PDA EU00018 CMC Regulatory Compliance for Biopharmaceuticals

Thursday, 22 September 2022	
09:00	**Welcome and Introduction**
09:10	**CMC Regulatory Compliance is Challenging for Biopharmaceuticals** • Discussion of the increasing diversity of biopharmaceuticals and the CMC regulatory challenges that they present
10:30	Coffee Break
11:00	• Understanding the similarities and differences in CMC regulatory compliance between FDA and EMA for biopharmaceuticals • Biopharmaceuticals are not chemical drugs – CMC regulatory compliance consequences of the major differences
12:30	Lunch Break
13:30	**Risk-Managed Biopharmaceutical CMC Regulatory Compliance Strategy** • Three (3) interactive components that protect patients – CMC, cGMPs, and Quality Systems • What the 'minimum CMC regulatory compliance continuum' means for biopharmaceuticals during clinical development
15:00	Coffee Break
15:30	• Effective CMC risk-management – the five (5) key design elements • Applying the principles of QbD and QRM to biopharmaceutical manufacturing
17:00	End of Training Course Day 1

PDA EU00018 CMC Regulatory Compliance for Biopharmaceuticals

Friday, 23 September 2022	
09:00	**Applied Risk-Managed Biopharmaceutical CMC Regulatory Compliance Strategy – Cell Bank through Drug Substance** • CMC strategy applied across the manufacturing process from cell banks to protein production to purification to drug substance • The necessity of confirming cell bank clonality and genetic stability
10:30	Coffee Break
11:00	• Importance and limitations of small-scale studies for biopharmaceuticals • Adequate and appropriate control of the biopharmaceutical manufacturing process from early clinical development into the marketplace • Extra CMC challenges of antibody-drug conjugates (ADCs)
12:30	Lunch Break
13:30	**Applied Risk-Managed Biopharmaceutical CMC Regulatory Compliance Strategy – Bulk Drug Substance through Administered Drug Product** • CMC strategy applied across the manufacturing process from bulk drug substance to formulation to drug product filling to final drug product to administered drug product • Formulation and container-closure challenges for biopharmaceuticals – Impact of components on the biopharmaceutical (e.g., protein aggregation) and impact of the biopharmaceutical solution on the components (e.g., glass delamination)
15:00	Coffee Break
15:30	**Demonstrating Biologic Comparability After Manufacturing Process Changes** • Three (3) key design elements of an effective risk-managed comparability exercise • Comparability contracts with regulatory authorities
17:00	End of Training Course