

# basics of Regulatory Affairs



TOPRA – The Organisation for Professionals in Regulatory Affairs



**A one-day foundation course for very new recruits, PAs, administrators and support staff in Regulatory Affairs and other related areas such as Medical, Manufacturing, Marketing etc. Suitable for staff in agencies and companies.**

## The purpose of the day

The world of Regulatory Affairs can be a confusing and complex place, particularly if you have no formal industry background.

The purpose of this Basics course is to provide you with a clear and concise understanding of the role played by Regulatory Affairs in obtaining and maintaining Marketing Authorisations for pharmaceutical products.

## The course tutors

All of the tutors on this course have many years of Regulatory Affairs experience and are currently working in the industry.

## What previous delegates have had to say about this course...

*"Speakers very clear, concise and informative"*

*"Excellent overview in such a short time!"*

*"Made things a lot clearer and gave me an understanding of how things link together."*

*"Well structured set of presentations and very informative."*

## What you will learn

- Regulatory Affairs: what is it and why is it needed?
- The role of the Regulatory Affairs professional within the company
- The role of the Regulatory Affairs professional – working with external Regulatory agencies and other bodies
- The European legislative framework
- How pharmaceuticals are controlled
- The contents of a basic application dossier
- Basic data requirements
- Overview of drug development
- Overview of clinical trials
- Marketing Authorisation Applications
- European procedures
- Post licensing
- Labels and leaflets
- Variations



And there will be quizzes and prizes too!

*This course will give a basic grounding in a relaxed, enjoyable environment.*

## Our promise

*We guarantee you will leave the course with a better understanding of the regulatory process and your role within it.*

For more information or to obtain a booking form, please contact TOPRA via email: [meetings@topra.org](mailto:meetings@topra.org) or tel: **+44 (0) 20 7510 2560** or go to the website: [www.topra.org/basicscourse](http://www.topra.org/basicscourse)

## One-day Foundation Course

### 2010 Dates:

Wednesday  
**10th February 2010**  
Wednesday  
**24th March 2010\***  
Wednesday  
**19th May 2010**  
Wednesday  
**4th August 2010**  
Wednesday  
**20th October 2010**

### Venue:

Danubius Hotel  
Regents Park,  
London, UK

\*will be held at the  
TOPRA Office,  
London, UK



### Lifelong Learning (LLL):

This conference contributes 5 hours of training to your LLL (sometimes known as Continuing Professional Development) and will enhance your Regulatory Skills relevant in the areas of human and veterinary medicines



Venue: Danubius Hotel Regents Park, London, UK

## ONE DAY Foundation Courses

### 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 **Email:** meetings@topra.org

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

Please indicate if in your regulatory experience you have worked in one or more of the following areas:

1) CMC  2) EU clinical trials  3) Variations  4) Medical Technologies

### Fees and Payment method

I would like a place on the following course

- Wednesday 10th February 2010 – Reference code BAS1110
- Wednesday 24th March 2010\* – Reference code BAS5110
- Wednesday 19th May 2010 – Reference code BAS2110
- Wednesday 4th August 2010 – Reference code BAS3110
- Wednesday 20th October 2010 – Reference code BAS4110

**Fee (Per course) £586.33 = £499.00 + £87.33 (17.5% GB VAT)**

Total

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  (preferred)

**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 342 739 840).

By signing below, I confirm that I agree with TOPRA's Terms & Conditions of Booking. These are available from the office or on the TOPRA website at: [www.topra.org/bookingTandC](http://www.topra.org/bookingTandC)

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

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

#### Payment:

- **Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Euro or Sterling.
- **Debit/Credit card:** for payment by card please complete the relevant details above. Cards accepted: AMEX, Debit MasterCard, Delta, Electron, Maestro, MasterCard, Solo, Visa. 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:

Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks & buffet lunch.

#### 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 £100 + GB VAT. Payment can be in Euro or Sterling. Substitutions may be made at any time.

#### 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