LIFECYLE MANAGEMENT OF A COMMERCIAL PLATFORM MONOCLONAL ANTIBODY PROCESS: THE PROMISE OF ICHQ12

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Key Words: monoclonal antibody, lifecycle management, ICH Q12

This presentation will focus on a case study of a commercial platform mAb process, registered in multiple territories globally, which has undergone iterative rounds of post approval change over the period of approximately a decade. The intent of this presentation is to provide lessons learned with respect to ensuring streamlined lifecycle management. The case study aims to provide a worked example of the pragmatic value that ICH Q12 has the potential to deliver in outlining a globally harmonized approach towards the technical and regulatory considerations for lifecycle management.

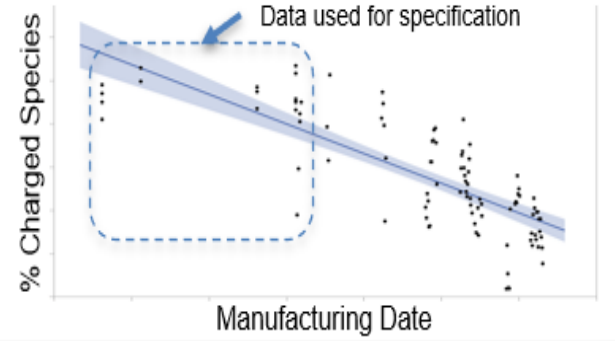

Figure 1 – Evolution of a downward shift in the observed process center for charge heterogeneity over time

Key facets of the discussion will focus on learnings with respect to commercial drug substance specification setting, regulatory filing implications stemming from process optimization efforts to maximize annualized productivity, the criticality of a robust feedback loop from commercial manufacturing back to process development and regulatory strategies towards future-proofing commercial submissions to allow for potential raw material improvements such as chromatography resins over the lifecycle of a molecule.

A particular emphasis will be placed on the application of prior knowledge to support regulatory filing, and the potential this approach provides to streamline post approval change management. In addition, novel approaches to mitigating the need for post approval change management will be described including considerations for selecting the optimal analytical methods for registration, the development of future-proofed patient centric drug substance release specifications and leveraging supply chain partnerships to frontload input variability into the process development cycle.