



Develop your skills, achieve your goals

For details
of in-company
training solutions
call +44 (0) 20 7017 7266

Applying expert knowledge to enhance your biomanufacturing capabilities

Introduction to Biopharmaceutical Manufacturing

Addressing critical elements in the manufacturing
and regulation of biopharmaceutical products

Course Dates:

23-24 February 2011, MWB, Victoria, London, UK

25-26 May 2011, MWB, Victoria, London, UK

- Rapidly obtain a clear, concise overview of the current regulations applicable to the production of biopharmaceuticals
- Distinguish the product safety concerns associated with manufacturing of biologically-derived products from traditional chemical products
- Understand the key elements of different expression systems and downstream processing steps
- Gain a regulatory perspective on the nature and format of process data required throughout the lifecycle of biopharmaceutical products



For more information go to www.pti-europe.co.uk/bioman

Call: +44 (0) 20 7017 7481 • Fax: +44 (0) 20 7017 7823

Email: registration@pti-europe.co.uk • Internet: www.pti-europe.co.uk/bioman

Introduction to Biopharmaceutical Manu

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

Course Overview

Biotechnological products are complex molecular entities, manufactured in living systems which are - by their nature - inexact. As a result, the composition of these products is influenced by the method of manufacture, making manufacturing control and characterization a challenge. Emerging concepts in the establishment of a process design space for biologically-derived products will be addressed. Products manufactured in living systems are also highly susceptible to the environment in which they are manufactured and quality of the raw materials used. A discussion of manufacturing facility requirements and the application of cGMP over the course of product development and commercialization will be included.

The benefits of attending this course include: Rapidly obtaining a clear, concise overview of the current regulations applicable to the production of biopharmaceuticals. Distinguishing the product safety concerns associated with manufacturing of biologically-derived products from traditional chemical products. Understanding the key elements of different expression systems and downstream processing steps. Getting a view from the perspective of regulators on the nature and format of process data required throughout the lifecycle of biopharmaceutical products. This two-day comprehensive overview course will address the following critical elements in the manufacturing and regulation of biopharmaceutical products:

DAY 1

- Nature and differences of various types of biotechnology products – when is it a drug vs a biologic, and why the difference matters
- Subsequent-entry biopharmaceuticals (eg biosimilar or follow-on biologics)
- Current ICH regulatory guidance document specifically applicable to biotechnology and biosimilar products
- Comparison of source of biopharmaceuticals – natural products (vaccines, blood products) compared to recombinant products (expression systems)
- Discussion of different expression systems: mammalian vs microbial cells; emerging cell substrates (eg insect systems)
- Establishment and characterization of master and working cell banks
- Control and consistency of cell-based processes – from quality of raw materials through integrity of process components to stability of end of production cells

DAY 2

- Detailed requirements for viral clearance/viral inactivation studies
- Critical factors in aseptic processing and aseptic facility operations
- Process optimization and characterization leading to process design space
- Key elements of process validation data to support proven acceptable ranges
- Emerging process control concepts from quality by design approaches
- Changes in process unit operation, production scale or manufacturing location
- Appropriate design of pre and post approval process comparability studies
- Where does all of this information go? Summary of the ICH Common Technical Document Module 3 production and manufacturing sections

Course Curriculum:

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

© Copyright IIR BV 2011. Due to unforeseen circumstances, the programme may change and IIR reserves the right to alter the venue and/or the course leader. IIR reserves the right to cancel the event.

Course Objectives:

- Overview of current regulatory documents applicable to biotechnology processes and facilities
- Review of expectations for process development, process validation and process comparability studies for biotechnology/biosimilar products
- Outline of manufacturing and facility information required in Module 3 of the ICH Common Technical Document (ICH M4Q)

Performance & Knowledge Objectives of this Course:

By attending this course, participants will obtain a clear, concise view of the current regulatory expectations for the manufacturing of biotechnology products from preclinical and clinical development to commercialisation. They will be able to identify the major product quality and safety concerns associated with biologically-based production processes. Practical aspects of process control – starting with raw materials and cell banks through upstream and downstream unit operations to purified bulk drug substance, then formulated/filled drug product – will be presented to give attendees a real-world perspective on biotechnology product manufacturing. Finally, attendees will be trained to understand the relevant sections of the Quality Module 3 of the ICH Common Technical Document where product and facility information is required to be presented to regulators for review and approval of clinical and commercial applications.

