

The Basics of Regulatory Affairs in the Context of Product Development

with Special Emphasis on Biopharmaceuticals and Advanced Therapy Medicinal Products



This seminar will offer participants a complete overview of the regulatory requirements and processes in the USA and the EU for biopharmaceuticals and advanced therapy products



18th – 20th July 2007, Rockville Education Center, Rockville MD

SPEAKERS



Dr. Chris Holloway
ERA Consulting Group



Dr. Dianne Jackson Matthews
ERA Consulting Group

TOPICS COVERED DURING THE SEMINAR

- Procedures for Marketing Authorisation in the EU
- Procedures for Marketing Authorisation in the USA
- Documentation and Dossiers - An Introduction to the Common Technical Document (CTD)
- Comparing and Contrasting Clinical Trial Applications: EU vs USA
- Manufacturing Issues
- Analytical and Control Issues
- Nonclinical and Clinical Issues

WHO WILL BENEFIT? WHO SHOULD ATTEND?

- Regulatory affairs professionals
- Project managers
- Development team members
- Investors focusing on the biologics industry
- Senior management
- Business development managers

All Participants receive a Course Certificate

Discounted fees for multiple delegates from the same company

Register before June 1 for discounted fee

REGISTER TODAY!

This three-day intensive training course is designed to provide attendees with a basic, yet thorough understanding of the regulation of drugs and biologics in Europe and the USA. The course addresses regulatory affairs from the perspective of product development, with special emphasis on biologics and advanced therapy medicinal products (gene and cell therapy products). Thus, the purpose of this course is to provide insight and appreciation of the regulatory requirements that are immediately relevant to those involved in product development.

The course covers manufacturing, preclinical and clinical development, and is intended to suit the needs of those requiring basic knowledge of both European and US regulatory affairs, for example in the context of manufacturing requirements, clinical trial applications or future Marketing Authorisation Applications. Similarities and differences in regulatory requirements and guidelines in the USA and Europe will be highlighted, where relevant, and practical case studies will be presented to illustrate key points of comparison.

ABOUT YOUR COURSE LEADERS

Dr. Chris Holloway
Group Director of Regulatory Affairs
ERA Consulting Group

Dr. Dianne Jackson Matthews
Deputy Group Director of Regulatory Affairs
ERA Consulting Group

Both speakers have more than 20 years of experience in regulatory affairs and product development relating to drugs, biotechnology-derived products and other biologics, as well as gene and cell therapy products. Together, they have been involved in projects on more than 300 biological medicinal products.

Their expertise covers initiation and management of agency interactions, the organization and review of CMC, preclinical and clinical development plans, the development of manufacturing strategies for biologics, including comparability exercises for process changes, authorship of expert reports and other regulatory documents for submission to authorities.

While Chris Holloway's expertise focuses primarily on Europe, Dianne Jackson-Matthews' experience covers both the USA and Europe, and more recently Australasia. Both Chris and Dianne are regularly invited speakers at international conferences and workshops on a variety of topics relating to the development and regulation of biologics.

LOCATION

ROCKVILLE EDUCATION CENTER
1801 Rockville Pike, 2nd floor
Rockville, MD 20852
Two blocks from the
Twinbrook Metro Station (red line)

COURSE CERTIFICATE

To record your participation, ERA Consulting will issue you with a certificate of attendance upon the successful completion of this course. This certificate will testify your endeavour in career and professional development and is intended to contribute towards your career advancement.

COURSE SCHEDULE

Registration begins at 1:15pm on the first day. The course will begin at 2:00pm on day one and at 9:00am on days two and three. The course will conclude at 5:30pm on days one and two and at 12:30pm on day three. Refreshment breaks will be offered around 10:30am and 3:30pm. Lunch will be provided on day two of the course from approximately 12:30 to 2:00 pm.



The ERA Consulting Group provides regulatory affairs and product development consulting services for biotechnology-derived medicinal products. With offices in Germany, UK, USA and Australia, we have unrivalled expertise, a proven track record and 20 years of experience, covering more than 250 products. Our clients range from biotech start-ups to the largest pharmaceutical corporations. ERA's input ranges from feasibility studies, regulatory diligence or development of regulatory strategy, to the compilation and submission of complete dossiers.

REGISTER TODAY!

COURSE AGENDA

DAY ONE: WEDNESDAY 18th July 2007
2:00pm – 5:30pm

Session 1: Procedures for Marketing Authorisation in the EU

- EU Regulations and Directives Governing Medicinal Products
- EU Institutions for the Authorisation of Medicinal Products
- The Centralised Procedure
- The Decentralised Procedure
- The Mutual Recognition Procedure
- EU Scientific Advice Procedures
- Orphan Medicinal Product Applications
- Exceptional Circumstances and Conditional Approvals

Session 2: Procedures for Marketing Authorisation in the USA

- The Federal Food, Drug and Cosmetic Act
- The Public Health Service Act
- New Drug Applications (NDAs)
- Biologics License Applications (BLAs)
- The Food and Drug Administration (FDA)
- Agency Interactions including Pre-IND Meetings
- Orphan Drug Applications
- Expedited or Fast-Track Review

