

Minimizing Compliance Risk at Regulated Nutrient Manufacturer



Today's laboratories are struggling to find ways to effectively solve their two most important issues: addressing regulatory compliance, including 21 CFR Part 11, and improving inefficient processes. Fortitech Inc.'s burgeoning task of managing and documenting ingredient blend quality procedures, invoked an initiative to fully automate lab operations. Dr. Panna Chaudhari, Director of Technical Affairs at Fortitech, Inc., presented her STARLIMS experiences at a Waters Chromatography Symposium.

Fortitech, Inc. is the world leader in the development of custom nutrient systems for the food, beverage and pharmaceutical industries. The company provides custom premixes containing a comprehensive selection of vitamins, minerals, amino acids, nucleotides, and nutraceuticals for top manufacturers around the world. Headquartered in New York City, the company has a global manufacturing and distribution network with facilities in the USA, Europe, Asia, South America and Mexico.

Prior to Implementing a LIMS

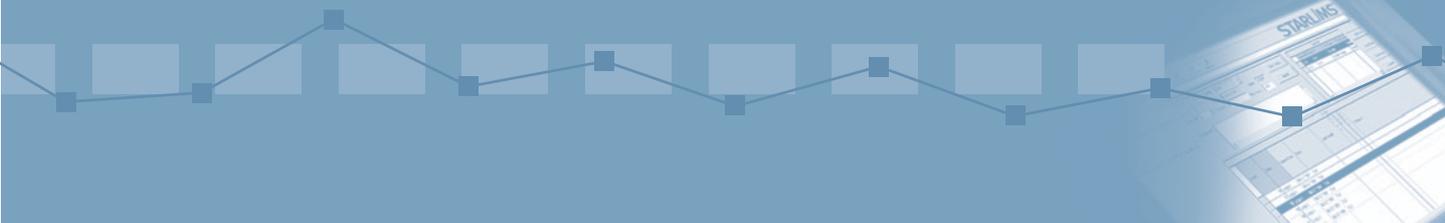
Fortitech realized that they had to tackle a number of issues: a growth surge challenging them to keep up with the workload; manual, time-consuming processes creating the possibility for errors; a slow and inefficient departmental workflow; and insufficient

handling of security and 21 CFR Part 11 Compliance Issues. The company's LIMS selection criteria comprised of: Fit and suitability; Flexibility; Technical know-how; Resources available for future support needs; Compatibility with the existing customized software program and Cost.

Why STARLIMS?

Fortitech found that the flexibility of STARLIMS, and the timely response and technical know-how of service personnel, met their requirements. Fortitech recognized that future resources for support will be available, and recommendations were received from clients with similar applications. STARLIMS demonstrated the ability to integrate with their existing Inventory Management Specification System (IMS), and a major advantage was the interface established with Millennium³², from the Waters® Corporation. The Millennium³² interface enables scientists and technical staff to seamlessly move electronic records between Millennium³² and STARLIMS without generating any additional non-controlled files. This is a superior enhancement for labs complying with 21 CFR Part 11 requirements encompassing security; data integrity, traceability, and audit trail generation. "A seamless interface between Millennium³² and STARLIMS improves our laboratory productivity and minimizes our compliance risk by eliminating manual data transfer," said Dr. Chaudhari.

**"STARLIMS' automatic data entry saves
1-2 hours per day per chemist"**



Design & Implementation

Chemists at Fortitech identified what was needed for each workflow process in terms of data entry, data transfer, calculations, validations and approval mechanisms. STARLIMS was installed for all stages of the workflow. Optimization, Modification and Validation processes were then conducted, followed by the system's move to production.

Benefits

STARLIMS has created an increase in productivity for the automated prioritizing system; the possibility of errors has been minimized, and a direct data entry system is now in place. A saving of about 1-2 hours every day, per chemist, now exists.

A streamlined inter-departmental workflow has been established by enabling Pre-Login of samples; as orders are taken and processed by the production personnel, STARLIMS pre-logs samples, and the lab chemist is informed of the workload arriving at the lab. The system is in compliance with 21 CFR Part 11 and there is an increase in overall data integrity and security.

STARLIMS is compatible with the existing IMS system. Fortitech are able to extract information such as product code number, date of manufacture, product name, customer name and so forth, minimizing duplication of effort and possible errors in the process.

Related information stays compiled in one folder. Fortitech are able to save about 50% of their resources associated with Sample Login.

The workload is automatically prioritized depending on the business needs, as STARLIMS is capable of scheduling the samples to be analyzed according to: delivery date, P.O. received date, sample-logging date, manufacture date, and laboratory turnover time.

The whole process has been made user friendly by employing an intuitive color-coding scheme. For example, in customer service inquiries regarding the status of analysis of premix, STARLIMS generates a report with: green for the analytes that meet customer specifications, red for Out of Specification (OOS), and yellow for the pending analytes. Dr. Chaudhari estimates that this alone is a resource saving of about 3-4 hours per day. Customers can be served in a timely manner, because current, accurate information is available on monitor screens.

Future Goal

Building on its' STARLIMS experiences in the US and the know-how related to streamlining its processes that has been gained, Fortitech intends to replicate the configured STARLIMS system at its other plants in South America, Europe and Asia Pacific.

STARLIMS Corporation delivers cost effective, easy-to-use collaborative Laboratory Information Management Systems (LIMS) to organizations in the public health, pharmaceutical, petrochemical, forensics, food & beverage, environmental and chemical industries. Full featured and highly flexible our multilingual LIMS solution provides complete traceability leading to regulatory compliance, without compromising process versatility.

A 15 year track record has earned us recognition for "future proofing" our customers' investments and serving as a platform for new implementations and straightforward conversions of legacy systems.

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