PDA EU00018 CMC Regulatory Compliance for Biopharmaceuticals

Thursday, 14 September 2023	
09:00	**Welcome and Introduction, collecting Attendees Expectations**
09:10	**CMC Regulatory Compliance is Challenging for the Recombinant Proteins and Monoclonal Antibodies** - Discussion of the increasing diversity of recombinant proteins and monoclonal antibodies and the CMC regulatory compliance challenges that they present
10:30	Coffee Break
11:00	- Protein-based biopharmaceuticals are not chemical drugs – CMC regulatory compliance consequences due to the major differences
12:30	Lunch Break
13:30	**Risk-Based Approach to Managing the CMC Regulatory Compliance Strategy for Recombinant Proteins and mAbs** - Defining the 'minimum CMC regulatory compliance continuum' for biopharmaceuticals during clinical development
15:00	Coffee Break
15:30	- Introduction of the ICH strategic risk-based approach of Quality by Design and Quality Risk Management to biopharmaceutical manufacturing and product testing
17:00	End of Training Course Day 1

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Friday, 15 September 2023	
09:00	**Applying the Risk-Managed CMC Regulatory Compliance Strategy – Master Cell Bank through Drug Substance through Drug Product** - Developmental genetics – necessity of clonality and genetic stability - Difference in CMC regulatory requirements for MCBs to enter First-in-Human clinical studies versus to obtain market approval
10:30	Coffee Break
11:00	- Importance/limitations of reduced-scale studies for biopharmaceutical protein production and purification - Extra CMC regulatory challenges of antibody-drug conjugates (ADCs)
12:30	Lunch Break
13:30	- Drug product challenges for biopharmaceuticals – Impact of contact surfaces on the biopharmaceutical (e.g., protein aggregation) and impact of the biopharmaceutical solution on contact surfaces (e.g., glass delamination) - Applied CMC strategy for the administered protein-based drug product
15:00	Coffee Break
15:30	**Challenges of Demonstrating Protein-Based Biopharmaceutical Comparability After Manufacturing Process Changes** - Three (3) key design elements for an effective risk-managed comparability exercise - Obtaining comparability contracts (PACMPs) with regulatory authorities
16:30	**Final Q&A**
17:00	End of Training Course