

# SPECTRUM

Quality Management Platform



**SOFCOM**

*Let's Sync & Excel*



# SPECTRUM

Quality Management Platform

- LIMS
- Stability
- Calibration
- Statistical Process Control
- Lab Inventory
- Reagents Management
- Process Monitoring
- Instrument Interface
- ERP Interface
  
- Complaint Handling (Internal or External)
- Out of Specification Handling
- Quality Risk Management
- Investigation & CAPA
- Deviation Management
- eDocs Management
- Change Control
- Supplier Qualification
- Internal Audit

# Laboratory automation ease compliance, reduce cost and harvest paragon data.

Data-driven labs achieve excellence in operations, fuel growth and empower people to see the big picture for future strategies.

Labs key function is testing a large number of samples with different protocol and technique, which generates an enormous amount of data. This extensive data gathering and tabulation process require meticulous care.

The process contains multiple steps, complex procedures and calculation that has a significant risk of manual errors or oversight. Spectrum makes such a complex task simple to execute and easy to manage.

Spectrum harvest data to support intelligent decisions. Spectrum maintains the data integrity by the well-defined process, taking away the onerous workload of data gathering, mathematical calculations and statistical operations on a day to day activities.

Spectrum has been developed to manage laboratory information and quality operations function in an integrated and controlled manner. The focus of Spectrum enterprise solution is an optimization, and performance of Laboratories. The efficient times and resources management increase the throughput of the process and enhance customer satisfaction.

## 21 CFR part 11 compliant solution

### 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.



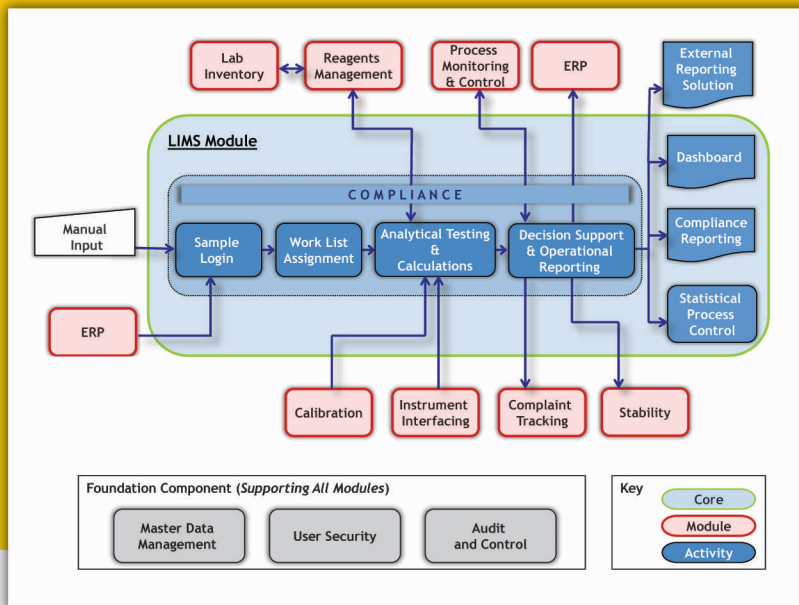
## A unique solution with integrated Statistical Process Control.

### Benefits

- Data Integrity
- 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.**

## Data integrity

Spectrum maintains a comprehensive audit trail of all actions on data with the user ID, work station, time and date to ensure data integrity. It also ensures the accuracy and consistency of data by acquiring data through its well-defined procedures and validated options, and maintains data accuracy through its entire life cycle.

In most companies the critical decision is based on data, hence data integrity becomes the most important element of business decisions. Spectrum provides consistent and reliable data for decision making and compliance reporting.

## 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 best quality practices with compliance & complete investigation management to eliminate the causes of non-conformities and other undesirable situations.

Compliance requirements can be a big challenge for regulated industries. The assurance of compliance entirely depends on how processes are defined and systems are used. Spectrum supports in putting best practices in place and embed effective controls to attain the maximum efficiency by reducing human errors. The solution also provides transparency in operations.

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.

