

Wyeth

Wyeth Meets Rigorous FDA Standards with AspenTech's Weighing & Dispensing Solution



Profile

Wyeth is one of the world's largest research-driven pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing and marketing of pharmaceuticals, vaccines, biotechnology products and non-prescription medicines that improve the quality of life for people worldwide.

Wyeth's Algete plant, located 25km outside Madrid in San Sebastián de los Reyes, is dedicated to producing sterile products. Major products being produced include Refacto® (hemophilia), Varidase® (anti-inflammatory) and Nystatin® (anti-fungus). The Algete plant has 350 employees serving approximately 6,000 customers located throughout Spain and exports to more than 20 other countries.

Business Challenges

In 2001, Wyeth decided to migrate the current ERP system to JD Edwards. At the same time, Algete plant management decided to re-evaluate its current Weighing & Dispensing system. **"At Wyeth, we consider Weighing & Dispensing to be a critical part of the pharmaceutical manufacturing process. We began to look for a solution that would allow us to further support Algete's specialized requirements, meet new regulatory requirements, such as 21 CFR Part 11, and achieve FDA approval in the short-term"** said Javier Suarez, Materials Manager, Wyeth Farma, S.A.

Wyeth's Algete plant is focused on the fermentation and purification of biological active ingredients. It performs both Active Pharmaceutical Ingredient (API) and Drug Product (DP) operations. For these reasons the Algete plant has many specialized requirements in order to comply with Wyeth's strict internal validation guidelines. The unique business challenges for a Weighing & Dispensing system at the Algete plant included:

Regulatory Compliance

- Good Manufacturing Practice (GMP)
- Meeting rigorous standards required by the U.S. Food and Drug Administration (FDA)
- European Agency for the Evaluation of Medical Products (EMEA)

Weighing & Dispensing Requirements

- Ability to convert biologically active ingredients from/to international units
- Ability to handle 9-10 variations of pharmaceutical forms
- Flexibility to adhere to the broad requirements of a small-medium size batch environment
- Capability to integrate seamlessly with ERP system
- Capability to be used in both primary bulk active (API) and secondary drug product (DP) manufacturing, including:
 - Fermentation / purification of biological drug substances (Varidase and Nystatin)
 - Aseptic processing and lyophilisation of biological drug products

Alignment with Strategic Corporate Objectives

- Desire to obtain FDA approval in order to achieve goal of becoming a worldwide supplier of Refacto

"We needed to become FDA compliant in order to fulfill our goal of becoming the worldwide supplier of Refacto. AspenTech's Weighing & Dispensing solution is a critical component for attaining this compliance and we are very pleased that our Weighing & Dispensing solution did not receive any observations from the FDA during the approval process. In addition, the Weighing & Dispensing solution integrates well with our business systems, which makes it easy for us to use the data in our ERP system."

Javier Suarez
Materials Manager
Wyeth Farma, S.A.

Solution

Wyeth considered several solutions before choosing AspenTech's Weighing & Dispensing solution, a component of Aspen Electronic Batch Record System (eBRS™) product. **"Part of the complexity of this project involved getting the biologically active ingredients from international units into weight. When you deal with this sort of potency issue, the multiplier (factor) to get the physical weight depends on each active ingredient batch. We needed a Weighing & Dispensing system that could handle our 9 to 10 variations of pharmaceutical forms and that could cope with our diverse requirements for our fermentation process and our aseptic environment,"** said Suarez.

As of mid-2003, after a 6-month period of implementation, trials and internal validation, the Algete plant is dispensing all of its raw materials through Aspen eBRS, which is completely integrated with JD Edwards. ERP Production Order and its detailed Bill of Materials (materials and quantities) are downloaded to Aspen eBRS, which creates the corresponding work order (control recipe). Current stock is also periodically downloaded in order to provide the ability to work (during a window period) even in cases where communication with the ERP is lost. Weighing operations, as well as other associated tasks (e.g. cleaning, scale standardization, etc.) are distributed and executed at the proper location and proper time (if sequencing is required) based on pre-set configuration and rules. During execution, the system guides the operator while monitoring and controlling the operations. Data resulting from these operations (consumptions, etc.) are uploaded to the ERP system both in real-time and when the entire order has been executed. All process relevant information is recorded and ready to be used in order to obtain regulatory or general-purpose reports. All described activities take place in full accordance with GMP and product safety regulations.

Reports being generated from the Aspen Weighing & Dispensing solution include:

1. **Batch Record** including all dispensing information for inspection by health authorities
2. **Dispensing Certificate** for final information on dispensing related to a specific batch
3. **Tracing and Tracking Information** of lots

About AspenTech

Aspen Technology, Inc. is a leading supplier of enterprise software to the process industries, enabling its customers to increase their margins and optimize their business performance. AspenTech's engineering solutions, incorporating Hyprotech's technologies, help companies design and improve their plants and processes, maximizing returns throughout their operational life. AspenTech's supply chain manufacturing solutions allow companies to run their plants and supply chain more profitably, from customer demand through to the delivery of the finished product. Over 1,200 leading companies rely on AspenTech's software every day to drive improvements across their most important engineering and operational processes. AspenTech's customers include Air Liquide, AstraZeneca, Bayer, BASF, BP, ChevronTexaco, Dow Chemical, DuPont, ExxonMobil, GlaxoSmithKline, Lyondell Equistar, Merck, Mitsubishi Chemical, Shell and Unilever. For more information, visit www.aspentech.com.

Wyeth worked closely with AspenTech on validating the Weighing & Dispensing system to comply with FDA regulations. "We were able to get the system validated and are well on our way to getting full FDA approval for the distribution of Refacto to the U.S. Once we receive approval, we will be one of the first pharmaceutical plants in Spain to receive FDA approval for sterile products and the only international Wyeth plant with FDA approval," said Suarez.

Business Benefits

AspenTech's Weighing & Dispensing solution has been integral in enabling Wyeth to integrate its ERP to the plant-floor. It has also been critical in facilitating Wyeth's strategic corporate objectives of meeting FDA requirements.

Other benefits include:

- No observations / warnings for Weighing & Dispensing during FDA approval process
- Reduction of human error
- Increase in 'first time right' percentage of batches
- Compliance with Good Manufacturing Practice (GMP)
- Generation of dispensing certificates for every batch
- Seamless integration with ERP system

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Vision

In November 2003, Wyeth's Algete plant received pre-approval inspection from the FDA with full approval expected in 2004. Regarding Wyeth's future relationship with AspenTech, Suarez commented, "Our goal is to continue to drive benefits with AspenTech and to remain in compliance with evolving industry standards."



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