

Synergizing statisticians and scientists: the essential 'salt' in CMC process development

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Abstract:

In the rapidly evolving landscape of technical development in the pharmaceutical industry, robust and cost-effective processes are of crucial importance. The implementation of Quality by Design (QbD) has emerged as a pivotal strategy in modern process development. This presentation will delve into Roche's adoption of QbD principles and illustrate the integral role statisticians play in implementing this process.

We start by introducing the QbD framework, which emphasizes the importance of understanding and controlling critical process parameters to ensure the highest level of product quality. By integrating well-established statistical methods like design of experiments (DoE) into the scientific risk assessments of the QbD approach, statisticians play a key role in enabling data-driven decision-making. Statisticians support in optimizing processes and reducing variability, acting as the essential 'salt' that enhances the efficiency and robustness of the CMC (Chemistry, Manufacturing, and Controls) process development. Through a series of examples, this presentation will highlight the fruitful collaboration between statisticians and scientists, showcasing how it leads to improved process understanding, reliable manufacturing, and ultimately, better patient outcomes.