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

Discovering our Ready to use Supplier management solution,

And we will uncover how to unlock the full potential of your data.
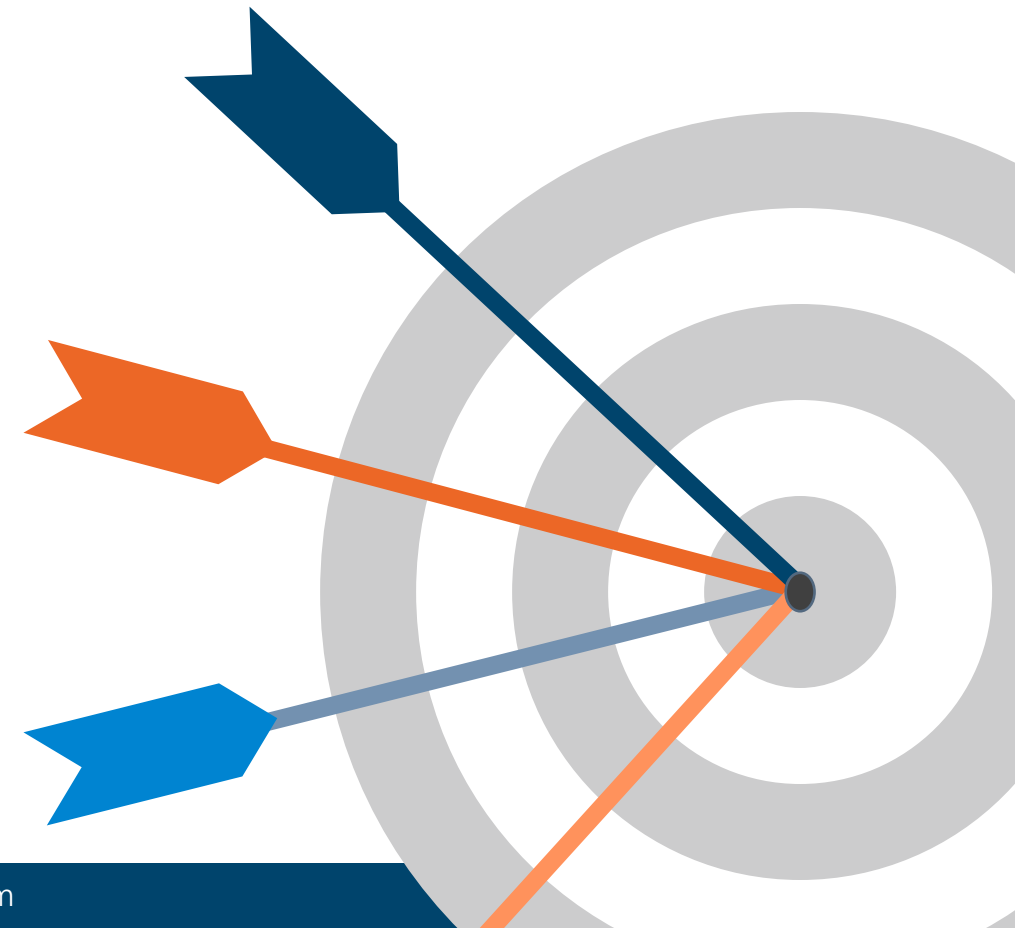
Agenda

1 Introduction

2 Core Model for Supplier Management

3 Use cases demonstration

4 Implementation

1 – Introduction

GMP Requirements for Supplier Management

› Qualification and Approval of Suppliers
  › Companies must **evaluate and approve suppliers** before purchasing materials (API, etc.)
  › Approval is based on **audits, questionnaires, CoA, and documented evidence**
  › A **supplier qualification program**

› Quality Agreements

› Ongoing Monitoring and Requalification (regular review)

