Monday, 12 October 2020

15:00

Welcome and Introduction

15:05

CMC Regulatory Compliance is Challenging for Biopharmaceuticals

Discussion of the increasing diversity of biologics, and the regulatory authority systems in place to control these evolving manufacturing processes and products

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16:30

Break

16:45

Risk-Managed CMC Regulatory Compliance Strategy

Five (5) key design elements of an effective risk-managed ‚minimum CMC regulatory compliance continuum' for biopharmaceuticals

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18:15

End of Day 1

Tuesday, 13 October 2020

15:00

Applied Risk-Managed CMC Regulatory Compliance Strategy

Detailed roadmap from starting material to drug product for a monoclonal antibody; General roadmap from starting material to drug product for a gene therapy virus

16:30

Break

16:45

Demonstrating Comparability After Manufacturing Process Changes

Three (3) key design elements of an effective risk-managed comparability exercise for biopharmaceuticals

18:15

End of Training Course