



# European Regulatory Affairs Course

March 2011 - November 2011





# 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 presentations from leading people from industry, academia and regulatory bodies (both national bodies and EMA). They will offer 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 wish to update your European regulatory affairs experience this course will perfectly match your needs!

We look forward to welcoming you as participant.

Dr. Hans van Bronswijk  
Chairman

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 (9 -11 March 2011)
- II Quality (20 - 22 April 2011)
- III Non-clinical reports (15 - 17 June 2011)
- IV Clinical reports (14 - 16 September 2011)
- V On the edge of pre- and post-marketing (9 - 11 November 2011)



# BOARD

## Course Programme Board

Dr. H. van Bronswijk, Parexel Consulting, Chairman

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

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

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

Dr Ir. P.J.M. Reijnders, Consultant Regulatory Affairs

Dr A.P. Sam, Merck Sharp & Dohme

# FACULTY

Dr A. Benbow	European Brain Council
Dr E.H.E. Biesheuvel	Merck Sharp & Dohme
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
Prof. dr. D.J.A. Crommelin	TI Pharma
Dr D.J. v.d. Dobbelsteen	Merck Sharp & Dohme
Ir. J.G.A. Essers	Solvay Pharmaceuticals
Prof. dr P.A. de Graeff	Groningen University/Dutch Medicines Evaluation Board
Dr J. Hulshof	Simon-Kucher & Partners
Dr D.B. Jefferys	Eisai Europe Ltd.
Prof. Dr V. Kiri	Parexel Consulting
Mrs. A.G. Kruger	Dutch Medicines Evaluation Board
Dr A. Lampo	Janssen Research and Development
Dr J.F.F. Lekkerkerker	NDA, Advisory Board Member
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
Em. Prof. dr G.J. Mulder	Leiden University/Dutch Medicines Evaluation Board
Em. Prof. dr P.W.J. Peters	Em. Professor of Teratology, Senator
Dr Ir. P.J.M. Reijnders	Consultant Regulatory Affairs
Dr A.P. Sam	Merck Sharp & Dohme
Dr F. Sauer	Honorary General Director European Commission
Prof. dr H. Schellekens	Utrecht University
Dr H.F. Schuring	Genzyme Europe BV
Dr. L. Tsang	Arnold & Porter LLP
Dr R.G.L. van Tol	Astellas Pharma BV
Prof. Dr J. Urquhart	AARDEX/Maastricht University
Dr L. Vromans	Merck Sharp & Dohme
Dr P. Walstra	Astellas Pharma Europe BV
Dr M. Weda	Dutch National Institute for Public Health and the Environment
Dr M. Zahn	3R Pharma Consulting

# MODULE I Introduction to EU drug regulatory affairs

## Wednesday 9 – Friday 11 March 2011

Moderator: Dr Ir. P.J.M. Reijnders, Consultant

### Wednesday 9 March

- 09.30 – 10.00 Welcome and introduction to the course  
**Dr Ir. P.J.M. Reijnders**
- 10.00 – 12.30 Rational for government control of medicines  
**Prof. dr H.G.M. Leufkens, Dutch Medicines and Evaluation Board**
- 14.00 – 17.00 The role and function of the EMA  
**EMA faculty**
- Evening Welcome reception and course dinner with keynote lecture

### Thursday 10 March

- 09.00 – 12.30 The evolution of the registration process over the years  
Dr J.J.F. Lekkerkerker, NDA Advisory Board Member
- 14.00 – 17.00 Other European registration procedures, why do they exist and how to deal with them  
**Mrs. A.G. Kruger, Dutch Medicines Evaluation Board**
- Evening Challenges and opportunities of the European registration procedures  
**Dr Ir. P.J.M. Reijnders**

### Friday 11 March

- 09.00 – 12.30 The role of the EU in public health and health policy  
**Dr F. Sauer, Honorary General Director E.C.**
- 14.00 – 17.00 Major trends and developments in the pharmaceutical industry  
**Dr N. McAuslane, CMR International Institute for Regulatory Science**

# MODULE II Quality

## Wednesday 20 – Friday 22 April 2011

Moderator: **Dr A.P. Sam, Merck Sharp & Dohme**

Wednesday 20 April

09.30 – 12.30 Pharmaceutical development – 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 the Environment**

Thursday 21 April

09.00 – 12.30 The Investigational Medicinal Product dossier  
**Dr A. A. Mende, Bundesinstitut für Arzneimittel und Medizinprodukte**

14.00 – 17.00 Key elements in the pharmaceutical dossier - interaction with the non-clinical and clinical dossier  
**To be announced**

Evening Case study

Friday 22 April

09.00 – 12.30 European quality requirements for biotechnology products  
**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 15 – Friday 17 June 2011

Moderator: **Prof. dr G.J. Mulder, em. Professor of Toxicology, Leiden University/Dutch Medicines Evaluation Board**