### Test Specification

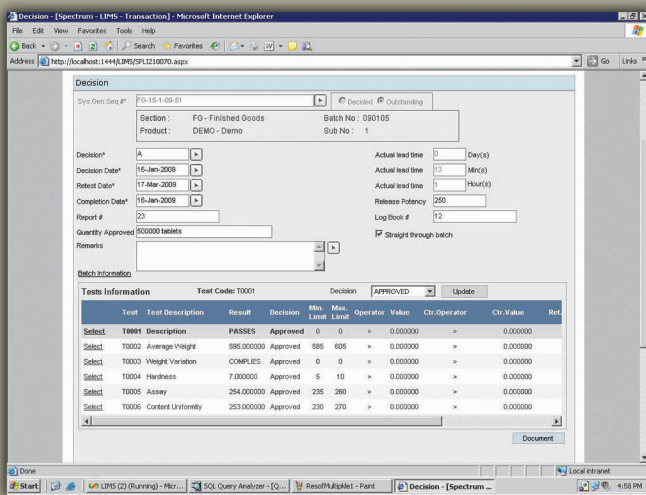
Spectrum allow users to easily configure different types of tests, including non-numeric tests such as appearance and colour, and numeric tests such as pH, assay and dissolution. It also supports complex formula calculations or any other test needed to comply with your organization's Standard Operating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

SPC is an integral part of Spectrum which provides an efficient means of acquiring information to facilitate process understanding, achieve continuous improvement and to share information and knowledge.

Spectrum provides the right foundation to enable a company to improve quality and achieve Total Quality Management (TQM).

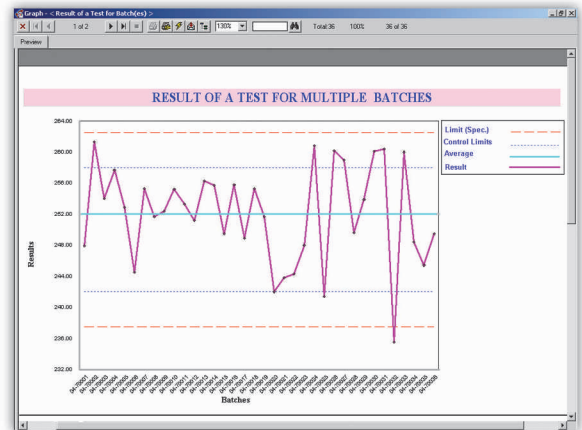
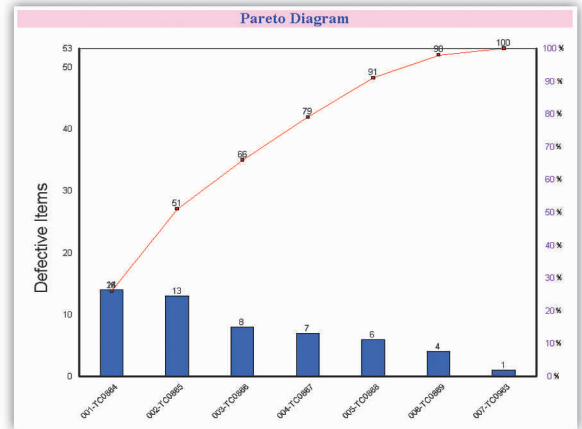
- Six Sigma monitoring
- Pareto diagram
- Histogram
- Scatter diagram
- Trend analysis
- x - chart
- $\bar{X}$  - chart
- R - chart, p - chart, s - chart
- $C_p$ ,  $C_{pk}$  analysis

Spectrum has the capability to acquire data directly from laboratory instruments.

Using the Instrument Interfacing functionality, testing data from electronic balances, HPLCs, pH meters and many other instruments can be transferred automatically to Spectrum, minimizing the chances of errors, and saving valuable man-hours. When integrated with the Instrument Calibration module, Spectrum checks the calibration record of each instrument before accepting the results.

## ERP Interface

The system can be easily integrated with all major ERP solutions. Its user-friendly interface minimizes extensive time and resources to deploy the application in a real time environment.



