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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.

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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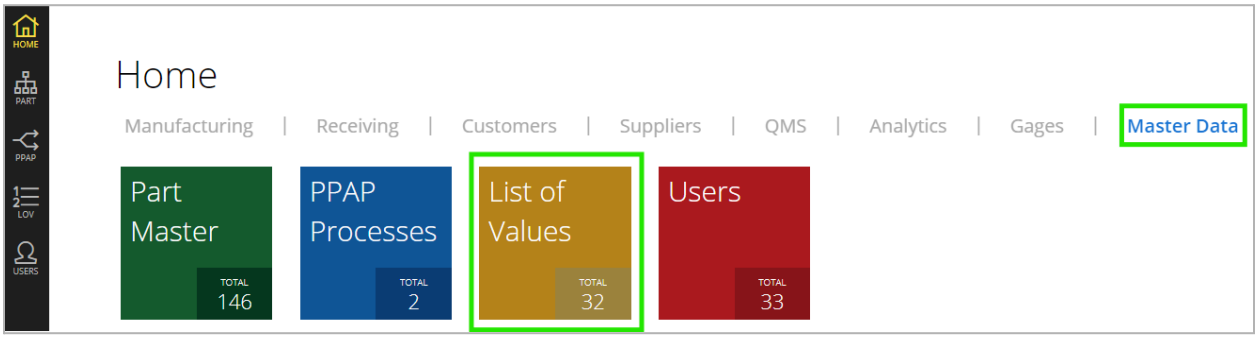

Once you are in the List of Values tile, you will find three QMS-related Lists of Values to fill out before uploading any documents into the QMS. We have explained how each is intended to be used within 1factory. To simplify this process, we have provided a pre-formatted file that you can complete and 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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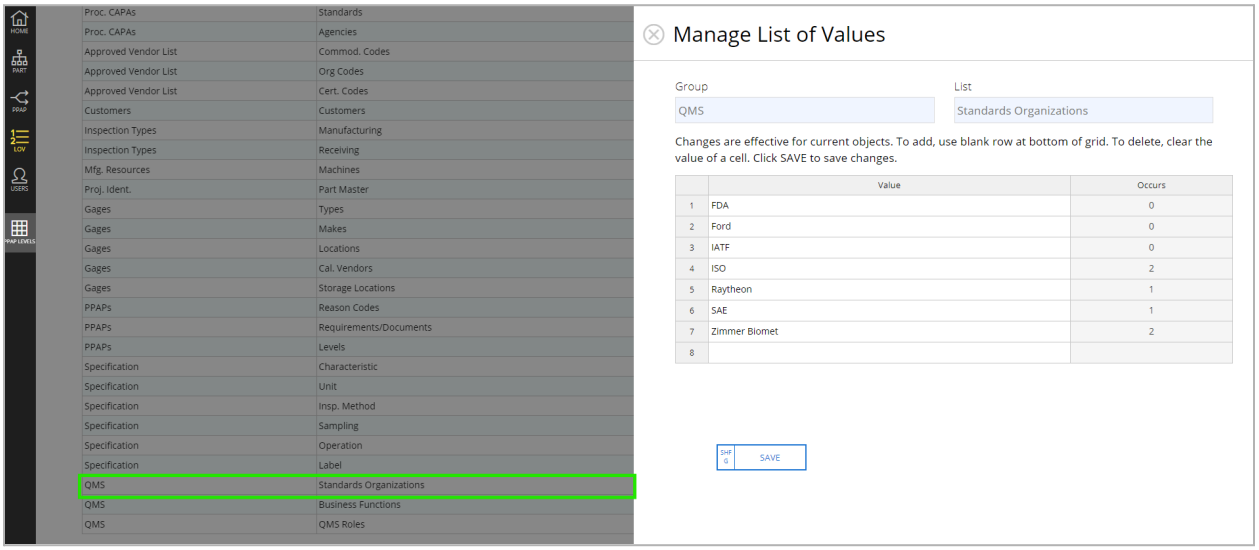
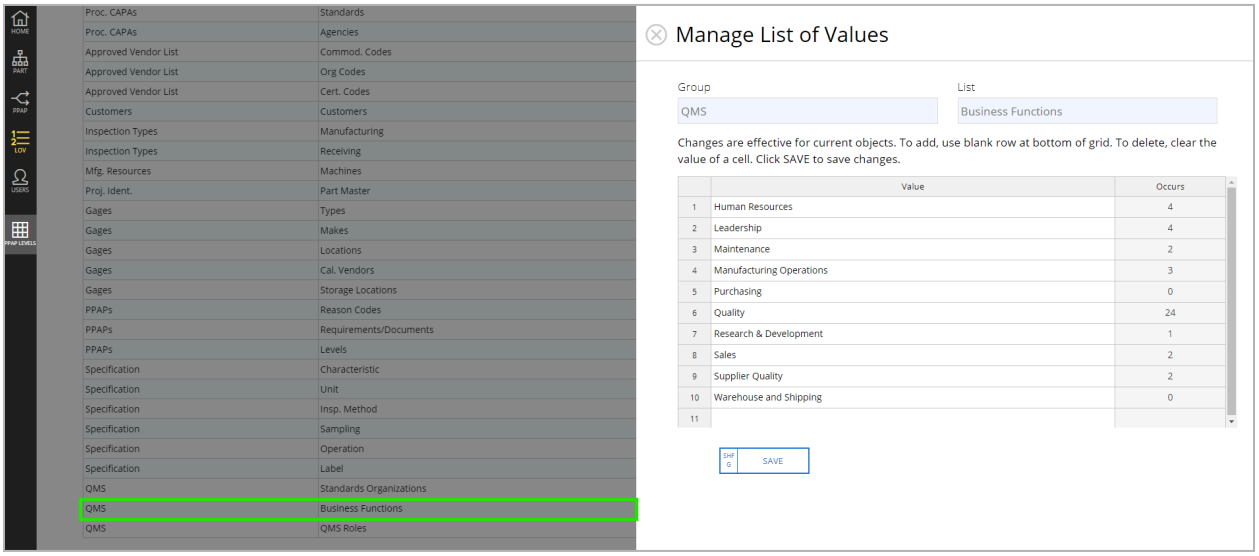


1.1.2 Business Function

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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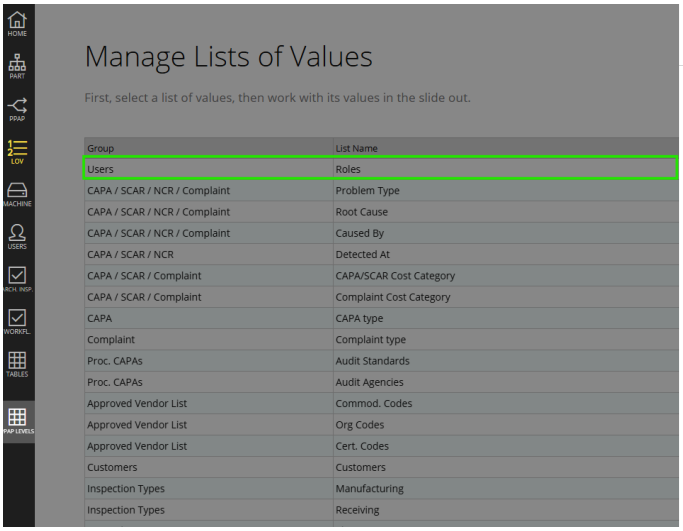
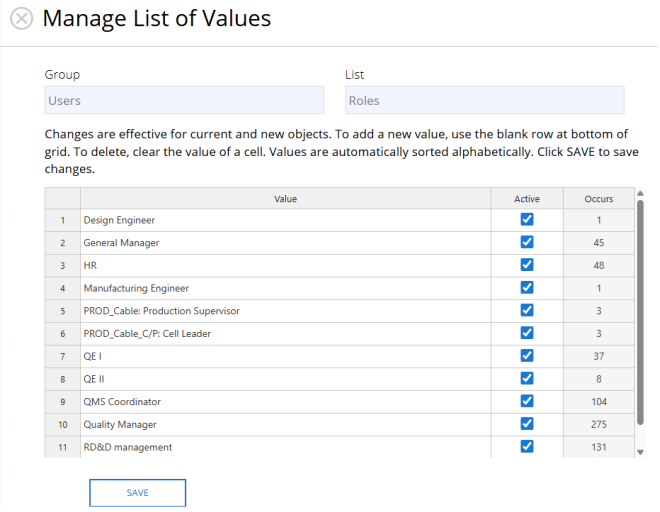
1.1.3 QMS Roles

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.





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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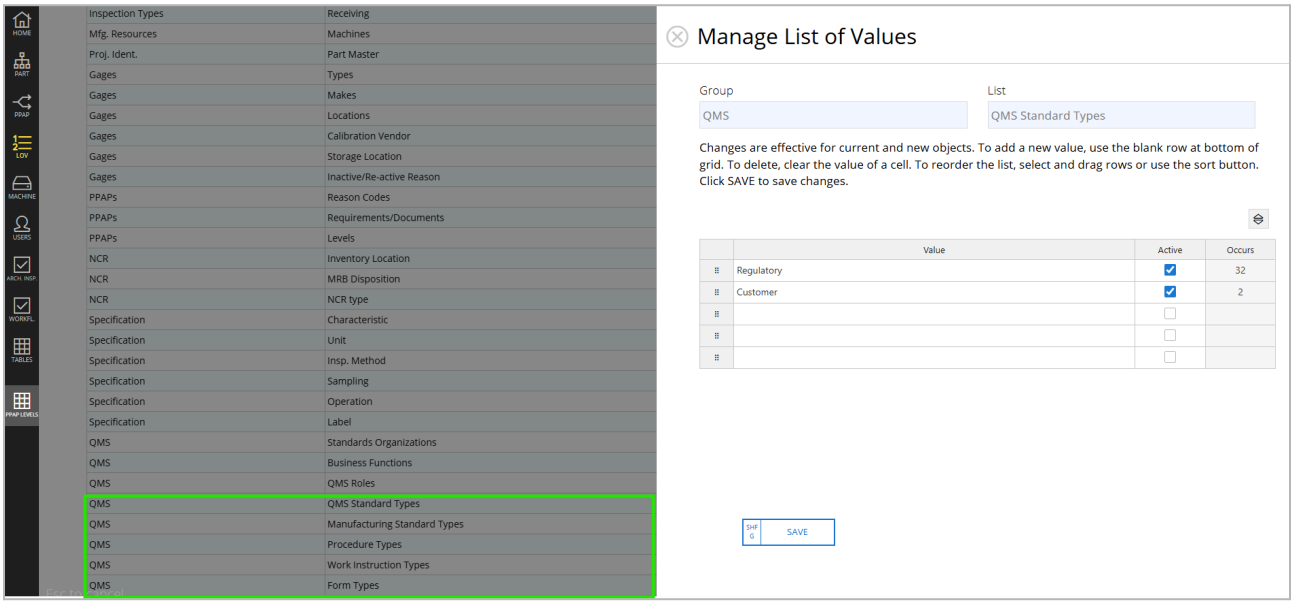

A separate Sub-Type List of Values exists for each of the following document types. The examples below are provided as a starting point and should be adjusted to reflect your organization's terminology and document categories.

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

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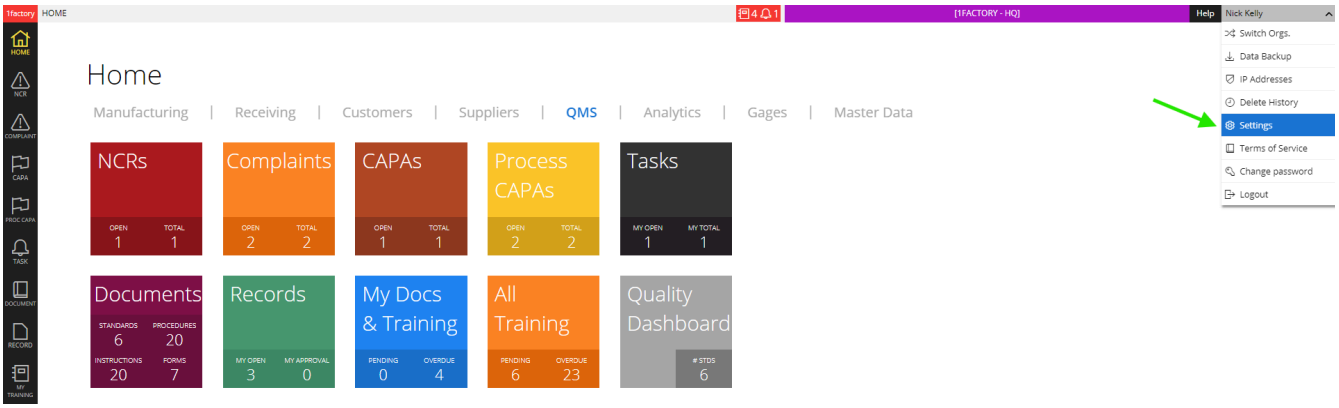
Once a Sub-Type List is configured, the **sub-type** field becomes available when creating a new document of that type. Sub-type is optional and can also be assigned or updated from the document detail page while the document is in **Draft** status. The sub-type column appears in each document list and 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

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.

- **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

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.

- **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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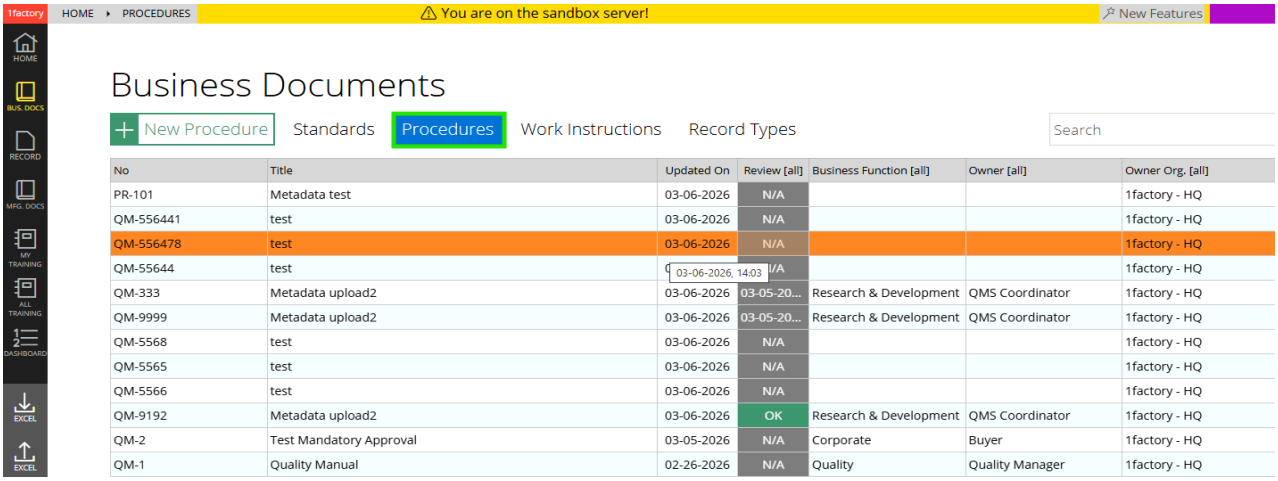
- **Review Period:** Number of months from release before a document review is due.
- **Last Review Date:** Date the document was last reviewed in your previous QMS. When set, the next review date is calculated from this date rather than the 1factory release date, ensuring review schedules carry over 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).



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

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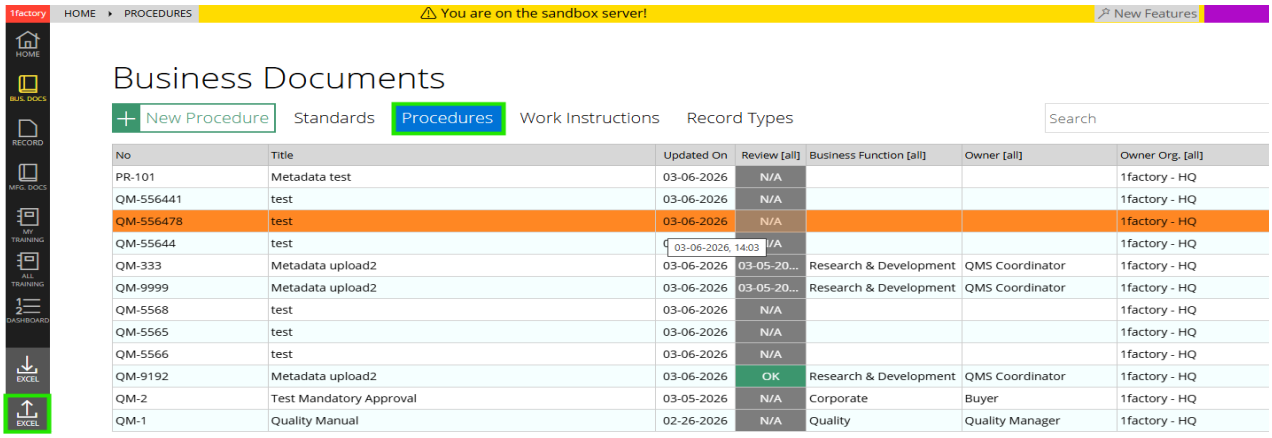
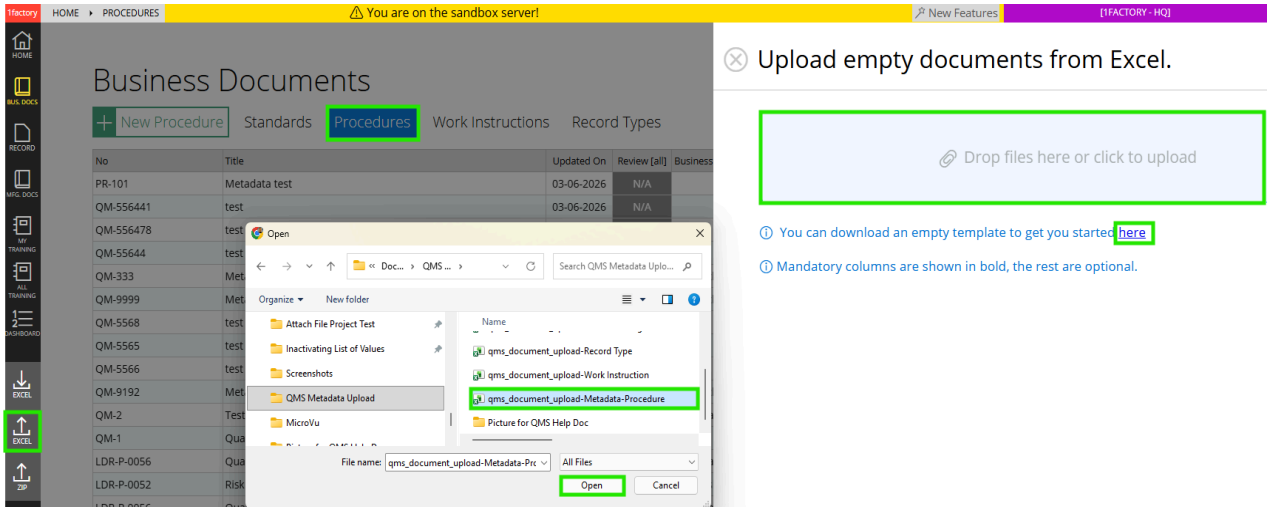


In the slideout that opens, click the green paper clip icon to attach your completed template file.



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

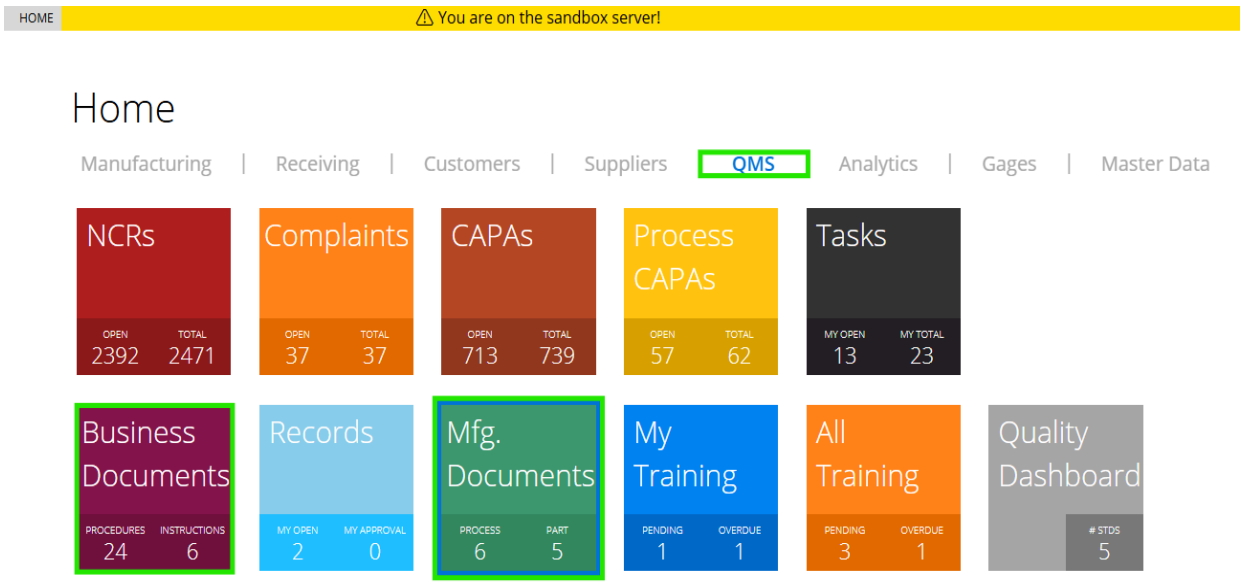
The ZIP file may contain a mix of primary document files and supporting attachments. Follow these naming conventions:

- **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, .xlsm), 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.



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

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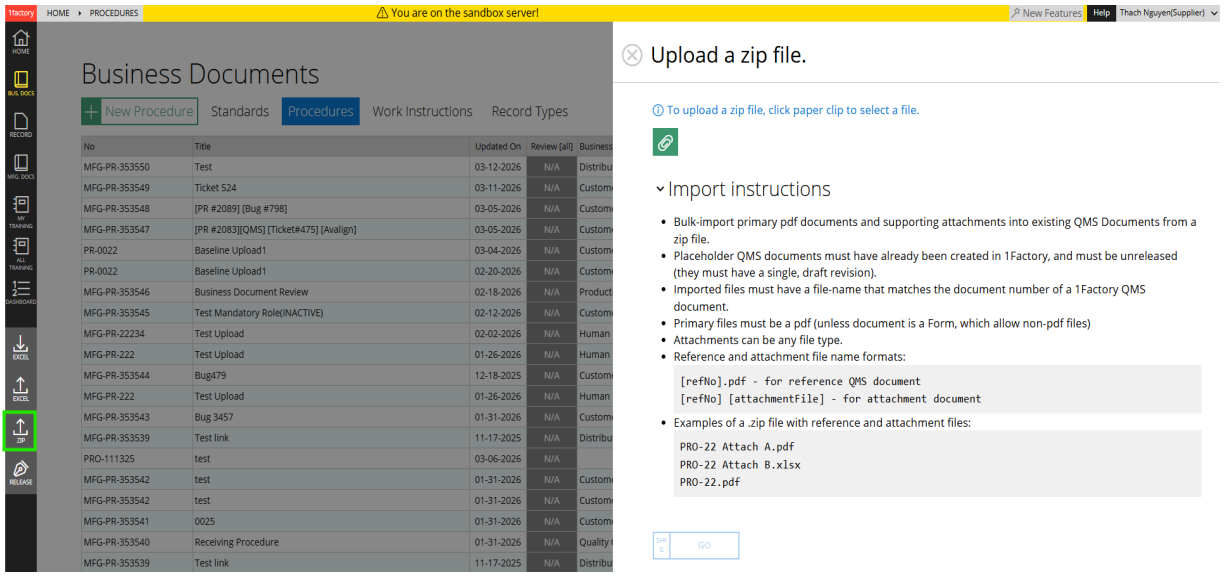
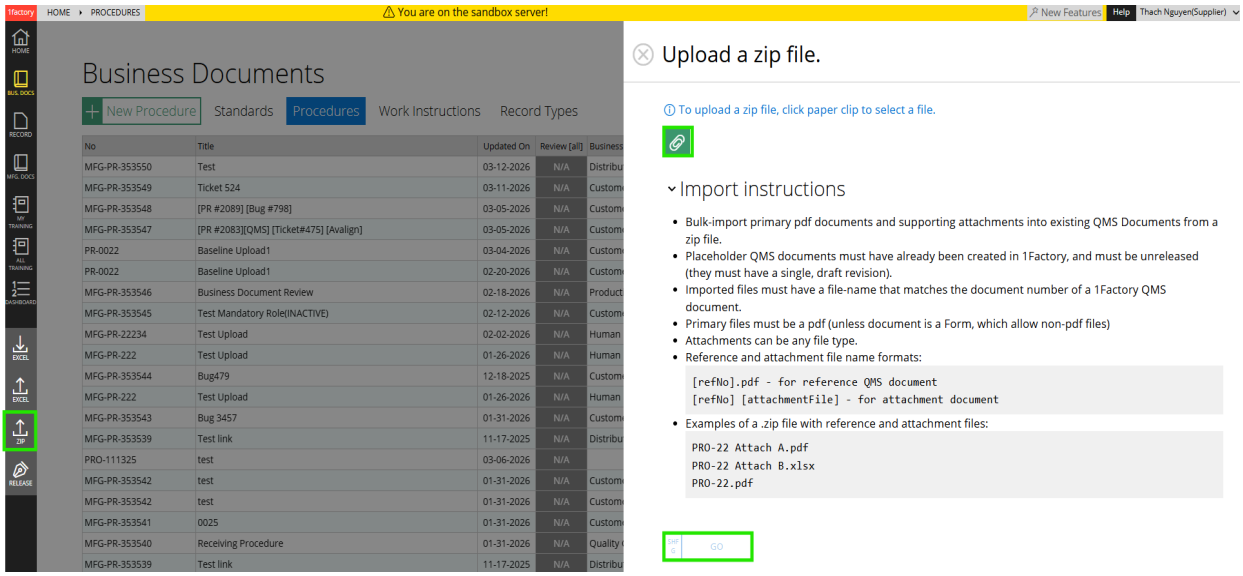


3. In the slideout, attach your ZIP file using the paper clip icon and click **Go**.



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

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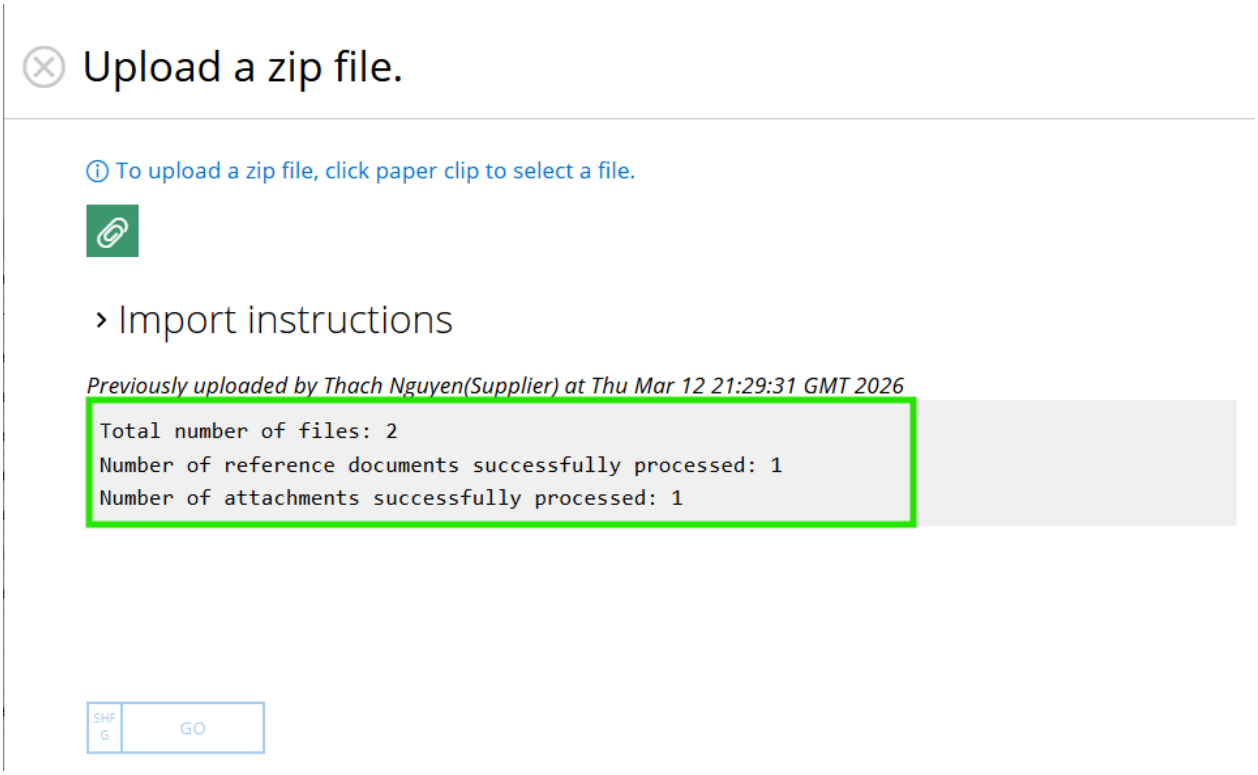

Note: *Only one bulk file import may run at a time per organization. If an import is already in progress, the slideout will display its status and provide an option to cancel. If your total file size exceeds the system limit, split your documents into multiple ZIP files and import them in batches.*

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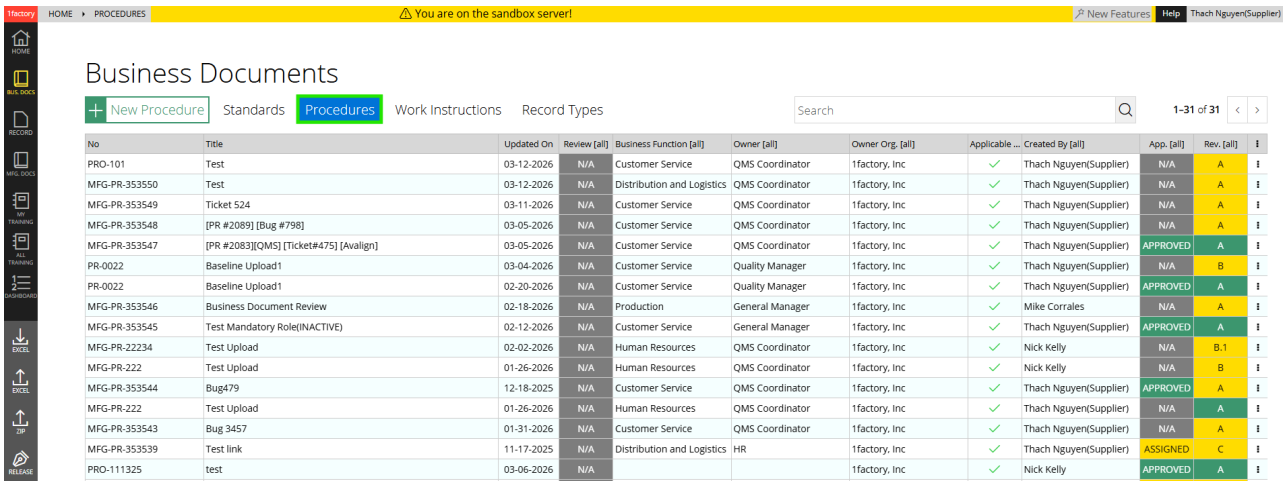
- The document has an external PDF file uploaded. Documents being authored natively in 1factory are excluded and should be released individually as they are completed.

