory Approver Controls

For organizations that require stricter approval sequencing, 1factory supports a multi-stage approval workflow through the **Mandatory Approver Controls Release** setting. This setting is available in QMS Settings when a Mandatory Approver Role is configured. All behaviors described below are only active when this setting is enabled.

1factory QMS User Manual

QMS Settings

- Enable QMS Onboarding: Yes Enables features to allow you to migrate documents into 1Factory from a legacy system.
- Quality Manual: QM-1 Quality Manual
- Mandatory Approver Role: QMS Coordinator
- Mandatory Approver controls release?: Yes** If Yes, only Mandatory Approver can release documents, and must approve before other approvers can review.
- Use alphabetic revisions: Yes
- Document Numbers: Your own numbers
- Standard Number Prefixes: EXT-, STD-
- Mfg. Standard Number Prefixes: MFG-
- Procedure Number Prefixes: QM-, tst-, QA-P-, SQA-P-, MTN-P, SAL-P, LC
- Work Instruction Number Prefixes: QA-WI-, PUR-WI-, MFG-WI-, LDR-WI-, HR-W
- Record Type Number Prefixes: QA-F-, MEMO-
- Allow external files as documents: Yes
- Periodic Document Reviews: Yes
- Document Review Period: 30 Review process starts this number of days before the scheduled review due date.

When a document is moved to **Pending Approval**, the Mandatory Approver is set to **Pending** while all other approvers are set to a **Waiting** status. Waiting approvers receive no notification and cannot submit an approval decision until the Mandatory Approver has approved the document.

QA-P-0062 Control of Non-conforming Material

1 Purpose

This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with EXT-P-0012, AS9100.

2 Definitions

- 2.1 Non-Conforming Material:** Material, component, or product that does not meet established specifications, quality standards, or customer requirements.
- 2.2 Non-Conformance Report (NCR):** A formal document used to record and track instances of nonconforming material, including details of the issue, root cause analysis, and corrective actions.
- 2.3 Complaint Management:** This is owned by customer service and they are responsible for reporting the issues to the
- 2.4 Corrective Action:** A process implemented to eliminate the root cause of a detected non-conformance to prevent recurrence.

3 Responsibilities

- 3.1 Quality Control (QC) Team:** The QC team is responsible for identifying non-conforming materials during inspections, documenting non-conformances in detail, and initiating Corrective Action Preventive Action (CAPA) processes. They maintain comprehensive records of all non-conformance investigations and ensure thorough tracking of quality-related issues in all process and division.

Manage

YES NO

Status	Role	Approver	Signed on
PENDING	QMS Coordinator	Emily Anderson	
WAITING	Operations Manager	Anthony Clark	
WAITING	Quality Manager	Ava Brown	

PENDING APPROVED REJECTED

Review Notes

Enter a review note (optional)

Versioning

DRAFT PENDING APPROVAL RELEASED

Release notes

Updated throughout...see redline markup.

Retraining required? Status

NO YES ACTIVE INACTIVE

Review interval (months)

24

SAVE

1factory QMS User Manual

Once the Mandatory Approver approves, all remaining approvers are advanced to **Pending** and receive their email notifications. If the Mandatory Approver rejects the document, all other approvers remain in **Waiting** status and the document must be returned to **Draft** before it can be re-routed.

The screenshot displays the 1factory QMS interface. On the left, a sidebar contains navigation icons for Home, Back, Related, Access, Manual, Quiz, Attachments, History, Impact, Settings, and Download. The main content area is divided into two panels. The left panel, titled 'QA-P-0062 Control of Non-conforming Material', contains sections for Purpose, Definitions, and Responsibilities. The right panel, titled 'Manage', contains a 'Minor Update?' section with 'YES' and 'NO' buttons. Below this is an 'Approval' section with a table of approvers and a 'PENDING' button. The table has columns for Status, Role, Approver, and Signed on. The 'PENDING' button is highlighted with a green box. Below the table is a 'Review Notes' section with a text area and a 'Versioning' section with 'DRAFT', 'PENDING APPROVAL', and 'RELEASED' buttons. The 'PENDING APPROVAL' button is highlighted with a blue box. Below the versioning buttons is a 'Release notes' section with a text area and a 'Retraining required?' section with 'NO', 'YES', 'ACTIVE', and 'INACTIVE' buttons. The 'YES' button is highlighted with a blue box.

Status	Role	Approver	Signed on
APPROVED	QMS Coordinator	Emily Anderson	Apr-03-2026
PENDING	Operations Manager	Anthony Clark	
PENDING	Quality Manager	Ava Brown	

By signing off and approving this document, I hereby certify that I have fulfilled all responsibilities associated with my role in the release of this document into the QMS. Emily Anderson - Apr-03-2026, 10:55

Review Notes
Apr-03-2026, 10:55 Emily Anderson Verified all actions to address risk have been conducted.
Enter a review note (optional)

Versioning
DRAFT PENDING APPROVAL RELEASED

Release notes
Updated throughout...see redline markup.

Retraining required? Status
NO YES ACTIVE INACTIVE

After the Mandatory Approver signs off, the document content and all Manage tab settings become read-only. The only actions available at that point are approval decisions for users with a **Pending** approval and release authority for users in the **Mandatory Approver Role**. Only users assigned to the Mandatory Approver Role can transition the document from **Approved** to **Released**. Release notes are mandatory when this setting is enabled.

Note: If the Mandatory Approver Role is changed in settings while a document is actively in the approval process and the new role does not appear in the document's approver list, the system reverts to standard behavior and all approvers proceed to **Pending** simultaneously.

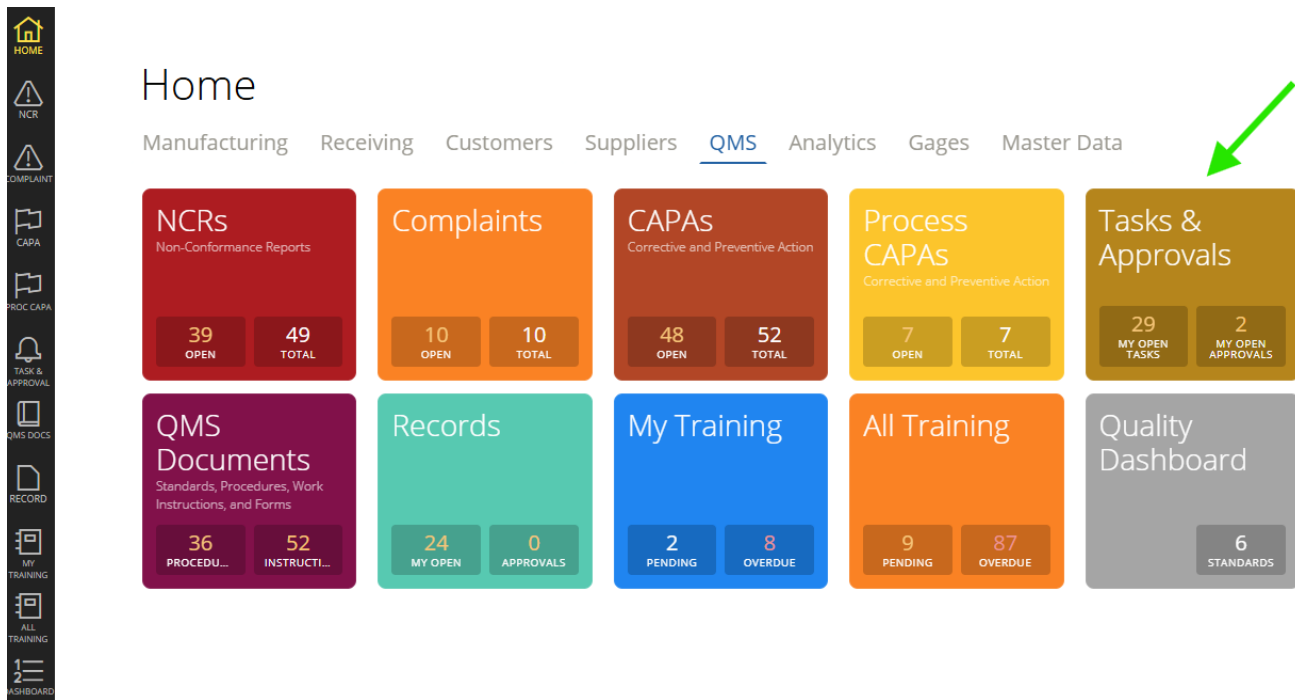
2.1.10 Tasks & Approvals

When a document is routed for approval, responsibility for moving it forward is distributed across multiple approvers, sometimes across multiple roles and organizations. Without a centralized view, quality managers are left chasing status updates individually or building manual reports in Excel. The **Tasks & Approvals** tile on the QMS tab provides a live, exportable reporting surface for all open and completed approval activity across documents, plans, and records.

Accessing Tasks & Approvals

Navigate to the **QMS** tab and click the **Tasks & Approvals** tile. The tile displays two counts: open **Tasks** and pending **Approvals** for the current user. Clicking either count opens the Tasks & Approvals page pre-filtered to that type and scoped to the logged-in user.

1factory QMS User Manual



The page has two tabs: **Tasks** and **Approvals**. A dropdown controls the scope of whichever tab is active:

- **My Tasks & Approvals** (default): scoped to the logged-in user
- **All Tasks & Approvals**: unfiltered view across all users and roles

The Tasks Tab

The Tasks tab displays all open quality action items assigned to you or your roles across the system. Each row shows the task **ID**, **Description**, the **Source** record it originated from (such as NCR-252978 or CAPA-871), the **Context** within that record, who **Created** the task, who it is **Assigned To**, the associated **Role**, the **Due Date**, any **Resolution** notes, and the current **Status**.

Status values are color coded for quick scanning:

- **Open**: Task is active and assigned
- **Unassigned**: Task exists but has not yet been assigned to a specific user
- **Closed**: Task has been completed and resolved

Due dates flagged with a warning icon indicate the task is past due.

Clicking anywhere on a task row opens the originating record directly in a new window, so you can act on it without losing your place in the list.

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Tasks & Approvals										
Tasks Approvals Search 1-50 of 97										
ID	Description	Source	Context	Created by [all]	Assigned to [all]	Role [all]	Due on [all]	Resolution	Status [all]	
115	Update ERP / Inventory	NCR-53	SCRAP	Michael Corrales		Purchasing Manager	APR-09-2026		UNASSIGNED	
114	Please complete section 3: Containment Plan	CAPA-50	Cont. plan	Emily Anderson	Emily Anderson		May-06-2026	complete and v...	CLOSED	
113	Quality Approval	NCR-52	USE AS-IS	Emily Anderson	Emily Anderson	Quality Engineer	May-05-2026	complete and v...	CLOSED	
109	Please complete section 3: Containment Plan	CAPA-49	Cont. plan	Emily Anderson	Emily Anderson		May-05-2026	complete and v...	CLOSED	
108	Quality Approval	NCR-51	USE AS-IS	Emily Anderson	Emily Anderson	Quality Engineer	May-05-2026	complete and v...	CLOSED	
97	Machine 12321 - Is leaking oil and is a safety risk. - Please address ASAP.	NCR-42		Michael Corrales	Emily Anderson		Dec-10-2025	verified and co...	CLOSED	
96	Please complete section 5: Corrective Actions	PCAPA-6	Corr. Act.	Michael Corrales	Michael Corrales		Dec-18-2025		CLOSED	
95	Please complete section 3: Containment Plan	SCAR-11	Cont. plan	Emily Anderson	Emily Anderson		Dec-11-2025		CLOSED	
94	Quality Approval	NCR-40	USE AS-IS	Emily Anderson	Emily Anderson	Quality Engineer	Dec-13-2025	okay....	CLOSED	
92	Please complete section 4: Root Cause Analysis	CAPA-44	Root Cause	Michael Corrales	Matt Stanley		DEC-17-2025		OPEN	

The Approvals Tab

The **Approvals** tab provides a structured list of all approval requests across QMS documents, plans, and records. Each row represents one assigned approver on one object revision, giving managers full visibility into who is pending, who has approved, and where bottlenecks exist.

