

## **Beyond Numerical Tools: Control Strategy Principles that Assure Product Quality Throughout Development**

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At Pfizer we have taken a lifecycle approach toward implementing control strategies for biotherapeutic products per ICH Q10. Developing process and product understanding to implement a holistic control strategy is critical to ensure consistent, quality products. The challenges of implementing control strategy principles for diverse modalities in early and late development are quite different. In early phase, targeted application of enhanced product characterization tools can influence molecular design and are critical to inform process development. Application of these tools needs to be focused and informed by platform knowledge, and ideally the information is rapidly available due to the short timelines and resource constraints in early development. By later stage, extensive product and process understanding needs to be translated into an understandable, robust, and defensible control strategy. Case studies where enhanced analytical characterization and deeper quality attribute understanding have been applied to phase appropriate control strategies will be discussed.

Efforts to simplify the sometimes complex quality attribute and control strategy tools are critical to ensure we are focusing on the scientific understanding of the product quality attribute profile for complex molecules. Looking forward, it is particularly critical to continue technical and organizational efforts to move aspects of control and product understanding closer to the point of impact during all stages of process development, rather than traditional reliance on retrospective and final release testing. Pfizer's efforts in these areas will also be presented.