


European Regulatory Affairs Course

September 2009 - June 2010

 SIR Institute for Pharmacy Practice and Policy
Theda Mansholtstraat 5b
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 www.stevenshof.nl

QUOTES

“Participating in the European Regulatory Affairs course was a great experience for me. The course gave a good overview of European regulatory procedures, Quality, Pre-clinical, Clinical and post-marketing requirements which has broadened my knowledge on European regulatory affairs. Having worked in the vaccines business for many years, it was good to get to know the requirements for drugs as well. I might need that knowledge in the future. Besides learning a lot about regulatory affairs, the course also helped me expand my network and gave me the opportunity to meet a lot of great people!”
Mrs. M. Mulder, Solvay Pharmaceuticals Inc., course participant 2006-2007

“The evening case study in the clinical module is asking for solutions of "simplified real life situations" in the clinical development of a new antidepressant. Combining daytime lecture information with guideline requirements into a scientifically/ethically sound clinical development plan is a real challenge for interacting discussions of industry/government participants.”
Dr J. Moors, Organon, a part of Schering-Plough, faculty

“When I was in medical school we thought duodenal ulcer was caused by psychological stress - it is mainly caused by an infection! As our knowledge of biology increases we will discover that there are mechanisms for diseases we do not understand yet and we are in for many surprises like this. Biological understanding of diseases will lead to more spectacularly innovative drugs than we were used to in the last decade. To be able to work with these compounds the knowledge of all professionals in the field will be challenged. The future lies therefore in collaboration between industry and academia, between users and producers of knowledge. As a hybrid between industry and academia I find that an exciting future.”
Prof. dr Adam Cohen, Leiden University, faculty

“What was the course good for? Well, for starters, it touched on practically every aspect of European regulatory practice from Directives to the underlying philosophy. Important thought: the trainers were often exceptional and pleasantly, the attendees freely shared their insights and experience, usually during the workshop sessions - so you can't get this from reading alone. Educational and enjoyable in one and extremely smoothly run! Well done SIR!”
Dr S. Long, Astellas Pharma Europe BV course participant 2006-2007

QUOTES

“The environment of the EMEA (European Medicines Evaluation Agency) in London is the ideal starting place for a course looking over the whole European Regulatory Affairs arena. By the experts of the EMEA themselves one will obtain insight in all European aspects of registration of medicines: scientific advise, registration procedures, pharmacovigilance, orphan drugs. However, national authorities are still the basis of the whole European system. That is why insight is given how a national authority acts, thinks and handles. Apart from the contents the context is important. That is why sufficient time is devoted to all aspects of European health and health policy and what will be the trends in the years to come. Apart from these trends, the major trends and developments in the pharmaceutical industry complement the whole picture.”

Dr Ir. P.J.M. Reijnders, Janssen-Cilag BV, faculty

“Following the ERA course 2005 has been a great pleasure to me. Discussing and sharing experience with experts from different fields enlarged my in-depth knowledge of drug development, ‘from birth to demise’. This enrichment is more than worth the effort to successfully complete the tough, but carefully organized course.”

Mrs. D.M.L. Nap, Dutch Medicines Evaluation Board, course participant 2005

“Both the content and the format of the ERA course have provided me with a profound insight in the regulatory processes that underpin the pharmaceutical marketplace. By helping me to better understand this critical determinant of drug use in clinical practice, this course has been a truly enriching experience.”

Mr. P. Stolk, Utrecht University, course participant 2005

“The complete route which a new investigational medicine has to go through is elucidated and discussed: from pre-clinical trials till reimbursement and post marketing surveillance and all relevant topics in between. A very useful course.”

Dr B. Kappelhoff, Boehringer Ingelheim, course participant 2006-2007

WELCOME

The well-known and high standard SIR European Regulatory Affairs (ERA) course has been designed to cover all aspects of regulatory affairs. The course is highly interactive with leading personalities from industry, academia and regulatory bodies (national bodies, EMEA), offering expert knowledge with practical exercises and case studies.

