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International Alliance for Biological Standardization

Globally Harmonized Specifications: Current State and Future Opportunities
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A Journey Toward Biologics Product Specification Harmonization: Look Back & Look Ahead

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Abstract

Introduction - Proper biologics commercial specification setting is an evolving endeavor across industry. At MSD, we always aim to test/release our biologicsproducts against set specifications to ensure product safety and efficacy.

Challenges - However, we are facing expedited product development cycle which complicates specification setting. There are also focus and pressure to tighten specs based on process experience and capability. Furthermore, clinical qualification of ranges maybe limited combined with unexpected (or unintended) changes such as rawmaterial changes during commercial manufacture.

Approaches Taken/Being Taken - In this presentation, we will present 2 case studiesfrom our commercial products (1 mAb and 1 vaccine) where we share our successes and failures in attempts for a balanced approach leveraging process experience, product knowledge, statistical modeling power, and clinical relevance.

Conclusion - Our goal is to have open, scientific dialogues with industry leaders and regulators while seeking insights/feedbacks in an informal setting.