

CRED WORKSHOPS

Training designed with you in mind



TOPRA – The Organisation for Professionals in Regulatory Affairs

Ref: CRED-CDI



CRED: Clinical Development

Early to Late Stage Clinical Development

Aims of the course

This 2 day workshop will provide an overview with practical advice from regulators and industry on the process of designing and conducting clinical trials from phase I (volunteers) through phases II, III and even clinical trials considerations beyond drug marketing approval. Case studies are used to support learnings from the formal presentations and to draw upon experiences of those attending. The aim of this practical workshop is to enable all those involved in medicines development to gain an appreciation of the points to consider when designing a clinical development programme to support a marketing application and also that clinical development extends beyond the marketing application.

Course content:

- An overview of pharmacokinetic and healthy volunteer studies including use of volunteers or patients, definition of the pharmacokinetic profile, the need for bioequivalence data and studies in sub-groups
- An overview of clinical pharmacodynamics including mechanism of action, onset of action and duration of effect, design considerations to maximise information obtained and determination of tolerability
- An insight into the specifics of clinical trial design at the different phases, including objectives of study, inclusion/exclusion criteria, choice of endpoints and comparators, and duration of trials. The impact of paediatric legislation.
- Statistical issues including the importance of good statistical planning and sample size, basic statistical techniques and choices
- Drug safety issues including the overall size of the safety database, pharmacological class effects, relevance of findings in animals, and analysis of clinical chemistry data and adverse events.
- Studies beyond marketing filing.

Who should attend

- The less experienced regulatory professional who requires comprehensive information on this subject
- The experienced professional who is a newcomer to this subject
- Anyone who wishes to update their knowledge on this subject.
- Persons from regulatory, medical, clinical and safety involved in phase I, II, III and IV trials

Speakers:

John Warren, Medicines and Health Care products Regulatory Agency (MHRA), UK

Basil Houdali, Lilly

Steve Pinder, Envestia Limited

Plus other invited speakers

Two-day
Course

Date:

Thursday – Friday
3-4 September 2009

Venue:

Radisson Portman
Hotel, London

All data correct at time of print.

For more information or to obtain a booking form, please contact TOPRA via email: meetings@topra.org or tel: **+44 (0) 207 538 9502** or go to the website: www.topra.org/credclinicaldev



Lifelong learning

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

email: meetings@topra.org tel: +44 (0) 20 7538 9502 fax: +44 (0) 20 7515 7836 web: www.topra.org/credclinicaldev

Two-day Course Date: **Thurs – Fri 3-4 September 2009** Venue: **Radisson Portman Hotel, London** Ref: **CRED-CDI**

Early to Late Stage Clinical Development

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

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 **£920.00** = £800.00 + £120.00 (15% GB VAT)

Non-Members **£1092.50** = £950.00 + £142.50 (15% GB VAT)

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).

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

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).

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 lunches & drinks reception on 3rd September 2009.

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 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. 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