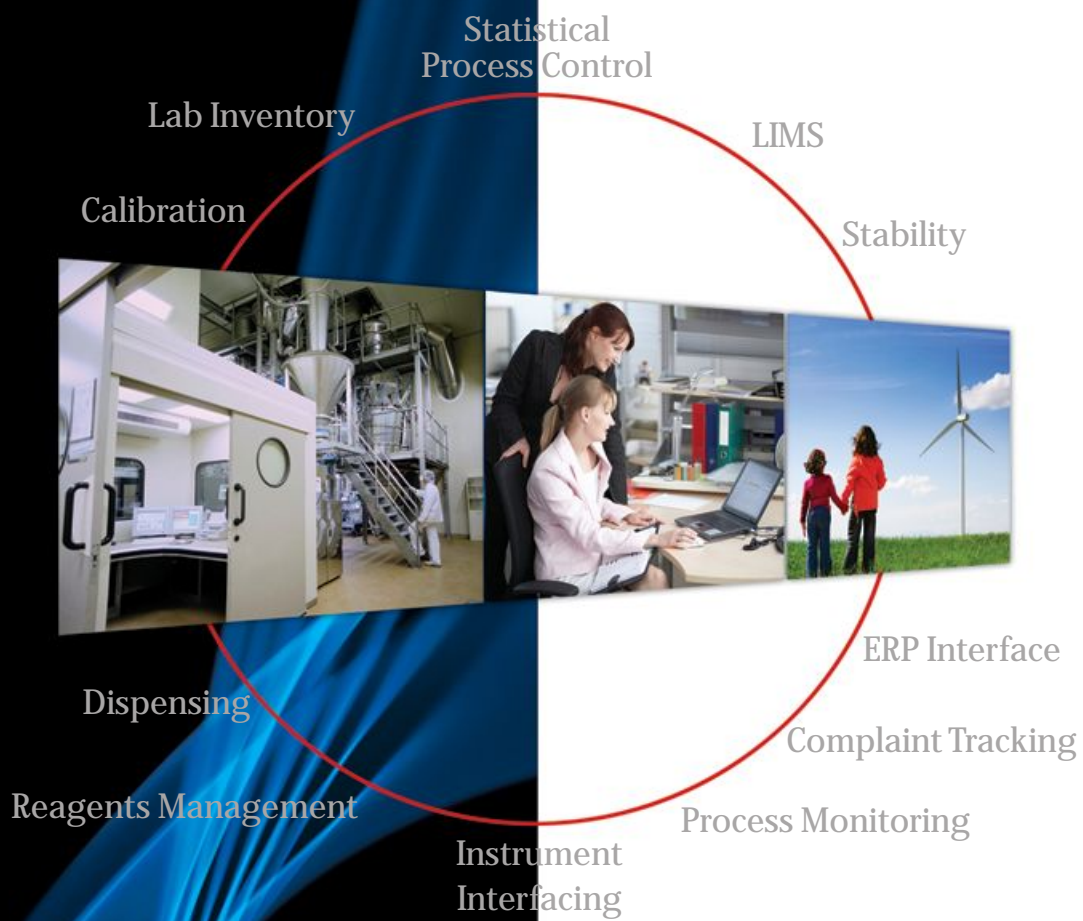


SPECTRUM

Laboratory Information Management System



SPECTRUM



Spectrum LIMS, a web-based solution that fits your needs, gives you control and helps you excel.

Spectrum LIMS (Laboratory Information Management System) is an FDA 21 CFR part 11 compliant software solution which caters for a laboratory's analytical and resource management needs, whilst monitoring compliance requirements.

Healthcare and environmental labs are usually pressed for time and resources. The key function of these labs involves testing a large number of samples, which generates an enormous amount of data. This extensive data gathering and tabulation process requires meticulous care. The multiple steps, complex procedures and calculations contain significant risks of manual errors or oversight. Spectrum LIMS makes such complex tasks simple to execute, organize, understand and manage.

Spectrum maintains data quality and integrity by taking away the onerous work load of data gathering, mathematical calculations and statistical operations on day-to-day activities.

Spectrum has been developed to manage laboratory information and quality operations functions in an automated and controlled manner. Spectrum LIMS is focused on optimizing laboratory performance, and time and resource management. Optimization helps increase the laboratory's throughput, saves cost, and enhances customer satisfaction.

ROI Case Study

A leading international pharmaceutical company implemented Spectrum at one of their plants. Previously they were using a renowned ERP system's quality module to manage analytical and reporting needs at their manufacturing facility, but found that the legacy system did not provide in-depth analysis and the data gathering required significant manual effort.

In particular, the preparation of the annual product review (requiring a complete set of batch data with historical and trend analysis) was onerous and difficult to manage.

Following the implementation of Spectrum, the time and effort included in preparing the annual product review data was reduced to a few clicks, saving the company significant cost from this process alone.



A unique solution with integrated Statistical Process Control.

