GMP Validation Center

HBT Labs Deploys BatchMaster ERP and GMP Validation Center's Services to Accelerate Commercialization

Process manufacturing ERP and GMP validation key accelerators for fast-growing, highly regulated pharma company

Company	HBT Labs, Inc.
Headquarters	Brea, CA
Industry	Pharmaceutical
Systems Replaced	QuickBooks

OVERVIEW

HBT Labs, a specialty pharmaceutical company, deployed BatchMaster Software's ERP for Pharmaceuticals solution and GMP Validation Center's software validation services to prepare for the commercialization of its products and comply with FDA regulatory requirements.

KEY BENEFITS

- Increased productivity and performance with an end-to-end ERP solution with advanced business automation and mobile task execution that replaced their legacy QuickBooks and manual, paper-based system
- Gained real-time visibility and control over business processes, plus reduced daily material searches from 2 hours to 5 minutes
- Validated the company's manufacturing processes to ensure compliance with FDA regulatory mandates and Good Manufacturing Practices (cGMP) requirements
- Implemented a world-class ERP solution built upon the SAP Business One platform that will support the company's business initiatives and growth objectives

HBT labs

CHALLENGE

HBT Labs is a technology-based, specialty pharmaceutical company developing and commercializing “High Barrier Therapeutic” injectable drugs. HBT Labs also conducts advanced scientific research into drug delivery systems, process development, patent analysis, and regulatory compliance.

Founded in 2013, the Brea, CA firm is implementing processes often required by FDA-regulated companies and preparing for the commercialization of its products. HBT’s research and development efforts focus on complex injectable pharmaceutical products to treat disease, including CNS disorders and cancer.

HBT has extensive experience in developing proprietary processes and technologies to produce complex drugs across multiple delivery platforms, including liposomes, nanoparticles, emulsions and long-acting injectable suspensions.

The company’s pipeline includes generic and 505(b)(2) products that target various treatment indications including cancer and CNS disorders. The company operates an FDA-inspected cGMP aseptic manufacturing facility licensed by the State of California, as well as research and development laboratories.

Before it enters the next stage of development, HBT needed to automate its paper-based systems and graduate from QuickBooks to a more mature business management (ERP) system equipped to handle pharmaceutical manufacturing of drugs with complex chemistry and manufacturing processes. As such, HBT also needed to improve its inventory system and adopt software validation of its processes to comply with Federal Food and Drug Administration manufacturing regulations.

HBT Labs created a highly organized and well documented set of processes that they meticulously, but manually tracked using spreadsheets and paper.

Existing Systems Unable to Accommodate Growth

"We are a young, fast-growing pharmaceutical company that's only about seven years into operation," says Janet Braun, chief operating officer. "We've been using QuickBooks and everything else is paper. We're developing processes and, in anticipation of commercialization, realized we needed something better than QuickBooks and we needed a manufacturing program to help with inventory and batches."

HBT operates in two buildings about a mile apart. Having paper-based systems complicated and lengthened processes that needed approval signatures. For example, someone would have to drive over to the other building to get a purchase order signed.

Manual Material Traceability of Batch Manufacturing Took Hours

Since inventory was tracked on paper, it was very time consuming to determine raw materials in a batch, track expiration dates or simply learn if they had enough raw material in inventory, says Rupinder Kaur, Materials Management Associate at HBT. "If a material went into five or six batches, tracing it in the paperwork would take a day," she says. "If it was just one or two materials, it would take a couple of hours."

Since she fielded requests of this nature at least once a day, she needed a consolidated system for all inventory information so they could track materials, better understand what they had in inventory, and spot trends. They also needed this information to help them plan better.

Initially, HBT looked for a standalone financial system but executives expanded the requirements to include a full ERP with process manufacturing functionality specifically geared for pharmaceutical companies.

"Digging through paper is really rife for mistakes and inefficiencies, and we also had to get a better process in place for inventory and manufacturing," Braun says. "It made sense to do it all at once."

High on the list of requirements was a single system that provided a high level of data transparency.

Validation Services Required for Process Manufacturing

HBT eliminated many large and expensive ERP solutions, such as Oracle and NetSuite, from consideration because they were not equipped to handle the company's unique requirements. Also because HBT found that many ERP solutions don't follow the required FDA guidelines. As an example, the larger ERP solutions typically perform software updates autonomously, which would not comply with HBT's regulatory requirements.

"Many small to mid-sized company ERP options don't work for the pharmaceutical industry and many don't understand the depth of the validation process we need," Braun says. "We didn't really look at some ERPs for that reason."

Pharmaceutical process validation provides confirmation that a manufacturing process is protected from variances that could interfere with the pharmaceutical product, the supply chain, or public health. In 2011, the FDA acknowledged that one-time testing was not enough to assure public safety, and began requiring companies to validate and document manufacturing and commercialization processes on an ongoing basis, subject to audits to ensure drug quality, effectiveness, and safety.

