

A Data Driven Way of Quality Events Management

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YOUR INFORMATION



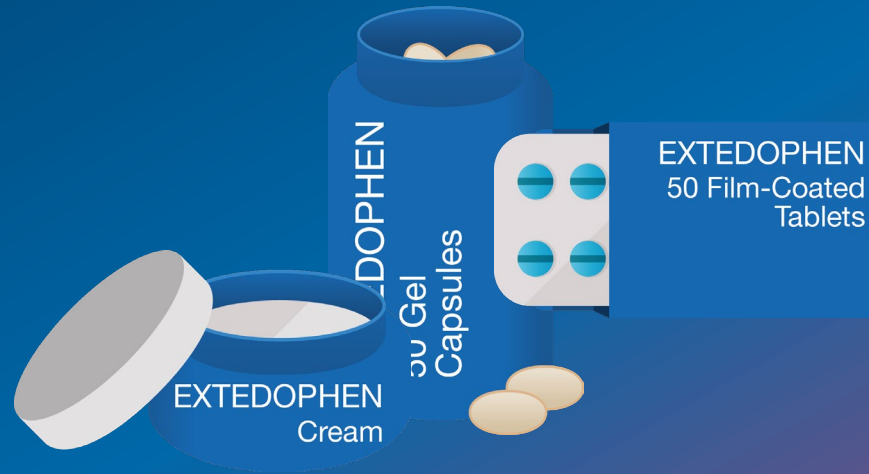
Nicole Sagner

Senior Pre-Sales Manager



Coming from Regulatory Affairs with touch points to other departments, I clearly understand the importance of consistent, valid and up-to-date data - specifically in case of interdepartmental processes.

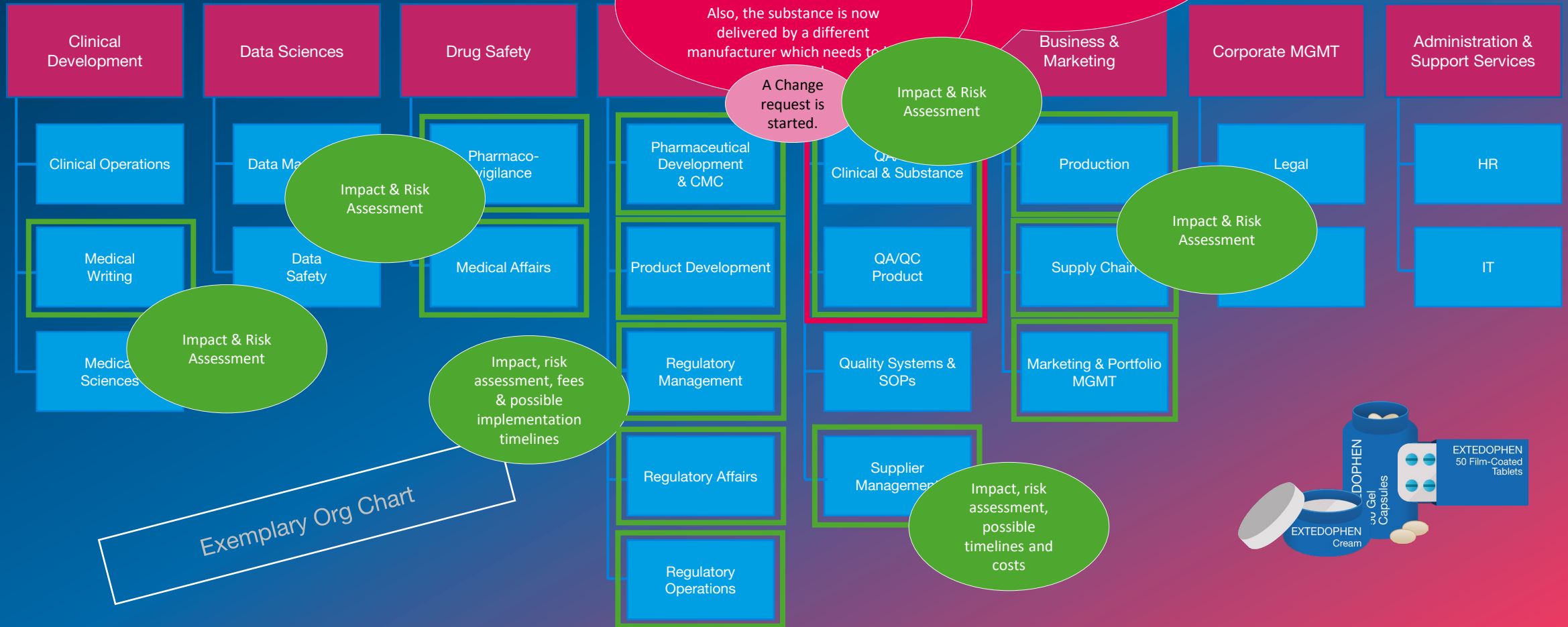
If something happens (a quality event), how to go ahead (not to lose time, identify the source, trigger actions, keep control)



