

Observations Made

PRESS RELEASE

Valdata Systems - Creating an Audit-Ready Plant

Valdata's Chemical Management System Incorporates Audit-Ready Features

April 3, 2012: You just received a call from your customer (or an FDA inspector), notifying you of an audit (if they aren't calling you from the parking lot)... are you ready? For companies relying on paper AUDIT CHECKLIST batch sheets, manual data entry and manually enforced / recorded Nonconformances Found Audit Satisfactory maintenance procedures and records, there is cause to worry.

According to BioPharm International, companies are best prepared for customer and FDA audits if they have:

> "invested the necessary resources toward understanding deviations and finding corrective actions to prevent them in the future, [and] established change controls and documentation practices that are carefully followed so that your company can respond to any type of problem ..."1

Valdata Systems has implemented a solution which gives companies a sense of confidence instead of panic. Valdata System's Chemical Management System offers real-time, paperless control over all aspects of the manufacturing process:

- Recipe Development
- Receiving
- Testing (LIMS)
- **Inventory Control**
- Pre-weigh
- Manufacturing
- Production

BioPharm International, "Conducting the Audit – Ready or Not, Here They Come", Nov 1, 2003

Valdata Systems - Creating an FDA-Ready Plant

Developed to meet the strictest guidelines (including FDA's CFR 21 Part 11), the software can produce an audit trail of every transaction. The system communicates directly with scales, so all pre-weigh and consumption data is guaranteed to be accurate which eliminates human error.

The system prompts and polices employees through every process from pre-weigh to resource maintenance, guaranteeing that no detail is left undone.

CEI in Ridgefield, NJ is one company who has gone through audits both with and without Valdata's Chemical Management System. According to Dan Hare, Vice President of Quality and Regulatory:

"It has completely changed the way we're audited. I've never had, since we put [Valdata's] system in, any corrective actions on an audit or observation in any negative way in our raw material handling system."

By investing in systems such as Valdata's Chemical Management System, which provides the ability to control processes efficiently and accurately records the data created, companies are better prepared to meet the strictest of guidelines ... even those set by the FDA.

About Valdata Systems

Headquartered in Fairfield, NJ, Valdata Systems is a premier provider of Chemical Management solutions specifically targeting the Pharmaceutical, Flavor & Fragrance, Nutraceutical and Chemical Manufacturing industries.

For more information on Chemical Management Systems, Inventory Control Systems, Recipe Manager and other products provided by Valdata Systems please visit: www.valdatasystems.com

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