Contribution ID: **25** Type: **not specified**

Estimating Stabilization Time in Continuous Manufacturing

This work develops a statistical framework to estimate stabilization time for core tablet batches produced by continuous roller compaction. Using simulated data from multiple production runs of a representative product, the project focuses on characterizing concentration stability during start-up and identifying an optimal start-up duration to guarantee product quality and consistency. The current approach employs a two-component segmented linear model (broken-stick) implemented via the gslnls package in R to separate a transient phase of rapid concentration change from a subsequent stable phase. Although this model captures overall process behavior, practical application has revealed limitations: stabilization-time estimates and their confidence intervals are sometimes unacceptably large, reducing interpretability for operational decision-making. These issues likely arise from sparse transient-phase sampling, within-batch variability, and model inflexibility for complex dynamics. To address these shortcomings, alternative techniques will be investigated with a focus on robustness and precision of estimated change times.
The two-component linear (broken stick) model is given as:

$$\mathrm{Y}_i = \beta_1 + \beta_2 \left(\left(1 - \frac{1}{1+\exp(-\gamma(time_i - \tau))} \right) time_i + \left(\frac{1}{1+\exp(-\gamma(time_i - \tau))} \right) \tau \right) + \epsilon_i$$

Where: Y_i is the concentration at time i γ is the numeric smoothness of transition between linear model components. Higher value gives a sharper changepoint. β_1, β_2, τ are the parameters of the model which defines the components of interest (see below), $\epsilon_i \sim N(0, \sigma^2)$ is the residual error with σ^2 variance.

Special/ Invited session

Classification

Mainly application

Keywords

stabilization, broken-stick model, continuous manufacturing

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Track Classification: Statistics in Pharma / Healthcare