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

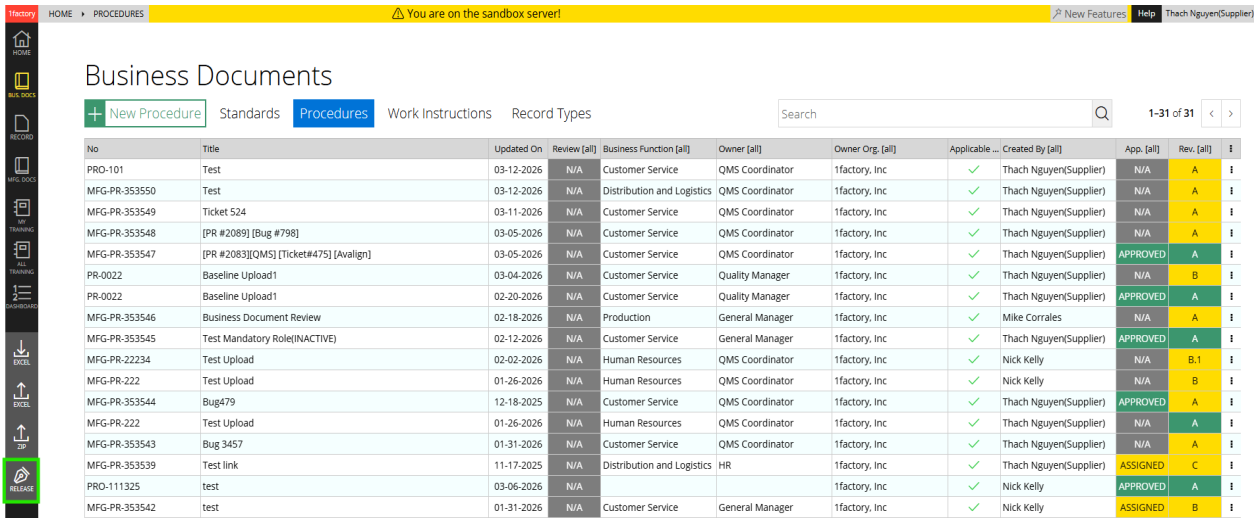
Performing a Bulk Release

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



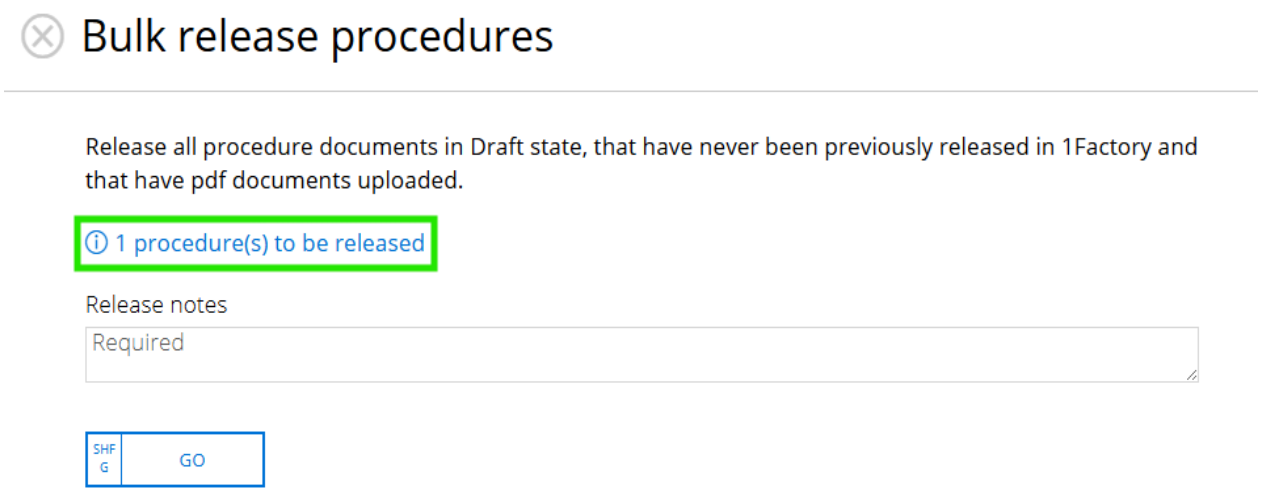
No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Owner Org. [all]	Applicable ...	Created By [all]	App. [all]	Rev. [all]
PRO-101	Test	03-12-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A
MFG-PR-353550	Test	03-12-2026	N/A	Distribution and Logistics	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

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

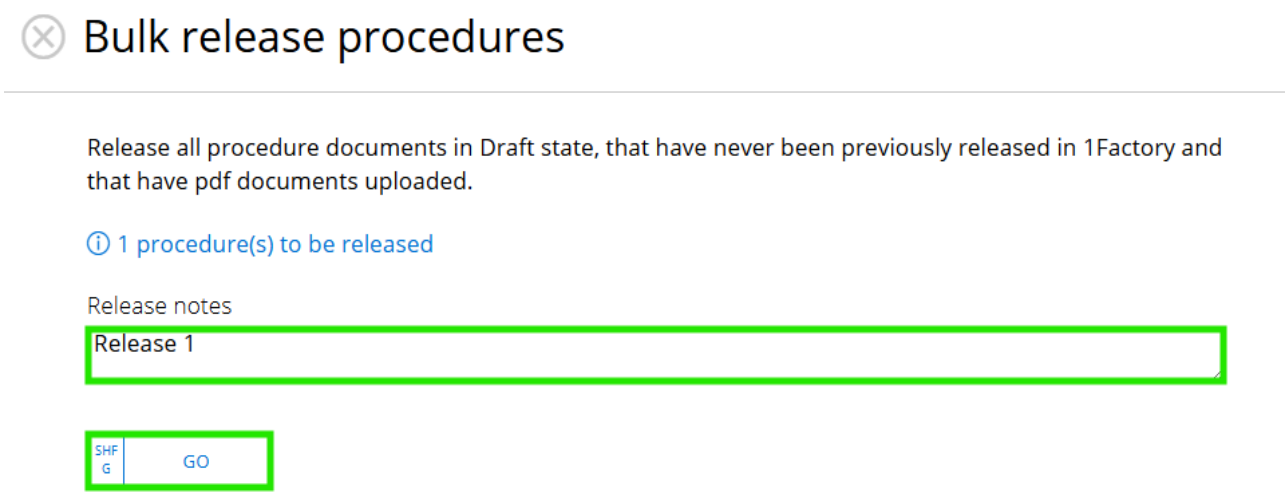


No	Title	Updated On	Review [all]	Business Function [all]	Owner [all]	Owner Org. [all]	Applicable ...	Created By [all]	App. [all]	Rev. [all]
PRO-101	Test	03-12-2026	N/A	Customer Service	QMS Coordinator	1factory, Inc	✓	Thach Nguyen(Supplier)	N/A	A
MFG-PR-353550	Test	03-12-2026	N/A	Distribution and Logistics	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

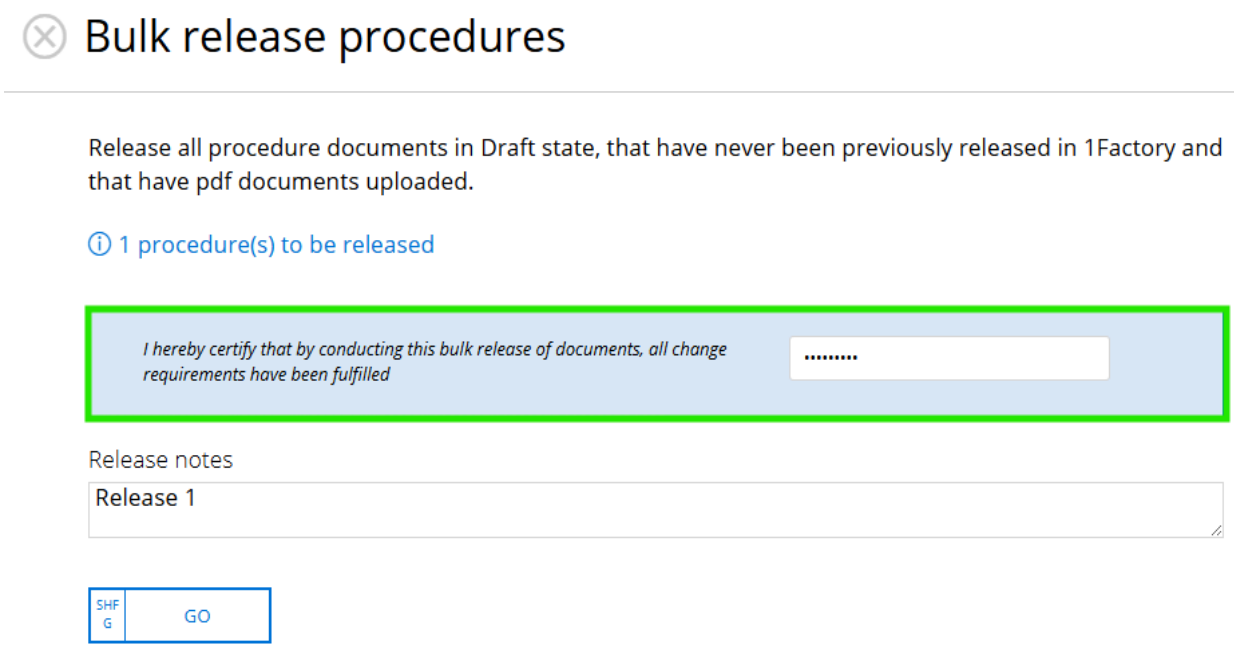
3. The slideout will display the count of documents eligible for release.



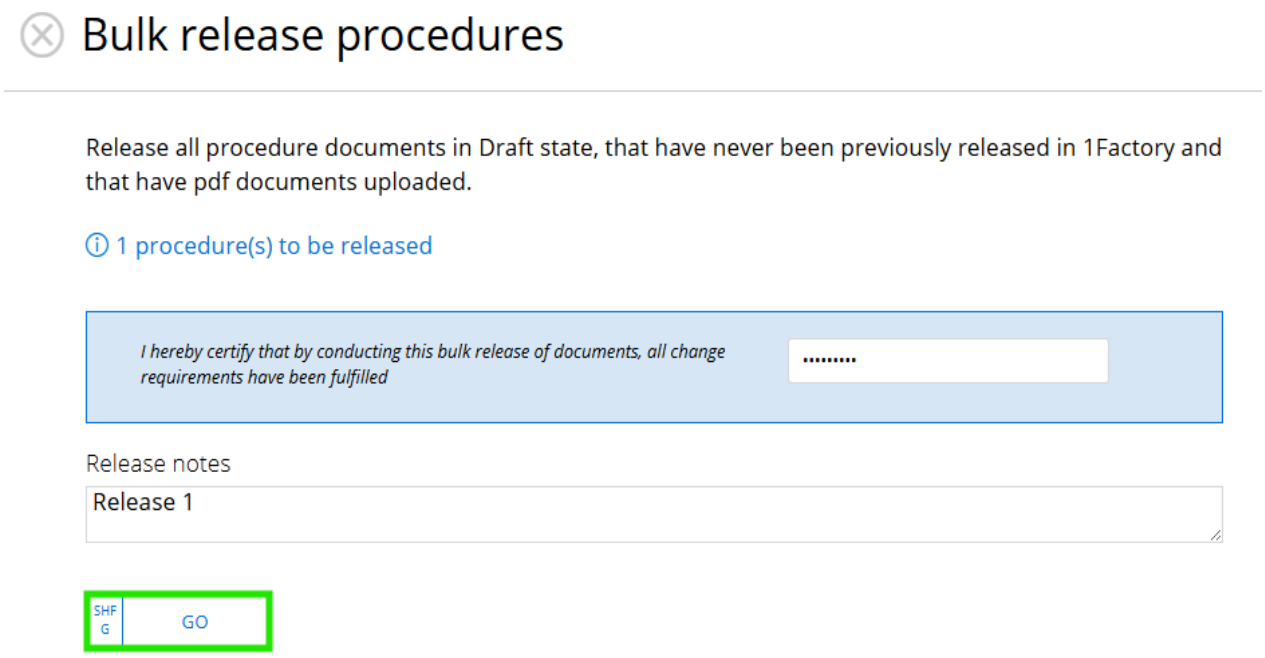
4. Enter release notes (required).



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.*



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



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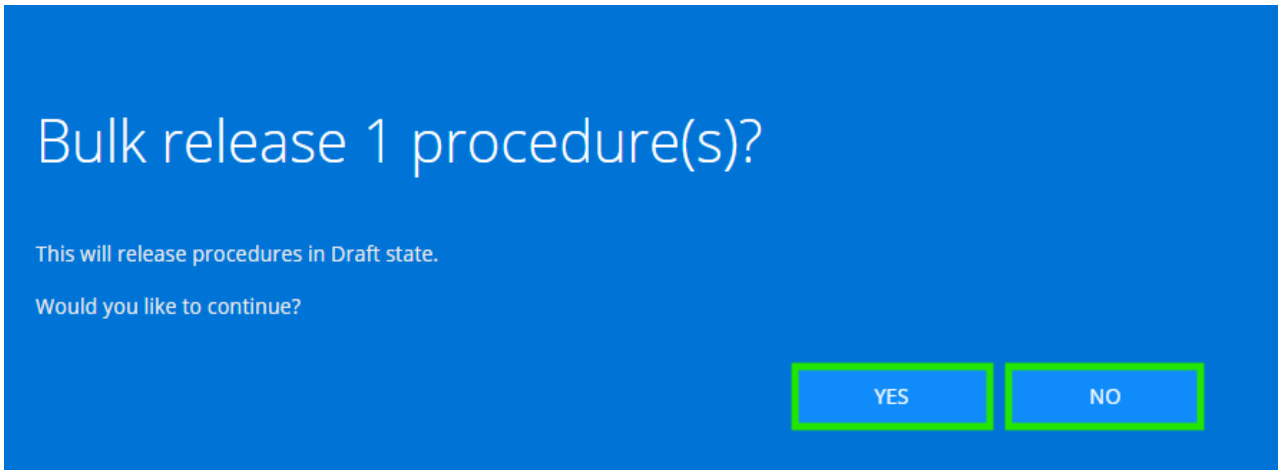

All documents uploaded by 1.3.2 Bulk File Import the status will be changed to Green

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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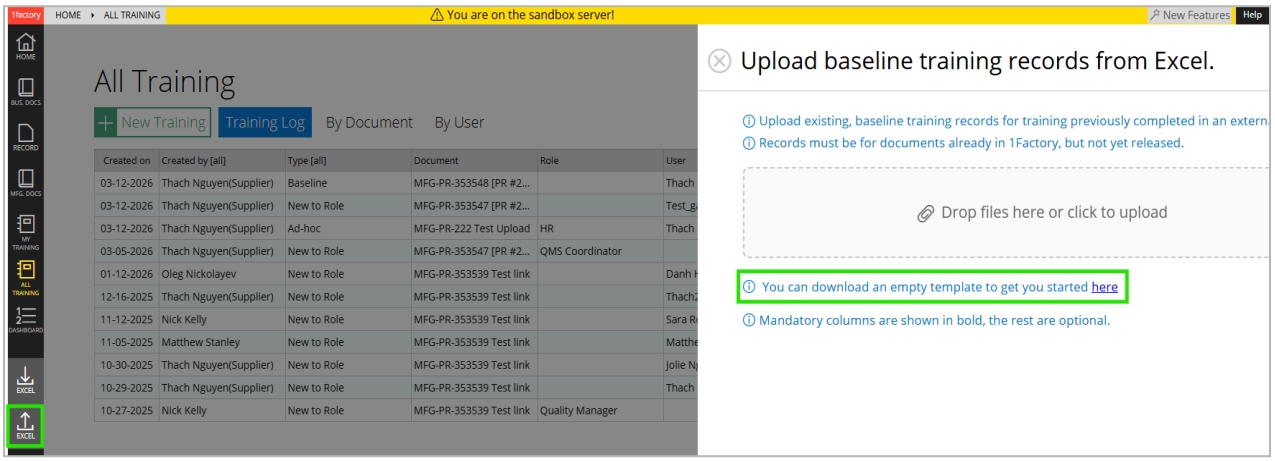

The system validates each row and returns errors for unrecognized users, unrecognized document numbers, released documents, or future-dated completion entries. If valid, baseline training records are created for each user, with retraining due dates calculated from the completed date and the document's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

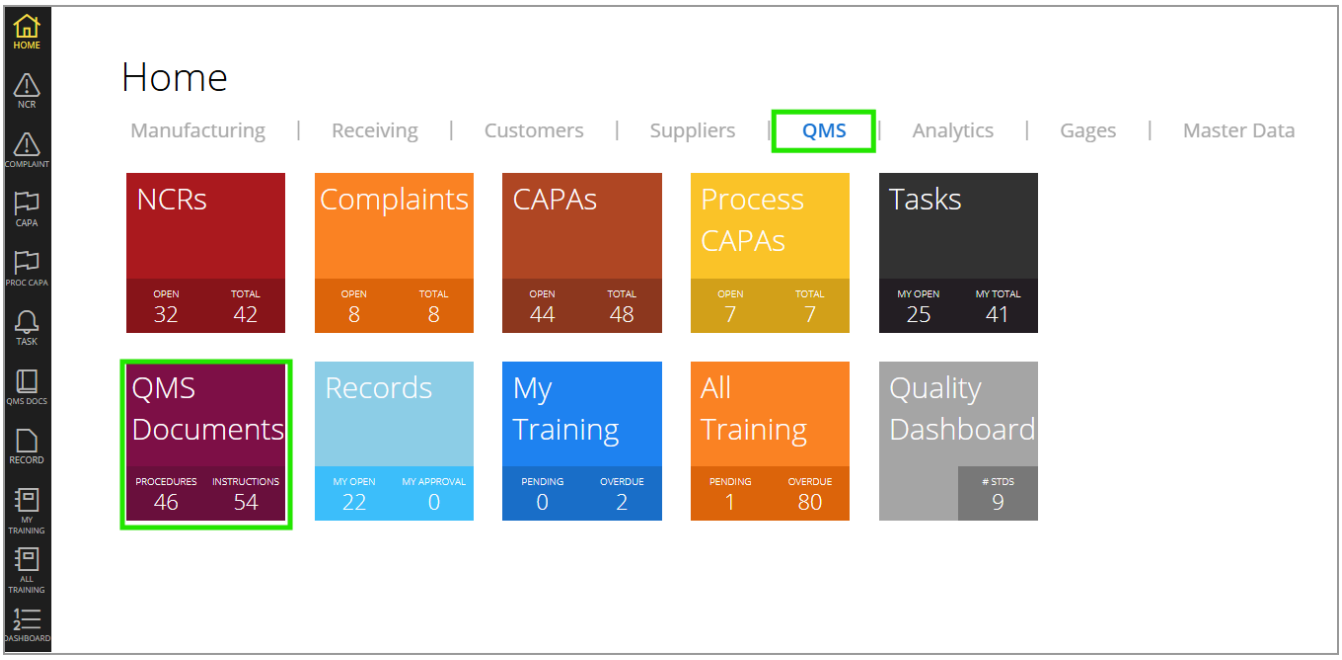
2.1.1 Creating Documents

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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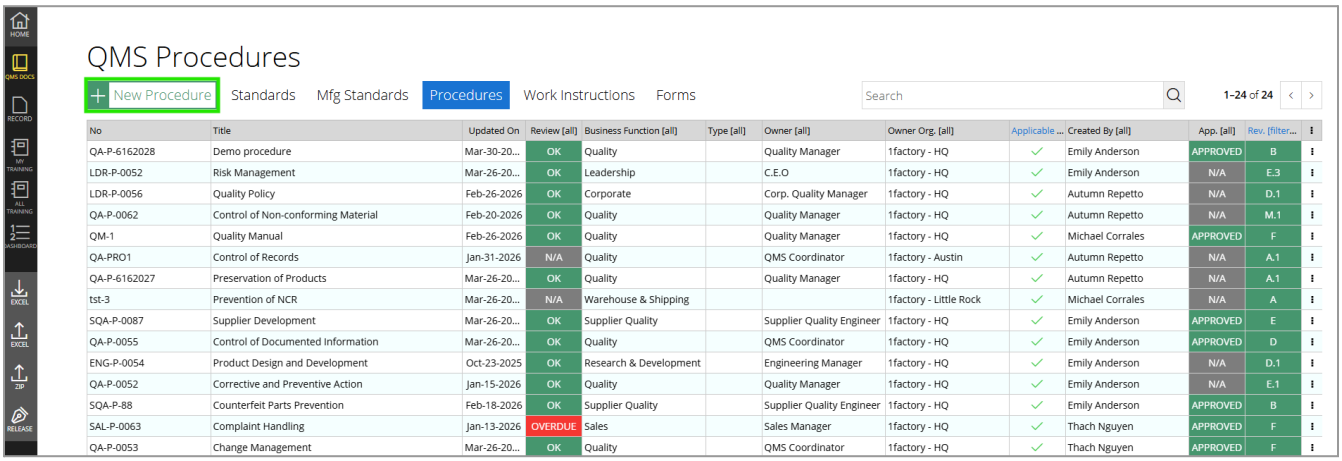

No	Title	Updated On	Review [all]	Business Function [all]	Type [all]	Owner [all]	Owner Org. [all]	Applicable ...	Created By [all]	App. [all]	Rev. [filter...
QA-P-6162028	Demo procedure	Mar-30-20...	OK	Quality		Quality Manager	1factory - HQ	✓	Emily Anderson	APPROVED	B
LDR-P-0052	Risk Management	Mar-26-20...	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
tst-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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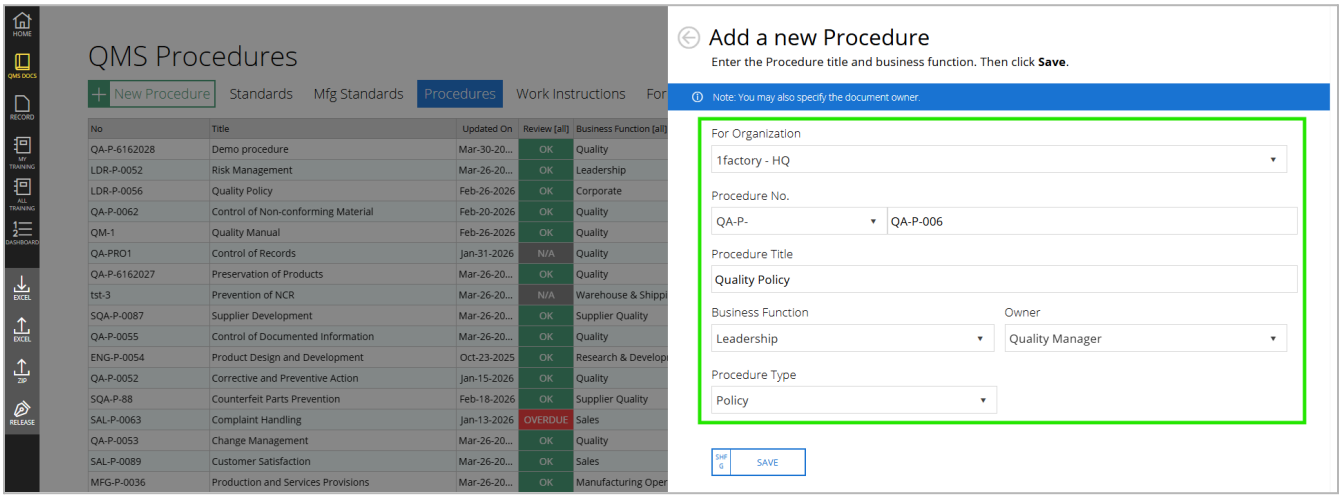

2.1.2 Editing Documents

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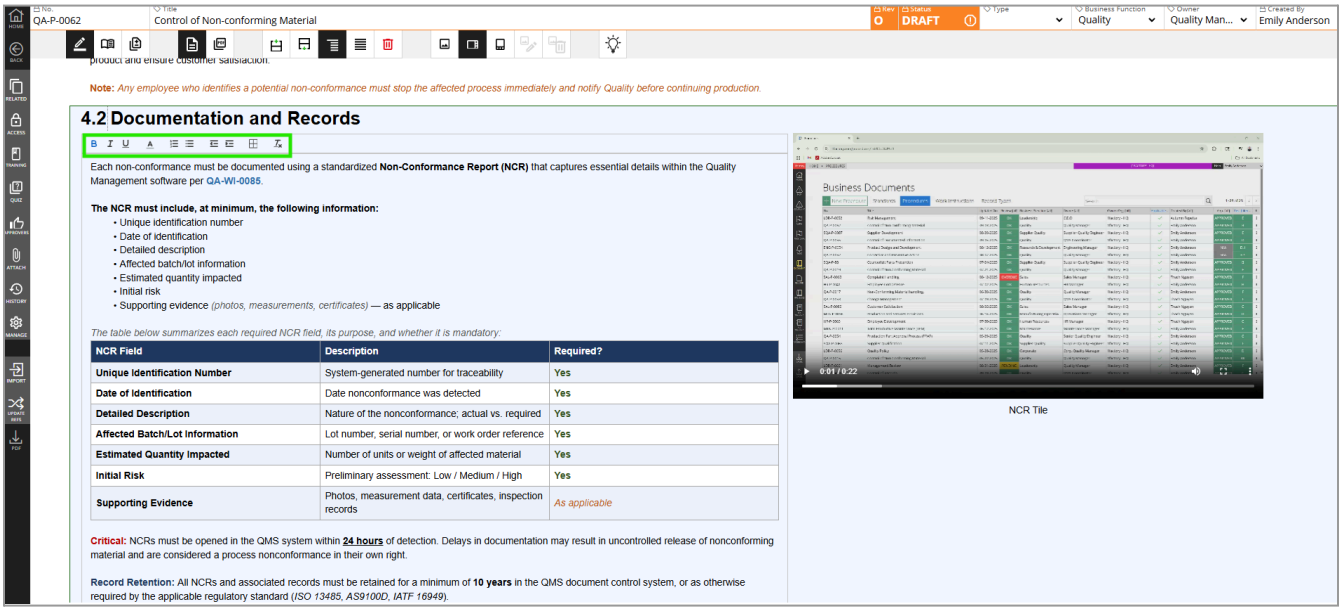
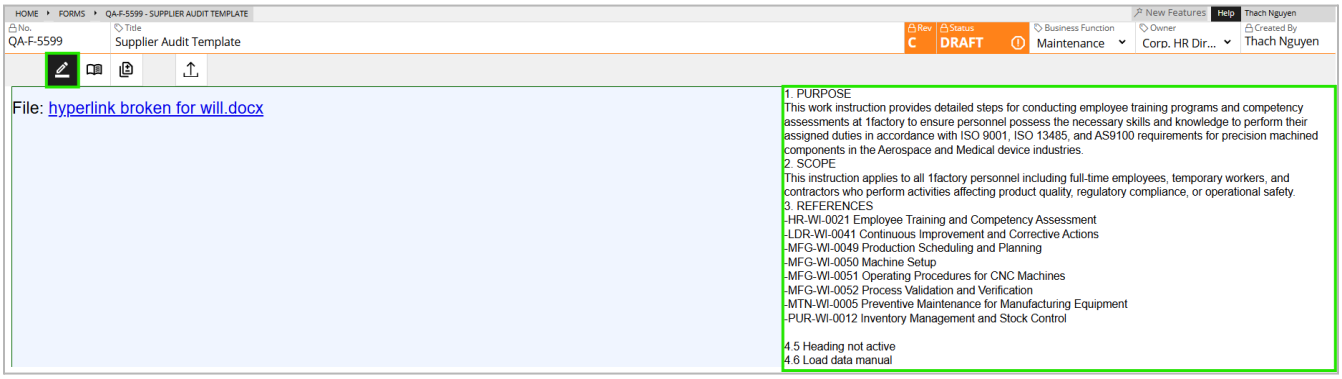
Begin drafting your document with headings and content. During your document drafting process, use 1factory's built-in editor to help you create documents quicker. This is particularly valuable when documenting complex requirements that require precise step-by-step instructions and clear formatting.



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.



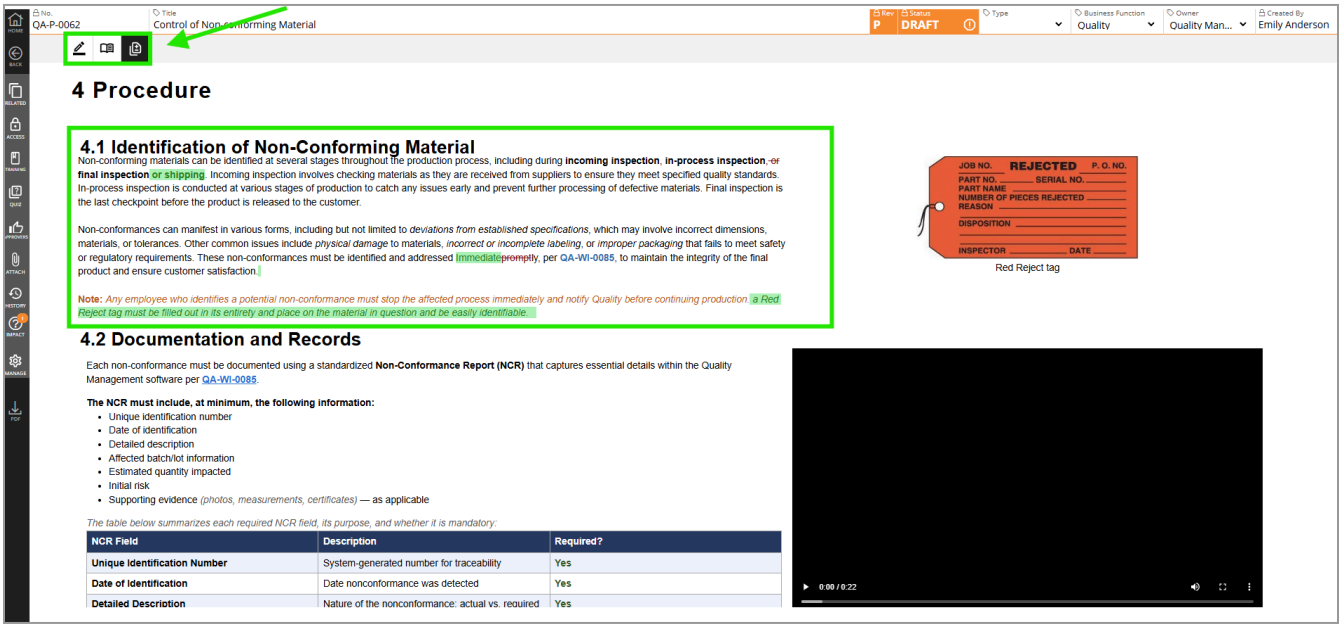
Step 2: Switch Between Editing Modes

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.

