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Optimising PAT for Continuous Direct Compression using Feed Frame Simulator and SentroPAT FO NIR Spectrometer

Friday, 30 May 2025 15:00 (20 minutes)

Monitoring formulation quality during Continuous Direct Compression (CDC) and therefore remaining within product specifications is complex and cannot easily be inferred from process measurements. Process Analytical Technology (PAT) sensors allow in-line process monitoring and control of Critical Quality Attributes (CQAs), reducing the time and effort required for both sampling and off-line analysis.

This work delves into optimising PAT for CDC, focusing on integrating Near-Infrared (NIR) spectroscopy with the Feed Frame Simulator (FFSIM). The project aims to enhance the accuracy and efficiency of the sensors and models, ensuring consistent product quality even for low-dose formulations.

Key components include optimising the acquisition parameters of the SentroPAT FO NIR spectrometer, such as the integration time and number of averages, as well as utilising the FFSIM for dynamic data collection and model development. This involves Principal Component Analysis (PCA) and Partial Least Squares (PLS) regression. By standardising data analysis methodologies and developing an integrated Real Time Release Testing (RTRT) strategy, the project seeks to address current challenges in PAT applications.

Future developments will explore the simultaneous use of multiple PAT instruments, including Raman spectroscopy and Light-Induced Fluorescence (LIF) spectroscopy, to further enhance process control. The ultimate goal is to create a robust, transferable PAT strategy for the CDC line, facilitating standardised practices across different sites and processes. This will provide insights for the development of new continuous manufacturing control strategies for low dose formulations.

Type of presentation

Contributed Talk

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