The following columns are available:

- **Name:** The document reference number and title, plan part master and description, or record identifier. Clicking the name opens the object in a new window.
- **Revision:** The revision or version the approval is for. Color coded to reflect current status, consistent with the document and plan list views. Filterable by status.
- **Type:** The type of object the approval is for: **QMS Document**, **Plan**, or **Record**. Filterable.
- **Sub-Type:** For QMS Documents only. Displays the document type (Procedure, Standard, Work Instruction, etc.) combined with any customer-defined Sub-Type configured in your List of Values. Filterable.
- **Approver:** The username of the assigned approver. Filterable.
- **Role:** The QMS role associated with the approval, where applicable. Plan approvals do not use roles. Filterable.
- **Days Open:** The number of days from when the approval was placed into **Pending** status to either the current date (if still open) or the date the approval was closed (if approved or rejected).
- **Last Activity:** The date of the most recent status change, including when the approval was made pending, approved, or rejected. Filterable by **Today** or **Past Week**, supporting daily status reporting without manual comparison.
- **Status:** Color coded and filterable. Values are:
 - **Assigned:** Pending, assigned to the current logged-in user
 - **Pending:** Pending, assigned to another user
 - **Approved**
 - **Rejected**

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HOME

ISS

COMPLAINT

DATA

REG DATA

Task & Approvals

Excel

Tasks & Approvals

Tasks Approvals

View: By Document Search

1-32 of 32 < >

Type [all]	Subtype	Source	Rev [filt...]	Updated [all]	Approvers [all]	Review Age	Status [all]
Work Instruction	QMS	D MGF-WKI-1013: QMS	A	05-05-2026	✓ Thach Nguyen	0	✓ APPROVED
Work Instruction	Process	D MGF-WKI-1012: WI-Work Instruction(Link To MFG Plan)	A	05-05-2026	✓ Thach Nguyen	0	✓ APPROVED
Procedure	Procedure Typ...	D MFG-PR-998887: Test Link MFG Plan1(Procedure)	A	05-05-2026	✓ Thach Nguyen	0	✓ APPROVED
Procedure	Procedure Typ...	D QA-PR1: Test Approval chain	A	05-05-2026	⊗ Nick Kelly ⊗ Thach Nguyen	0	⊗ PENDING
Work Instruction	Part Specific	D MGF-WKI-1011: Test email send1123	A	04-28-2026	✗ Thach Nguyen		✗ REJECTED
Work Instruction	Process	D MGF-WKI-1010: [Bug #1084]PR 2270	A	04-28-2026	⊗ Thach Nguyen ⊗ Thach Nguyen		⊗ PENDING
Procedure		D PRO-25: Pro8989-Thach	B	04-28-2026	✓ Thach Nguyen		✓ APPROVED
Work Instruction	Part Specific	D MGF-WKI-1009: Test Training yes/no	B	04-20-2026	✓ Thach Nguyen		✓ APPROVED
Procedure	Procedure Typ...	D MFG-PR-998883: Test training 1	B	04-20-2026	✓ Thach Nguyen		✓ APPROVED
Work Instruction	Part Specific	D MGF-WKI-1008: Ticket1015	A	04-13-2026	✓ Thach2 Nguyen2		✓ APPROVED
Work Instruction	Process	D MGF-PI-156901: How to MFG for...	B	04-06-2026	✓ Mike Corrales		✓ APPROVED
Work Instruction	Process	D WI-10: Test Approver for ITT	A	04-06-2026	✓ Thach Nguyen ⊗ jolie Nguyen		⊗ PENDING
Procedure		D MFG-PR-998881: S85686	A	04-06-2026	⊗ Api-Test-Pro Nguyen		⊗ PENDING
Procedure		D MFG-PR-55: Test Quality	A	04-06-2026	✓ Thach Nguyen		✓ APPROVED
Procedure		D MFG-PR-353548: [PR #2083]QMS (#475) [Align]	A	03-23-2026	✓ Thach Nguyen		✓ APPROVED
Procedure		D PR-0022: Baseline Upload1	A	04-06-2026	✓ Thach Nguyen		✓ APPROVED
Procedure		D MFG-PR-353545: Test Mandatory Role(INACTIVE)	A	02-12-2026	✓ Thach Nguyen		✓ APPROVED
Plan	Receiving	D 164919 C	1	02-04-2026	✓ Danh Ho		✓ APPROVED
Procedure		D MFG-PR-353544: Bug479	A	12-18-2025	✓ Thach Nguyen		✓ APPROVED
Plan	Manufacturing	D 12162025-Test Plan Approver A	1	12-16-2025	⊗ Thach2 Nguyen2		⊗ PENDING
Standard	Regulatory	D WI-P-ST-1002: New Standard ISO90014-2	022598	01-31-2026	✓ Thach Nguyen		✓ APPROVED
Record		D RC-202-1: Test		11-12-2025	⊗ Thach Nguyen		⊗ PENDING

Federated QMS Visibility

For organizations operating a Federated QMS, the Approvals tab shows approvals for all documents owned by the current organization. Users in the **parent organization** have visibility across all child organizations, supporting cross-org approval monitoring without requiring a separate login or report.

Exporting the List

Both the Tasks and Approvals lists can be exported to Excel using the **Excel** button in the command bar. The export respects any filters currently applied, allowing quality managers to generate targeted reports by status, approver, object type, or date range for audit preparation, KPI reviews, or daily standup reporting.

HOME

ISS

COMPLAINT

DATA

REG DATA

Task & Approvals

Excel

Tasks & Approvals

Tasks Approvals

View: By Document Search

1-32 of 32 < >

Type [all]	Subtype	Source	Rev [filt...]	Updated [all]	Approvers [all]	Review Age	Status [all]
Work Instruction	QMS	D MGF-WKI-1013: QMS	A	05-05-2026	✓ Thach Nguyen	0	✓ APPROVED
Work Instruction	Process	D MGF-WKI-1012: WI-Work Instruction(Link To MFG Plan)	A	05-05-2026	✓ Thach Nguyen	0	✓ APPROVED
Procedure	Procedure Typ...	D MFG-PR-998887: Test Link MFG Plan1(Procedure)	A	05-05-2026	✓ Thach Nguyen	0	✓ APPROVED
Procedure	Procedure Typ...	D QA-PR1: Test Approval chain	A	05-05-2026	⊗ Nick Kelly ⊗ Thach Nguyen	0	⊗ PENDING
Work Instruction	Part Specific	D MGF-WKI-1011: Test email send1123	A	04-28-2026	✗ Thach Nguyen		✗ REJECTED
Work Instruction	Process	D MGF-WKI-1010: [Bug #1084]PR 2270	A	04-28-2026	⊗ Thach Nguyen ⊗ Thach Nguyen		⊗ PENDING
Procedure		D PRO-25: Pro8989-Thach	B	04-28-2026	✓ Thach Nguyen		✓ APPROVED
Work Instruction	Part Specific	D MGF-WKI-1009: Test Training yes/no	B	04-20-2026	✓ Thach Nguyen		✓ APPROVED
Procedure	Procedure Typ...	D MFG-PR-998883: Test training 1	B	04-20-2026	✓ Thach Nguyen		✓ APPROVED
Work Instruction	Part Specific	D MGF-WKI-1008: Ticket1015	A	04-13-2026	✓ Thach2 Nguyen2		✓ APPROVED
Work Instruction	Process	D MGF-PI-156901: How to MFG for...	B	04-06-2026	✓ Mike Corrales		✓ APPROVED

2.1.11 Document Effectivity

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Optional Feature: Document Effectivity is disabled by default. To enable it, navigate to **QMS Settings** and set **Documents are Immediately Effective** to **No**. See **Section 1.2** for configuration details.

In most manufacturing environments, releasing a revised procedure and training personnel on it happen simultaneously. For organizations operating under FDA 21 CFR Part 820 or ISO 13485, that is not enough. Auditors require documented evidence that personnel completed training *before* a procedure became active in production. Without a formal separation between "released for training" and "effective in production," organizations are left managing that gap with external spreadsheets, disconnected audit trails, and manual coordination.

Document Effectivity closes that gap. When enabled, a **Pending Release** status is introduced between **Approved** and **Released**. During Pending Release, the document is distributed to assigned personnel for training, carries a visible **PENDING - UNRELEASED** watermark in-app and on printed copies, and is not accessible to general users through the standard Released document view. On a defined **Effective Date**, and once any configured training threshold has been met, the document automatically transitions to **Released**. The full sequence is documented and timestamped, providing auditors with a complete chain of evidence.

Step 1: Move the Document to Pending Release

Once all required approvers have approved the document, return to the **Manage** tab. With Document Effectivity enabled, a **Pending Release** status will appear between **Approved** and **Released** in the versioning control.

Select **Pending Release** and set the **Effective Date**. The Effective Date defaults to the current date plus the **Time to Complete** value from the document's training plan. If no training plan is configured, it defaults to the current date. The date must be set to the current date or a future date.

The screenshot displays the 'Manage' tab for document QA-P-0062, titled 'Control of Non-conforming Material'. The document is currently in the 'PENDING RELEASE' status. The 'Effective Date' is set to 'May-21-2026'. A green arrow points to the 'Effective Date' field. The document content is visible on the left, showing sections 1 Purpose, 2 Definitions, and 3 Responsibilities. The right panel shows the 'Approval' section with a table of approvers, the 'Review Notes' section, the 'Versioning' section with a status flow (DRAFT, APPROVED, PENDING RELEASE, RELEASED), the 'Release notes' section, and the 'Retraining required?' section.

Status	Role	Approver	Signed on
APPROVED	QMS Coordinator	Emily Anderson	May-06-20...

PENDING RELEASE

By signing off and approving this document, I hereby certify that I have fulfilled all responsibilities associated with my role in the release of this document into the QMS. Emily Anderson - May-06-2026, 08:57

Review Notes
May-06-2026, 08:57 Emily Anderson Verified all actions to address risk have been accounted for to release this into the QMS.
Enter a review note (optional)

Versioning
DRAFT APPROVED PENDING RELEASE RELEASED

By signing off and releasing this document, I hereby certify all requirements associated with the release of this document into the QMS have been fulfilled. Enter password to sign

Release notes
Updated Throughout, see redline mark up & Impact Assessment for further details.

Effective Date
May-21-2026 ⓘ This document will be automatically released on the effective date so long as 98% of users have completed the training by then.

Retraining required? Status
NO YES ACTIVE INACTIVE

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If eSignatures are enabled for your organization, you will be required to complete the release eSignature before saving. If **Mandatory Approver Controls Release** is enabled, only users assigned to the **Mandatory Approver Role** can move a document to Pending Release.

Helper text below the **Effective Date** field describes exactly when and how the document will be released based on your current settings. This text updates dynamically as you change the date or threshold values.

Effective Date

May-21-2026



i This document will be automatically released on the effective date so long as 98% of users have completed the training by then.

Step 2: Personnel Complete Training

Once the document enters **Pending Release**, training assignments are automatically generated for all roles defined in the document's training plan, and notification emails are sent. Personnel access the document from their **My Training** list. The document is clearly marked as not yet released.

HOME

MY TRAINING

RELEASE NOTES

COMPLETE

No. QA-P-0062

Title Control of Non-conforming Material

Rev U Status RELEASING ✓

i Read the document, and click "complete" to confirm you have understood it.

1 Purpose

This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with [EXT-P-0012](#), AS9100.

2 Definitions

2.1

Non-Conforming Material: Material, component, or product that does not meet established specifications, quality standards, or customer requirements.

2.2

Non-Conformance Report (NCR): A formal document used to record and track instances of nonconforming material, including details of the issue, root cause analysis, and corrective actions.

2.3

Complaint Management: This is owned by customer service and they are responsible for reporting the issues to the Quality Engineer

2.4

Corrective Action: A process implemented to eliminate the root cause of a detected non-conformance to prevent recurrence.

Step 3: Automatic Release

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The system checks training completion every time a user completes training on the document, and also checks all Pending Release documents hourly against their **Effective Date**. As soon as both conditions are met, the document is automatically moved to **Released**, stakeholders are notified, and the Effective Date is recorded as the actual release date.

If the training threshold is met but the Effective Date has not yet arrived, the document remains in **Pending Release** until the date passes. If the Effective Date passes but the threshold has not been met, the document remains in **Pending Release** and the Effective Date column turns **red** to signal the overdue status.

Note: Once a document is **Released**, its status will not revert even if training completion subsequently drops below the threshold, for example if additional ad-hoc training is added after release.

Using Effective Date Only (No Training Threshold)

Organizations that want to schedule a future release date without gating on training completion can set the **Training Completion Threshold** to **0** in QMS Settings. With a threshold of **0**, the document moves automatically from **Pending Release** to **Released** on the Effective Date regardless of training status. This allows quality teams to pre-schedule document releases for planned change events, product launches, or scheduled procedure updates while still maintaining a formal, auditable effective date in the system.

Manual Override by Mandatory Approver

A user assigned to the **Mandatory Approver Role** can release the document manually at any time, bypassing the Effective Date and training threshold. To do this, open the **Manage** tab while the document is in **Pending Release** and change the status to **Released**. If eSignatures are enabled, the approver must complete a signature attesting to the override. **Release notes are required** and must include a justification for bypassing the standard release conditions.

The Mandatory Approver can also change the **Effective Date** while a document is in Pending Release, provided the new date is the current date or a future date. If the training threshold has already been met and the Effective Date is changed to the current date, the document immediately moves to **Released**. A confirmation modal will appear before the change is saved.

A document can also be returned from **Pending Release** back to **Approved** (or **Draft**, if no approvals are configured), which cancels all training generated for the pending release. This action requires a **release note justification** and an eSignature if enabled.

Minor Revisions and Effectivity

Minor revisions skip the **Pending Release** status entirely and are always immediately released. The **Effective Date** for a minor revision is automatically set to the date of release. The Manage tab dynamically adjusts available status options based on whether a revision is marked as **Minor Update**.

