8.5.0

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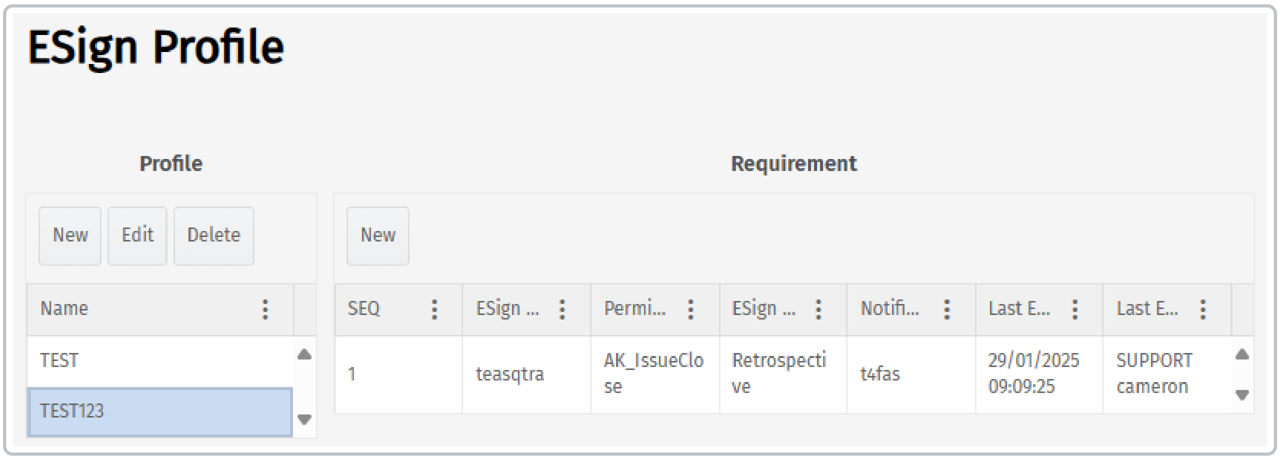
Relates to version
Tags: 8.5

e-Signature Profile

In regulated environments it is often a requirement for records to be signed and to comply with the FDA CFR 21 Part 11 regulations. Any electronic signature must contain the meaning of the signature (e.g., a signature for collecting the data, a signature for approving it, etc.).



e-Signature Profile provides a universal place to define the meaning of signatures, who may sign and when they must sign. It will be rolled out to various areas of the product but initially, will be used for the data collection for device and batch history records (eDHR).

eDHR Profile

In regulated environments, it is required to demonstrate that manufacturing was carried out according to design specifications and to the required quality standards.

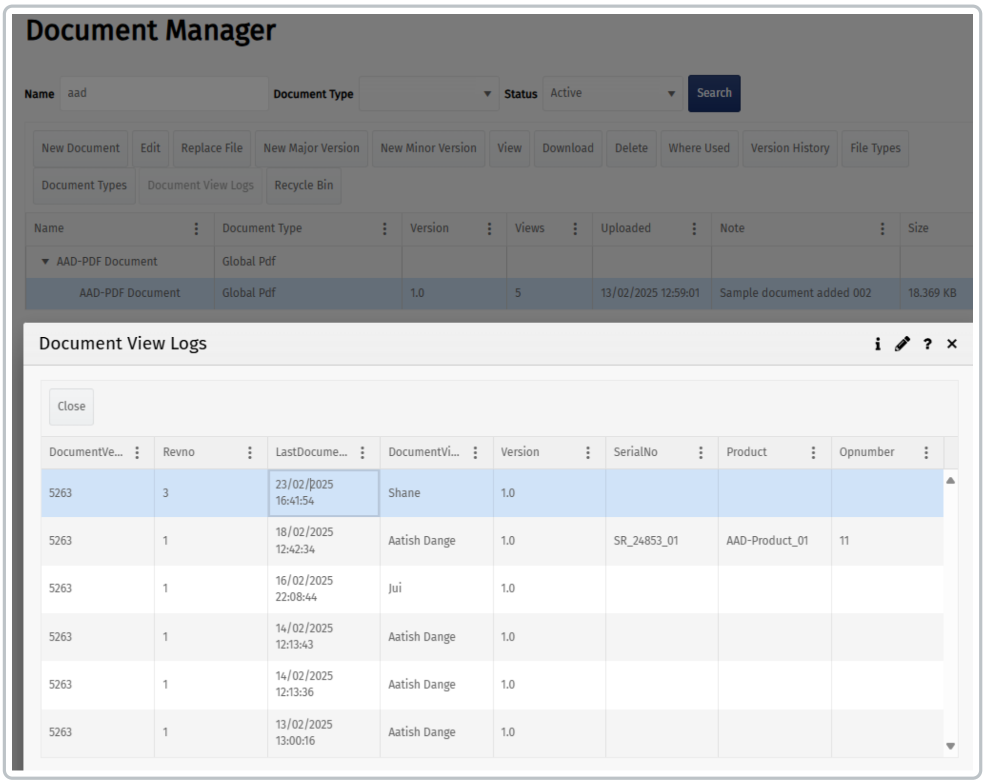
Medical device regulations, including ISO 13485 and FDA CFR 21 part 11, mandate that records are collected and retained in a secure way. eDHR profiles allow you to define what data needs to be stored in a blockchain-based immutable audit trail for device or batch history records.

