

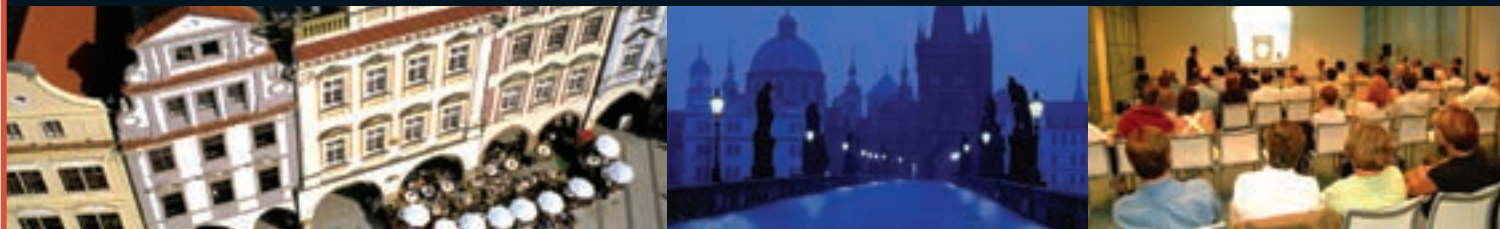
The **17th**

Autumn Introductory Course



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: IC2/11



TARGET THE HEART OF EUROPEAN REGULATORY AFFAIRS

Carefully researched and updated each year by practising Regulatory Affairs Professionals. Attend this course and return to your office a more confident Regulatory Affairs Professional.

Learning outcomes for TOPRA Introductory Courses

The Regulatory Function and the EU Environment

- The role and importance of the Regulatory Affairs Function and how it fits into the product development process
- The EU regulatory environment, the organisations involved and how legislation is developed.
- Future developments in the pharmaceutical industry
- The importance of regulatory strategy
- Successful interaction with authorities

The Marketing Authorisation Application, Science, Content and Structure

- The fundamentals of chemical and pharmaceutical development and the regulatory requirements
- The importance of Good Manufacturing Practice and Good Clinical Practice
- The need for pharmacology, pharmacokinetic and toxicology data
- Clinical development and the conduct of clinical trials

- The content and structure of Marketing Authorisation Applications in the Common Technical Document format
- How to be ready for electronic submissions and eCTD
- The importance of Product Information; SmPCs, labelling and leaflets

EU Regulatory Procedures

- The theory and practical reality of the Centralised Procedure
- The theory and practical reality of the decentralised and mutual recognition procedures
- How to choose and use the procedures
- The importance of scientific advice

Post Authorisation Activities

- Aspects of a successful life-cycle management
- The requirements and procedures for variations and renewals
- The importance of pharmacovigilance and risk management

Specialist Core Areas

- An understanding of medical device technology
- An understanding of biotechnology products
- An understanding of abridged applications, including generics
- Paediatric development

For updates on the programme and speakers as well as other important information please visit www.topra.org/autumnintrocourse

Five-Day Residential Course

Date:

Monday 31 October
to Friday 4 November
2011

Venue:

Andels Hotel, Prague,
Czech Republic

**EARLY BIRD
SAVINGS**

Register before
15th August to take
advantage of our
reduced fees



**Autumn Intro
30* hours**

Lifelong Learning (LLL)

*For more information
please visit [www.topra.org/
lifelonglearning](http://www.topra.org/lifelonglearning)

email: meetings@topra.org tel: +44 (0) 20 7510 2560 fax: +44 (0) 20 7537 2003 web: www.topra.org

The **17**th

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TOPRA – The Organisation for Professionals in Regulatory Affairs



The Regulatory Affairs function within the pharmaceutical industry is absolutely pivotal to the successful development and licensing of safe and effective medicines, to the benefit of patients' health worldwide.

- Chosen by Regulatory Affairs Managers who wish to get their people up-to-speed on current EU regulatory practices
- Looks at the bigger picture, focusing not only on EU legislation and regulatory procedures, but also on the central role that Regulatory Affairs plays in a modern pharmaceutical company and in the development of new drugs from early non-clinical investigations, through human clinical trials, via manufacturing, testing and supply, to post-approval maintenance.

