



SoftTrace

quality management in action at FMC

Customer:

FMC International

- Wallingstown, Little Island, Co. Cork, Ireland
- Newark, Delaware, USA

FMC BioPolymer

FMC Corporation - one of the world's leading producers of pharmaceutical, food and beverage ingredients – is a diversified chemical company serving agricultural, industrial and consumer markets globally for more than a century. The company employs approximately 4,900 people worldwide.

Delivering high quality solutions and maintaining a strong focus on customer needs is a key priority for FMC. At ISO accredited facilities in Cork and Newark, FMC produces consistently high quality products and provides additional support to customers competing in global and regional markets.

Our ultimate objective in implementing SoftTrace LIMS and In-Process was to streamline efficiencies, automate transactions, improve data access throughout the manufacturing process, streamline product release and disposition and considerably enhance GMP compliance and rapid response capabilities. SoftTrace works for FMC because it has been designed specifically to enforce GMP compliance and it integrates easily with our ERP, laboratory, process automation and barcoding systems.

Eileen Dennehy
Quality Manager

Challenges:

- Replace paper-based and legacy systems with an electronic quality management system and integrate data from plant automation, barcoding and financial systems.
- Maintain full, demonstrable compliance with current and emerging regulations
- Maximise returns from current resources
- Achieve production efficiencies and waste reductions
- Achieve increased production control and real-time control over production parameters
- Enforce adherence to quality and validation rules, eliminate the potential for human error and maintain the integrity of the quality data chain
- Achieve real-time monitoring of ingredient, process and manufacturing quality data to batch and sub-batch level
- Achieve time savings and communication enhancements in QC testing and the implementation of production adjustments

Solution:

- **SoftTrace LIMS and In-Process modules** integrated with FMC's laboratory instruments, barcoding, plant automation and SAP ERP systems

Key Benefits:

- Full visibility on all quality and process data from ingredients through production to finished product dispatch
- Superior plant management via real-time, live data and integration with SAP
- Superior yield and plant management capabilities via increased visibility of production parameters
- Full integration with laboratory instruments and plant automation systems leading to elimination of paper records and optimal use of existing resources
- Increased throughput in micro plate sample testing
- Real-time results validation and sample disposition calculations based on user defined cascading specifications, with non-conformances clearly flagged
- Enforced GMP and guaranteed adherence to quality and validation rules – that drives a best practice quality management culture
- Enhanced instrument calibration control including automatic alerts, certification and a full calibration history
- Significant time saving and communication in QC testing via pre-defined test plans, frequencies and calculation formulae
- Real-time access to management information (graphs, reports and enquiries) for better decision making
- Significant reduction in the time needed to compile QA and regulatory requirements reports
- Cost savings and a rapid return on investment
- Improved customer service

Quality Management – Mission Accomplished

FMC has deployed **SoftTrace LIMS and In-Process** at its manufacturing facilities in Cork and Delaware for more than a decade. At both locations, the system was implemented as part of a facilities' upgrade designed to improve efficiencies and strengthen the company's global leadership position.

FMC chose SoftTrace as an integrated quality management solution to meet the challenges of achieving enhanced product quality management while, at the same time, driving down costs. The decision to meet current and emerging challenges with SoftTrace was based on its specific focus on FMC's production planning, cost control, product quality management and batch process requirements.

Having been designed to manage the data associated with both continuous and discrete processes, at FMC SoftTrace provides real-time access to all quality and traceability data. It facilitates chemical and micro-packaging analysis on a seven day continuous basis and monitors all laboratory results against predetermined target and upper limits and specifications. SoftTrace highlights out-of-specification packing process results and automatically determines the disposition of all finished products. This data is then used to determine the profile of the SAP inventory.

SoftTrace has been designed to enforce GMP compliance and eliminate the threat of quality breakdowns as a result of oversight or human error. This has meant paying particular attention to areas such as system security, traceability, audit trailing, data management and change control facilities. SoftTrace facilitates generating electronic alerts, automatically highlighting out-of-specification results, generating reports and trends and exercising tight control over stock and product movements. Real-time data validation guarantees compliance with quality procedures and ensures that the quality data chain cannot be inadvertently broken.

Eileen Dennehy, FMC's Quality Manager, agrees that as well as providing demonstrable regulatory compliance and optimised product release capabilities SoftTrace has helped FMC increase production efficiency and reduce costs.

The level of data integration and visibility SoftTrace provides naturally has had the knock on effect of improving internal efficiencies. Instant access to quality and production data allows for proactive decision making and that means increased output and reduced production and administration costs.

Eileen Dennehy

A Quick Return on Investment

Due to a focus on quality control and traceability, SoftTrace matched FMC's requirements with little customisation or process re-engineering so that it was easy to rapidly implement with minimum disruption to the business. The software's competitive cost and significantly reduced consulting, design and implementation period with prioritisation of critical processes provided a quick return on investment.

SoftTrace was easy to implement and it is easy to use. The SoftTrace team worked closely with us to make sure that the software matched our processes. They used their expertise to make process re-engineering suggestions that resulted in improved yields and materials control. We are confident that the system has the essential flexibility and scalability to meet our current and future demands. It's a prove solution from a company with a strong track record.

Eileen Dennehy



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