

Biotechnology



TOPRA – The Organisation for Professionals in Regulatory Affairs

Reference: Bio 3/09



Understanding Your Biotech Product – Analytical and Bio-analytical Characterisation

Aims of the course

- To ensure that delegates have the appropriate knowledge in the field of analytical and bio-analytical characterisation to allow them to undertake their professional roles and specifically as follows:
- The techniques used to characterise biopharmaceutical medicinal products
- Regulatory requirements and expectations for characterisation data at different stages of the product development cycle
- Impact of process variables on product quality
- Requirements for comparability assessment following process changes
- Importance of characterisation techniques in a biosimilar product MAA.

Who should attend

The conference is designed for regulatory staff who are working with biotechnology-derived products, particularly those who may not have first hand manufacturing or process development experience, and those who are new to regulatory affairs. This conference would also be useful for anyone wishing to refresh his or her knowledge in the area.

Programme includes

- Analytical characterisation concentrating on *in vitro* and biophysical techniques
- Bio-analytical techniques concentrating on bioassays and agency expectations for bioassays
- Impact of process variables on product quality
- Comparability assessment example following a major process change (a case study from Wyeth)
- Regulatory Agency perspective on comparability
- Biosimilars

Speakers include

- **Paul Chamberlain**, Director, NDA Advisory Board, UK
- **Brendan Fish**, Director Bio-analytical Group, MedImmune, UK
- **Brian Fitzpatrick**, Associate Director of Analytical Development, Wyeth, Eire
- **Stephen Fitzpatrick**, Head of CMC RA, UCB Pharma Ltd, UK
- **Kowid Ho**, Biologicals/Biotechnology Unit, AFSSaPS, France
- **Paul Jeffreys**, Senior Manager RA, Eisai, UK
- **Meg Leahey**, Associate director, Wyeth Biotech, Eire
- **Cecil Nick**, Vice President, Parexel Consulting, UK
- **Jane Robinson**, NIBSC, UK

One-day
Biotech Meeting

Dates:

Wednesday
28th January 2009

Venue:

Radisson SAS
Portman Hotel,
London, UK



Lifelong Learning (LLL):

The Meeting contributes 6 hours per day 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

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

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

Understanding Your Biotech Product – Analytical and Bio-analytical Characterisation

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

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 5) Biotech

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

Members **£581.63** = £495.00 + £86.63 (17.5% GB VAT)

Non-Members **£699.13** = £595.00 + £104.13 (17.5% GB VAT)

CREDit voucher Tick here if you have a CREDit voucher to claim your discount. Please attach your voucher.

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).

SIGNATURE	DATE
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Terms and conditions *(Please note: new TOPRA bank details)*

Payment:

- Cheques:** must be made payable to TOPRA and drawn on a UK bank in either Sterling or Euro.
- Debit/Credit cards:** 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 on receipt of full payment.

Please note: Fee excludes accommodation and travel. The delegate ticket includes refreshments at coffee breaks and buffet lunches. Unless stated otherwise the official language of all our meetings is English. It may be necessary for reasons beyond the control of the organisers to alter the dates, venue, timing and content of the programme *(including speakers)* without prior notice; TOPRA regrets that it cannot accept liability for losses incurred by delegates in these circumstances. Meals requiring special preparation *(such as Kosher)* may incur additional costs.

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. For cancellations after this time, or if the delegate fails to attend the course, no refund of fees will be given. Substitutions may be made at any time. TOPRA reserves the right to cancel the course at any time without liability. In these circumstances, delegates will be offered an alternative date, a credit note or a full refund.

Additional support: Please advise TOPRA, at least one month before the meeting, if you have any disability that may require additional support. TOPRA makes no distinction in its admission policy with regards to disability. TOPRA will make every reasonable effort to supply delegates with services that meet their needs.

Liability: TOPRA regrets that it cannot accept liability for losses incurred by delegates in the event of postponement or other alterations to the meeting, i.e. timing, venue, etc. Normal TOPRA terms and conditions apply; please contact the TOPRA office for further details.

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