



ELAN SOFTWARE
SYSTEMS

A Siemens Business

MANUFACTURING INTELLIGENCE FOR LIFE SCIENCES

At a Glance

Vision

Manufacturing Intelligence for Life Sciences

At Elan Software, we think, act and conduct business the way Life Science companies do. Since Elan's inception, our vision has been to simplify, secure and improve the processes of Life Science manufacturers. Our drive is to help Life Science industries achieve lean manufacturing, optimize operational processes, exceed regulatory compliance, promote total quality, reduce cost and accelerate time-to-market.

Mission

Providing Best-of-Breed MES

Elan Software Systems is a leading provider of Manufacturing Execution Systems (MES) dedicated to the Life Science industries. Elan Software enables FDA-regulated industries to streamline, control and track their production processes while guaranteeing compliance with FDA and cGMP regulations. Elan Software is a pioneer in business process technology applied to Manufacturing Execution Systems.

Expertise

FDA-Regulated Industry

With over 20-year regulated industry experience, Elan Software has developed a solid expertise in understanding, analyzing and optimizing manufacturing processes. With embedding GAMP methodologies from the ground-up, Elan Software offers robust, pre-validated, Life Science-specific solutions to effectively translate manufacturing processes into operational excellence.

Worldwide References



ADWYA
ASTRAZENECA
BAXTER
BAYER
BELLCO SOLUDIA
CATALENT
DELPHARM
DEPOLABO
ELAIAPHARM
EUGENE PERMA
EXPANSCIENCE
FAMAR
FAREVA
GENITOPE
IPSEN
JOHNSON & JOHNSON
LABORATOIRES CHEMINEAU
LABORATOIRES SEROBIOLOGIQUES
LABORATOIRES SERVIER INDUSTRIE
LANCASTER
LFB
MASSACHUSETTS BIOLOGIC LAB.
MAYOLY SPINDLER
MERCK
MERIAL
NOVARTIS
ORIL INDUSTRIE
PATHEON
PIERRE FABRE
RECIPHARM
ROTTENDORF PHARMA
SAIPH
SANOFI AVENTIS
SANOFI PASTEUR
SCHERING PLOUGH
SHISEIDO
SIGMA PHARMACEUTICALS
SOGIVAL
STAGO
SYNERLAB
TAKEDA
UCB
YVES ROCHER



CHALLENGES for Global Life Sciences

Exceed Regulatory Compliance

Ensuring compliance with worldwide regulations and standards, fostering quality across processes and providing greater visibility are top concerns for Life Science manufacturers. XFP-MES ensures high regulatory compliance with necessary cGMP features. Complete manufacturing traceability, audit trails, batch genealogy and electronic archiving facilitate information retrieval and online validation.

Increase Cost Effectiveness

Reducing costs and improving operational performance account for major issues of Life Science companies. XFP-MES eliminates errors, significantly reduces scrap and process delays. Seamlessly integrated with ERP and automation systems, the solution automatically performs data monitoring, controls and calculations. This leads to higher productivity, safer production and shortened cycle times.

Accelerate Time-To-Market

With endless R&D cycle, limited patent life and growing generic competition, being able to produce better and faster is also on top of the list. The XFP-MES solution simplifies and secures complex manufacturing processes, promoting efficient manufacturing throughout the plant. Directed manufacturing, real-time non conformance communication, material flow management and accelerated e-batch review are just a few deliverables from XFP that speed time-to-market.

Promote Lean Manufacturing

Solutions that streamline processes and support Process Analytical Technology (PAT), Quality by Design (QbD), Lean and 6-Sigma initiatives are on manufacturers' radar screens. With advanced technology, XFP-MES enables manufacturers to master, control and optimize processes. The ISA-88 compliant workflow enables users to define e-work instructions, complex routings and any plant-related processes.

XFP-MES

Fostering Quality and Performance

The XFP-MES Suite empowers manufacturers with ISA 95-compliant MES solutions, streamlining processes and fostering quality throughout the plant. Powered by advanced workflow technology, XFP-MES enables manufacturers to design, execute, monitor, control, analyze and improve operational processes, whatever their complexity.

Open, modular and scalable, XFP-MES enables Life Science companies to either pick and choose the processes they want to automate or deploy a prepackaged MES application.