› Risk-Based Approach

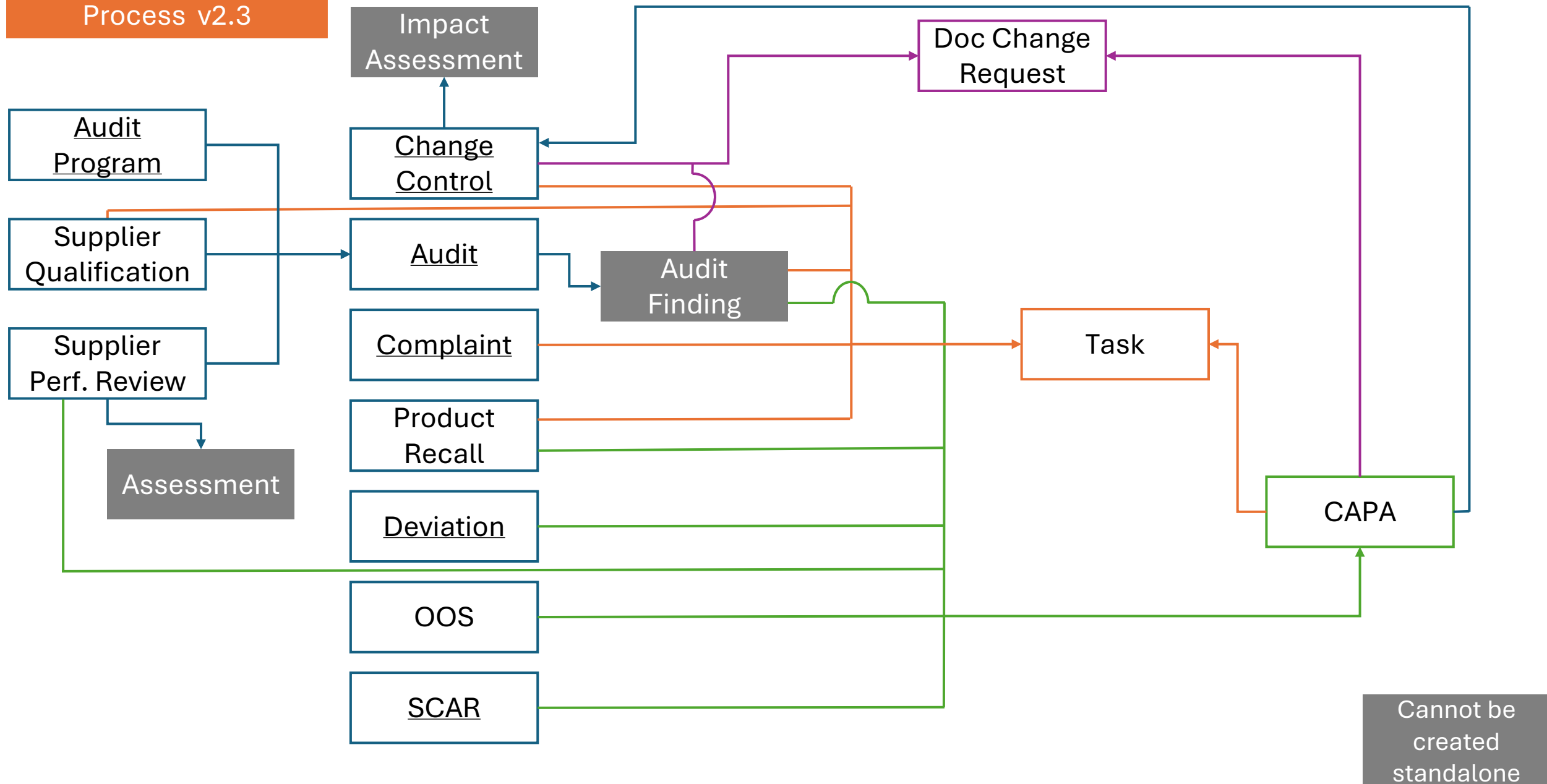