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Utilizing Finite Mixture Models to identify machine reading errors in the context of Continuous Manufacturing

Continuous manufacturing (CM) in the pharmaceutical sector integrates the various discrete stages of traditional batch production into a continuous process, significantly decreasing drug product manufacturing time. In CM, where all process units are directly linked, it is crucial to continuously monitor the current process state and maintain consistent product quality throughout manufacturing.

In-process control monitoring is a vital component of the CM control strategy. Given the need to analyze a large volume of data in real time, it is essential to differentiate between genuine process deviations and those caused by machine reading errors. Additionally, given the high volume and frequency of data generated, reevaluating whether an observation is truly an outlier or is a result of measurement error can be both challenging and time-consuming.

To address this challenge, finite mixture models were employed to a case study monitoring various critical quality attributes of tablets, specifically hardness, weight, thickness, and diameter, throughout the entire production process. The evaluation primarily focused on hardness values, with the assumption that both precise and imprecise measurements (resulting from reading errors, e.g. when tablet is not positioned properly in the machine) were present. Various classification thresholds (derived from either the quantile of the correctly-measured group or on the conditional classification curves) were determined based on the model outcomes. Performance of the method was investigated using simulated data based on actual production run.

Special/ Invited session

Classification

Mainly application

Keywords

finite mixture model, outlier detection, process monitoring, continuous manufacturing

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