This provides certainty that the records are stored in a compliant and immutable way that can be easily demonstrated to an auditor.

Document View Log

In 8.5, the **Document View Log screen** can be accessed from a link added to the **Document Manager** screen.

The log shows who viewed the document and when. When viewed in a workflow action, the log also provides the serial number, product details and operation number of the job being worked on at the time the document was viewed.



Power BI Time Zone Configuration

When you collect data in one time zone but view it in another time zone, in some instances you might want to view it in your local time and in others, you might want to view it in the originating time.

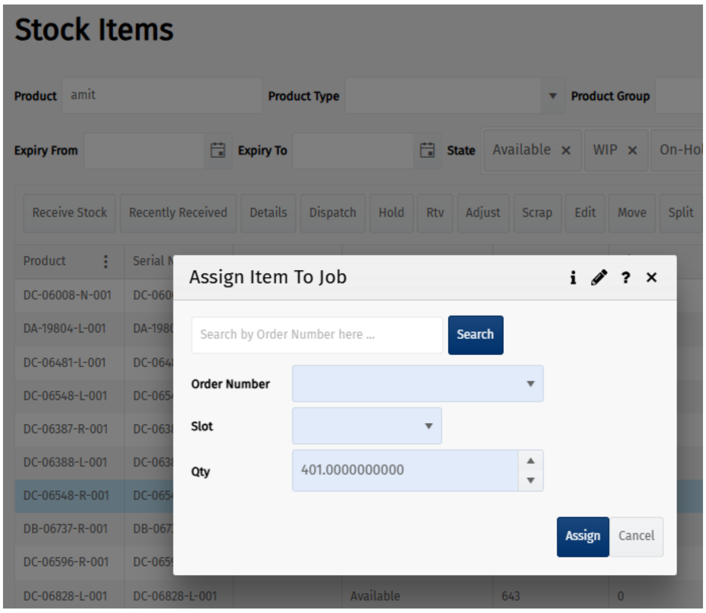
In 8.5, Power BI reports have been enhanced to display either the local time zone (your browser time) or the plant time zone. This update accommodates companies with multiple factories across different time zones. The time zone that is displayed is defined in the design of the report. Both local and other time zone options are now supported.

Kitted Material Usage

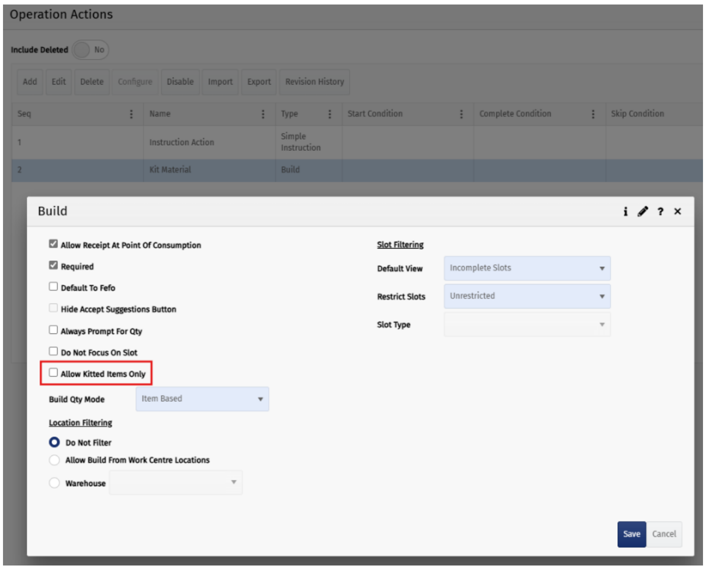
Prior to 8.5, although you could assign material to a job through kitting, you couldn’t restrict material use to only kitted material. Now it is possible to restrict that if you choose to.