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.



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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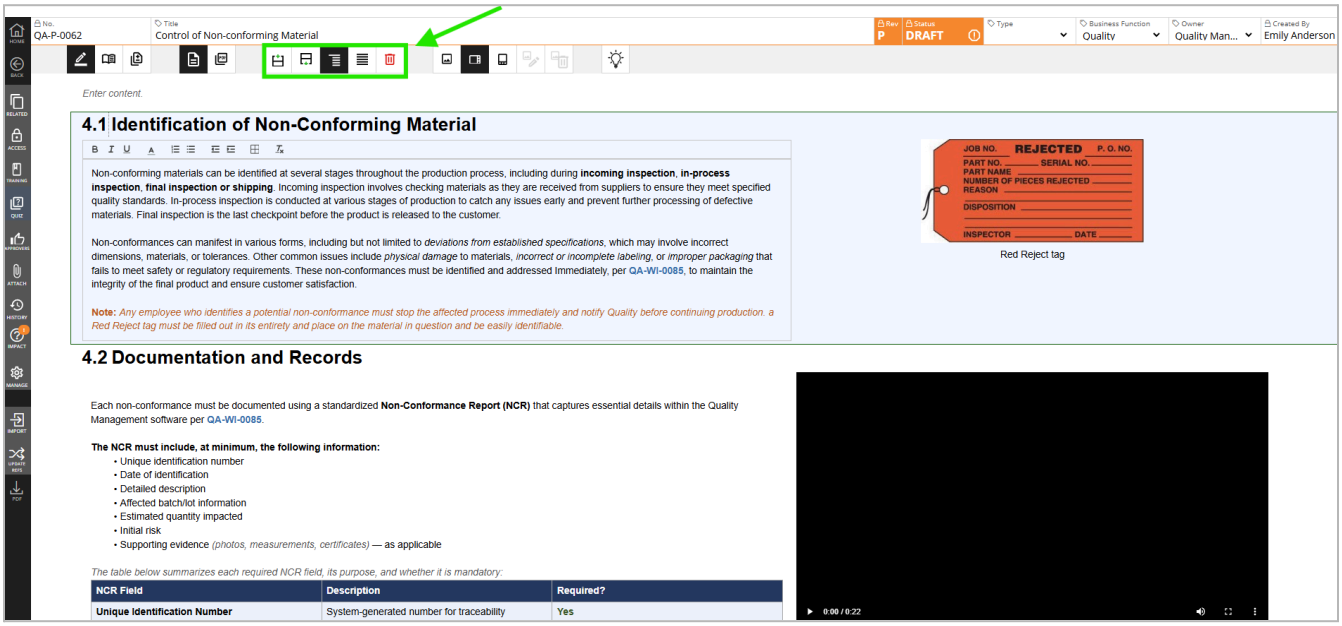

Step 4: Insert Images and Videos

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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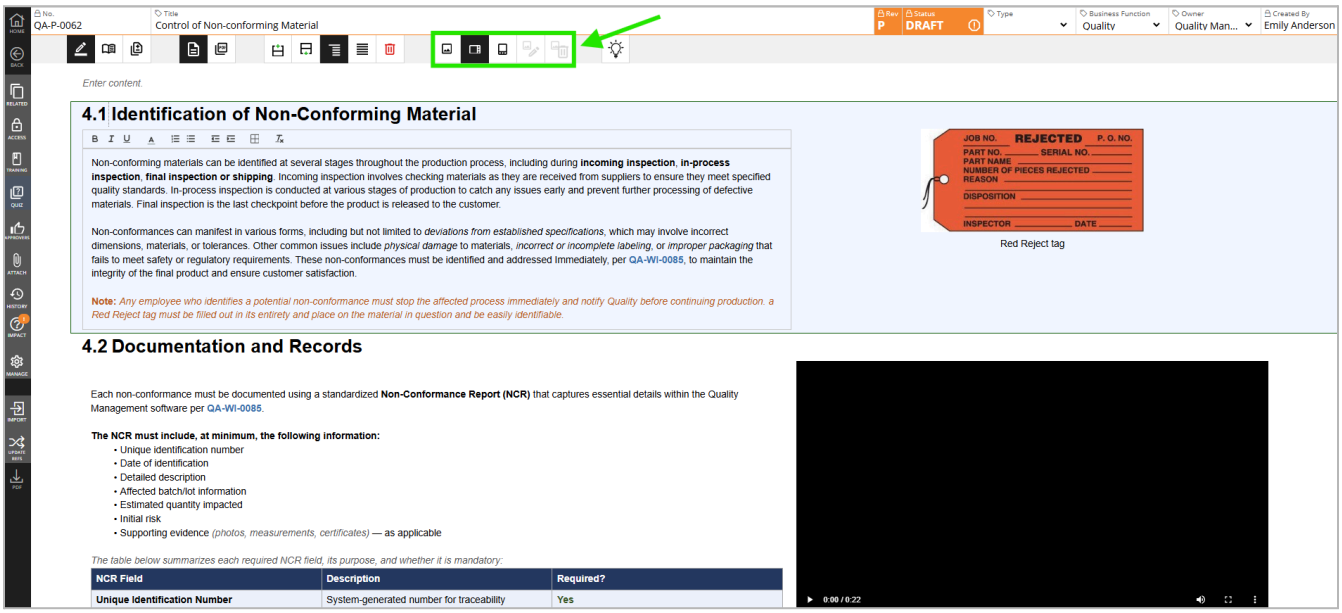
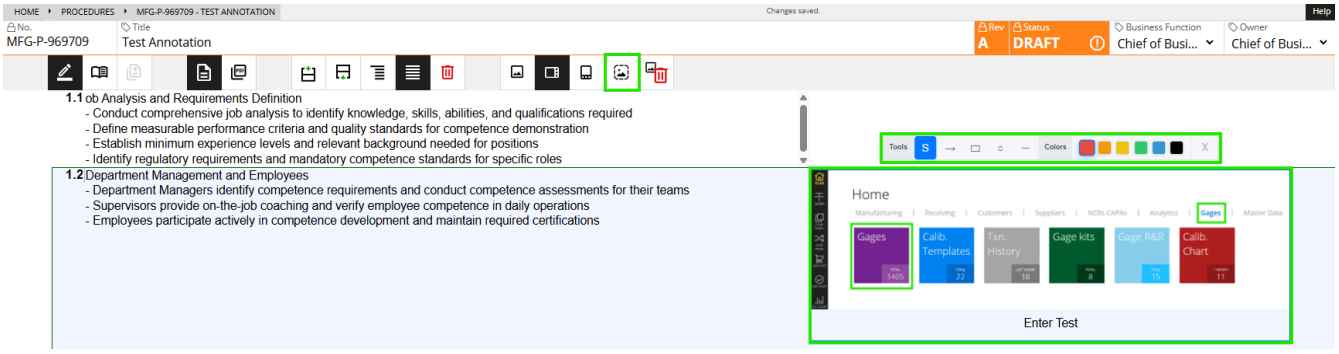


Image Annotation for Document Drafting

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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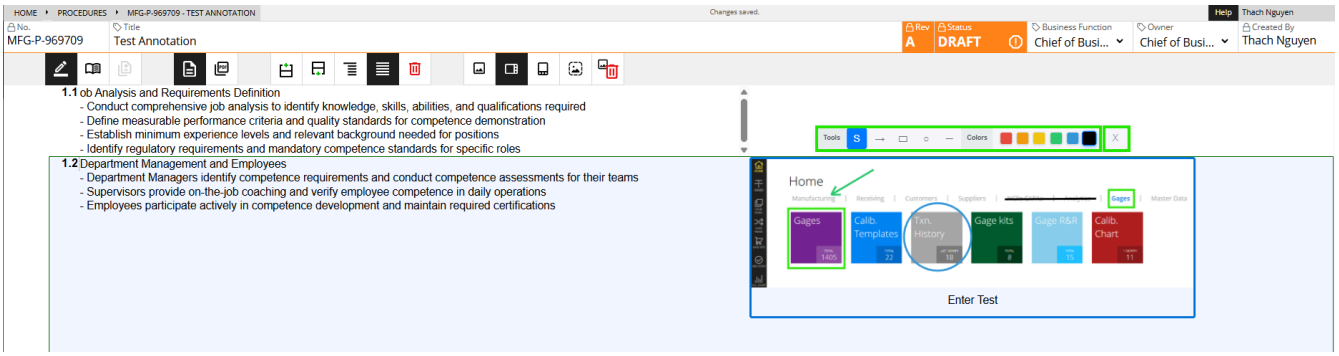
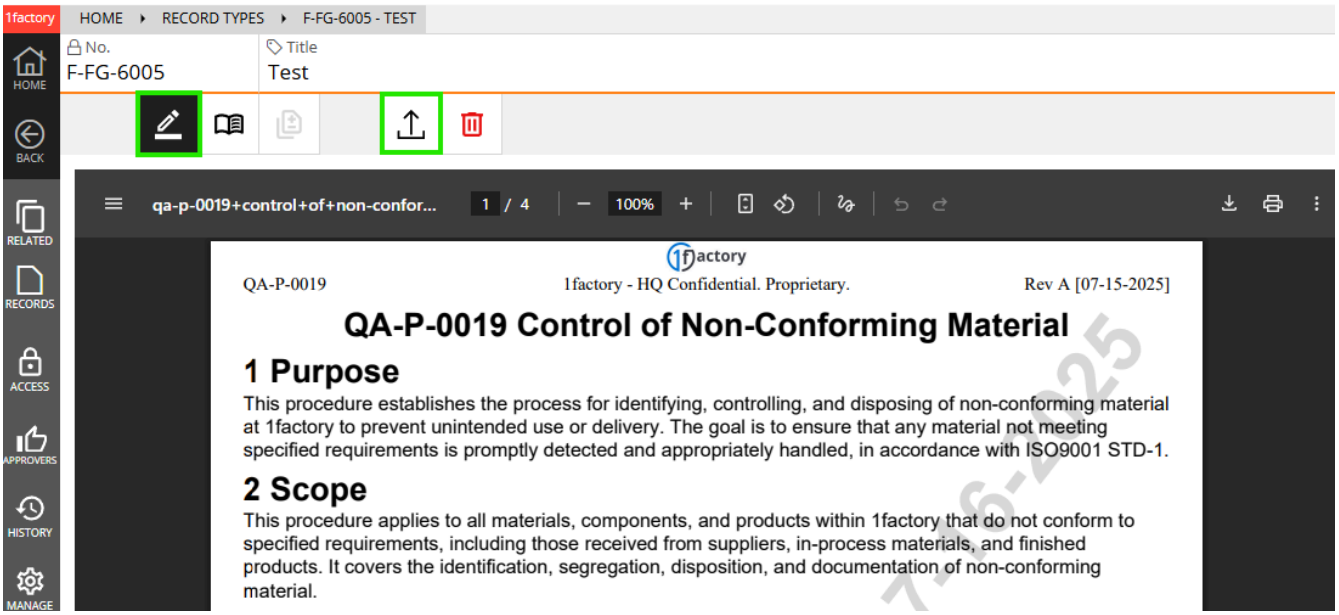


Forms: Unlike other document types, Forms do not support native rich-text content authoring. Instead, the controlled document is an uploaded file. In Editing Mode, click the Upload Form Document icon, click the paper clip icon to select your file, and click Go. Supported file types include PDF, Word (.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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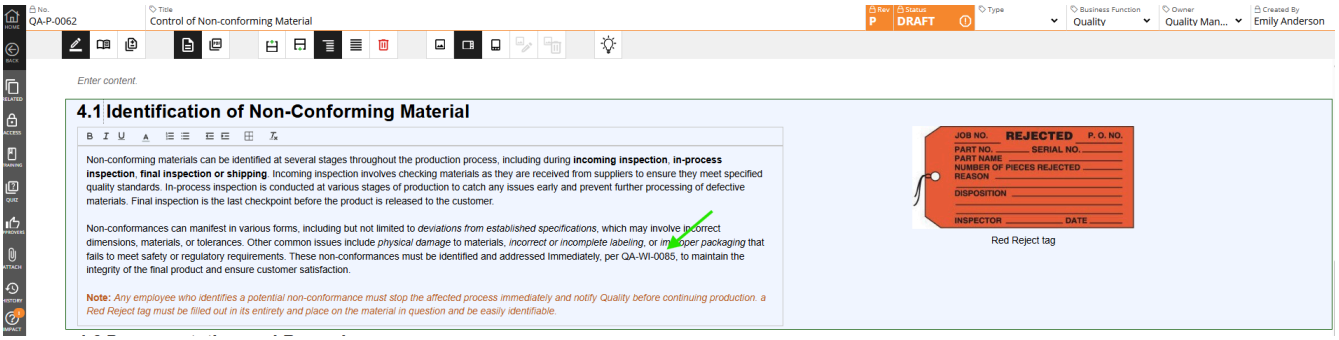
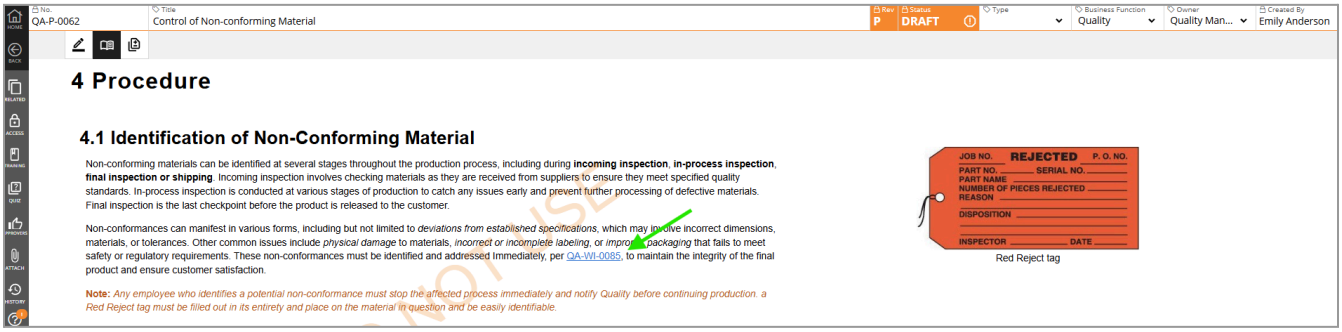


Step 2: Activate the hyperlink

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



***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.

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

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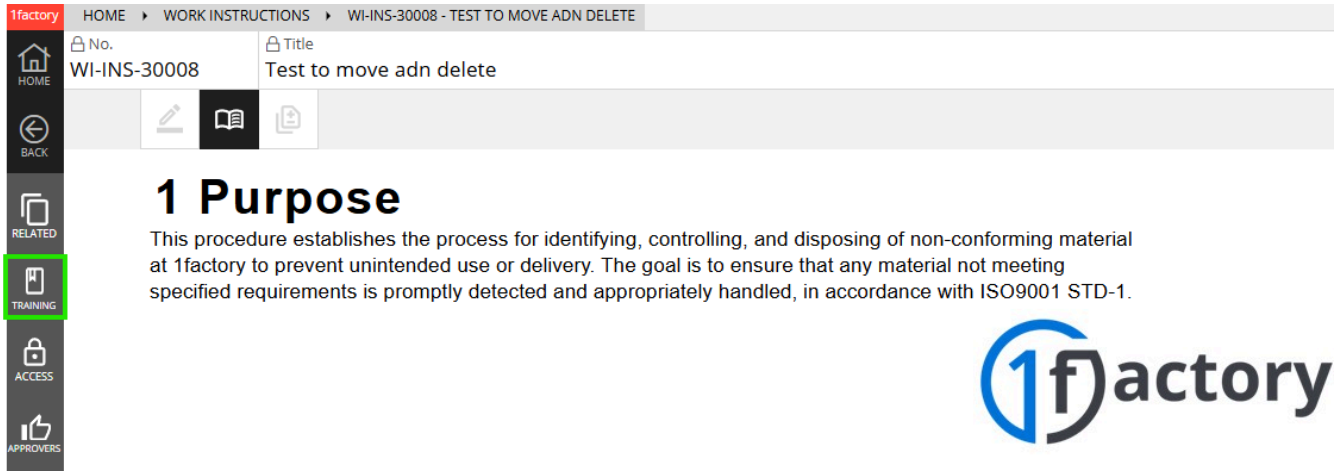
2.1.4 Assigning Training

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.

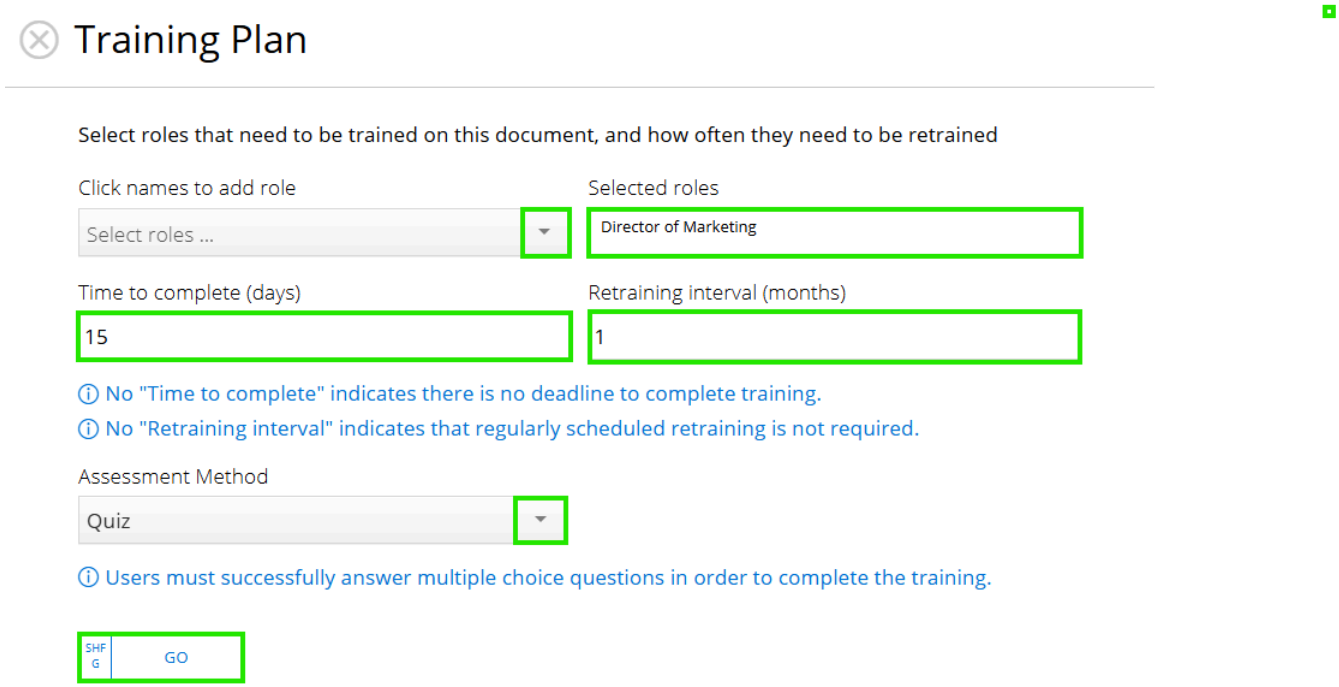
Step 1: Assign the training

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



Step 2: Configure training parameters

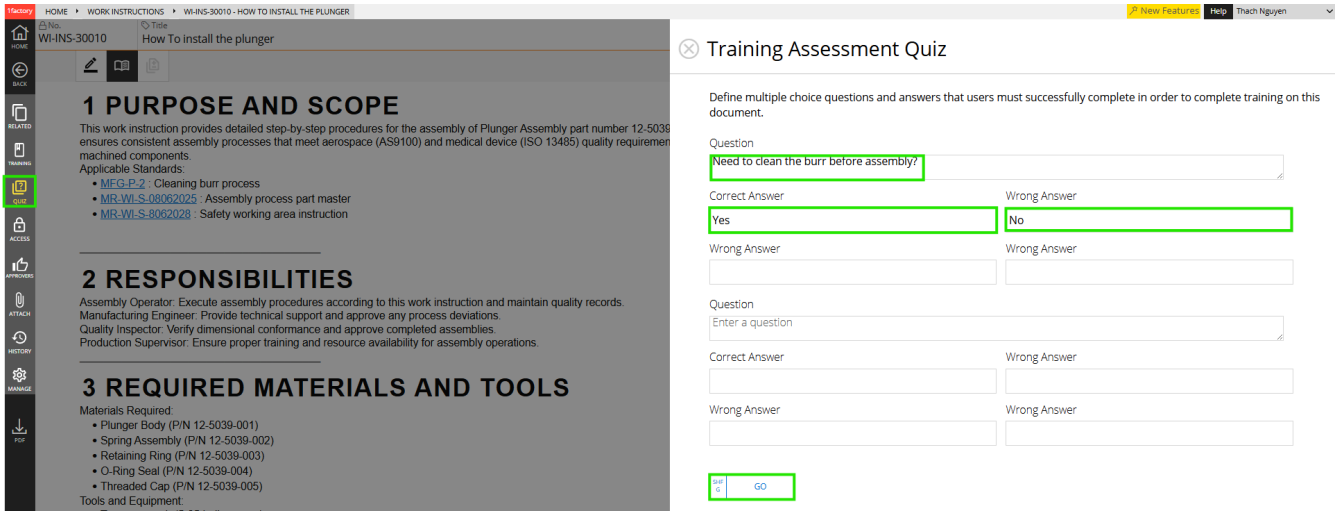
- **Select Roles**: Choose which QMS roles require training
- **Time to Complete**: Set deadline for training completion after document release
- **Retraining Interval**: Define automatic retraining schedules if document isn't revised within time frame
- **Assessment Method**: Select Self Assessment,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



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



2.1.5 Assigning Document Approvers

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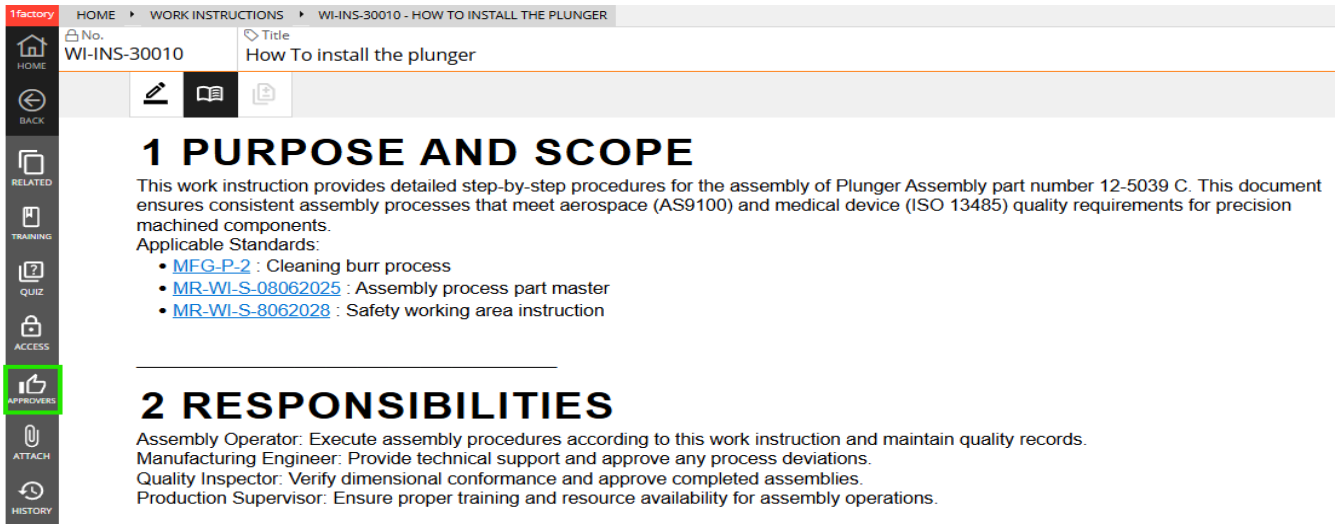
Define the approval workflow before documents become active in the QMS, ensuring proper review and authorization.

Step 1: Assign Approvers

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



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

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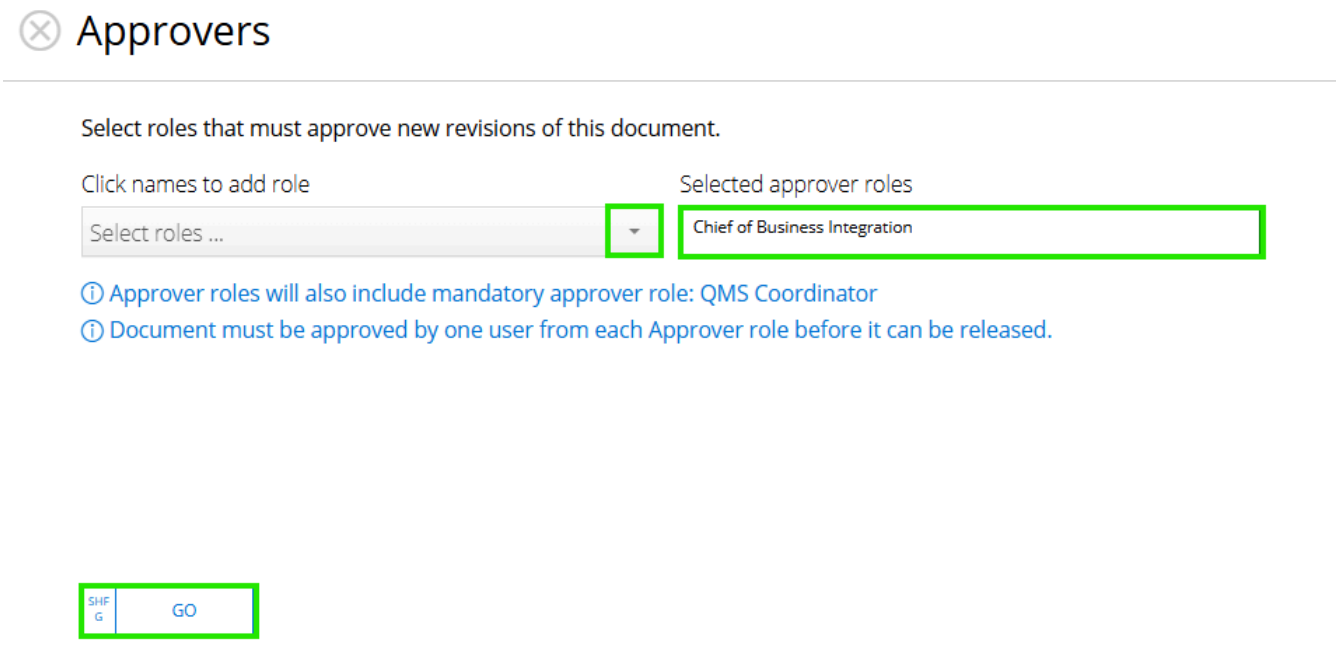


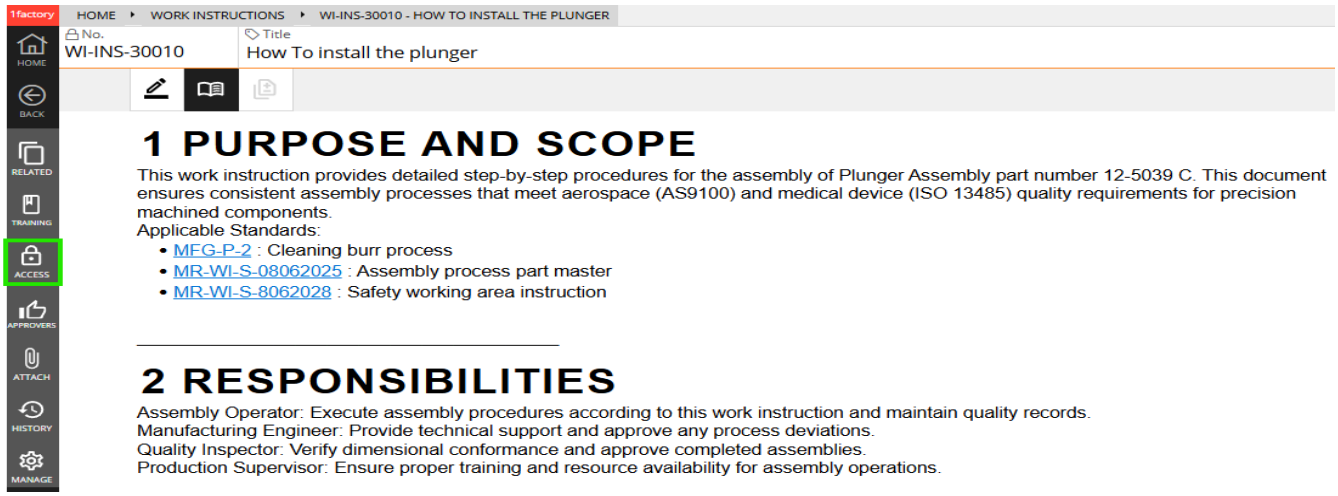
***Note**: If your document requires more than two roles with multiple approvers, select a different approver name for each role.*

