GlaxoSmithKline

GlaxoSmithKline Speeds Up Batch Release Time: A Study in Digital Transformation

aspentech | Case Study

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

CHALLENGE

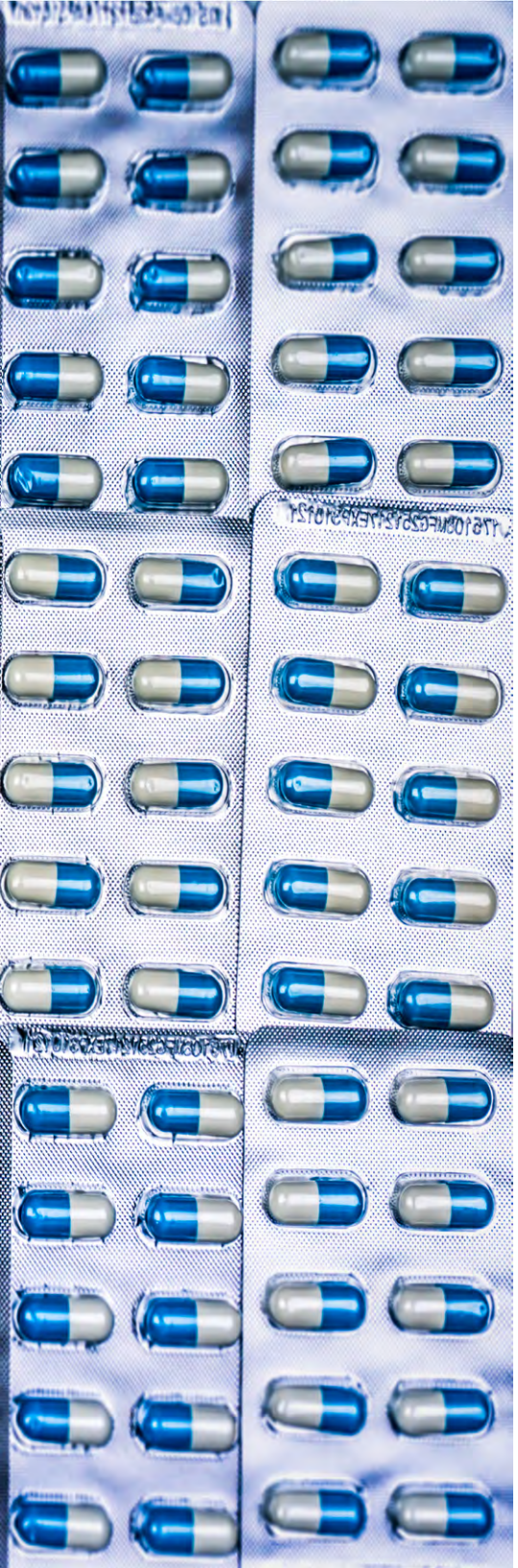
- GSK wanted to re-evaluate the structure of its batch record to improve batch release time.

SOLUTION

Adopted Aspen® MES solutions to reduce manual effort and speed up batch release time.

BENEFITS

- Improved equipment usage and throughput
- Accelerated batch release time
- Reduced cycle time for record review and release
- Automated manual records, documentation and log book entries



Introduction

GlaxoSmithKline (GSK) is a science-led global healthcare company that researches and develops a broad range of innovative medicines and brands. With manufacturing facilities in over 70 sites worldwide, GSK's goal is to consistently deliver outstanding quality, service, and value to 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 – over 10 million manual record entries per year. The elapsed time for preparation and review for each batch is 10 days.

Identifying Challenges and Finding the Right Solution

GSK wanted to review the structure of its batch production record and associated workflows as part of a continuous improvement process. Reducing batch review time usually results in faster batch cycle time, meaning higher throughput at the production facility and faster cash-to-cash cycle time. AspenTech was selected for this process due to integration with other solutions, such as Aspen InfoPlus.21® and GSK's existing plant automation software (DCS).

The pilot project was a resounding success, reducing order preparation time by 95% and record review time by over 50%. 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.

Manual Process Slows Batch Release Time

The pharmaceutical industry is inherently complex, and GSK is not immune. Many of the company's processes require operators to routinely perform a number of manual data entries, along with other production tasks. For example, 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. Over the years, more and more details have been required in the batch record. This important but bloated documentation slowed down manufacturing processes with manual steps, and the paper trail made quality investigations drag out longer than needed.

Conquering the Complexity

GSK began with a pilot project at three sites: device assembling and packing at two sites in two countries, plus solid dose manufacturing at a site in another country. GSK formed a core group to engage with the three sites, set expectations, and steward results.

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 GSK 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 operators to execute much faster than before. The improved structure also enables GSK to improve equipment utilization and changeover time.

Feedback and Looking Ahead

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

The solution has significantly reduced the burden on plant operators by simplifying the batch record and automating the process. Feedback from operations 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."

aspentech | Technology That Loves Complexity

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