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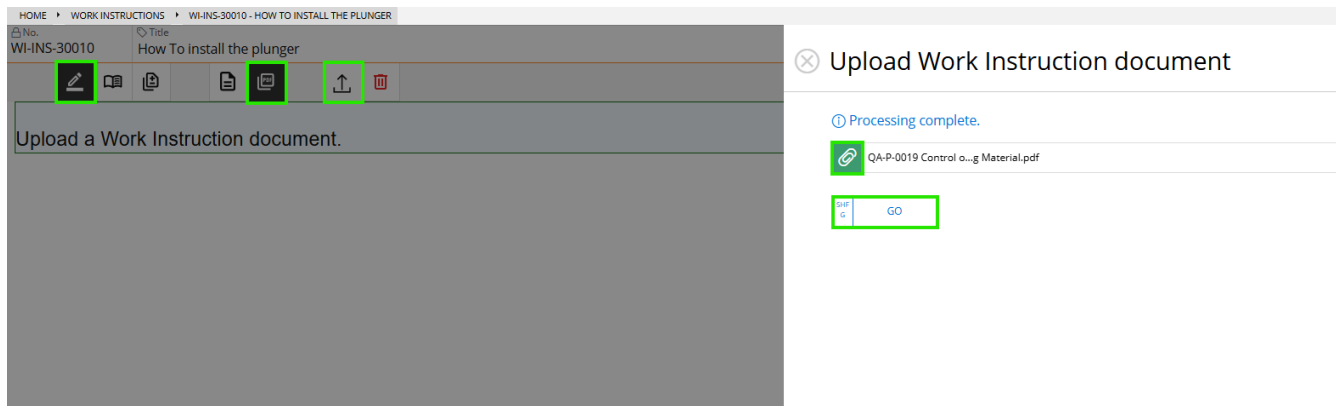
2.1.12 External/Legacy Files

Not Available For: Standards (uses PDF Reference Document instead)

When "Allow external files as documents" is enabled, use existing PDFs or Office documents as controlled versions.

Step 1: Upload PDF file

1. In Editing Mode, click PDF icon
2. Click **Upload Document** icon
3. Select file using paper clip icon
4. Click **Go** button



Step 2: Review uploaded content

- PDFs display in read-only mode
- Word documents appear as downloadable links
- Switch between PDF review and **Edit in 1Factory** as needed

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HOME ▸ WORK INSTRUCTIONS ▸ WI-INS-30010 - HOW TO INSTALL THE PLUNGER

No.	Title
WI-INS-30010	How To install the plunger

☰ qa-p-0019+control+of+non-confor... 1 / 4 - 90% +     

QA-P-0019 1factory - HQ Confidential. Proprietary. Rev A [07-15-2025]

QA-P-0019 Control of Non-Conforming Material

1 Purpose

This procedure establishes the process for identifying, controlling, and disposing of non-conforming material at 1factory to prevent unintended use or delivery. The goal is to ensure that any material not meeting specified requirements is promptly detected and appropriately handled, in accordance with ISO9001 STD-1.

HOME ▸ WORK INSTRUCTIONS ▸ WI-INS-30010 - HOW TO INSTALL THE PLUNGER

No.	Title
WI-INS-30010	How To install the plunger

File: [for alex link balloon 14 and 4 2 diff plan in manuf .docx](#)

2.1.13 Document Import Options

1factory offers two methods to import existing content into your QMS documents.

Option 1: Automated Document Import

Transfer content from Word, PDF, or .txt files while preserving formatting.

Step 1: Open Import feature

Click the **Import** tile on the left vertical menu.

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The screenshot displays the 1factory QMS interface. At the top, a breadcrumb trail shows 'HOME > PROCEDURES > PRO-63 - HOW TO CREATE NCR'. Below this, a header bar contains fields for 'No.' (PRO-63), 'Legacy No.' (QA-P-6162026), and 'Title' (How to create NCR). A 'New Features' button is visible in the top right. A vertical sidebar on the left contains icons for various functions: HOME, BACK, RELATED, TRAINING, QUIZ, APPROVERS, ACCESS, ATTACH (with a red notification badge), HISTORY, MANAGE, HINTS, and IMPORT (highlighted with a green box). The main content area features a toolbar with icons for editing, saving, and other document actions. The document content begins with the heading '1 Purpose and Scope', followed by a paragraph explaining the procedure's purpose. This is followed by the heading '2 Responsibilities', which includes a sub-section '2.1 Design and Development Management' with three bullet points, and '2.2 Technical and Quality Personnel' with three bullet points. The document also includes a section '2.3 Customer and Regulatory Interface' with three bullet points.

1 Purpose and Scope

This procedure establishes the systematic approach for product design and development activities to ensure products meet customer requirements, regulatory standards, and organizational quality objectives. This procedure applies to all new product development, product modifications, and design changes within the organization.

2 Responsibilities

Enter content.

2.1 Design and Development Management

- Design and Development Manager oversees the entire design process and ensures resource allocation
- Project Team Leaders coordinate cross-functional activities and manage project communications
- Engineering Managers provide technical guidance and approve design decisions within their domains

2.2 Technical and Quality Personnel

- Design Engineers execute technical design activities and create specifications
- Quality Assurance validates design outputs and ensures compliance with standards
- Manufacturing Representatives provide input on producibility and manufacturing constraints

2.3 Customer and Regulatory Interface

- Customer Representatives participate in design reviews and approve customer-affecting outputs
- Regulatory Affairs personnel ensure compliance with applicable regulations and standards
- Marketing personnel provide market requirements and competitive analysis input

Step 2: Copy and paste content

1. Copy content from source file
2. Paste into Import Content field
3. Select format option:
 - **Inline:** For continuous text
 - **Number & Heading:** For structured sections
4. Choose action:
 - **REPLACE:** Overwrites existing content
 - **ADD:** Inserts at current position
5. Click **Go** button

1factory QMS User Manual

⊗ Import Content

Text imported here will be automatically organized into sections in this document.

1. PURPOSE AND SCOPE

This work instruction provides detailed step-by-step procedures for the assembly of Plunger Assembly part number 12-5039 C. This document ensures consistent assembly processes that meet aerospace (AS9100) and medical device (ISO 13485) quality requirements for precision machined components.

Import sub-sections as:

INLINE	NUMBER & HEADING
--------	------------------

Add to existing doc, or replace it:

ADD	REPLACE
-----	---------

SHF G	GO
----------	----

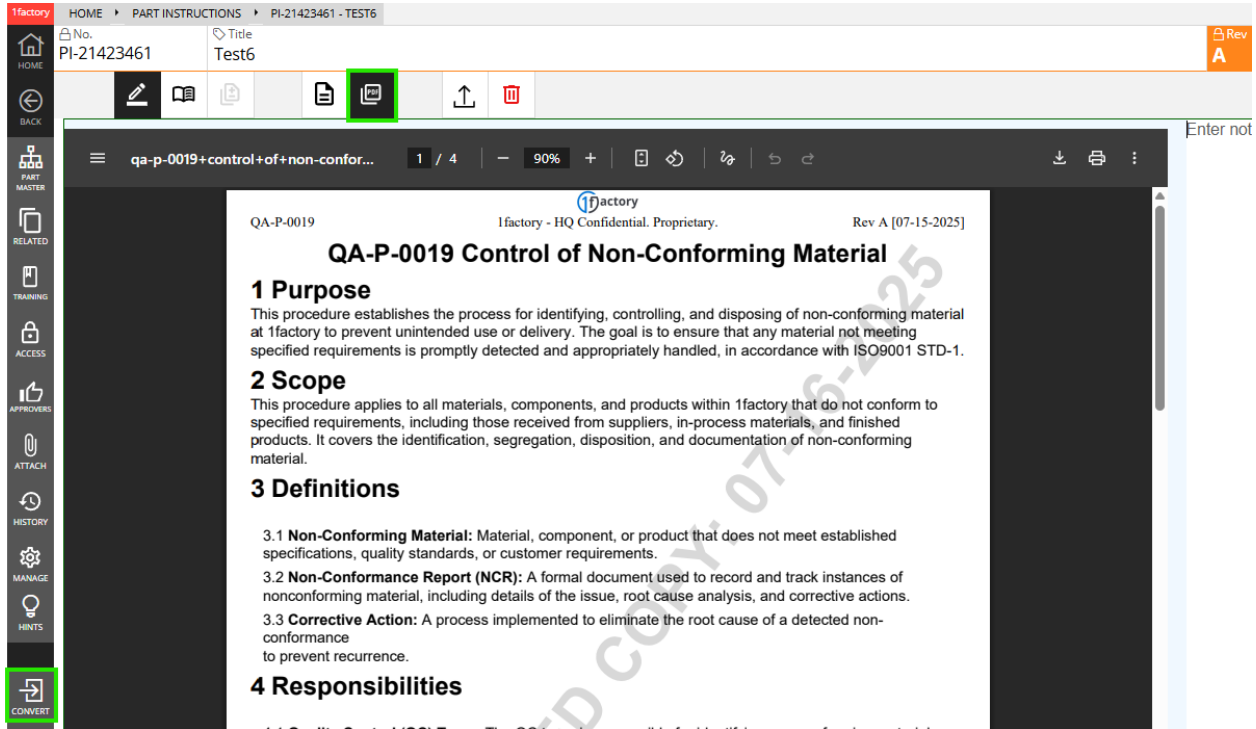
Option 2: Convert PDF File

Transform complete PDFs into native 1factory format.

Step 1: Initiate conversion

Click the **CONVERT** button on the left vertical menu.

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Step 2: Configure settings

- **Sub Section Format:** Choose INLINE or NUMBER & HEADING
- **Image Position:** Select BOTTOM or RIGHT
- Click **Go** to process

⊗ Convert PDF file

Converts PDF file to automatically organized sections. PDF file remains unchanged.

Convert sub-sections as:

INLINE	NUMBER & HEADING
--------	------------------

Display attachments at:

BOTTOM	RIGHT
--------	-------

SHF	GO
-----	----

Step 3: Verify results Switch to **Edit Mode** to review and compare converted content.

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HOME > PROCEDURES > PRO-63 - HOW TO CREATE NCR

☆ New Features

△ No.
PRO-63

Legacy No.
QA-P-6162026

Title
How to create NCR



1 Purpose and Scope

This procedure establishes the systematic approach for product design and development activities to ensure products meet customer requirements, regulatory standards, and organizational quality objectives. This procedure applies to all new product development, product modifications, and design changes within the organization.

2 Responsibilities

Enter content.

2.1 Design and Development Management

- Design and Development Manager oversees the entire design process and ensures resource allocation
- Project Team Leaders coordinate cross-functional activities and manage project communications
- Engineering Managers provide technical guidance and approve design decisions within their domains

2.2 Technical and Quality Personnel

- Design Engineers execute technical design activities and create specifications
- Quality Assurance validates design outputs and ensures compliance with standards
- Manufacturing Representatives provide input on producibility and manufacturing constraints

2.1.14 Update Reference Legacy Document

Available when "1factory with legacy numbers" is enabled. Automatically updates document number references during QMS migration.

Step 1: Enable legacy numbers

1. Click your name > **Settings**
2. Navigate to **QMS Settings**
3. Select "1factory with legacy numbers"
4. Click **Save**

HOME > SETTINGS

☆ New Features

Help | Thanh Nguyen

Expand all Collapse all

> SSO Settings:

> Log-in Settings:

✓ QMS Settings:

Quality Manual MGF-P-9999 PDF

Mandatory Approver Role QMS Coordinator

Use alphabetic revisions Yes

Document Numbers 1Factory with legacy numbers

Data Backup

IP Addresses

Delete History

Report Bug

Settings

Terms of Service

Change password

Logout

Step 2: Update references

1. Open document in Draft status and **Editing Mode**
2. Click **UPDATE REFS** tile
3. Confirm update (action cannot be undone)

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4. Legacy numbers change to 1factory numbers

The screenshot displays the 1factory QMS interface. At the top, the browser address bar shows the URL: 1factory.co/work_instructions/work_instruction?ID=931&f3=0&page=0. The interface includes a top navigation bar with 'HOME', 'WORK INSTRUCTIONS', and 'WI-10 - HOW TO INSTALL THE PLUNGER'. Below this, a header section contains fields for 'No.' (WI-10), 'Legacy No.' (WI-INS-30010), and 'Title' (How To install the plunger). A vertical sidebar on the left contains icons for HOME, BACK, RELATED, TRAINING, ACCESS, APPROVERS, ATTACH, HISTORY, MANAGE, HINTS, IMPORT, and UPDATE REFS. The main content area is titled '1 PURPOSE AND SCOPE' and contains the following text: 'This work instruction provides detailed step-by-step procedures for the assembly of Plunger Assembly part number 12-5039 C. This document ensures consistent assembly processes that meet aerospace (AS9100) and medical device (ISO 13485) quality requirements for precision machined components. Applicable Standards: - MFG-P-2 : Cleaning burr process - MR-WI-S-08062025 : Assembly process part master - MR-WI-S-8062028 : Safety working area instruction'. Below this is the section '2 PREREQUISITES' with the text: 'Before beginning assembly operations, verify the following conditions are met: The operator must be trained and certified on this work instruction per procedure HR-P-0008 "Training and Competency Management." All required materials have passed incoming inspection and are within specification limits as documented on Certificate of Conformance. Assembly fixture AF-12-5039 has current calibration status and is within calibration due date. Work area is clean and free from contamination sources that could affect product quality. Environmental conditions are within specification: Temperature 68-78°F, Humidity 45-65% RH.' The final section is '3 ASSEMBLY PROCEDURE' with the text: 'Step 1: Initial Setup and Preparation Position assembly fixture AF-12-5039 on work surface and secure using fixture clamps. Verify fixture is clean and free from debris or damage. Gather all required materials and tools listed in Section 3. Inspect each component for visible damage, contamination, or defects before proceeding. Don required safety equipment including safety glasses, nitrile gloves, and anti-static wrist strap connected to grounded work surface. Step 2: Plunger Body Preparation Remove Plunger Body (P/N 12-5039-001) from protective packaging using clean handling procedures. Inspect machined surfaces for burrs'.

