



CMC ANALYTICAL, COMPARABILITY AND STABILITY STUDIES FOR BIOTECHNOLOGY PRODUCTS: CURRENT EXPECTATIONS, PRACTICAL CONSIDERATIONS

Holiday Inn Atrium, Singapore, 21-22 May 2009

Course Outline

Lecture Sessions

The course is based on the Theory behind conducting Stability Studies as specified and required by European and USA Guidelines. It also explains why CMC, Analytical and Comparability studies are important and what is Actually Required for you to ensure that your Biotech Product testing Processes are effective and efficient.

Discussion of Ongoing Resources for Biotechnology Analytical CMC Issues

A significant proportion of the course will be devoted to discussion periods on the following which will provide delegates with an opportunity to have their specific questions answered.

1. Professional organizations
2. Professional journals
3. Discussion groups
4. Forums, symposia and conferences
5. Books on biotechnology products

Group Interactions

Meet like-minded colleagues, exchange views and benchmark your practice against current industry best practices.

Special Discount !!
For those who register before
30 April 2009 !!

You should attend

This in-depth interactive and carefully designed course is suited to anybody working in the field of Biotech products. The course will be particularly useful for staff from all parts of the Biotech industry, including:

- Regulatory Affairs
- Analytical Development
- Product Development
- Research and Development
- Method Validation groups
- Quality Assurance
- Quality Control
- Contract Manufacturing and Testing
- Suppliers and vendors of analytical Equipment

Register NOW ! Avail of the Group Discounts !!
Limited Seats Available ! Register before 30 April 2009

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Workshop Leader : Nadine M. Ritter, Ph.D.

Nadine Ritter has over 15 yrs of in-depth biotechnology industry experience in the technical, quality and regulatory elements of product development for a variety of protein and peptide therapeutics and diagnostics. She is a protein analytical biochemist with hands-on expertise in the design and execution of biopharmaceutical CMC studies using a wide array of analytical methodologies. Her technical specialties include test method selection and optimization for biotechnology product characterization, release and stability testing; analytical test method qualification and validation; pre- and post- approval product comparability studies; and assay technology transfers.

Additionally, Nadine has considerable experience in the management of laboratories that conduct R&D, GLP and cGMP studies for biotechnology product physiochemical and functional testing. Currently, she routinely performs third-party quality and compliance audits ranging from small start-ups to multinational pharmaceutical corporations. She has delivered numerous invited presentations on many different technical and quality topics, and has published articles and book chapters on biotechnology CMC analytical studies and analytical laboratory practices.

For many years, Nadine has been an active member of several professional scientific organizations dedicated to improving technical, quality and regulatory elements of biotechnology product development. She is a highly-regarded member of various scientific review boards as well as program organizing committees in the biopharmaceutical industry. She is a founding member of the WCBP CMC Strategy Forum, an industry-FDA scientific discussion group (www.casss.org). She has recently been selected US chair of the PDA Biotechnology Analytical Method Development Task Force.

Nadine M. Ritter, Ph.D., Senior Consultant, Biologics Consulting Group, Inc.

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The Organiser

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Biotechnology CMC Regulatory Requirements

1. Why do biotechnology products have different CMC requirements than traditional chemical products?
2. Which specific worldwide regulations detail CMC analytical and stability study requirements for Biotech products?
3. What CMC characterization, comparability, release specification and stability data packages are required for a biotechnology product per the current ICH Common Technical Document (M4Q)?
4. When should these individual studies be done during the product development lifecycle?
5. Which CMC analytical development studies have the most critical project planning considerations Based on their time and material requirements for biotechnology products?
6. What are some of the current regulatory CMC “hot buttons” for biotechnology analytical and stability Studies?

Biotechnology Product Specifications; Comparability and Stability Issues

1. What four elements are critical for establishing reliable, meaningful product specifications?
2. What are the expectations for heterogeneity in biotechnology products?
3. What is the concern about product and process related impurities?
4. What are the important elements of a comparability study for a biotechnology product?
5. What additional comparability considerations impact biosimilar/bigeneric products?
6. How are biotechnology reference standards established, and when should they be changed?
7. What are the clinical trial requirements for biotechnology stability studies?
8. What are the commercial requirements for biotechnology stability studies?
9. Why is it difficult to directly extrapolate shelf life for biotechnology products simply from Accelerated Stability data?

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Biotechnology Analytical Methodology (contd.)

1. What are the various characteristics of a biotechnology product that require analytical assessment?
2. What types of analytical methods are currently expected to be used for different types of Biotechnology products?
3. What are some of the performance characteristics typically seen with the physiochemical and Functional methods used with biotechnology products?
4. What types of system suitability measures are appropriate for different types of biomolecular Methods?
5. What determines a method to be suitable for the intended use of characterization, comparability, release or Stability testing?
6. What is the difference between method qualification and method validation?
7. When is method qualification acceptable, and when is method validation necessary?

Implementation of Biotechnology Laboratory Tests

1. What are the laboratory operational issues that can impact reliable method performance?
2. What are some of the hidden sources of method variability for typical biotechnology methods?
3. What are key considerations for laboratory investigations of out of spec results?
4. What are the requirements related to making changes in analytical methods?
5. What issues should be considered in analytical method technology transfer studies?
6. What are the requirements related to changing analytical laboratory testing sites?
7. What quality practices are necessary for CMC analytical studies during product development?
8. What are the necessary deliverables from the analytical development/validation group?

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Venue : Holiday Inn Atrium, 317, Outram Road, Singapore 169075
Dates : 21-22 May 2009

For Registration and Sponsorship details, Please Contact :

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7, Toh Guan Rd East #08-01, Alpha Industrial Building, Singapore 608599.

Registration Fee : SGD 1500 Per Person
Early Bird Discount* SGD 1250 Per Person *For those who register before 30 April 2009
Group Discount SGD 1250 Per Person **For 4 or more persons from the same organization.**

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