Business Use Case



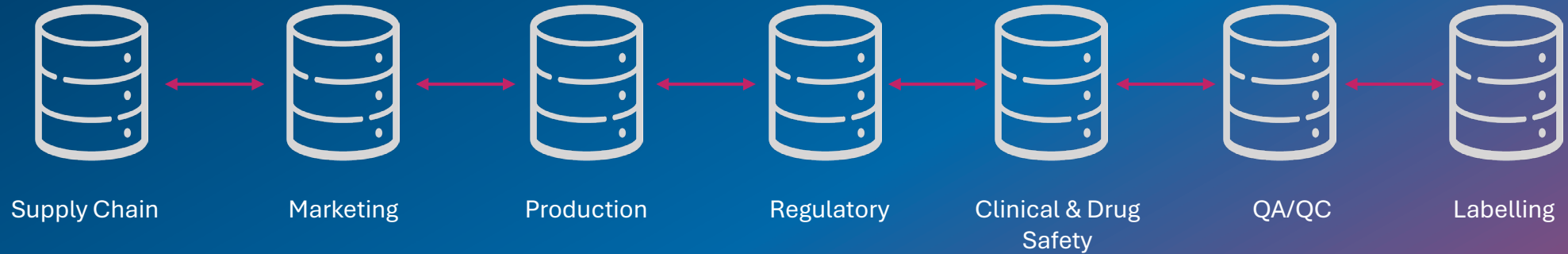
Business Use Case



How does everyone knows what to do?

How does everyone knows the current
status?

Typical System Landscape



Product Core Data



MedDRA

WHO

EDQM

ISO IDMP
(SPOR)