Key features of the course

- A winning combination of lectures and interactive case studies that afford you the opportunity to put theory into practice
- An international speaker panel with representatives from industry, contract houses and regulatory agencies
- Residential course providing plenty of time for exchanging knowledge and sharing experiences with fellow students and speakers



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Overview

The Course is presented by over 30 speakers and facilitators, all respected authorities in their fields. No other course of its kind enables delegates to interact with so many leading regulatory professionals.

The Autumn Introductory Course has been running successfully for 17 years. This experience, combined with the feedback we receive from our presenters and delegates, ensures that the TOPRA Introductory Course is always up-to-date and in tune with the needs of the pharmaceutical industry.

- Most comprehensive course available of its kind
- 17 years of experience
- Over 30 speakers and facilitators
- Detailed course notes
- Industry and Regulatory Agency specialists
- European perspective

Why attend?

The Course is widely accepted by both Industry and Regulatory Agencies as the most comprehensive of its kind. The Course provides new Regulatory Affairs professionals with a good understanding of the different functions involved in the product development process and their inter-dependencies. In addition, a good legislative overview will be gained, with case studies providing delegates with practical experience of working in a project team on a variety of regulatory challenges.

Over the five days, delegates will have a unique opportunity to meet their peers, network with leading Industry and Regulatory Agency specialists from Europe and experience working in a team-based environment.

- Develop your understanding of drug development and the role of Regulatory Affairs
- Gain confidence as a Regulatory Affairs professional
- See the bigger picture
- Become more proactive
- Experience working in project teams
- Interact with Regulatory Agency and Industry leaders
- Network with colleagues

Who should attend?

Delegates should ideally have a minimum of six months' professional regulatory experience to gain maximum benefit from the Course. The Course is also suitable for those wishing to refresh their regulatory knowledge and for allied professionals who want to understand drug development and its interface with Regulatory Affairs.

- People new to Regulatory Affairs who want to acquire a comprehensive foundation
- Regulatory Professionals wishing to update their knowledge
- Allied Professionals wishing to understand the role of Regulatory Affairs

Course structure

The objectives of each part of the course are achieved by use of lectures, interaction with the lecturers and case studies.

Each programme day includes a case study. These accurately tailored case studies enable delegates to turn theory into practice. In small teams you will be able to focus on subjects such as chemical pharmaceutical development, clinical trial authorisations, choice of regulatory procedure and variations. In addition, facilitators are available to assist.

Each session is fully documented with copies of all slides so that delegates can focus on the presentations. The course notes provide an up-to-date overview of current trends in Regulatory Affairs as well as being useful reference material for future use.

In order to promote networking, the course includes a welcome cocktails reception on the Monday evening and other social opportunities will be made available during the week.



Please note that all programmes covered in this brochure could be subject to changes.

PROGRAMME

MONDAY 31 OCTOBER – FRIDAY 4 NOVEMBER

Venue: Andels Hotel, Prague, Czech Republic



Monday 31 October 2011

- **Welcome and Opening Address**
Ronald de Meijer, Astellas Pharma Europe BV
- **How does Regulatory Affairs fit into the picture?**
(Speaker TBC)
- **Development of Pharmaceutical Legislation**
Rui Dos Santos Ivo, Apifarma (TBC)
- **Common Technical Document Module 1: Administrative Information & Prescribing Information**
Alistair Stuart, Takeda Global R&D Centre (Europe) Ltd
- **Common Technical Document Module 2: Overviews and Overall Summaries**
Patrick Salmon, Irish Medicines Board, Alternate delegate CHMP (TBC)
- **Case Study 1 – Ice breaker**
Marion Kreitz, Bencard Allergie GmbH

Tuesday 1 November 2011

- **Chemical-Pharmaceutical data from a R&D perspective**
Stefan Hirsch, Novartis Pharma AG (TBC)
- **Common Technical Document Module 3: Quality Data from a dossier perspective**
Carole Murcott, Novartis Pharma AG
- **Non-Clinical (Safety) Data from a R&D perspective**
Jerry Browne, GlaxoSmithKline
- **Common Technical Document Module 4: Non-Clinical (Safety) Data**
Jerry Browne, GlaxoSmithKline
- **Biotech products**
(Speaker TBC)
- **Case Study 2 – Chemistry and Pharmacy**
Feddo Hillen, Remedium Reg Affairs
Jason Thwaites, Patheon UK Limited
Carole Murcott, Novartis Pharma AG

