Title: Vaccines are Biologicals with Unique Specificities

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The enhanced approach/Quality by Design (QbD) represents the current preferred strategy for CMC process development and control strategy implementation for biologics, including vaccines.
However, vaccines possess unique characteristics that distinguish them from other biological products, particularly biotherapeutics and monoclonal antibodies. These specificities include their mechanism of action (immunogenicity as the basis for efficacy rather than a safety risk), route of administration, and dosing regimens.
Current regulatory frameworks and pharmacopoeial standards sometimes fail to account for these vaccine-specific attributes, applying requirements more suitable for other biologics and/or less applicable to the enhanced approach based on risk analysis and prior knowledge.
In this presentation, we will discuss concrete examples of CQAs that may be managed differently for vaccines as compared to other biologics, such as process-related impurities, subvisible particles, uniformity of dosage/content, and potency.
The implementation of QbD principles for vaccines requires recognition that while all specification tests address Critical Quality Attributes (CQAs), not all CQAs necessitate to be controlled by a specification test, particularly when process controls can reliably ensure consistent quality.
This presentation advocates for a more flexible approach to vaccine specifications that acknowledges their unique characteristics while maintaining appropriate quality standards through risk-based assessment and comprehensive control strategies tailored to vaccine-specific attributes.

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