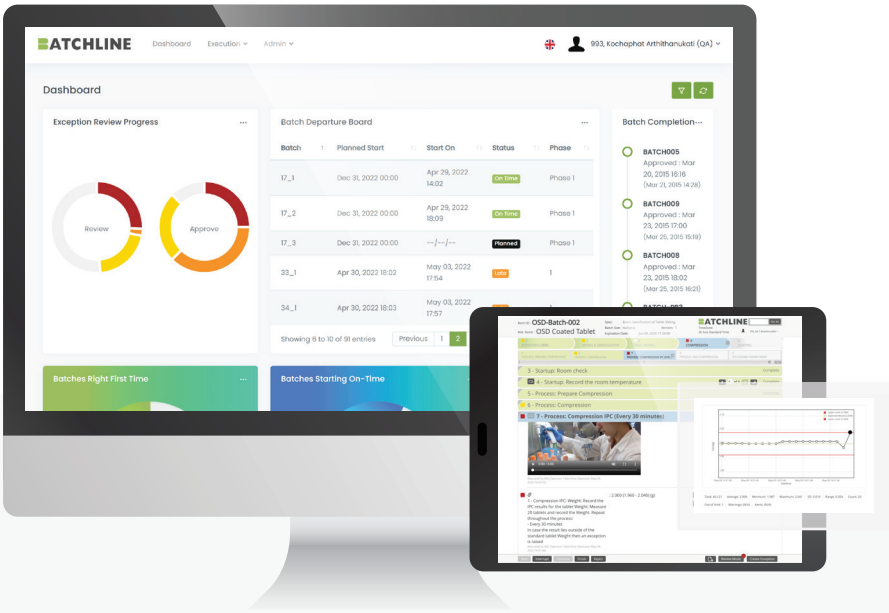
BATCHLINE

CASE STUDY

GLOBAL BIOTECH PRODUCTS



COMPANY OVERVIEW

Company Name:
Global Biotech Products

Focus:
Vaccine Biological pharmaceutical

Location:
Chachoengsao, Thailand

Employees: 130

Opened in 2000, the GBP facility is located on 24,000 square meters in Chachoengsao province, with 6,000 sq.m dedicated to manufacturing. GBP has a production capacity of 20 million doses per year, depending on the type of vaccine.

The power of electronic batch recording in the pharmaceutical manufacturing industry.

GBP is the 1st Vaccine Biological pharmaceutical plant in Thailand, a joint venture between Thailand's government pharmaceutical organization (GPO) and France's Sanofi Pasteur. In 2020, GBP approached us highlighting the pain points within their production shop floor, particularly batch production entry time and strong data integrity expectations.

“We faced extreme challenge around the physical movement of paper in sterile and production areas. The maintenance of paper batch record comes with its own efforts, human error are inevitable resulting in difficulty to enforce data integrity” says Karuna Tuncharoen (Production Manager).

After a careful analysis of their current process, we identified several areas where improvements could be made.

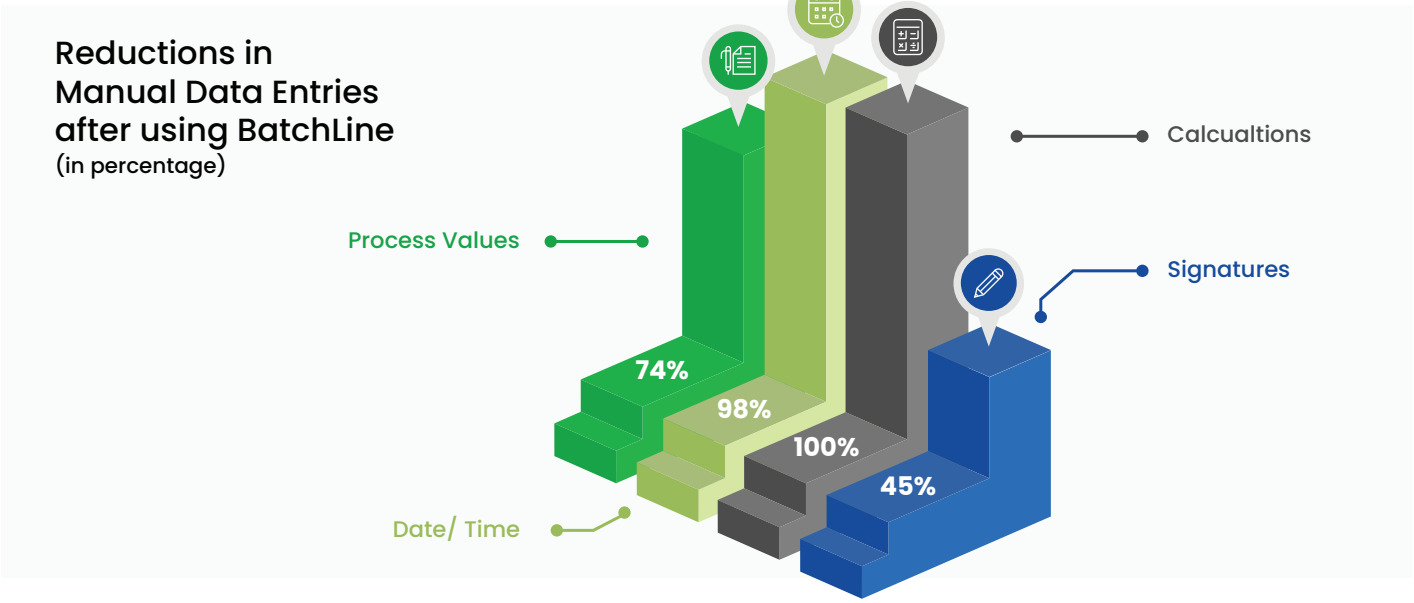
An Electronic Batch Record (EBR) system was considered a strong enabler of existing issues, and with support from the management team, BatchLine cloud-based EBR was set as a high-priority initiative for the site.

