

<b>Department:</b> R&D	<b>Process:</b> Design Control	<b>Effective Date:</b> 2024-05-01	<b>Doc no.:</b> 04903	<b>Version:</b> 1
<b>Author(s):</b> Reka Fodor		<b>Reviewer(s):</b> Jacob Sjørnslev; Marc Murphy Bruun	<b>Approver(s):</b> Reka Fodor; Jacob Sjørnslev	

# Release Notes for SimplerQMS 3.2

## Version History

Version	Date	Description	Author
1	2024-04-30	First version of release notes for SimplerQMS 3.2	Reka Fodor

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## Contents

- 1. Introduction .....3**
  - 1.1. Purpose of the Document.....3
  - 1.2. Objectives for SimplerQMS 3.2 based on customer feedback.....3
  - 1.3. Planned release dates.....3
- 2. Summary of 3.2 release .....4**
  - 2.1. Major New Features .....4
  - 2.2. Major Improvements .....5
  - 2.3. Bug Corrections .....6
  - 2.4. Updated Resources from SimplerQMS.....6
  - 2.5. Key improvements released by M-Files.....6
- 3. Feature Deep Dive .....7**
  - 3.1. Approval and Review Groups .....7
  - 3.2. Revision History on Document Classes .....8
  - 3.3. Product Update Actions .....9

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## 1. Introduction

### 1.1. Purpose of the Document

This document describes the differences between SimplerQMS 3.1 and SimplerQMS 3.2. It serves as a comprehensive reference to help users understand the changes and improvements introduced in the latest software update.

### 1.2. Objectives for SimplerQMS 3.2 based on customer feedback

SimplerQMS 3.2 is largely shaped by the invaluable feedback from our users. We've listened and acted upon your input to make meaningful changes. Reference numbers (SQ numbers) are included to ensure transparency and keep you informed about how your feedback has directly influenced the enhancements and updates in this release.

The changes are divided into major and minor updates of existing functionality coming with SimplerQMS 3.2.

There are no prerequisites in SimplerQMS 3.2 to be met or managed by customers prior to roll-out.

### 1.3. Planned release dates

The release to the Training Environment for exploring the new features will take place over the weekend beginning 2024-05-03.

Customer updates will start on the weekend of 2024-05-10 and are scheduled to conclude by 2024-05-19. All updates will be performed outside of business hours to minimize disruption.

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## 2. Summary of 3.2 release

### 2.1. Major New Features

#### Approval and Review Groups

##### **Simplified role assignment with Approval and Review Groups**

QA Responsible users can set up Approval and Review groups to be used on Documents, Templates, Collections, and Quizzes, allowing users to assign tasks to entire teams or departments at once. You can customize whether each team member must complete the task or if a single team member's completion suffices. This new feature simplifies the assignment of users and ensures flexibility in task completion when entire departments are involved. Initial creation and setup of these groups are limited to QA Responsible users, but they can be delegated and managed by an assigned Responsible Person afterward. (SQ-404, SQ-108)

#### Revision History on Documents

##### **Revision History Configuration for Document Classes**

The Revision History feature is designed to streamline the process of tracking changes between document versions. This is done by embedding this information directly into the document's metadata for the following document classes: Quality Documents, Recorded Issue Documents, Audit Plan Documents, and CAPAs. The option is configurable and controlled at the Document Type level, letting you determine where revision history is mandatory. When enabled, these document types will have a new field on the Metadata Card requiring users to document "Changes in This Version" before routing for approval. The full Change History is then added to the released PDF page, just before the Signature page. (SQ-343)

#### Product Items

##### **Product Item Updates through New Action Type**

The new Product Update Actions introduce a selectable Action Type field, offering a choice between the existing Standard Action and a new Product Update option. This new feature allows you to update values for Product Items like Short Title, Product Number, Product Type, and Description through the related Action. For updates to take effect, the Product Item must be part of an active Change Request, and the Action must relate to that same Change Request. This provides a seamless way to align product details during change management processes. (SQ-619, SQ-454)

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## 2.2. Major Improvements

### Person

#### **Automate Availability with Leave End Date Field**

When a user is set to Unavailable, a new Leave End Date field appears on the Metadata Card. Once the specified date is reached, the system will automatically set the user status back to Current. This feature simplifies managing user availability by eliminating the need for manual updates when employees return from leave. (SQ-534)

### Product Item

#### **Improved Product Management**

### Masterdata

The Product Type field allows you classify Product Items based on their stage or purpose in the manufacturing process, providing more accurate data organization. You can fully control the value list for this field, with a new Product Type object controlled by the Metadata Administrator, allowing you to create custom classifications to fit your specific needs. (SQ-4)

### Learning Rule

#### **Learning Rules only update after approval**

Learning Rules in the "Awaits Updates" status will not generate training records for newly added documents, templates, or quizzes until it is approved again. This change ensures that only approved Learning Rules trigger training records, providing better control over training processes and reducing the risk of unauthorized training changes. (SQ-681)

