

Department: R&D

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Reviewer(s): Jacob Sjørsløv; Marc Murphy
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Sjørsløv; Reka Fodor

Release Notes for SimplerQMS 3.1

Version History

Version	Date	Description	Author
1	2023-10-02	First version of release notes for SimplerQMS 3.1	Reka Fodor

Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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Contents

- 1. Introduction3**
 - 1.1. Purpose of the Document.....3
 - 1.2. Objectives for SimplerQMS 3.1 based on customer feedback.....3
- 2. Summary of 3.1 release4**
 - 2.1. Major New Features4
 - 2.2. Major Improvements5
 - 2.3. Minor updates:6
 - 2.4. Bug Corrections7
- 3. Feature Deep Dive8**
 - 3.1. Non-Quality Records – File Class8
 - 3.2. Visual Workflows9
 - 3.3. Home Dashboard.....10

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Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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1. Introduction

1.1. Purpose of the Document

This document describes the differences between SimplerQMS 3.0 and SimplerQMS 3.1. 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 3.1 based on customer feedback

SimplerQMS 3.1 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 our users informed about how their feedback has directly influenced the enhancements and updates in this release.

The changes are divided into major and minor updates of existing functionality from SimplerQMS 3.1.

There are no prerequisites in SimplerQMS 3.1 to be met or managed by customers, prior to roll-out of SimplerQMS 3.1.

Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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2. Summary of 3.1 release

2.1. Major New Features

Non-Quality Files

New document Class

The File class is tailored for non-quality related documentation, providing a seamless solution for efficient organization and management of your files. Optional metadata enables you to organize your files with ease and find them in view structures together with your quality documentation, creating more transparency between departments. Filed records maintain the original file name and format without PDF conversion. (SQ-260, SQ-370)

Home Dashboard

Personalized metrics right on the front page

A revamped home dashboard, putting personalized metrics at your fingertips. Stay on top of pending training, actions and tasks, and effortlessly manage documents assigned for your review and approval, all from one convenient hub. (SQ-461)

Visual Workflows

Gain a clear, visual representation of workflows

Easily gain a clear, intuitive representation of our workflows, identify the next and previous steps, and access valuable additional information through convenient links to the Knowledge Base. (SQ-198, SQ-426)

Customer Audit

Manage customer audits

Enhancing your audit management capabilities within SimplerQMS, customer audits receive the same comprehensive feature set as other audit classes. This change is aimed at simplifying your audit management and ensuring that you can maintain detailed records of your customer-related audits. (SQ-247)

Permission Delegation

Delegate Responsibility during Extended Leave or Departure

You can now delegate Responsible Person and Author permissions from one user to another, whether on a permanent basis or until a specified expiry date. Documents on classified document types are respected by this feature. (SQ-61, SQ-403)

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2.2. Major Improvements

Supplier Audit flow **Added workflow for documentation**

Supplier audits feature has an added workflow path for collecting requested documentation during the audit. This provides an alternative to the supplier issue/CAPA process or confirming no findings during the audit. Updated workflow will be added to KB shortly. (SQ-469)

Recorded Issues **Initial review before Issue Handling**

All recorded issues now allow the option of an initial review process before being sent for Issue Handler Assessment, allowing more stakeholders to provide data and resolution on issues raised. Updated workflow will be added to KB shortly. (SQ-447)

Equipment **Reassign to Responsible Person(s)**

Supplier
Tasks & Actions

In editable states for equipment, suppliers, actions, or tasks the existing Responsible Person (RP) has the ability to define new Responsible Person(s) in the metadata. This feature allows for a smooth transition of responsibility, refreshing the metadata and ensuring that these objects are assigned to the newly defined individuals. (SQ-504)

Doc Control **Reassign to New Author(s)**

Quiz

In the states of New Draft and Await Updates the "Reassign to New Author(s)" state transition is applied for Templates, Change Requests, CAPAs, Recorded Issues and Collections. This reassignment can be carried out by either the Responsible Person or the Process Manager. Clicking the state transition refreshes the document's metadata and ensures that the document is assigned to the newly defined authors. (SQ-485)

