



Impacts of Constituent Material Variability on the Performance and Quality of Pharmaceutical Dosage Forms

Guest Editor:

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Message from the Guest Editor

Dear Colleagues,

The performance and quality of pharmaceutical dosage forms are dependent on both the properties of constituent materials (API and excipients) and the manufacturing process. Understanding the impact of material variability on dosage form performance and identifying critical material attributes are central to the quality by design (QbD) approach to drug development. Monitoring critical material attributes and adjusting process parameters, by the application of process models, is a key aspect of Quality by Control (QbC). The advent of drug product continuous manufacture, together with the pharmaceutical sector's evolution towards QbC and Pharma 4.0, has increased the need for an advanced understanding of how the variability of constituent material properties impacts drug product performance and quality. This Special Issue aims to summarize the latest advances in Process Analytical Technology (PAT) techniques to study variability in constituent pharmaceutical materials, present the latest findings as well the design of process models to control for material variability and finally elucidate future directions.





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