Benefits

Cost Saving

Continuous Improvement

Compliance Reporting

Resource Optimization

Knowledge Management

Information Sharing

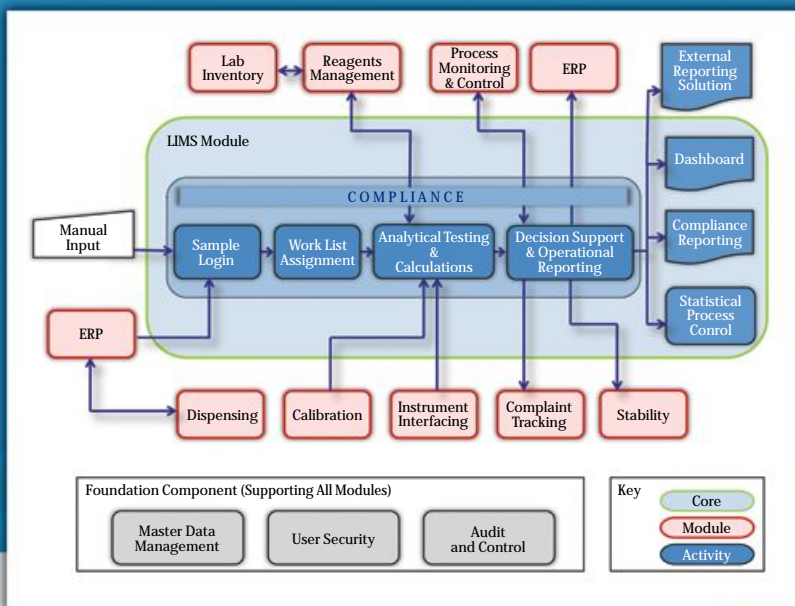
Efficient Time Management

Minimize Errors

Increase Throughput

Spectrum's software architecture provides complete flexibility to configure the application according to your organization's specific needs.

Spectrum is a completely user-configured application that is easy to implement. Defining your quality domain is a simple activity, yet it comprehensively depicts a true picture of your processes. Steps of the processes are logically sequenced and provide complete information on each process event or activity. From quality of raw materials to the completion of the finished product, Spectrum monitors the end-to-end process.



The solution is scalable across multiple plants and geographical locations. Scalability of the solution provides the opportunity to use Spectrum in an integrated environment or to deploy its different modules independently.

SPECTRUM MODULES

- LIMS
- Stability
- Calibration
- Process
- Inventory
- Reagents
- Complaints
- Dispensing

Spectrum Implementation has zero percent failure rate.

Sofcom's aim is to make the implementation and support of our solutions as simple and easy as possible for our clients. Spectrum implementation has zero percent failure rate and we have developed tools to assist our clients for quick deployment of our solution. Most of our clients find that the solution can be configured and ready to use within a few weeks.

Spectrum provides the functionality to manage a wide range of testing activities.

Spectrum supports the gathering and sequencing of samples for organic, inorganic, chemical, toxic testing or indeed any other analytical test where specific standards and procedures are followed.

Spectrum can easily process multiple types of samples and can undertake various different calculations or processes on each one. Sample testing can be grouped or performed individually as required. These groups can be by type of test (e.g. micro-biological, toxic etc.) or by type of products (e.g. raw material, semi-finished goods etc.)



Spectrum ensures that internal SOPs and performance parameters are deployed correctly.

Comprehensive testing procedures can be configured within Spectrum to control and manage a wide range of different types and methods of test. When a new sample is logged into the system, it automatically assigns the tests to be performed (as per the configuration of the corresponding sample type) with the relevant parameters, such as the required number of readings and decimal places. The user can also attach any additional tests required to be performed on each sample.

Test Specification

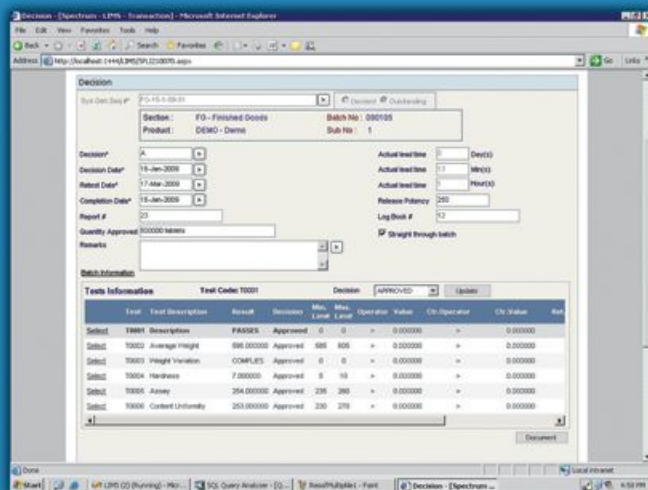
Spectrum allow users to easily configure different types of tests, including non-numeric tests such as appearance and colour, and numeric tests such as pH, assay and dissolution. It also supports complex formula calculations or any other test needed to comply with your organization's Standard Operating Procedures (SOPs).

Test Limits

Each test can carry different types of limits to facilitate test behaviour monitoring. Spectrum maintains both control/quality limits and passing limits to achieve Total Quality Management (TQM). The system prompts the user when it recognises an A-typical test result.

