



THE JOINT PHARMACEUTICAL ANALYSIS GROUP

<www.jpag.org>

Biosimilars and analytical challenges

**A one-day symposium held
at the Royal Pharmaceutical Society of Great Britain**

*In association with the Academy of Pharmaceutical Sciences
Therapeutic Biomolecules and Vaccines Focus Group*

Thursday 11 June 2009

Scope

New versions of innovator biopharmaceutical products present multiple challenges for manufacturers and regulatory agencies alike. Small differences in manufacturing processes or formulations can have significant effects on product safety and efficacy. Consequently, biosimilar products are not authorised in the European Union or the USA through the simplified procedures that are allowed for small molecule generics.

This symposium will provide an overview of the regulatory and intellectual property landscape for biosimilars, before examining advances in techniques to compare chemical and functional properties and then presenting case studies in this field.

Who should attend

This symposium will be of interest to pharmaceutical scientists and managers, as well as regulatory professionals, responsible for introducing innovator or biosimilar products, who wish to establish or extend their knowledge in this rapidly evolving area.

There will be an opportunity to present **Posters** on the broad subject area of the symposium, subject to acceptance of a submitted abstract; details are on page 2

A customised certificate attesting four hours credit for Continuing Professional Development will be included in the delegate pack for all registrants.

Programme

- 09.30** **Registration and coffee**
- 10.00** **Introduction**
Dr Ray Munden, Chairman, *Joint Pharmaceutical Analysis Group*
- 10.10** **Regulatory overview for biosimilars: European Union**
Dr Christian K Schneider, *Paul-Ehrlich-Institut, Germany, and member of the EU Biosimilars Working Party*
- 10.45** **Regulatory overview for biosimilars: USA**
Dr Lincoln Tsang, *Arnold and Porter LLP*
- 11.20** **Intellectual property overview for biosimilars**
Nick Sutcliffe, *Mewburn Ellis LLP*
- 11.55** **Techniques for comparing post-translational modifications**
Dr Daryl Fernandes, *Ludger*
- 12.30** **Lunch, Exhibition and Poster viewing**
- 13.45** **Techniques for comparing biological potency**
Dr Lee Coney, *NDA Analytics*
- 14.20** **Techniques for comparing immunogenicity**
Dr Robin Thorpe, *NIBSC*
- 14.55** **Industry case study**
Speaker to be confirmed
- 15.30** **Manufacturing process: what makes biotechnology medicinal products different?**
Dr Fotis Fotiou, *Johnson & Johnson*
- 16.05** **Closing remarks**
Dr Ray Munden, Chairman, *Joint Pharmaceutical Analysis Group*
- 16.15** **Close**

**** Abstracts** for presentation as **Posters** should be submitted to the Programme Co-ordinator, Dr Geoff Sharpe [GeoffsGSQ@aol.com] **by Friday 22 May**, following the instructions on the JPAG website.

Joint Pharmaceutical Analysis Group
Biosimilars and analytical challenges, Thursday 11 June 2009

Registration form

Please send completed registration forms (one per person; fax or photocopies are accepted) to the Secretariat: Science Programme Admin Assistant, 3rd floor, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN

Delegate fees (*include registration, documentation, lunch and refreshments*). Please tick the appropriate box:

JPAG members	£145	<input type="checkbox"/>
Other members of RSC or RPSGB **	£195	<input type="checkbox"/>
<i>Bona fide</i> students, retired or unemployed members of RSC or RPSGB	£30	<input type="checkbox"/>
Not members of JPAG, or RSC or RPSGB	£245	<input type="checkbox"/>

[****Details** on how members of RPSGB and RSC can join JPAG are on the JPAG website.]

I enclose payment of £..... [Please note that there is no charge for VAT]

I wish to submit an abstract for Poster display ☐

Details of delegate:

SURNAME: _____ (BLOCK CAPITALS PLEASE)

TITLE (Miss/Mrs/Mr/Dr/Professor) _____ FORENAME _____

ORGANISATION _____

ADDRESS _____

POSTCODE _____

TEL: _____ FAX _____ e-mail _____

Payment of delegate fee: Fees are payable to “The Joint Pharmaceutical Analysis Group” [NOT the Royal Pharmaceutical Society]. Please indicate method of payment:

☐ Cheque in GB pounds sterling payable to “**The Joint Pharmaceutical Analysis Group**”

☐ Bank Transfer: use Sort Code: 30-99-93. Account Number: 00779842 at Lloyds TSB Bank, 41-43 South Street, Worthing, West Sussex, BN11 3AU. **Quote reference: 0609**

Delegate fees are payable upon registration and are not refundable. Notified substitution is allowed at any time.

Enquiries should be addressed to the Secretariat: Science Programme Admin Assistant. Tel 020 7572 2640; Fax: 020 7572 2506; E-mail: <events@rpsgb.org>

Block bookings for students (to include documentation but not lunch) can be made by Academic supervisors who should ask for details from the Secretariat.

Further information on the programme, submission of abstracts for Poster presentation, location of the venue and local hotels is available on the JPAG website at:
<www.jpag.org>

JPAG symposium and conference programmes in 2009

Thursday 5 March 2009

Royal Pharmaceutical Society, London

Clinical trials directive: five years on

Wednesday 11 March, 2009

Royal Pharmaceutical Society

Organised by the Particle Characterisation Interest Group and the Analytical Division of the Royal Society of Chemistry

Training meeting on particle size analysis

Thursday 23 April 2009

Royal Pharmaceutical Society, London

Impact of ICH Q8, Q9 and Q10: fact or fiction?

Thursday 11 June 2009

Royal Pharmaceutical Society, London

Biosimilars and analytical challenges

Monday 3 August 2009

Glasgow.

IUPAC General Assembly

JPAG symposium:

Quality assurance of medicines and detection of counterfeits

Submission deadline for podium presentation is 15 January and for poster presentation is 5 June.

For details see: www.iupac2009.org

Monday 7- Wednesday 9 September 2009

Manchester International Conference Centre

British Pharmaceutical Conference

JPAG symposium: **Combating counterfeit medicines**

JPAG symposium: **Emerging technologies in point-of-care testing**

Presentation of short papers in pharmaceutical analysis. Eligible presentations to be considered for award of the Conference Analytical Science Award (bursary to attend a future conference)

Thursday 15 October 2009

Joint symposium with the Inhalation Focus Group of the Academy of Pharmaceutical Sciences
Royal Pharmaceutical Society, London

Analysis of inhaled products

For current information see the JPAG website: <www.jpag.org>