The course is designed for professionals who need to familiarise themselves with the full range of administrative, technical and scientific EU requirements. Opportunities will be provided for the information and insight to be applied directly to the participant's scientific, industrial or governmental organisation. Participants will preferably have previous university training in the biomedical or related disciplines, such as medicine, pharmacy, biochemistry, pharmacology and toxicology.

Considered a great success over the past years, the SIR ERA course is viewed by leading authorities as an established learning vehicle for professionals in regulatory affairs, both in industry and government.

Whether you need a good regulatory and scientific knowledge base on which to build, or you wish to update your European regulatory affairs experience this course will perfectly match your needs!

We look forward to welcome you as participant.

Dr H. Buurma
Course Director

Mrs. T.M. Bakker-Krol
Course Manager

INTRODUCTION

The course covers three major areas:

- * The scientific basis and rationale of the information on quality, safety and efficacy as required by the various registration systems available for pharmaceutical products in Europe, in the context of other systems (FDA, ICH).
- * The review of the common procedures within the European system including the Centralised and Mutual Recognition procedures, the Common Technical Document, and the like, in close interaction with regulatory bodies and key experts from the industry.
- * The strategic and tactical aspects of the drug approval process in positioning of new medicinal products in the market place (SmPC, labelling, 'fourth hurdle' issues, scenarios for market entry).

The programme is divided into five modules, each lasting three days.

- I Introduction to EU drug regulatory affairs (16 –18 September 2009)
- II Quality review (4-6 November 2009)
- III Non-clinical reports (3-5 February 2010)
- IV Clinical reports (7-9 April 2010)
- V On the edge of pre- and post-marketing (9-11 June 2010)

Confirmation

Upon receipt of your registration, each registrant will receive an invoice as confirmation.

Hotel Accommodation

Hotel expenses for each module, including two overnight stays, luncheons, dinners and accommodation, will approximately be Euro 500,--.

The course manager will arrange hotel accommodation upon request.

Course Organisers

For more information, please contact Mrs. T.M. Bakker-Krol or Dr H. Buurma

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GENERAL INFORMATION

Course data

Module I	16 - 18 September 2009
Module II	4 - 6 November 2009
Module III	3 - 5 February 2010
Module IV	7 - 9 April 2010
Module V	9 - 11 June 2010
Examination	10 September 2010

Location

Module I will take place in the vicinity of the EMEA in hotel Hilton Docklands London, United Kingdom.

The participation of EMEA staff will be a valuable addition, encouraging personal and functional contacts with the agency and creating a broad European perspective.

The venue for the remaining four modules (module II-V) will be Hotel Kasteel Oud Poelgeest in Oegstgeest, The Netherlands (www.oudpoelgeest.nl)

Official Language

The official language is English (no simultaneous translation)

Certificate

A Professional Certificate of Regulatory Affairs will be offered to participants who choose to write and pass the examination at the end of the course. The examination is a full academic assessment and needs a one day time commitment. Course participants are highly recommended to apply for this examination.

Registration

The course fee is Euro 7095,- that is exempt from VAT.

You are invited to register through our website www.stevenshof.nl. Early registration is recommended, as the number of participants will be limited.

