CASE STUDY



GlaxoSmithKline Speeds Up Batch Release Time with MES Technology



"The system allows us to focus on the exceptions, rather than having to review every entry on a batch."

- Peter Iles-Smith, MES Technical Director, Global Manufacturing and Supply, GlaxoSmithKline GlaxoSmithKline (GSK) is a science-led global healthcare company that researches and develops a broad range of innovative medicines and brands. They have manufacturing facilities in over 70 sites. GSK's goal is to consistently deliver outstanding quality, service, and value to their patients and consumers with zero defects.

The sheer volume of GSK's business is enormous. Multiple packaging lines handle upwards of 10,000 batches per year, with each batch record including over 1,000 manual entries. This equates to over 10 million manual record entries per year. The elapsed time for preparation and review for each batch is 10 days. GSK wanted to review the structure of their batch production record and associated workflows as part of a continuous improvement process.

Global pharmaceutical industry leader relies on Aspen Production Execution Manager to ensure procedural control, thereby speeding up batch release time.

CUSTOMER PROFILE - GlaxoSmithKline - *Pharmaceuticals*

CHALLENGE

GSK wanted to re-evaluate the structure of their batch record in an attempt to improve batch release time.

SOLUTION

Aspen Production Execution Manager to reduce manual effort and speed up batch release time.

BENEFITS

- Automate the documentation process
- Reduce cycle time for order and record review
- Accelerate batch release time
- Improve equipment utilization and changeover time
- Reduce manual log book entry



GSK evaluated the market for a solution and selected Aspen Production Execution Manager as their workflow management product, building on their Aspen InfoPlus.21[®] foundation. A project was defined to initially cover three plant sites in three countries. Since implementing the solution, GSK has seen a dramatic improvement in their ability to complete batch documentation in a timely fashion, speeding up batch release time and accelerating time-to-market.

CHALLENGES TO BATCH RELEASE TIME

The pharmaceutical industry is inherently complex and GSK is not immune. Many of their processes impose operators to routinely perform a large number of manual data entries, along with other production tasks. The number of manual data entries per year for the Multi-Dose Powder Inhaler (MDPI) Assembly & Pack at Ware amounts to 10 million, involving 3,000 man-hours per year to capture Process Equipment Logbook (PEL) events. The required detail of the batch record has accumulated over many years. A review of the data requirements revealed opportunities to streamline the batch record, which would result in a speedier time to release.

CONQUERING THE COMPLEXITY

After evaluating the market for a batch solution, GSK made a logical choice in choosing Aspen Production Execution Manager, building on their Aspen InfoPlus.21 foundation. GSK decided to start small by piloting the project at three plant sites: device assembling and packing at two sites and two countries, as well as solid dose manufacturing at one site in another country. They formed a core group to engage with the three sites and set expectations.

The results have been dramatic. Aspen Production Execution Manager creates and maintains electronic records automatically as the batch moves through the production process, reducing manual effort while keeping the SOP visible. In addition, a thorough review of the audit process revealed that they could significantly reduce the amount of information required to support a batch. The cycle time for order preparation has now been reduced by 95% and record review reduced by 50%, enabling GSK to execute much faster than before. The improved structure also enables GSK to improve equipment utilization and changeover time.

FEEDBACK AND LOOKING AHEAD

The solution has significantly reduced the burden on plant operators by simplifying the batch record and automating the process. Feedback from the user community has been extremely positive:

- "It's easier to do what the SOP says and know when challenges are due."
- "The system keeps me on the right track. I always know where I am in the process."
- "The system keeps count, so I can focus on the inspection."
- "The system leaves us more time to deal with the issues."

Since the pilot project was a huge success, GSK plans to further roll out the technology across all target operations in a phased approach. They see Aspen Production Execution Manager as a key component towards meeting their end goal of zero defects.



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Worldwide Headquarters

Aspen Technology, Inc. 20 Crosby Drive | Bedford, MA 01730 | United States phone: +1-781-221-6400 | fax: +1-781-221-6410 | **info@aspentech.com**

Regional Headquarters

Houston, TX | United States phone: +1-281-584-1000

São Paulo | Brazil phone: +55-11-3443-6261

Reading | United Kingdom phone: +44-(0)-1189-226400

Singapore | Republic of Singapore phone: +65-6395-3900

Manama | Bahrain phone: +973-13606-400

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