BatchLine cloud-based EBR solution was selected for its benefit of reduced IT costs, improved scalability, and increased flexibility for production.

The paper-based aseptic production concerns

The production and quality assurance team reported several high-priority issues associated with paper-based batch production. One of the main challenges faced by the team was the tedious aseptic technique and the difficulty of the physical movement of paper in sterile production areas.

It is compounded by Data Integrity issues. Information required for the processes is often duplicated and transcribed leading to more effort thus resulting in human errors. **Another challenge** that the quality assurance team faced was that they have **no visibility into the current status of production** and what is required to coordinate review activities. This can lead to long delays during batch production, which can be frustrating for both the production and QA personnel.



The solution: Electronic Batch Record [EBR]

Our team had the opportunity to visit the GBP production facility after their successful completion of 16 commercial batches manufactured using our BatchLine application.

The shift to Batchline EBR was substantial improvements in the efficiency of manufacturing personnel. It was also reported that the application assists them in eliminating common data integrity issues and deviations related to human error.

"Our typical production review time was 5 hours on paper. After go-live with BatchLine, it took our production team 3 batches to familiarize ourselves with the system. Thereafter, the team enjoyed a 60% improvement spending 2 hours on exception review and additional relevant documents before passing it over to QA personnel." says Wannee Piyacharoen (Product Quality Operation Manager)

Currently, 90% of the product are exported to Vietnam, South Korea and Australia. The application enables us to replicate processes and products for a different market. The roll-out of product SKUs can be deployed within a quick timeframe.

> “BatchLine helps improve our data integrity, especially in the IPC data entry & review process. The number of exceptions fell from 30 to an average of 12 exceptions. The application helps to eliminate exceptions generated due to human errors which were common in the past.”

Wannee Piyacharoen
(Product Quality Operation Manager)

SUMMARY

Challenges	The maintenance of paper batch record and visibility into the current status of production
The Solution	BatchLine Electronic Batch Record application BATCHLINE
The Result	Through the implementation of BatchLine EBR, the factory has seen a 60% reduction in data entry time and a 50% reduction in time required for quality reviewing and approval. The system assists the operators, supervisor and QA personnel to avoid mistakes or correct errors in a process almost immediately. Real-time data visibility also enables quality personnel to conduct a review by exception and achieve right-first-time production.

> “Batchline BR application enable our operators, supervisors and QA to focus their attention on processes that contribute to product quality. We are very pleased with the results and improvements.”

Boonrak Thawornrungroaj
(Managing Director)

60%
Reduce Production review time

50%
Increase QA review and approval rate

About BatchLine

BatchLine is a compact and robust cloud-based digital Batch Record system built on modern web technology. The software will help reduce your time and effort in producing, reviewing, and approving your batch records, and leverages rapid deployment and validation techniques enabling faster implementation while meeting compliance requirements for GMP/FDA regulated companies. It comes with powerful process management and execution tools with scalable architecture. With flexible pricing options, it will meet the requirements and budgets of any pharmaceutical manufacturer from medium to large sizes.

Learn more at www.BatchLine.com