

Solution Overview

OpenText Incident Management & Investigations for Extended ECM

The recording, management, and investigation of incidents is critical for regulatory requirements, but it is not the only compelling reason to investigate incidents. This process helps organizations and stakeholders to learn and improve by identifying problems in their operations, processes and work practices promoting greater quality, efficiency, and safety.

OpenText™ Incident Management & Investigations for Extended ECM automates this process to collect, analyze, investigate, and address incidents, providing the organization guidance on how to reduce the risk of recurrence. Reporting and trend analysis can provide insights into how to improve quality in all areas of the business.

ID	Title	Incident Type	Impact Rating	Status	Created By	Current Assignee	Category	Department	Created Date	Target Due Date	CAPA Request
BI-000047	test drive CAPA presentation	Non-Conformance	Minor	BI Completed	Heron Miller	-	IT	Information Technology (IT)	02/24/2023	03/24/2023	CR 000063
BI-000040	In process protein A OOS ELISA Assay	Deviation	Minor	Investigation	Heron Miller	CAPAM Investigator	Quality Control	Quality Assurance (QA)	02/24/2023	03/24/2023	-
BI-000045	Temperature outside of BR PNR	Deviation	Moderate	BI Completed	Heron Miller	-	Manufacturing	Production	02/24/2023	03/24/2023	CR 000052
BI-000044	Test-drive CAPA presentation	Non-Conformance	Minor	Risk Assessment	Heron Miller	-	IT	Information Technology (IT)	02/20/2023	02/27/2023	-
BI-000043	Test drive CAPA presentation	Non-Conformance	Minor	Investigation	Heron Miller	BPA CAPA BI- Investigators	IT	Information Technology (IT)	02/20/2023	02/27/2023	-
BI-000042	pH OOS bioreactor 1234			Classification	Heron Miller	CAPAM Classifier	Manufacturing	Production	02/15/2023		-
BI-000041	Duplicate number for SOPs	Deviation	Moderate	BI Completed	Heron Miller	-	IT	Information Technology (IT)	02/15/2023	02/26/2023	CR 000051
BI-000040	Mixed chemicals during unloading	Deviation	Critical	Risk Assessment	Heron Miller	BPA CAPA BI- Approvers	Process	Production	02/08/2023	02/16/2023	-
BI-000039	Testing workflow	Deviation	Moderate	Investigation	Heron Miller	CAPAM Investigator	Incident	Maintenance	01/30/2023	01/30/2023	-

General

- **Enterprise-wide Incident Management:** Provide employees with the ability to record and manage Incidents and related activities.
 - Demonstrate Incident management, improve quality
- **Centralized location for all Incident & Investigation records:** Ensure quick and consistent responses to problems.
 - Increase efficiency and prevent recurrence of incidents
- **Collaborate in Incident & Investigation workspaces:** Access all incident data and use analysis tools to determine Incident root cause.
 - Improve incident root cause determination
- **Independent Incident Management & Investigation workflows:** Pre-configured system workflows provide defined processes and a systematic way of capturing your organization's Incidents & Investigations.
 - Increase collaboration, reduce duplication of effort and data
- **Incident history and trends:** Report and understand all Incident & Investigation and investigation activities.
 - Maintain compliance, improve processes
- **Effectiveness checks:** Individual corrective and preventive action effectiveness checks confirm initial resolution.
 - Repeating Incident Management effectiveness checks verifies overall solution success. Continuous quality control, confirmation of Incident Management resolution
- **Easy access to a full audit trail and associated documents:** Search for documents related to each Incident 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 Incident tasks.
 - Improve collaboration, increase efficiency
- **Clear visibility of all processes:** Complete end-to-end visibility of your Incident processes to understand the who, what, and when of each Incident.
 - Better control. Increased efficiency
- **Extended ECM security features:** Benefit from the user access, permissions, and collaboration features of Extended ECM.
 - Maintain compliance and security
- **Easy deployment and simple to use:** An add-on solution that seamlessly integrates to OpenText Extended ECM with no Extended ECM experience required
 - Save time in deployment, simplify and increase user adoption

Single system

- **Single system for all Incident information:**
A central database for all Incident & Investigations information, giving all personnel and departments easy access to find evidence that a problem was recognized and evaluated. Content is fully searchable using the Extended ECM search engine.
 - Provide access to records in all departments, increase efficiency, and improve quality
- **Form Builder for Incident Management & Investigations:** Configurable Form Views using Form Builder with drag and drop user interface.
 - Reduces costs, is easy to use and eliminates need for developer resources

Compliance

- **Audit trail:** Full audit trail of Incident details and management, the investigations that took place, and employees involved.
 - Demonstrate and maintain regulatory compliance

- **Permissions:** Define and control all the users involved in the Incident Management process. Permissions ensure only approved users can create, see, review, and carry out incident activities.
 - Ensure correct users have appropriate access
- **Procedure compliance:** Ensure all Incident and related Investigations occur in a controlled manner and according to an organization's standard operating procedures.
 - Maintain regulatory compliance

Integration and enterprise systems

- **Integrates with Enterprise Systems:** The Incident Management and Investigations 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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