Presenters

Bringing together the best in the industry

Gregory DESGRANDCHAMPS

Product manager - Quality

Greg joined the Ennov team in January 2024 after more than 20 years in the pharmaceutical industry. His responsibilities included the management of quality applications – among others the Ennov application - and compliance for computerized systems.

At Ennov, he makes sure that the quality solutions and associated deliverables meet the expectations of the industry. For this, Greg´s experience on the other side of the fence is invaluable.

Objectives

Discover the latest and coming improvements in:

› *The Ennov platform*

› *The Quality Core Model*

to enhance quality management for YOU!
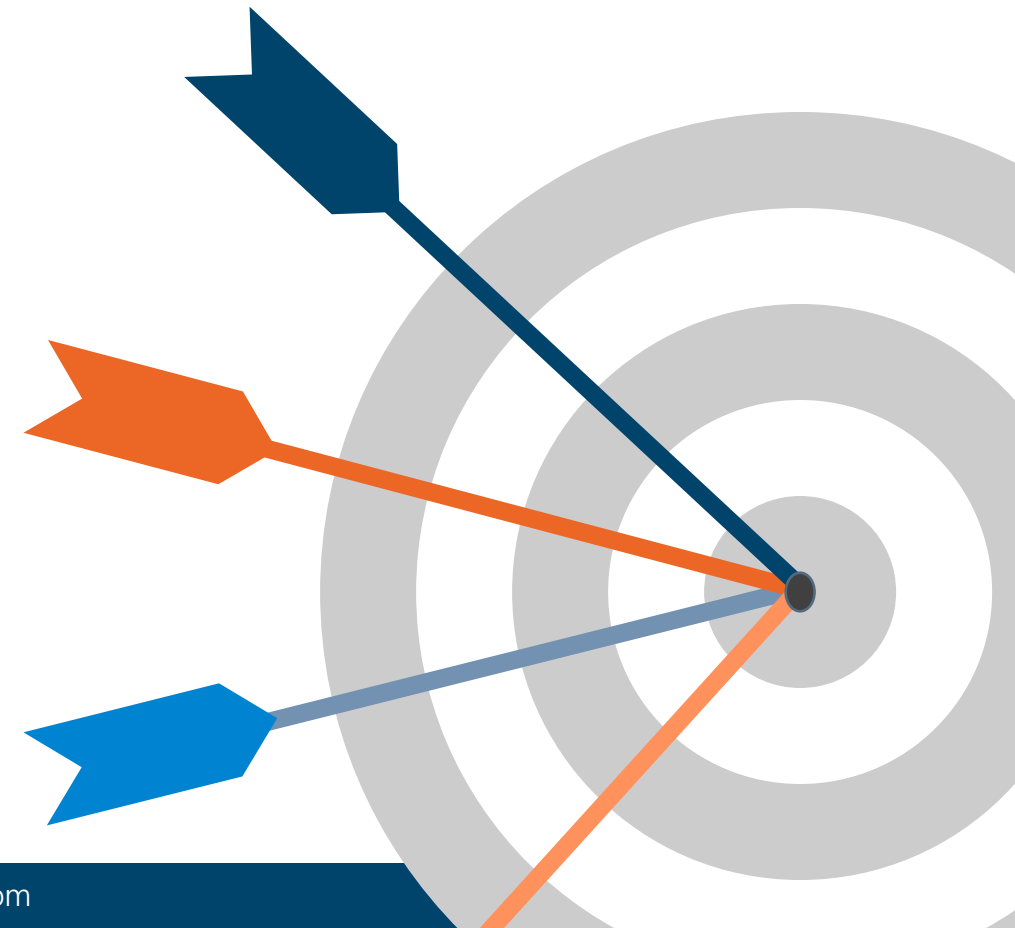
Agenda

1 Core Model

2 Roadmap

3 New features demonstration

1 – Core Model

What Makes Ennov Unique

› A single platform hosting all our Innovations and Technologies

› A comprehensive business management solution that will streamline your operations and ensure compliance.