The **Allow Kitted Items Only** checkbox has been incorporated into the **Build** action configuration screen within **Operation Actions**. This feature limits the materials used in the job to only those that have been specifically assigned to it. When ticked, it only lets you use kitted items for the current job.

You assign an item to a job as shown in the image below.



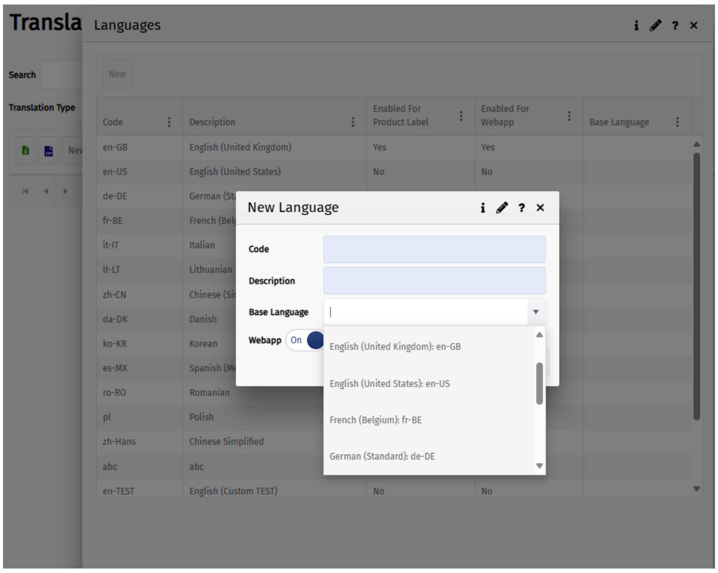
To restrict the job to using just its kitted/assigned items, the **Allow Kitted Items Only** checkbox must be ticked in the **Build** configuration screen.



Custom Language Creation

The product ships with translations for certain core languages. If your language wasn't supported by the core translations, you could create a custom language based on one of the core translations. For example, if the system only had regular French, but you wanted Canadian French, you could create custom translations for Canadian French. Historically, you would need to maintain all the custom translations from the point of creation.

In 8.5, you can base a custom language off a system language so that you only need to override the phrases you want to override but leave the rest of the translations as is. When new releases come along with new phrases, the custom language will inherit what's updated in the base language without requiring you to do anything.



Unlike system languages, custom language translations are not affected during an upgrade.

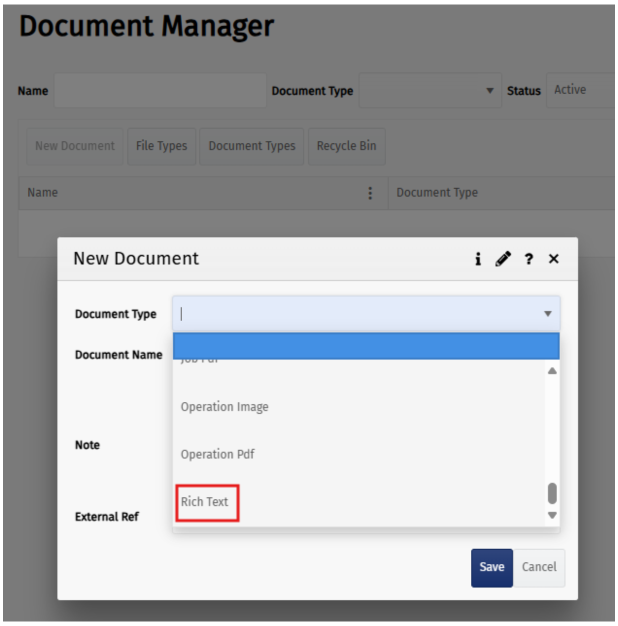
After the custom language is created, you can define translations for it. The system will check if a translation exists for the custom language. If it doesn't, it checks if one exists for the base language. If it doesn't, it will use English.

RTF Document Management

Historically, the only way to create a Rich Text Format (RTF) document was in a workflow action. You had to create an RTF action and put the RTF document on the action. It wasn't version controlled, it couldn't be referenced from anywhere else, and you couldn't add it on a page with anything else like an image or a case data collection. You could only use the RTF document from within the action.

