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# CMC Analytical, Comparability and Stability Studies for Biotechnology and Biosimilar Products

## Current Expectations & Practical Considerations

Course Dates:

22-23 March 2011, MWB Victoria, London, UK

11-12 October 2011, MWB Victoria, London, UK

- What are the 9 required analytical CMC studies?
- What are the 4 key elements for setting specs?
- What are 7 current and emerging hot-button items?



“ *Excellent course and content. Trainer was superb.  
Best course I have attended* ”

R&D Manager, Biozyme Labs

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# CMC Analytical, Comparability and Stability Studies for Biotech

**Course Agenda** Registration will be at 9.00am, the course will start at 9.15am and will finish by 5.00pm

## Programme

### Biotechnology CMC Regulatory Requirements

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

### Practical Session:

#### Biotechnology Product Specifications; Comparability and Stability Issues

- What four elements are critical for establishing reliable, meaningful product specifications?
- What are the expectations for heterogeneity in biotechnology products?
- What is the concern about product and process related impurities?
- What are the important elements of a comparability study for a biotechnology product?
- What additional comparability considerations impact biosimilar/biogenic products?
- How are biotechnology reference standards established, and when should they be changed?
- What are the clinical trial requirements for biotechnology stability studies?
- What are the commercial requirements for biotechnology stability studies?
- Why is it difficult to directly extrapolate shelf life for biotechnology products simply from accelerated stability data?

### Course Curriculum:

To find out more about related PTI courses, please contact our account management team on +44 (0) 20 7017 7267/7159/7164

### Practical Session:

#### Biotechnology Analytical Methodology

- What are the various characteristics of a biotechnology product that require analytical assessment?
- What types of analytical methods are currently expected to be used for different types of biotechnology products?
- What are some of the performance characteristics typically seen with the physicochemical and functional methods used with biotechnology products?
- What types of system suitability measures are appropriate for different types of biomolecular methods?
- What determines a method to be suitable for the intended use of characterization, comparability, release or stability testing?
- What is the difference between method qualification and method validation?
- When is method qualification acceptable, and when is method validation necessary?

### Practical Session:

#### Implementation of Biotechnology Laboratory Tests

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

### Discussion Session:

#### Discussion of Ongoing Resources for Biotechnology Analytical CMC Issues

- Professional organizations
- Professional journals
- Discussion groups
- Forums, symposia and conferences
- Books on biotechnology products

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## Course Objectives:

To provide attendees with a clear, concise, but comprehensive overview of all relevant regulatory, technical and quality elements necessary to assure successful design, implementation and documentation of the required CMC analytical and stability studies for biotechnology products, including emerging biosimilar products. Key deliverables from each phase of development will be illustrated. Current 'hot-button' CMC analytical and stability issues will be presented, and strategies for preventing (or remediating) gaps will be presented. **Attendees will be given a CD containing a complete set of all regulatory documents and industry white papers currently applicable to biotechnology product analytical CMC requirements that covers the entire product development lifecycle.**

## Performance & Knowledge Objectives of this Course:

Attendees will be given a comprehensive overview of the phase-specific requirements for CMC analytical characterization, comparability, release and stability of biotechnology products from the pre-clinical phase through clinical trials to commercialization and post-approval. Analytical considerations for a wide variety of biopharmaceuticals will be discussed, including monoclonal antibodies, therapeutic proteins, gene therapy, vaccines, and complex products (eg antibody drug conjugates). Details will be presented on establishing and maintaining product reference standards, designing successful comparability tests (including specifics for biosimilar studies), setting meaningful product specifications, conducting forced degradation studies, tech transfer and bridging changes in analytical methods and generating effective stability protocols. Critical elements of laboratory quality practices that significantly impact the reliability of test data from R&D through cGMP will be illustrated.

## Your Distinguished PTI Trainer – Nadine Ritter:

Nadine Ritter has been a protein scientist for over 25 yrs. After 10 yrs in funded academic research, she moved into the biotechnology industry at a major pharmaceutical firm. Currently, she is a CMC technical, regulatory and quality consultant and instructor for the biopharmaceutical industry, where she provides expertise in analytical test method selection and optimization for product characterization, release and stability testing; analytical test method qualification and validation, as well as pre- and post- approval product comparability studies, and assay bridging/technology transfers. In addition, she routinely performs third-party laboratory quality and compliance audits for small start-ups to multinational pharmaceutical corporations and contract testing laboratories

Dr. Ritter has delivered numerous invited presentations worldwide on many different technical and quality topics, and has published articles and book chapters on biotechnology CMC analytical studies and laboratory quality practices. Nadine has been an active member of several professional scientific organizations dedicated to improving analytical 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 and EU CMC Strategy Forum, an industry-regulatory scientific discussion group ([www.casss.org](http://www.casss.org)). She has recently been appointed co-chair of the PDA Biotechnology Analytical Method Development Task Force.

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## Who should attend?

- QC release and stability analysts
- Stability program managers
- Product scientists and test method technical experts (R&D and QC)
- Process analytical chemists and process development scientists
- Quality assurance specialists
- GMP compliance auditors
- Regulatory affairs CMC authors or reviewers
- Analytical and stability laboratory managers (R&D through GMP)
- Project managers with CMC responsibilities
- Business managers with CMC responsibilities
- Key staff from biotech academic incubators and small start-ups
- Contract testing labs



# CMC Analytical, Comparability and Stability Studies for Biotechnology and Biosimilar Products

22-23 March 2011, MWB Victoria, 10 Greycoat Place, Victoria, London, SW1P 1SB, UK. Tel: +44 (0) 207 960 6000

11-12 October 2011, MWB Victoria, 10 Greycoat Place, Victoria, London, SW1P 1SB, UK. Tel: +44 (0) 207 960 6000

Course code: CSJ119  
Course code: CSJ120

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## HOW MUCH?

**Course fee includes: workbook, lunch, refreshments, post-event follow up call**

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