2.1.6 Document Access Control

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

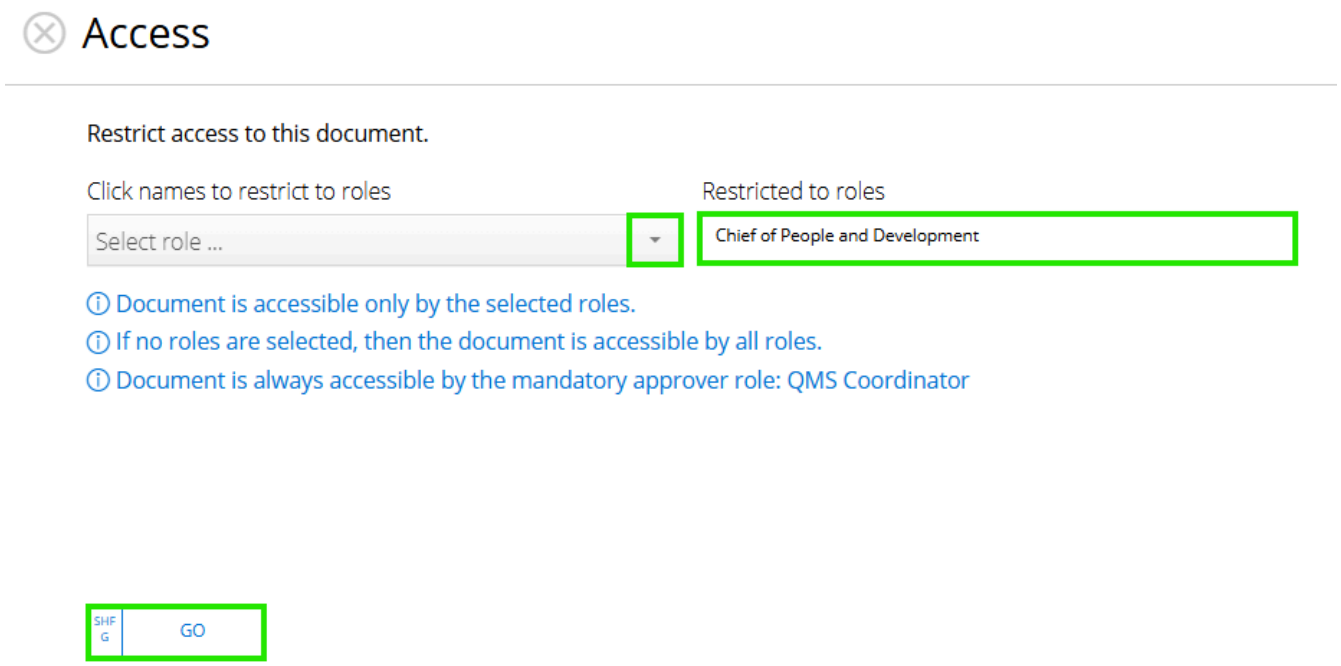
Step 1: Initialize Access Controls

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



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



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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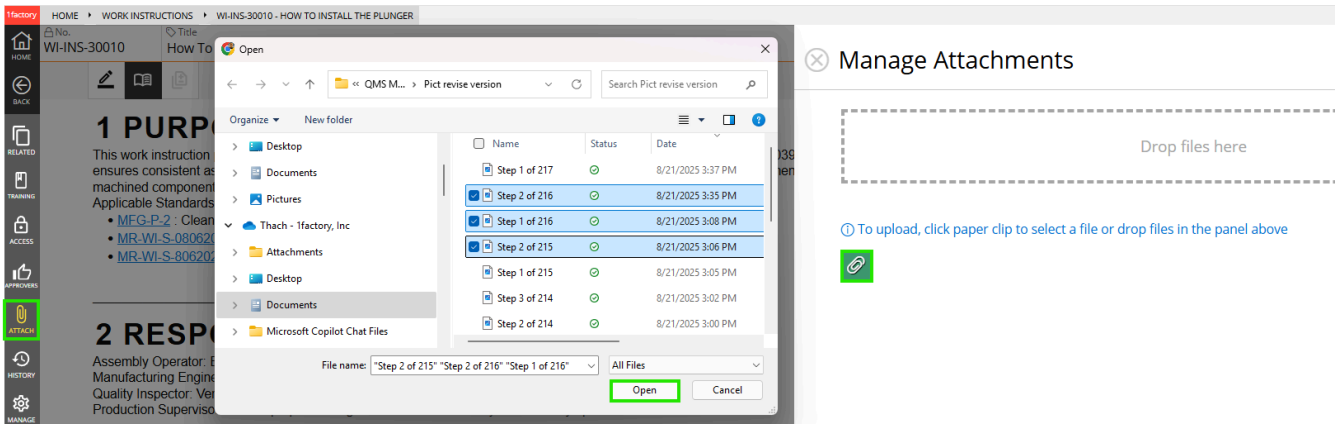
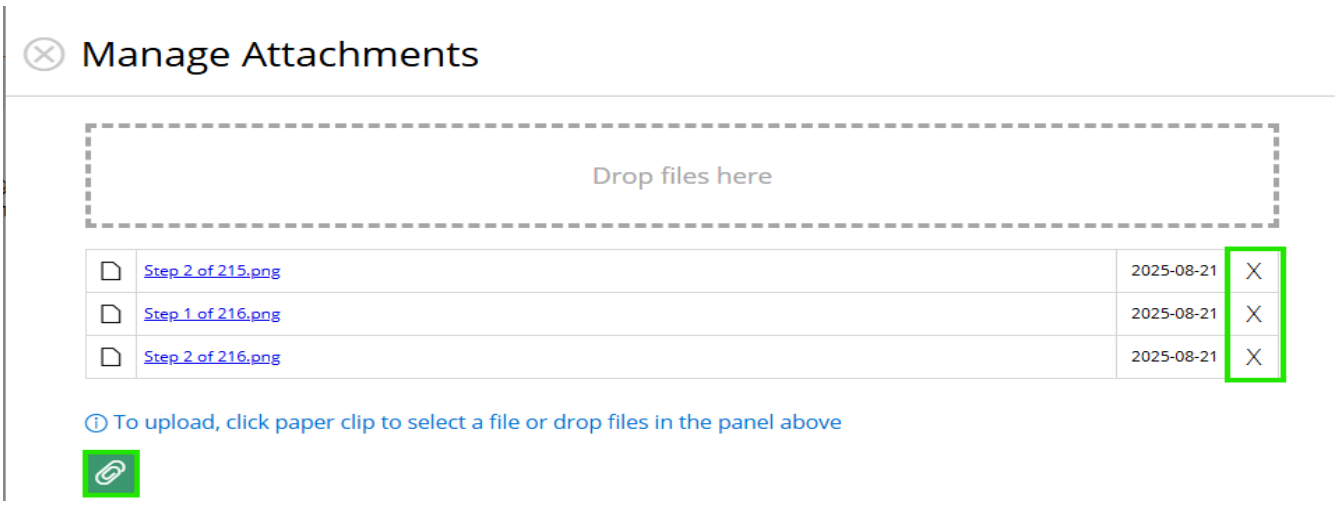


Step 2: Select and manage files

- 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

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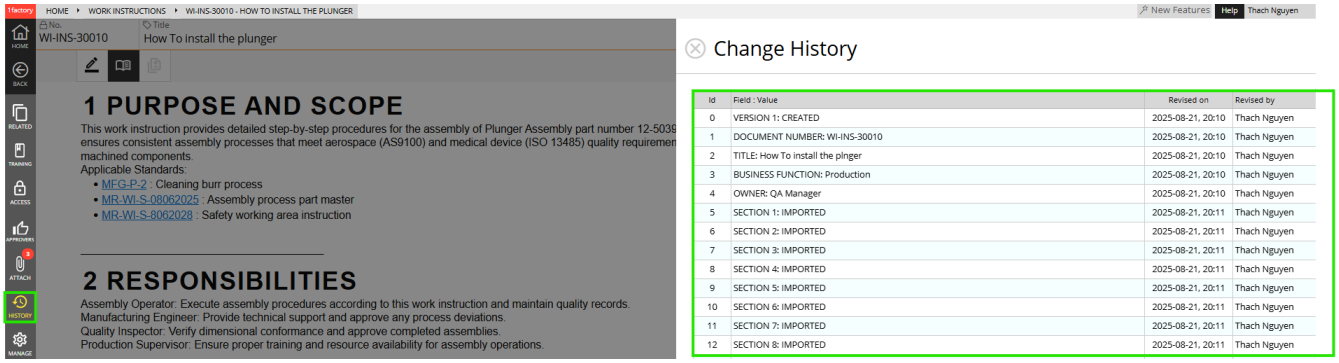
Provides a complete audit trail of all changes and activities, maintaining compliance with regulatory requirements.



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.

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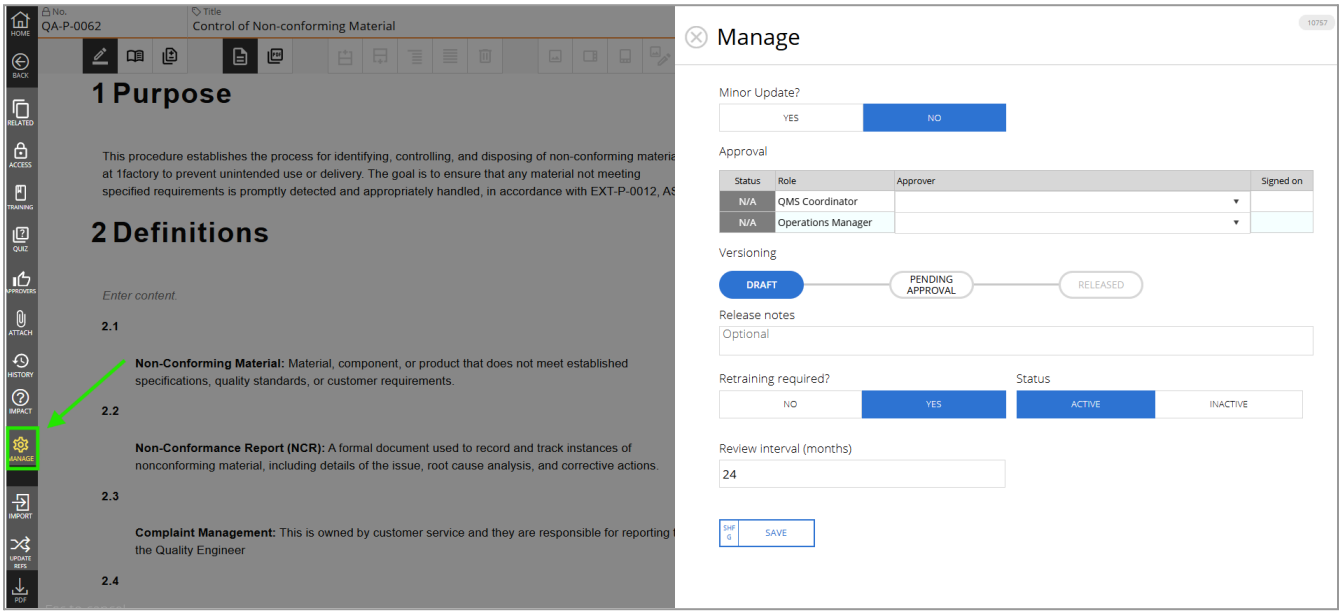
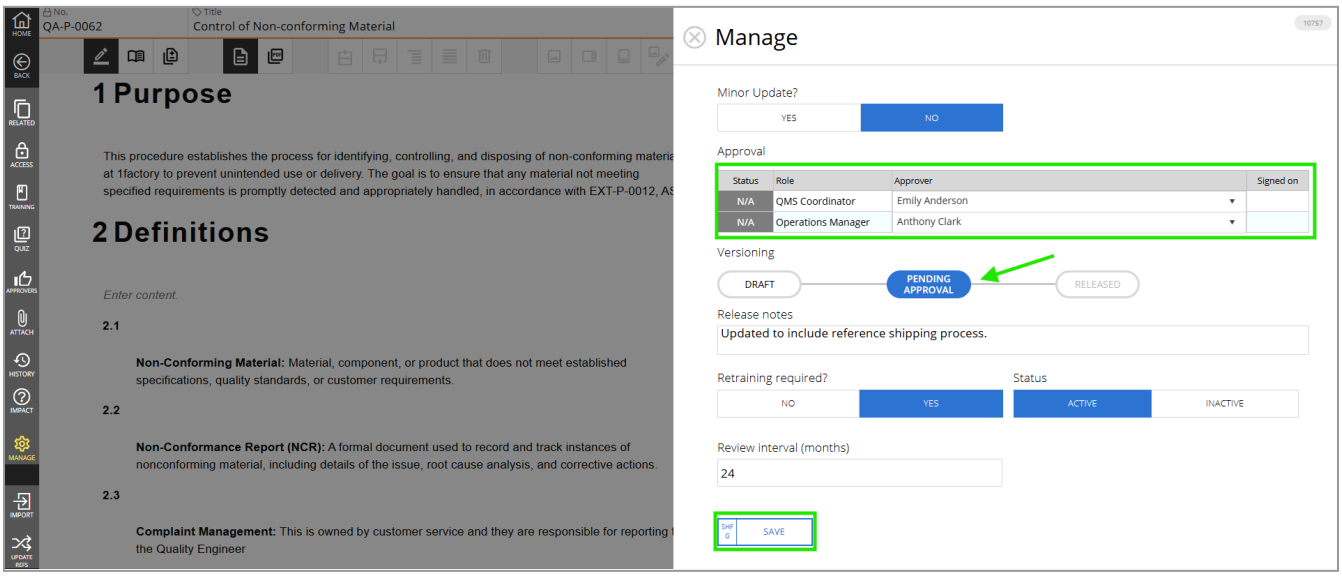


Step 2: Route for Approval

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.



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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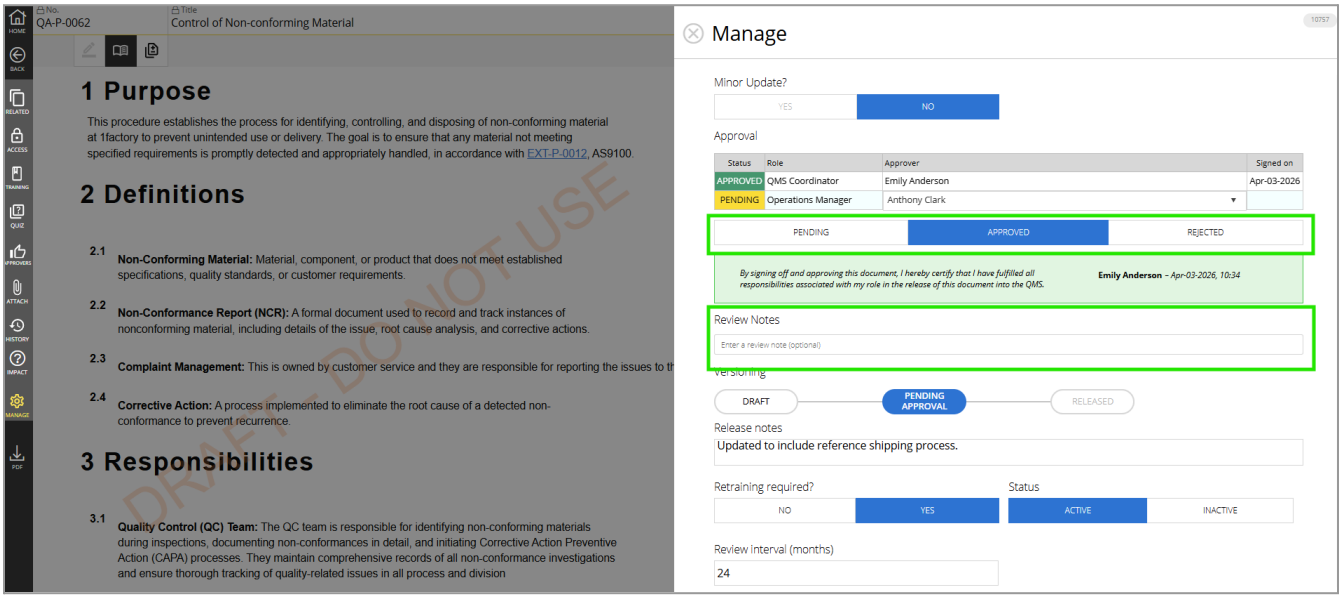

If the document is **rejected**, the document author receives an email notification. The author can then either return the document to **Draft** status to make the requested changes and re-route for approval, or discuss the reason for rejection directly with the approver before taking further action. 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**.

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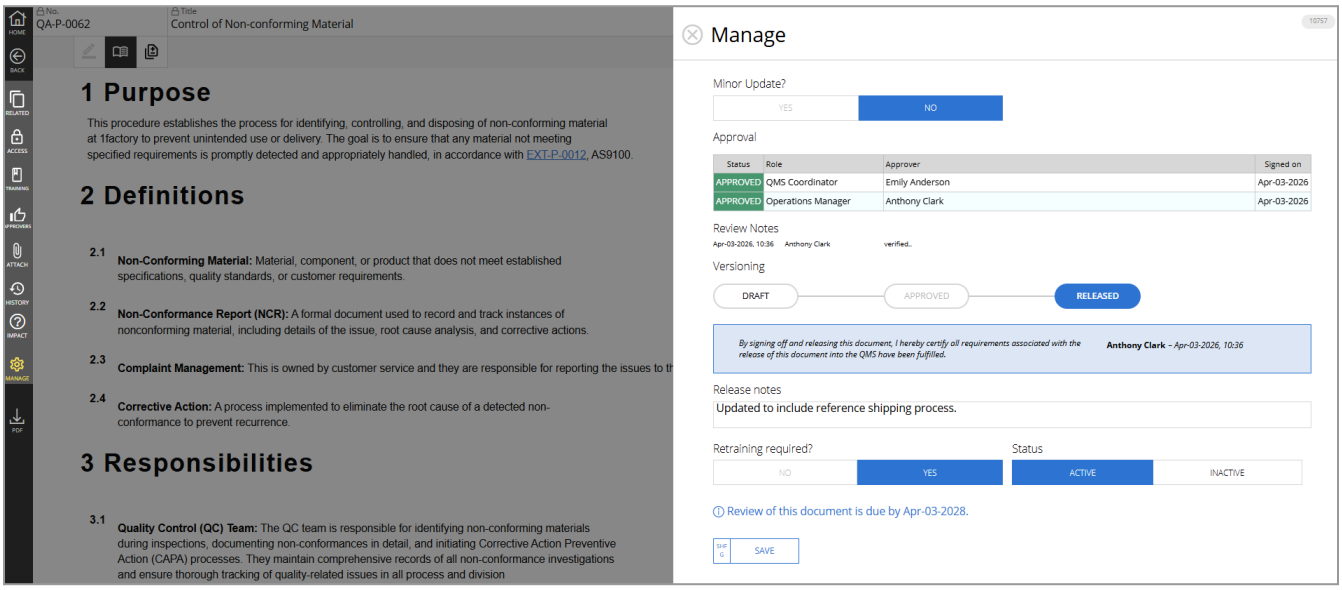

Minor Update Process

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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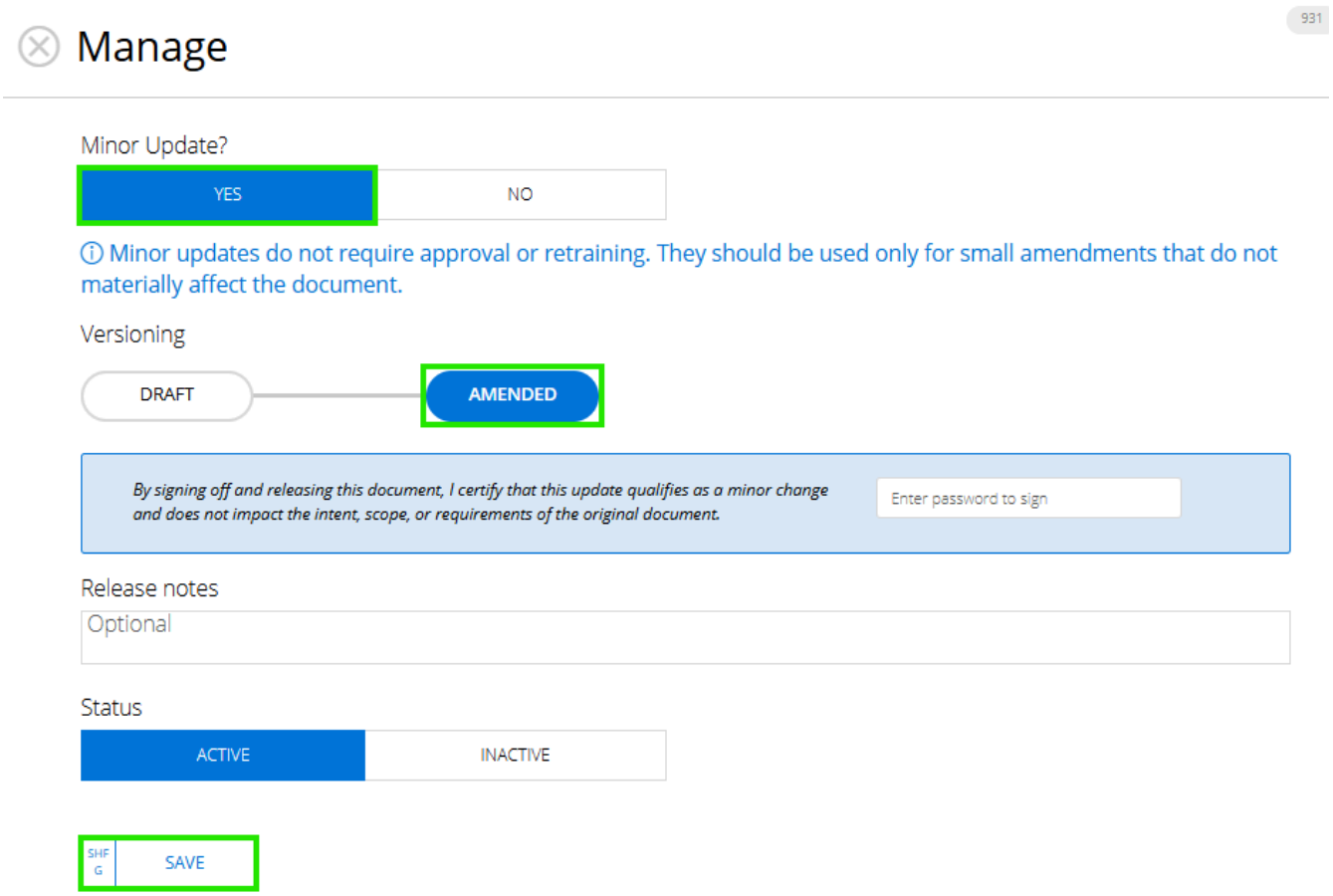

Note: *Minor updates use a decimal revision format (for example, A becomes A.1). Minor updates can be completed by any user holding the* ***Mandatory Approver Role****.*

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.

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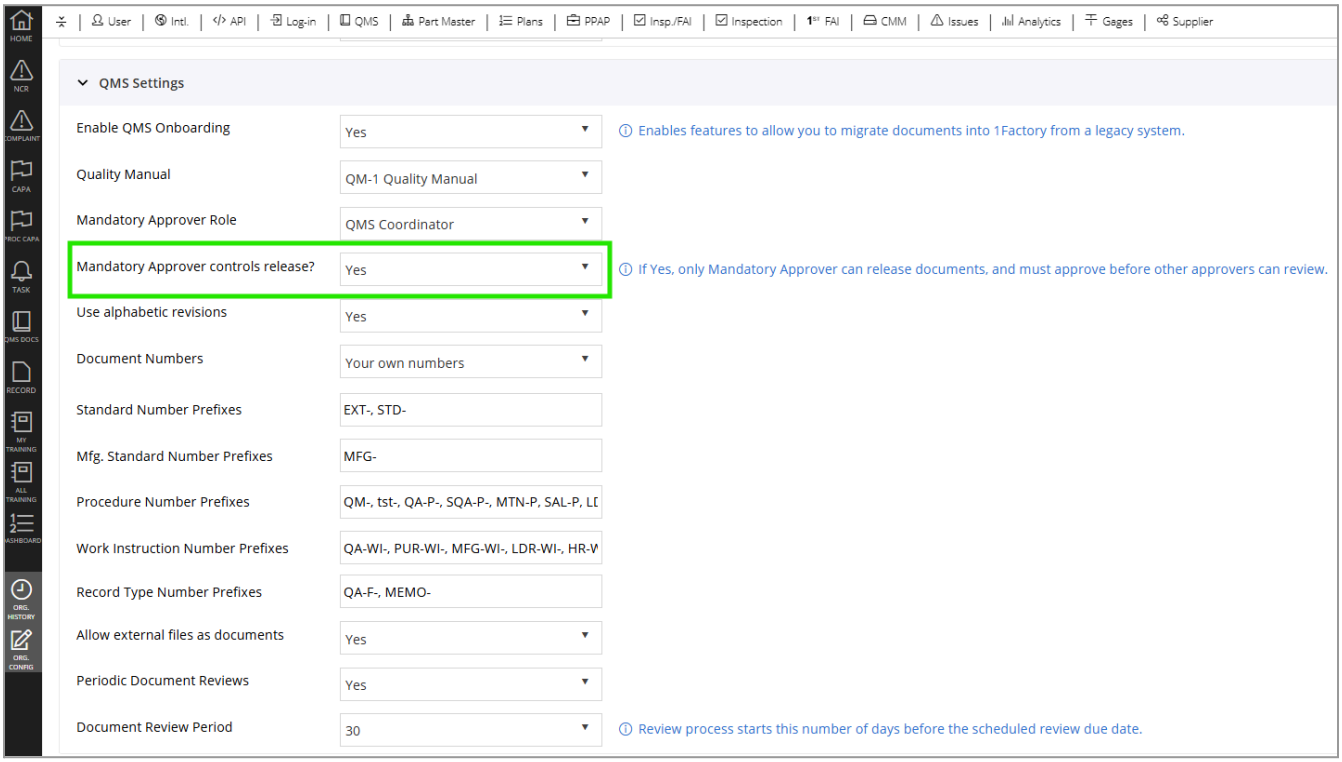
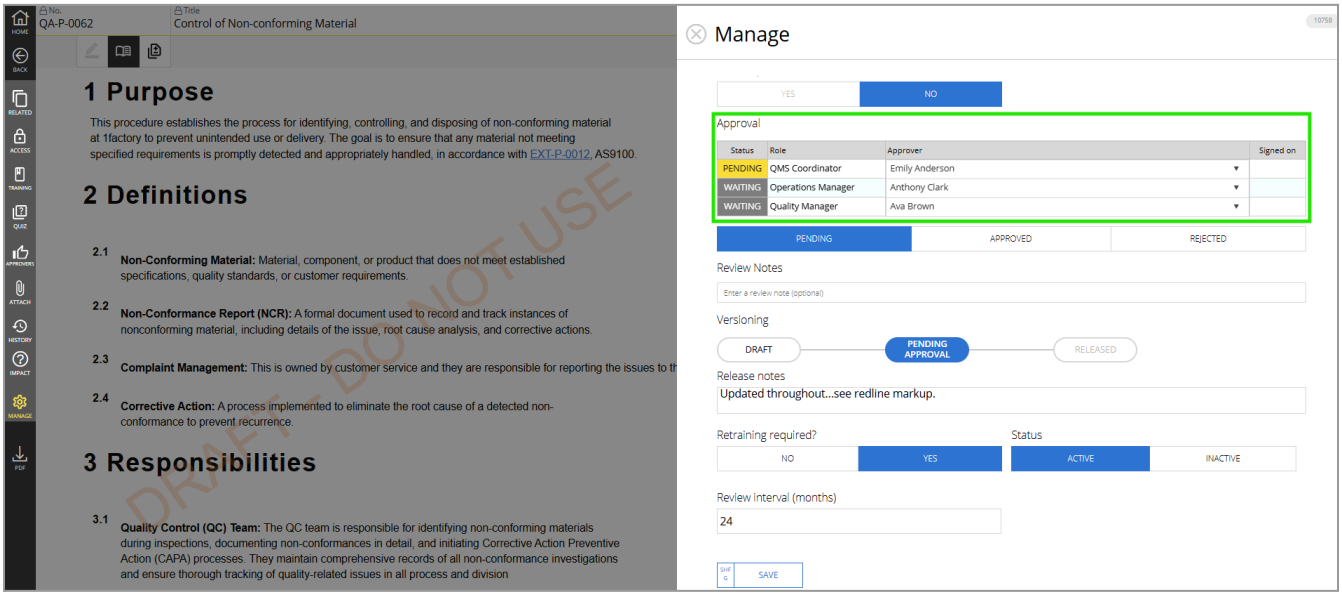


When a document is moved to **Pending Approval**, the Mandatory Approver is set to **Pending** while all other approvers are set to a **Waiting** status. Waiting approvers receive no notification and cannot submit an approval decision until the Mandatory Approver has approved the document.



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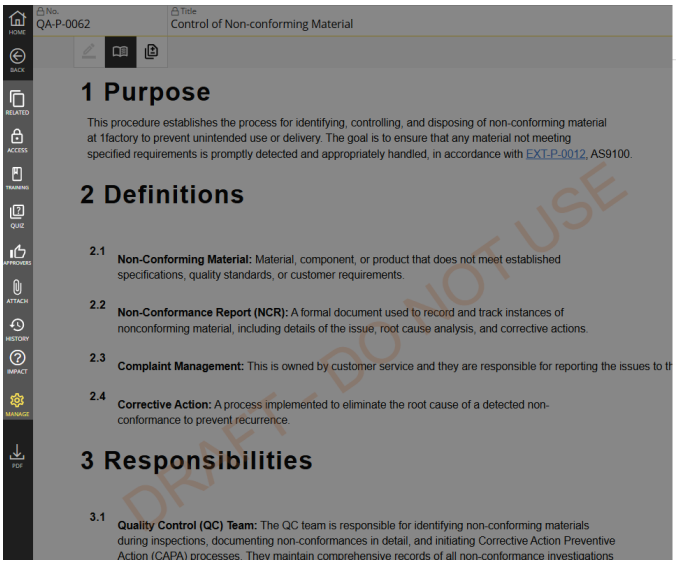
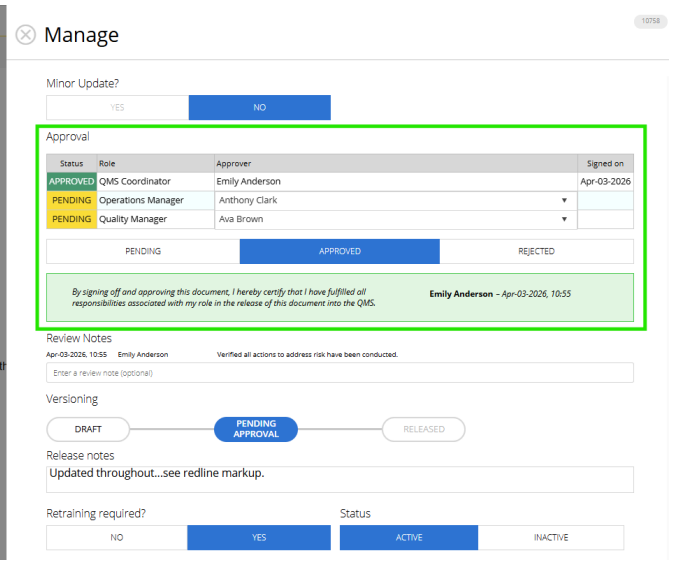
Once the Mandatory Approver approves, all remaining approvers are advanced to **Pending** and receive their email notifications. If the Mandatory Approver rejects the document, all other approvers remain in **Waiting** status and the document must be returned to **Draft** before it can be re-routed.





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.