In 8.5 we now support the management of RTF documents in the Document Manager. This update enhances the flexibility and usability of RTF documents. It allows you to do the following:

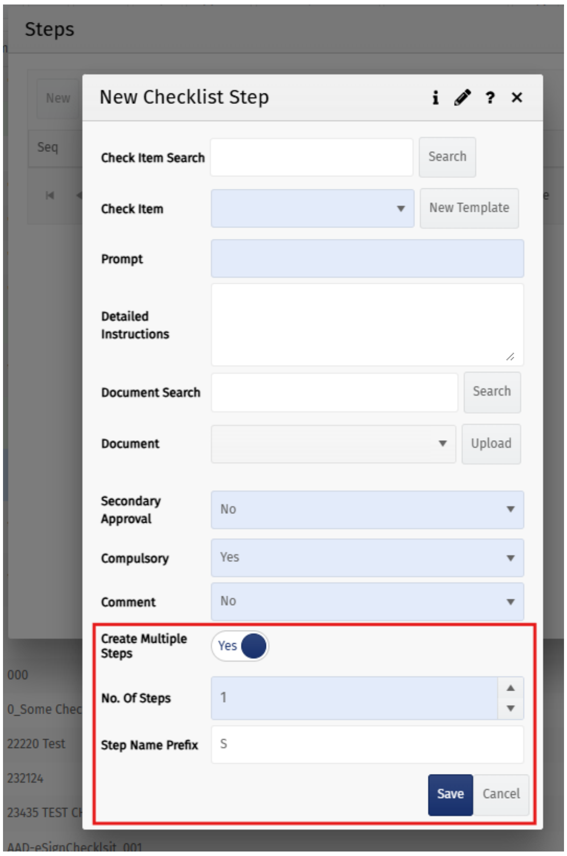
- Version control them which adds a layer of accountability and traceability.
- Reference them from within workflows like any other document. This means that you can now put an RTF document on an action along with other controls.
- Reference the same RTF document from multiple actions.



Checklist Simplification

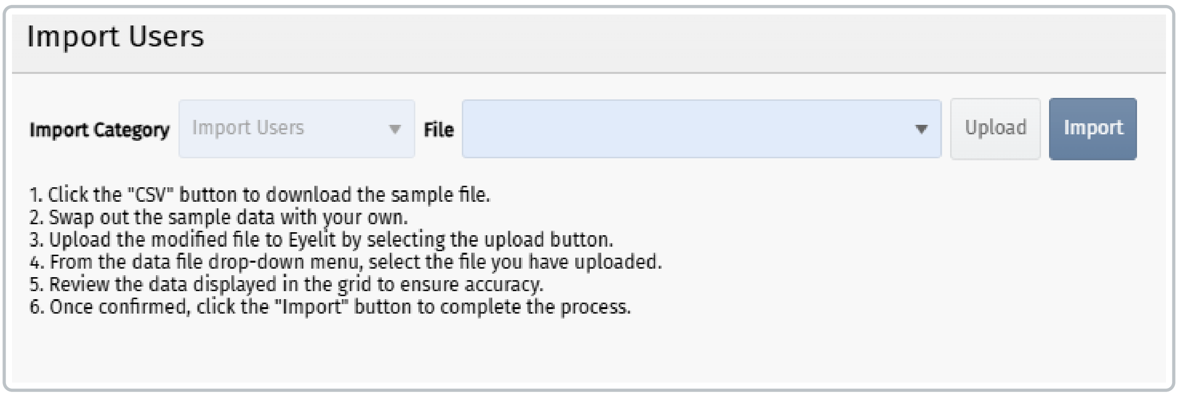
In Checklists, the **Steps** screen was simplified and references to “samples” were removed as it was ambiguous and caused confusion (for example, multiple measurements might relate to multiple positions on a single sample).

You can create multiple steps by setting the “Create Multiple Steps” toggle to *Yes* and specifying how many steps to create. Then provide the prefix to use for the name of each step created.



