THE REGULATION OF rDNA TECHNOLOGY DERIVED DRUGS: BIOTECH SPECIFIC ASPECTS

11 March 2010, Conf. No. B3-5510 **W**

MANAGEMENT FORUM

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REGISTRATION INFORMATION

Dates
11 March 2010 Start: 09.30 – Finish: 17.30

Registration & Coffee
11 March 2010 09.00

Venue
The Rembrandt Hotel, 11 Thurloe Place, London SW7.

Directions
Opposite V&A Museum.
Nearest Underground station: South Kensington.
Map available on Website under Hotels and Venues.

Accommodation
A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7, at a special rate of £133.92 (Superior), £152.18 (Executive) both including English breakfast. Excluding VAT – subject to availability.
A special rate for Friday, Saturday and Sunday of £120.87 (Superior) including English breakfast excluding VAT – subject to availability when booked as additional nights.
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk
All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.

Fee
£545 + VAT. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.
15% Early Bird discount if you book before: 24 December 2009 and tick this box ☐.
(Discount only applies to full delegate rate).

Conference No. B3-5510

Discounted Rates
Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request.

Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee of £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.
NB: Cancellations must be received in writing by lesley@management-forum.co.uk.

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

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THE REGULATION OF rDNA TECHNOLOGY DERIVED DRUGS: BIOTECH SPECIFIC ASPECTS

MANAGEMENT FORUM

Topics to be covered at this seminar:

- Principles and Practice of Cell Banking
- Development Genetics
- Manufacturing Process Development and Validation
- Adventitious Agents and Viral Safety
- Nonclinical Safety Considerations
- Product Comparability and Biosimilarity
- Regulatory Documentation

Chairman:
Dr Mark Richardson Richardson Associates Regulatory Affairs Ltd

Seminar Leaders:
Sue Green Shore Limited
Dr Elaine Harris UCB Celltech
Tony Hitchcock Cobra Manufacturing
Cecil Nick Parexel Consulting
Dr David Snodin Parexel Consulting
Dr Martin Wisher BioReliance

Many of our courses can be delivered in-house.
For more information please contact
sarah.packham@management-forum.co.uk

CPD CERTIFIED
The CPD Certification Service

11 March 2010
The Rembrandt Hotel, London

WHY SHOULD YOU ATTEND?

- Gain a refresher/update on the technical aspects specific to the regulation of rDNA derived medicinal products
- Improve your knowledge of the differences between the regulation of rDNA products and conventional small molecule drugs
- Compare experiences with delegates from across Europe

** Please note – the seminar assumes a scientific background and a basic knowledge of drug regulatory affairs*

WHO SHOULD ATTEND?

- Life scientists moving into biotech regulatory affairs
- Technical and scientific decision makers in biotech start up operations
- Those with a life science background in the financial sector involved in due diligence or regulatory portfolio
- Those from small molecule backgrounds transferring to biotech product regulatory affairs

DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speakers, which will be a valuable source of reference for the future.

ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

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.

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

CHAIRMAN

Dr Mark Richardson is a Consultant with Richardson Associates Regulatory Affairs Ltd, specialising in drug development regulatory affairs for small molecule, biotech and advanced therapy products.

SPEAKERS

Sue Green is a regulatory consultant who has worked in global regulatory affairs for 20 years, primarily focused on providing regulatory advice and support in the drug development of biotech and advanced therapy medicinal products.

Dr Elaine Harris has 22 years experience in biologics manufacture, analysis and Quality Assurance. In 2007 Elaine joined UCB's Quality Assurance department where she is responsible for cell banking activities and Drug Substance manufacture for clinical and commercial phase biologics projects.

Tony Hitchcock is Head of Manufacturing Technologies at Cobra Biomanufacturing plc. He has over 24 years of experience in the large-scale manufacture of biopharmaceuticals.

Cecil Nick is a regulatory professional with over 25 years experience. Cecil joined PAREXEL in February 2001 and has been involved with issues relating to clinical development. He has worked with a number of oncology therapies including VEGF inhibitors, monoclonals, other biologicals and vaccines.

Dr David Snodin has been involved in regulatory toxicology for over 30 years. Since 2002 he has worked for PAREXEL, his current title is Vice President – Nonclinical Consulting.

Dr Martin Wisher is Senior Director, Scientific and Regulatory Affairs at BioReliance, a leading contract testing company. Martin has over 24 years' experience in the contract services industry.

Register on-line at www.management-forum.co.uk or telephone +44 (0)1483 730071, fax 730008

PROGRAMME

9.30 Welcome and introduction
Dr Mark Richardson, Richardson Associates Regulatory Affairs Ltd
- Outline of the day
- Summary of regulatory concerns specific to rDNA products

9.45 Development Genetics
Dr Mark Richardson, Richardson Associates Regulatory Affairs Ltd
- Definitions, terminology and jargon
- Expression vector design, construction and characterisation
- Vector disposition, copy number and stability
- Guidance and reality
- Regulatory expectation for IMPs and for MAA

10.45 Coffee

11.00 Cell Banks and Raw Materials
Dr Elaine Harris, UCB Celltech
- Principles and practice of cell banking
  - Outline of applicable guidance
  - Regulatory information: origin, provenance and history of cell substrates
  - Characterisation
  - Testing and validation of cell bank
- Raw material qualification: materials of animal/biological origin
- Regulatory expectation for IMPs and for MAA

11.45 Manufacturing Process Development and Validation
Tony Hitchcock, Cobra Manufacturing
- Principles and practice of process development and validation
- Regulatory expectations; changes in scale and GMP compliance during development vs. process consistency and validation at MAA

12.30 Lunch

13.45 Adventitious Agents and Viral Safety
Dr Martin Wisher, BioReliance
- Special concerns of mammalian systems
- Control of materials vs. capability of process to ensure AA safety
- Principles and practice of viral validation
- Regulatory expectations for IMPs and at MAA

14.45 Nonclinical Safety Considerations
Dr David Snodin, Parexel Consulting
- rDNA product specific safety concerns
- Principles of safety evaluation
- Regulatory guidelines for nonclinical evaluation of biotech products
- Model pharm/tox for MAbs
- Regulatory expectations for IMPs and at MAA

15.30 Tea

15.45 Product Comparability and Biosimilarity
Cecil Nick, Parexel Consulting
- Concept of comparability
- Consequences of any process change and regulatory expectation of supporting comparability data
- The role of comparability principles in the development of biosimilar products

16.30 Regulatory Documentation
Sue Green, Shore Limited
- What goes into the IMPD and the MAA?
- rDNA product dependent flexibility of the structure and format
- Practical advice

17.15 Round up and close of seminar