MOMEnTUM Project:

A Modelling approach to Design Predict and Control manufacturing processes

Johnson & Johnson

SSPC

THE CHALLENGE

The Manufacture of pharmaceutics, biopharmaceutics and chemical products is complex and costly. Predictive modelling of process change helps to reduce waste and down time. In drug product manufacturing, most models used for the prediction of direct compression (DC) and roller compaction (RC) processes are process-parameters-based; meaning that the models do not consider the material characteristics. The variability in the same equipment and different equipment size and brand has an impact on the ability to process and transferability of complex blends and models. Another technology used in drug product manufacturing is Spray Drying (SD) however, the handling and processing of large molecule APIs at elevated temperature is uncommon and challenging. The Johnson & Johnson Automation Centre of Excellence (ACoE), presented a challenge to the SSPC to develop a modelling approach that would minimize manufacturing cycle time and develop cost effective, optimized processes for the manufacture of pharmaceuticals and biopharmaceuticals

THE SOLUTION

SSPC researchers combined existing theoretical approaches with a Design of Experiment (DoE) approach to develop 3 models that consider the physiochemical properties of excipients and APIs:

1. **A Continuous Manufacturing tablet compression integrated work stream** that allows J&J to predict compression behaviour from powder properties as well as convert between operating conditions of one press to another was developed. This required extensive characterization of a wide range of materials, across a range of equipment. The goal here was to build on existing modelling approaches to enable prediction of tablet critical quality attributes, tablet press performance and control settings enabling faster tech transfer to other lines or evaluation of new product powder properties as suitable candidates for Continuous Manufacturing.
2. **A Continuous Manufacturing Roller compaction work stream** to assess roller compaction behaviour of specific blends to J&J was developed. The modelling approach developed has been integrated into the J&J modelling library and is helping to inform J&J with respect to standards, technology transfer and equipment selection. These models are contributing to the reduction of technology transfer timeline and cost associated with Design of Experiments.
3. **A predictive model for the Spray Drying of Biopharamceuticals** was developed. SSPC researchers developed a spray drying modelling approach for removing moisture and compared this approach to the more commonly used freeze drying approach. Spray drying is an alternative technique to freeze drying that provides lower operation costs, continuously and with higher efficiency.

THE IMPACT

Participation in this project has benefited J&J through increased process understanding and ultimately leading to increased competitiveness by leveraging the diverse skillset and experience of the SSPC team.

"As we improve our understanding of the science and engineering in the development of emerging technologies, the SSPC collaboration with J&J allows us to better serve our customers and patients. This project supports our future growth by allowing a more efficient evaluation of the transformation of batch-mode processes to continuous manufacturing- mode one, which in turn enables production cycle time reductions, reduction of risk of rejects, scrap and re-processing and promotes easier implementation of real time release."
Jorge Belen, Scientific Fellow, Janssen Supply Chain Technical Operations, Johnson & Johnson.