BOARD

Course Programme Board

Dr. H. van Bronswijk, Chairman

Dr H. Buurma, SIR Institute for Pharmacy Practice and Policy

Prof. dr H.G.M. Leufkens, University of Utrecht

Prof. dr G.J. Mulder, Leiden University/Dutch Medicines Evaluation Board

Dr Ir. P.J.M. Reijnders, Janssen-Cilag BV

Dr A.P. Sam, Schering Plough

FACULTY

Dr A. Benbow	GlaxoSmithKline, United Kingdom
Dr E.H.E. Biesheuvel	Schering-Plough
Prof. dr H. Blume	SocraTec R&D, Germany
Dr H. van Bronswijk	Parexel Consulting
Dr C. Brouwer	Dutch National Institute for Public Health and Environment
Prof. dr A.F. Cohen	CHDR/Leiden University
Dr D.J. v.d. Dobbelsteen	Schering-Plough
Ir. J.G.A. Essers	Solvay Pharmaceuticals
Prof. dr P.A. de Graeff	Groningen University/Dutch Medicines Evaluation Board
Dr J. Hulshof	Lilly Nederland BV
Dr D.B. Jefferys	Eisai Europe Ltd.
Dr E. Krajnc	Schering-Plough
Mrs. S. Kruger	Dutch Medicines Evaluation Board
Dr R. Laing	WHO, Switzerland
Dr A. Lampo	Johnson & Johnson Pharmaceutical Research and Development Europe, Belgium
Dr J.F.F. Lekkerkerker	Former Chairman Dutch Medicines Evaluation Board
Prof. dr H.G.M. Leufkens	Utrecht University/Dutch Medicines Evaluation Board
Dr N. McAuslane	CMR International Institute for Regulatory Science
Dr A.A. Mende	Bundesinstitut für Arzneimittel und Medizinprodukte
Prof. dr G.J. Mulder	Leiden University/Dutch Medicines Evaluation Board
Prof. dr P.W.J. Peters	University Medical Centre Utrecht
Dr Ir. P.J.M. Reijnders	Janssen-Cilag BV
Dr A.P. Sam	Schering-Plough
Dr F. Sauer	Public Health, European Commission
Prof. dr H. Schellekens	Utrecht University
Dr H.F. Schuring	Genzyme Europe BV
Dr R.G.L. van Tol	Astellas Pharma BV
Prof. Dr J. Urquhart	AARDEX/Maastricht University
Dr L. Vromans	Schering-Plough
Dr P. Walstra	Astellas Pharma Europe BV
Dr M. Weda	Dutch National Institute for Public Health and Environment
Dr M. Zahn	3R Pharma Consulting

MODULE V On the edge of pre- and post-marketing

Wednesday 9 – Friday 11 June 2010

Moderator: Prof. dr H.G.M. Leufkens, Utrecht University/Dutch Medicines and Evaluation Board

Wednesday 9 June

09.30 – 12.30 Legislative Challenges in Drug Regulatory Affairs
To be decided

14.00 – 17.00 Priority Medicines for Europe and the World
Dr R. Laing, World Health Organization

Evening Case study
Dr R.G.L. van Tol, Astellas Pharma BV

Thursday 10 June

09.00 – 12.30 Compliance, persistence and dose changes after marketing
Prof. dr J. Urquhart, AARDEX/University of Maastricht

14.00 – 17.00 Keeping good drugs on the market:
pharmacovigilance in practice
Prof. dr H.G.M. Leufkens

Evening Final course diner

Friday 11 June

09.00 – 12.30 Access to new products, European systems for pricing and reimbursement
Dr J. Hulshof, Lilly Nederland BV

14.00 – 17.00 Global issues and challenges on the edge of pre- and postmarketing of drug products
To be decided

MODULE IV Clinical reports

Wednesday 7 – Friday 9 April 2010

Moderator: Dr H. van Bronswijk

Wednesday 7 April

09.30 – 12.30 Integrative clinical assessment: putting results of clinical studies in the context of patients' benefit
Prof. dr P.A. de Graeff, Groningen University/Dutch Medicines Evaluation Board

14.00 – 17.00 Clinical trials in drug development. Design, planning and execution
Dr H. van Bronswijk

Evening Case study
Dr L. Vromans, Organon, Schering Plough

Thursday 8 April

09.00 – 12.30 Data management and analysis in clinical development
Dr E.H.E. Biesheuvel, Schering Plough and
Ir. J.G.A. Essers, Solvay Pharmaceuticals.