SOLUTION

Industry-Specific ERP, Software Validation Services Maximize ROI

After evaluating several ERP solutions including Oracle and NetSuite, HBT selected BatchMaster with SAP Business One because of BatchMaster's long-standing success and track record in Life Sciences and process manufacturing, and because its functionality aligned with current Good Manufacturing Practice (cGMP) requirements.

BatchMaster has supported the unique requirements of small to midsize process manufacturers for over 30 years. Seeing a need in the process manufacturing marketplace because of the complex nature of FDA's validation requirements, BatchMaster created a spinoff called GMP Validation Center, which provides software validation as a service.

The close alignment between the sister companies, BatchMaster and GMP Validation Center, was another top reason HBT Labs chose BatchMaster, Braun says. The synergies, depth, and cross-sharing of knowledge between BatchMaster and GMP Validation Center allowed HBT to use a single project manager who could flex between the two providers, making the implementation smoother, easier, more cost effective, and less time consuming for HBT. HBT also saw that it would gain long-term benefits post-implementation from the close coordination of the two sister companies, such as seamless synchronization and coordination for future updates, upgrades, and overall changes to ensure that its ERP and ongoing validation and compliance stay current with its evolving business requirements.

Braun and Kaur liked that BatchMaster and GMP spent time learning HBT's business, crafted a specific implementation plan for them, and provided best practices and process improvements throughout the implementation, which included the full ERP system and software validation all at the same time.

"They were very patient with us," Braun says, adding that this was her and Kaur's first ERP implementation. "We are a young, lean firm working on everything as we grow and they were very patient and there for us."

"Because we were doing software validation remotely, it added an element of complexity," Braun adds. "But with GMP Validation Center's excellent management of the project and both teams' equal reciprocal effort, even with the pandemic, it was possible to continue working and complete the validation project in time."

BENEFITS

Automation and Control of Pharmaceutical Processes

With the deployment of BatchMaster with SAP Business One with software validation, HBT Labs is much more efficient, automated, and prepared to tackle its next stage of growth, which includes commercialization, Braun says.

BatchMaster with SAP Business One provides better financial controls, and the connection between accounting and material handling is much more transparent.

"The approval processes are more rigorous and there's much more oversight of who can approve an item at different levels, and simply knowing what's out there in inventory is critical," Braun says.

There's no longer a need to drive between locations because items like processing every PO can be electronically approved, she says.

Improved Material and Lot Visibility

Because BatchMaster provides a single system to view inventory and material quantities throughout the entire sales order, MRP, and manufacturing processes, HBT Labs has greater visibility into inventory levels allowing them to better manage materials on hand and turns. BatchMaster's process manufacturing expertise allows HBT to remain compliant with industryspecific and federal regulations, in terms of labeling, lot traceability reports, transactional audit reports, and shipping documentation.

Kaur has saved hours by having that information at her fingertips. "It's nice to quickly access a record rather than shuffling papers," she says. "If a material went into five or six batches it would take a day for me to find the information. Now, it takes under five minutes to find all that information."

BatchMaster's Warehouse Management System has allowed HBT to use bar codes, print labels, and get rid of paper-based processes, Braun says. The company also implemented BatchMaster's Fixed Asset Management capabilities for its accounting team, providing much better transparency into company assets.

"That was critical," she says. "QuickBooks doesn't have a fixed asset system."

FDA-Compliant ERP Software

Importantly, HBT Labs now has a single, FDA-compliant ERP system to grow on.

"I found the GMP Validation Center's team to be very knowledgeable of FDA requirements. They suggested ways to improve management of raw materials in a GMP-acceptable manner, which helped us a lot," says Kaur.

Adds Joelle Yang, HBT quality assurance manager, "We already had a QMS system, and I was worried how challenging it will be to maintain data that was in sync with BatchMaster Software. But with GMPVC team's thorough understanding of BatchMaster and SAP Business One, they were able to map our processes in a regulatory acceptable way without any overlap in activities."

About BatchMaster Software

BatchMaster Software is a world-leading ERP solution that helps formula-based, process manufacturers streamline their operations and scale up production, while reducing costs and complying with ever more stringent regulatory mandates. BatchMaster Software is an eWorkplace Manufacturing solution. eWorkplace Manufacturing is a global provider of market-leading, industry-specific software and services focused on the manufacturing and distribution industries. eWorkplace Manufacturing, Inc. is headquartered in Irvine, CA with offices, sales, and support throughout North America, Latin America, and the Asia-Pacific.

About GMP Validation Center

GMP Validation Center provides software validation services to FDA-regulated manufacturers in the life sciences, pharmaceuticals, biotechnology, medical device, nutraceuticals, healthcare, and food and beverage industries. Its team has deep expertise in FDA compliance and ERP software.

GMP Validation Center is a spinoff of BatchMaster Software and eWorkplace Manufacturing, Inc.