Overview

The principles and practices of Quality by Design (QbD) for biopharmaceutical, biosimilar, and other biologic manufacturing processes are here now, with regulatory authority expectation for market approval submissions to include at a minimum the quality target product profile (QTPP), identification of critical quality attributes (CQAs) and justification of critical process parameters (CPPs). The principles and practices of QbD are applicable for both in-house and contracted-out biopharmaceutical development, manufacturing and testing.

Unfortunately, there is so much confusion today about what QbD is and isn’t: What is so different about QbD? Must QbD include a thorough multi-variate analysis of design space? Does QbD guarantee regulatory freedom to independently make future manufacturing process changes? Does QbD mean no future manufacturing problems?

Before launching into QbD, biopharmaceutical manufacturers must first have a firm understanding of the unique challenges facing biologics, and then a thorough understanding of the International Council on Harmonization (ICH) strategic guidances (Q8, Q9, Q10, Q11) for this enhanced approach.

Practical suggestions to help your company apply QbD to your biopharmaceutical, biosimilar or other biologic development program will be provided by examining what has worked already for other companies. The six (6) key steps of QbD will be examined and discussed carefully. Also, this course will identify the limitations of the QbD approach.

Who Should Attend:
This course is designed specifically for those involved in or interested in an enhanced control system for biopharmaceuticals, including

- Senior Management
- Directors and Managers/Supervisors
- QA/QC
- Regulatory Affairs
- Manufacturing
- Process Development

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

- Explain the importance and underlying principles of an effective QbD approach for biopharmaceuticals, biosimilars and other biologics
- Gain a firm understanding to apply the principles of QbD to all types of biologic products – recombinant proteins, monoclonal antibodies, biosimilars, gene therapy products and cell-based medicines
John Geigert, PhD, BioPharmaceutical Quality Solutions

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 and biologic industry. He has over 35 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 Biotech 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. 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.

TRAINING COURSE AGENDA

Thursday, 17 November 2016

9:00 – 18:00

9:00  Welcome & Introduction

9:10  Applying QbD Requires Understanding the Challenges Due to the Complexity of Biologics

10:30  Coffee Break

11:00  Applying QbD Requires Understanding the Systematic Principles Laid Out in ICH Q8, Q9, Q10 and Q11 – Quality Risk Management, Knowledge Management

12:30  Lunch Break

13:30  Six Steps to an Effective Implementation of a Biopharmaceutical Control System

15:00  Coffee Break

15:30  Practical Examples Illustrating Successfully Applied QbD For Biopharmaceuticals

18:00  End of Course