



*Making Medicines Affordable*

## *First EGA Symposium on “Biotech Generics”*

**Book Now Only 40 Places Available!**

**Friday 23 May 2003**

**The Rembrandt Hotel**

**11 Thurloe Place - London SW7 2RS UK**

*Chaired by*

*John Greenwood, Director of Regulatory Affairs GeneMedix & Chair EGA Biotech WG*

**10.30 Welcome Note and Overview of the Political/Legal Environment for Comparable/Similar Off-Patent Biotechnology-derived Medicinal Products**

- EGA and EU developments at the level of the European Commission, European Parliament and Council Working Group
- IGPA and ICH developments

Suzette Kox, EGA Senior Scientific & Regulatory Affairs Advisor

**11.00 Strategies to Market: Understanding the headway being made in developing and licensing Generic Biologics**

- Identifying the market and understanding the potential hurdles
- Access to cell lines that are high yielding and produce ‘comparable’ products
- Ability to manufacture at low cost without compromising quality
- Managing the regulatory hurdles
- Remaining competitive in a dynamic market

Paul Edwards, CEO GeneMedix - UK

**Consultant’s Point of View: The route to comparable biological medicines**

- Is the current regulatory view based on sound Quality, Safety & Efficacy concerns?
- Are the perceived risks from multi-source biotech products real?
- How much supporting data are required to adequately characterise against the comparator?
- What is the legal basis for bio-comparable medicines?
- What routes are open to filing with limited data?
- Where do we go from here?

Cecil Nick, Senior Regulatory Consultant, Worldwide Regulatory Affairs PAREXEL International - UK

12.15 Coffee Break

**12.30 Comparability of Medicinal Products Containing Biotechnology-derived Proteins as Drug Substance**

- Essential vs. biological similarity
- Legal vs. scientific aspects
- Comparability programmes
- Emerging EU guidance
- International harmonisation

Pekka Kurki, CPMP Member and Chairperson of the Ad-Hoc Working Group on (Pre)-clinical comparability of Biotechnology Products, EMEA

13.15 Lunch

**Organized by**



**Friday 23 May 2003**  
**The Rembrandt Hotel**  
**11 Thurloe Place - London SW7 2RS UK**

**14.15 Unwanted Immunogenicity of Biological Products**

- Immunogenicity evaluation in comparability studies
- Types of essays used & their characteristics
- Examples of findings with cytokines
- Importance of unwanted immunogenicity for biological products

Robin Thorpe, Head of Immunobiology, NIBSC National Institute for Biological Standards and Control UK

**Audience Interactive Panel Discussion on the Challenges and Prospects for Comparable/Similar Biotechnology-derived Medicinal Products**

Panellists: Paul Edwards, Cecil Nick, Pekka Kurki, John Purves, Robin Thorpe, Robert Zeid

15.15 Coffee Break

**15.30 Structure Activity Relationship: Concepts and Applications**

- Assessing comparability on the basis of product characteristics to safety & efficacy
- Overview of analytical, bioequivalence, and clinical requirements
- Overview of SAR for varying biotech product classes
- Overview of surrogate endpoints and utility of clinical bridging studies vs. post-market surveillance

Robert Zeid, Principal Consultant, TLI Development - NC/USA

**Third Part Patents - a block or just a hurdle?**

- Infringement exemptions in EP - research exemption and "Bolar"
- Process patents - infringement and validity issues

Nicola Baker-Munton, Managing Director, Stratagem IPM Ltd - UK

16.45 Closing notes from the Chair of the day

Conference ends at 17.00



**APPLICATION TO REGISTER**  
**To be sent back by fax at +32-2 5339819**

Title (Mr./Ms.): ..... First Name: ..... Family Name: .....

Company: ..... Job title: .....

Company VAT No. & Country: .....

Company Address: .....

Postal Code: ..... City: ..... Country: .....

Tel No: ..... Fax No: .....

E-mail: ..... Website: .....

*Please note all prices are inclusive of coffee breaks & lunch. The VAT is compulsory.*

- My Company/Association is a Member of the EGA and will pay the Member Fee of (£420.00 + 17.5%VAT) = **£493.50**.
- My Company/Association is not a Member of the EGA and will pay the normal Non-Member Price of (£520.00 + 17.5%VAT) = **£611.00**.

*Please note that the registration will not be effective until payment is made!*

**Method of payment - Please note that the bank charges are your responsibility**

By **Bank transfer** to the account name: *GPA Conferences, HSBC Bank*

Sort Code: *40-19-23* Account: *31372513* - United Kingdom

**Cancellation policy: cancellations must be made before 23 April 2003. After this point we are NOT able to refund your fee. Should you be UNABLE to attend a substitute delegate is welcome at no extra charge.**

Signature: ..... Date and Place: .....

For Accommodation please contact directly the Hotel  
Tel: +44 20 7589 8100 Fax: +44 20 7225 3476  
Bedrooms at 130 £ are reserved until the 25 April 03

*If you need any information please contact:*  
*Annette Bourgelle (annette@gpaconferences.com)*  
*Cristina Romagnoli (cristina@gpaconferences.com)*  
Tel: +32-2-5339814 Fax: +32-2-5339819

**Organized by**



5 St. James' Street, Dover CT16 1QP UK  
GB 624587030