A-VAX: Applying Quality by Design to Vaccines

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Abstract

The A-VAX Quality by Design (QbD) case study was the third in a series of industry efforts to illustrate application of QbD principles in pharmaceutical research and development. The case study follows the development pathway of a model pentavalent polysaccharide- virus-like particle (VLP) conjugate vaccine for the prevention of cooties, a fictitious infectious disease inflicted by the organism *X. horrificus* in children. While some of the same principles as the A-Mab case study are illustrated, the A-VAX case study emphasizes the differences which may broaden the scope and enhance the value of QbD approaches. Specifically A-VAX introduces clinical considerations in vaccine development and highlights the historical challenges of developing potency assays with specifications which ensure patient safety and efficacy. Other differences acknowledge the unique challenges of vaccine supply, and thus the need for robust manufacture and control. The case study was further informed by the availability of ICH Q11 and FDA's Guidance on Process Validation. Finally, a chapter on return in investment (ROI) was included as a framework for evaluating the value of a QbD to vaccine manufacturers, regulatory authorities, and patients.

Learning Objectives

- Understand principles in A-VAX which may enhance vaccine development, and which may be applied more broadly to biopharmaceutical development.
- Introduce a framework for evaluating the benefit of applying QbD principles during vaccine development.
- Propose further opportunities to work within industry and together with regulators to reinvent development and expedite delivery of valuable products to customers in need.