DAY TWO: THURSDAY 19th July 2007
2:00pm – 5:30pm

Session 5: Manufacturing Issues (with special reference to Biopharmaceuticals)

- Good Manufacturing Practice Guidelines and Expectations
- Process Development and its Role in the Marketing Authorisation
- The Importance of Raw Material Controls
- Process Validation and Evaluation
- In-Process Controls and their Role in the Demonstration and Documentation of Consistency and Comparability
- Handling Scaling-Up and Other Process Changes
- Case studies of 'comparability' exercises at the CMC level

Session 6: Analytical and Control Issues (with special reference to Biopharmaceuticals)

- The European Pharmacopoeia, National Pharmacopoeia, the USP and their Status in Analytics and Control
- Method Development and Validation
- Characterisation, Extended Analytical Testing and Routine Control of Drug Substance and Drug Product
- The Concept of Comparability
- Content, Potency and Impurities *versus* Contaminants
- How to Define Specifications

DAY TWO: THURSDAY 19th July 2007
9:00am – 12:30pm

Session 3: Documentation and Dossiers: An Introduction to the CTD

- Module 1: Administrative details and prescribing information
- Module 2:
 - The Quality Overall Summary
 - The Nonclinical Summary and Overview
 - The Clinical Summary and Overview
- Module 3: Presenting Quality/CMC Information
- Module 4: Presenting Nonclinical Information
- Module 5: Presenting Clinical Information

Session 4: Comparing and Contrasting Clinical Trial Applications: EU vs USA

- The EU Clinical Trial Directive and Associated Regulations
- The Investigational Medicinal Product Dossier (IMPD)
- Clinical Trials and Investigational New Drug (IND) Applications in the USA
- Other Measures for Clinical Trial Applications
 - Ethics Committees
 - Special Committees for Gene Therapy Products
 - Issues relating to GMOs and safety reporting

DAY THREE: FRIDAY 20th July 2007
9:00am – 12:30pm

Session 7: Nonclinical and Clinical Issues (with special reference to Biopharmaceuticals)

- Nonclinical Programme Design for Biopharmaceuticals
- Nonclinical Safety at the Various Stages of Clinical Development
- Product Requirements During Nonclinical Development
- Clinical Trial Design for Biopharmaceuticals
- Biopharmaceutical Assay Requirements in the Nonclinical and Clinical Evaluation of Biopharmaceuticals
- The Special Role of Immunogenicity in the Nonclinical and Clinical Evaluation of Biopharmaceuticals

Session 8: Miscellaneous and Question and Answer Session

In this session, we usually address topics that have arisen during the course, as being of special interest to the attendees. This is an opportunity for attendees to ask any specific and more detailed questions that have not been answered during the course.

In addition, we present thoughts and ideas on how all those involved in research and development can add value to the project in terms of future marketing authorisation.

REGISTER TODAY!

REGISTRATION FORM

DELEGATE INFORMATION

NAME	
JOB TITLE	
DEPARTMENT	
COMPANY	
ADDRESS	
POST/ZIP CODE	
TEL	
FAX	
EMAIL	
WEBSITE	

COST STRUCTURE	BEFORE JUNE 1ST, 2007	AFTER JUNE 1ST, 2007
1 delegate	US\$ 645.00	US\$ 795.00
2 delegates (from the same company or institution)	US\$ 595.00 per delegate	US\$ 645.00 per delegate
3 or more delegates (from the same company or institution)	US\$ 445.00 per delegate	US\$ 495.00 per delegate

Government employee discount: deduct US\$ 150 per delegate from the above rates

TERMS AND CONDITIONS

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PAYMENT: Prepayment is required for all registrations. Upon receipt of the registration form and payment by cheque (we regret that credit cards are not accepted), delegates will be sent a registration confirmation and an appropriate receipt for their records. Registration will be possible on the day of the event 'at the door' subject to availability, which cannot be guaranteed except for advanced registrations. For those registering at the event, payment will be required on the day by cheque.

FEE: This includes all technical sessions, lunch, refreshments and documentation. It does not include the cost of accommodation and travel.

CANCELLATIONS: Refunds for cancellations received in writing before 1st July 2007 will be subject to a service charge of 50% of the registration fee. We regret that no refunds can be made for cancellations received after 1st July 2007. A registration may be transferred to a delegate from the same company or organisation at anytime.

In the unlikely event that this conference has to be cancelled for any reasons, intERActions and the ERA Consulting Group are not liable for any costs incurred by delegates in connection with their attendance. However, in this eventuality all paid registrations will be refunded in full.

DATA PROTECTION: The personal information shown, or provided by you, will be held on a database and may be shared with companies within the ERA Consulting Group only. They may be used to keep you up-to-date with developments in your industry. If you do not wish your details to be used for this purpose, please email info@eraconsulting.com.

EASY WAYS TO REGISTER

To reserve your place:

Call: +1-202-234-9378

Fax: +1-202-237-2172

Email: info@eraconsulting.com

To complete registration, **mail** the form with your cheque to:

ERA Consulting (USA) Llc.

P.O. Box 33005

Washington, DC 20033

USA

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