sapio sciences

Product Sheet

GxP Validation

Importance of GxP Validation in the Lab

GxP Validation is a cornerstone of regulatory compliance in laboratory environments, ensuring that processes, equipment, and systems adhere to the stringent standards set forth by regulatory bodies such as the FDA and EMA. This validation is critical for maintaining data integrity, ensuring product safety, and achieving operational excellence. By adhering to GxP guidelines, laboratories can minimize errors, comply with internal policies and SOPs, enhance reproducibility, and safeguard the quality of their outputs, which is essential for pharmaceutical, biotechnology, and other highly regulated industries. In essence, GxP validation underpins the reliability and credibility of laboratory results, fostering trust and compliance in the scientific community and beyond.

Validation Package Options

Sapio offers two different GxP Validation packages to suit the needs of different clients. More information about each package is available on the following pages.

Option 1

Platform Validation Documentation

This package provides a comprehensive set of validation documents approved and executed by Sapio, including key elements like the Validation Plan, Design Specification, and Operational Qualification (OQ). It's suitable for clients of all sizes, offering full documentation support for the Sapio Informatics platform. Ideal for companies seeking to reduce validation timelines.

Option 2

Platform Validation Package

In addition to the documents in the first package, this option includes extensively drafted validation templates and guidance documents, such as the GXP Risk Assessment Form and User Requirements Specification Template. It is perfect for companies needing detailed templates and additional guidance for their validation processes, ensuring a more tailored and extensive approach to compliance.

Sapio offers validation support and documentation including IQ and OQ for our customers. Sapio has an approved Master Validation Plan (MVP) that outlines the approach for the validation of the system to meet GxP regulations.

The MVP also encompasses maintaining the system in a validated state. The validation methodology is based on ISPE GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (2022) Second Edition.

The methodology also includes the following regulations and guidances:

1. **FDA Computer Software Assurance for Production** and Quality System Software Draft Guidance for Industry and Food and Drug Administration Staff
2. **FDA 21 CFR Part 11- Electronic Records;** Electronic Signatures
3. **Eudralex Volume 4 Annex 11-** Computerised Systems

The set-up of the platform is automated using Infrastructure as Code (IaC) as a means of provisioning and deploying the platform, foundations and informatics.

All Validation documents are maintained in site eQMS. Documents are version controlled. Validation documents are available for viewing on Sapio's Virtual Data Room.

Option #1: Platform Validation Documentation

This package is good for all clients regardless of company size. This package includes all the documents that Sapio has approved and executed.

- Validation Plan (VP)
- Design Specification (DS)
- System Requirements Specification (SRS)
- Functional Risk Assessment (FRA)
- Installation Qualification (IQ) Executed
- Operational Qualification (OQ) Executed
- Requirements Traceability Matrix (RTM)
- Validation Summary Report (VSR)
- 21 CFR Part 11 / EU Annex 11 Assessment
- Data Integrity Checklist
- Validation Certificate

This package is available as a:

Initial or First Year Purchase:
This includes all documents to support a specific version of Sapio Informatics platform

Documents will be available in a Virtual Data Room

Renewal (Subscription):
This includes copies of all documents for each version of the Sapio platform as validation completes (3 or more versions per year)

Option #2: Platform Validation Package

This package includes all the documents from Option #1 as well as a collection of extensively drafted validation templates. This package is good for all companies regardless of size. This package includes all the following documents, templates and guidances:

- Validation Plan (VP)
- Design Specification (DS)
- System Requirements Specification (SRS)
- Functional Risk Assessment (FRA)
- Installation Qualification (IQ) Executed
- Operational Qualification (OQ) Executed
- Requirements Traceability Matrix (RTM)
- Validation Summary Report (VSR)
- 21 CFR Part 11 / EU Annex 11 Assessment
- Data Integrity Checklist
- Validation Certificate
- Customer Validation Package Document
- Sapio Customer Validation Package Flow
- GXP Risk Assessment Form
- Supplier Audit Report Template
- System Risk Assessment Template
- Validation Plan Template
- User Requirements Specification Template
- Performance Qualification Template
- Requirements Traceability Matrix Template
- Validation Summary Report Template

This package is available as a:

Initial or First Year Purchase: This includes all documents, templates and guidances to support a specific version of Sapio Informatics platform

Renewal (Subscription): This includes copies of all documents, templates and guidance for each version of the Sapio platform as validation completes (3 or more versions per year)

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