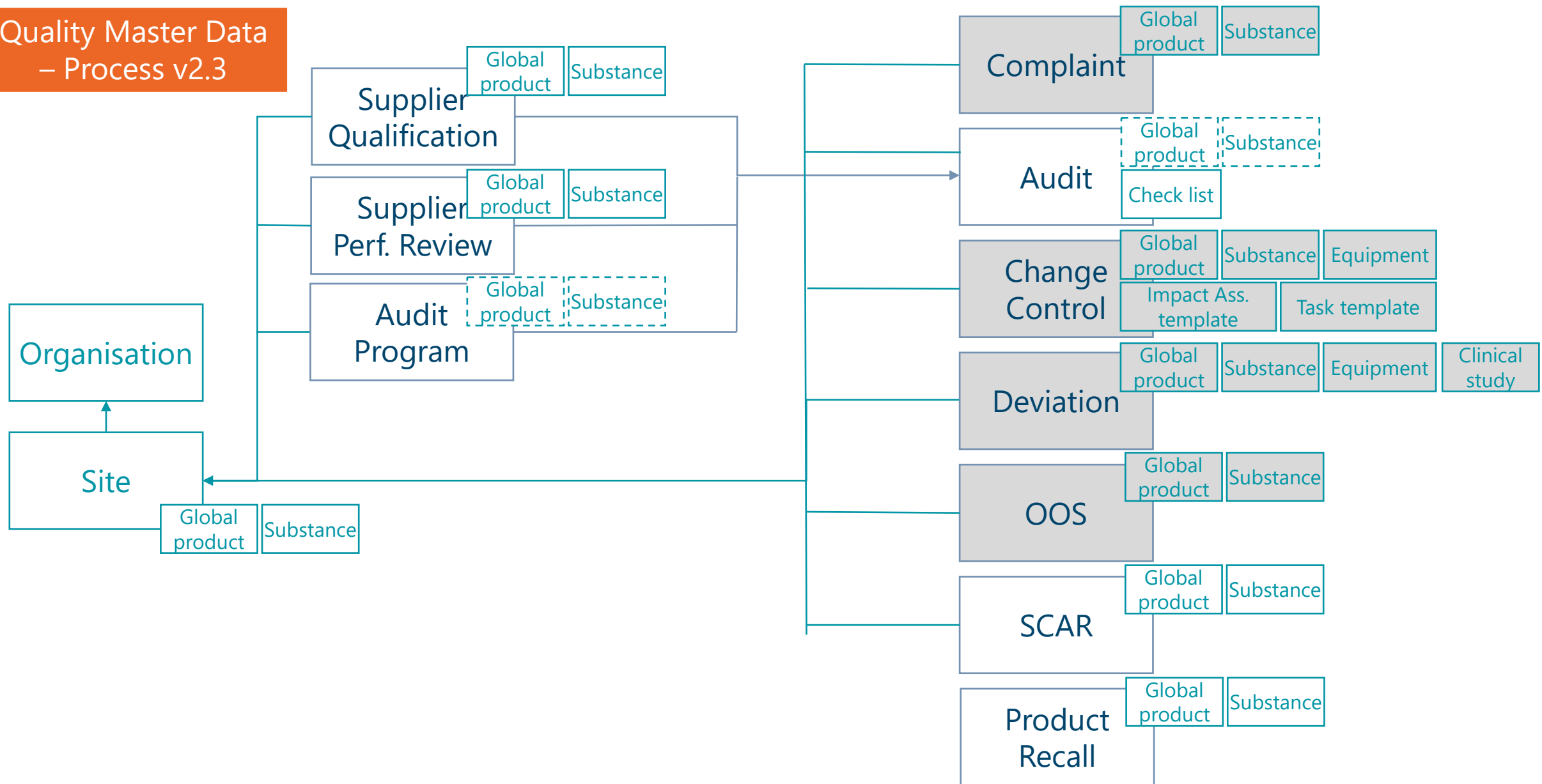# 2 –
Core Model for Supplier Management