2.1.15 Document PDF Export

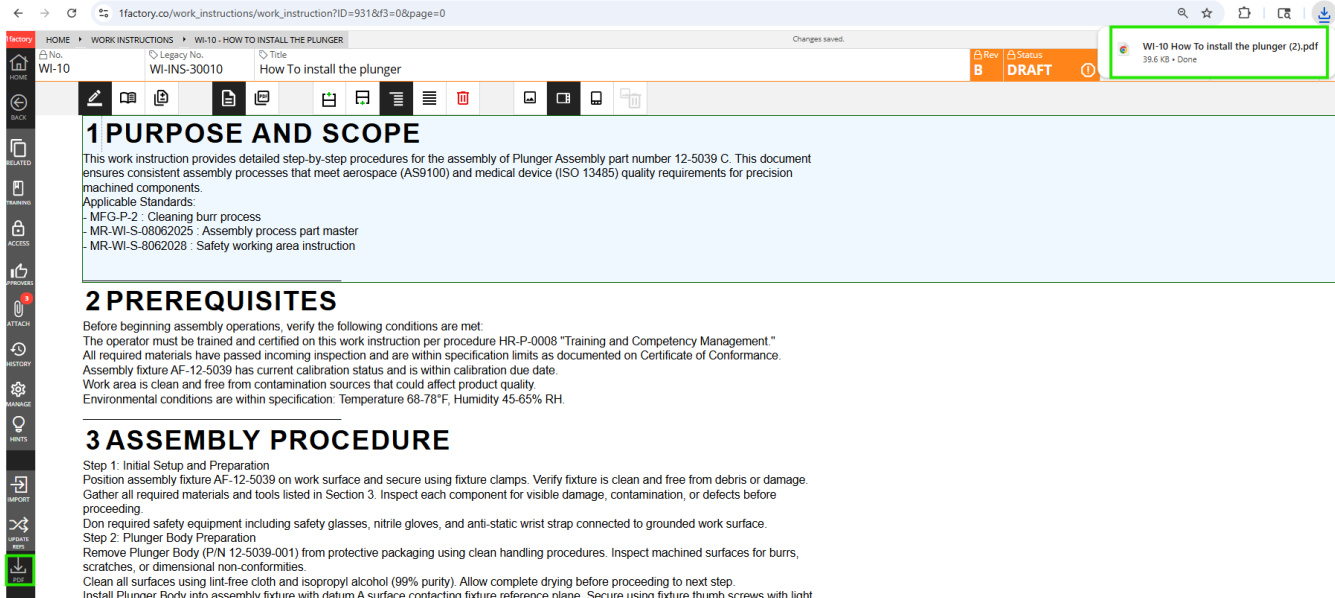
Not Available For: Record Types (use Form Download instead)

Generate PDF versions for offline use, printing, or external distribution.

Export Process:

1. Click **PDF** tile on left vertical menu
2. File downloads automatically with:
 - Complete document content
 - All formatting and images preserved
 - Document metadata (number, revision, date)
 - Watermarks indicating document status

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2.2 Document Type Specific Features

While common features provide consistency across the QMS, each document type has unique capabilities designed for its specific purpose.

2.2.1 Standards Unique Features

Standard Business documents in 1factory QMS store **external** requirements and regulatory standards that your organization must comply with, such as **ISO 9001:2015**, **AS9100D**, **FDA regulations**, or **customer-specific requirements**. These controlled documents serve as the foundation for your quality management system by establishing the compliance framework that all other QMS documents must support. Standards are typically issued by external organizations like **ISO**, **SAE**, **FDA**, or **your customers** specific requirements, and maintaining current versions is critical for regulatory compliance and certification maintenance. These documents support the **Quality Manual** and other QMS documentation throughout your organization.

PDF Reference Document

- Upload external regulatory documents in PDF format
- Access through Reference Document feature in editing mode
- Supports PDF format only

2.2.2 Quality Manual Unique Features

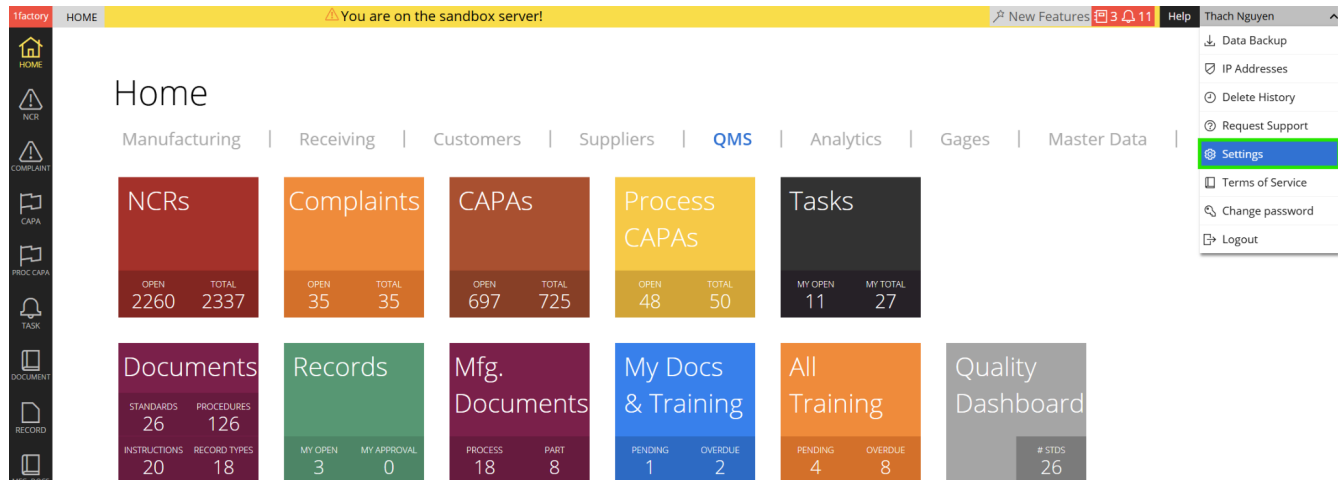
1Factory provides a powerful **Quality Manual** solution that transforms isolated **Standards** and **Procedures** into an integrated compliance framework. Unlike standalone documents, the Quality

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Manual creates systematic linkage between external requirements and internal implementation, delivering comprehensive compliance visibility essential for regulated organizations.

Step 1: Select Procedure for Quality Manual Creation

Select the **Procedure** document that will serve as the foundation for your Quality Matrix design. Navigate to the top right corner of your profile and click the dropdown menu to select Settings.



Navigate to **QMS Settings** and use the dropdown menu to select the appropriate **Procedure** document, or type directly in the search box to locate the specific **Procedure** number. Click the **Save** button at the bottom of the Settings page to confirm your selection.

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1factory

HOME ▸ SETTINGS

You are on the sandbox server!

HOME

NCR

COMPLAINT

CAPA

PROC CAPA

TASK

DOCUMENT

RECORD

MFG. DOCS

MY TRAINING

[Expand all](#)

[Collapse all](#)

▸ Log-In Settings

▾ QMS Settings

Quality Manual

Mandatory Approver Role

Use alphabetic revisions

Document Numbers

Standard Number Prefixes

Procedure Number Prefixes

Work Instruction Number Prefixes

MGF-P-1565 Test

PRO-1 test

MFG-P-1 Test PDF processing

MGF-P-PR1562 [PR 1562]

MGF-P-PR1557 [PR1557]

MGF-P-PR1549 [PR 1549]

MGF-P-1563 Test Import Doc

MGF-P-1566 nomad tst

MGF-P-08062025 Test Import1

MGF-P-8062026 12312

MGF-P-1567 Test Routing Approval

MGF-P-1565 Test

MGF-P-8062027 Check the training assignment

MGF-P-8062028 Test training

Step 2: Access the Selected Procedure Document

Navigate to the **QMS** module and click the **Documents** tile. Within **Business Documents**, select the **Procedures** tab to locate the Procedure document selected in Step 1.

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Important: Select the Draft Revision (typically marked in yellow) rather than the Released version (marked in green).

No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Created By [all]	App. [all]	Rev. [filter...]	
MGF-P-1564	Test	2025-09-21	N/A	CNC	QMS Coordinator	Thach Nguyen	N/A	3	
MGF-P-1564	Test	2025-09-10	N/A	CNC	QMS Coordinator	Thach Nguyen	APPROVED	2	
MFG-P-2	Cleaning burr process	2025-08-21	N/A	Distribution and L...	Chief of People an...	Thach Nguyen	APPROVED	2	
MGF-P-9999	PDF	2025-08-21	N/A	Chief of Business I...	Chief of Business I...	Thach Nguyen	N/A	2	

Step 3: Access Quality Matrix Function

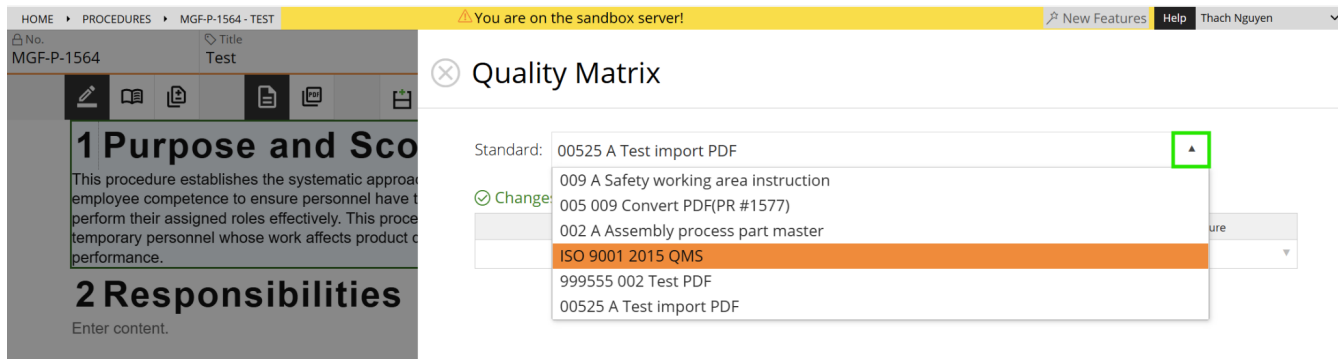
On the left menu bar, locate and click the **MATRIX** icon. An empty grid interface will open, allowing you to design your **Quality Matrix**. The matrix displays **Standard Clause** numbers in one column with corresponding references to **Quality Manual Sections** and **implementing Procedures**.

Standard Clause	Quality Manual Section	Implementing Procedure
-----------------	------------------------	------------------------

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Step 4: Configure Quality Matrix Elements

Select the required **Standard** document from the dropdown menu at the top of the page. For example, select ISO 9001 if applicable to your organization.



Configure the following elements:

- **Standard Clause:** Enter the specific clause number from external standards (such as ISO 9001:2015, AS9100D, ISO 13485, or FDA 21 CFR Part 820). This field creates direct traceability links and transforms your Quality Manual into a compliance navigation tool. For example, entering "4.4.1" links that section to ISO 9001's process approach requirements.
- **Quality Manual Sections:** Select the appropriate section from the dropdown menu that corresponds to your **Procedure** document content. This section links directly with the document body content you are developing.
- **Implementing Procedures:** Use the dropdown menu to specify the **Procedures** that support the **Standard Clause** and **Quality Manual Section**. This field creates traceability links between high-level Quality Manual policies and specific procedures that execute those policies in operations.

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HOME » PROCEDURES » MGF-P-1564 - TEST

You are on the sandbox server! Changes saved! Help | Thach Nguyen

MGF-P-1564 Test

Quality Matrix

Standard: ISO 9001 2015 QMS

Changes saved.

Standard Clause	Quality Manual Section	Implementing Procedure
8.5.1 Control of production and service provision	8 Manufacturing Control Procedure	ENG-P-0054 Product Design and Development
8.5.1 Control of production and service provision	8 Manufacturing Control Procedure	

7 Training and Development
Enter content.

8 Manufacturing Control
Enter content.

Step 5: Manage Quality Matrix Items

1factory provides **Insert** and **Remove** functionality to add or delete matrix items as needed. The system automatically saves changes during matrix operations (entering or modifying **Standard Clauses**, selecting **Quality Manual Sections**, or changing **Implementing Procedures**). Progress indicators showing "Saving change" and "Change Saved" appear in the top left corner.

To simplify setup, open the attachment at the bottom of this section titled "[Standard Clauses – For Quality Matrix](#)". This file includes clauses from common standards (ISO 9001:2015, AS9100D, ISO 13485:2016, IATF 16949:2016, and 21 CFR Part 820). Simply copy and paste the clauses your organization is required to meet directly into the Quality Matrix.