DIN

Snomed

ICH

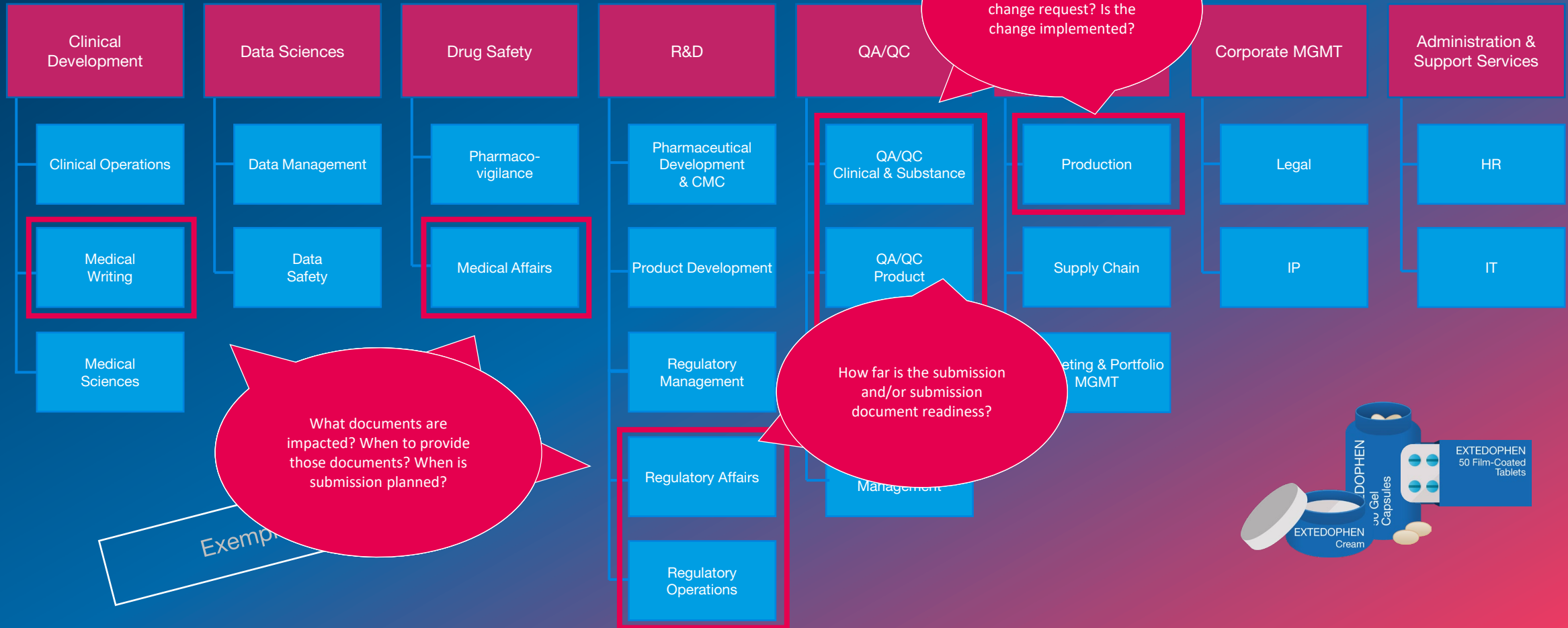
Other

Intern

A unified data approach: Data Integrity and Efficiency all over

- **360 Degree View of Data:**
By consolidating data from disparate sources into a unified model, organizations gain a comprehensive view of their data assets. This holistic perspective enables better decision-making, improved operational efficiency, and enhanced strategic planning.
- **Efficiency Gains:** By streamlining data management processes and reducing complexity, a unified data approach helps organizations optimize resource utilization and lower operational costs. Automation and centralized governance contribute to overall efficiency gains.
- **Faster Insights:**
Unified data models facilitate faster data analysis, allowing businesses to access real-time insights, identify trends and respond swiftly to market changes, thereby gaining a competitive edge.
- **Standardization and Normalization:** A unified data model improves data quality and consistency by standardizing and normalizing data across disparate sources. This minimizes errors and discrepancies, enhancing the reliability of analytical results
- **Reduced IT burden:** Centralizing data reduces the need for extensive IT handholding, allowing teams to access data independently and efficiently.
- **AI and Machine Learning:** A unified data approach supports the development of AI and machine learning models by providing clean and consistent data, enabling organizations to leverage advanced analytics and predictive capabilities.

Business Use Case



Business Use Case

The screenshot displays the EXTEDO PULSE software interface, which is a quality management system. The interface is divided into several sections:

- Header:** Includes the EXTEDO PULSE logo, navigation menus (File, Edit, Tasks, Tools, Settings, Help), a Smart Search bar, and a notification bell icon with a red '1'.
- Navigation Tree (Left):** A sidebar menu with categories like 'Quality - Multitenant - EXTEDOpulse', 'Tasks', 'Dashboards', 'MDM - Controlled Vocabularies', 'MDM - Product Core Data', 'QUAL - Learning Management', 'QUAL - Quality Events, CAPAs, CR and Complai...', 'QUAL - Quality Management', and 'REG - Medical Device Information'. The 'QUAL - Quality Events, CAPAs, CR and Complai...' section is highlighted with a red box, and 'Customer Complaints' is selected.
- Top Bar:** Shows active tabs for 'CORE Product', 'Registered Product', 'Regulatory Activity', 'Customer Complaints', 'Quality Document', and 'Change Request'. The 'Customer Complaints' tab is highlighted with a red box.
- Main Content Area:** Displays a list of 'Latest Versions' of quality events. A 'Send Workflow' button is highlighted with a green box. Two pop-up windows are shown:
 - Quality Event: QE-00012:** Shows details for an investigation, including a table of records with columns for Date, Author, and Comment. The 'Send Workflow' button is also visible in this window.
 - Quality Event: QE-00013:** Shows details for a CAPA (Corrective and Preventive Action) item, including a table of CAPA items with columns for CAPA ID, Title, and Lifecycle state. The 'Send Workflow' button is also visible in this window.

Business Use Case

The screenshot displays the EXTEDO PULSE software interface. The left sidebar contains a navigation tree with categories like Quality - Multitenant - EXTEDOpulse, Tasks, Dashboards, MDM - Controlled Vocabularies, MDM - Product Core Data, QUAL - Learning Management, QUAL - Quality Events, CAPAs, CR and Complai..., Action Item, CAPA, Change Request, Customer Complaints, Quality Event, QUAL - Quality Management, REG - Medical Device Information, REG - Regulatory Documents, REG - Regulatory Information, and REG - Regulatory Intelligence. The main area shows a search for 'Change Request: CR-00024' with a table of results. A modal window is open for 'Change Request: CR-00024', showing details such as 'Activity Type: Variation Type IB', 'Activity Status: Approved', and 'Application: Acetylcystein 100 mg Powder for Oral Solution - DCP EU'. The modal also displays 'Affected Activities' and 'Impacted Data'.

