

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

Tried & tested
Now in its 13th
Successful year
2009

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

One-day Foundation Course

2009 Dates:

Thursday
12th February 2009

Thursday
14th May 2009

Thursday
13th August 2009

Thursday
15th October 2009

Venue:

Radisson SAS Portman Hotel, 22 Portman Square, London, W1H 7BG.



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: Radisson SAS Portman Hotel, 22 Portman Square, London, W1H 7BG.

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, 7 Heron Quays, Marsh Wall, London E14 4JB, UK

Fax: +44 (0) 20 7515 7836 **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 7538 9502 or meetings@topra.org

Dr Mr Mrs Ms Other

Family name

First name Male Female

Company name

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

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 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.

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 below fees. Please contact the TOPRA office for details.

Fees and Payment method

I would like a place on the following course

- Thursday 12th February 2009 – Reference code BAS1/09
- Thursday 14th May 2009 – Reference code BAS2/09
- Thursday 13th August 2009 – Reference code BAS3/09
- Thursday 15th October 2009 – Reference code BAS4/09

Fee (Per course) £573.85 = £499.00 + £74.85 (15% 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

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).

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
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Please note:

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

Discounted fees:

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Cancellations:

All cancellations must be received in writing 21 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.

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