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⊗ Quality Matrix

Standard: ISO 9001 2015 QMS ▼

✔ Changes saved.

Standard Clause	Quality Manual Section	Implementing Procedure
8.5.1 Control of production and service provision	8 Manufacturing Control Procedure ▼	ENG-P-0054 Product Design and Development ▼
8.5.1 Control of production and service provision	2 Responsibilities ▼	▼
8.5.1 Control of production and service provision	2 Responsibilities ▼	▼

⊕ ⊖ Use +/- buttons to insert or delete rows as needed.

Step 6: Release the Quality Manual

Upon completing the **Quality Matrix** configuration, navigate to the Manage button on the left menu bar to release this **Procedure** document as your organizational **Quality Manual**. Follow the standard document release workflow and click the Save button to finalize the process.

Important: Once the Quality Manual is released, the **Quality Dashboard** will automatically update to display the Quality Matrix relationships, providing real-time compliance mapping between your external standards (ISO 9001, AS9100, etc.) and internal procedures for audit preparation and management reviews.

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The screenshot displays the 1factory QMS interface. On the left, a sidebar contains navigation icons for Home, Back, Metrics, Related, Documents, Access, Approvals, Attach, History, and Manage (highlighted). The main content area shows a document titled 'MGF-P-1564' with sections: 1 Purpose and Scope, 2 Responsibilities, 3 Competence Requirements Determination, and 4 Competence Requirements Determination. A 'Manage' modal is open on the right, featuring a 'Minor Update?' toggle (YES/NO), an 'Approval' table, 'Review Notes' input, 'Versioning' buttons (DRAFT, APPROVED, RELEASED), 'Release notes' input, 'Retraining required?' toggle (NO/YES), 'Status' buttons (ACTIVE/INACTIVE), and a 'Review interval (months)' input (15). A 'SAVE' button is at the bottom.

Status	Role	Approver	Approved on
APPROVED	QMS Coordinator	Thach Nguyen	2025-09-22

Retraining required?	Status		
NO	YES	ACTIVE	INACTIVE

2.2.3 Procedures Unique Features

The **Procedures** module in 1factory QMS is designed to store and manage **internal documents that outline the operation of your Quality Management System**. These are the core operational documents that define how your organization executes its quality processes.

The **Procedures** essentially serve as the backbone of your QMS documentation hierarchy, sitting between high-level **Standards** (external requirements) and detailed **Work Instructions** (step-by-step tasks).

Automatic Linkage from Standards

Procedures can be selected and linked directly to Standards clause via the **Quality Matrix** within your Quality Manual, creating traceable compliance demonstration.

Impact Assessment

Organizations can configure a standard list of Impact Assessment Questions under **Master Data** in the **Tables** tile. The Tables tile is only visible to users with the **Manage Settings and LOV** permission. To configure questions, navigate to **Master Data > Tables**, select the **Impact Assessment Questions** row, and enter your questions in the free-text table. Each row represents one question. To delete a question, clear its text and click **Save**. All changes to the question list are tracked in audit history and can be viewed from the command bar on the Tables detail page.

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Impact Assessment Questions

① An impact assessment answering all questions must be completed before procedures can be submitted for approval. If no questions are defined here, then impact assessments are NOT required for procedures.

Questions
Does this change affect the safety or performance of the medical device or its components?
Does this change impact any regulatory submissions, technical files, or design dossiers associated with this product?
Does this change require notification to or approval from any regulatory authority (FDA, CE, etc.) prior to implementation?
Does this change affect any validated processes, equipment, or software systems?
Does this change impact customer or contractual requirements, including customer-specific quality agreements?
Does this change affect the product's labeling, instructions for use, or accompanying documentation?
Does this change require updates to associated procedures, work instructions, or forms within the QMS?
Does this change affect supplier qualifications, approved vendor lists, or incoming inspection requirements?
Does this change require personnel to receive additional training beyond the standard training assigned to this document?
Does this change affect any risk management documentation, including FMEA, risk assessments, or hazard analyses?

1 of 10 SAVE

Note: The question format is intentionally open-ended. If your organization wishes to number questions, do so manually within the question text itself.

When at least one Impact Assessment Question has been configured, an **Impact Assessment** icon appears in the command bar for every Procedure in **Draft** status. The icon is not shown when a document is flagged as a **Minor Update** in the Manage tab, as minor updates do not require an impact assessment.

Completing the Impact Assessment

Click the **Impact Assessment** icon to open the slideout. The table presents each configured question with three columns: the question text (read-only), a **Yes/No/N/A** response dropdown, and a free-text comments field.

The following rules apply when completing the assessment:

- Every question must have a response of **Yes**, **No**, or **N/A** selected before the document can be routed for approval. Responses of **Yes** or **No** additionally require a comment to be entered. Leaving a response empty or leaving a required comment blank will block the document from being moved to **Pending Approval** status. If validation fails, the Versioning control in the Manage slideout will display an error and prevent the status change.
- The Impact Assessment table is editable only while the document is in **Draft** status and only by users who have edit access to the document. Once the document moves to **Pending Approval** or beyond, the table becomes read-only and can be viewed but not modified. All changes made to the table are recorded in the document's audit history.
- Each new revision of a Procedure starts with a blank assessment. Answers from previous revisions are not carried forward, ensuring each revision is evaluated independently.

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1 Purpose and Scope

This procedure establishes the systematic approach for controlling the creation, review, approval, distribution, maintenance, and disposal of internal and external documents affecting quality management system compliance.

2 Responsibilities

Document control is a systematic process for managing documents organized, tracked, and distributed in a consistent and controlled manner.

2.1

Document Control Manager

- Maintain master document register and distribution
- Coordinate document review and approval process
- Ensure proper document identification and version control
- Monitor document review schedules and update requirements

2.2

test

2.3

Impact Assessment Questions

① All questions must be answered before this procedure can be submitted for approval. Yes or No answers must have also have comments entered for them.

Questions	Impact	Comments
Does this change affect the safety or performance of the medical device or its components?	No	Change is limited to document formatting and section numbering only. No functional or design changes were made.
Does this change impact any regulatory submissions, technical files, or design dossiers associated with this product?	Yes	Technical file Section 4.2 references this procedure. QA Manager to review and confirm no update to submission is required.
Does this change require notification to or approval from any regulatory authority (FDA, CE, etc.) prior to implementation?	No	Change is administrative in nature and does not trigger any regulatory notification thresholds.
Does this change affect any validated processes, equipment, or software systems?	No	No validated processes or equipment are referenced or affected by this revision.
Does this change impact customer or contractual requirements, including customer-specific quality agreements?	No	No customer quality agreements reference this procedure directly.
Does this change affect the product's labeling, instructions for use, or accompanying documentation?	No	This procedure is internal only and has no bearing on product labeling or IFU content.
Does this change require updates to associated procedures, work instructions, or forms within the QMS?	Yes	WI-14 and FRM-07 will need to be revised in the next revision cycle to align with updated terminology in this document.
Does this change affect supplier qualifications, approved vendor lists, or incoming inspection requirements?	N/A	No supplier-related content was modified in this revision.
Does this change require personnel to receive additional training beyond the standard training assigned in this document?	Yes	Quality Engineers and incoming inspection staff will require a one-time briefing due to the updated acceptance criteria in Section 4.

SHF 5 SAVE

2.2.4 Work Instructions Unique Features

Work Instructions in 1factory QMS are detailed, step-by-step documents that provide specific guidance on how to perform individual tasks within your quality management system. These documents serve as the operational level of your QMS hierarchy, sitting below **Procedures** and providing the detail needed for consistent task execution. **Work Instructions** are particularly critical in regulated industries where standardized execution of quality processes is essential for compliance with standards such as **ISO 9001**, **AS9100**, **ISO 13485**, and **FDA** regulations.

Cross-Reference in Procedures

- Automatically creates bidirectional links when referenced
- Supports detailed "how-to" documentation structure
- Maintains consistency when procedures change

2.2.5 Record Types Unique Features

The **Record Type** list is used to store documents that will later become **Records** within 1factory. These Record Types are typically referenced by other QMS documents such as **Work Instructions**, **Procedures**, or **Process Instructions**. For example, a Work Instruction for "Creating a New Supplier in the QMS" may reference a **Record Type** called "New Supplier Audit Form." When users need to document supplier evaluations, they would create Records using this controlled form template. **Record Types** are also in 1factory QMS are controlled documents that serve as templates for creating **Records** within your quality management system.

Record Creation Configuration

1. Click **Records** tile on left menu

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2. Configure user roles and permissions
3. Click **Go** to save configuration

Important: Must complete this step to create records from this Record Type

Form Download

- Click **FORM** download tile
- Downloads the template file uploaded during creation
- Used as blank form for creating records

No Training Assignment

- Training features not available for Record Types
- Records themselves serve as evidence of completed activities

2.2.6 Manufacturing Standards

Manufacturing Standards are technical reference documents that define specifications, requirements, and acceptance criteria for production operations. These documents establish standardized methods for manufacturing processes, material requirements, inspection protocols, and quality characteristics specific to your manufacturing operations. Examples include industry process standards (**ASTM B580**, **ASTM B841**), customer-specific manufacturing requirements (packaging specifications, part marking standards), and internal production specifications.

Unlike **Standard Business** documents that support organization wide QMS compliance, **Manufacturing Standards** operate exclusively within the manufacturing realm. These documents do not support the **Quality Matrix** feature but instead provide production-level technical guidance that ensures consistent manufacturing execution and product conformance.

PDF Reference Document

- Upload external regulatory documents in PDF format
- Access through Reference Document feature in editing mode
- Supports PDF format only

2.2.7 Courses Unique Features

A new machine operator joins the floor and needs to be authorized on lockout tagout procedures before touching any equipment. Instead of reading a written procedure, they watch a short training video, then answer a few questions to confirm they understood it. That training assignment, video, and quiz all live in a Course.

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Courses are a QMS document type built specifically for delivering training content. They live in their own tile on the QMS tab and follow the same document control backbone as every other QMS document type: numbering, approvals, access control, and training assignment all work the same way.

Accessing Courses

Courses are managed from **QMS Tab > Courses tile**. This tile is only visible to users with the **Manage Courses** permission. Regular users do not see the Courses tile directly. They only interact with Course content through their assigned training in **My Training**.

Numbering

Courses can be assigned a custom prefix if your organization uses its own numbering scheme. If using 1factory numbering, Courses are automatically assigned the fixed prefix *CSE*.

Content Types

Courses are restricted to external content, the same model used for Standards. There is no native content editor for Courses. Supported content types are:

- **PDF**
- **PowerPoint**
- **Video** (max file size 100MB)

When a Course contains a video file, the document screen displays a video player instead of the standard PDF viewer.

Uploading a file is optional. If your training content is hosted externally, simply add the link to the **Description** field instead of uploading a file.

Linking Courses to Other Documents

Courses can be linked to and from other QMS documents the same way Forms and other external documents are linked. A Work Instruction can reference a Course, and a Course's description field can reference back to related QMS documents.

Standard Document Features

Courses retain the full set of standard document features, including:

- **Training:** Assign Courses to roles through a training plan, the same as any other QMS document.
- **Approvals:** Courses follow the same approval workflow as other documents, with one difference described below.
- **Access Control:** Restrict Course visibility by role or organization.

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- **Federation:** Courses are visible across federated organizations the same way other QMS documents are.

Mandatory Course Approver

Courses use a separate mandatory approver role from regular QMS documents. This is configured in QMS Settings as the **Mandatory Course Approver Role**, and works the same way the Mandatory Approver Role does for documents: it is automatically included as a required approver on every Course, and controls release authority if Mandatory Approver Controls Release is enabled. Organizations can select any QMS role for this setting, including the same role used as their Mandatory Approver Role for documents, if they don't need separate approval authority for training content.

3.0 Records

Records in 1factory QMS capture and maintain objective evidence of quality activities by transforming controlled **Record Type**. **Records** are generated from controlled **Form** templates, each receiving a unique auto-incremented identifier (e.g., STS-1, STS-2, STS-3). Only authorized roles can create Records based on the configured permissions established when creating and releasing Record Type.

For example, when a Quality Inspector documents a supplier audit, they access the "**New Supplier Audit Form**" and create a Record against it. The system ensures they use the latest approved version, captures required data, routes it through proper approval workflow, and maintains it as permanent quality evidence for ISO certification reviews.