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 Master Data – Process v2.3

3 –
Use cases demonstration

Unified Platform

Regulatory

Pharmacovigilance

Quality

Clinical

Commercial

Recurrent problems encountered

Difficulties encountered

› Resources (scattered data, manual processing)

› Data reliability and integrity

› Lack of harmonization / Unconsistency

› Access to data and history

Consequences

› Non-exhaustive history of events

› Reduced productivity

› Loss of information, risk of errors, missed deadlines

› Difficult to leverage quality and manage risks

01 Use cases

Use case 1: Supplier audit

Use case 2: Supplier review

02 Audit and Review preparation: how to use Ennov data?

Audit

Supplier review

Audit and Review preparation

› How ENNOV facilitate the Audit and Review preparation?

- **Form**
  - Links on forms lead to a list of related documents and processes

- **Navigators** : QMS, Supplier management
  - Views group data by category

- **KPIs**
  - Dashboards provide facets for easy monitoring

- **Search**
  - The search page can be customized by type
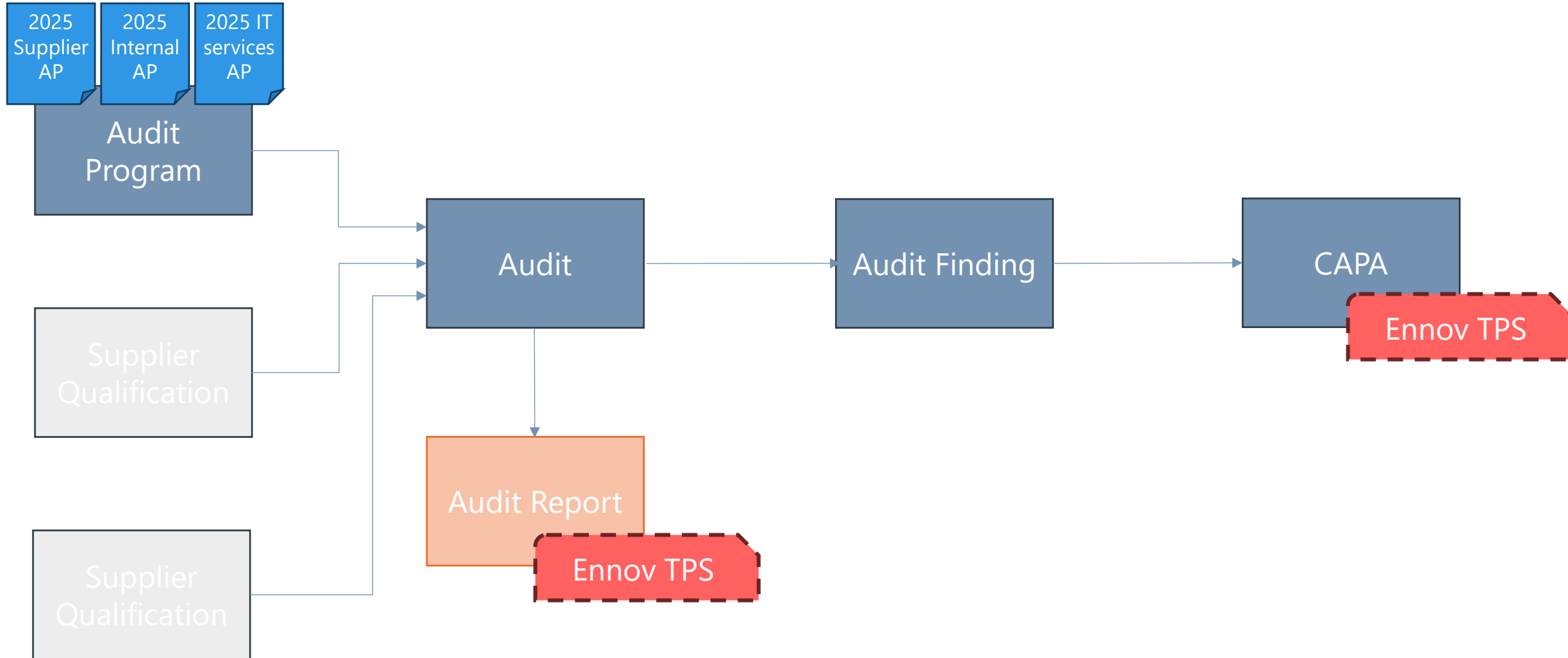
03 Use case #1: Supplier audit

Definition

Demonstration

Use case #1: Supplier audit

› Pharmaceutical laboratories must carry out periodic audits of component manufacturers and critical service providers.

