## Solution Overview

OpenText Corrective Actions/Preventive Actions (CAPA) for Extended ECM

CAPA (Corrective Action/Preventive Action) is a business process that helps an organization improve the quality of its products and services. This is achieved by collecting and analyzing information and identifying and investigating product, process, and quality problems to determine the best course of action to address issues and prevent recurrence. Verifying and communicating corrective and preventive actions to the responsible people and management is essential for dealing with product, process, and quality problems.

OpenText™ Corrective Actions/Preventive Actions (CAPA) for Extended ECM automates the CAPA process in a single system while using the document management and security features of OpenText™ Extended ECM. Workflows provide standardized Incident Management and CAPA review and approval processes in a central location. Dedicated workspaces capture all investigation and CAPA actions to ensure CAPAs are effectively completed.
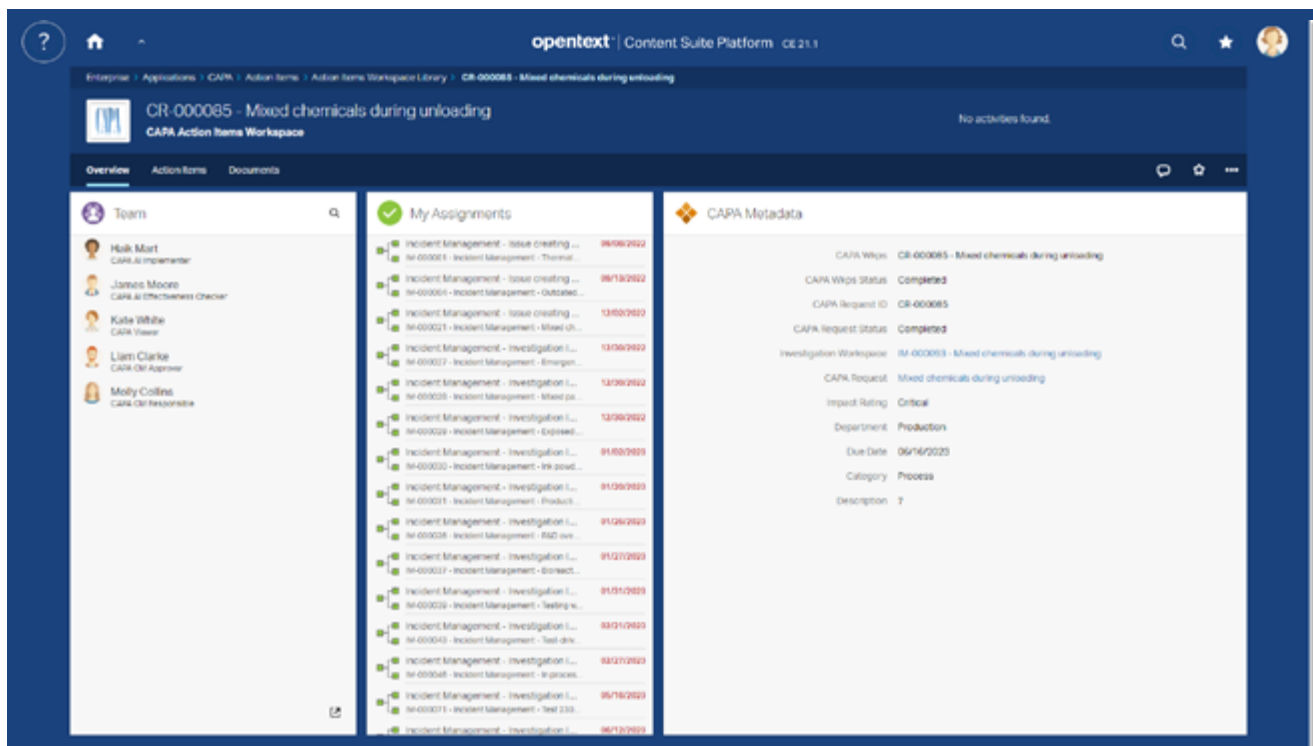
General

→ **Enterprise-wide Incident Management:** Provide appropriate employees with the power to record incidents and related activities

- Demonstrate incident management, improve quality

→ **Single system for all CAPA records:** Ensure quick and consistent responses to problems

- Increase efficiency and prevent recurrence of incidents

→ **Collaborate in Investigation workspaces:** Access all incident data and use analysis tools to determine incident root cause

- Improve incident root cause determination

→ **Independent Corrective Action/Preventive Action workflows:** Work with defined processes and a systematic way to capture your organization's CAPAs using pre-configured system workflows

- Increase collaboration, reduce duplication of effort and data

→ **CAPA history and trends:** Report and understand all CAPA activities. Minimize NCRs

- Maintain compliance, improve processes

→ **Effectiveness checks:** Individual corrective and preventive action effectiveness checks confirm initial resolution. Repeating CAPA effectiveness checks verifies overall solution success

- Continuous quality control, confirmation of CAPA resolution

→ **Easy access to a full audit trail and associated documents:** Search for documents related to each CAPA and see a full audit trail of all activities

- Save time, demonstrate compliance

→ **Real-time data and reporting:** Out-of-the-box configurable reports and dashboards to show real-time data

- Improve decision-making, increase efficiency

→ **Notifications:** Internal or email notifications ensure employees are assigned appropriate CAPA tasks

- Improve collaboration, increase efficiency

→ **Clear visibility of all processes:** Complete end-to-end visibility of your CAPA processes to understand the who, what, and when of each CAPA

- Improve control, increase efficiency

→ **Security features:** Benefit from the user access, permissions, and collaboration features of Extended ECM

- Maintain compliance and security

→ **Quickly deployed and easy to use:** An add-on solution that seamlessly integrates to OpenText Extended ECM, with no Extended ECM experience required

- Save time in deployment, reduce training time and increase user adoption

Single system

→ **Single system for all CAPA information:**
A central database for all CAPA information
(incidents, investigations, CAPAs), giving all
personnel and departments easy access to
find evidence that a problem was recognized,
evaluated and corrected with preventive actions
put in place. Content is fully searchable using the
industry-leading Extended ECM search engine

- Access records in all departments, increase
  efficiency and improve quality

→ **Form Builder for CAPA:** Configurable form
views using Form Builder with drag and drop
user interface

- Eliminates need for developer resources,
  is easy to use and reduces costs

Compliance

→ **Audit trail:** Full trail of why the CAPAs were
launched, what actions were taken, the employees
involved, and what preventive actions have been
put in place. Use the compare widget to view and
compare document versions across the document
lifecycle

- Demonstrate and maintain regulatory
  compliance

→ **Permissions:** Define and control all the users
involved in the CAPA process. Permissions ensure
only approved users can see, review, and carry
out CAPAs

- Ensure correct users have appropriate access

→ **Procedure compliance:** Ensure all CAPAs occur
in a controlled manner and according to your
organization's standard operating procedures

- Maintain regulatory compliance

Integration and enterprise systems

→ **Integrates with enterprise systems:** The CAPA
solution can be connected to enterprise systems
such as SAP®, Oracle®, Microsoft® SharePoint®
and more via OpenText Extended ECM

- Simplify user access, increase user
  adoption, and reduce errors

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