› Ennov Core Models concept

The concept of Ennov core models

Circles: RIM, RIM Device, Submission Dossier, Artworks, Quality, Promo. Mat., eTMF, CTMS, EDC surrounding central **Master Data**
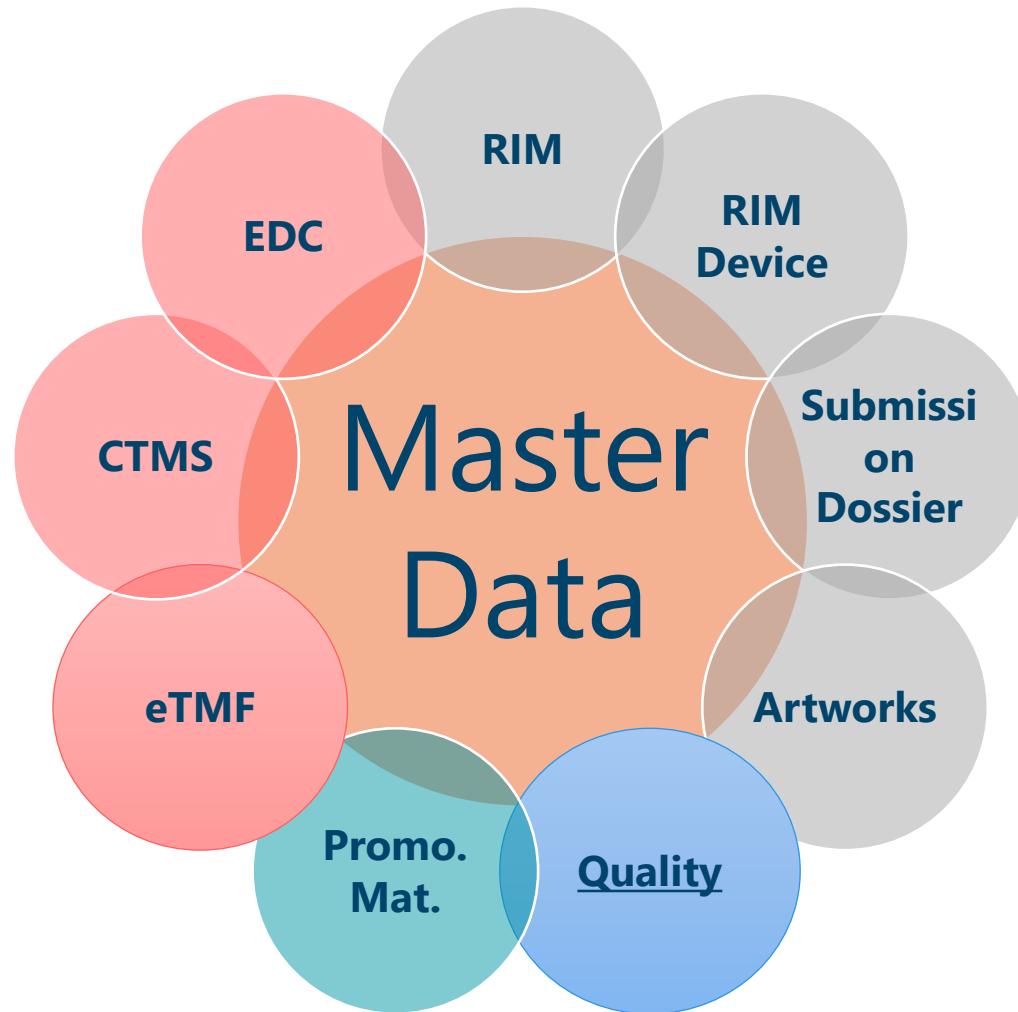
› An Ennov Core Model is an **out-of-the-box** solution

› Design to meet specific **business needs**

› Built around a common core, **Master Data,** on a **unified platform** and **fully configurable**
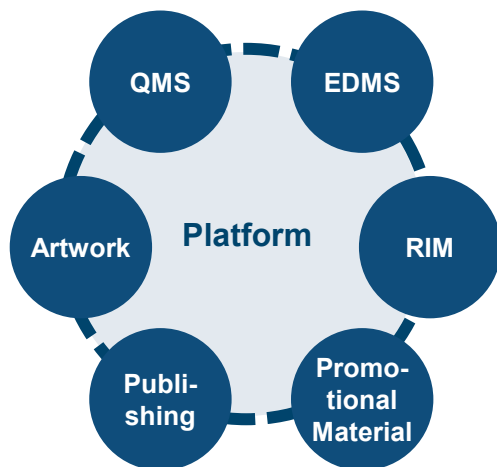
Unified Platform Benefit Example

Change Control – A Cross-domain workflow that benefits from unified data
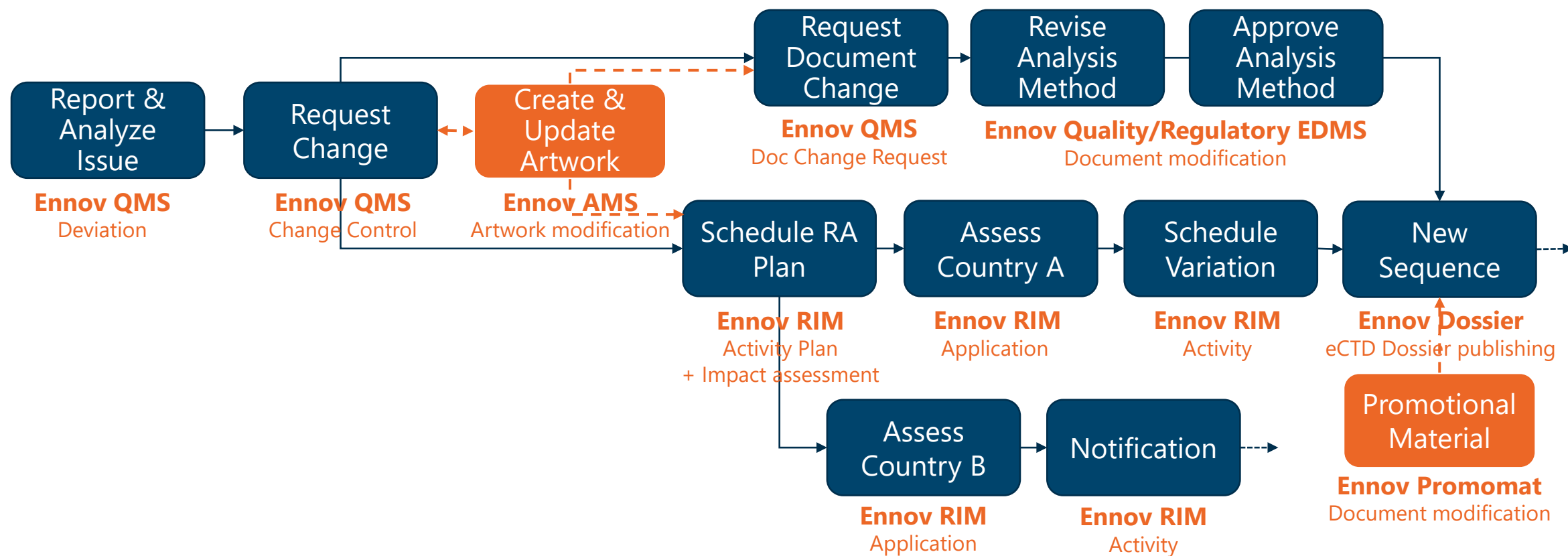
2 – Quality Roadmap