### Document Management

#### **Archive Field Renamed to Label for Clarity**

### Masterdata

The Archive field has been renamed to Label for improved clarity and usability. This change does not affect the field's functionality; it simply provides a more intuitive naming convention to help users understand its purpose. If you previously used the Archive field, it will exist in the same place as Label without any other operational changes. (SQ-676)

### Learning Rule

#### **Performance Optimization**

SimplerQMS has developed a new backend application handling the Approval and Review flow, designed to improve system performance by reducing unnecessary system calls. (SQ-678, SQ-673, SQ-672)

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### 2.3. Bug Corrections

- SQ-693:** Missing Periodic Task carry-over settings  
**Fix:** Added settings for Periodic Tasks that allow relations to Affected Processes, Customer Audits, and Files to carry over from a completed task to the next scheduled one.
- SQ-698:** Fixed default values for Learning Rule Grace Period  
**Fix:** Default values have been changed from 2 Weeks to 14 days, as the Week option was discontinued.

### 2.4. Updated Resources from SimplerQMS

As part of our ongoing commitment to deliver improvements, we have developed updated version(s) of relevant procedures and templates that can be integrated into your QMS following the latest release. Our aim is to ensure that these resources remain current and aligned with the most recent advancements.

- Download the latest version of our Document Control SOP containing information on the new Approval and Review Groups.

Along with the release of system improvements, we aim to streamline access to our monthly release notes. From this point forward we'll be posting all our release notes on [this page](#). We recommend bookmarking it to stay up-to-date with all future updates.

### 2.5. Key improvements released by M-Files

**Description:** Word-to-PDF conversions can cause text to be incorrectly aligned in the resulting PDF

**Standard Feature:** Server changes were introduced to mitigate the issue of text being realigned in the PDF Processing of Word Documents.

**Description:** Number formatting incorrect in Word-to-PDF conversion with M-Files Compliance Kit

**Standard Feature:** When M-Files Compliance Kit converts a Word document to PDF, decimal numbers can be shown incorrectly in the resulting PDF. has been fixed for Word Documents.

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### 3. Feature Deep Dive

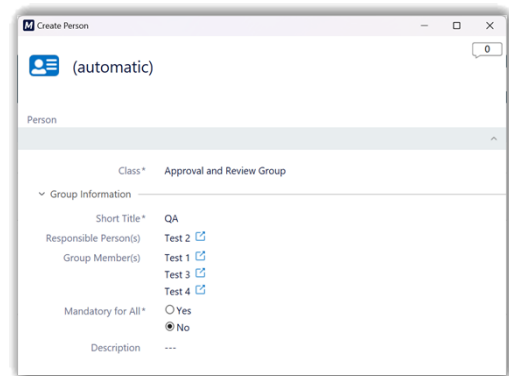
#### 3.1. Approval and Review Groups

Creating and managing Approval and Review Groups is straightforward. As a Quality Assurance Responsible user, start by creating a Person and select the Class "Approval and Review Groups". Here, you can give the group a title, assign a responsible person for group management, and choose its members.

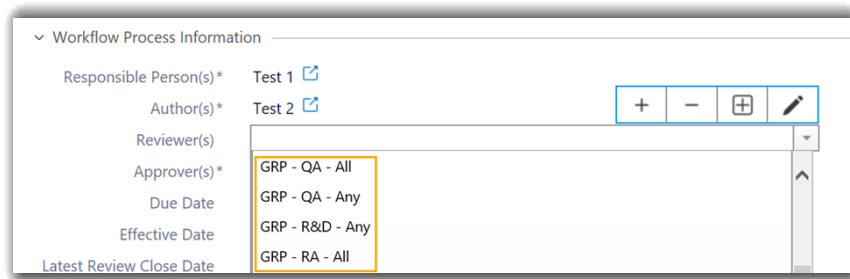
The "Mandatory for All" field determines whether the group is an "All" group, requiring all members to complete the task, or an "Any" group, where only one member needs to complete it.

Each group requires approval from Quality Assurance Responsible before it can be used.

The QA user as well as any assigned responsible person can manage the group members or even deactivate it if needed.



Once a group is created, it can be assigned to review and approval tasks on all Document Classes, Templates, Document Collections and Quizzes, just like any regular user. When the relevant state is reached, all members will receive notifications about the new pending assignment. The workflow dynamics differ based on the type of group assigned—whether it's an "Any" or "All" group. In the case of an "Any" group, the task is considered complete once any member of the group takes action. For an "All" group, all members must complete their assigned tasks for the overall task to be considered finished.



Before activating Approval and Review Groups, your company's relevant procedures should be adjusted to allow for group approvals and reviews.

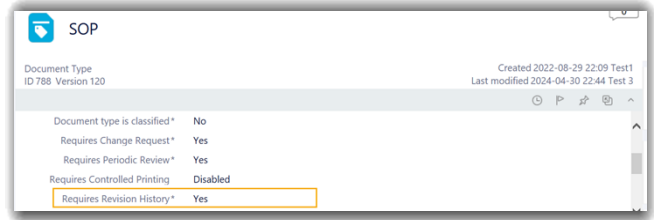
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### 3.2. Revision History on Document Classes

To start using this feature, the Metadata Administrator identifies which Document Types should require Revision History and then enables the setting.