3.1 My Records

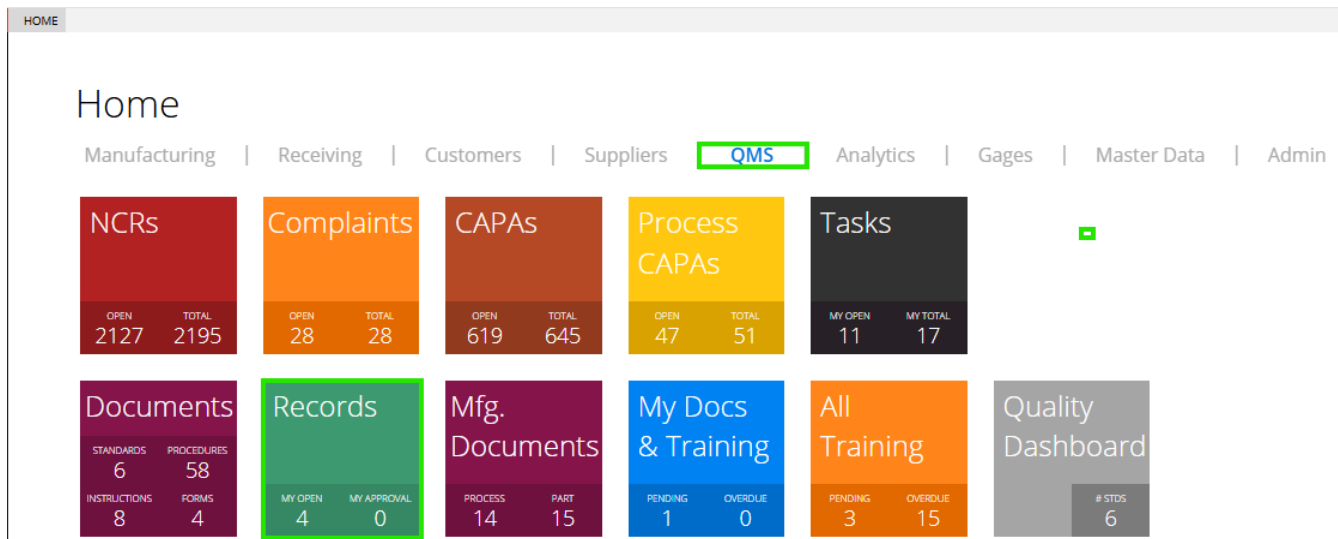
My Records are the Records created by users who have signed in the system based on the **Forms** have been approved by the appropriate person and the status is Released.

3.1.1 Create New Record From My Records

Step 1: Create new Record

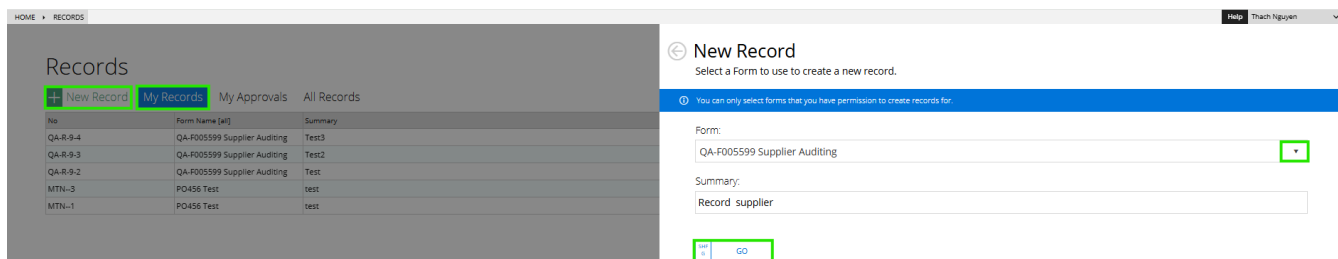
Navigate to the **QMS** tab in your 1factory dashboard. Click on the **Records** tile.

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Step 2: Create New Records

Click **My Records** and then **New Record** to initiate the record creation process. Select the appropriate **Form** you would like to use for your Record from the dropdown menu. Note that only Record Type that have had their role permissions assigned during form configurations, and have been approved and are in **Released** status will appear in the dropdown menu, ensuring compliance with your document control procedures. After making your selection, click the **Go** button.

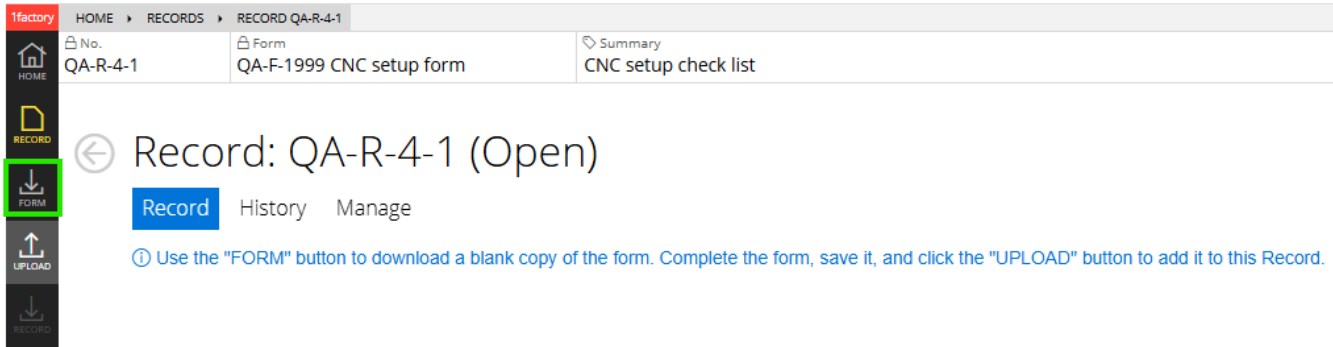


3.1.2 Download and Upload the Form

Step 1: Download the blank Form

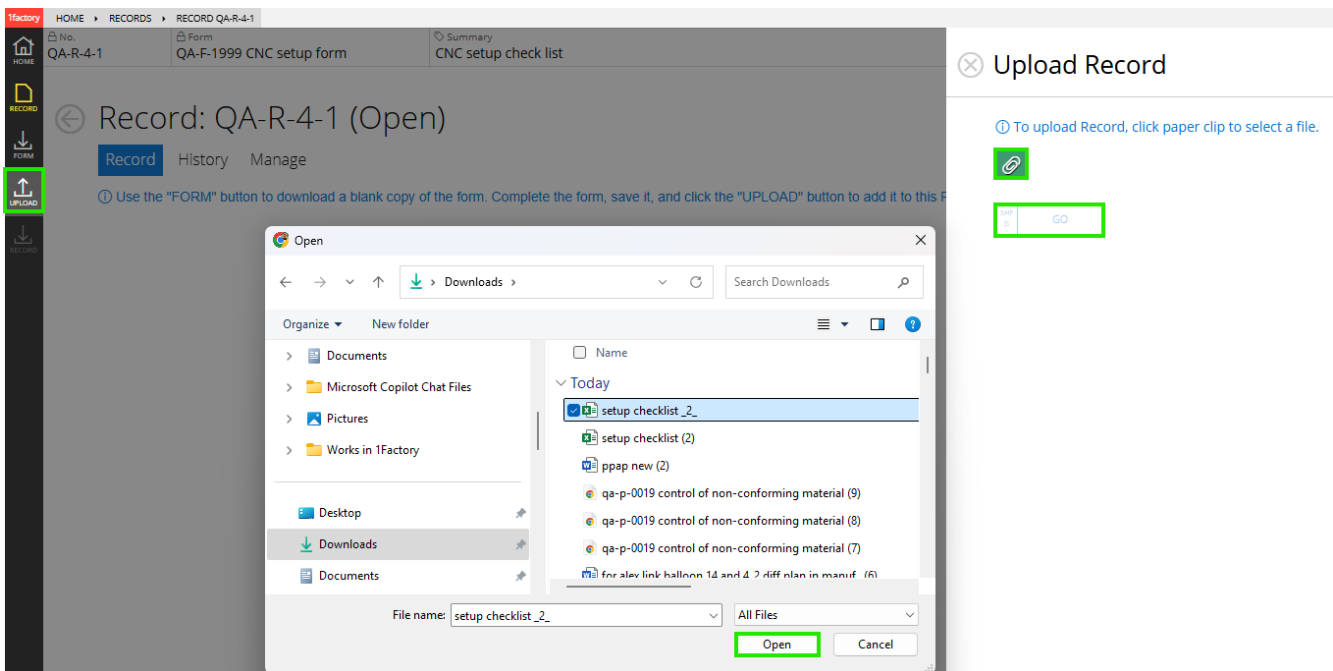
On the left vertical menu, click the **FORM** download icon to download the blank **Form** template.

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Step 2: Upload the completed Form

After downloading the Form template, open the file and complete all required fields with the necessary information. Once all information has been filled out, navigate to the left vertical menu and click the **UPLOAD** icon to upload the completed Form as your Record file.



3.1.3 Document Management

The Document Management feature provides centralized control for managing the **Record** document lifecycle from creation to release. This ensures proper workflow management and compliance with quality management system requirements.

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Key management capabilities include:

- **Status Control** - Manage document status transitions (**Open**, **Approval**, **Closed**)
- **Approval Routing** - Route documents through the defined approval workflow

The management interface provides a centralized location for document administrators to control all aspects of the process document lifecycle while maintaining audit trails and compliance documentation.

Step 1: Request Approval

Navigate to the **Manage** tab, select **Approval** as the status, and choose the appropriate Approver from the dropdown menu. Click the **Save** button to submit the **Record** for approval.

Record: QA-R-4-1 (Open)

Record File: [setup_checklist_2_1.xlsx](#)

Manage

Status: OPEN, **APPROVAL**, CLOSED

Approval

Status	Role	Approver	Approved on
N/A	Quality Manager	Thach Nguyen	

SAVE

Step 2: Check the Status

Once the **Record** has been approved, the status will automatically change from **Approval** to **Closed**.

Manage

Status: OPEN, APPROVAL, **CLOSED**

Approval

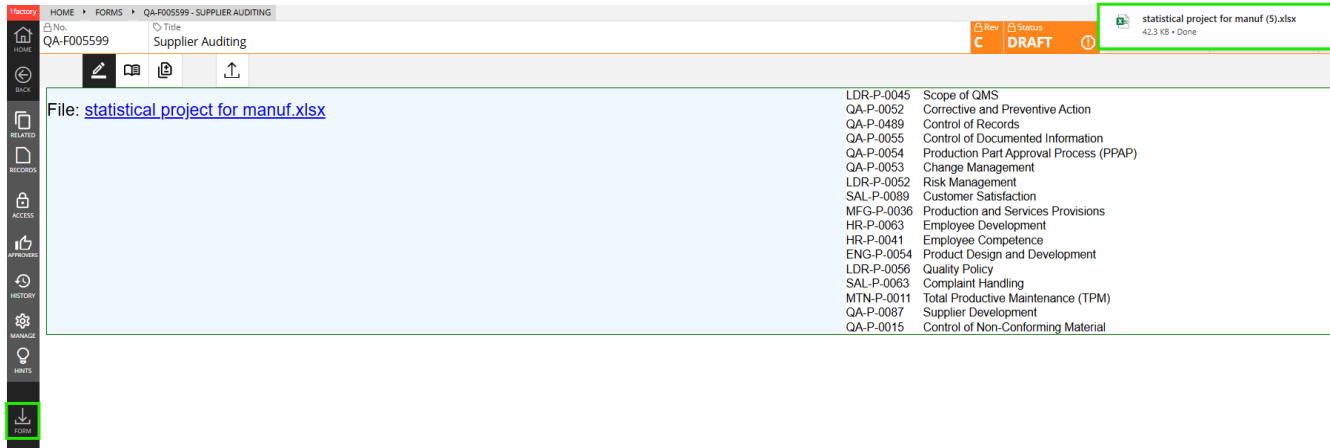
Status	Role	Approver	Approved on
APPROVED	Quality Manager	Thach Nguyen	07-18-2025

SAVE

Step 3: Download a Record

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The download **RECORD** feature allows you to generate your **Record** document for offline use, printing, or external distribution. On the left vertical menu, click the **RECORD** download icon to open the export feature. Your exported file will appear in the top right corner of the screen.



3.1.4 Document History

The **History** feature provides a complete audit trail of all changes and activities related to your **Record** document. This maintains compliance with regulatory requirements and supports quality management system traceability.

Key history tracking capabilities include:

- **Revision History** - Complete record of all document versions and changes
- **User Activity** - Track who made changes, when, and what was modified
- **Status Changes** - Log all status transitions (Open, Approval, Closed, etc.)
- **Approval Records** - Maintain records of all approval decisions and comments
- **Access Logs** - Monitor document viewing and editing activities
- **Upload/Download File** - Monitor Record up/download

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Change History

Id	Field : Value	Revised on	Revised by
0	CREATED BY: Thach Nguyen	07-18-2025, 15:03	Thach Nguyen
1	SUMMARY: CNC setup check list	07-18-2025, 15:03	Thach Nguyen
2	NEW UPLOAD: setup checklist _2_.xlsx	07-18-2025, 15:30	Thach Nguyen
3	NEW UPLOAD: qa-p-0019 control of non-con...	07-18-2025, 15:34	Thach Nguyen
4	NEW UPLOAD: setup checklist _2_ _1_.xlsx...	07-18-2025, 15:35	Thach Nguyen
5	APPROVER Quality Manager: Thach Nguyen	07-18-2025, 16:55	Thach Nguyen
6	STATUS: Approval	07-18-2025, 16:55	Thach Nguyen
7	APPROVAL Quality Manager: Approved	07-18-2025, 17:03	Thach Nguyen
8	STATUS: Closed	07-18-2025, 17:03	Thach Nguyen

3.2 My Approvals

The My Approvals module stores all **Records** awaiting your **Approval** before they are released within the organization. This centralized approval system ensures that only authorized personnel can validate quality documentation, maintaining compliance with regulatory requirements for controlled records. To review all **Records** that require your approval, follow the steps below.