EXTEDO PULSE powered by **caraz** File Edit Tasks Tools Settings Help

Quality - Multitenant - EXTEDOpulse

Search

Tasks

Dashboards

MDM - Controlled Vocabularies

MDM - Product Core Data

QUAL - Learning Management

QUAL - Quality Events, CAPAs, CR and Complai...

Action Item

CAPA

Change Request

Customer Complaints

Quality Event

QUAL - Quality Management

REG - Medical Device Information

REG - Regulatory Documents

REG - Regulatory Information

REG - Regulatory Intelligence

Navigation Tree

CORE Product Registered Product Regulatory Activity Customer

Properties Create Delete Status Manager Send Workflow Audit

Latest Versions

Search Results

Change Request: CR-00024

Change Request Risk Assessment Affected Activities Affected Data

Affected Activities:

... Select Remove

Application	Activity Type
Acetylcystein 100 mg Powder for Oral Solution - NAT CA (ANDS) (CA 5895/187)	Initial Marketing Au
Acetylcystein 100 mg Powder for Oral Solution - NAT DE (ENR 1245789)	Initial Marketing Au
Acetylcystein 100 mg Powder for Oral Solution - NAT US (ANDA) (125478)	Initial Marketing Au
Acetylcystein 100 mg Powder for Oral Solution - NAT ZA (N/A)	Initial Marketing Au

Dump

Regulatory Activity: Variation Type IB (Approved, 2023-04-25) - Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)

General Properties Timeline Attachments

Activity Type:* Variation Type IB

Activity Status:* Approved

Application:*

Name	Procedure Type	Application Name	Procedure ...	Country
Acetylcystein 100 mg Powder for Oral Solution - DCP EU (NO/H/0896/001)	Decentralised Procedure	Acetylcystein 100 mg Powder for Oral Solution - DCP EU	NO/H/0896/0...	Norway, Finland

Displaying 1 record(s)

Impacted Data:

Activity Identifier: NO/H/0896/001/IB/001

Activity Description: Change in manufacturing method for Acetylcystein 100 mg Powder for Oral Solution

Assigned To: Sagner, Nicole (sagner)

Is Follow-up to Activity:

Change Request Information

Change Request No: CR-00024

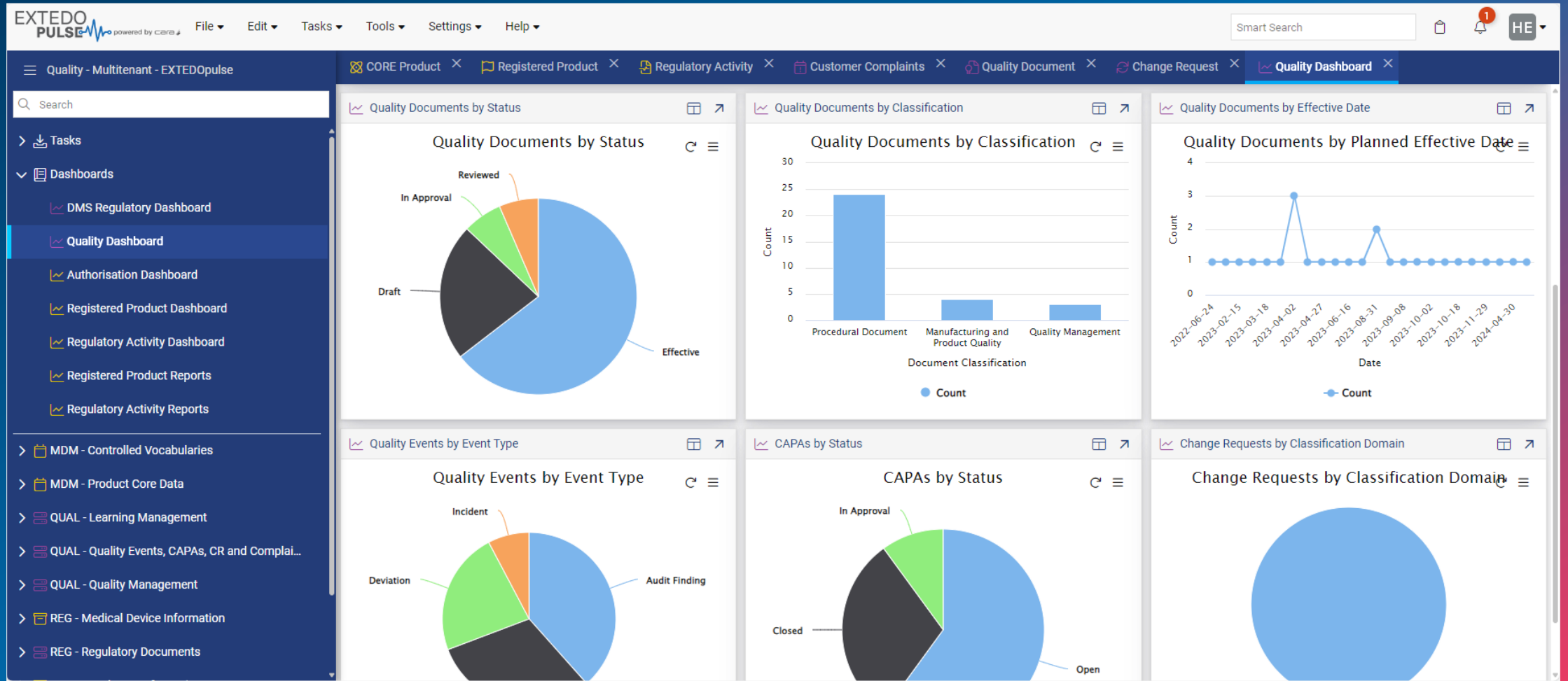
Change Request Name: Change manufacturing method for Acetylcysteine

