

## DATA SHEET

# OpenText Extended ECM: Add-on for GxP Systems

Computer system validation and quality processes for hosted cloud services for life sciences



Adheres to GAMP 5 risk-based approach for compliant GxP systems



Includes documented practices in qualification package



Meets requirements to qualify cloud services for audit-readiness

In the life sciences industry, adherence to Good Practices (GxP) is essential to guarantee the safety, quality, and effectiveness of products. This includes ensuring that computer systems used for GxP operations are developed, validated, and operated correctly for their intended purposes.

Life sciences companies must thoroughly evaluate GxP vendors and providers, focusing on their quality systems, software development, and qualification processes. Other critical areas, like configuration and records management, security practices, and training programs, must also be strong to ensure compliance with regulations and industry standards.

As a vendor of hosted cloud services and software for the life sciences sector, OpenText maintains a life sciences governance program to meet regulatory requirements and uphold product integrity. The OpenText Life Sciences Governance program provides reliable support for computer systems validation. Rigorous validation processes for defined qualified cloud services ensure that they meet the highest standards for data integrity, security, and reliability. The program is designed to meet regulatory requirements and industry standards, providing our clients with an assurance of compliance and reliability.

OpenText qualified cloud services are developed as a baseline, with the expectation that clients will implement specific configurations and customizations to support their processes. Where specific configurations and customizations are designed, the client is responsible for documenting all configurations designed and performance qualified (PQ) in their instance.

OpenText maintains these instances with strict change management and security controls, ensuring compliance with global information security policies, business continuity, and disaster recovery processes. Our commitment to continuous improvement means we evolve with our customers, providing ongoing support for long-term reliability and compliance, especially in data security and integrity.

OpenText models its quality and controls after components of ISO 9001, ISO 27001, regulated electronic records and signatures, and others including:

- **Quality management system**

- ISO 9001 Quality Management System

- **Electronic records and signatures**

- 21 CFR Part 11 – Electronic Records/Signatures
- EU GMP Annex 11 – Electronic Records/Signatures

## Associated OpenText products

- OpenText™ Extended ECM CE Private Cloud
- OpenText™ Core Archive for SAP® Solutions

### • Good practices

- GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems
- General Principles of Software Validation
- GAMP 5 IT Infrastructure Control and Compliance
- Data Integrity and Compliance with Drug cGMP

### • Security

- ISO 27001 Framework as the OpenText Security Governance model
- OpenText Global Information Security and associated standard operating procedures, which are based on ISO 27001

## Security and risk management

Regulated organizations have obligations to comply with GxP regulations and guidance. OpenText has a shared responsibility framework to help you comply with these requirements.

As a service provider, OpenText understands the importance of our role in a GxP shared responsibility framework with regulated organizations. We commit to clearly defining our responsibilities and roles in our cloud services, ensuring effective communication and reporting, and complying with training requirements. Our focus on data integrity and security includes implementing robust measures. We also adhere to rigorous change management procedures, support customer audits, and maintain robust documentation and record-keeping practices. By fulfilling these responsibilities, we contribute to the successful management of GxP activities and regulatory compliance.

Deliverable	Description
Customer system qualification	Establishes documented evidence that a computer system: <ul style="list-style-type: none"><li>• Has been developed according to quality software development principles.</li><li>• Provides functional capabilities required by its users and will continue to do so over time.</li></ul>
Quality audits	Coordinate, prepare, and host life sciences quality audits.
Qualification packages	Includes user requirements specification and traceability matrix, as well as a validation summary report issued by OpenText for each major release. Verification reports are delivered upon request for each instance.
Hyperscaler support	OpenText™ Extended ECM is available on Google Cloud Platform™.

## 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](https://www.opentext.com).

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