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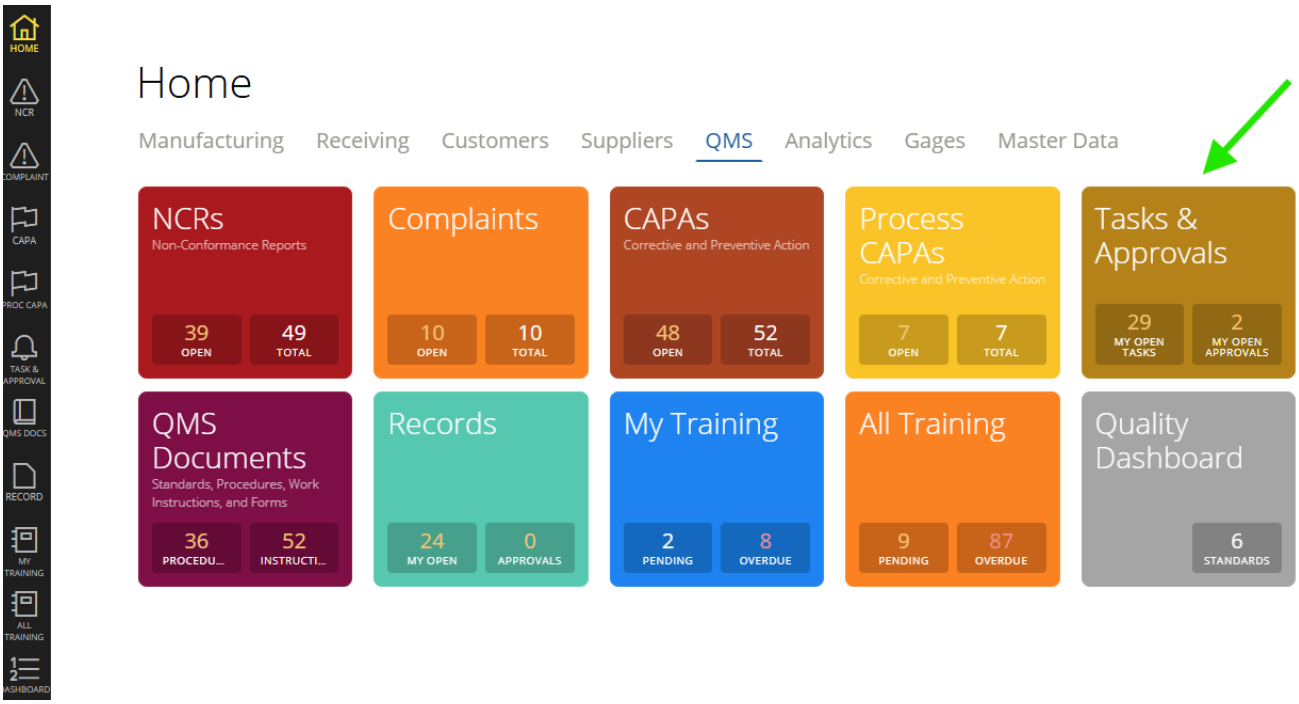

The page has two tabs: **Tasks** and **Approvals**. A dropdown controls the scope of whichever tab is active:

- **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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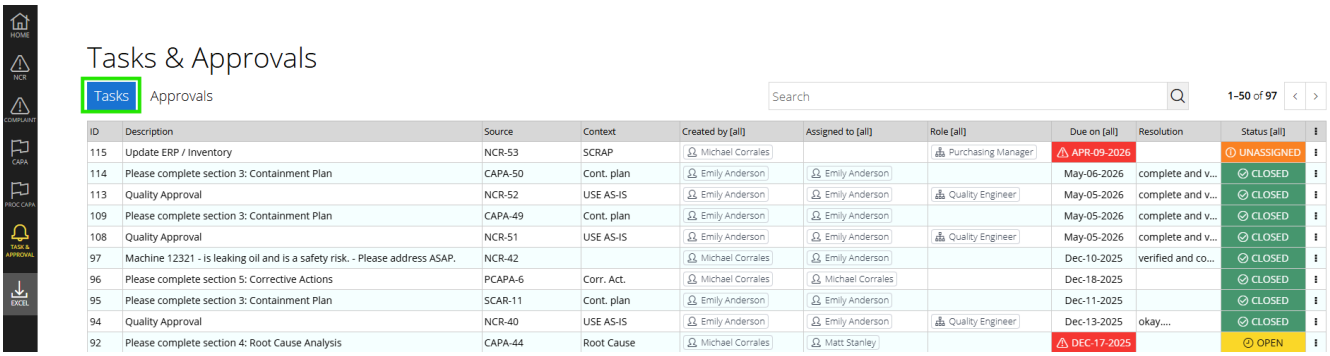

ID	Description	Source	Context	Created by [all]	Assigned to [all]	Role [all]	Due on [all]	Resolution	Status [all]
115	Update ERP / Inventory	NCR-53	SCRAP	Michael Corrales		Purchasing Manager	APR-09-2026		UNASSIGNED
114	Please complete section 3: Containment Plan	CAPA-50	Cont. plan	Emily Anderson	Emily 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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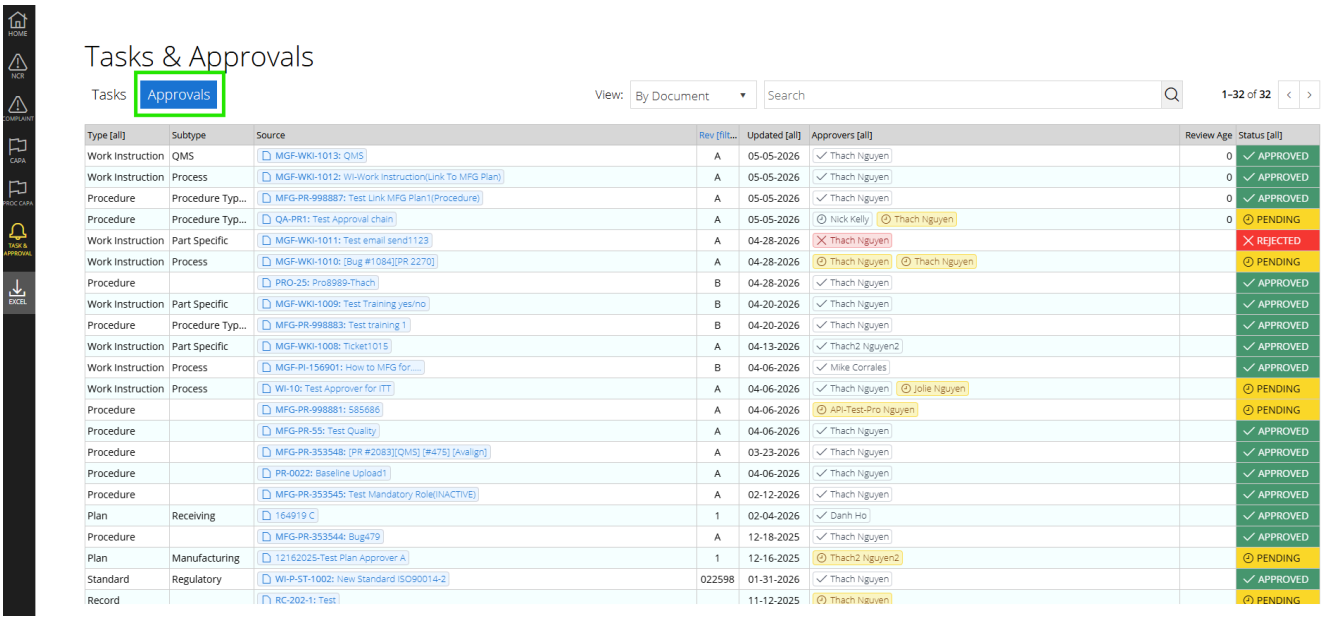
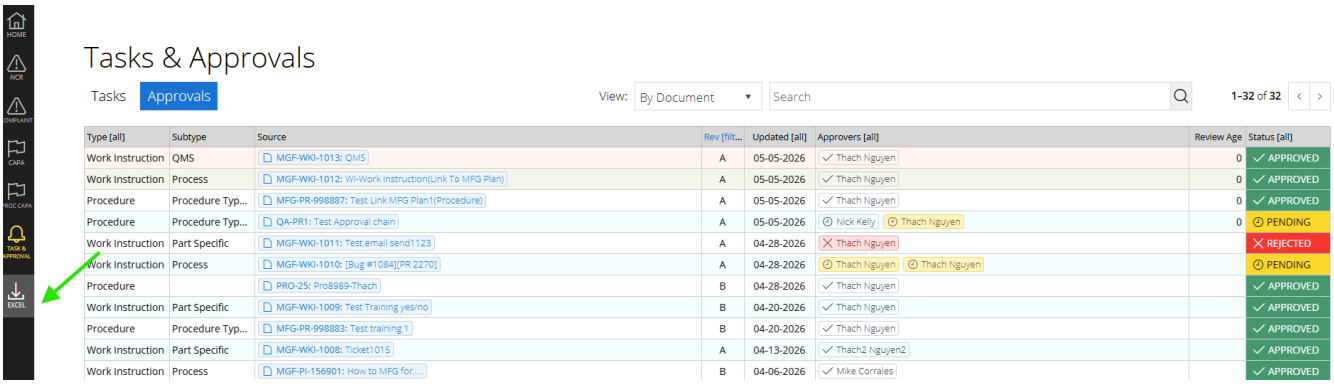


Federated QMS Visibility

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.



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.

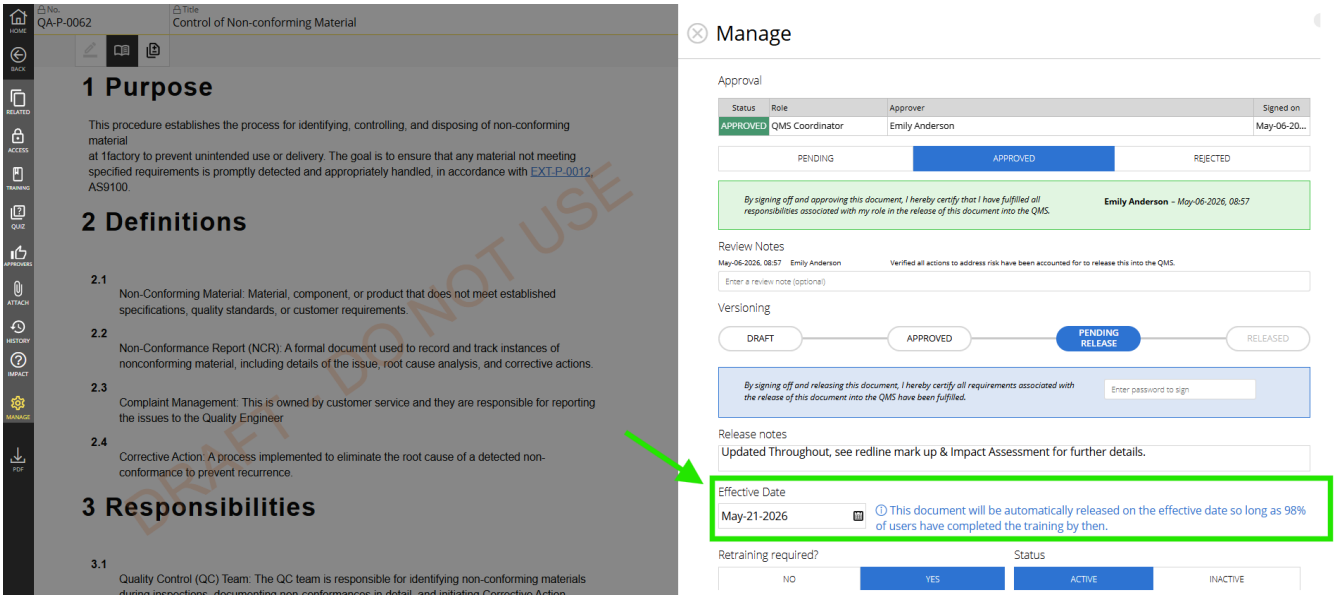
In most manufacturing environments, releasing a revised procedure and training personnel on it happen simultaneously. For organizations operating under FDA 21 CFR Part 820 or ISO 13485, that is not enough. Auditors require documented evidence that personnel completed training *before* a procedure became 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.



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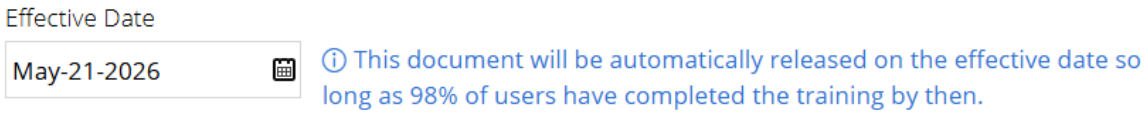
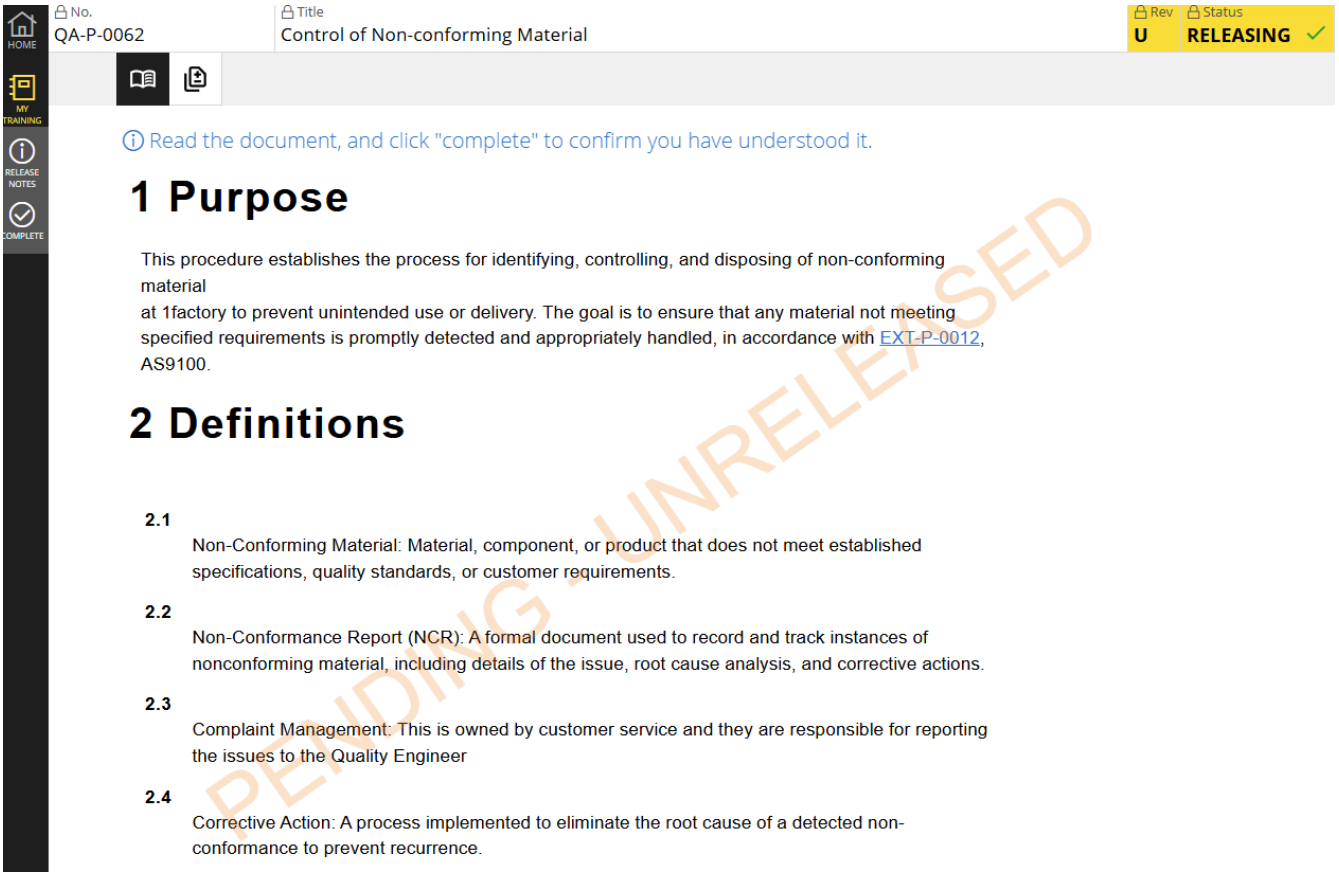
If eSignatures are enabled for your organization, you will be required to complete the release eSignature before saving. If **Mandatory Approver Controls Release** is enabled, only users assigned to the **Mandatory Approver Role** can move a document to Pending Release.

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.



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.



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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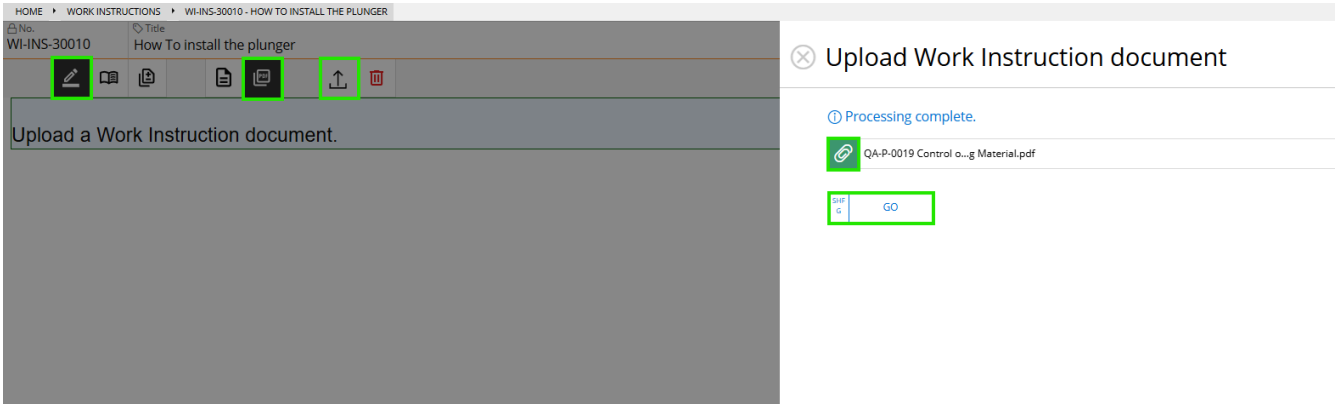
2.1.12 External/Legacy Files

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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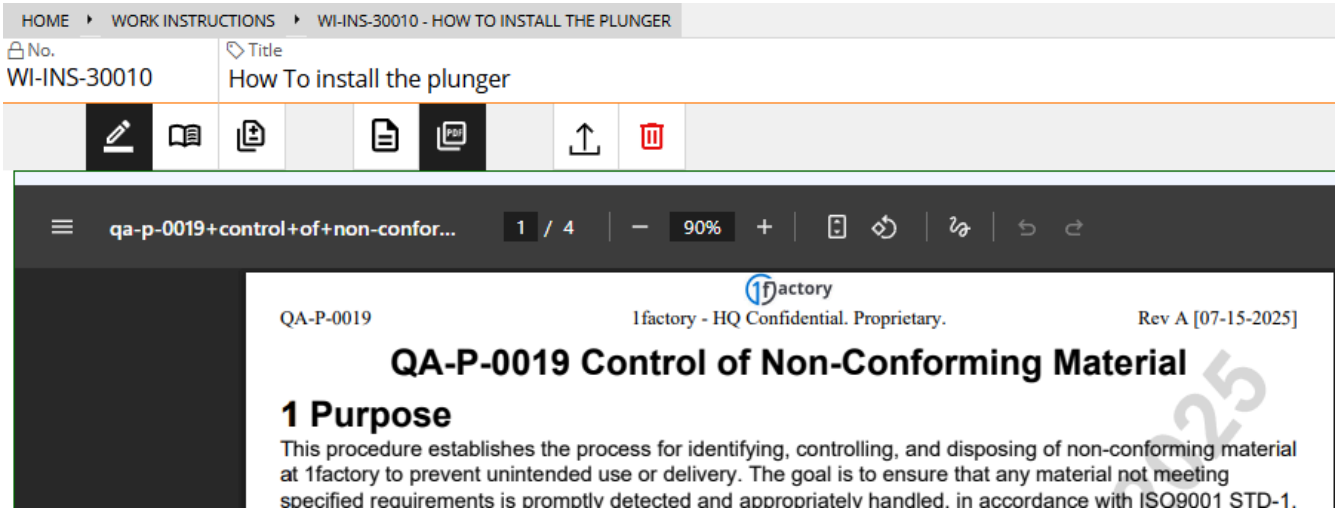

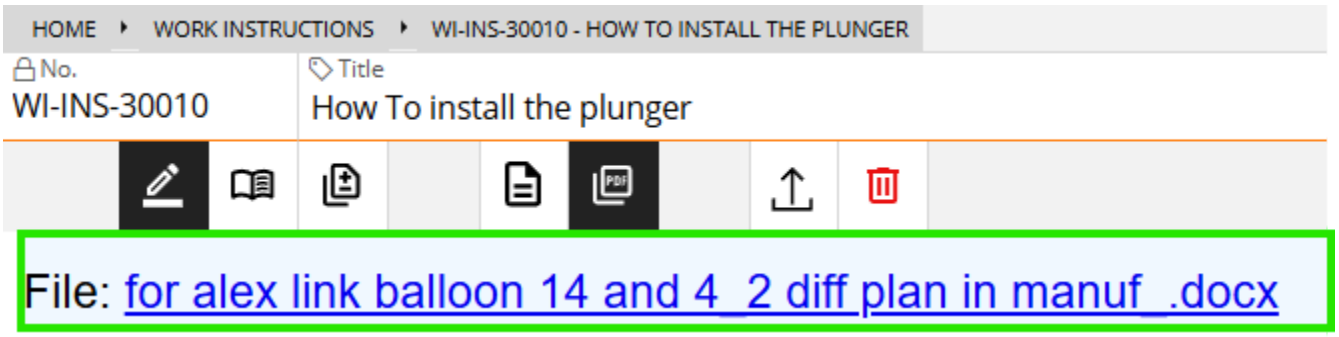

2.1.13 Document Import Options

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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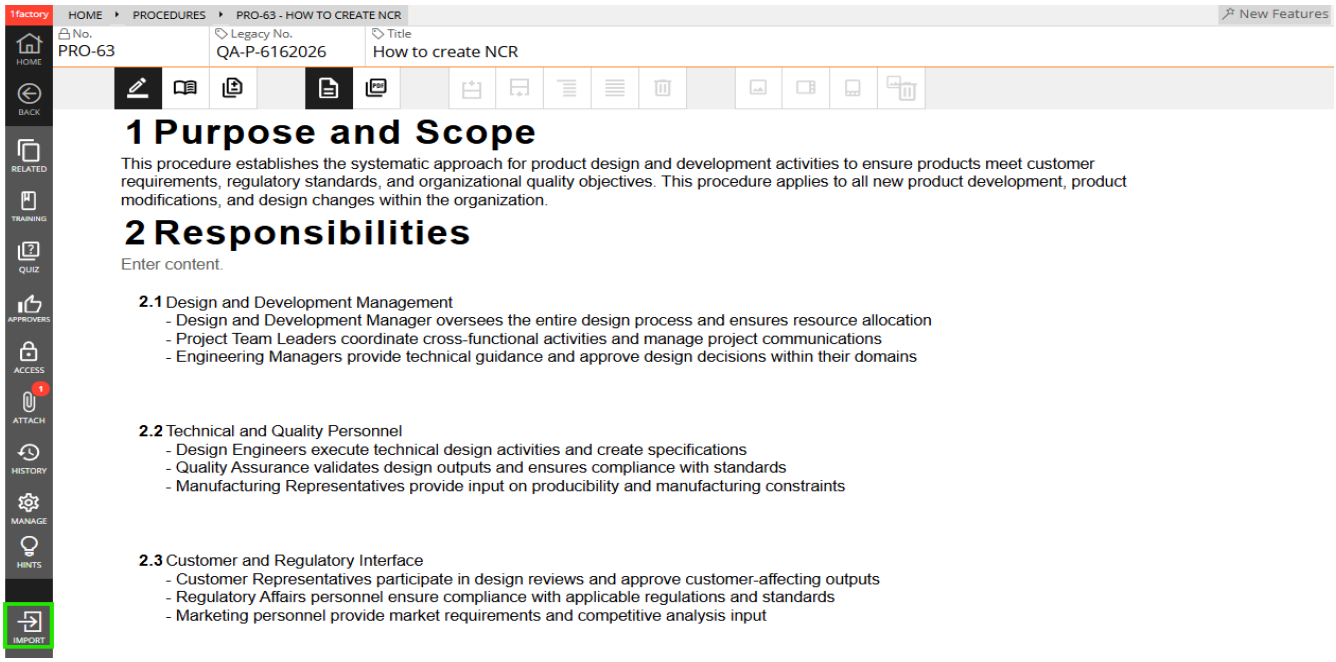
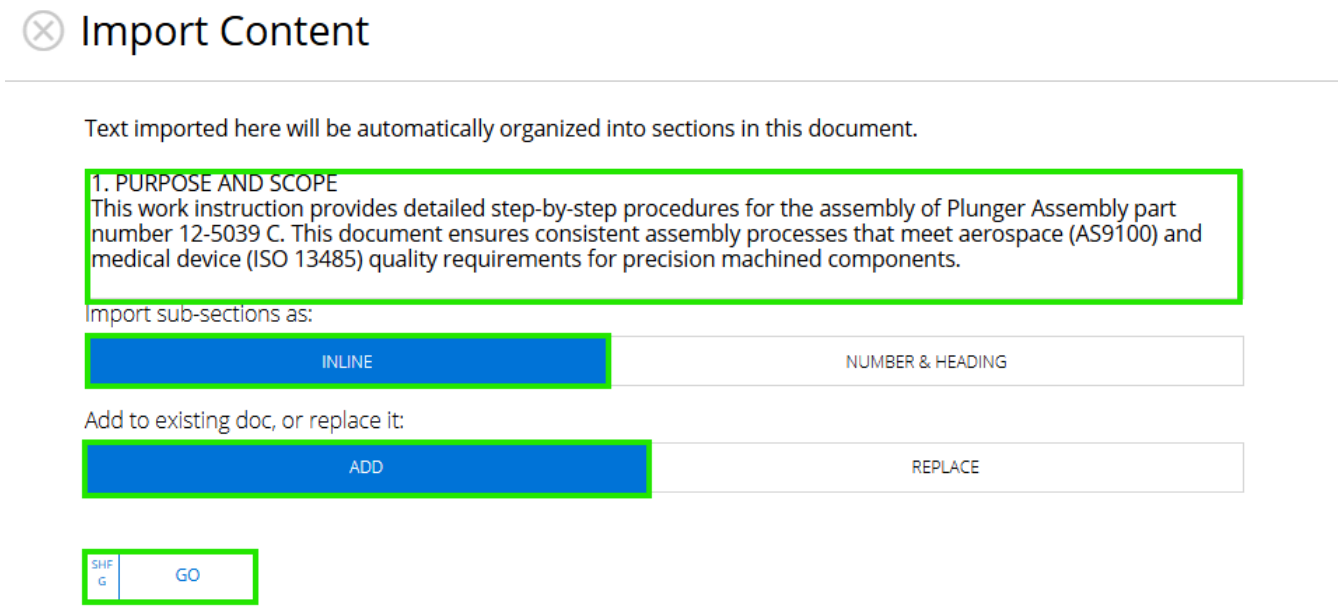


Step 2: Copy and paste content

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



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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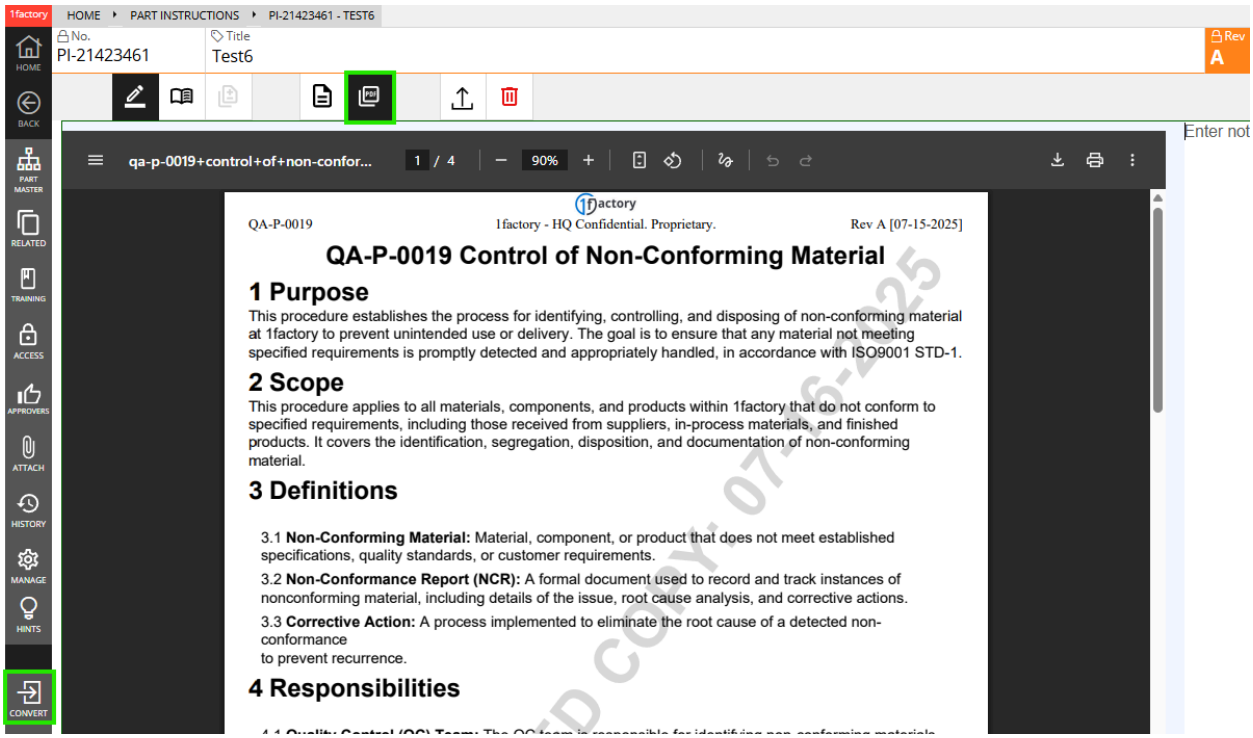
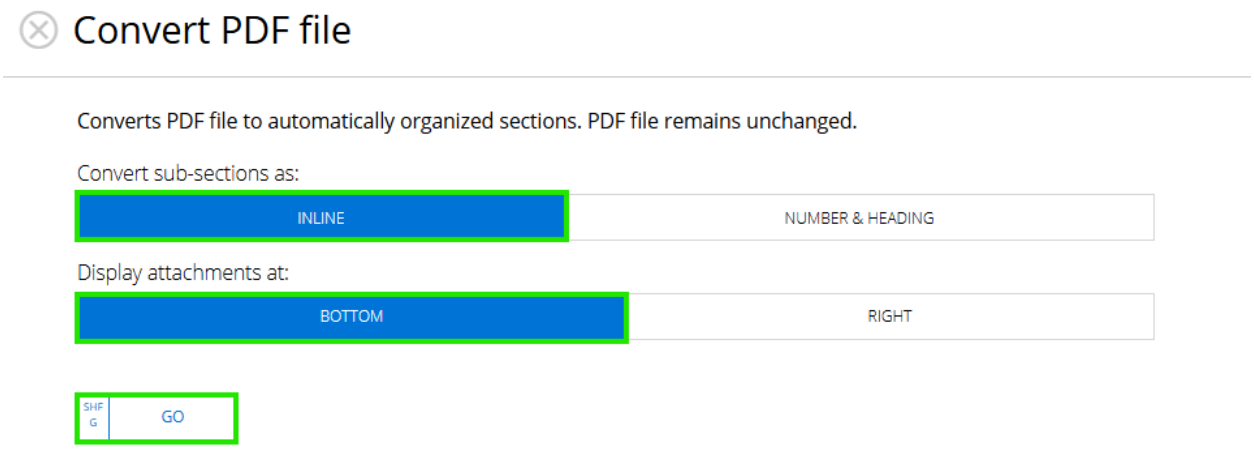


