Event Agenda

CMC Regulatory Compliance Strategy for Biopharmaceutical Manufacturing Training Course (PDA 526)

DAY 1

8:30	**Welcome and Introductions**
9:00	Challenge from the Biopharmaceutical Landscape • Increasing diversity from both protein-based (rproteins, mAbs, bispecific Abs, ADCs, biosimilars) and gene therapy-based (AAV, mRNA, genetically modified patient cells) biopharmaceuticals • Role for genetic/process/analytical dev groups, Mfg, QA/QC and reg affairs, along with the regulatory authorities, in establishing manufacturing control and patient safety
10:30	**Break**
10:45	CMC Regulatory Compliance Differences • Why biopharmaceuticals cannot be regulated like chemical drugs • Differences between protein-based and gene therapy-based biopharmaceuticals
12:00	**Lunch**
13:00	Risk-Managed CMC Regulatory Compliance • 'Minimum CMC regulatory compliance continuum' strategy for biopharmaceuticals • Risk-based approach recommended by regulatory authorities – ICH Q8 (QbD)/ICH Q9 (QRM)
14:30	**Break**
14:45	Applied Risk-Based CMC Regulatory Compliance Strategy for Biopharmaceuticals • Raw materials • Starting materials
16:00	**End of Day 1**

DAY 2

8:30	**Recap Day 1**
9:00	Applied Risk-Based CMC Regulatory Compliance Strategy for Biopharmaceuticals – Drug Substance • Upstream manufacturing process control • Downstream manufacturing process control
10:30	**Break**
10:45	Applied Risk-Based CMC Regulatory Compliance Strategy for Biopharmaceuticals – Drug Product • Formulation and filling process control • Clinical administration and device concerns
12:00	**Lunch**
13:00	Challenges in Demonstrating Product Comparability • 3 risk-based concerns that must be addressed for process changes • PACMPs and biosimilarity requirements
14:30	**Break**
14:45	Critical CMC Strategic Meetings with Regulatory Authorities • CMC deficiencies that can delay clinical advancement or market approval • Necessity of an open discussion and team approach with regulatory authorities
16:00	**End of Event**