Wednesday 2 November 2011

- **Clinical (Efficacy) Data from a R&D perspective**
Carol Pitcher, AstraZeneca
- **Clinical Trial Authorisations**
Anne Lenihan, Pfizer Ltd
Jason Thwaites, Patheon UK Limited
- **Paediatrics**
Azzura Ravizza, Pfizer Ltd
- **Common Technical Document Module 5: Clinical (Efficacy) Data**
Linda Troy, AstraZeneca
- **Pharmacovigilance and Risk Management**
Susanne Becker, spm² - safety projects & more GmbH
- **e-Submissions**
Hans van Bruggen, eCTDconsultancy
- **Case Study 3 – Clinical Trial Case Study**
Anne Lenihan, Pfizer Ltd
Jason Thwaites, Patheon UK Limited

Thursday 3 November 2011

- **The Role and Structure of EMA. An introduction to the Centralised Procedure: the Theory**
EMA (Speaker TBC)
- **An Introduction to the Centralised Procedure: the Practice**
Belinda Cole, GlaxoSmithKline
- **The Mutual Recognition Procedure & the Decentralised Procedure: the Theory**
Kora Doorduyn-van der Stoep, Medicines Evaluation Board in The Netherlands, Dutch member of CMDh
- **The Mutual Recognition Procedure & the Decentralised Procedure: the Practice**
Dan Sullivan, Generics UK Ltd (A Mylan Company)
- **Scientific advice and interaction with authorities**
Kevin Hartley, Assensus Consulting Ltd
- **Choice of Procedure**
Vicky Jones, Takeda Global R&D Centre (Europe) Ltd
- **Case Study 4 – Choice of Procedure**
Vicky Jones, Takeda Global R&D Centre (Europe) Ltd

Friday 4 November 2011

- **Variations and renewals**
Ronald de Meijer, Astellas Pharma Europe B.V.
- **Abridged applications and generics,**
Matthias Finkler, Finkler GmbH
- **Life Cycle Management**
Andrew Willis, Catalent Pharma Solutions
- **An Introduction to TOPRA**
Lynda Wight, TOPRA
- **The Registration of Medical Devices**
Jonathan Hughes, ConvaTec (TBC)
- **Case Study 5 – Variations**
Ronald de Meijer, Astellas Pharma Europe B.V.
- **Closing remarks**
Lynda Wight, TOPRA

**FULLY
BOOKED
EVERY YEAR!**

Register early to avoid
disappointment

The **17th**

Autumn Introductory Course



Date: 31 October – 4 November 2011 Venue: Andels Hotel, Prague, Czech Republic

Reference: IC2/11



“Speakers were excellent – content was excellent, an all round grounding in Regulatory Affairs...”

What is TOPRA?

The organisation for professionals involved in all aspects of international healthcare Regulatory Affairs. A leading provider of high-quality education, training, information and support services, and networking opportunities.

Our objectives

- To educate regulatory professionals to the highest standards of professional competence
- To inform all members in a rapid, accurate and accessible manner, of the latest developments in global regulatory affairs
- To provide a forum for networking at local, regional and international levels for all professionals, whether they be in companies, agencies, or working independently, so that they may share experiences and knowledge to the benefit of the whole profession
- To support members in their professional careers
- To raise the status of healthcare Regulatory Affairs and its contribution to public health throughout industry and the wider community including universities and government

Important course information

Course timings

The Introductory Course begins with registration on Monday 31 October from 14.00. The first lecture starts at 14.30 on Monday and the Course ends on Friday 4 November at 15.30

Contact TOPRA

If you have any enquiries, or require more information, please contact the Meetings Coordinator at the TOPRA office. See details below.

TOPRA, Bellerive House, 3 Muirfield Crescent, London E14 9SZ

Tel: +44 (0) 20 7510 2560 Fax: +44 (0)20 7537 2003

E-mail: meetings@topra.org

Venue

Andels Hotel, Prague, Czech Republic

Tel: + 420 296 889 688

Fax: + 420 296 889 999

Email: info@andelshotel.com

Web: www.andelshotel.com



TOPRA, Bellerive House, 3 Muirfield Crescent, London E14 9SZ

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