Step 2: Configure settings

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



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

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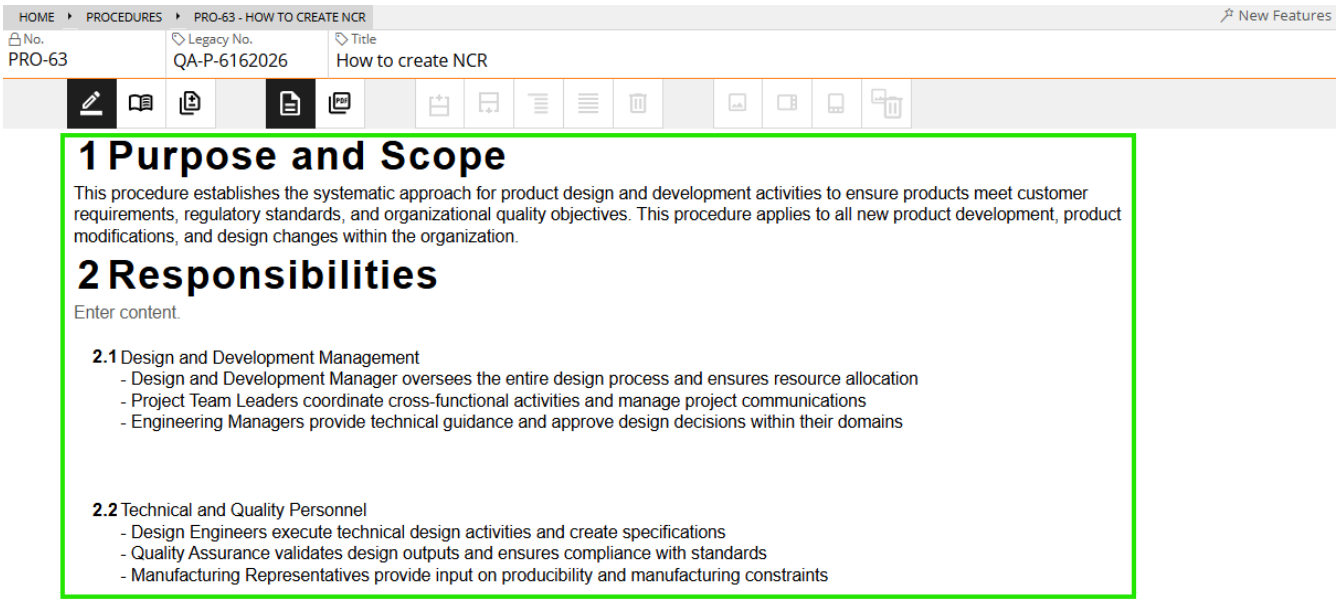
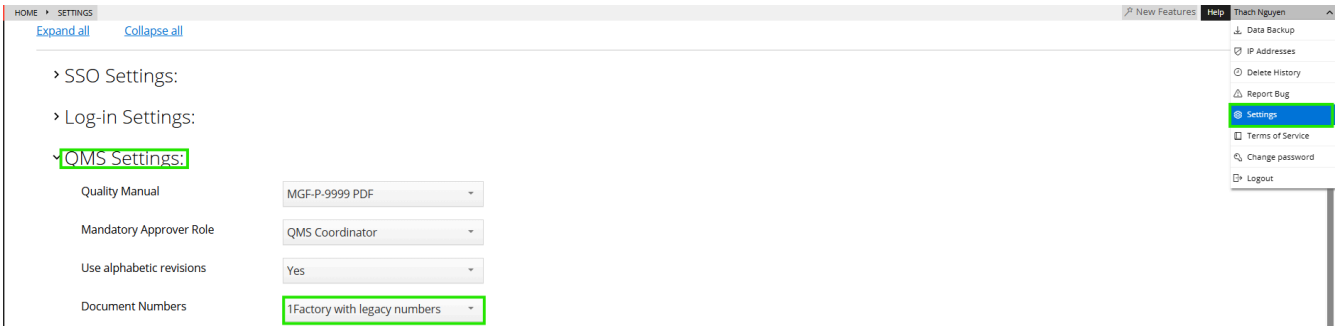


2.1.14 Update Reference Legacy Document

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

Step 1: Enable legacy numbers

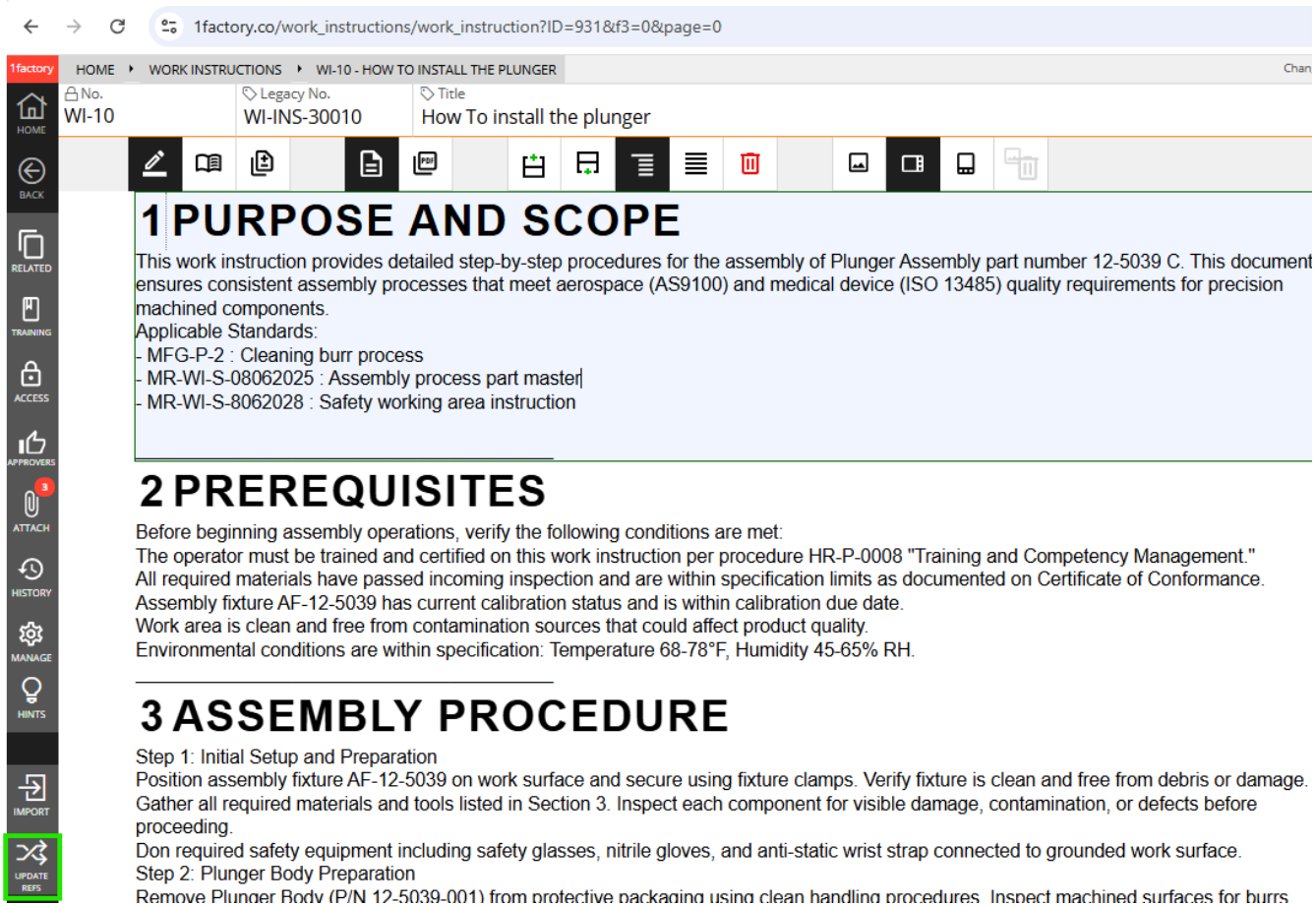
1. Click your name > **Settings**
2. Navigate to **QMS Settings**
3. Select "1factory with legacy numbers"
4. Click **Save**



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)

4. Legacy numbers change to 1factory numbers



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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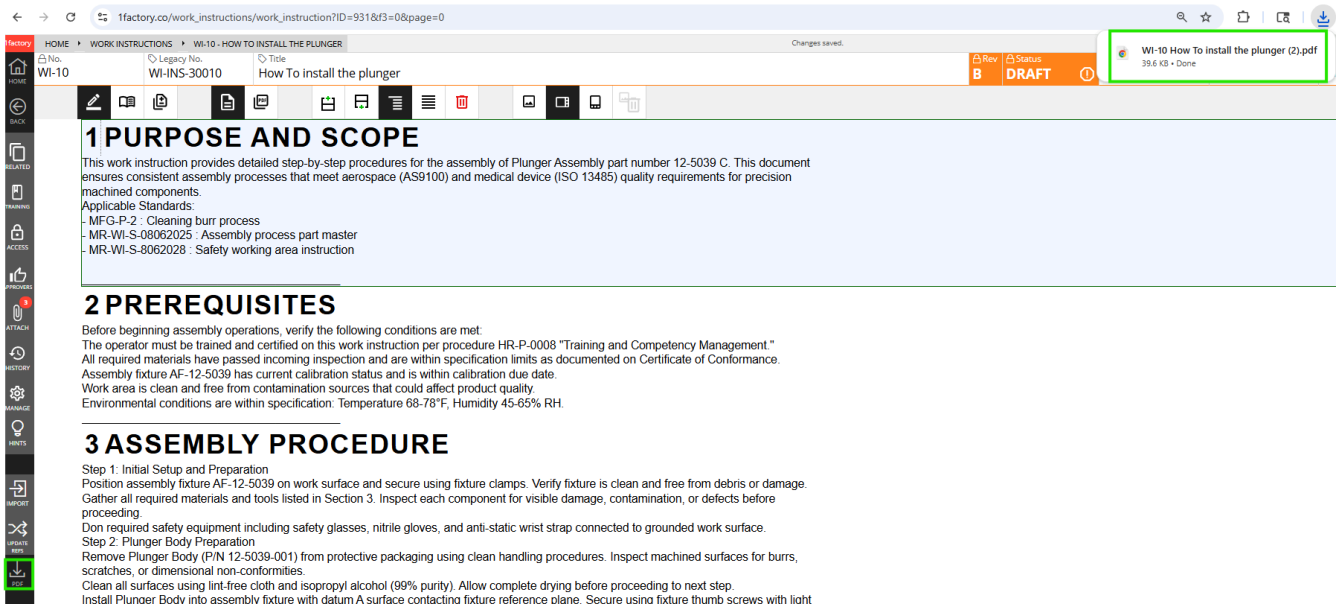


2.2 Document Type Specific Features

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

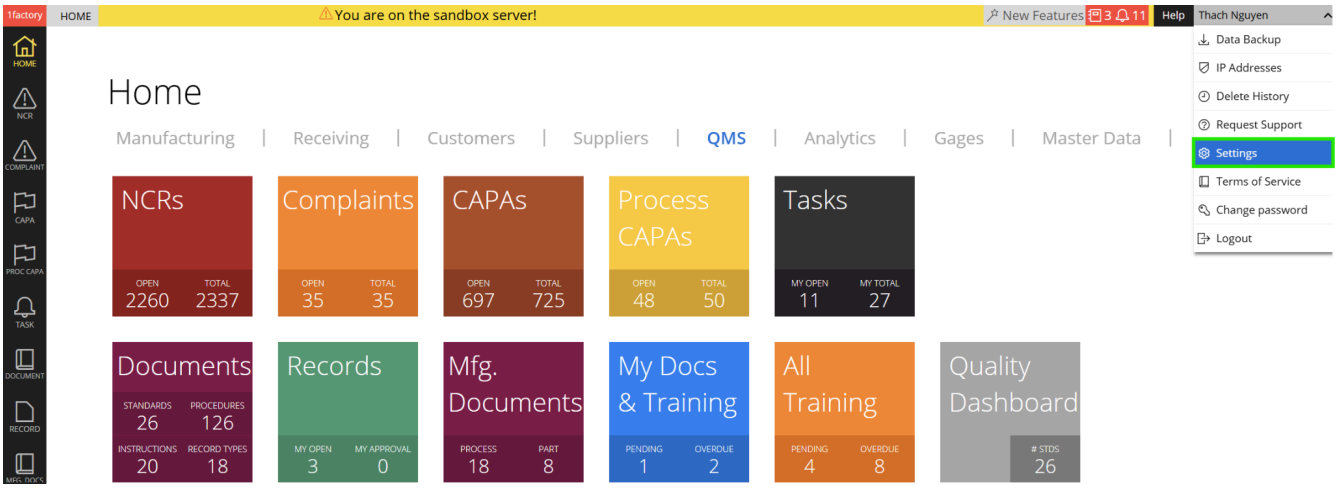
1Factory provides a powerful **Quality Manual** solution that transforms isolated **Standards** and **Procedures** into an integrated compliance framework. Unlike standalone documents, the Quality

1factory QMS User Manual

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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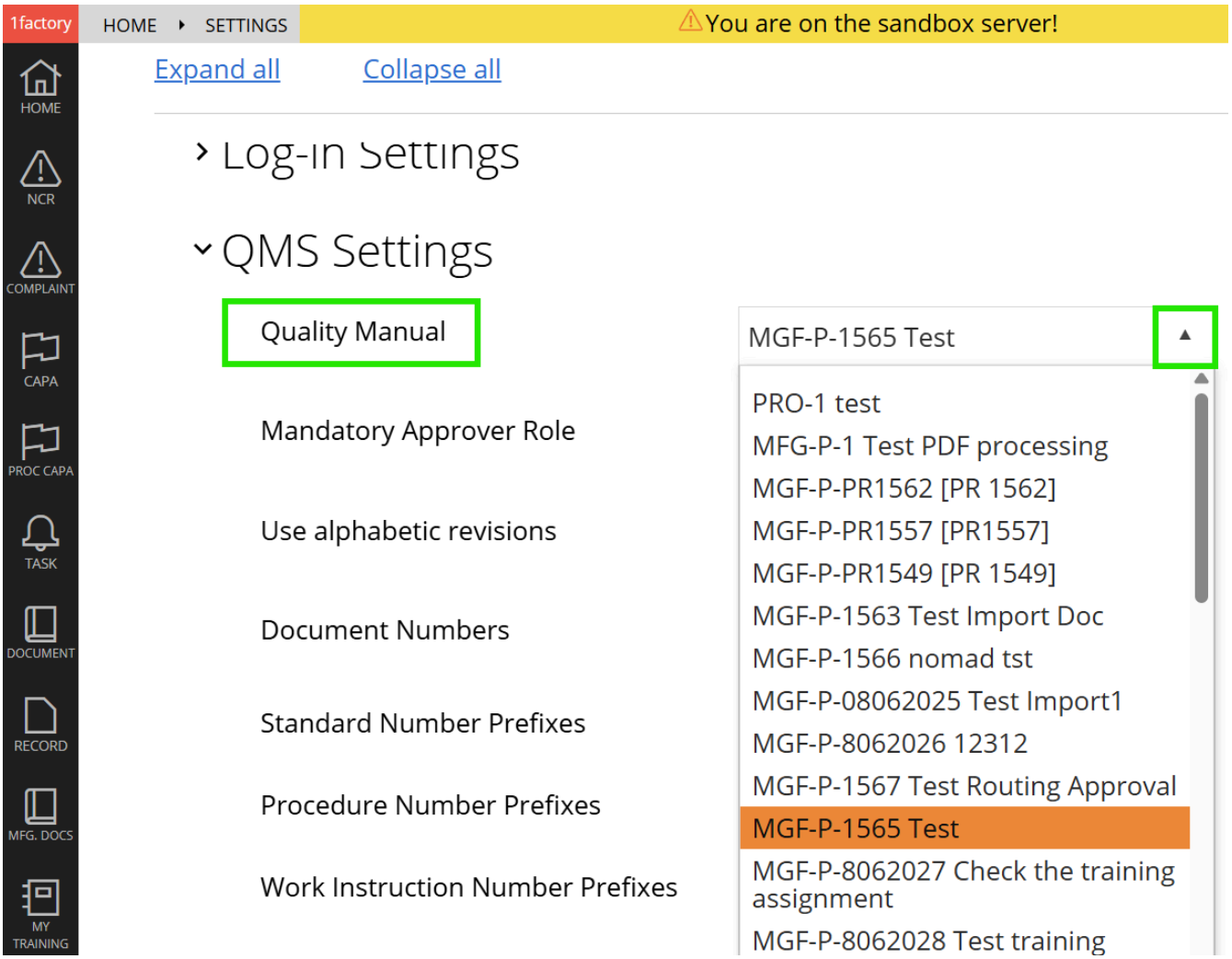

Step 2: Access the Selected Procedure Document

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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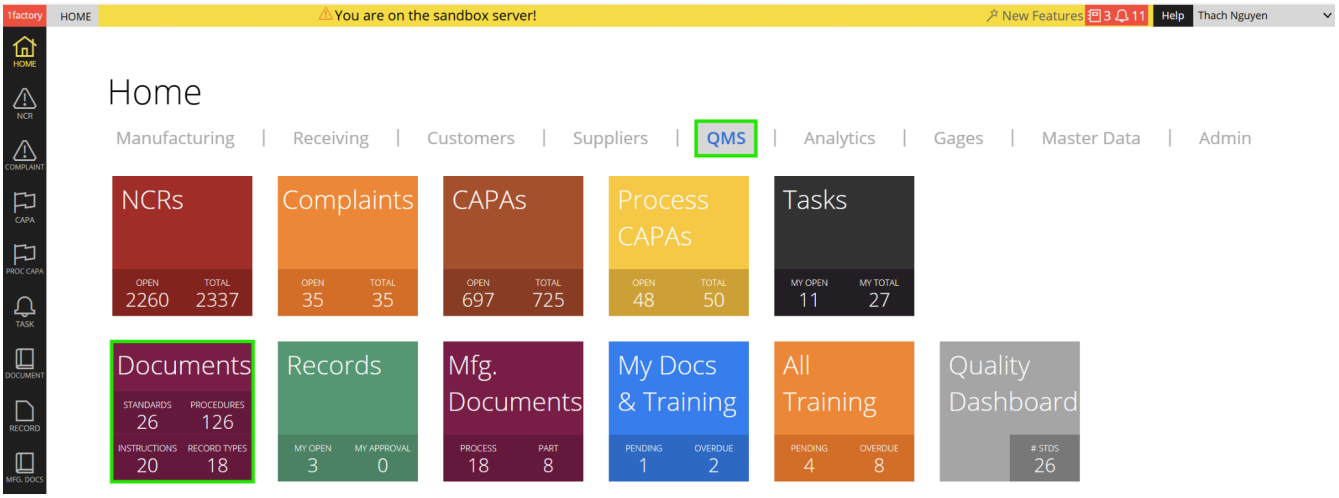
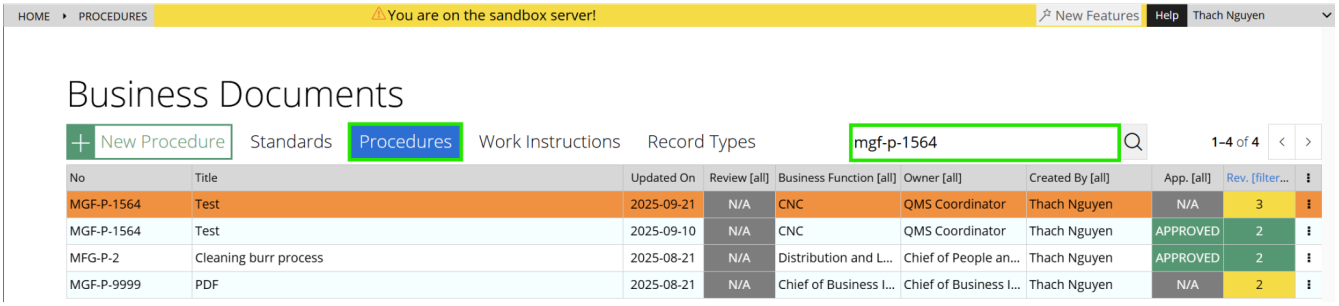
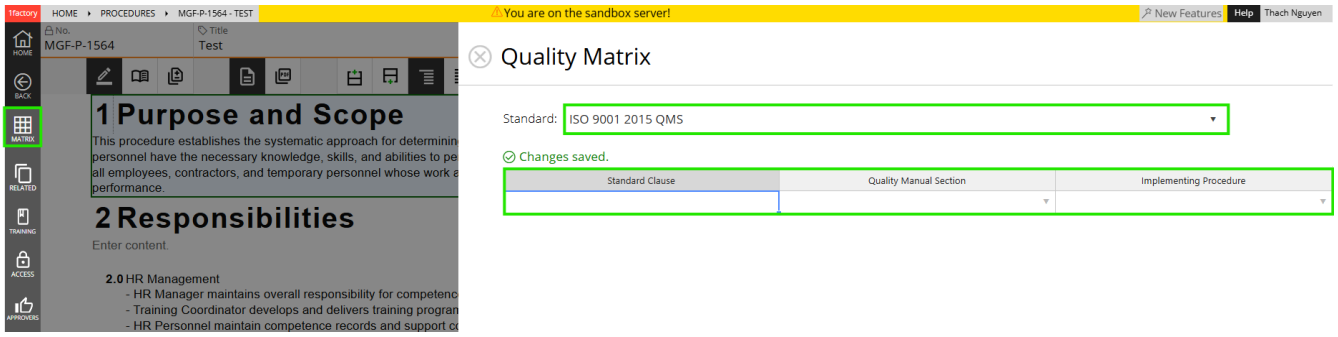


Important: Select the Draft Revision (typically marked in yellow) rather than the Released version (marked in green).



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**.



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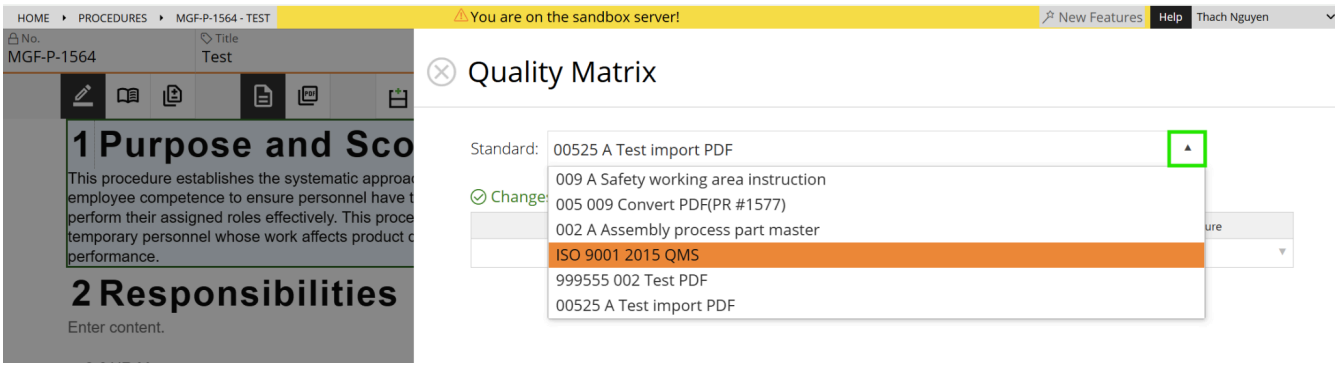
Step 4: Configure Quality Matrix Elements

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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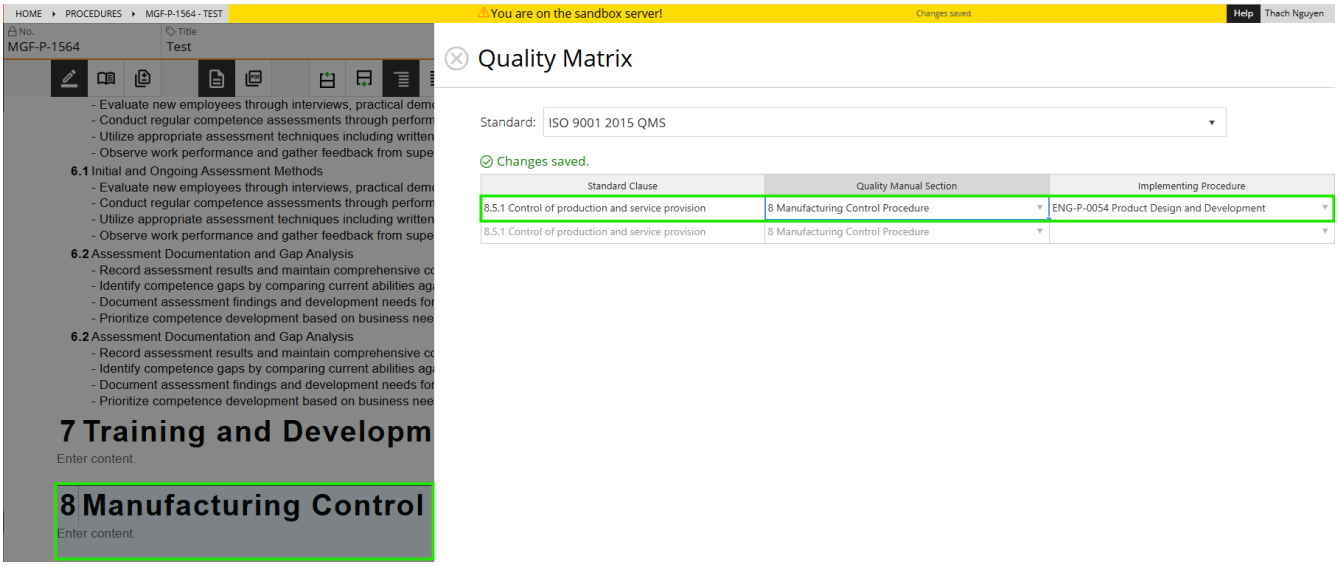

Step 5: Manage Quality Matrix Items

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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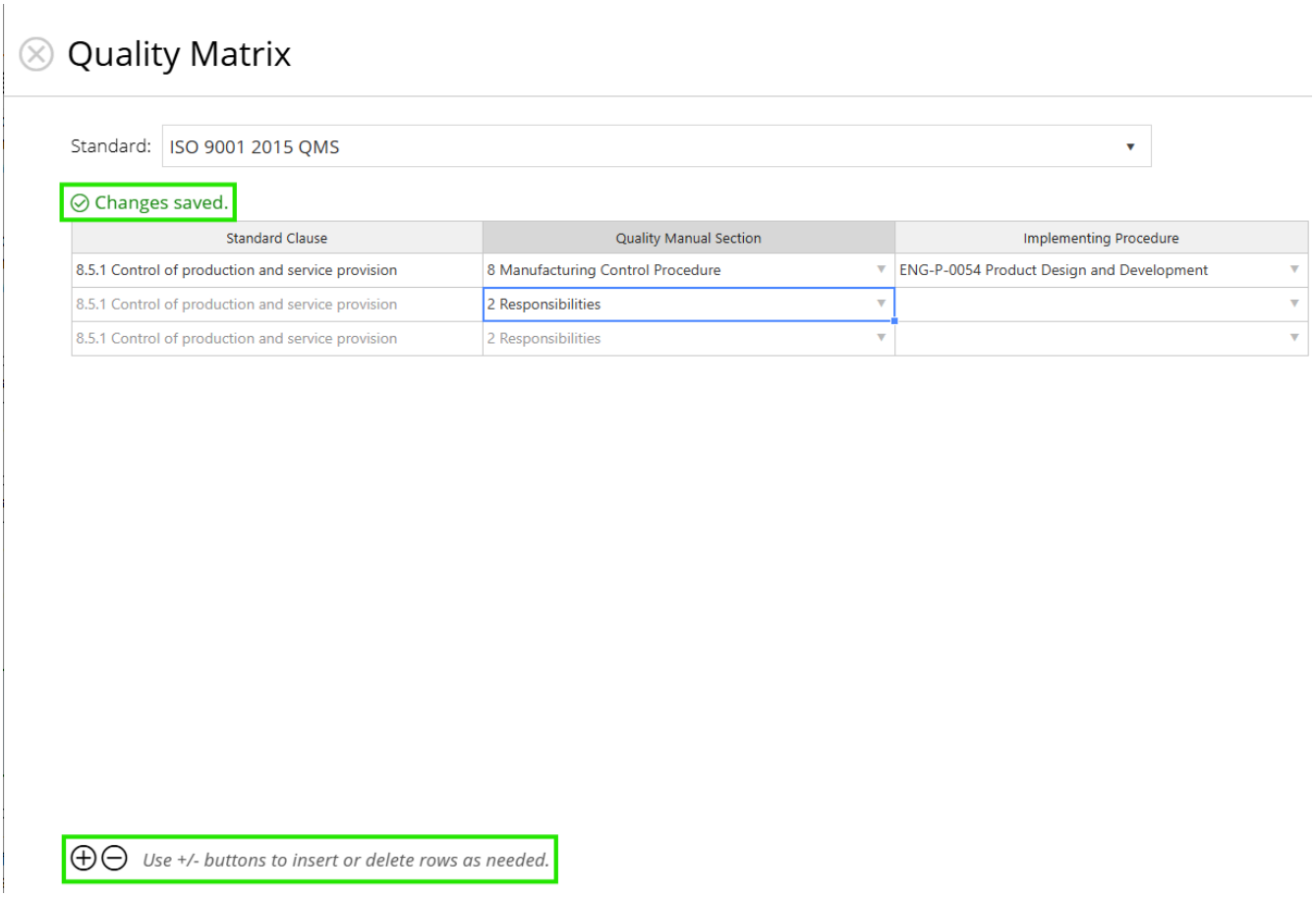