› They must organize an annual audit program to identify the sites to be audited

› The audit is then carried out, the results recorded in an audit report and the actions followed up in CAPAs.

Audit programming → **Performing audits** → **Drafting an audit report & CAPAs**

Use case #1: Supplier audit

Use case #1: Supplier audit demo

04 Use case #2: Supplier review

Definition

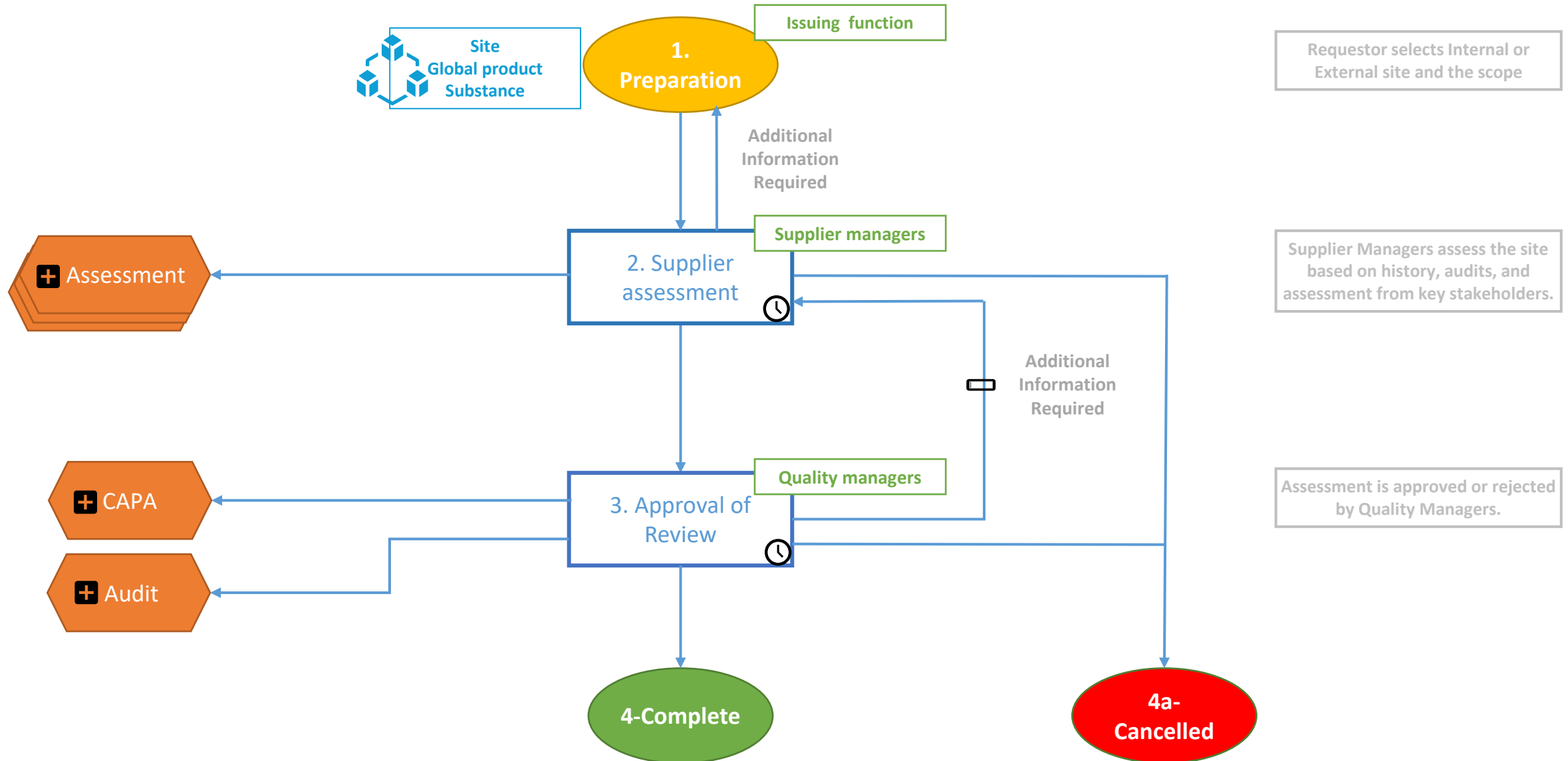Demonstration

Use case #2: Supplier review

› Definition

Periodic and structured evaluation of the performance and conformity of suppliers (or subcontractors) involved in the manufacture of medicines.