Test	Specification	Result	Status	Analyst	Date
DESCRIPTION	0.5% white, flat disc, level edged tablets, double scored on one side	PASS	Pass	BAATC	20/Jan/2008
AVERAGE WEIGHT	365 - 402 mg (Theor: 365mg)	367.0 mg	Pass	BAATC	20/Jan/2008
UNIFORMITY	± 12 Rp	0.56% (10.000 0.0 Rp)	Pass	BAATC	20/Jan/2008
DISINTEGRATION	Minimum 90% within 15 minutes	100% (30.000 30.000 0.0 Rp)	Pass	BAATC	20/Jan/2008
COEFFICIENT OF VARIATION	SD - 10% (Theor: 10%)	0.56% (365.000 365.000 mg/tablet)	Pass	BAATC	20/Jan/2008
WEIGHT VARIATION	± 7.5% from the Average Weight	PASS	Pass	BAATC	20/Jan/2008
ASSAY, ACID	95% ± 2% (Theor: 95%)	100.00 mg/tablet	Pass	BAATC	20/Jan/2008

Remarks: Satisfactory

Decided By: *[Signature]* Date: 22/Jan/2008 09:15 AM

Approved By: *[Signature]* Date: 22/Jan/2008 09:30 AM

**Approved**

Batch	Supplier	Test Procedure #	AVERAGE WEIGHT	HARDNESS	DISINTEGRATION TIME	ASSAY, ACID
722701	Not Applicable	PAS285	362.8	(Min) 7.3 - (Max) 9.1	8.00	246.22
722702	Not Applicable	PAS285	366.1	(Min) 6.9 - (Max) 9.2	6.00	246.52
722703	Not Applicable	PAS285	361.5	(Min) 6.5 - (Max) 9.8	10.00	246.20
722704	Not Applicable	PAS285	368.3	(Min) 8.1 - (Max) 10.2	9.00	246.08
722705	Not Applicable	PAS285	369.4	(Min) 7.3 - (Max) 8.2	8.00	247.36
722706	Not Applicable	PAS285	362.2	(Min) 8.1 - (Max) 9.2	7.00	252.56
722707	Not Applicable	PAS285	362.4	(Min) 6.3 - (Max) 8.9	10.00	253.10
722708	Not Applicable	PAS285	362.4	(Min) 7.5 - (Max) 9	9.00	249.10
722709	Not Applicable	PAS285	366.8	(Min) 8.8 - (Max) 10.2	9.00	251.56
722712	Not Applicable	PAS285	362.0	(Min) 7 - (Max) 9	10.00	253.98
Minimum:			362.4	6.8	6.00	246.22
Maximum:			369.4	10.2	10.00	253.98
Average:			367.8	9.3	8.69	249.68
Standard Deviation:			3.847366	0.727796	1.348977	2.794286

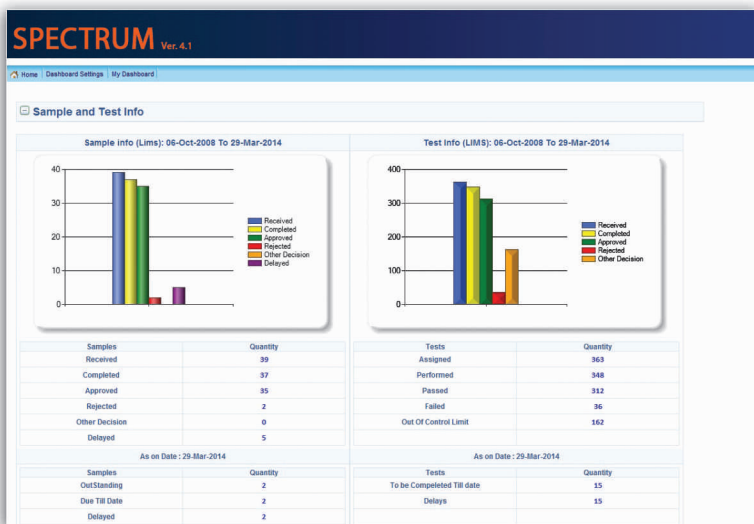
## Comprehensive MIS

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



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