

Developing an Appropriate Design Space Strategy to Mitigate Variability in Downstream Processing Operations

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Lot to lot variability in chromatography adsorbent properties can result in unacceptable purification performance. The column operating conditions may need to be designed to be adsorbent lot specific to achieve acceptable performance. In this presentation, we discuss some of the development challenges associated with adsorbent lot variability and how a design space strategy can be used to mitigate such risks, by providing additional flexibility in selecting the appropriate column operating conditions. Several case studies will be presented.