Results

The results can be transferred through Instrument Interfacing directly from an instrument or entered manually. Entry screens automatically adopt the user-defined procedures for each specific test and automatically perform simple or complex calculations (as required) to obtain the final result. Detailed information from these activities is maintained for reporting, trend analysis and to identify opportunities for optimization.



Performance measurement is a key factor in driving business excellence. This depends on how processes can be measured against their potential and against internal and external standards and benchmarks. Spectrum ensures that internal standards and performance parameters are deployed and adhered to correctly, identifying the potential to strengthen processes for performance improvement and resource optimization. The system includes intelligence to analyze comparative data, historical data and trends, to drive continuous improvement.

Repeat Test Results

Spectrum accepts any number of repeat test results and records them for further analysis. The user can increase the number of raw data readings for each repeat test as required.

Final Review

On completion of sample or batch testing, the decision screen displays all of the relevant information about the batch/sample, from its receipt and initial raw data readings, to the final results.

Spectrum also supports result based decisions for batch and samples. The system prompts the user when test results fall beyond the configured passing or control limits.

Revalidation / Retest

Spectrum provides information to the user for the batches which are due for revalidation or retest within specified time ranges, providing visibility about scheduled activities. For the revalidation of batches and samples, Spectrum follows the configured revalidation protocol of each corresponding product/material.

Resource Management

Spectrum generates and manage comprehensive work list for testing work-load and laboratory time and resources to be distributed across different analysts on a test level at the point the sample is received. The system keeps track of each testing activity on samples received to enable managers and technicians to see the exact status and the work load of each sample.

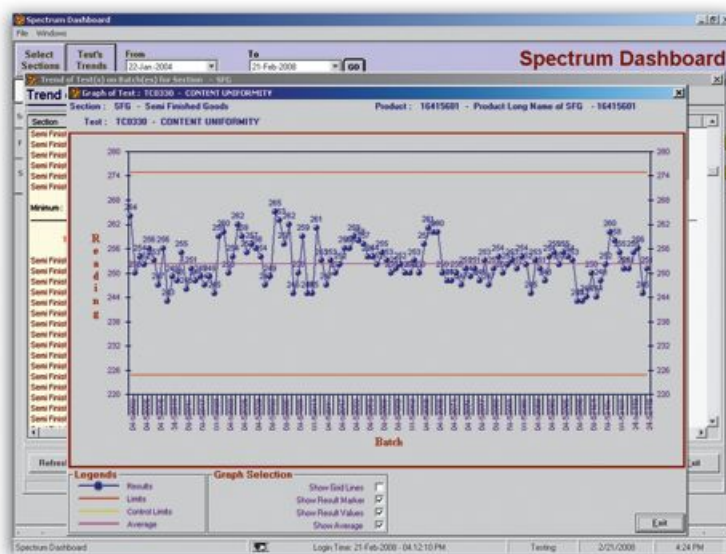
Comprehensive MIS

Spectrum has a comprehensive Management Information System (MIS), which is the keystone for successful planning and operations. Senior management rely on these programs to evaluate the overall quality operations performance, while production teams use the system to manage process information and facilitate knowledge sharing.

Spectrum provides a wide variety of reports and inquiries, ranging from simple listings, through analytical reports to decision-support reporting.

All reports and inquiries have user-defined selection criteria and provide multiple views of the information from a single report or inquiry. Spectrum can generate historical reporting to help with trend analysis, sample behavior, supplier performance, analyst performance and to support the compilation of annual/periodic product reviews

Prompts and alerts are available in the system.



The Dashboard facility in Spectrum provides senior management with a comprehensive view of all the relevant operational performance at a single glance to support key decision-making and to serve as a hub for information sharing.

Support

Spectrum post-implementation support is provided by a dedicated team of trained and experienced professionals. The strength of our team is demonstrated by our business domain knowledge and our focus on understanding each customer's needs.

Our on-going development efforts and upgrade strategy demonstrate our commitment to continually improving our product and providing long term return on our customer's valuable investment.



We find Sofcom good business partners....

"LIMS and the Stability modules are effective laboratory tools for the management of analytical and stability data. Our lab has benefited greatly from these tools, resulting in significant time saving, no more manual data entries and allowing the monitoring of cycle time for analysis per batch / per analyst for productivity improvement; just a click and we can get trend sheets for as many years as we want! The systems are validated and are compliant with advanced GLP requirements like Electronic Signatures, Audit Trails, System Security, Historical Data Retention etc... We find Sofcom good business partners and are working closely with them to develop more innovative solutions aimed at continuous improvement in pharmaceutical manufacturing".

Ms. Ruby Shaikh
Senior Manager Quality Control
Bristol Myers Squibb Pakistan



www.spectrumtqm.com

Sofcom (Private) Limited
Sofcom House, ST-9
Block 5, Gulshan-e-Iqbal
Karachi-75300, Pakistan
Ph: +9221 4966991
Fax: +9221 4809032
contact@sofcom.net

Sofcom USA Inc.
2727 Curtiss St.
Downers Grove
IL 60515
Ph: +1 630 353 4300
Fax: +1 630 663 4547
contactusa@sofcom.net