To allow a phased rollout and control over when this feature is activated, all existing document types are set to "No" upon upgrade.

This approach gives you the flexibility to choose when and how to enable Revision History in your workflows.

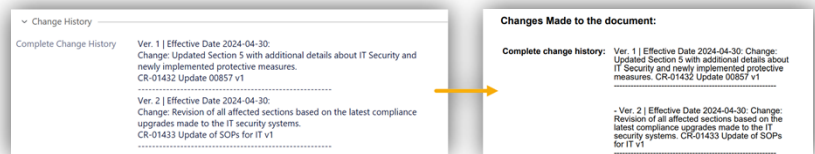


Once enabled, documents within the selected types will require users to fill in the "Changes in This Version" field before sending them for approval, capturing the details of the latest changes.



Documents currently in draft are updated with this requirement immediately, while released documents will require this field upon their next update.

Once changes are recorded, the full Change History is stored in a metadata field and included in the released PDF document, appearing just before the signature page. If a document is controlled by an associated Change Request, this connection is automatically reflected in the Change History as well.



For our existing customers, [this quick guide](#) outlines best practices for transitioning from document-based revision history to this built-in feature.

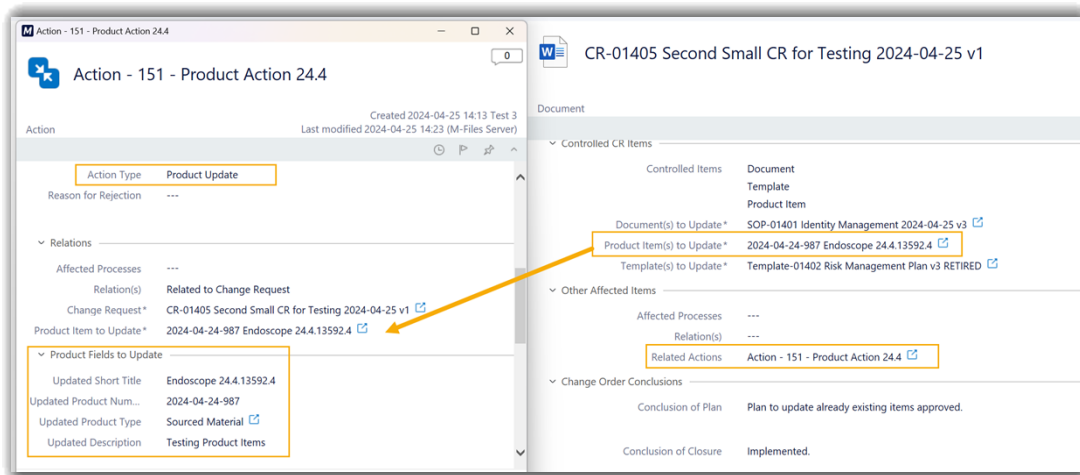
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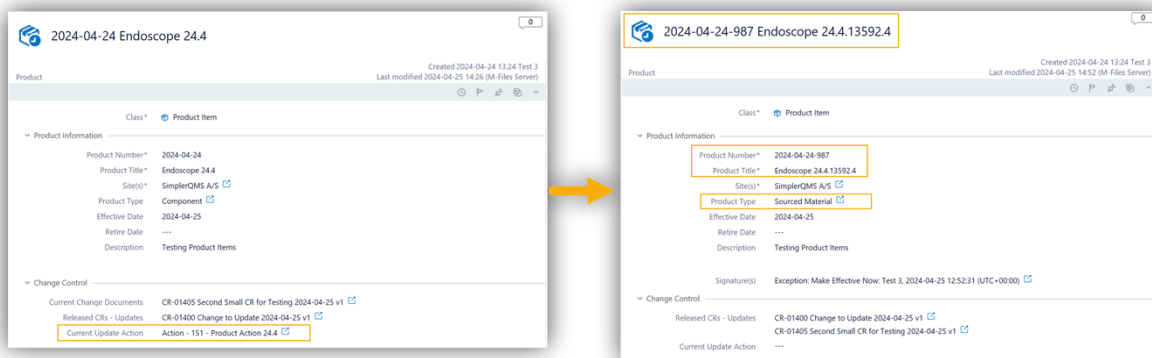
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### 3.3. Product Update Actions

The process starts by linking the updatable Product Item to a Change Request. This workflow is integrated into the Change Control, ensuring that any updates go through the correct approval workflows, reducing the risk of errors or unauthorized changes to a product item. Once the Change Request Plan is approved, create a Product Update Action and connect it to the product item. Both the action and the product item must be associated with the same Change Request for the updates to occur.



After the action is submitted, the responsible assignee will have preloaded information from the current product item, which can then be modified as needed on the Action metadata card. When the action is completed and the Change Request is approved, any changes made through the action are automatically applied to the product item.



**Signatures:**

<b>Controlled Document Approved:</b>	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.	
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<b>Controlled Document Approved:</b>	I hereby state that I have found no errors in the contents of this controlled quality document. The document is ready for release.	
Name:	<b>Jacob Sjørsløv</b> simplerqms.com\js	
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