sapio sciences

Product Sheet

Sapio GMP LIMS

Unmatched Flexibility for Your GMP Manufacturing Processes

Highly regulated manufacturing industries like pharmaceuticals, food and beverage, and chemicals demand the ability to comply with regulations and rapidly adapt as requirements evolve seamlessly. Maintaining compliance requires a LIMS system that can be easily configured to support your GMP-validated processes and meticulous documentation requirements.

Sapio Sciences offers a comprehensive and flexible no/low-code GMP solution that integrates Laboratory Information Management System (LIMS) and Electronic Lab Notebook (ELN) functionalities to manage end-to-end GMP workflows. Designed to streamline processes, ensure data integrity, and maintain compliance with regulatory requirements, the Sapio GMP LIMS solution is a powerful tool for regulated environments.

QC LIMS

Material and Product Management

- Configurable dashboards displaying key information such as sampling plans, related compounds, and inventory.
- Registration and management of unique drug products and their associated metadata.
- Creation and management of drug product batches linked to corresponding drug products.

Batch Creation and Sample Management

- Creation of new batches with detailed information like lot number, manufacturing date, and batch size.
- Automatic generation of sampling plans based on pre-configured criteria.
- Requesting and receiving samples for QC testing, including the ability to reject compromised samples.
- Full sample storage management with configurable storage locations and hierarchies.

Analytical Testing and Results

- Manual and automated recording of analytical data.
- Pre-configured assays and analytical types with specified acceptance criteria.
- Automatic pass/fail determination based on defined acceptance criteria.
- Capture of multiple analytical parameters and results for each sample.

Certificate Generation and Approval

- Automatic generation of Certificates of Analysis (COA) and Certificates of Release.
- Electronic signature support for certificate approval and release, ensuring data integrity and compliance with regulations such as 21 CFR Part 11.
- Embedding of COA within the Certificate of Release for comprehensive documentation.

QC LIMS Process

GSK abbvie Bristol Myers Squibb Biogen Genentech labcorp NOVARTIS Johnson&Johnson

Environmental Monitoring Program

Site, Equipment, and Storage Management

- Tracking and management of manufacturing sites, equipment, and storage units.
- Recording of equipment details, including maintenance schedules and associated metadata.
- Hierarchical organization of storage units such as rooms, freezers, shelves, and boxes for precise sample location tracking.

Routine and Testing Plan Setup

- Definition of environmental monitoring routine templates with specific measurement types and sampling intervals.
- AI-powered generation of testing plans from uploaded site images.
- Manual creation and assignment of testing plans, customizable by measurement types, intervals, and responsible personnel.

Measurement and Result Recording

- Scheduling and tracking of environmental monitoring measurements.
- Recording of measurement results with numeric values, pass/fail statuses, and comments.
- Automatic evaluation of results against pre-defined criteria, triggering alerts for out-of-specification measurements.
- Association of measurements with specific locations, equipment, and personnel for comprehensive traceability.

Data Visualization and Analysis

- Interactive visualization of environmental monitoring data, including trend charts, heat maps, and statistical summaries.
- Drill-down capabilities to investigate specific measurements, locations, or time periods.
- Identification of trends, outliers, and potential issues through advanced data analytics and reporting.

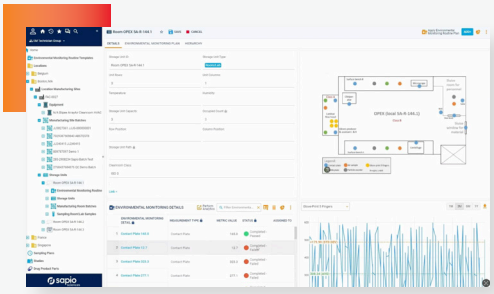
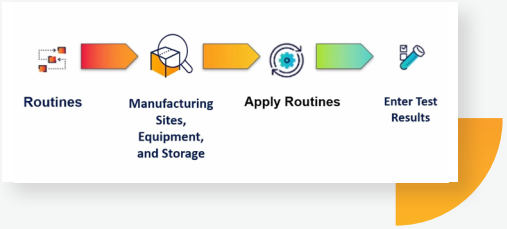


Figure 1. Environmental Monitoring Routine Templates



Environmental Monitoring Process

Stability Testing

Study Setup and Material Assignment

- Initiation of stability studies directly from drug product batches and associated samples.
- Definition of study types, storage conditions, and study durations.
- Assignment of specific samples to stability studies with tracking of sample quantities and locations.

