BIOTECHNOLOGY PRODUCT DEVELOPMENT

APPLICATION TO REGISTER

24 & 25 June 2003 – Conf. No. B6-8203

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If you have NOT received confirmation seven days after registering, please call **+44 (0)1483 570099** and ask for Registration Department.

REGISTRATION INFORMATION

Dates **24 & 25 June 2003**

Times **24 June 2003** **Start 09.30 – Finish 16.30**
25 June 2003 **Start 09.15 – Finish 16.00**

Registration & Coffee
24 June 2003 **09.00**

Venue
The De Vere Cavendish Hotel, 81 Jermyn Street, London SW1.

Directions
Nearest Underground station: Piccadilly Circus.
Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at the De Vere Cavendish Hotel, 81 Jermyn Street, London SW1, at a special rate of £140.43 bed and breakfast excl. VAT – subject to availability.
Hotel Tel: +44(0)20 7930 2111.
Hotel Fax: +44(0)20 7839 4369.
All bookings should be made directly with the hotel quoting Management Forum and your credit card number.

Conference Fee
£995 +17.5% VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Discounted Rate
Available on application for personnel from non-profit making organisations and registered charities.

Conference No. B6–8203.

In the event of circumstances beyond its control, Management Forum reserve the right to alter the programme, the speakers, the date or the venue.

Cancellation Policy:
Over 14 days prior to the Seminar: Refund of fee less £75. 7-14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
N.B. Cancellations must be received in writing.

There will be exhibition spaces and promotional opportunities available at this meeting. We would welcome the chance of discussing how we could tailor these to your particular requirements. For further information please contact Vicki Elliott at Management Forum (email: vicki@management-forum.co.uk)

Assessment of Strategies and Techniques for Successful

BIOTECHNOLOGY PRODUCT DEVELOPMENT

Key topics to be addressed at this event:

- Regulatory Strategy for European Clinical Development
- Requirements for Clinical Trials with Biotechnology and Gene Therapy Products
- Regulatory Challenges of Biotech Generics
- Accelerating Pre-Clinical Development
- Biopharmaceutical Product Development
- Legal and Regulatory Issues Regarding Quality Aspects for Product Registration of Biotech Products
- Safety or Toxicity Testing?
- Disputed Relevance of Safety Testing: How to Comply with the Regulations
- Pharmacogenetics in Drug Development
- New Problems for the Clinician in Vaccine Development

Chairmen:

Day One: **Dr Mark Richardson,** Director of Regulatory Affairs, ORION Clinical Services

Day Two: **Dr Stephen Lockhart,** Senior Director, European Clinical Research, Wyeth Vaccines Research

With a Panel of Expert Speakers

24 & 25 June 2003
De Vere Cavendish Hotel, London

INTRODUCTION

'Biopharmaceuticals' are a growth zone in the pharmaceutical industry, however they risk outrunning experience of taking them through the preclinical, clinical and industrial phases of development and regulation.

The presentations and discussions in this meeting have been selected to describe the problems faced by developers, and how they have achieved some successes and have tackled problems, using examples ranging from discovery to registration. There will be particular concentration on the importance of collaboration with regulatory systems to ensure efficiency in delivering new, effective therapies.

The speakers have considerable experience of all sides of the industry and they have been asked to discuss how they have identified and resolved difficulties.

WHO SHOULD ATTEND

This meeting is directed at scientists, clinicians, regulators and managers developing medicines for humans, as it will extend from the early stages of defining future products through preclinical studies to clinical investigation, and regulatory application. It will be of equal value to those responsible for quality assurance and manufacture, to toxicologists, kineticists, those designing and running clinical trials and to strategic planners and regulatory managers in the pharmaceutical industry.

