In the eyes of regulatory authorities, the quality issues of biologics are definitely different from chemical drugs because of: (1) use of living source materials to produce the biologic, (2) increased complexity of biologic manufacturing processes and (3) increased complexity of the biologic molecules themselves. While chemical drugs can become generics, biologics products are best viewed as biosimilars, and not as bio-generics.

Biologics are highly susceptible to adventitious agent contamination – prions, viruses, mycoplasmas, and bacteria/fungi microbes. Risk control procedures – such as barriers to entry, testing to confirm absence, and inactivation/removal – are essential. Lessons can be learned from reported contaminations of biologic manufacturing processes. Compared to chemical drugs, biologics have a more complex process-related impurity safety profile, especially due to the living system-related impurities (e.g., host cell proteins, host cell DNA).

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
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COURSE DESCRIPTION

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Quality Challenges for Biologics Are Different
• Painting the landscape: biologic, specified biologic, biopharmaceutical, biosimilars, etc.
• Two different U.S. pharmaceutical laws that impact biologics
• Biologics are not chemical drugs – 3 major areas
• How these differences are managed by the regulatory agencies

Criticality of QA/QC Involvement with Biologic Processes
• Why it is important to have QA/QC involved in the manufacturing process earlier than later
• Quality does not come cheaply – what is the value of QA/QC in biologic manufacturing
• Value of QA/QC during clinical development
• Detecting biologic counterfeits

Developing a Corporate Quality Strategy for Biologics
• Five (5) key elements of an effective quality risk management strategy for biologics
• Revolutionary impact of strategic ICH Q8, Q9 and Q10 on biologics
• Implementation of a clinical phase-appropriate quality strategy
• Critical importance of inter-company quality agreements for biologics

Uniqueness #1 – Challenge of Adventitious Agents
• Plenty of nightmares for biologic manufacturing – prions, viruses, mycoplasmas, bacteria/fungi
• Reported prion, viral and mycoplasma contaminations of biologic products
• Designing an effective risk minimization strategy for these agents
• Not detected does not mean not present – surprises still happen

Uniqueness #2 – Biological Functional Activity (Potency)
• Therapeutic functional activity, not content, for biologic strength
• Functional assay landscape: bioassay, surrogate, assay matrix
• Clinical phase-appropriate development of potency assays
• Underestimation of resources needed to optimize and control these assays

Uniqueness #3 – Complexity of Impurity Profiles
• Comparison of impurity profiles for chemical drugs vs biologics
• Magnitude of process-and product-related impurities for biologics
• Applying a quality risk management strategy to the impurity profile of biologics
• Examples of how to develop the control systems for host cell proteins and protein aggregation

Biological Characterization, Release and Stability Testing
• Know your complex biologic molecule – characterization
• State of the art testing, fingerprinting
• Comparison of release/stability testing for chemical drugs vs biologics
• Clinical phase-appropriate implementation of testing

Challenge of Biologic Specification Setting and Expiry Dating
• Specification setting for critical quality attributes
• Regulatory authority recommendations for clinical phase-appropriate setting of specs
• Examples of 4 types of specs used with biologics
• Comparison of determining expiry dates for chemical drugs vs biologics

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INSTRUCTOR CREDENTIALS
Trevor Deeks, Ph.D. has 40 years of experience in pharmaceutical development, manufacturing, quality control and quality assurance, at least half of this time has been spent working with biologics. He is registered as an eligible QP under EC Directive and has also practiced as a registered Pharmacist in the UK. He now resides in Maryland and has his own consulting business. He has a Ph.D. in Peptide Chemistry and has extensive expertise in aseptic processing and in a wide range of unique and unusual biotechnology processes, including protein expression products, live vaccines, tissue culture products, and cell-based products.

He has practiced as a QP since 1983 and his QP experience includes commercial batch release, investigational medicinal products and “Specials”. He has established and operated Quality Systems in compliance with the European Clinical Trials Directive and with global regulatory expectations (FDA, WHO, ANVISA, etc.). He has led scale-up and technology transfer projects for large and small molecules, has managed many projects with contract manufacturing organizations, has undertaken a number of evaluations of new technologies, and has performed due diligence evaluations of such products for acquisition.

LEARNING OBJECTIVES
At the end of the course you will:
• Understand the critical importance and underlying principles for the QA/QC of biologics and biopharmaceuticals, and know how these principles differ from those for chemical-origin drug products
• Be able to develop a clinical-phase appropriate, cost-effective strategy to effectively manage the quality lifecycle through clinical development into commercialization of diverse biologic/biopharmaceutical manufacturing processes and products, including establishing effective inter-company quality agreements with outsourced contractors
• Have the tools and understanding necessary to adequately address biosafety (adventitious agents), potency (biological functioning bioassays) and impurity profile issues for biologic and biopharmaceutical products; and how to set appropriate and adequate product specifications and expiration dates