Step 6: Release the Quality Manual

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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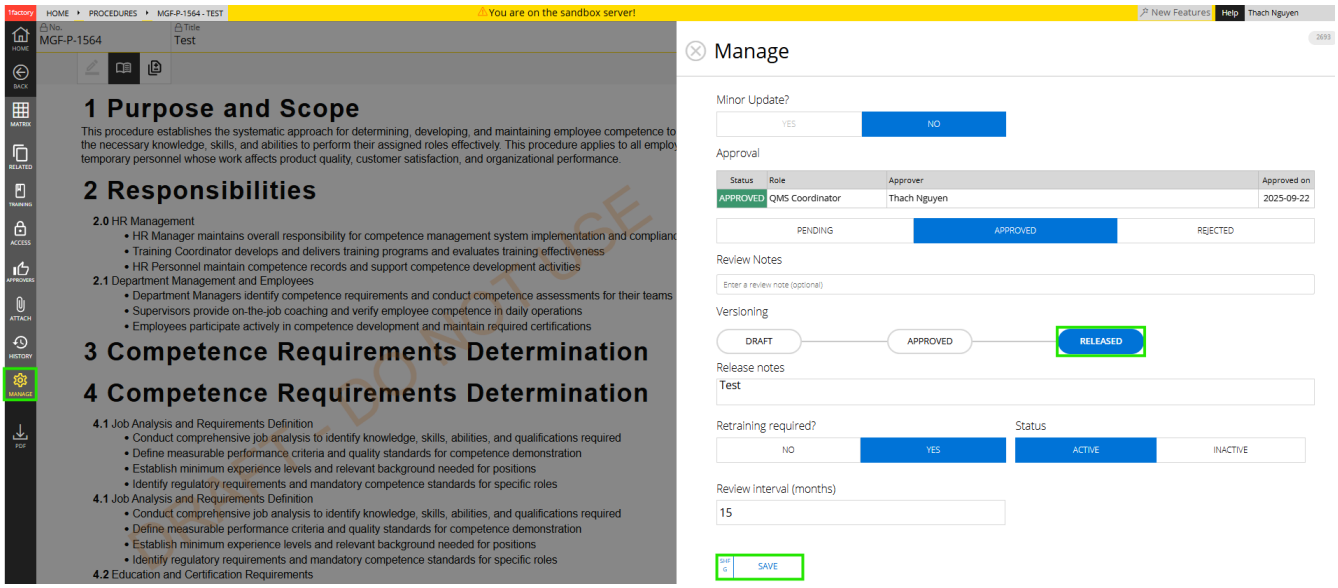

2.2.3 Procedures Unique Features

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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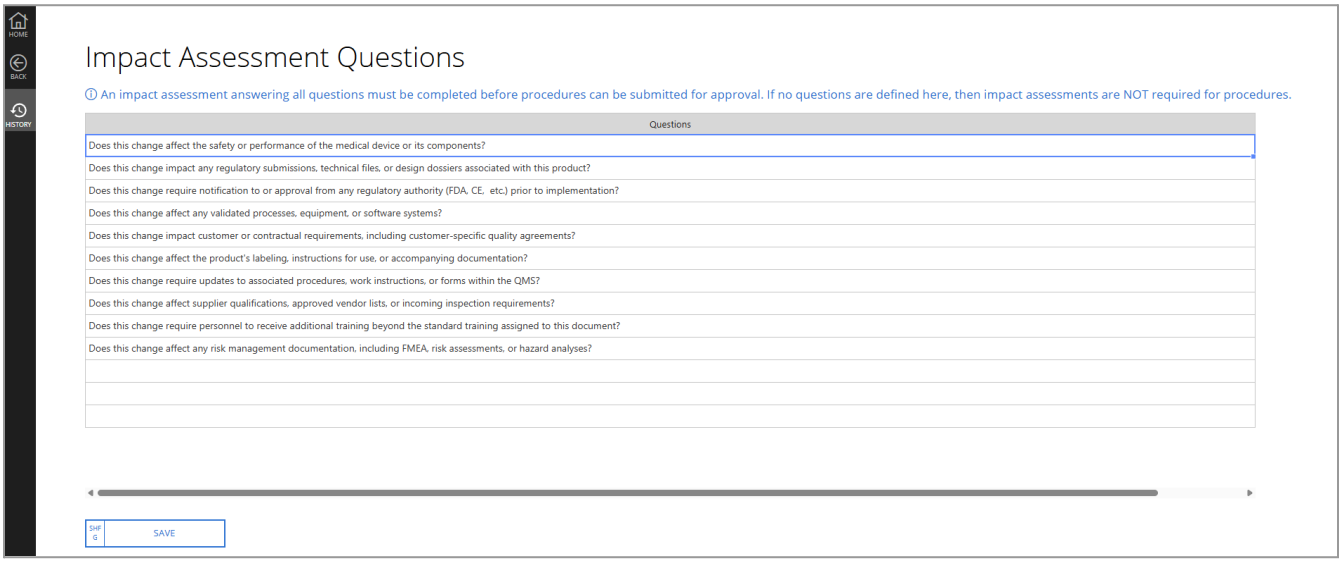

Note: *The question format is intentionally open-ended. If your organization wishes to number questions, do so manually within the question text itself.*

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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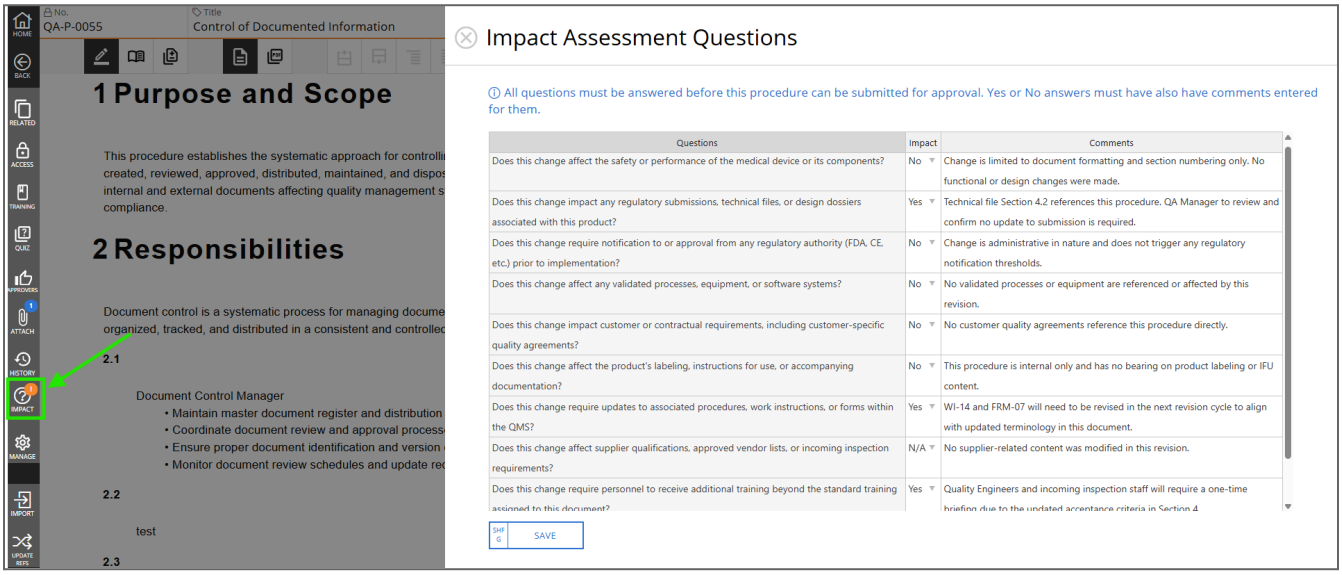

2.2.4 Work Instructions Unique Features

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

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.

- **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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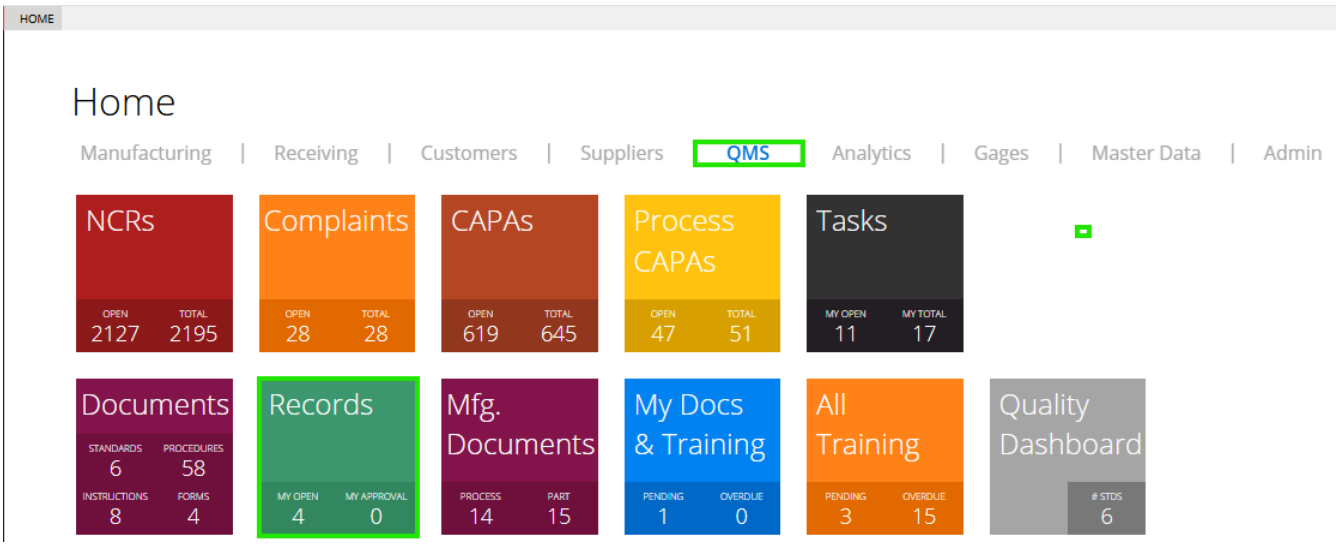
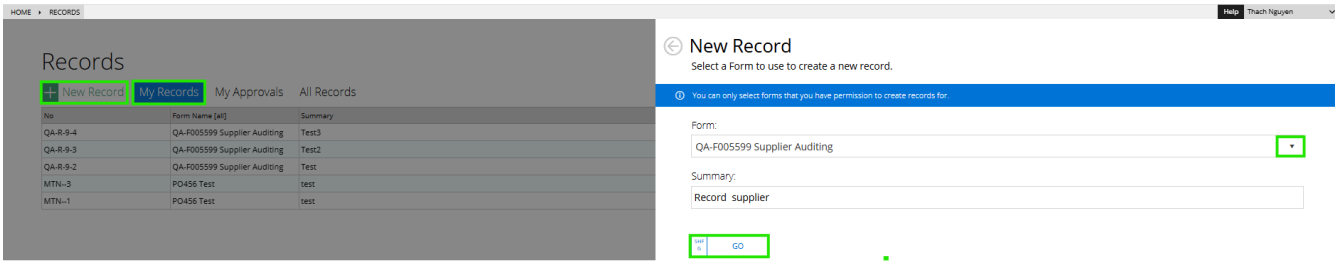


Step 2: Create New Records

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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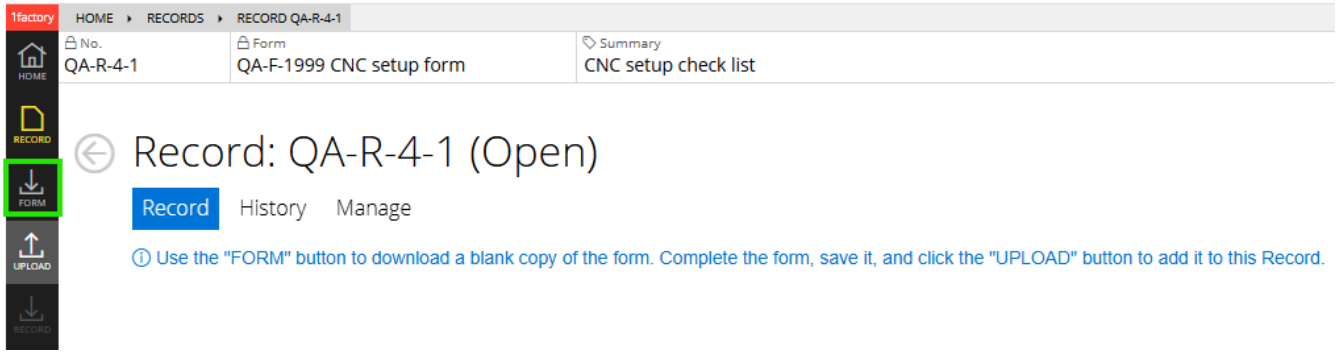
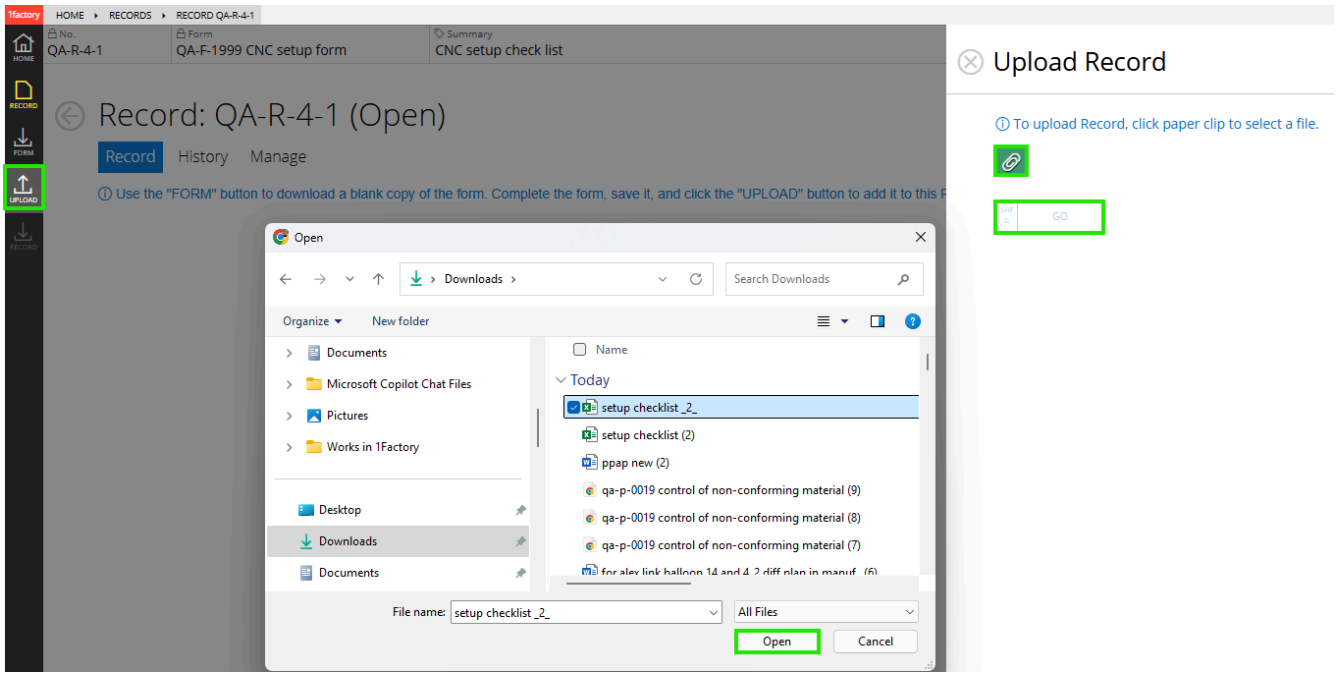


Step 2: Upload the completed Form

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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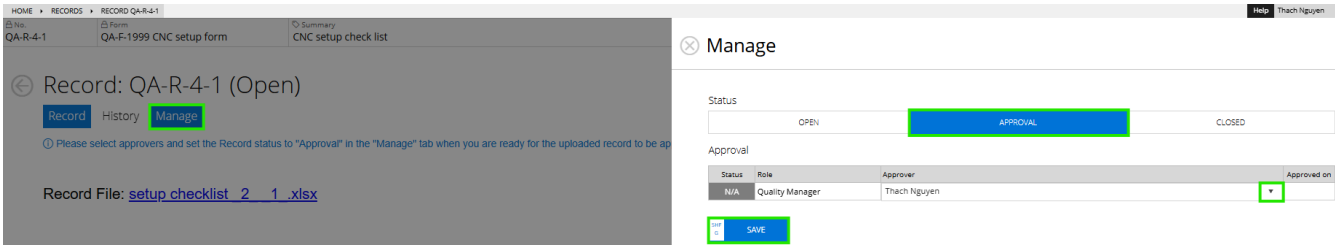
Key management capabilities include:

- **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.

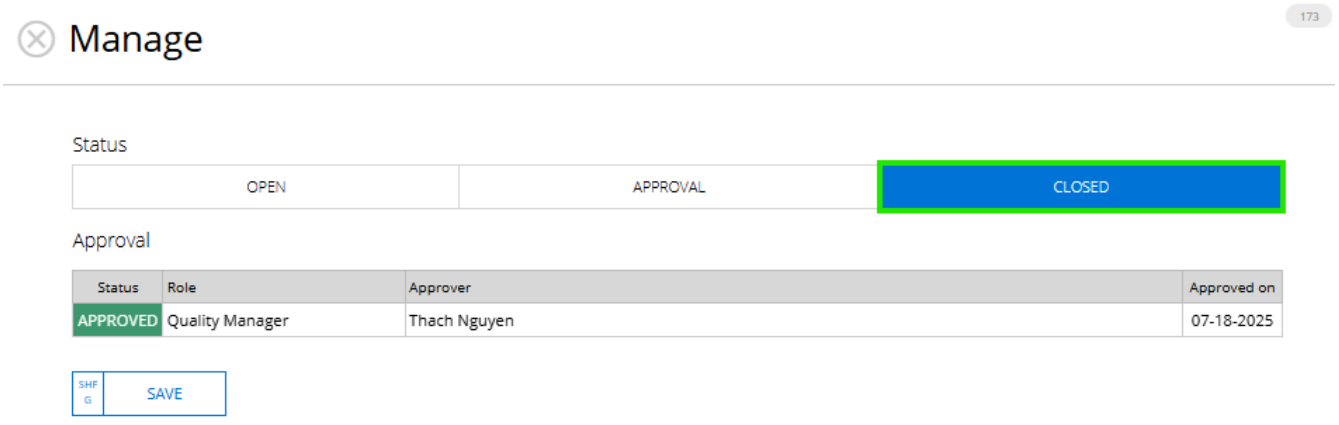
Step 1: Request Approval

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.



Step 2: Check the Status

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



Step 3: Download a Record

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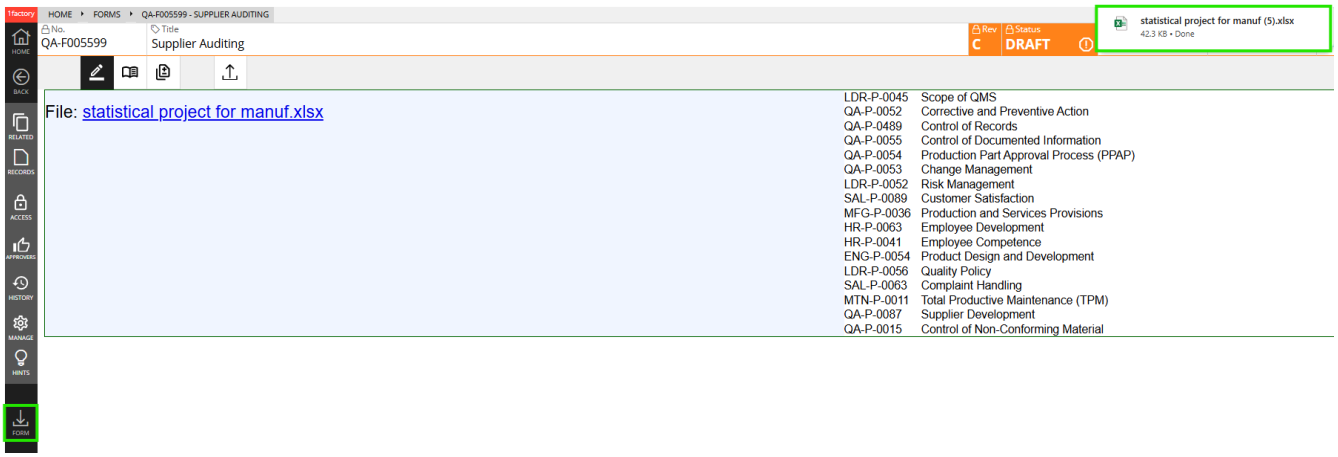
The download **RECORD** feature allows you to generate your **Record** document for offline use, printing, or external distribution. On the left vertical menu, click the **RECORD** download icon to open the export feature. Your exported file will appear in the top right corner of the screen.



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

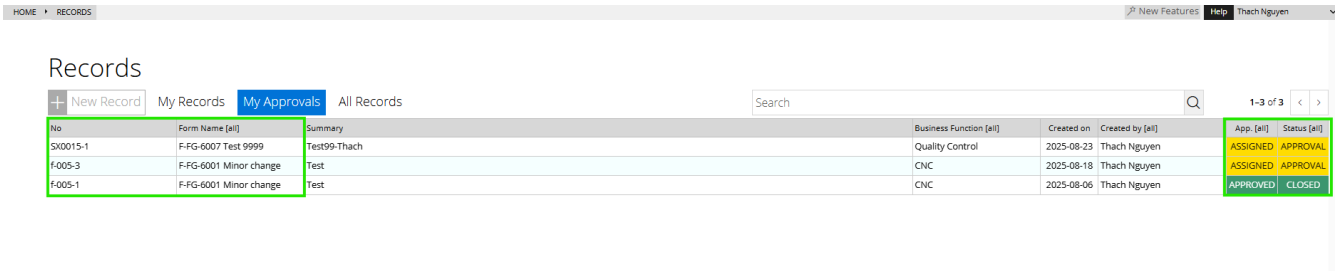
Id	Field : Value	Revised on	Revised by
0	CREATED BY: Thach Nguyen	07-18-2025, 15:03	Thach Nguyen
1	SUMMARY: CNC setup check list	07-18-2025, 15:03	Thach Nguyen
2	NEW UPLOAD: setup checklist _2_.xlsx	07-18-2025, 15:30	Thach Nguyen
3	NEW UPLOAD: qa-p-0019 control of non-con...	07-18-2025, 15:34	Thach Nguyen
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**.



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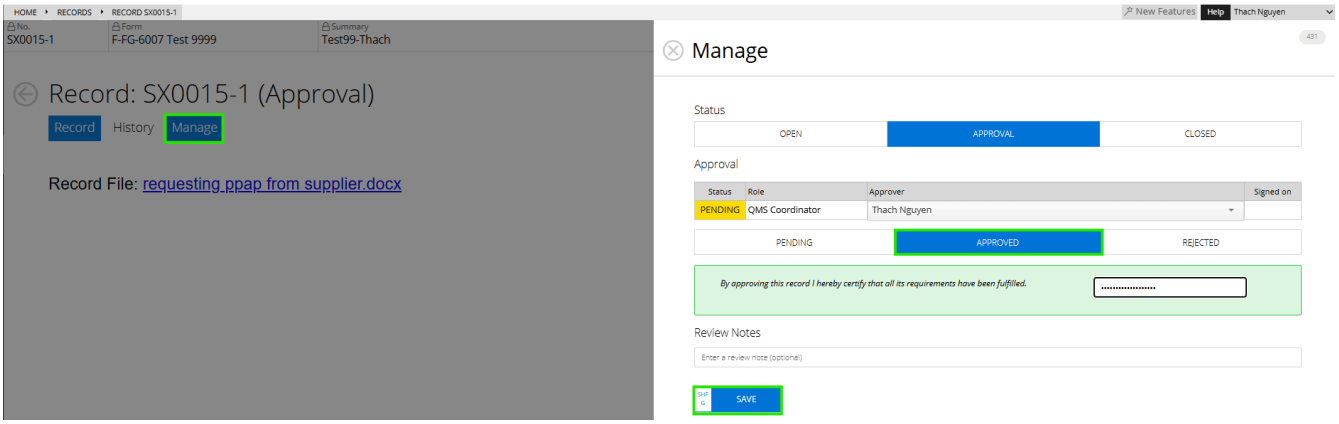
3.2.2 Open and Review for Approval

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.



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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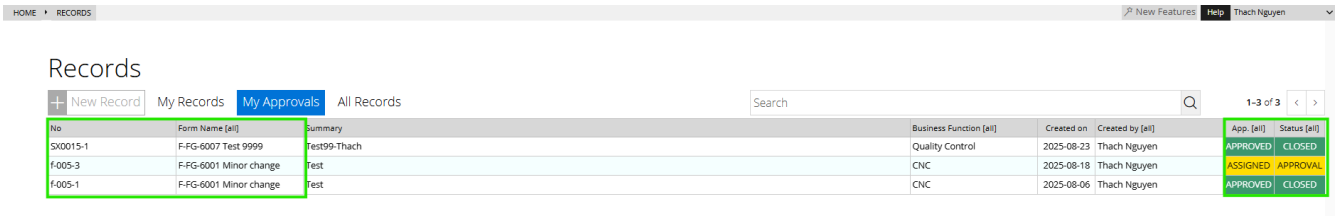
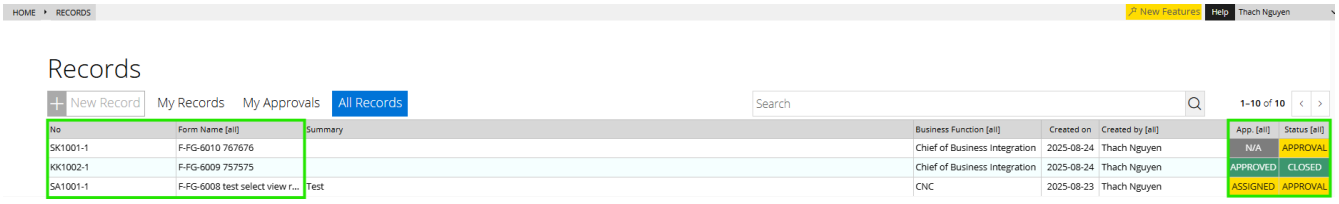
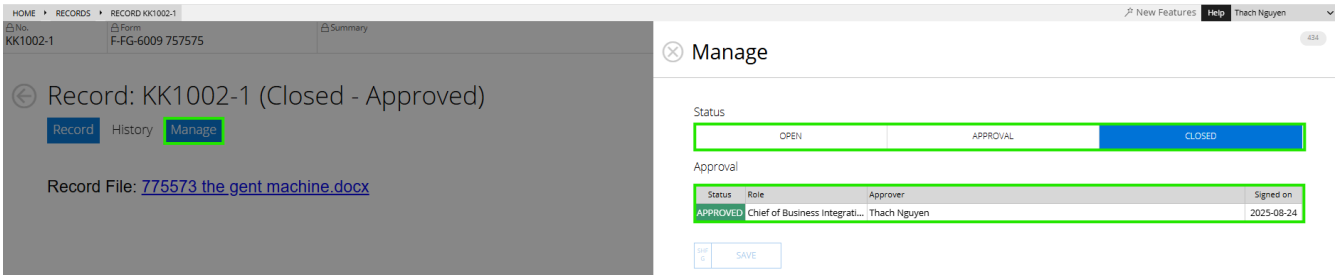


3.3 All Records

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.





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

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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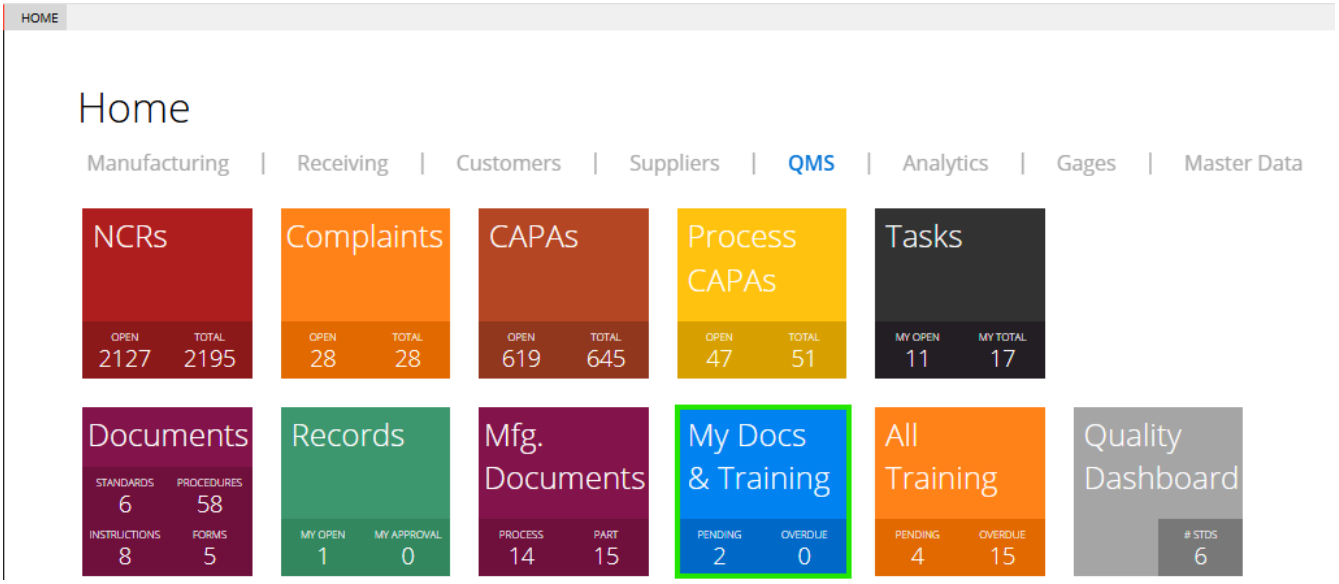

Step 1: Review Training Assignments

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**

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	06-06-2028	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-[PR-1493]	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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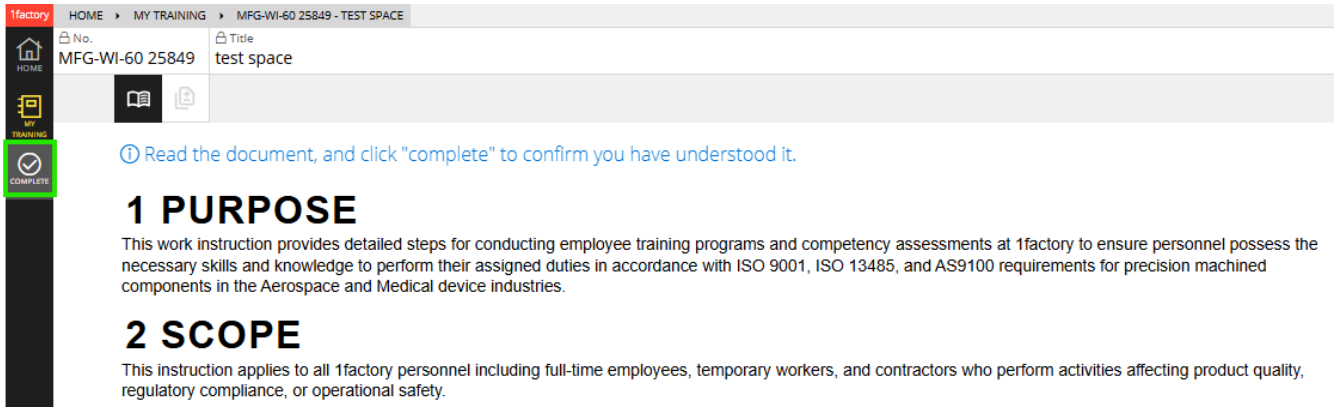
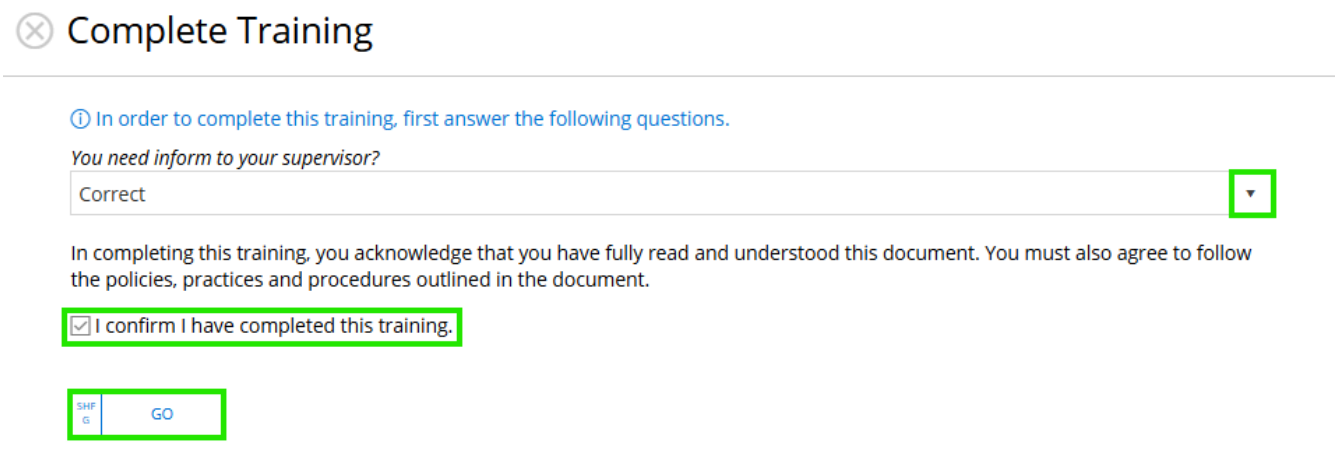
Select the specific training assignment you wish to complete from your training queue. Review the document content thoroughly to understand the requirements, procedures, or standards covered. Once ready to demonstrate competency, click the **Complete** tile located on the left side of the menu bar.