3.2.1 Access My Approvals List

Navigate to the **My Approvals** tab. All **Records** requiring your review will be displayed with their corresponding **Record** number and **Form** name. The system shows only those records where you are **Assigned** as the approver and the Status is **Approval**.

HOMERECORDS

New FeaturesHelpThach Nguyen

Records

New Record

My Records

My Approvals

All Records

Search

1-3 of 3

No	Form Name [all]	Summary	Business Function [all]	Created on	Created by [all]	App. [all]	Status [all]
SK0015-1	F-FG-6007 Test 9999	Test99-Thach	Quality Control	2025-08-23	Thach Nguyen	ASSIGNED	APPROVAL
F-005-3	F-FG-6001 Minor change	Test	CNC	2025-08-18	Thach Nguyen	ASSIGNED	APPROVAL
F-005-1	F-FG-6001 Minor change	Test	CNC	2025-08-06	Thach Nguyen	APPROVED	CLOSED

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3.2.2 Open and Review for Approval

Open each **Record** individually to review the content. Navigate to the **Manage** tab where you can either **Approve** or **Reject** each Record based on your assessment. After making your selection, click the **Save** button to process your decision.

The screenshot displays the 'Manage' interface for Record SX0015-1. The left sidebar shows the record details, including the title 'Record: SX0015-1 (Approval)' and the record file 'requesting ppap from supplier.docx'. The 'Manage' tab is selected. The main content area shows the 'Approval' section with a status bar indicating 'PENDING', 'APPROVAL', and 'CLOSED'. Below the status bar, there is a table with columns for Status, Role, Approver, and Signed on. The table shows a single entry with Status 'PENDING', Role 'QMS Coordinator', and Approver 'Thach Nguyen'. Below the table, there are buttons for 'PENDING', 'APPROVED', and 'REJECTED'. The 'APPROVED' button is highlighted. Below the buttons, there is a text area for 'Review Notes' with a placeholder 'Enter a review note (optional)'. At the bottom, there is a 'SAVE' button.

Status	Role	Approver	Signed on
PENDING	QMS Coordinator	Thach Nguyen	

3.2.3 Monitor Record Status Changes

After you **Approve** or **Reject** a Record, the status will automatically update to reflect your decision. Approved **Records** will move to **Closed** status, while rejected **Records** will be returned to the submitter for correction. This audit trail maintains compliance with quality management standards and provides traceability for regulatory reviews.

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No	Form Name [all]	Summary	Business Function [all]	Created on	Created by [all]	App. [all]	Status [all]
SK0015-1	F-FG-6007 Test 9999	Test99-Thach	Quality Control	2025-08-23	Thach Nguyen	APPROVED	CLOSED
F-005-3	F-FG-6001 Minor change	Test	CNC	2025-08-18	Thach Nguyen	ASSIGNED	APPROVAL
F-005-1	F-FG-6001 Minor change	Test	CNC	2025-08-06	Thach Nguyen	APPROVED	CLOSED

3.3 All Records

The **All Records** module provides a comprehensive view of all organizational records that you are authorized to access based on the permissions configured in the **Record Type** settings. By accessing the **All Records** tab, you can view all **Records** and **Forms** within your authorization scope, including their current status (**Open**, **Approval**, or **Closed**) and assigned **Approvers**, while maintaining regulatory compliance through role-based access controls that ensure users only see records appropriate to their responsibilities within the quality management system.

No	Form Name [all]	Summary	Business Function [all]	Created on	Created by [all]	App. [all]	Status [all]
SK1001-1	F-FG-6010 767676		Chief of Business Integration	2025-08-24	Thach Nguyen	N/A	APPROVAL
KK1002-1	F-FG-6009 757575		Chief of Business Integration	2025-08-24	Thach Nguyen	APPROVED	CLOSED
SA1001-1	F-FG-6008 test select view r...	Test	CNC	2025-08-23	Thach Nguyen	ASSIGNED	APPROVAL

Record: KK1002-1 (Closed - Approved)

Record File: [775573 the gent machine.docx](#)

Status

OPEN APPROVAL CLOSED

Approval

Status	Role	Approver	Signed on
APPROVED	Chief of Business Integrati...	Thach Nguyen	2025-08-24

DISCARD SAVE

4.0 Training

Training management is a cornerstone of quality system compliance, ensuring that your workforce maintains the competencies required by ISO standards and regulatory bodies. In regulated manufacturing environments, untrained personnel performing critical tasks can lead to product defects, compliance violations, and audit findings that jeopardize certifications. For example, when a medical device manufacturer implements a new sterilization procedure, operators must demonstrate

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documented competence before performing the process—otherwise, incorrect parameters could compromise product sterility and patient safety.

1factory's Training module automates this critical compliance requirement by automatically generating training assignments whenever documents are created or revised, sending email notifications to affected personnel, tracking completion status in real-time, and maintaining permanent training records with digital signatures. When auditors request evidence of training during ISO 9001, AS9100, or FDA inspections, the system instantly provides comprehensive reports showing who was trained, when training occurred, which document revision was used, and proof of competency assessment—eliminating the manual spreadsheets and paper records that often lead to audit findings.

4.1 Assigning Training

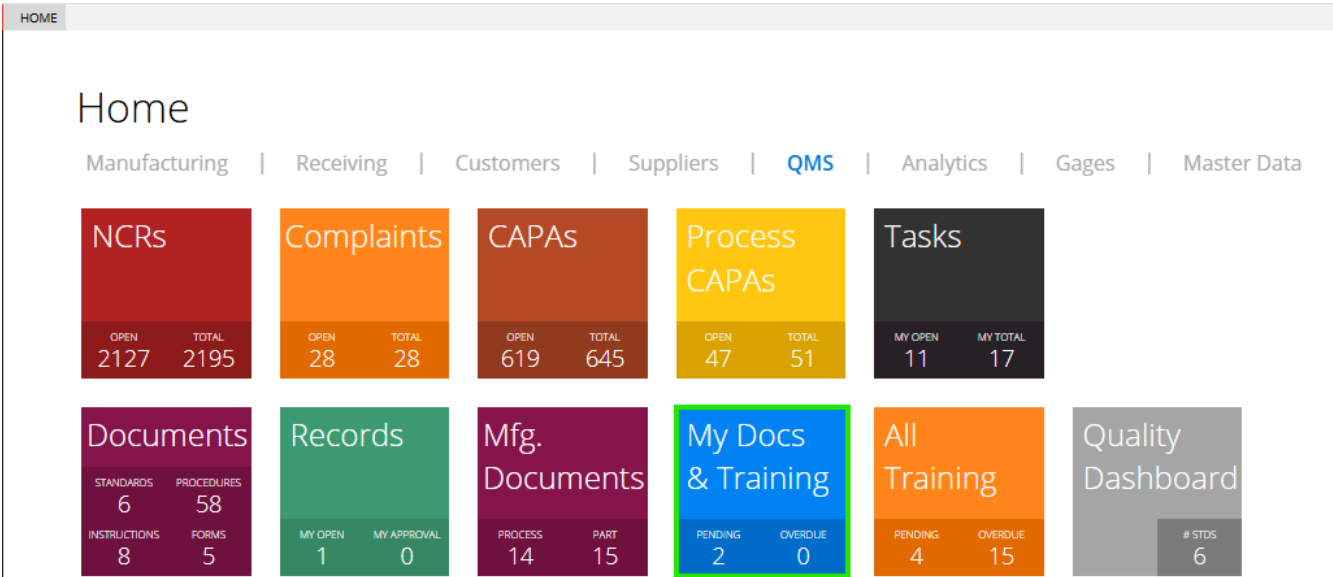
The **Assigning Training** feature is a fundamental QMS component that creates mandatory training requirements for controlled documents (**Standards, Procedures, Work Instructions, Process Instructions, and Part Specific Instructions**). This capability ensures personnel obtain proper instruction and certification prior to executing related quality processes, confirming that only competent individuals perform critical activities required for maintaining ISO certifications and regulatory compliance. Training can be generated through two methods: **Automated training** and **Ad-hoc**.

4.1.1 Automated Training on a QMS Document

Automated Training is a systematic method where training assignments are automatically generated during QMS document creation. When document authors configure training requirements, the system automatically assigns training tasks to designated QMS roles, ensuring that personnel receive timely notification and access to essential quality documentation training.

Navigate to the **QMS** tab in your 1factory dashboard. Click on the **My Docs & Training** tile to access your personalized training assignments.

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Step 1: Review Training Assignments

Upon accessing this interface, the system presents a comprehensive list of documents requiring your training completion, displaying:

- Document number and title
- Training due date
- Current completion status
- Certificate expiration status
- Overall training progress

My Training

Documents | Training History

No	Title	Training description	Due By	Completed	Expires	Status
MFG-WI-60 25849	test space	New Role added to document training plan	08-03-2025			PENDING
QA-P-[PR 1505]	Self Assessment	New revision of document released				PENDING
[PR 1504]	Quiz Button must be appear	New Role added to document training plan		06-20-2025		COMPLETE
QA-P-0489	Control of Records	New Role added to document training plan	07-03-2025	06-13-2025	06-13-2026	COMPLETE
QA-P-0052	Corrective and Preventive Action	New Role added to document training plan	06-28-2025	06-13-2025	06-13-2027	COMPLETE
LDR-P-0045	Scope of QMS	New Role added to document training plan	06-23-2025	06-13-2025	06-13-2027	COMPLETE
QA-P-490-1	test	Test	05-15-2025	06-12-2025		COMPLETE
LDR-P-0061	Management Review	New Role added to document training plan	06-27-2025	06-12-2025	06-12-2027	COMPLETE
SQA-P-0063	Supplier Qualification	New Role added to document training plan	06-27-2025	06-12-2025	06-12-2027	COMPLETE
ENG-P-00002	Test case 254	New revision of document released	06-19-2025	06-06-2025	06-06-2026	COMPLETE
MFG-WI-[PR1493]	Need training	New revision of document released	06-21-2025	06-06-2025	06-06-2026	COMPLETE
[PR 1493]	Need Training	New Role added to document training plan	06-21-2025	06-06-2025	06-06-2026	COMPLETE
12345678	Test	New revision of document released	06-16-2025	06-06-2025	06-06-2026	COMPLETE
ENG-P-[PR1493]	Need Training	New Role added to document training plan	06-21-2025	06-06-2025	06-06-2026	COMPLETE
QA-WI-[PR 1493]	Test	New Role added to document training plan	06-21-2025	06-06-2025	06-06-2026	COMPLETE

Step 2: Access Training Content

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Select the specific training assignment you wish to complete from your training queue. Review the document content thoroughly to understand the requirements, procedures, or standards covered. Once ready to demonstrate competency, click the **Complete** tile located on the left side of the menu bar.

1factory

HOME

MY TRAINING

COMPLETE

HOME > MY TRAINING > MFG-WI-60 25849 - TEST SPACE

No.

MFG-WI-60 25849

Title

test space

BOOK

DOCUMENT

① Read the document, and click "complete" to confirm you have understood it.

1 PURPOSE

This work instruction provides detailed steps for conducting employee training programs and competency assessments at 1factory to ensure personnel possess the necessary skills and knowledge to perform their assigned duties in accordance with ISO 9001, ISO 13485, and AS9100 requirements for precision machined components in the Aerospace and Medical device industries.

2 SCOPE

This instruction applies to all 1factory personnel including full-time employees, temporary workers, and contractors who perform activities affecting product quality, regulatory compliance, or operational safety.

Step 3: Complete Training Assessment

Quiz Method

Complete all assessment questions using the provided dropdown menus. Select the checkbox confirming "I confirm I have completed this training" and click the **Go** button to submit your completed assessment.

⊗ Complete Training

① In order to complete this training, first answer the following questions.

You need inform to your supervisor?

Correct



In completing this training, you acknowledge that you have fully read and understood this document. You must also agree to follow the policies, practices and procedures outlined in the document.

☒ I confirm I have completed this training.

SHF
GO

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Self Assessment Method

Select **"Yes"** to confirm training completion and provide your digital signature as verification of competency. After entering all required information, click the **Go** button to finalize your self-assessment.

⊗ Complete Training

① In order to complete this training, first answer the following questions.

yes

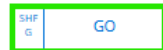
yes



① Sign below to complete this training.

In completing this training, I acknowledge that I have fully read and understood this document. I agree to follow the policies, practices and procedures outlined in the document.

.....

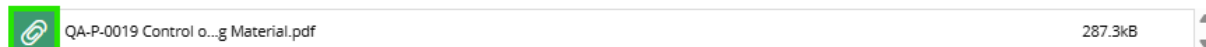


External Certificate Method

Click the paper clip icon to upload your external training certificate (PDF format required). This method accommodates training completed outside the 1factory system while maintaining centralized training records. Click the **Go** button after uploading the documentation.

⊗ Complete Training

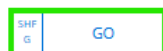
① Processing complete.



[Certificate of Completion](#)

In completing this training, you acknowledge that you have fully read and understood this document. You must also agree to follow the policies, practices and procedures outlined in the document.

☒ I confirm I have completed this training.



