CMC Regulatory Compliance for Biopharmaceuticals

Overview

Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products.

These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the regulatory requirements for these challenging products. Companies clearly understand the critical importance of their human clinical study strategy, but frequently, the development of a strategy for CMC is an afterthought. Add the frequent lack of CMC regulatory compliance experience in some companies, coupled with the complexity of the biological manufacturing processes and products, and this can be a recipe for disaster.

This course will provide insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and human cells) from early clinical stage development through market approval. The course emphasis will include FDA, EMA and ICH guidance.

Who Should Attend:

This course is designed specifically for those involved in or interested in the manufacture and control and CMC regulatory issues of biopharmaceuticals, including Senior Management, Directors and Managers/Supervisors, QA/QC, Regulatory Affairs, Manufacturing and Process Development personnel.

Learning Objectives:

Upon completion of this course, you will be able to:

- Explain the importance and underlying principles of an effective CMC regulatory strategy for biopharmaceuticals to move your products through clinical development into the marketplace
- Explain the importance and underlying principles for CMC regulatory compliance of biopharmaceuticals and how this leads regulatory agencies to have different CMC regulatory requirements for biotech products compared to pharmaceuticals of chemical origin.

John Geigert, *PhD, BioPharmaceutical Quality*

John Geigert is President of BioPharmaceutical Quality Solutions, which for the last 15 years has specialized in providing CMC regulatory strategy consulting for the biopharmaceutical industry. He has over 40 years of CMC industrial experience and leadership in the biopharmaceutical industry. He has held senior management positions as Vice President of Quality at both IDEC Pharmaceuticals Corporation in San Diego and Immunex Corporation in Seattle, and he was Director of Product Development at Cetus Corporation in Berkeley. At these companies, he helped lead the CMC efforts to obtain regulatory approvals for 6 biopharmaceutical products now commercially available in the U.S. and in Europe. John Geigert has served on the PDA Board of Directors, currently chairs the PDA Biopharmaceutical Advisory Board, and has served as an expert member of the USP Biotechnology Committee. He is the author of the book The Challenge of CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics 2nd Edition, and has written extensively for RAPS Focus (What Senior Management Needs to Know About CMC Regulatory Compliance for Biotech Products (Aug-Nov 2009, 4-part series)), Demystifying CMC Regulatory Strategy (Sept 2011-Mar 2012, 4-part series). John Geigert obtained his B.S. in Chemistry from Washington State University and his Ph.D. degree in Organic/Analytical Chemistry from Colorado State University.

7 Jun 2018

Thursday, 29 November 2018 — 9:00 – 17:00

9:00	Welcome and Introduction
CMC Regulatory Challenges for Biopharmaceuticals are Different	
9:10	– Painting the Terminology Landscape: Biologic, specified biologic, biopharmaceutical, biosimilar, CBER, CDER, EMA, ...
10:30	Coffee Break
11:00	– Understanding the CMC Differences of Biopharmaceutical Regulation between FDA and EMA – Biopharmaceuticals are not Chemical Drugs – Regulatory Compliance Consequences of the four Major CMC Differences
12:30	Lunch Break
How to Develop an Effective Corporate CMC Risk-Managed Control Strategy for Biopharmaceuticals	
13:30	– Three Major Forces that Shape the CMC Regulatory Compliance Strategy of all Biopharmaceuticals – Five Key Elements of an Effective Corporate CMC Regulatory Compliant Strategy
15:00	Coffee Break
15:30	– Impact of the Quality by Design (QbD) on Biopharmaceutical CMC Strategy – Necessity of a Clinical Phase - Appropriate CMC Regulatory Compliance Strategy
17:00	End of Day 1

Friday, 30 November 2018 — 9:00 – 17:00

Applying a CMC Risk-Managed Control Strategy to the Biopharmaceutical Manufacturing Process	
09:00	– Four Myths about Biopharmaceutical Starting Material – the Master Cell Bank – Necessity of Confirming Clonality and Genetic Stability
10:30	Coffee Break
	– Importance and Limitations of small-scale Studies for Biopharmaceuticals
	– Clinical Phase - Appropriate Control of the Biopharmaceutical Manufacturing Process
	– Formulation and Container-Closure Challenges for Biopharmaceuticals – Impact of Components on the Biopharmaceutical (e.g., protein aggregation) and Impact of the Biopharmaceutical on Components (e.g., glass delamination)
12:30	Lunch Break
Challenge of Managing Manufacturing Process Changes and Demonstrating Biologic Product Comparability – Not an Easy Task!	
13:30	– Need for Risk-based, Sequential and Clinical Phase - Appropriate Comparability Studies – Demonstrating Biologic Product Comparability – Justifying CMC Differences
15:00	Coffee Break
15:30	– "Comparability Protocol" and "Post Approval Change Management Protocol"
	– Extreme Comparability of Biosimilars: Limitations of CMC Comparison, Fingerprinting – CMC Biosimilarity Successes and Failures
17:00	End of Training Course