14.00 – 17.00 Designing a clinical drug development programme
Dr A. Benbow, GlaxoSmithKline UK

Evening Case study

Friday 9 April

09.00 – 12.30 Challenges in clinical development of new drugs
Prof. dr A.F. Cohen, CHDR/Leiden University

14.00 – 17.00 Risk/benefit evaluation in medical technology (drugs, devices)
Dr D.B. Jefferys, Eisai Europe Ltd.

MODULE I Introduction to EU drug regulatory affairs

Wednesday 16 – Friday 18 September 2009

Moderator: Dr Ir. P.J.M. Reijnders, Janssen-Cilag BV

Wednesday 16 September

09.30 – 12.30 The scientific basis and rationale of the registration process
Dr J.J.F. Lekkerkerker, Former Chairman Dutch Medicines Evaluation Board

14.00 – 17.00 The role and function of the EMEA
EMEA faculty

Evening Welcome reception and course dinner with keynote lecture

Thursday 17 September

09.00 – 12.30 Major trends and developments in the pharmaceutical industry
Dr N. McAuslane,
CMR International Institute for Regulatory Science

14.00 – 17.00 Challenges and opportunities of the European registration procedures
Dr Ir. P.J.M. Reijnders

Evening Other European registration procedures, why do they exist and how to deal with them
Mrs. S. Kruger, Dutch Medicines Evaluation Board

Friday 18 September

09.00 – 12.30 The role of the EU in public health and health policy
Dr F. Sauer, Public Health, European Commission

14.00 – 17.00 Rationale for government control of medicines
Prof. dr H.G.M. Leufkens, University of Utrecht

MODULE II Quality Review

Wednesday 4 – Friday 6 November 2009

Moderator: Dr A.P. Sam, Schering-Plough

Wednesday 4 November

09.30 – 12.30 The Quality Module– a general introduction
Dr A.P. Sam

14.00 – 17.00 Regulatory aspects of pharmaceutical development
Dr M. Zahn, 3R Pharma Consulting

Evening Case study
Dr M. Weda, Dutch National Institute for Public Health and Environment

Thursday 5 November

09.00 – 12.30 From product Specification File to Investigational Medicinal Product dossier
Dr A. A. Mende, Bundesinstitut für Arzneimittel und Medizinprodukte

14.00 – 17.00 Key elements in the pharmaceutical dossier
Dr M. Weda

Evening Case study

Friday 6 November

09.00 – 12.30 Quality requirements for biotechnology products in Europe
Dr H.F. Schuring, Genzyme Europe BV

14.00 – 17.00 Biotechnology in a changing health care environment
Prof. dr H. Schellekens, Utrecht University/Dutch Medicines Evaluation Board

MODULE III Non-clinical reports

Wednesday 3 – Friday 5 February 2010

Moderator: Prof. dr G.J. Mulder, Leiden University

Wednesday 3 February

09.30 – 12.30 Essentials of pharmacology, pharmacokinetics and toxicology
Prof. dr G.J. Mulder

14.00 – 17.00 Timing of toxicology studies within the framework of the clinical investigation programme
Dr A. Lampo, Johnson & Johnson Pharmaceutical Research and Development Europe

Evening Case study
Dr P. Walstra, Astellas Pharma Europe BV

Thursday 4 February

09.00 – 12.30 Pre-clinical regulatory affairs
Dr C. Brouwer, Dutch National Institute for Public Health and Environment

14.00 – 17.00 Bio-availability and bio-equivalence as important links between pharmaceutical quality and drug efficacy and safety
Prof. dr H. Blume, SocraTec R&D

Evening Case study

Friday 5 February

09.00 – 12.30 Carcinogenicity and mutagenicity studies
Dr E. Krajnc and Dr D.J. van den Dobbelsteen, Schering-Plough

14.00 – 17.00 Reproduction and teratogenicity studies
Prof. dr P.W.J. Peters, University Medical Centre Utrecht