Roadmap

› What?
  › A planned vision of the product's evolution
  › Highlights major milestones, priorities, and direction
  › Insights (regulatory, customer feedbacks, market and tech. trends, and Ennov's strategy)
  › A communication tool, not a detailed project plan

› Why?
  › Align all stakeholders on the strategy
  › Provide visibility, transparency and confidence to customers

› How?
  › There 2 roadmaps
    › New and enhanced **Features** roadmap
    › **Core model** roadmap

Quality Features Roadmap
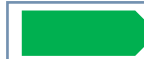
	Current version	Future major version	Future minor version

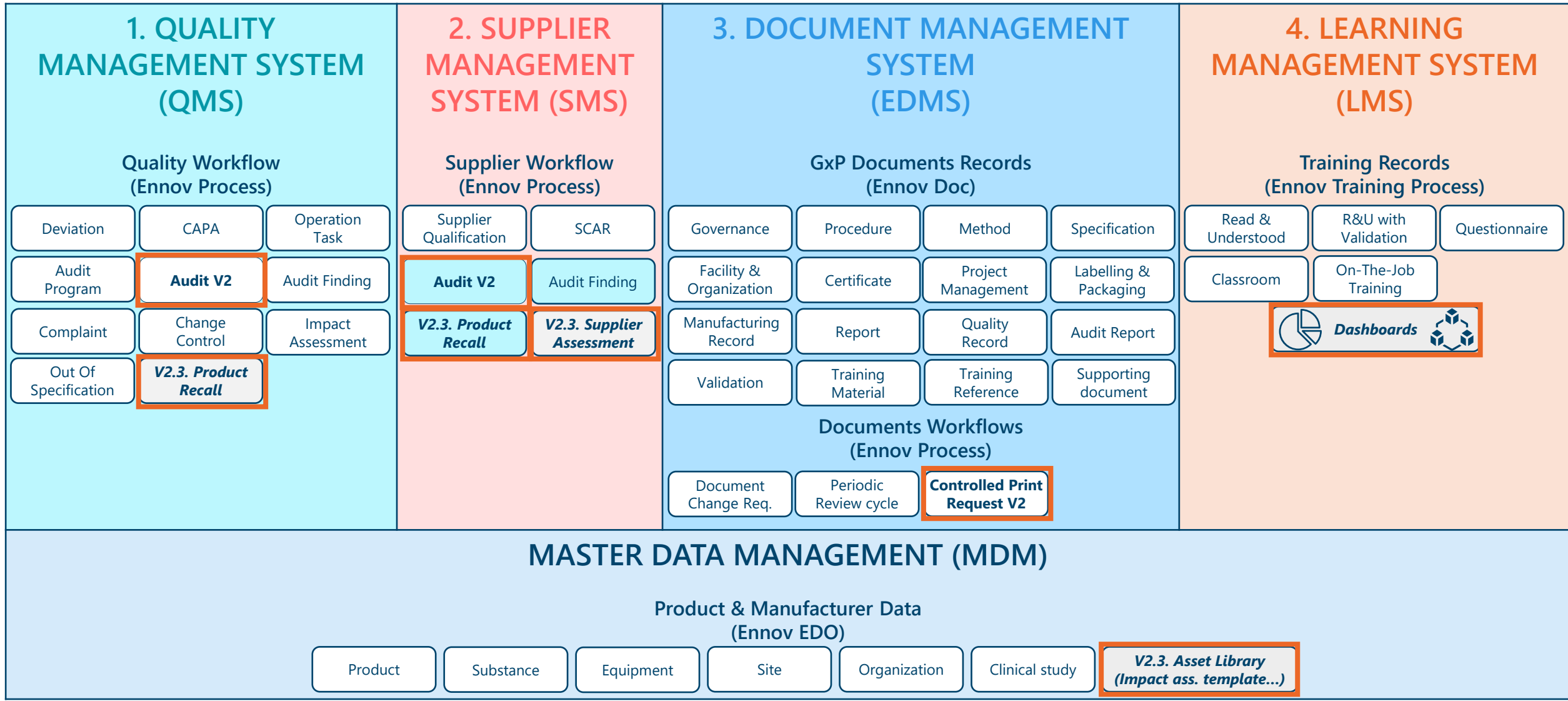|	2025				2026			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
	10.4		11.0		11.1		11.2	
Doc	▸ Hard copy management improvements ▸ Table of content Auto-update		▸ Chatbot to query content		▸ Monitoring of co-authoring ▸ Signature improvements		▸ Co-Author ▸ Acknowledgment data analysis	
Process	▸ Enhanced supplier quality capability ▸ Vote step improvements		▸ Enhanced audit capability		▸ Co-Investigator ▸ External contributors		▸ Summary generation ▸ Target date based automatic process creation	
Training	▸ Out of the box dashboards ▸ Module evaluation improvement		▸ Automatic MCQ generation for a module ▸ Automatized Skills matrix		▸ Training checklist management		▸ MCQ Statistics ▸ Training calendar ▸ Co-Trainer & AI Tutor	
Productivity and business continuity	▸ Content and Document Translation ▸ Summary generation		▸ New Ennov homepage ▸ Comment consultation tracking		▸ Teams & SharePoint Integration ▸ Retention period management		▸ Office 365 viewer	

