REGULATION, QUALITY, AND COMPLIANCE IN

ADC MANUFACTURING

VIRTUAL SESSION

10 & 11 SEPTEMBER, 2024

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€249

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€199

offer ends on June 28th 2024

CLICK HERE TO RESERVE YOUR SPOT NOW

We are excited to invite you to a pivotal two-day training session on **Regulation, Quality, and Compliance in ADC Manufacturing**, scheduled for the **10th and 11th of September, 2024**. This event promises to be a transformative experience for professionals involved in the complex world of Antibody-Drug Conjugates (ADCs).

ABOUT

The manufacturing of Antibody-Drug Conjugates (ADCs) is intrinsically complex and a strong chemistry, manufacturing and control (CMC) strategy is vital due to the complex nature of these therapeutics and history of failures at both early and late stages. This training encompasses a comprehensive understanding of the primary technical and regulatory (FDA and EMA) challenges; focusing on the specific requirements for ADCs, which combine the targeting capabilities of antibodies with the cell-killing or effector capabilities of payload drugs. The overall operational excellence and Quality approach is highlighted as well as the critical points for control to ensure the consistency, purity and stability of ADCs, given their high potency and specific targeting mechanisms. Training also covers good manufacturing practices (GMP) procedures - especially tech transfer, documentation and facility controls. The latter being crucial for minimizing cross-contamination risks. This training combines theoretical knowledge with workshopping for deeper understanding to prepare professionals for the unique challenges in ADC manufacturing.

WHO SHOULD ATTEND?

This training is essential for professionals from leading pharma manufacturing companies, including:

- Quality
- Quality assurance
- Quality Control
- CMC Managers/ Heads
- Compliance
- Regulatory Affairs
- QA/QC Managers
- Analytical Scientists
- Development Scientists
- Manufacturing
- Process Development
- Upstream/Downstream
- R&D Scientists
- Operations
- & VC/investors in Biologics

TRAINER PROFILE:

Dr. Len Pattenden

Managing Director, **CMC Biopharma Ltd**

Len has over 30 years of experience in both industry and academia. Len has been a company founder, COO and GMP site head/license holder, overseeing biopharma development and manufacture as well as outsourced CDMO activities. Len has undertaken development and manufacturing of 18 new biological entities, including first-in-man/first-in-class cell and gene therapies, viral vectors, biologics, and monoclonal antibodies. Len's regulatory and licensing experience covers the MHRA, EMA and FDA. Len works as a CMC consultant for small and large pharmaceutical companies. He is a member of a Regulatory working group, the ISPE and BIA

TRAINING HIGHLIGHTS:

- An understanding of the mechanism of action and pharmacology important to success of ADCs
- An understanding of the key steps and technical challenges of GMP ADC manufacture that create market-approval delays
- An insight into Regulatory drivers and how this impacts assessment of filings
- Operational excellence and Quality by Design (QbD) principles applied to ADCs
- Change management and tech transfer for ADCs
- Critical points for control to establish good CMC-compliant regulatory practices for ADCs

METHODOLOGY:

The participants will acquire knowledge through interactive sessions that are structured like lectures, allocating ample time for various activities, Q&A sessions, and discussions. Additionally, the training emphasises practical learning, incorporating case studies, breakout sessions, interactive polls, and examples from real-case scenarios.

ADDITIONAL FEATURES:

- Online participants zone – a single source for all training materials as well as pre and post training communications
- Access to the recorded sessions for 7 days

TRAINING SCHEDULE

10 & 11 SEPTEMBER, 2024

14:00 - 18:15 PM UK time

9:00 AM - 1:15 PM US EST time

Price: 249 Euro

EARLY BIRD DISCOUNT OF 25%

199 Euro

AGENDA

DAY 1
10 SEPTEMBER, 2024
14:00 - 18:15 PM UK time
9:00 AM - 1:15 PM US EST time

14:00 -15:00 (uk time)

Lecture 1: Introduction to ADCs and Mechanism of Action

Title: *Unveiling the Complexity: Introduction to ADCs and Their Mechanism of Action*

- Foundational lecture delves into the intricate world of ADCs
- Exploring ADC unique mechanisms of action to leverage the targeting precision of antibodies combined with the potent cell-killing abilities of payload drugs
- Understand the critical role of this mechanism in the success of ADCs and the challenges associated with their complex nature

15:00 -16:00

Lecture 2: GMP ADC Manufacturing: Key Steps and Technical Challenges

Title*: Navigating Complexity: GMP Manufacturing of ADCs - Steps and Challenges*

- Dive into the heart of ADC manufacturing, exploring the key steps and technical challenges that often lead to market-approval delays
- This lecture provides a comprehensive understanding of the intricacies involved in producing high-quality ADCs
- Emphasis is the critical need for a robust CMC strategy to overcome challenges and ensure manufacturing success.

16:00-16:15 **Coffee Break**

16:15 - 17:00

Lecture 3: Regulatory Landscape for ADCs - FDA and EMA Perspectives

Title: *Regulatory Navigate: ADCs and Regulatory Drivers from FDA and EMA*

- Explore the regulatory landscape governing ADCs with a focus on FDA and EMA perspectives.
- Understand the specific requirements and expectations from regulatory bodies, gaining valuable insights into how these impact the assessment of filings.
- Navigate through the regulatory intricacies to pave the way for successful submissions and approvals.

