

Regulatory Procedures for Pharmaceuticals in the United States and Europe: Introductory Course with Special Emphasis on Biopharmaceuticals



This seminar will offer participants an introduction to the regulatory requirements and processes in the USA and the EU medicinal products, including biopharmaceuticals



29th – 30th October 2007, Melbourne, Australia

SPEAKERS



Dr. Chris Holloway
ERA Consulting Group



Dr. Dianne Jackson Matthews
ERA Consulting Group

TOPICS COVERED DURING THE SEMINAR

- Procedures for Marketing Authorisation Applications in the USA
- Procedures for Marketing Authorisation Applications in the EU
- Comparing and Contrasting Clinical Trial Applications: EU vs USA
- Nonclinical and Clinical Issues

WHO WILL BENEFIT? WHO SHOULD ATTEND?

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

All Participants
receive a
Course Certificate

Discounted fees for
multiple delegates from
the same company

Register before
1st October for
discounted fee

REGISTER TODAY!

This one-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 biological medicinal 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 focuses on the regulatory pathways and preclinical/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 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 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 pharmaceuticals, 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

Karstens at CQ
123 Queen St, Melbourne, VIC 3000,
Australia

An underground car park is located in the building. Entrance is from Little Collins Street. Trams 31, 109 and 112 travel along Collins Street, the closest tram stop is on the corner of Queen and Collins Street. Trams 86, 95 and 112 travel along Bourke Street, the closest tram stop is on the corner of Bourke and Queen Street.

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 12:30pm on the first day. The course will begin at 1:30pm on day one and at 9:00am on day two. The course will conclude at 6:30pm on day one and at 1:00pm on day two. Refreshment breaks will be offered around 3:00pm (Day 1) and 10:30am (Day 2).



The ERA Consulting Group provides regulatory affairs and product development consulting services for 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 300 products. Our clients range from biotech start-ups to the largest pharmaceutical corporations.

REGISTER TODAY!

COURSE AGENDA

DAY ONE: MONDAY 29th October 2007
1:30pm – 5:30pm

DAY TWO: TUESDAY 30th October 2007
9:00am – 1:00pm

Session 1: 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

Session 2: 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

A questions and answers session will follow this section of the course.

Session 3: 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

Session 4: 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

A questions and answers session will follow this section of the course.

NETWORKING RECEPTION • MONDAY 29th October • 5:30pm – 6:30pm

All delegates are invited to join the speakers at the networking reception, which begins at 5:30pm on Monday 29th October. This will be held in the same venue as the training course. This is an opportunity to discuss any issues with the speakers and to network with other delegates. Drinks and finger food will be provided during this networking reception.

IN-HOUSE TRAINING

How many times have you been interested in a great course that you know would benefit your entire organisation, but the time investment and travel costs prohibit sending a large group? ERA Consulting understands the importance of a comprehensive training programme that will ensure high-quality employee performance at a reasonable price.

ERA's in-house training gives individual companies the opportunity to receive ERA's quality educational opportunities without the added travel costs or loss of valuable office time in a group setting. These training offerings are instructed by the same experts who teach in the IntERActions seminars, and can be tailored to meet your company's particular training objectives.

The costs for this training are all inclusive. You provide the delegates, the audiovisual equipment, and learning-friendly environment, and ERA supplies the instructors and the learning material.

For more information about in-house training, contact Paul Cronin at info@eraconsulting.com

REGISTER TODAY!

REGISTRATION FORM

DELEGATE INFORMATION

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

COST STRUCTURE	BEFORE 1 st OCTOBER	AFTER 1 st OCTOBER
1 delegate	AUS 425.00 + GST	AUS 525.00 + GST
2 delegates* (from the same company or institution)	AUS 375.00 + GST per delegate	AUS 475.00 + GST per delegate
3 or more delegates* (from the same company or institution)	AUS 325.00 + GST per delegate	AUS 425.00 + GST per delegate

* If registered at the same time

All prices are subject to 10% GST

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. 10% GST are applicable to all fees.

CANCELLATIONS: Refunds for cancellations received in writing before 12th October 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 12th October 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: +61-7-3331-3900

Fax: +61-7-3870-0048

Email: info@eraconsulting.com

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

ERA Consulting (Australia) Pty. Ltd.
Level 3, 88 Jephson Street
Toowong QLD 4066
Australia

INTERESTED IN CUSTOMISED IN-HOUSE TRAINING?

Contact: Paul Cronin
info@eraconsulting.com