Quality Core Model v2.3 – October 2025

1. QUALITY MANAGEMENT SYSTEM (QMS)

Quality Workflow (Ennov Process)

Deviation	CAPA	Operation Task
Audit Program	**Audit V2**	Audit Finding
Complaint	Change Control	Impact Assessment
Out Of Specification	*V2.3. Product Recall*	

2. SUPPLIER MANAGEMENT SYSTEM (SMS)

Supplier Workflow (Ennov Process)

Supplier Qualification	SCAR
Audit V2	Audit Finding
V2.3. Product Recall	*V2.3. Supplier Assessment*

3. DOCUMENT MANAGEMENT SYSTEM (EDMS)

GxP Documents Records (Ennov Doc)

Governance	Procedure	Method	Specification
Facility & Organization	Certificate	Project Management	Labelling & Packaging
Manufacturing Record	Report	Quality Record	Audit Report
Validation	Training Material	Training Reference	Supporting document

Documents Workflows (Ennov Process)

Document Change Req.	Periodic Review cycle	**Controlled Print Request V2**

4. LEARNING MANAGEMENT SYSTEM (LMS)

Training Records (Ennov Training Process)

Read & Understood	R&U with Validation	Questionnaire
Classroom	On-The-Job Training	

Dashboards

MASTER DATA MANAGEMENT (MDM)

Product & Manufacturer Data (Ennov EDO)

Product	Substance	Equipment	Site	Organization	Clinical study	*V2.3. Asset Library (Impact ass. template…)*

Quality Core Model v2.4 - 2026

Supplier Management

Quality Management

MDM
Master Data Management

Learning Management

Document Management

Risk Management
- Risk matrix
- Risk review

Design Management
- Requirements
- Design
- Features management
- Verification & validation

Validation Management
- Validation & Qualification
- Calibration
- Non-conformity

Computerized Software Validation challenges

Regulatory Compliance

Documentation

Time and Resources

System complexity

Change management

Risk management

› Regulatory requirements for life science companies

› Ensuring consistent documentation and audit readiness

› Time and Resources consuming

› Require business and technical expertise

Computerized Software Validation challenges

Ennov services ↑

- Compliant with regulations (21 CFR p11, GxP and Annex 11)

- Readiness for GMP Annex 11 revision (2026)

- ISO 9001 & 27001 Quality, Saas & Cloud solutions compliance

- Complete validation file

- Time and Resources consuming

- Change & Version upgrade management

Customer challenges ↓
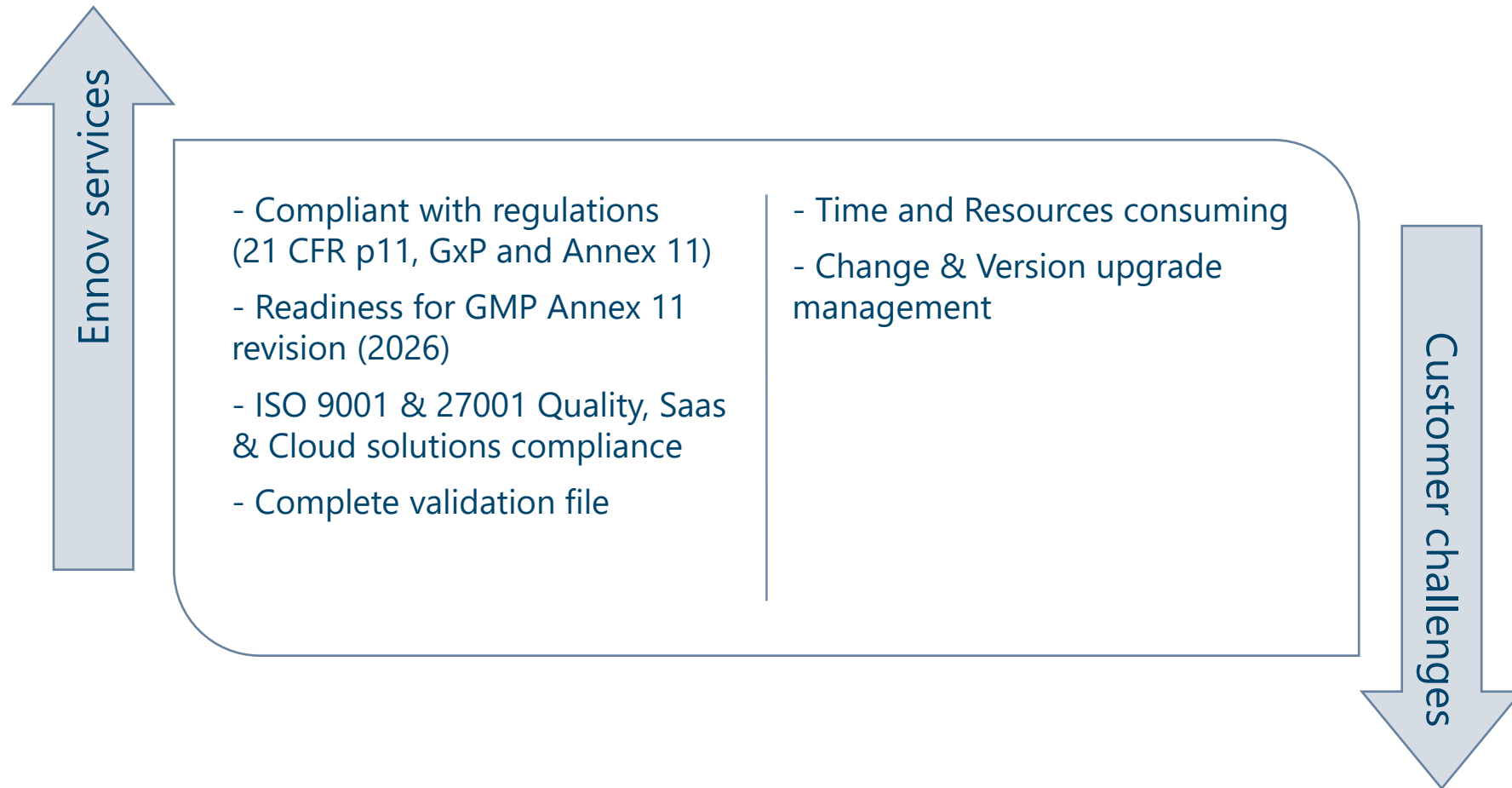
› Statement: CSV is frequently identified as a potential issue in project and update scenarios.

