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Data sheet

- **Improves efficiency and reduces risk** of non-compliance by eliminating error-prone manual work

- **Speeds time-to-market** with streamlined quality processes

- **Minimizes potential financial losses** stemming from non-compliance

- **Eliminates capital costs** for hardware, software and implementation

- **OpenText™ Documentum™**
- **OpenText™ Documentum™ for Life Sciences**
- **OpenText Cloud**
- **OpenText™ AppWorks Platform**

OpenText Core for Quality Management

Simplifying quality processes for efficiency and compliance

Quality management is the foundation of every Life Sciences company. It serves as the framework for consistent operations and compliance with the extensive regulations that ensure patient safety and product quality. Key to compliance is the ability to assess deviations from these requirements and implement effective corrective and preventive actions (CAPA) to address them.

OpenText™ Core for Quality Management delivers an intuitive, streamlined and tailored user experience for completing nonconformance and CAPA tasks. The application features automated workflows that guide users through processes, eliminating repetitive manual effort to make complex processes simple and efficient. Embedded analytical and trending tools facilitate reporting for analysis and audit readiness. The cloud-based application natively integrates with OpenText content management systems, seamlessly linking quality management systems (QMS) and enterprise content management (ECM) systems at logical points in the process and ensuring a single, authoritative source for regulated content.

Delivered in the cloud, OpenText Core for Quality Management immediately helps improve productivity with fast deployment without significant configuration, accelerating readiness and availability backed by a qualified infrastructure and validated installation. It enhances the value of existing investments in OpenText solutions with new quality management capabilities.
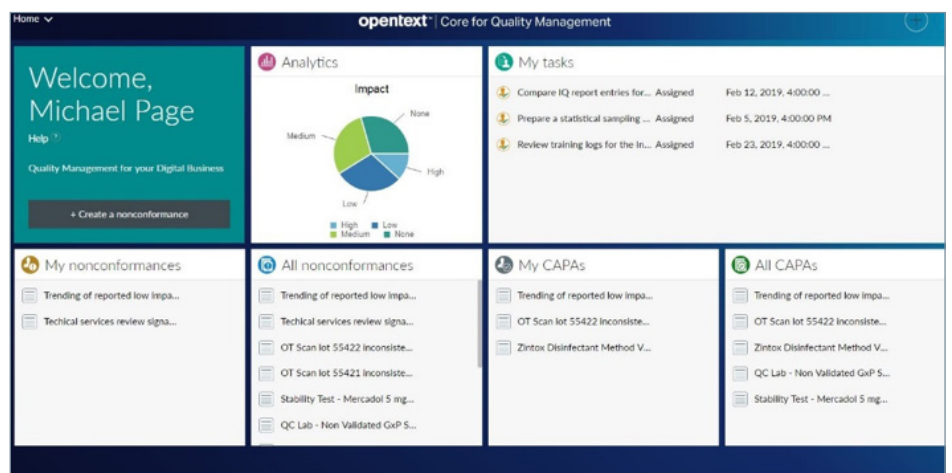
Feature name	Description
Nonconformance and CAPA records management	Workflows with clear, role-based ownership for tasks and deliverables based on industry best practices
Intuitive, modern experience	Personalized, simple and at-a-glance layout allows quick access to easy-to-use features
Insightful quality metrics trends	Automatic tracking of key quality data points, providing live on issue classification, risk, recurrence and process improvement
Embedded root cause analysis tools	Tools that guide users through problem analysis techniques to assist during the complex processes of issue investigations and root cause determination
Reminders and record status notifications	Record owners and task assignees stay informed about time-sensitive actions and decisions, ensuring tasks remain on target

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Feature name	Description
Seamless content management integration	Search and link functionality connects documents that need to be updated or referenced as part of a CAPA plan, dramatically simplifying navigation and reducing manual effort
Electronic records/electronic signature compliance	Support for electronic record/electronic signature (ERES) regulatory requirements, with permanent history logs and encrypted, time-stamped electronic signatures
Qualified cloud deployment	Deployment on a qualified, controlled infrastructure certified against ISO and SOC requirements, offering a favorable starting point for a risk-based approach to validation

With a modern interface, Core for Quality Management provides easy access to all relevant information needed to complete nonconformance and CAPA tasks.

About OpenText

OpenText, The Information Company, enables organizations to gain insight through market leading information management solutions, on-premises or in the cloud. For more information about OpenText (NASDAQ: OTEX, TSX: OTEX) visit: opentext.com.

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