

34th Introductory Course Spring



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

What is TOPRA?

Our vision...

To be the organisation for professionals involved in all aspects of international healthcare Regulatory Affairs, which is 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 30 April from 08.30. The first lecture starts at 10.00 on Monday and the Course ends with lunch on Friday 04 May at 13.00.

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

Wotton House, Guildford Road, Dorking, Surrey, RH5 6QQ

Tel: +44 (0) 1306 730 000

Fax: +44 (0) 1306 737 200

Email: wotton@principal-hayley.com

Website: www.principal-hayley.com/venues-and-hotels/wotton-house

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

IT'S A MARATHON NOT A SPRINT

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

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34th Introductory Course Spring

Beginning a career in Regulatory Affairs

5 day residential course

Date 30 April – 04 May 2012

Venue Wotton House, Guildford Road,
Dorking, Surrey, RH5 6QQ

Reference: IC1/12

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

**IT'S A MARATHON
NOT A SPRINT**



Spring Introductory

30* hours Lifelong learning (LLL)

*For more information please visit www.topra.org/lifelonglearning

34th Spring Introductory Course



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 and promotional activities

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

'It has definitely widened my knowledge of the regulatory environment and allowed me to meet fellow regulatory professionals.'

'Highly recommended! I feel I now have an excellent overview of ALL aspects of Regulatory Affairs. It was a great opportunity to hear lectures/talks on topics presented by highly respected key leaders in the area and to interact with all levels of Regulatory Affairs Professionals.'

Date: Mon 30 April to Fri 04 May 2012 **Venue:** Wotton House, Guildford Road, Dorking, Surrey, RH5 6QQ

Overview

The Course is presented by over 50 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 Spring Introductory Course has been running successfully for over 30 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**
- **Over 30 years of experience**
- **Over 50 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 their 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.

The TOPRA Introductory Course combines formal presentations with highly interactive workshops and breakout sessions. At the end of each day (Monday to Thursday) a tailored case study enables delegates to turn the theory into practice. Delegates are encouraged to work within a project team environment and to develop their communication skills. With a high facilitator to delegate ratio, there is always someone available to provide assistance.

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 the evenings there are further opportunities to network, have some fun, or simply relax.

Key Speakers

Course content is delivered by speakers with experience from key EU Regulatory Authorities, Companies and Industry Associations and may include:

- Amgen
- BfArM
- Biogen Idec
- GlaxoSmithKline
- IMB
- MHRA
- Pfizer
- PMCPA

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*'Offers the most comprehensive
grounding in Regulatory
Affairs reflecting the latest
developments in European
legislation and best practices.'*



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
- The importance of Good Manufacturing and Clinical Practice
- The need for pharmacology, pharmacokinetic and toxicology data
- Clinical development including paediatrics 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; SmPC's, 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 successful life-cycle management
- The requirements and procedures for variations and renewals
- The importance of pharmacovigilance and risk management

Specialist areas

- An understanding of Medical Device Technology
- An understanding of Biotechnology products
- An understanding of Abridged applications including Generics
- Advertising

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Ways to book

Please complete in block capital letters and return this form with payment to TOPRA using one of the following methods:

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

Fax: +44 (0) 20 7537 2003

On receipt of your booking form we will confirm your provisional place in writing and provide directions to the venue. An invoice will be sent separately. To ensure admission, payment must be received prior to the meeting.

If you have any queries, contact us on: +44 (0) 20 7510 2560 or meetings@topra.org

Dr Mr Mrs Ms Other

Family name

First name Male Female

Company name

VAT reg. no.

Job title

Telephone

Fax

E-mail

Work Address

City Postcode

Country

Invoice Address
(If different from above address)

City Postcode

Country

Special dietary requirements

Experience in the Subject Area

Negligible Average Considerable

Your current role

Generics CRO European role Global role Local affiliate

Other

Experience in Regulatory Affairs Years Months

Fees and Payment method

Members **£3,720.00** = £3,100.00 + £620.00 (GB VAT 20%)

Non-Members **£4,200.00** = £3,500.00 + £700.00 (GB VAT 20%)

Including 4 night's accommodation & all meals

The VAT rate charged will be the prevailing rate at the time of invoicing.

Cheque enclosed Cheque No

Bank transfer Date of transfer / /

Please charge my debit/credit card Purchase Order No.

Debit/Credit card details

(For cards accepted, see payment section below)

Debit Card Visa MasterCard American Express

Card No

Expiry date /

Security code *Visa, MasterCard, Debit cards: the last 3 digits AFTER the card number in the signature area of the card.*

Card holder name (as given on card)

Billing address for card (must be provided if different from the Work Address)

City Postcode

Country

TOPRA will seek authorisation from the card-issuing company before confirming any reservation (VAT Registration No.: GB 342 7398 40).

I confirm I have read and accept TOPRA's standard Terms & Conditions of Booking. These are available from the office or on the TOPRA website at www.topra.org/bookingTandC

SIGNATURE	DATE
<input type="text"/>	<input type="text"/>

Terms and conditions (Please note: TOPRA's standard Terms & Conditions are available on the website at www.topra.org/bookingTandC).

Payment:

- Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Sterling or Euro.
- Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Visa Electron, Maestro, MasterCard, Visa, Visa Debit. All cards will be charged in Sterling.
- Bank Transfers:** may be made to Lloyds TSB Bank PLC. Please quote the delegate's name and the course reference in the transmission details. The delegate must pay all bank charges.
- Sterling Transfers:** Account No: 00340310, Sort Code: 30-00-09, IBAN: GB45 LOYD 3000 0900 3403 10, BIC LOYDGB21013
- Euro Transfers:** Account No: 86330987, Sort Code: 30-00-09, IBAN: GB19 LOYD 3000 0986 3309 87, BIC LOYDGB21013
- Your place is secured only upon receipt of full payment.

Please note:

The registration fee includes four nights accommodation from Monday 30th April and all meals from Monday until the close of the course on Friday. Travel is not included. If you do not wish to be photographed, please make this known at registration.

Discounted fees:

Personnel in full-time education, working in academia (full-time) or working for a statutory regulatory body may be entitled to a discount on the above fees. Please contact the TOPRA office for details.

Cancellations:

All cancellations must be received in writing 28 calendar days before the start of the course and will be subject to an administration fee of £150 + GB VAT. Payment can be in Euro or Sterling.

Data Protection:

- We may occasionally send you promotional or other information about TOPRA's products and services. If you do not wish to receive this information, you can opt out of future communications by ticking this box
- We may occasionally send you promotional or product information from organisations and companies other than TOPRA. If you do not wish to receive this information, you can opt out of future communications by ticking this box