› Objectives

o Ensure that suppliers continue to meet quality, regulatory and contractual requirements

o Identify compliance deviations, incidents and changes

o Manage supplier relationship: continue, CAPA, new audit, discontinue…

Use case #2: Supplier review

Site
**Global product
Substance**

Issuing function

**1.
Preparation**

Requestor selects Internal or External site and the scope

Additional
Information
Required

Supplier managers

Assessment

2. Supplier
assessment

Supplier Managers assess the site based on history, audits, and assessment from key stakeholders.

Additional
Information
Required

CAPA

Quality managers

3. Approval of
Review

Assessment is approved or rejected by Quality Managers.

Audit

4-Complete

**4a-
Cancelled**

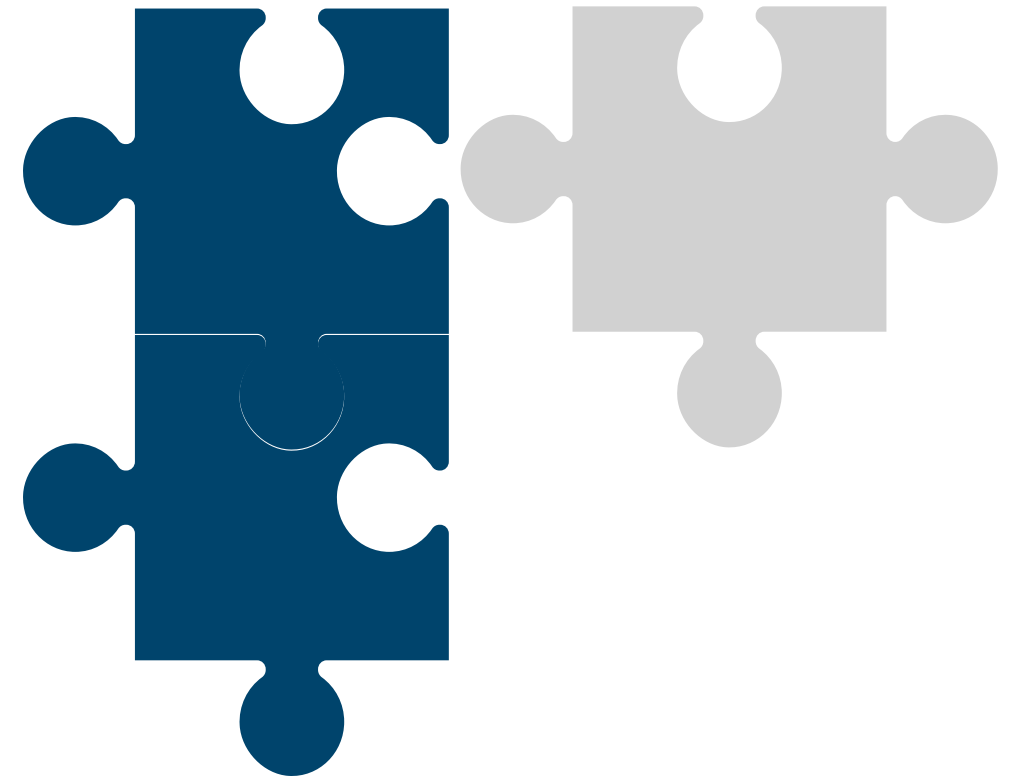# Use case 2: Supplier review demo

4 – Implementation

Implementation

› 2 options,

  › Installation from Core Model
    1. Installing the quality core model
    2. Fine tuning
       ○ Workshop
       ○ Slight configuration

  › Integration with your existing configuration
    1. Analysis of existing configuration
    2. Transfer of one or more processes
    3. Adaptation with your configuration
       ○ Workshop
       ○ Configuration