Innovative solution for CSV: Test Automation

› Test automation solution with AccelQ

› Quality Core Model validation is **fully automatized**

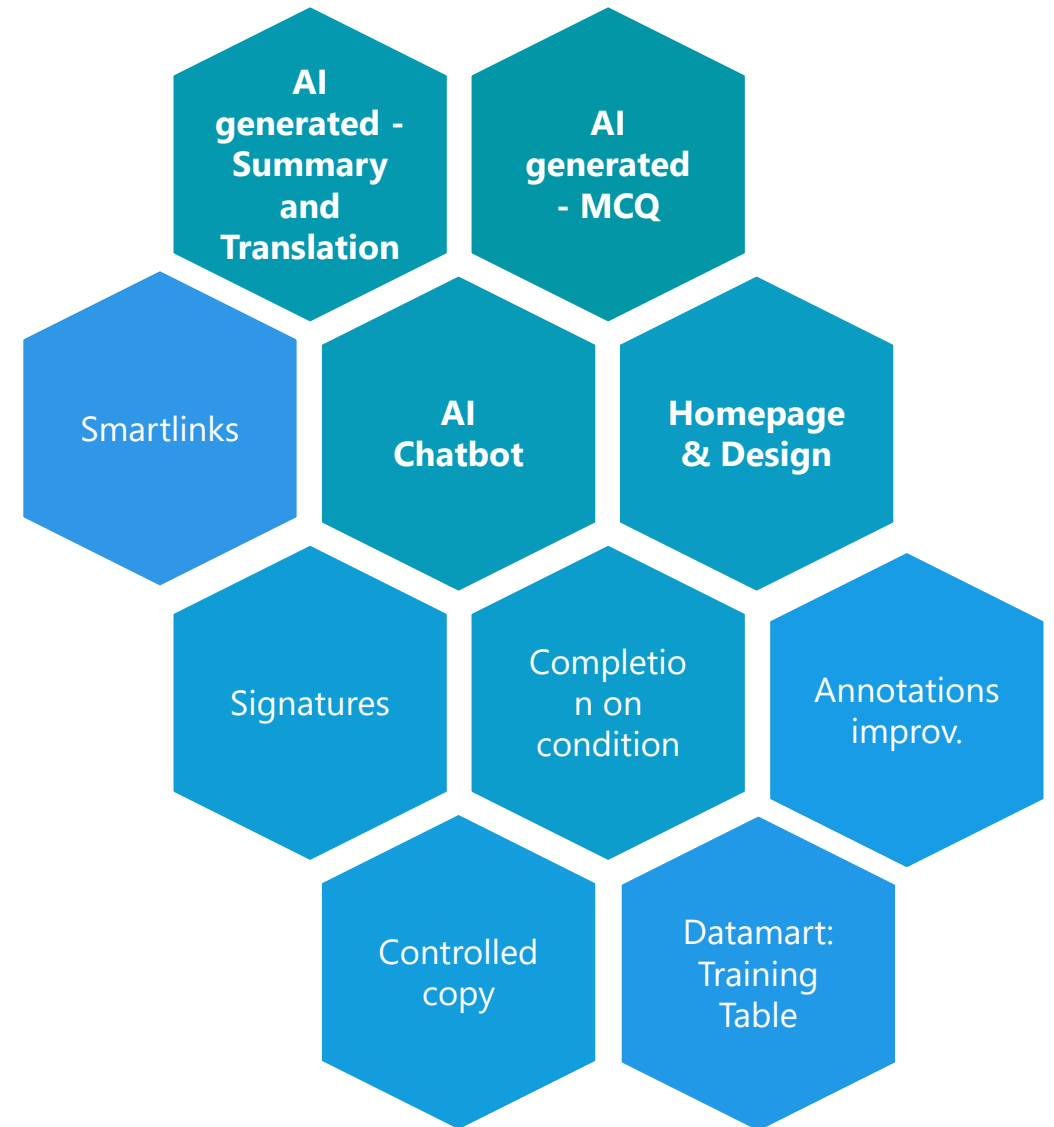› 25 testsheet scripts
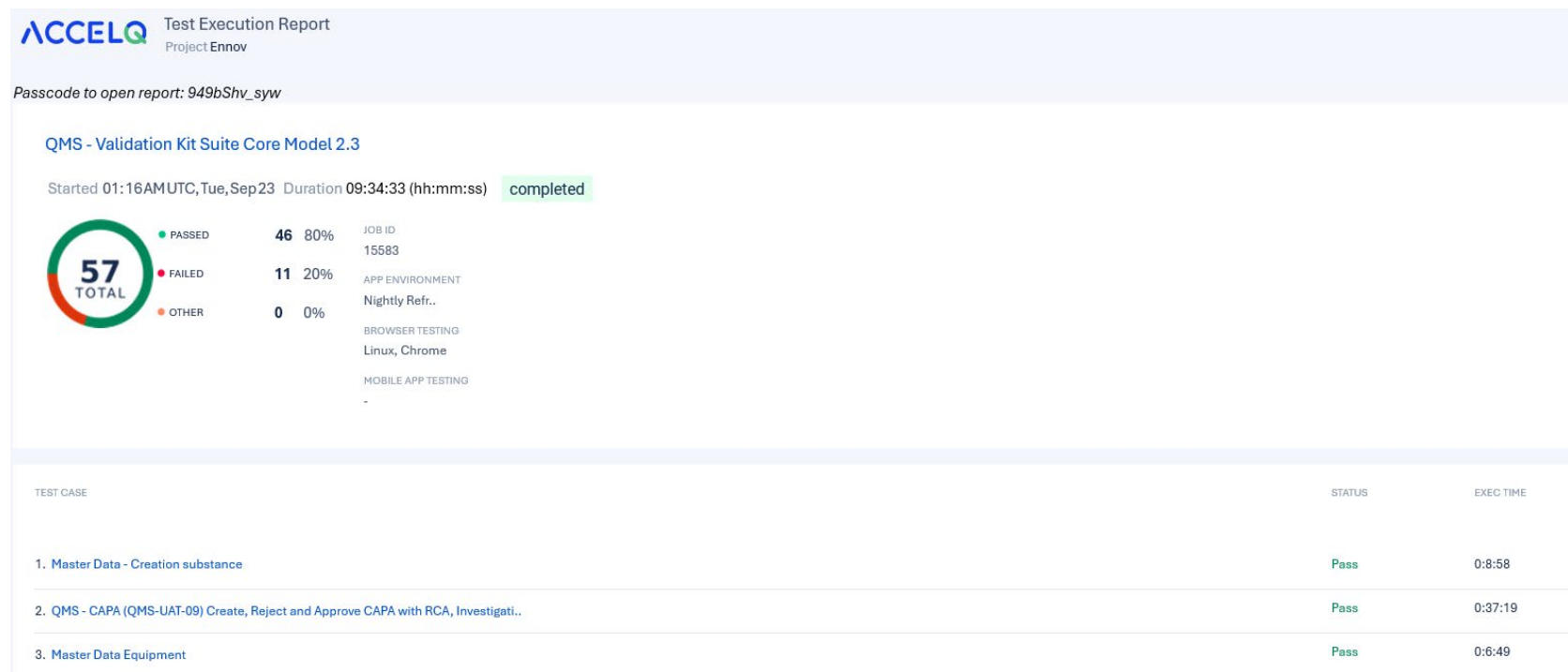
Innovative solution for CSV: Test Automation