Dump Cancel

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Displaying 1 - 7 of 7

Business Use Case

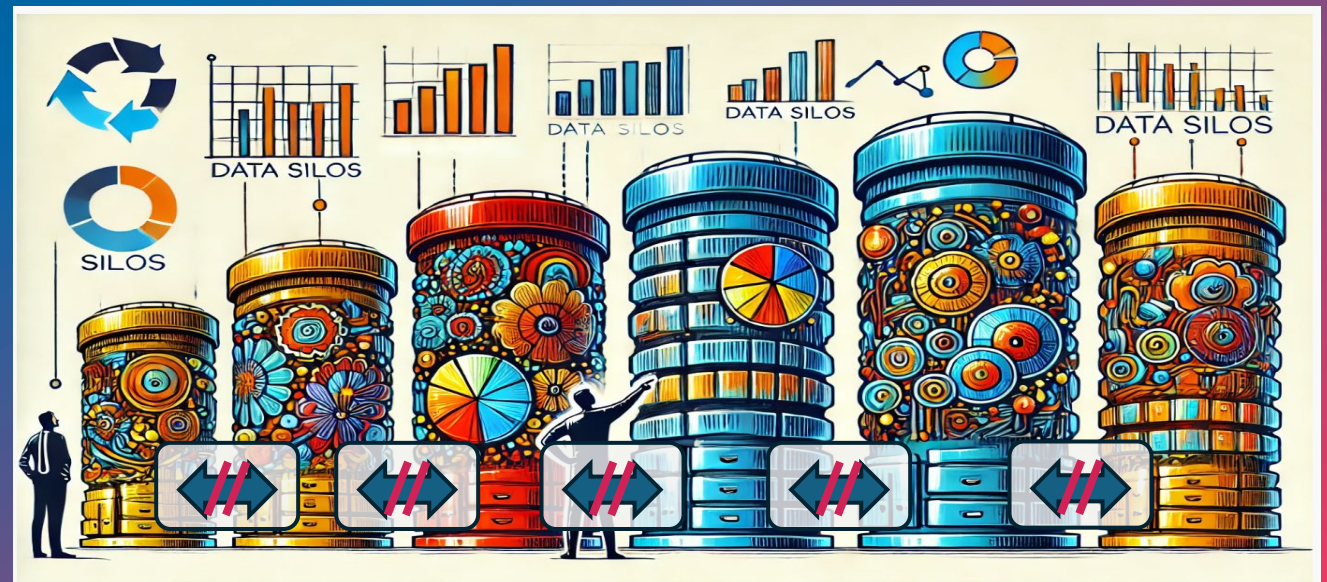


Summary

A **unified data approach, data transparency and intelligent data communication** not only enhances **operational efficiency and decision-making** but also supports strategic initiatives like innovation, and (regulatory) compliance, making it a valuable asset.

Without accurate and up-to-date data it can be more difficult and time consuming deal with and react on quality events and CAPAs.

Data is power and your key to measure, assess, decide and act.



Thank You for Your Attention!