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.



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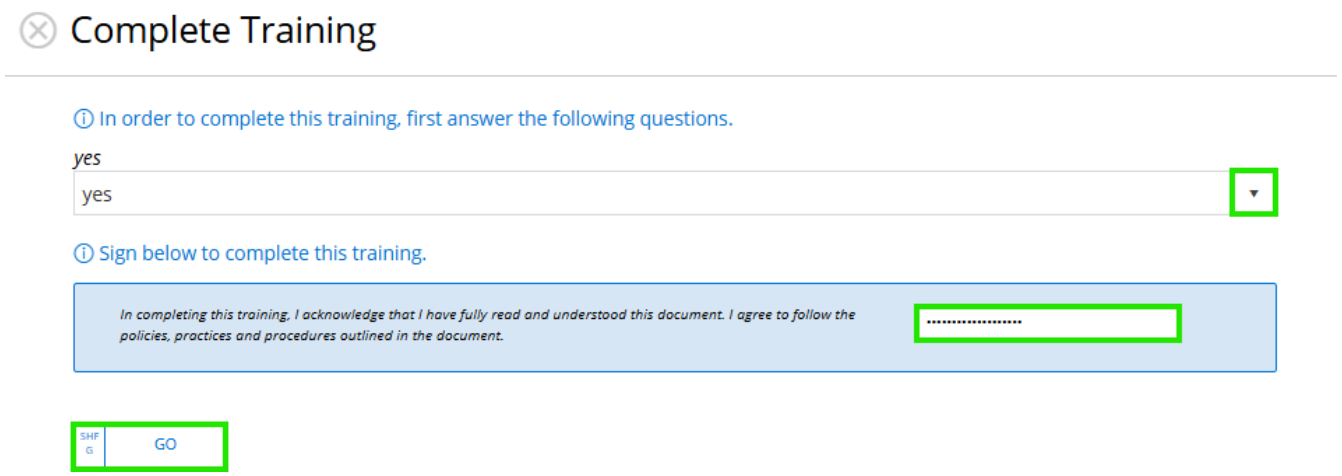
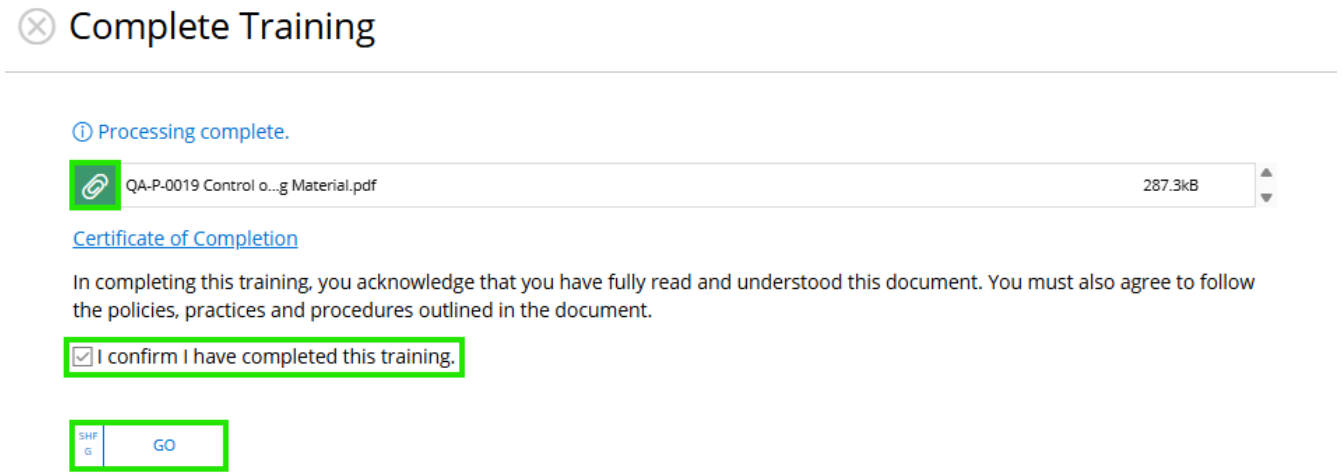
Self Assessment Method

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.



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.



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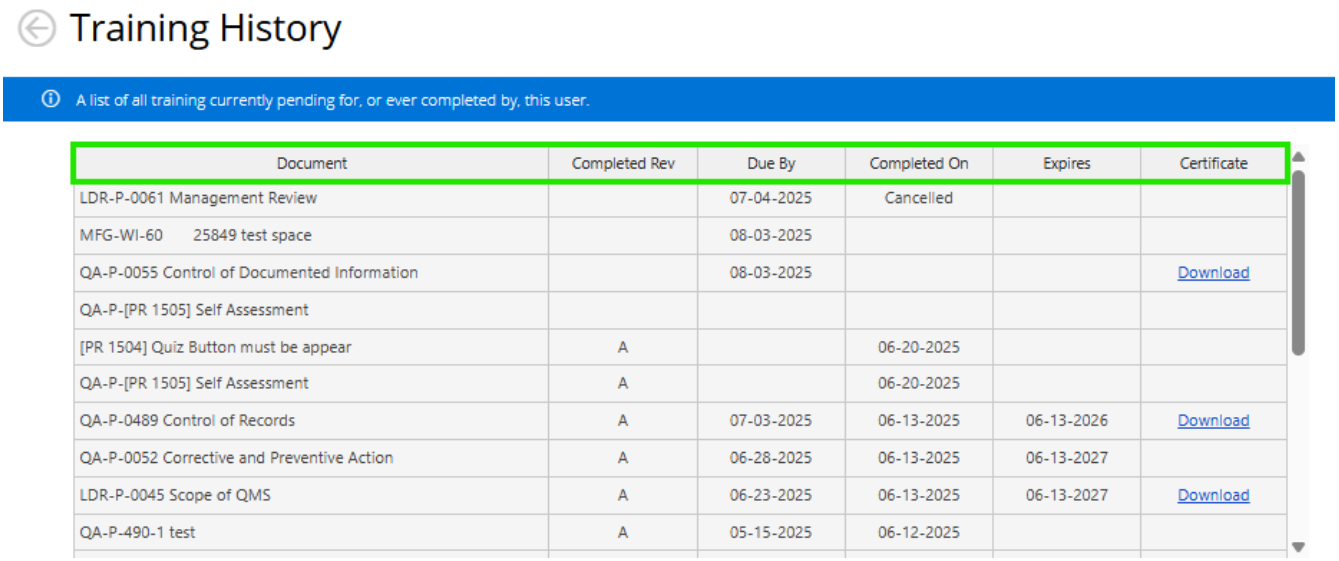
Step 4: Training History Management

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**



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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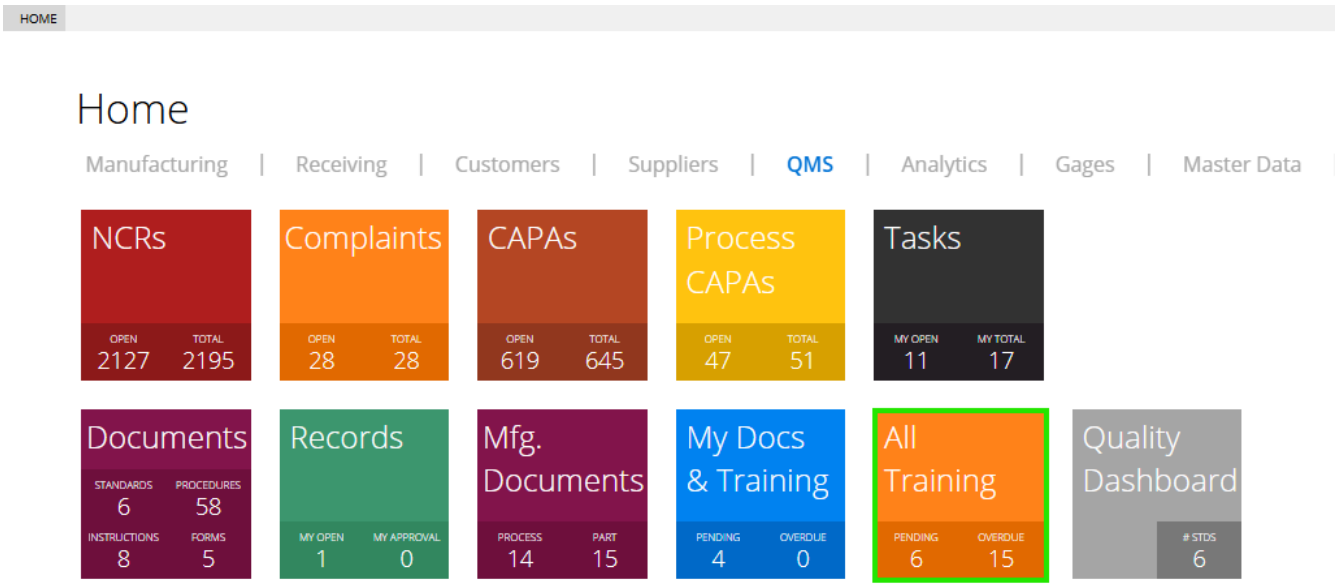
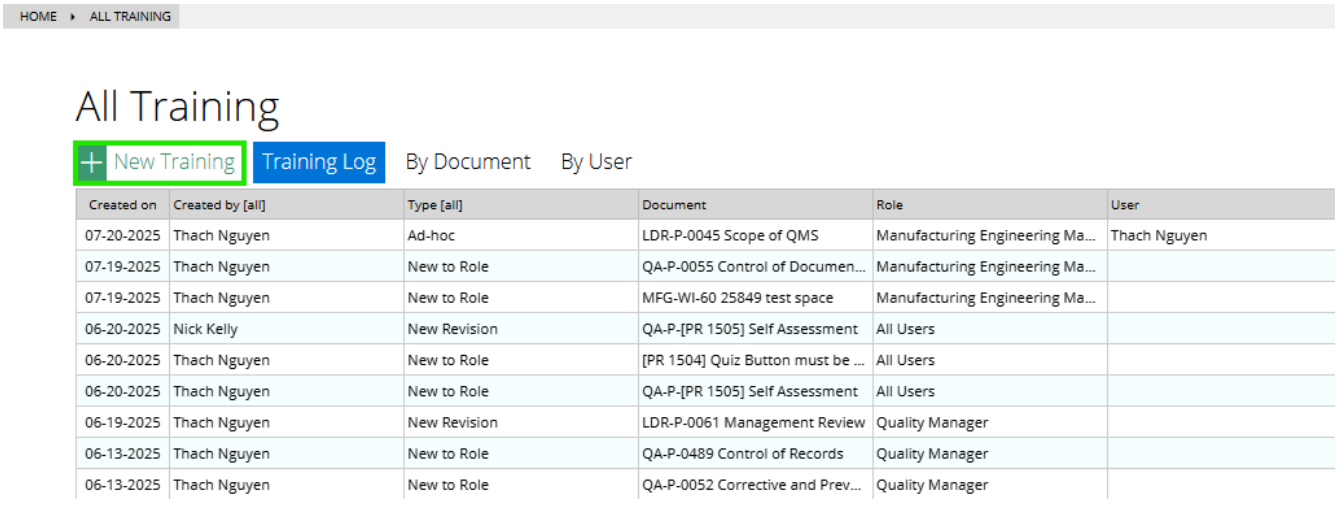


Step 1: Initiate Ad-hoc Training Assignment

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



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	

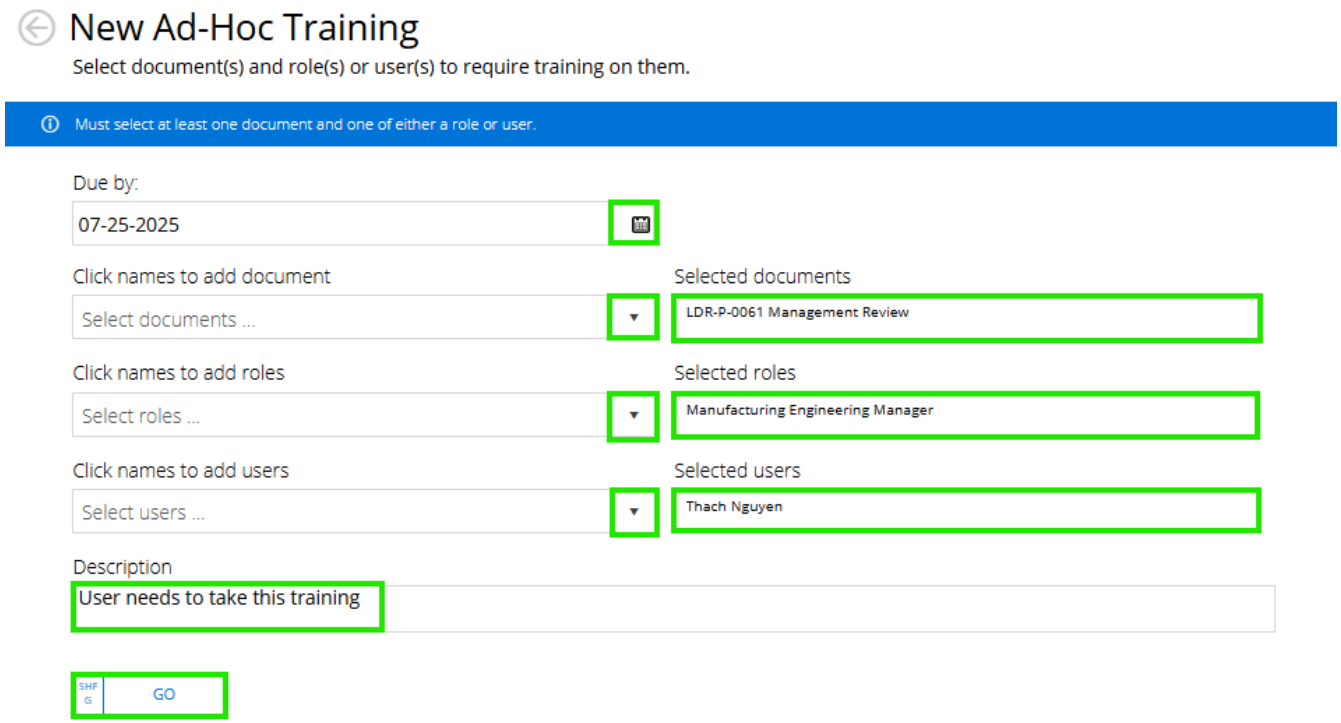
Step 2: Configure Training Parameters

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

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

- **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.



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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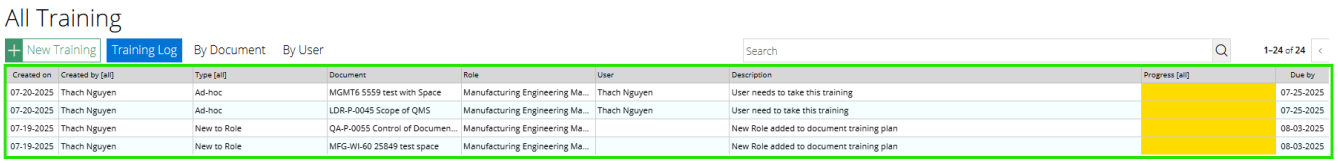
4.2 Monitoring Training

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



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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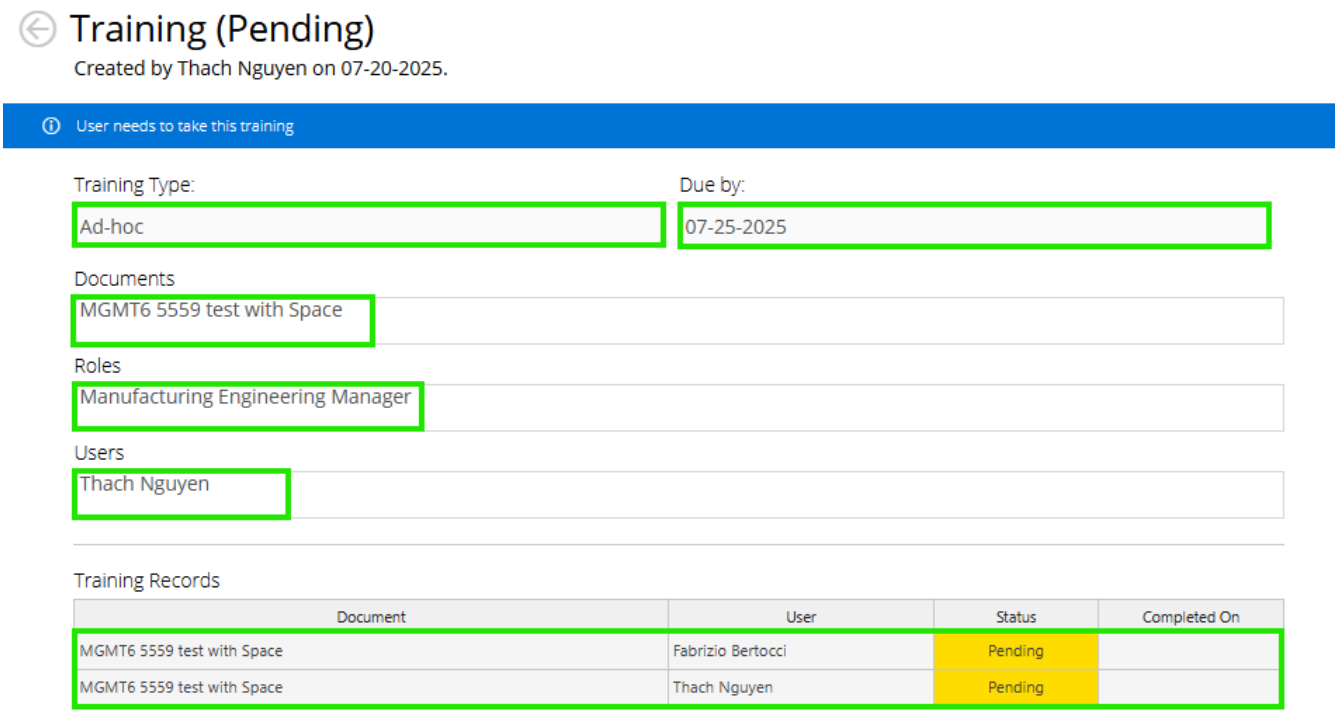
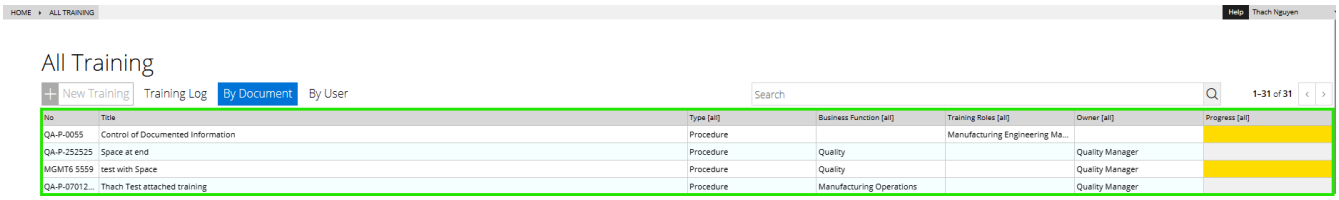


Review By Document

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



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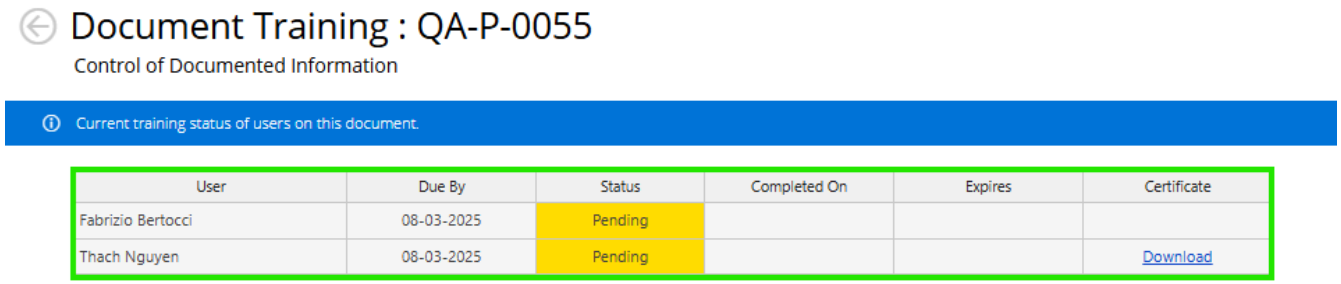
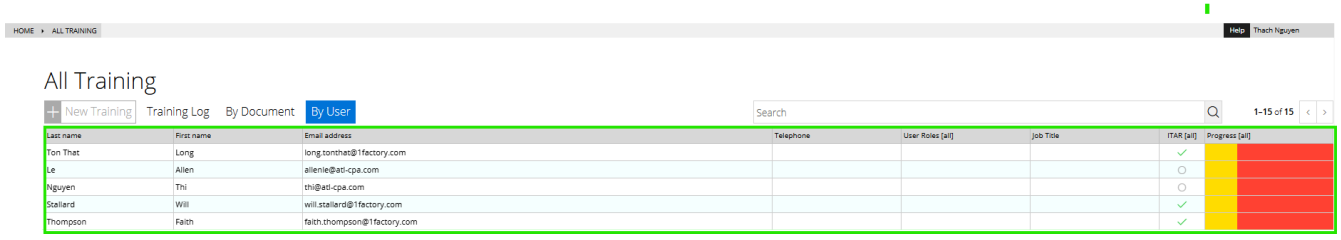
Individual Training Details: Click on any document to access user-specific training information including assigned User, Due Date, completion Status, Completed On date, certificate Expiration, and Certificate details.



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



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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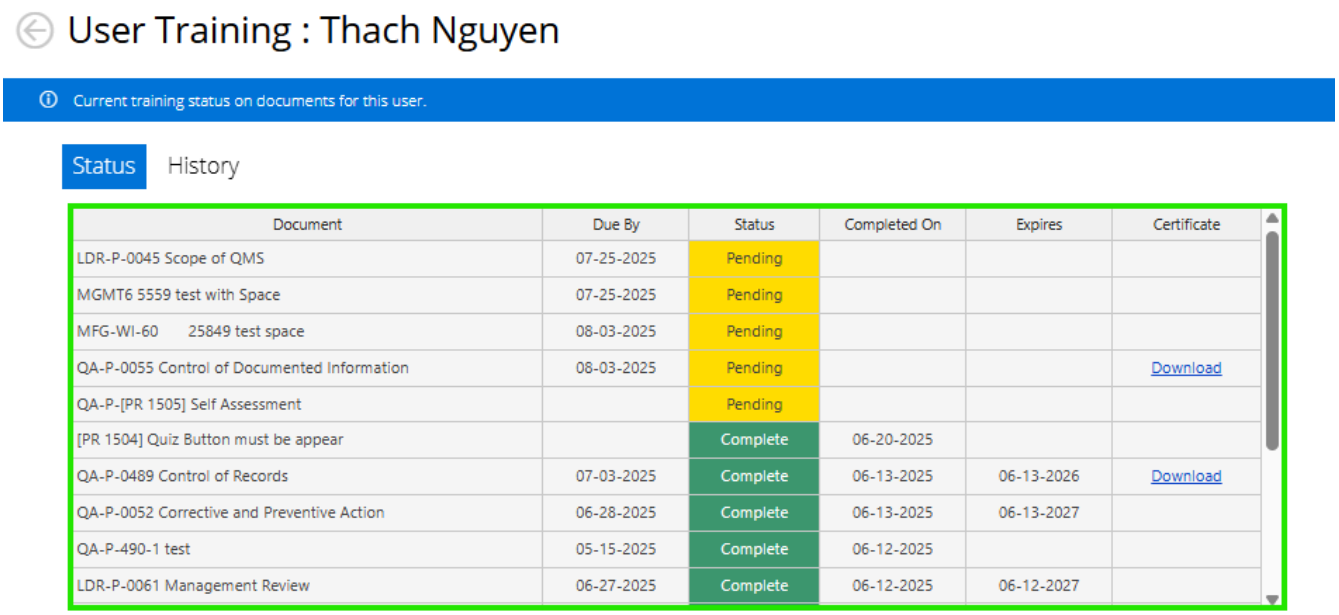
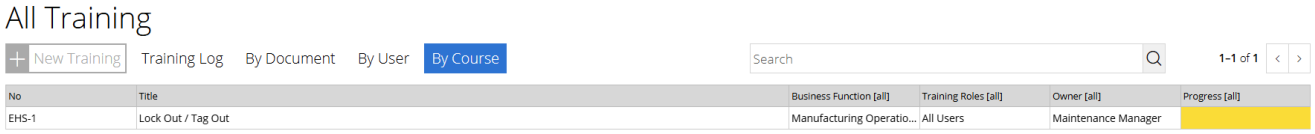


Training History Access: Navigate to the **History** tab within any user's profile to review all documents previously assigned to that user and their complete training history, providing comprehensive audit trails for regulatory compliance and performance evaluations.

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



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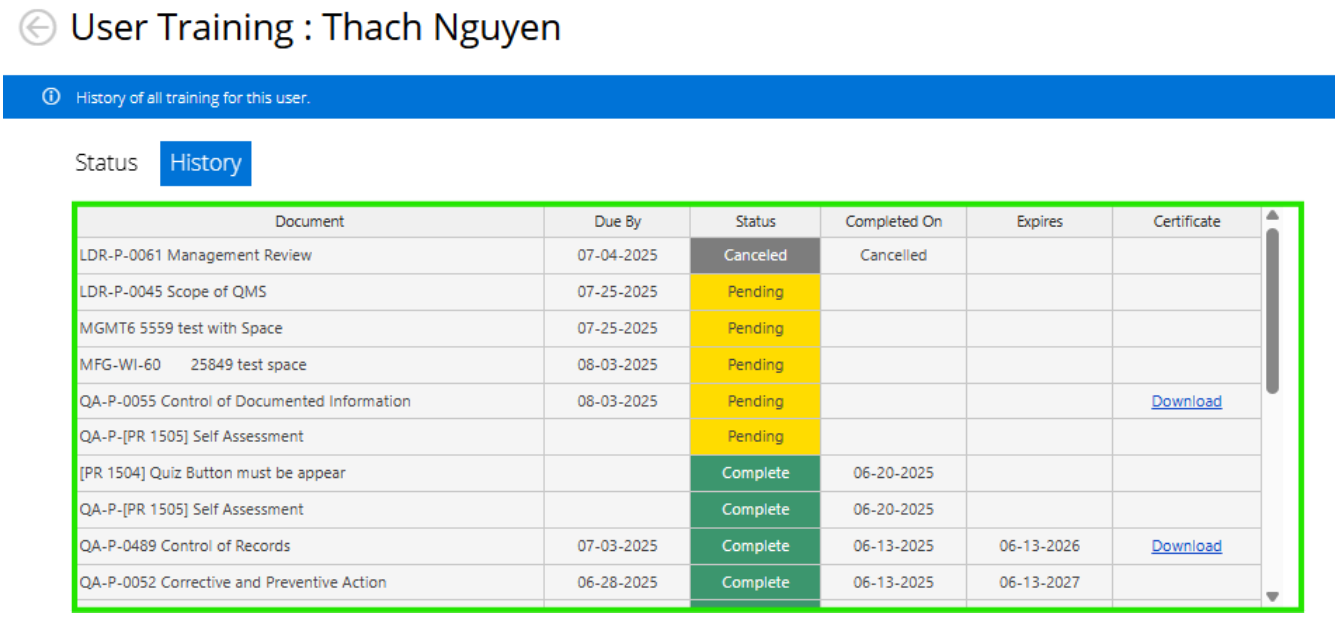
These four review methods ensure quality managers can monitor training compliance from multiple perspectives, supporting both individual development tracking and organizational training effectiveness measurement.



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