Understand the interplay between process parameters and resin variability

A QbD-approach to biopharma process development

Balancing process outcome

The need to understand the interplay between CPPs and CMAs on process outcome grows with the increased molecular diversity

"2/3 of all manufacturing deviations are related to raw materials (mostly cell culture media, but also resins and filters)"

"Resin variability is a blind spot to us" "Most processes show no impact of resin variability but this is molecule dependent"

The interplay between process parameters and resin attributes might lead to process variation

Ranges for process parameters Resin variability within specification

Risk of process variation

Risk assessment: our recommendations for when to study impact of resin variability

How can you ensure a robust process performance?

How when you consider the possible impact of resin variability?

Learn more about process characterization