## COURSE FEE

$2650.00 PER PERSON

## EARLY BIRD DISCOUNT

If you register at least thirty days in advance you will receive a $200 discount on the course.

## ADDITIONAL DISCOUNTS

Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CfPIE.

## CANCELLATION POLICY

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CFPIE reserves the right to alter the venue, if necessary.

***Substitution Policy - Classroom Courses***

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

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CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.

## ABOUT CfPIE

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

## HOW TO REGISTER

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
Suite 295
Malvern, Pennsylvania 19355

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# CMC REGULATORY COMPLIANCE FOR BIOPHARMACEUTICALS, BIOSIMILARS AND OTHER BIOLOGICS

**INSTRUCTOR: JOHN GEIGERT, PH.D.**

ALL 2020 COURSE DATES WILL BE OFFERED VIRTUALLY THROUGH LIVE INTERACTIVE SEMINARS

Sept 15 – 17, 2020 (EDT)
Sept 21 – 23, 2020 (BST)

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## COURSE DESCRIPTION

This course will help the attendee to develop a CMC regulatory compliance strategy for biopharmaceuticals, biosimilars and other biologics, addressing the five core elements that comprise an effective strategy: (1) embracing the full spectrum of CMC activities, (2) addressing unique requirements for specific biologic manufacturing processes, (3) addressing unique requirements for specific biologic products, (4) aligning with the strategic ICH Q8/Q9/Q10 guidances, and (5) applying a clinical phase-appropriate approach. The critical importance of communicating CMC regulatory compliance strategy with the regulatory authorities at CMC-focused meetings will be stressed. In addition, this course will also help the attendee to better understand the CMC regulatory compliance requirements for Quality by Design applications and for biosimilars.

## WHO SHOULD ATTEND

This three-day CMC regulatory compliance course is designed for senior management, directors, managers, supervisors, project planners and professional staff seeking to develop or implement a Chemistry, Manufacturing & Controls (CMC) regulatory compliant strategy for biopharmaceuticals, biosimilars or other biologics. Typical attendees include: Senior Management, Project Managers, Regulatory Affairs, Manufacturing, and Quality and Development personnel.

# INSTRUCTOR CREDENTIALS

John Geigert, Ph.D., RAC, is President of BioPharmaceutical Quality Solutions, which for the last 12 years has specialized in providing CMC regulatory strategy consulting for the biopharmaceutical and biologic industry.

Dr. Geigert 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 for Cetus Corporation in Emeryville, CA. At these companies, he led the CMC efforts to obtain regulatory approvals for 6 biopharmaceutical products (4 recombinant proteins and 2 monoclonal antibodies) now commercially available in the U.S. and Europe.

He has served on the PDA Board of Directors, co-chaired the PDA Biotech Advisory Board, and served as an expert member of the USP Biotechnology Committee.

He obtained his B.S. in Chemistry from Washington State University, and his Ph.D. degree in Organic/Analytical Chemistry from Colorado State University.

# LEARNING OBJECTIVES

At the end of the three-day course attendees will:

- Gain a solid understanding of the CMC regulatory compliance requirements and expectations (FDA, EMA, ICH, WHO) for biopharmaceuticals, biosimilars and other biologics, and understand why regulatory authorities treat biologics different than chemical drugs
- Have the tools and understanding to carry out an effective product comparability study after a change in a biologic manufacturing process, learning how to avoid the many pitfalls, and how to communicate and defend the study to a regulatory authority
- Understand the CMC challenges for biosimilars under the US FDA, European Medicines Agency (EMA) and World Health Organization (WHO) requirements, especially with the innovator's CMC development being blinded to the biosimilar manufacturer
- Understand the strengths and limitations of Quality by Design (QbD)- quality target product profile (QTPP), critical quality attributes (CQAs), critical process parameters (CPPs) and justification of the control strategy – for biologic manufacturing processes
- Be able to package the CMC information for biologics into the common technical document (CTD) format, including placement of the CMC biosimilarity study and QbD content
- Learn how to avoid major delays in clinical development or market approval due to an ineffective CMC regulatory compliance strategy for biologics

# FIRST DAY

**CMC Regulatory Challenges for Biologics are Different**

- Understanding the terminology landscape: biologic, specified biologic, biopharmaceutical, biosimilar
- The regulatory authorities (FDA, EMA/NCA) and regulatory review pathways (IND/IMPD, NDA/BLA, MAA centralized procedure) for biologics
- Five (5) CMC regulatory compliance differences between the two U.S. pharmaceutical laws for biologics
- Biologics are not chemical drugs – four (4) unique CMC regulatory compliance challenges presented by biologics
- Biosimilars are not 'bio-generics''

**How to Develop an Effective Corporate CMC Risk-Managed Regulatory Compliance Strategy for Biologics**

- Two (2) major forces that shape the CMC regulatory compliance strategy of all biologics
- Five (5) essential elements of an effective CMC regulatory compliant strategy
- Impact of the strategic ICH guidances (Q8/Q9/Q10) on all biologics
- Potential benefits and limitations of Quality by Design (QbD) for biologics
- Necessity of a clinical phase-appropriate CMC regulatory compliance strategy

**Applying the CMC Regulatory Compliance Risk-Managed Strategy to Control of Biologic Manufacturing Processes (Part 1)**

- Critical importance of biologic starting materials
- Four (4) myths about cell banks
- Necessity of demonstrating appropriate clone selection

# SECOND DAY

Applying the CMC Regulatory Compliance Risk-Managed Strategy to Control of Biologic Manufacturing Processes (Part 2)

- Genetic stability determination
- Importance, and limitations, of small-scale studies for biologics
- Clinical phase-appropriate control of the biologic manufacturing process, including applying a Quality by Design approach
- Timing difference for process validation between biologics and chemical drug processes
- Formulation and container-closure challenges for biologics – impact of components on the biologic (e.g., aggregation) and impact of the biologic on components (e.g., glass flaking)
- Illustration of Quality by Design (QTPP, CQAs, CPPs, risk-ranking) in selecting the control system for host cell proteins (HCPs)

Challenge of Managing Manufacturing Process Changes and Demonstrating Biologic Product Comparability – Not an Easy Task

- Risk-based, sequential, clinical phase-appropriate comparability studies Demonstrating biologic product comparability – justifying CMC differences
- Difference between a comparability study and a comparability protocol
- Extreme comparability of biosimilars: limitations of CMC comparison, fingerprinting, which biologics currently are being considered for biosimilars
- EMA biosimilars – CMC biosimilarity successes and failures

# THIRD DAY

Critical CMC-Focused Strategic Interactions with Regulatory Authorities for Biologics

Maximizing the value of CMC interactions with the regulatory authorities for your biologic

Avoiding biologic market approval delays of months/years – clinical holds and refusals to file – due to an ineffective CMC regulatory compliance strategy

FDA PDUFA CMC-focused strategic meetings (pre-IND, EOP2 and pre-submission)

FDA BsUFA meetings for biosimilars (BIAM and BPDs)

EMA strategic meetings (scientific advice and pre-submission)

How to word CMC questions to evoke a reactive response from the regulatory authority

Preparing Module 3 (CMC) For Biologic Submissions

Module 3 for biologics – clinical development and market submissions

Location of biologic CMC information in Modules 1, 2.3 and 3

Placement of QbD content (QTPP, CQA, CPP, etc.) into Modules 2.3 and 3

Placement of the CMC biosimilarity study for biosimilars into Modules 1 and 3

Similarities and differences between the FDA and EMA review of these submissions