CAPA **View all CAPA Actions in a property**

A new metadata property designed to collect and consolidate all CAPA-related actions on the CAPA metadata card, making it easy to assess if all necessary actions are related. (SQ-494)

Justification to reschedule CAPA Effectiveness

A mandatory justification property is implemented when rescheduling CAPA Effectiveness Assessments. The added metadata property ensures that

Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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important details surrounding the rescheduling decision are captured and documented. (SQ-488)

Product

Product Lot expiry date

Product lots now include optional expiration date and transition to an "expired" state on the defined date. Product Managers can choose to archive expired lots so that these archived lots no longer can be used as a reference for documentation. Expired lots are assigned to Product Managers, who will have the authority to archive the expired lots once all related documentation is completed. (SQ-489)

Controlled Printing

Available on old documents and templates

If Controlled Printing is enabled, it now applies to all documents and templates, including historical ones created before the feature was turned on. While overlays are not applied to these pre-existing records, you can still utilize Controlled Printing to create controlled print items as needed. (SQ-500, SQ-502)

2.3. Minor updates:

UI Improvements

Icon unification

We've made an important enhancement to the visual consistency of our platform. Icons have been unified across different workflow states and object creator buttons. With consistent icons, navigating through workflow states and creating objects becomes more straightforward, reducing the learning curve and ensuring a seamless user experience for all our users. (SQ-169)

Periodic Task

New property for Affected Processes

Processes can now be related to periodic tasks. (SQ-509)

Audit

Processes available on all audit classes

Regulatory Inspections and Supplier Audits now have a metadata field for Affected Processes to capture the audit scope. (SQ-97)

General

Optimised Built-in views

Views related to the Home Dashboard have been enhanced to provide comprehensive data. All Documents view includes the File class so quality and

Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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non-quality records can be viewed together seamlessly. Enhanced Person view includes columns for delegated employees.

2.4. Bug Corrections

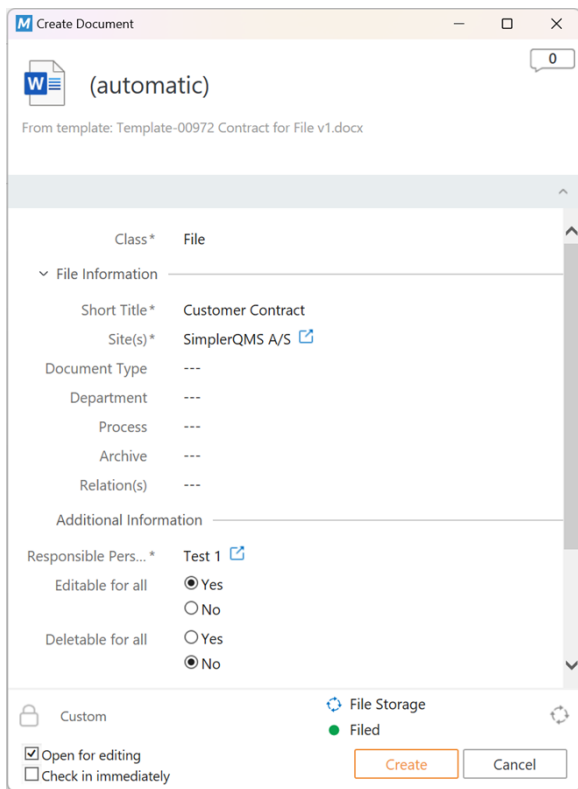
- 1. SQ-539:** Due Date remains filled on docs and templates after update
Fix: Due Date emptied out at Awaits Updates on Docs and Templates
- 2. SQ-488:** CAPA Effectiveness Assessment title captures for learning state
Fix: State name removed from default title

Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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3. Feature Deep Dive

3.1. Non-Quality Files – File Class

Introducing Files, that offer a versatile and streamlined approach, suitable for various document types that are not considered a quality record such as sales documents, financial reports, research notes, emails, and more.