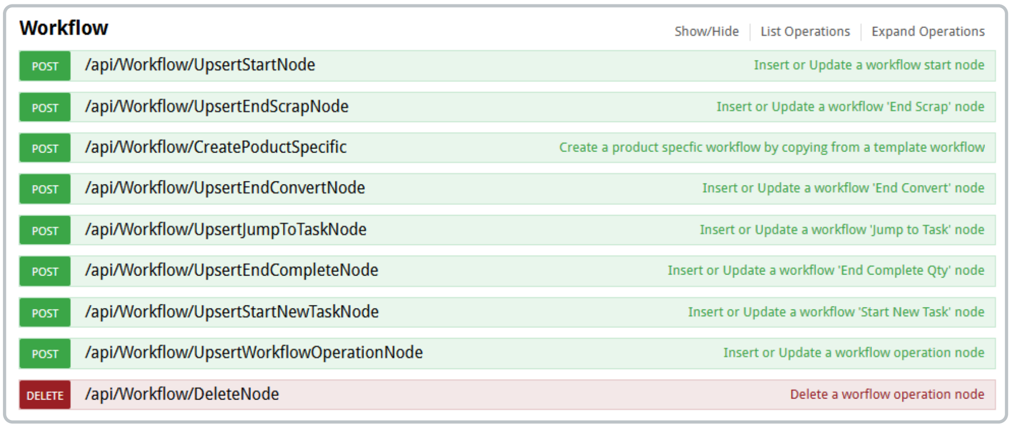
Import Users Instructions

The format for importing users in a CSV format created confusion. In 8.5, the **Import User** screen provides clear instructions for importing users in a CSV file.



Public API

The Workflow API was extended to include operations against workflow nodes.



Job on Hold

It used to be possible to put a job on hold whilst someone was working on it. In 8.5 validation was added to check that there is no active activity log for the job. If it is being worked on, it will throw an error when trying to put it on hold.

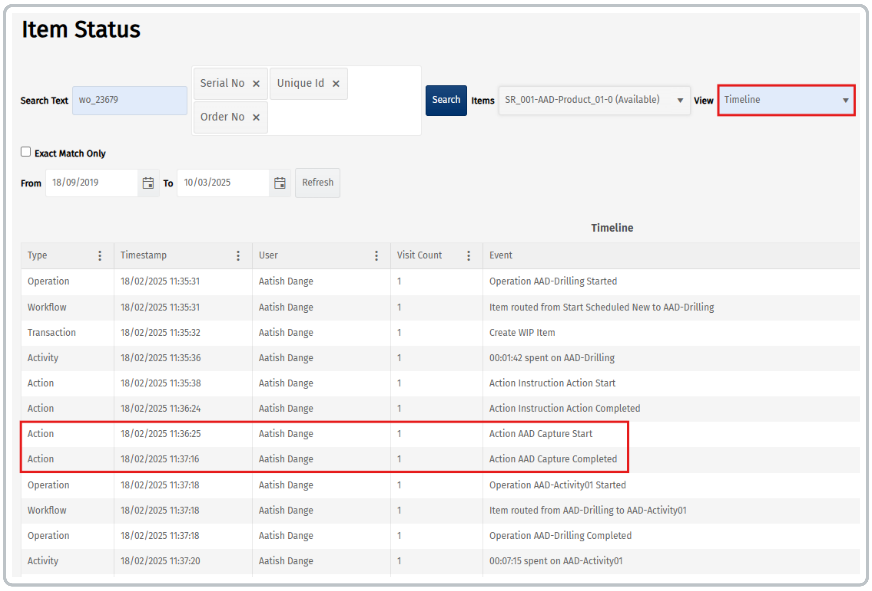
Workflow Signatures

When we create a workflow and approve a workflow version that requires a signature, it must be signed. However, it used to be possible to obsolete this work without requiring a signature.

In 8.5, you must provide a signature to obsolete a workflow that required a signature when it was created as obsoleting a workflow could have a significant impact.

Item Status Timeline

Action start and completion times were added into the Item Status, Timeline view.



Inventory Shown on Build Screen in Virtual Test Mode

When we are in **Virtual Test Mode**, you should only be allowed to consume virtual test inventory as you are never able to consume production inventory doing a test.

However, the UI allowed you to select production inventory and then would error when you clicked okay. In 8.5, production inventory does not show and therefore cannot be selected.

Additions to the Recycle Bin

You can create two workflow versions in draft, e.g., ver 2.5 and ver 2.6. You can delete version 2.5 and approve 2.6. Version 2.5 disappears making it look like a version has just gone missing.

To keep track of deleted workflows, and workflow versions, they've been added to the **Recycle Bin** in 8.5.

Workstation Improvements and Database Paging

The Eyelit MES-M workstation has undergone considerable usability and performance improvements. Along with customisable buttons and a less cluttered feel, the workstation now benefits from server-side paging to greatly reduce processing and response times.