XFP-MES Operation Process Library

Key Features



- ISA 95 Integration
- Material Flow Management
- Inventory Management
- Weigh & Dispense
- ISA 88 Process Design
- Directed Manufacturing
- Equipment Management
- OPC-based Integration
- eBR Review
- 21 CFR Part11 e-Signatures
- Audit Trail
- Batch Genealogy
- Archiving
- Access Management





Design

XFP-MES provides powerful capabilities to graphically model, maintain and optimize manufacturing processes, with no IT skill required. Change Management enables a fast and reliable process maintenance and evolution.

Execute

XFP-MES manages process execution and assigns the right operations to the right person. To name a few, work instructions, electronic SOPs, data entry and signatures are displayed online via user-friendly interfaces.

Monitor

Manufacturing variables are tracked and controlled in real time. In case of deviations, XFP-MES instantly alerts users and automatically generates inquiries and/or corrective actions to undertake.

Control

The ability to automatically apply real-time controls and validation to every critical step of the operation process is the guarantee for high quality and security of the manufactured products.

Analyze

XFP-MES provides a central repository of enterprise-wide operational processes combined with ready-to-use connectors for fast integration with Business Intelligence solutions. Thus, online reporting, instant dashboards and Key Performance Indicators are easily put in use.

Improve

With XFP-MES, manufacturers gain visibility of their operation processes. Key information is available in real-time for process analysis and improvement. Aligned with lean manufacturing strategies, XFP-MES is the right solution to improve process reliability and robustness.



Prepackaged MES Solutions for Fast Deployment

XFP-MES provides Life Science companies with prepackaged solutions promoting manufacturing and quality excellence.



Electronic Batch Record

Paperless cGMP manufacturing

XFP eBR is your solution for paperless manufacturing. As a complete electronic batch record system, XFP eBR provides advanced features to design, streamline and manage operation processes. Powered by an advanced workflow engine, XFP eBR directs manufacturing, allows for eBR review and integrates real time business controls.



Weigh & Dispense

Fast and secured weighing

XFP Weigh & Dispense guides and secures operators in their critical weighing and dispensing tasks, performs automatic controls and calculations, eliminating error risks and speeding the weighing cycle. Extensive use of barcode technology, intuitive screens, 15+ off-the-shelf weighing modes makes the system easy-to-operate and fast-to-deploy.



Warehousing

Smart shop-floor Logistics

XFP Warehousing controls and pilots material flows in real time, from ingredient receipt in the warehouse to dispatching. It provides a comprehensive materials tracking system, down to the container/lot level, performing automatic checks on quality and inventory (FIFO, FEFO rules, quantity, etc.) at each step of the production.



Core

Passport for Compliance and Integration

XFP Core provides 21CFR Part11 e-signatures, audit trail, batch genealogy and eBatch records. XFP Core provides the integration hub to ERP, LIMS, automation systems via OPC and third party applications. And because mobility brings agility, XFP-MES works with mobile devices. XFP Core enables cluster and multithreaded architecture, supporting large number of concurrent users and optimizing load balancing.

Professional Services as Final Ingredient to Success

Committed to best practices, our professional services team and certified partners provide continuous knowledge and expertise to ensure customer satisfaction throughout the product deployment lifecycle and beyond.

Successful Implementation

Our experienced project managers and consultants excel at building multi-competency project teams, communicating regularly, and ensuring smooth global deployment. Experienced managers using proven methodologies ensure that projects are completed on time and within budget. Services may include the following activities: requirement analysis, time and budget management, specifications, solution integration, software qualification, go live and daily support to deploy, maintain and extend XFP-MES solutions.

Strong Validation Support

Validation services assist customers to guarantee successful regulation compliance. Quality experts can set up process risks analysis, create validation master and test plans, provide IQ/OQ/PQ protocols, on-site qualification tests and bring assistance during FAT and SAT performance. As customers are always responsible for final validation, Elan Software makes sure to issue a validation report to facilitate this required process.

Professional Training Services

Professional training from Elan Software is an expansion of our core principle of guaranteed excellence and expertise. Proper training is essential to ensuring our customer's employees will understand how their solution is designed to work and why. Elan Software has developed standard training programs, enabling end users and partners to reach complete operational autonomy, without any IT skill required.

Dedicated Customer Support

Elan Software customer support team is comprised of the most talented and skilled professionals dedicated to FDA-regulated environments. Our support team is available to work with customers around their schedule. Customer Support services are available via phone, email, on-site or through the Elan Software On-line Customer Support Center.





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