ATTENDANCE LIMITED TO 30

This limitation, a unique feature of all MANAGEMENT FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

CHAIRMEN

Dr Mark Richardson
Director of Regulatory Affairs, ORION Clinical Services

Dr Stephen Lockhart
Senior Director, European Clinical Research, Wyeth Vaccines Research

SPEAKERS

Dr Stephen Brewer
Bioproducts Technology Consultant, UK

Dr Paul Edwards
CEO, GeneMedix, UK (invited)

Dr Duncan McHale
Director and Head of Clinical Pharmacogenetics, Pfizer, UK

Dr Kieran O'Donovan
Technical Support Manager, Protherics, UK

Dr Jenny Sims
Senior Project Team Representative, Biotechnology, Novartis Pharma AG, Switzerland

Dr Lincoln Tsang
Of Counsel, Arnold & Porter, UK (previously Head of Biologicals and Biotechnology, Medicines Control Agency, UK)

Dr Francois Verdier
Head of Product Safety Assessment, Aventis Pasteur SA, France

A Certificate of Attendance for Professional Development will be given to each participant who completes the course.

Day One — 24 June 2003

09.30 **Chairman's Welcome and Introduction**
Dr Mark Richardson ORION Clinical Services

09.40 **Regulatory Strategy for European Clinical Development**
- National requirements
- National procedures and timings
- Choices for streamlining clinical development
- Implications of the European Clinical Trial Directive

Dr Mark Richardson ORION Clinical Services

10.30 **Discussion**

10.40 **Coffee**

10.40 **Requirements for Clinical Trials with Biotechnology and Gene Therapy Products**
- What is a clinical trial?
- CTX versus CTC
- What data are required?

Speaker to be confirmed

11.50 **Regulatory Challenges of Biotech Generics**
Dr Paul Edwards GeneMedix (invited)

12.40 **Discussion**

12.45 **Lunch**

14.00 **Biopharmaceutical Product Development**
- Sourcing of raw material
- Cell banking
- Process development and validation
- Product characterisation.

Dr Kieran O'Donovan Protherics

14.50 **Discussion**

15.00 **Tea**

15.20 **Pharmacogenetics in Drug Development**
Dr Duncan McHale Pfizer

16.10 **Discussion**

16.20 **Chairman's Concluding Remarks**

16.30 **End of Day One**

Day Two — 25 June 2003

09.15 **Chairman's Welcome and Introduction**
Dr Stephen Lockhart Wyeth Vaccines

09.30 **Accelerating Pre-Clinical Development**
- Process development is a rate-limiting step in pre-clinical development of most biologics
- Understanding the process of process development
- How to accelerate process development: technical and management aspects
- Avoiding pitfalls when outsourcing process development

Dr Stephen Brewer Bioproducts Technology Consultant

10.20 **Discussion**

10.30 **Coffee**

10.50 **Legal and Regulatory Issues Regarding Quality Aspects for Product Registration of Biotech Products**
Dr Lincoln Tsang Arnold and Porter

11.40 **Safety or Toxicity Testing?**
- What are the safety issues?
- Safety-related-to-quality issues
- Safety-related-to pharmacology issues
- Importance of understanding pharmacological/biological activity
- Assessment of 'pharmacological toxicity' related to exposure in biologically relevant animal models

Dr Jenny Sims Norvatis Pharma AG

12.30 **Discussion**

12.45 **Lunch**

14.00 **Disputed Relevance of Safety Testing: How to Comply with the Regulations**
- Do we have a full freedom in the design on non-clinical safety studies for biotech products?
- How to deal with species specific issues such as autoimmune reactions?
- How to design reprotox studies?
- Is it possible to apply safety pharmacology and pharmacokinetics requirements to biotech products?

Dr Francois Verdier Aventis Pasteur SA

14.50 **New Problems for the Clinician in Vaccine Development**
Vaccines and immunotherapeutics are a growth area. However, there are many challenges in developing these products. These cover assessment of both efficacy and safety. The regulatory environment has changed substantially in the last few years. In addition, many new technologies are emerging from the laboratory and each has great potential but also brings new challenges. This presentation will cover some of the newer problems in both the scientific and regulatory fields.
Dr Stephen Lockhart Wyeth Vaccines Research

15.40 **Discussion**

15.45 **Chairman's Concluding Remarks**

16.00 **Tea and Close of Seminar**