17:00 - 18:00

Lecture 4: Operational Excellence and Quality by Design (QbD) in ADCs

Title: *Operational Mastery: Applying Quality by Design (QbD) Principles to ADCs*

- This lecture illuminates the path to operational excellence in ADC manufacturing through the application of Quality by Design (QbD) principles.
- Learn how to integrate systematic approaches to achieve the desired product quality consistently.
- Emphasis on the importance of a proactive, quality-focused mindset in ADC development and production.

18:00 - 18:15 **Summing up & End of day 1**

AGENDA

DAY 2
11 SEPTEMBER, 2024

14:00 - 18:15 PM UK time

9:00 AM - 1:15 PM US EST time

14:00 -15:00 (uk time)

Lecture 5: Change Management and Tech Transfer for ADCs

Title: *Seamless Transitions: Change Management and Tech Transfer in ADC Manufacturing*

- Uncover the intricacies of change management and tech transfer specific to ADCs.
- Understand the challenges and strategies for ensuring smooth transitions in processes, technologies, and facilities.
- Equip yourself with the knowledge and tools necessary to minimize disruptions and maintain product integrity throughout the ADC lifecycle

15:00 -16:00

Lecture 6: Critical Control Points for CMC Compliance in ADCs

Title*: Mastering Consistency: Critical Control Points for CMC Compliance in ADCs*

- Delve into the critical control points that are pivotal for ensuring CMC compliance in ADC manufacturing.
- Explore strategies to establish and maintain consistency, purity, and stability of ADCs, considering their high potency and unique targeting mechanisms.
- Emphasis is the importance of stringent controls for regulatory adherence.

16:00-16:15

Coffee Break

16:15 - 17:00

Lecture 7: Good Manufacturing Practices (GMP) for ADCs

Title: *Beyond Basics: Good Manufacturing Practices (GMP) for ADCs*

- Elevate your understanding of GMP procedures specific to ADC manufacturing.
- Focus on key aspects such as tech transfer, documentation, and facility controls.
- Practical insights into implementing GMP principles to ensure product quality, minimize risks, and meet regulatory standards in the dynamic landscape of ADC production.

17:00 - 18:00

Lecture 8: Workshop on ADC Manufacturing Challenges and Solutions

Title: *Bridging Theory and Practice: Workshop on ADC Manufacturing Challenges and Solutions*

- Concluding the training with a hands-on approach, this workshop allows participants to apply theoretical knowledge to real-world scenarios.
- Engage in problem-solving exercises and collaborative discussions to deepen understanding and prepare for the unique challenges in ADC manufacturing.
- Synthesize the learnings from the entire course to enhance practical skills and readiness.

18:00 - 18:15

Summing up key takeaways from the training

Lecture 1: Introduction to ADCs and Mechanism of Action

Title: *Unveiling the Complexity: Introduction to ADCs and Their Mechanism of Action*

Summary: This foundational lecture delves into the intricate world of Antibody-Drug Conjugates (ADCs), exploring their unique mechanism of action. Gain insights into how ADCs leverage the targeting precision of antibodies combined with the potent cell-killing abilities of payload drugs. Understand the critical role of this mechanism in the success of ADCs and the challenges associated with their complex nature.

Lecture 2: GMP ADC Manufacturing: Key Steps and Technical Challenges

Title: *Navigating Complexity: GMP Manufacturing of ADCs - Steps and Challenges*

Summary: Dive into the heart of ADC manufacturing, exploring the key steps and technical challenges that often lead to market-approval delays. This lecture provides a comprehensive understanding of the intricacies involved in producing high-quality ADCs, emphasizing the critical need for a robust CMC strategy to overcome challenges and ensure manufacturing success.

Lecture 3: Regulatory Landscape for ADCs - FDA and EMA Perspectives

Title: *Regulatory Navigate: ADCs and Regulatory Drivers from FDA and EMA*

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Lecture 5: Change Management and Tech Transfer for ADCs

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UPCOMING
PHARMA TRAININGS

31 July, 1 & 2 August

Advanced Training in Biopharmaceutical Manufacturing - CMC Masterclass

Dr. Len Pattenden, Managing Director, CMC Biopharma Ltd

6 & 7 August

Method Validation - Update on ICHQ14 and ICHQ2 - Analytical LifeCycle Management, Validation and Transfer of Analytical Methods

Dr. Ralph Nussbaum, Vice President Quality Management , Auregen BioTherapeutics GmbH

13, 14, 15 August

Advanced Training in Biopharmaceutical Technology Transfer - Technology Transfer

Dr. Len Pattenden, Managing Director, CMC Biopharma Ltd

10 & 11 September

Regulation, Quality, and Compliance in ADC Manufacturing - Masterclass

Dr. Len Pattenden, Managing Director, CMC Biopharma Ltd

23 & 24 September

Advanced Enterprise Risk Management

Phil Griffiths, CEO , Business Risk Management Ltd

7 & 8 October

Method Validation Entry Level Europe - Masterclass

Dr. Ralph Nussbaum, Vice President Quality Management , Auregen BioTherapeutics GmbH

10 & 11 October

Method Validation Entry Level US - Masterclass

Dr. Ralph Nussbaum, Vice President Quality Management , Auregen BioTherapeutics GmbH

RESERVE YOUR SPOT TODAY!

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