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Beyond Control Charts: Adaptive, Model-Based Condition Monitoring with Generative AI for Biomanufacturing Process Monitoring – Mark Wolff, SAS

Biomanufacturing processes generate high-frequency, high-dimensional process data along with intermittent analytical assessments. Statistical process control is predicated on fixed control limits and an assumption of stable and predictable conditions that may not be present in complex biological systems used for production of large-molecule therapeutics. Living organisms, raw material attributes, and operating conditions all vary inherently.

This presentation describes an intelligent condition monitoring framework that extends classical statistical process control through the integration of two analytically distinct but complementary components. Model-based monitoring develops empirical or mechanistic representations of expected process behavior and evaluates observed departures in real time, supporting predictive detection of process drift and informed adjustment of operating conditions within established design space boundaries. Statistical anomaly detection operates concurrently, applying multivariate methods to identify signals that fall outside the explanatory scope of existing process models, evaluating the deviations for which no model exists.

Upon confirmation of a deviation or anomaly, an automated prompt generation layer queries a structured, vectorized knowledge base containing process development records, batch histories, regulatory guidance, and curated scientific literature. This process automates root cause analysis of the anomaly. A large language model operating under retrieval-augmented generation returns a structured response comprising a contextual explanation of the deviation, ranked probable contributing factors, and recommended corrective actions. Validated outcomes are collected and used to refine both the monitoring models and the knowledge base, supporting consistent and informed responses to recurring deviation patterns across batches and campaigns and creating an intelligent, learning system.

The framework is designed to meet regulatory expectations for process control, traceability and explainability. Statistical process monitoring and governed generative AI are integrated to support early deviation and anomaly detection, reduce investigational burden, minimize waste and improve yield and quality.