› Compelling advantages
  › For Quality of solution,
    › **Autonomous execution duration 9h**
    › Frequent nighttime execution

  › For Customer projects,
    › Core model: Validation documents available
    › Customisation and adjustments: differential validation
      › Manual execution or,
      › Adjustment of automated tests
    › Re-executable during version upgrades or modifications

› Innovation to increase your risks control level, reduce workload and break through barriers

3 – New features demonstration

Looking back over the past 12 months

› 3 new versions

   › 10.3: 2024 October
   › 10.4: 2025 May
   › 11.0: 2025 October

› **More than 20 new features per version!**

› Have a look on Release Notes

AI generated - Summary and Translation

AI generated - MCQ

Smartlinks

AI Chatbot

Homepage & Design

Signatures

Completion on condition

Annotations improv.

Controlled copy

Datamart: Training Table

ennov
Software for Life

Unified Platform
Regulatory
Pharmacovigilance
Quality
Clinical
Commercial

Platform

01 Design and Homepage

› **New Design** to enhance user experience and facilitate navigation

› **New Homepage** to offer a more targeted, visual, and efficient experience
  › Business management oriented
  › Tailored to each user's profile and priorities
  › Complete and concise overview
  › New features
    › Scrolling personalized messages in banner
    › List of comments to view
  › Customizable

02 AI Chatbot

› Use data from the Ennov datasource (documents, processes) to formulate its responses