#### Wednesday 15 June

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

14.00 – 17.00 Pre-clinical regulatory affairs  
**To be decided**

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

#### Thursday 16 June

09.00 – 12.30 Timing of toxicology studies within the framework of the clinical investigation programme  
**Dr A. Lampo, Janssen Research and Development**

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 17 June

09.00 – 12.30 Carcinogenicity and mutagenicity studies  
**Dr D.J. van den Dobbelsteen, Merck Sharp & Dohme**

14.00 – 17.00 Reproduction and teratogenicity studies  
**Prof. dr P.W.J. Peters, Em. Professor of Teratology, Senator**

# MODULE IV Clinical reports

**Wednesday 14 – Friday 16 September 2011**

**Moderator: Dr H. van Bronswijk, Parexel Consulting**

Wednesday 14 September

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|---------------|---|
| 09.30 – 12.30 | Clinical trials in drug development. Design, planning and execution<br><b>Dr H. van Bronswijk</b>   |
| 14.00 – 17.00 | Integrative clinical assessment: putting results of clinical studies in the context of patients' benefit<br><b>Prof. dr P.A. de Graeff, Groningen University/Dutch Medicines Evaluation Board</b> |
| Evening       | Case study<br><b>Dr L. Vromans, Merck Sharp &amp; Dohme</b>   |

Thursday 15 September

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|---------------|--|
| 09.00 – 12.30 | Data management and analysis in clinical development<br><b>Dr E.H.E. Biesheuvel, Merck Sharp &amp; Dohme and Ir. J.G.A. Essers, Solvay Pharmaceuticals</b> |
| 14.00 – 17.00 | Designing a clinical drug development programme<br><b>Dr A. Benbow, EBC</b>  |
| Evening       | Case study   |

Friday 16 September

- |               |  |
|---------------|--|
| 09.00 – 12.30 | Challenges in clinical development of new drugs<br><b>Prof. dr A.F. Cohen, CHDR/Leiden University</b>        |
| 14.00 – 17.00 | Risk/benefit evaluation in medical technology (drugs, devices)<br><b>Dr D.B. Jefferys, Eisai Europe Ltd.</b> |

# MODULE V

On the edge of pre- and post marketing

**Wednesday 9 – Friday 11 November 2011**

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

Wednesday 9 November

09.30 – 12.30 Legislative Challenges in Drug Regulatory Affairs  
**Dr L. Tsang, Arnold & Porter LLP**

14.00 – 17.00 Challenges in pharmaceutical sciences in the future  
**To be decided**

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

Thursday 10 November

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 V. Kiri, Parexel Consulting**

Evening Final course diner

Friday 11 November

09.00 – 12.30 Access to new products, European systems for pricing and reimbursement  
**Dr J. Hulshof, Simon-Kucher & Partners**

14.00 – 17.00 The final say, synthesis of regulatory and innovation trajectories  
**Prof. dr H.G.M. Leufkens & Dr H. Van Bronswijk**

# GENERAL INFORMATION

## **Course data**

Module I	9 - 11 March 2011
Module II	20 - 22 April 2011
Module III	15 - 17 June 2011
Module IV	14 - 16 September 2011
Module V	9 - 11 November 2011
Examination	13 January 2012

## **Location**

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

The participation of EMA 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](http://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 7195,-- that is exempt from VAT or BTW.

You are invited to register through our website [www.stevenshof.nl](http://www.stevenshof.nl). Early registration is recommended, as the number of participants will be limited.



### **Confirmation**

Upon receipt of your registration, each registrant will receive a 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 Organiser**

For more information, please contact Mrs. T.M. Bakker-Krol

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# 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, faculty

“The ERA course is a must for people working in the regulatory environment who want to broaden the regulatory knowledge. Valuable information is acquired helping improve your daily work, giving background information on the route from drug discovery to reimbursement and as a bonus you meet many interesting colleagues”

Mr. L.A.E. van Kruijsdijk, Lundbeck BV, course participant 2009-2010

“Participating in the ERA course was a both professionally as personally enriching experience. This course ranges from the philosophy and history behind medical product regulatory affairs to actual practice and all between. The course was well organized, the contents were state of the art and the speakers were top in their fields. Next to that, the interaction, discussions and collaboration between industry and regulatory authorities was an experience which I think both parties enjoyed and enriched to a great extent. ”

Mr. J. van Wijngaarden, Medicines Evaluation Board, course participant 2009-2010

“The ERA course provides a great opportunity to interact with and learn from national and international experts in drug development and regulatory affairs, and to gain more in-depth knowledge and insight in the world of European Regulatory Affairs.”

Mr. R. Vermeulen, Centocor BV, course participant 2009-2010

## QUOTES

“As a result of the ERA course I learned to see both the views from the companies and the regulators. A great way to meet fellow regulators. A great way to get to realise how Difficult, but challenging it is to develop medicines.”

Mr. L. Bongers, Medicines Evaluation Board, course participant 2009-2010

“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

“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

“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

“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

Institute for Pharmacy Practice and Policy



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