Training Course Agenda

PDA EU00191 CMC Regulatory Compliance Strategy for Recombinant Proteins, Monoclonal Antibodies and Biosimilars

DAY 1 – Thursday 26 September 2024	
9:00	**Welcome and Introduction** • Collecting Participants Expectations
9:10	**Challenges from the Protein-Based Biopharmaceutical Landscape (90 min)** • Discussion of the CMC challenges due to the increasing diversity of these market-approved biopharmaceuticals (rProteins, mAbs, BsAbs, Fc fusion proteins, Fab fragments, ADCs, biosimilars) • The critical role that Genetic/Process/Analytical Development groups, Manufacturing, QA/QC and Regulatory Affairs have in assuring that CMC regulatory compliance protects patients
10:30	***Coffee Break***
11:00	**CMC Regulatory Compliance Differences (90 min)** • Overview of the FDA/EMA regulatory systems in place for these products (IND → BLA; IMPD → MAA) • Why these products are not regulated like chemical drugs
12:30	***Lunch Break***
13:30	**Risk-Managed CMC Regulatory Compliance Strategy (90 min)** • Why a risk-managed approach to CMC regulatory compliance is absolutely necessary for these products • Introduction to the 'Minimum CMC Regulatory Compliance Continuum' risk-based approach
15:00	***Coffee Break***
15:30	**Recommended Risk-Based Approach for Biopharmaceuticals (90 min)** • How three interactive risk-based components protect patients – CMC Regulatory, cGMPS, Quality System • Application of Quality by Design (QbD) – QTPP, CQA, CPP – and Quality Risk Management (QRM)
17:00	***End of Training Course Day 1***

DAY 2 – Friday 27 September 2024	
9:00	**Applied Risk-Managed CMC Regulatory Compliance Strategy Across the Manufacturing Process (90 min)** • Raw materials and components – risk reduction procedures • Starting materials (MCB/WCB) • Upstream cell culture production processes
10:30	***Coffee Break***
11:00	**Applied Risk-Managed CMC Regulatory Compliance Strategy Across the Manufacturing Process (90 min)** • Downstream purification processes to the bulk drug substance stage • Conjugation of the drug substance (pegylation, antibody-drug conjugates (ADCs)) • Formulation and drug product manufacturing processes • Administering the final drug product prepared in the clinic
12:30	***Lunch Break***
13:30	**Challenges in Demonstrating Product Comparability After Manufacturing Changes (90 min)** • Regulatory authority guidance in planning for product comparability studies • Three risk-based considerations to reduce residual uncertainty of product comparability • Biosimilarity and interchangeability for biosimilars • Industry experience in implementing product comparability after manufacturing process changes
15:00	***Coffee Break***
15:30	**Critical Manufacturing/Quality-Focused Meetings with Regulatory Authorities (90 min)** • CMC regulatory compliance deficiencies can seriously delay clinical development advancement • Meeting opportunities with regulatory authorities for biopharmaceuticals • Intensity of the regulatory authority review process to obtain market approval
16:30	**Q&A**
17:00	***End of Training Course***