You can simply drag and drop files for quick storage with a minimum requirement of added metadata. Alternatively, you can make use of the structured guidance of templates to easily draft documents, ensuring that every piece of documentation within your organization starts from a quality-approved foundation.

With optional metadata, you can maintain the flexibility to organize files within your existing view structures. Additionally, you have the option to add relations, ensuring that you can track and connect files as needed to meet your specific organizational requirements.

Editable and deletable toggles grant you the freedom to decide whether only the responsible person can delete or an added author can edit the document or if

everyone who has access can do it. Access to the files is governed by the standard permission settings defined by the site in addition to project permissions and classified document types. Hence, access permission follows the same principles as for Quality Documents.

Deleted Files can be restored for 90 days when moved to delete state. After 90 days the files are removed from any search or view but any deleted file can be recovered by SimplerQMS A/S support.

As opposed to the Uncontrolled Attachment, where a unique ID is assigned, the document type becomes a part of the title and the attachment turns into a PDF automatically, File titles

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will only have the short title and **no** document number or document type added to it. The file format is also kept as the original filed record without PDF conversion per overview table below.

The File class expands capabilities in SimplerQMS by adding a document management solution on top of the management of quality documents and records. The chart below outlines some key differences between the main document management classes.

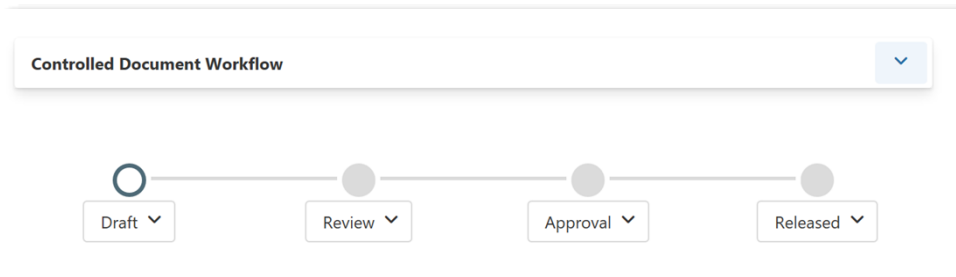
Class	QMS – DOCUMENT CONTROL CLASSES			NON-QUALITY FILES
	Templates	Quality Documents (QD)	Uncontrolled Attachment (UA)	File
Purpose	Templates are mainly used to create QDs (i.e. SOPs, WIs, SOP attachments/supporting documents). A template may also be used for creating other Templates or Non-Quality files. Use the target class on the template's metadata card to determine what class a template is converted to when used to produce a document.	QDs are CFR21 Part 11 quality controlled documents and records with a draft, review and approval workflow. QDs serves a broad range of use cases (SOPs, WIs etc) and can also be used as supporting documents to CRs, CAPAs etc.	Often used to store external documentation (i.e. suppliers ISO certificates) without the need for an approval flow or released documents with electronic signatures.	The File class is often used to store non-quality related files (i.e. finance or marketing files) usually stored in file folders (SharePoint). Files can be related to all other files and objects (Persons, Departments, Processes etc) in SimplerQMS.
Workflow (Simplified)	Draft->Review->Approval Update or Retire	Draft->Review->Approval Update or Retire	Filed Update or Archive	Filed Deleted
Deletable	No (Retired)	No (Retired)	No (Archived)	Soft deleted (Restorable)
Electronic signature	Yes	Yes	No	No
Released (PDF) version generated	Automatically	Automatically	Automatically	Not supported
Version control	Yes	Yes	No	No
Audit trail	Yes	Yes	Yes	Yes
Training possible	Yes	Yes	No	No
User group access	All Contributors	All Contributors	Uncontrolled Attachment	Non-Quality Files (currently tied to All Contributors)
Doc Type examples	Determined by target class	SOP, WI, Meeting Minutes	Supplier Certificate, External Training Record	Finance Report, Customer Tracker, Sales Quote
Unique ID	Part of the standard number sequence and added in the document title Each template is assigned a System generated unique ID on Metadata	Part of the standard number sequence and added in the document title Each document is assigned a System generated unique ID on Metadata	Part of the standard number sequence and added in the document title Each attachment is assigned a System generated unique ID on Metadata	Not part of the standard number sequence and not added in the document title Each file is assigned a System generated unique ID on Metadata

For more details, please read the work instruction on our knowledge base or write to support@simplerqms.com to get guidance on how to get started.

Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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3.2. Visual Workflows

One of the standout features of this update is the ability to view a graphical representation of your workflow. Instead of sifting through complex lists or trying to decipher textual descriptions, you can now see your workflow laid out in a clear and visual format. This not only makes your processes more accessible but also enhances your overall comprehension of how they work.



With this feature, you can easily identify the next and previous steps within your workflow. This simplifies decision-making and allows you to anticipate what actions are needed to keep your processes running smoothly. It's like having a roadmap right at your fingertips.

Symbols Legend

Symbol	Description
○	Current Step
●	Completed Step
●	Next Step
—	Completed transition
—	Uncompleted (future) transition
-----	Completed steps - not visible in schema
-----	Uncompleted steps - not visible in schema

You

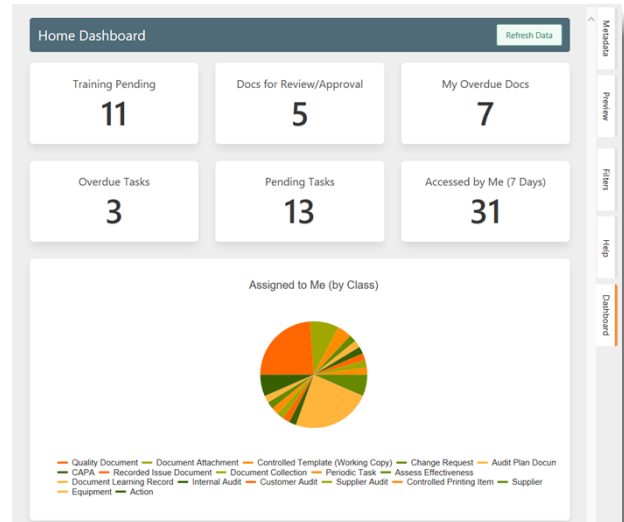
can access additional information through links to the knowledge base. This means that if you ever need more details or context about a particular step or aspect of your workflow, it's just a click away, promoting informed decision-making.

This feature is currently only available on the Windows Client.

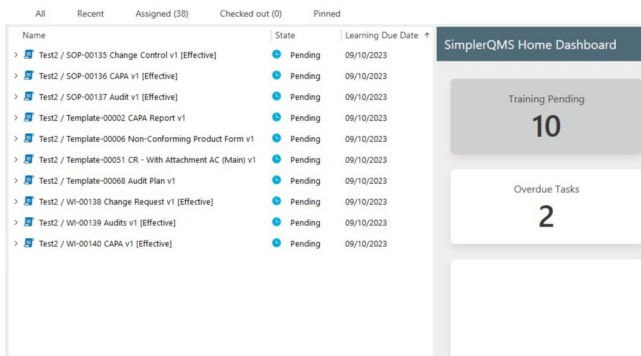
Department: R&D	Process: Deployment	Effective Date: 2023-10-04	Doc no.: 03375	Version: 1
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3.3. Home Dashboard

A significant upgrade to the Simpler QMS start screen, designed to enhance your user experience and provide valuable insights right at your fingertips. Our revamped start screen now features a personalized dashboard that puts essential metrics front and center, making it easier than ever for you to stay on top of your tasks and responsibilities.



You don't need to navigate through layers of




menus or sift through lengthy lists. A simple click on any tile takes you directly to a corresponding view, so you can address pending items with ease. It's all about making your workflow smoother and more efficient.


With real-time updates, you can see the latest assignments that require your attention. Your dashboard keeps you in the loop, allowing you to respond promptly to new tasks and responsibilities as they arise.


Last update at: Sun Oct 01 2023 13:27:00 GMT+0200 (Romance Daylight Time)

This feature is currently only available on the Windows Client.

Signatures:

Controlled Document Approved:	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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