opentext[™]

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 auditreadiness 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,

opentext[™]

Good practices

- GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems
- General Principles of Software Validation

.