Software Validation: What Life Sciences Businesses Need to Know

Strict process control is fundamental for life sciences businesses. Not only is it important for accurate manufacture of drugs and devices that can make the difference between life and death, it also is mandated by the U.S. Food and Drug Administration (FDA) and similar regulatory bodies in other countries.

The manufacture and distribution of food and drugs is heavily regulated as a public health measure. Verifying the right materials are used for manufacture, and accurately tracking and logging every step in the process is necessary for ensuring public safety. These are outlined in U.S. Code of Federal Regulations (CFR) Title 21, which defines the Good Manufacturing Processes and Quality System Management principles companies must use to comply with the law.

The FDA not only sets rules around process for life sciences firms, it also sets rules for ensuring process. The software used by life sciences firms must be audited by law to make sure that the controls and processes a business expects actually take place correctly. This process of verifying that a life sciences business' software performs as expected is called software validation.

Validation is Proof that the System Performs Correctly

Software validation is simply checking that the software is configured correctly.

"The definition of software validation is that it is documented evidence that the system is installed and set up as intended," says Archie O'Leary, vice president of sales for one of the leading life sciences validation firms, **Arbour Group**. "It is validation that the system operates as intended and that there are procedural controls in place for it's use and that people are trained."

A particular formula must be followed when manufacturing a specific drug, for instance. Validation checks that the correct formula is listed in the software. Specific materials are needed from a specific list of verified vendors for the manufacture of the drug, so validation confirms that the system handles this correctly and does not allow the purchase of materials from non-approved vendors.

Drugs must be manufactured in a particular way to meet FDA guidelines as well, such as being produced at facilities that have been certified. So validation checks that the software system requires this and is operational at these centers. The output of the manufacturing process itself must be tracked and traceable in case defects are discovered and a recall is required. So the software process for tracking and tracing is checked.

There are many other validation checks as well. In the case of quality management, for instance, the FDA requires validation of processes such as electronic signatures, recall and hold functionality, traceability features such as serialization and lot control, non-conformance reporting (NCRs), corrective and preventive actions reports (CAPAs) and calibration and test protocols.

"All of these are regulated processes," notes O'Leary. "The FDA doesn't care about things such as the general ledger. They just want to make sure that certain processes are verified in the system."

The process for validating a system is simply to document the software processes and then have a verified third-party check to ensure that what a company says is happening is actually taking place.

"We go in and test that things actually work as specified," says O'Leary.

Prepackaged Industry Solutions Make Validation Easier

As a result of the strict process control needs of the industry, and the need for validating these processes, almost all life sciences businesses use enterprise resource planning software (ERP) to run operations. ERP systems are end-to-end backend software solutions that handle all parts of a business from manufacturing and sales to shipping and financial management.

Some of what ERP handles for life sciences business include:

- Formula/Recipe Management
- Document Management
- Supplier Management
- Serial Number Tracking
- Lot Number Tracking
- Traceability and Recall Management
- Supply Chain Manufacturing
- Advanced Planning
- Quality
- Order Processing and Available-to-Promise
- Laboratory Information Management System
- Warehouse Management
- Plant Equipment
- Accounting
- Revenue Recognition
- Sales Expense Tracking and Management

ERP systems are general software solutions that can be configured for businesses of any type, much as a spreadsheet can serve many different use cases depending on the user. There are preconfigured ERP solutions that are tailored to specific industry verticals, however, cutting the time required for setup.

These prepackaged industry solutions are particularly valuable for life sciences firms, because starting with a system that has been pre-validated can dramatically cut down on the cost of configuration and verification.

“I think prepackaged is the way to go,” says O’Leary at Arbour Group. “As any IT project manager would tell you, What are my risk and how do I reduce them? Well, prepackaged is certainly a way to reduce risks.”

Many third-party auditors also frequently have experience with the underlying systems used with prepackaged ERP, which further reduces the time and cost of validating a company’s system.

“We have pre-configured validation solutions for systems like SAP Business ByDesign,” says O’Leary. “We’ve done enough of them that we have a test-script library that represents the more prevalent functions in the manufacturing process for a life sciences company.”

Prepackaged ERP solutions almost always serve as a good starting place for a new backend systems rollout. For life sciences firms, however, the advantages are even greater because of validation considerations.

Get Help with Software Validation

Navigator Business Solutions has been helping businesses with ERP implementation and software validation for more than 25 years as an SAP Gold Partner. We’re deeply familiar with the software needs of life sciences firms, and we offer several prepackaged industry solutions for specific life sciences business such as pharmaceuticals and medical device manufacturing.

If you would like help with ERP or the software validation process, please call one of our consultants at **(801) 642-0123** or email us at **info@nbs-us.com**.