Study Parameter and Time Point Definition

- Setup of study parameters such as assay types, acceptance criteria, and testing procedures.
- Definition of time points for sample testing with specific intervals and testing windows.
- Automatic creation of testing requests and tasks based on defined time points and parameters.

Sample Testing and Result Recording

- Scheduled pull and testing of samples according to defined time points.
- Recording of stability testing results with numeric values, pass/fail statuses, and comments.
- Automatic evaluation of results against defined acceptance criteria.
- Comprehensive traceability by associating results with specific samples, time points, and testing parameters.

Reporting and Trend Analysis

- Generation of configurable stability summary reports presenting study results clearly.
- Identification of trends, degradation patterns, and shelf-life projections based on stability data.
- Comparative analysis of stability profiles across different batches, formulations, or storage conditions.
- Integration with ELN for seamless access to stability study protocols, reports, and associated experimental data.

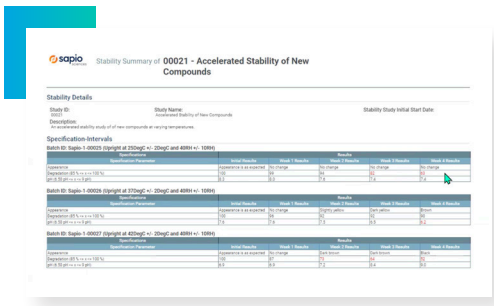
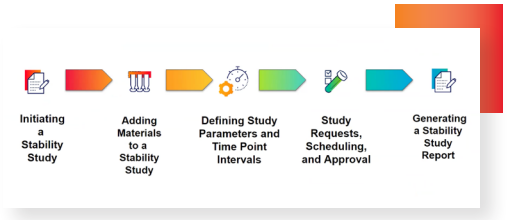


Figure 2. Generating a Stability Study Report



Stability Process

Advanced Search and Analytics

Powerful Search Capabilities

- Targeted searching across multiple data types including samples, batches, products, and testing results.
- Advanced query builder for constructing complex search criteria.
- Saved searches for quick access to frequently used queries.

Data Visualization

- Interactive tools for creating charts, graphs, and dashboards.
- Customizable charting options including bar charts, line charts, scatter plots, and heat maps.
- Drill-down and filtering capabilities for exploring data at various levels of granularity.

Statistical Analysis and Reporting

- Built-in tools for performing common statistical calculations.
- Advanced statistical tests for hypothesis testing and trend identification.
- Automated generation of statistical reports and summaries.

Data Export and Integration

- Export of search results, charts, and reports to common formats such as CSV, Excel, and PDF.
- Integration with third-party data analysis and visualization tools.
- Seamless integration with Sapio ELN for linking experimental data, protocols, and reports to GMP data.

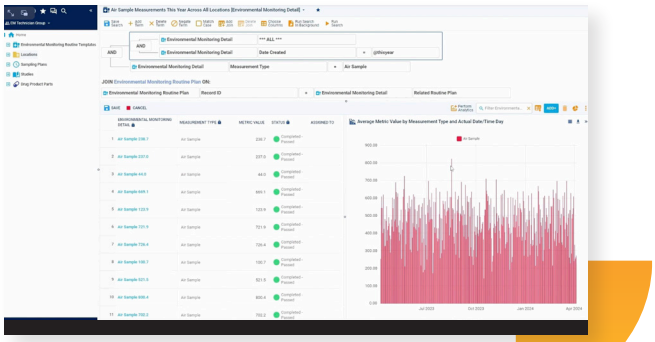


Figure 3. Power Search

Key Features

- Configurable dashboards and workflows
- Complete sample lifecycle management
- Integrated data management for data integrity and traceability
- Automated pass/fail determinations
- Electronic signature support for certificates and approvals
- AI-assisted environmental monitoring setup and visualization
- Advanced search and analytics capabilities
- Automated stability study scheduling and reporting
- Seamless ELN and LIMS integration
- Compliance with regulatory requirements including 21 CFR Part 11

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Contact Us for a Demo

Discover how Sapio GMP LIMS can transform your GMP workflows and ensure compliance. Book a demo today at sales@sapiosciences.com.