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Step 4: Training History Management

The training history module maintains comprehensive records of all completed training activities, including:

- Document name and associated revision number
- Original due date and actual completion date
- Certificate proof of training
- Expiration dates of the training

← Training History

ⓘ A list of all training currently pending for, or ever completed by, this user.

Document	Completed Rev	Due By	Completed On	Expires	Certificate
LDR-P-0061 Management Review		07-04-2025	Cancelled		
MFG-WI-60 25849 test space		08-03-2025			
QA-P-0055 Control of Documented Information		08-03-2025			Download
QA-P-[PR 1505] Self Assessment					
[PR 1504] Quiz Button must be appear	A		06-20-2025		
QA-P-[PR 1505] Self Assessment	A		06-20-2025		
QA-P-0489 Control of Records	A	07-03-2025	06-13-2025	06-13-2026	Download
QA-P-0052 Corrective and Preventive Action	A	06-28-2025	06-13-2025	06-13-2027	
LDR-P-0045 Scope of QMS	A	06-23-2025	06-13-2025	06-13-2027	Download
QA-P-490-1 test	A	05-15-2025	06-12-2025		

This automated training system ensures consistent knowledge transfer while maintaining detailed documentation required for ISO certification maintenance and regulatory audit readiness.

4.1.2 Ad-hoc Training on a QMS Document

1factory provides a flexible **Ad-hoc Training** feature that enables quality managers and administrators to assign training on any QMS document to specific roles or individual users outside of the standard automated training schedules. This capability is particularly valuable when **immediate training** is required due to process changes, corrective actions, or new employee onboarding.

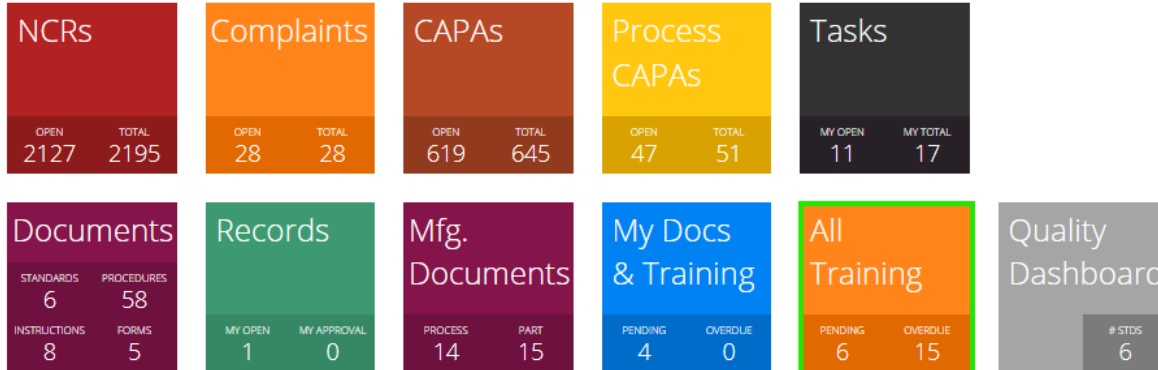
Navigate to the **QMS** tab in your 1factory dashboard. Click on the **All Training** tile to access the training management interface.

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HOME

Home

Manufacturing | Receiving | Customers | Suppliers | **QMS** | Analytics | Gages | Master Data



Step 1: Initiate Ad-hoc Training Assignment

Within the **Training Log** tab, click the **New Training** button to begin creating a custom training assignment for your selected personnel.

HOME > ALL TRAINING

All Training

+ New Training Training Log By Document By User					
Created on	Created by [all]	Type [all]	Document	Role	User
07-20-2025	Thach Nguyen	Ad-hoc	LDR-P-0045 Scope of QMS	Manufacturing Engineering Ma...	Thach Nguyen
07-19-2025	Thach Nguyen	New to Role	QA-P-0055 Control of Documen...	Manufacturing Engineering Ma...	
07-19-2025	Thach Nguyen	New to Role	MFG-WI-60 25849 test space	Manufacturing Engineering Ma...	
06-20-2025	Nick Kelly	New Revision	QA-P-[PR 1505] Self Assessment	All Users	
06-20-2025	Thach Nguyen	New to Role	[PR 1504] Quiz Button must be ...	All Users	
06-20-2025	Thach Nguyen	New to Role	QA-P-[PR 1505] Self Assessment	All Users	
06-19-2025	Thach Nguyen	New Revision	LDR-P-0061 Management Review	Quality Manager	
06-13-2025	Thach Nguyen	New to Role	QA-P-0489 Control of Records	Quality Manager	
06-13-2025	Thach Nguyen	New to Role	QA-P-0052 Corrective and Prev...	Quality Manager	

Step 2: Configure Training Parameters

Complete the following required fields to establish your **ad-hoc training** assignment:

- **Due Date:** Set the completion deadline for the training assignment

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- **Documents:** Select the specific QMS document(s) or Course(s) requiring training from your controlled document library.
- **Roles:** Choose the QMS roles that need to complete this training
- **Users:** Assign training to specific individual users as needed
- **Description:** Provide context and instructions for the training requirement

After configuring all parameters, click the **Go** button to activate the training assignment.

← New Ad-Hoc Training

Select document(s) and role(s) or user(s) to require training on them.

ⓘ Must select at least one document and one of either a role or user.

Due by:

07-25-2025



Click names to add document

Select documents ...



Selected documents

LDR-P-0061 Management Review

Click names to add roles

Select roles ...



Selected roles

Manufacturing Engineering Manager

Click names to add users

Select users ...



Selected users

Thach Nguyen

Description

User needs to take this training

SHF
G

GO

Training Notification Process Once you click the **Go** button, the system automatically:

- Sends email notifications to all assigned users
- Creates training tasks within each user's 1factory dashboard
- Tracks assignment status and completion progress
- Maintains audit records of the ad-hoc training activity

This feature ensures that critical knowledge transfer occurs promptly when process changes, corrective actions, or urgent compliance requirements demand immediate attention, supporting your organization's commitment to maintaining a competent and informed workforce.

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4.2 Monitoring Training

1factory provides four comprehensive methods to monitor and review all training activities within your organization, ensuring complete visibility into training compliance and progress across your QMS.

Training Log Review

The **Training Log** tab displays a comprehensive list of all training documents, including ad-hoc training assignments, with key information such as:

- **Created On:** Date the training was assigned
- **Created By:** User who initiated the training assignment
- **Type:** Training category (scheduled, ad-hoc, retraining)
- **Document:** Associated QMS document requiring training
- **Role:** QMS roles assigned to complete the training
- **Due By:** Training completion deadline

All Training

+ New Training		Training Log	By Document	By User	Search				1-24 of 24	
Created on	Created by [all]	Type [all]	Document	Role	User	Description	Progress [all]	Due by		
07-20-2025	Thach Nguyen	Ad-hoc	MGMT6 5559 test with Space	Manufacturing Engineering Ma...	Thach Nguyen	User needs to take this training		07-25-2025		
07-20-2025	Thach Nguyen	Ad-hoc	LDR-P-0045 Scope of QMS	Manufacturing Engineering Ma...	Thach Nguyen	User need to take this training		07-25-2025		
07-19-2025	Thach Nguyen	New to Role	QA-P-0055 Control of Document...	Manufacturing Engineering Ma...		New Role added to document training plan		08-03-2025		
07-19-2025	Thach Nguyen	New to Role	MFG-WI-60 25849 test space	Manufacturing Engineering Ma...		New Role added to document training plan		08-03-2025		

Detailed Training Information: Click on any specific training entry to view comprehensive details including Training Type, Due Date, associated Documents, assigned Roles, Users, and complete Training Records with completion status and history.

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← Training (Pending)

Created by Thach Nguyen on 07-20-2025.

① User needs to take this training

Training Type:

Ad-hoc

Due by:

07-25-2025

Documents

MGMT6 5559 test with Space

Roles

Manufacturing Engineering Manager

Users

Thach Nguyen

Training Records

Document	User	Status	Completed On
MGMT6 5559 test with Space	Fabrizio Bertocci	Pending	
MGMT6 5559 test with Space	Thach Nguyen	Pending	

Review By Document

The **By Document** tab organizes training information by QMS document, displaying:

- **Document No.:** Controlled document identifier
- **Title:** Document name and description
- **Type:** Document category (Standard, Procedure, Work Instruction, etc.)
- **Business Function:** Associated organizational department
- **Training Role:** QMS roles requiring training on this document
- **Owner:** Document owner responsible for content
- **Progress:** Overall completion percentage across all assigned users

HOME > ALL TRAINING							Help Thach Nguyen
All Training							
+ New Training Training Log By Document By User							
Search							1-31 of 31 < >
No	Title	Type [all]	Business Function [all]	Training Roles [all]	Owner [all]	Progress [all]	
QA-P-0055	Control of Documented Information	Procedure		Manufacturing Engineering Ma...			
QA-P-252525	Space at end	Procedure	Quality		Quality Manager		
MGMT6 5559	test with Space	Procedure	Quality		Quality Manager		
QA-P-07012...	Thach Test attached training	Procedure	Manufacturing Operations		Quality Manager		

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Individual Training Details: Click on any document to access user-specific training information including assigned User, Due Date, completion Status, Completed On date, certificate Expiration, and Certificate details.

← Document Training : QA-P-0055

Control of Documented Information

① Current training status of users on this document.

User	Due By	Status	Completed On	Expires	Certificate
Fabrizio Bertocci	08-03-2025	Pending			
Thach Nguyen	08-03-2025	Pending			Download

Review By Users

The **By Users** tab provides a person-centric view of training assignments, displaying:

- **Last Name / First Name:**
- **Progress:** Individual training completion percentage

HOME • ALL TRAINING Help Thach Nguyen

All Training

+ New Training

Training Log

By Document

By User

1-15 of 15 < >

Last name	First name	Email address	Telephone	User Roles (all)	Job Title	ITAR (all)	Progress (all)
Ton That	Long	long.tonthat@1factory.com				✓	
Le	Allen	allenle@aci-cpa.com				○	
Nguyen	Thi	thi@aci-cpa.com				○	
Stallard	Will	will.stallard@1factory.com				✓	
Thompson	Faith	faith.thompson@1factory.com				✓	

User Training Portfolio: Click on any user to view their complete training profile including assigned Documents, Due Dates, completion Status, Completed On dates, certificate Expiration dates, and Certificate records.

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← User Training : Thach Nguyen

① Current training status on documents for this user.

Status History

Document	Due By	Status	Completed On	Expires	Certificate
LDR-P-0045 Scope of QMS	07-25-2025	Pending			
MGMT6 5559 test with Space	07-25-2025	Pending			
MFG-WI-60 25849 test space	08-03-2025	Pending			
QA-P-0055 Control of Documented Information	08-03-2025	Pending			Download
QA-P-[PR 1505] Self Assessment		Pending			
[PR 1504] Quiz Button must be appear		Complete	06-20-2025		
QA-P-0489 Control of Records	07-03-2025	Complete	06-13-2025	06-13-2026	Download
QA-P-0052 Corrective and Preventive Action	06-28-2025	Complete	06-13-2025	06-13-2027	
QA-P-490-1 test	05-15-2025	Complete	06-12-2025		
LDR-P-0061 Management Review	06-27-2025	Complete	06-12-2025	06-12-2027	

Training History Access: Navigate to the **History** tab within any user's profile to review all documents previously assigned to that user and their complete training history, providing comprehensive audit trails for regulatory compliance and performance evaluations.

Review By Course

The By Course tab organizes training information by Course, displaying:

- **Course No.:** Controlled Course identifier
- **Title:** Course name and description
- **Business Function:** Associated organizational department
- **Training Role:** QMS roles requiring training on this Course
- **Owner:** Course owner responsible for content
- **Progress:** Overall completion percentage across all assigned users

All Training

+ New Training	Training Log	By Document	By User	By Course	Search	1-1 of 1	<	>
No	Title	Business Function [all]	Training Roles [all]	Owner [all]	Progress [all]			
EHS-1	Lock Out / Tag Out	Manufacturing Operatio...	All Users	Maintenance Manager				

Individual Training Details: Click on any Course to access user-specific training information including assigned User, Due Date, completion Status, Completed On date, certificate Expiration, and Certificate details.

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These four review methods ensure quality managers can monitor training compliance from multiple perspectives, supporting both individual development tracking and organizational training effectiveness measurement.

← User Training : Thach Nguyen

History of all training for this user.

Status **History**

Document	Due By	Status	Completed On	Expires	Certificate
LDR-P-0061 Management Review	07-04-2025	Canceled	Cancelled		
LDR-P-0045 Scope of QMS	07-25-2025	Pending			
MGMT6 5559 test with Space	07-25-2025	Pending			
MFG-WI-60 25849 test space	08-03-2025	Pending			
QA-P-0055 Control of Documented Information	08-03-2025	Pending			Download
QA-P-[PR 1505] Self Assessment		Pending			
[PR 1504] Quiz Button must be appear		Complete	06-20-2025		
QA-P-[PR 1505] Self Assessment		Complete	06-20-2025		
QA-P-0489 Control of Records	07-03-2025	Complete	06-13-2025	06-13-2026	Download
QA-P-0052 Corrective and Preventive Action	06-28-2025	Complete	06-13-2025	06-13-2027	

5.0 Quality Dashboard