Smart Process Analytics for the End-to-End Batch Manufacturing of Monoclonal Antibodies

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Abstract

For many modern biopharmaceutical processes, manufacturers develop data-driven models using data analytics/machine learning (DA/ML) methods. The challenge is how to select the best methods for a specific dataset to construct the most accurate and reliable model. This article describes the application of smart process data analytics software to industrial end-to-end biomanufacturing datasets for monoclonal antibody production to automate the determination of the best DA/ML tools for model construction and process understanding. The application demonstrates that smart process data analytics software captures product- and process-specific characteristics for two different monoclonal antibody productions. This study provides tools that can be widely applied to biomanufacturing processes for root cause analysis, prediction, and control.

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