› Subject to the Ennov AI license

eDoc

03 Annotations enhancements

› PDF annotations available since V10

› Reply to an annotation

› Assign a status to an annotation

› Filters in the annotations panel
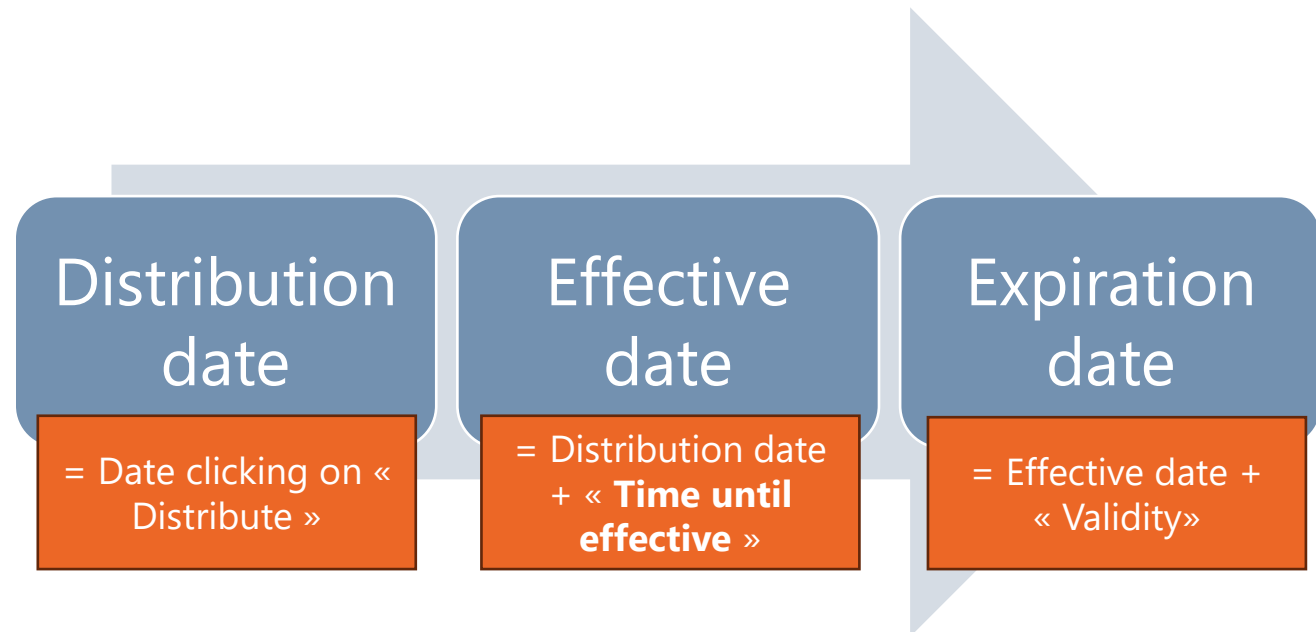
› Saving, retain and viewing intermediate versions

04 Signatory

› 10.3 Certified Signature (subject to license)
  › Adding an Adobe Approved Trust List certificate
  › The signature certificate is downloaded with the document
  › Can be used with Ennov TPS (external signature)

› 10.3 User can modify their signature image from their profile menu

› 10.4 Assign a function as signatory

› 11.0 Option to allow a user to sign at several steps

05 Distribution timeline

› Define a **standard time** between document distribution and effective date

› Configurable option at Unit or Unit-Type level

› The Date of distribution field can be added to the form

Distribution date	Effective date	Expiration date
= Date clicking on « Distribute »	= Distribution date + « **Time until effective** »	= Effective date + « Validity»

06 Archived document

› 10.3 Redesign of Archived document form to improve visualisation

› 10.3 Restricting access to an archived document
  › Accessible metadata
  › Access to document limited to issuer and admin

› 10.4 Cancellation form: ability to exclude or include

07 Acknowledgement / read & Understood (doc)

› Issuer and signatories: Now considered to have read and understood the document

  › No notification
  › No action in to do list
  › Acknowledgement / read & Understood = Distribution date

Return receipts

Last name	First name	User type	Last notification date	Number of notifications	Viewing date (RR)	Read & Understood
admin	Ennov	Electronic	22 May 2025	1		
ADMIN	Ennov	Electronic	22 May 2025	1		
DESGRANDCHAMPS	Gregory	Electronic		0	22 May 2025	22 May 2025
KINANGA	Katell	Electronic		0	22 May 2025	22 May 2025
LAURAT	Arnaud	Electronic	22 May 2025	1		
MASSE	David	Electronic		0	22 May 2025	22 May 2025

08 Hard copies management

› **Identify, verify, secure and trace hard copies**

› Substitute « Controlled print server » module

› A <u>set</u> of new features,
  › Overlayed document on request
  › Enriching available bookmarks for overlaying (header/footer too)
  › Overlay template management
  › New object type in the Quality Core Model: Distribution point

› Can be used with or without EDO and Smartlinks

09 Automatic table of contents update

› Perform during converting a Word document (with Conversion Server)

  › Conversion format: Bookmark only or PDF
  › The document must include a table of contents

› Execution step:

  › Draft conversion
  › Send for approval
  › Distribution

Table of Contents

Introduction 2

Ways of Writing Initial Draft 3

Tools to improve productivity... **Error! Bookmark not defined.**

Editing the final Draft... 3

Conclusion... 4

10   New AI features

› 1 - Documents translation

› 2 - Documents summary

› Create or view "translated" content

› Languages supported to date

› French, German, English, Chinese, Danish, Spanish, Italian, Japanese, Dutch, Polish, Portuguese, Russian

› Other languages on request

› Subject to license (AI)