Your Distinguished PTI Trainer

Dr Ruth Wolff, Senior CMC Consultant, Biologics Consulting Group, USA

Over the course of her academic and professional career, Dr Wolff progressed from basic research through increasingly applied research in somatic cell/medical genetics and identification of epitopes for vaccine development, to cell line safety testing for biopharmaceuticals in a natural evolution toward regulatory review. While at the FDA, she participated directly in the regulatory activities in application review, policy development, and international regulatory coordination. During this time, as researcher, reviewer and manager, she acquired experience with a wide range of disciplines and technologies, sponsors and products, submissions and processes, with the goal of bringing safe and effective products to the public in a timely manner. In her current role and CMC consultant, she is responsible for the scientific and regulatory review and analysis of a wide range of therapeutic products at all stages of product development, from pre-IND development through post-marketing. She provides regulatory, scientific and manufacturing analysis and support, develops product-and facility-related regulatory documents for submission, reviews SOPs and validation packages and performs facilities audits for a wide array of biotechnology products world-wide.

Tailored Training Solutions

All PTI's training courses can be customised to meet exact requirements and delivered by our experienced trainers on-site.

- Save valuable time and expenditure
- Address your teams' specific needs with a tailored training approach
- Find solutions to real problems by incorporating your own case studies and examples
- Increase communication and performance by training your department as a team

For more details or initial consultation, please contact the PTI Tailored Training Team, on +44 (0) 20 7017 7266 or email tailoredtraining@pti-europe.co.uk



Introduction to Biopharmaceutical Manufacturing

23-24 February 2011, MWB Victoria, 10 Greycoat Place, Westminster, London, SW1P 1SB
25-26 May 2011, MWB Victoria, 10 Greycoat Place, Westminster, London, SW1P 1SB

Course code: CNS301
Course code: CNS302

FIVE EASY WAYS TO REGISTER

Telephone: +44 (0) 20 7017 7481



Email: registration@pfi-europe.co.uk

Fax: Complete and send this registration form to: +44 (0) 20 7017 7823



Web: www.pfi-europe.co.uk/bioman



Mail: this completed form together with payment to: Customer Service Manager, Informa UK Ltd, PO Box 406 Blythe, KT14 6WL

HOW MUCH?

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

Tick	Date	Code	Full Price	VAT	TOTAL PRICE
<input type="checkbox"/>	23-24 February 2011	CNS301	£1445.00	£216.75	£1661.75
<input type="checkbox"/>	25-26 May 2011	CNS302	£1445.00	£216.75	£1661.75

The VAT rate is subject to change and may differ from the advertised rate. The amount you are charged will be determined when your invoice is raised.
 Please send me information on onsite training

If booking 4 weeks or more in advance, tick here to receive **£100 off the Full Price**

Yes! I would like to receive information about future events and services via fax SMS/MMS
Mobile no: _____ Signature _____

Yes! I would like to receive information about upcoming events by email. By giving you my email address I am giving ONLY IIR companies the permission to contact me by email

TWO EASY WAYS TO PAY

Credit Card. Please debit my: VISA AMEX DINERS MASTERCARD

Card No:

Expiry Date: Signature: Please send me an invoice.

3-Digit Security Code: Please send me an invoice.

What Happens If I Have to Cancel? Confirm your CANCELLATION in writing 2 weeks before the date of the course (30 February 2011, CNS301/17th May 2011, CNS302) and receive a refund less a 50% + VAT service charge. Should you cancel between this date and 1 week before the date of the course (16th February 2011, CNS301/18th May 2011, CNS302) then you will receive a refund less a 100% + VAT service charge. Regularly, no refunds can be made for cancellations received less than one week prior to the conference. Within 10 working days prior to the start date of the course the customer may reschedule a booking to another date at a 50% rescheduling fee or within 46 hrs of a 100% rescheduling fee by advising Pharmaceutical Training International UK of such rescheduling in writing. For full terms and conditions visit www.pfi-europe.co.uk/terms

Data Protection: The personal information shown on this form, and/or provided by you, will be held on a database and may be shared with other companies in the Informa Group in the UK and internationally. If you do not wish your details to be available to other companies in the Informa Group please contact the Database Manager at the above address.
Tel: +44 (0)20 7017 7017, Fax: +44 (0)20 7017 7828 or email: integrity@itlid.co.uk

Occasionally your details may be obtained from, or made available to, external companies who wish to communicate with you offers related to your business. You do not have to provide your details to these companies. Please tick the box if you do not wish to receive such offers.
 Additional Requirements: Please notify IIR at least one month before the course date if you have any additional requirements e.g. wheelchair access, large print etc.

Your VIP number is on the address label. If there is no label, please quote
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

PERSONAL DETAILS

 Please photocopy this form for additional delegates

Delegate (Mr/Mrs/Ms) _____

Job title _____ **Company** _____

Address _____

Telephone _____ **Fax** _____

Email _____

Approving Manager _____

Booking Contact _____

Please photocopy this form for additional delegates

Our statement of integrity can be found on our website at www.iir-conferences.com/feedback

Incorrect Mailings: If you are receiving multiple mailings or you would like us to change any details or remove your name from our database, please contact the Database Manager at the above address. Tel: +44 (0)20 7017 7077.

Fax: +44 (0)20 7017 7828 or email: integrity@itlid.co.uk - quoting the reference number printed on the mailing label.