10.3
11.0

11 Various eDoc enhancements

› "Links to": possible now to link document(s) not yet effective
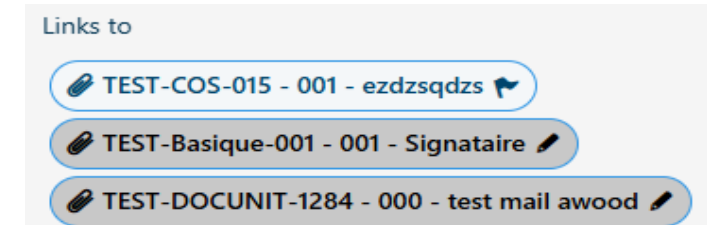
› "Integrate an existing document": ability to hide button

12 Various eDoc enhancements

› Version

    › Label update, "Revision" => "Version"

    › Version number is no longer editable (option in properties)

› Document created from a template

    › Autonaming "[P_REF]_[P_REVISION]_[P_TITLE].extension" (limited to 50 characters)

› Source backup

    › Automatically performed when a contributor checks in the document

Title *

Test version

Reference

Version *

000

Source document *

📄 RD.SP.2115_000_ENNOV11.1 - Overlay and Print control improvements.docx

13 Oct 2025, 16:28   System   Check out backup   SOPEM-0057_v000_Draft_01.pdf

eProcess

13 Improvements to the polling step

› New options for interrupting a voting step

› 1 - Stop as soon as the polling cannot be successful

  › Example: 3 voters, 100% positive votes

    › Voter 1 : Yes => continue

    › Voter 2: No => stop (failure)

Polling

☐ Set a minimum count of positive votes
☑ Set a percentage of positive votes

Required positive votes' minimum percentage

| 100 |

Required cast votes' minimum percentage

| 100 |

The poll / vote's result is evaluated if the minimum percentage of cast votes is reached. The voting step's result is a success if the required minimum percentage of positive votes is reached

☑ Interrupt if polling cannot be successful

› 2 – Interrupt button for unit administrator

› Comment icon on signature

✕ MASSE David
22 May 2025, 10:13
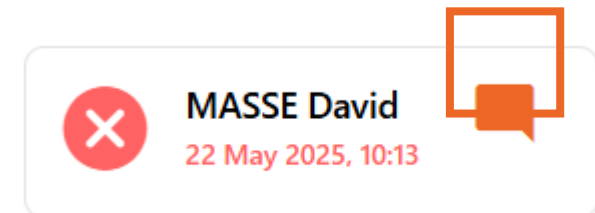
14 Completion on condition

› To automatically execute a "Complete" for the current step

› Replace automatic step "WaitForSubProcess"

› Illustration of a use case:
  › Complete CAPA only when all associated tasks have been completed
  › Managing dependencies between tasks
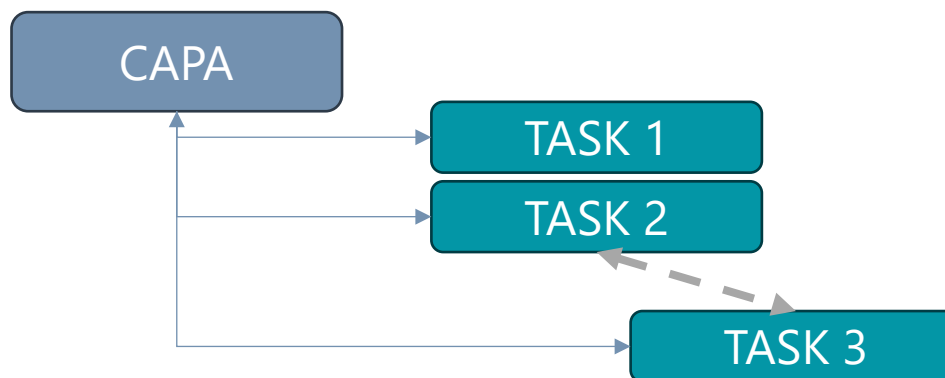
eTraining

15 AI generated Training MCQs

› Feature to generate MCQs:
  › On a document or,
  › On a module

› Combine efficiency and compliance

› MCQ in a minute

› Subject to the Ennov AI license

16 Business table and dashboards

› New generic table: Training

› Available to all (if training module)

› Allow to create Training Dashboards
  › Included in the Quality Core Model

› New widget: Cross table => Skills matrix

17 Various enhancements

› Training scope field (scope of application for dashboard)

› Module evaluation method is generated in last

› Module configuration checks

› MCQ form improvements

› MCQ restricted access

Utilities

18 Users

› Duplicate a user's profile and roles

Copy a user profile and roles

› From a source user to a target user
› No copying of personal data, audit trail and license

› Re-activate a user

Show deactivated users

Activate

› Button to display archived users
› Re-activate button

19 Smartlinks

- › Creation tag also available in creation mode
  - › New attribute « subObject » if true,
    - › Visible in edition mode
    - › Auto close
  - › If « visibleViewMode = true », creation tag also available in consultation mode

- › Automatic update of reverse link in parent process process

```
<div class="customCreationButton" actionName="Subprocess" subObject="true" visibleViewMode="true"
>Create Subprocess(es)</div>
```

20 Comment

> New predefined values available for comment recipients:
>> Recipients (Doc + Process)
>> Contributors, Proofreaders (Doc)
>> Signatories (Doc)
>> Current Step's candidates (Process)
>> Current Step's manager (Process)

> Recipients are displayed