BIOTECHNOLOGY FOR THE NON-BIOTECHNOLOGIST

APPLICATION TO REGISTER

23-25 September 2009, Conf. No. M9-6109

Please PRINT your details:

Title..... First name .....
(Dr, Mr, Mrs, etc)

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W

YOU MAY REGISTER BY:-

+44 (0) 1483 730008

Management Forum Ltd, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK

www.management-forum.co.uk

E-mail: registrations@management-forum.co.uk

If you have NOT received confirmation seven days after registering, please contact Registration Department.

REGISTRATION INFORMATION

Dates 23-25 September 2009

Times 23 September 2009 Start 09.00 – Finish 17.00
Drinks Reception Start 17.00 – Finish 18.00
24 September 2009 Start 08.30 – Finish 17.00
25 September 2009 Start 08.30 – Finish 16.30

Registration & Coffee
23 September 2009 08.30

Venue
Radisson SAS Hotel, Steinentorstrasse 25, CH-4001 Basel, Switzerland

Accommodation
A limited number of bedrooms have been reserved at Radisson SAS Hotel, Steinentorstrasse 25, CH-4001 Basel, Switzerland
Hotel Tel: +41 61 227 29 75
Hotel Fax: +41 61 227 29 05
Email: Esther.Mueller@RadissonSAS.com
All bookings should be made directly with the hotel quoting Management Forum and your credit card number.

Conference Fee
£1,680. The fee includes course documentation as well as mid-session refreshments, lunch and Drinks Reception on Day One. Invoice and confirmation will be forwarded to you.
Conference No. M9-6109

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.

Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact Judith Black
(email: judith.black@management-forum.co.uk)

MANAGEMENT FORUM LTD., 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK
Tel: +44 (0)1483 730071 Fax: +44 (0)1483 730008 Website: www.management-forum.co.uk

BIOTECHNOLOGY FOR THE NON-BIOTECHNOLOGIST

The purpose of this training course is to:
Provide Non-Biotechnologists with the basic theory to understand Principles, Techniques and the Potentials of Biotechnology

Companies that have previously attended this event:

AVECIA LIMITED
BUSINESS MONITOR INTERNATIONAL
CARDINAL HEALTH
CENTRE FOR ENTERPRISE & INNOVATION
D. YOUNG & CO.
EMEA
F. Hoffman-La Roche Ltd
IDIS LTD
JANSSEN PHARMACEUTICA NV
KINESIS PHARMA BV
KPMG
LEO PHARMA A/S
MERIAL SAS
PFIZER GLOBAL R&D
ROCHE PRODUCTS LTD
Shire Pharmaceuticals Dev Ltd
TEFEN EUROPE
WYETH PHARMACEUTICALS

Topics to be covered at this meeting:

Day One
- Introduction to Biotechnology
- Introduction to Molecular Biology
- Re-Expression of Proteins
- Development of Production Organisms
- Fermentation Technology and Large Scale Production

A highly successful training course!

Day Two
- Process Optimisation and Scale-Up
- Analysis of Biopharmaceuticals
- Product Recovery and Purification
- Formulation Design of Biopharmaceuticals
- Process Economics

For personnel new to working with Biotechnology products!

Day Three
- Patenting of Biotech Inventions
- Patent Workshop
- Regulatory Considerations
- Regulatory Applications and Consequences, Comparability and Equivalence
- Advances in Regulation: Biosimilars
- Current and Future Developments

Anyone requiring an overview

Chairman:
Dr Adekunle Onadipe
Associate Research Fellow, Bioprocess R&D Cell Line Development, Pfizer Inc., USA

Please see inside for full panel of speakers

CPD CERTIFIED
The CPD Certification Service

23-25 September 2009
Radisson SAS Hotel, Basel, Switzerland

INTRODUCTION

The purpose of this training course is to provide Non-Biotechnologists with the basic theory to understand principles, techniques and the potentials of Biotechnology.

Biotechnology combines disciplines such as Molecular Biology, Biochemistry, Chemistry, Microbiology, Chemical Engineering and Computing. This rapidly advancing science offers new and exciting opportunities to mankind, especially in the fight against disease.

WHO SHOULD ATTEND

This training course will be of interest to Non-Biotechnologists and personnel new to working with biotechnology products and anyone requiring an overview of the requirements, development and regulation of Biotechnology products. It will be particularly useful to personnel in:

- **Quality Control and Quality Assurance**
- **Registration and Regulatory Affairs**
- **Legal and Patents**
- **Finance**
- **Accounts and Investment**
- **Information Technology**
- **Engineering**
- **Sales and Marketing**
- **Health and Safety**
- **Risk Management**
- **Anyone who needs to gain a broad understanding of Biotechnology**

RECENT ATTENDEES

- **Qualified Person**
- **Business Development Manager**
- **Process and Biosafety Consultant**
- **Risk Management Officer**
- **Operations Director**
- **Finance Director**
- **Global QA Manager**
- **Patent Attorney**
- **Head of Patents and Trademarks**
- **Head Development and Strategic Planning**
- **Outsourcing Quality Executive**
- **Financial Controller**
- **IP Manager**
- **Process Engineer**
- **Pharmacist**
- **Director Regulatory Affairs**
- **Regulatory Project Manager**
- **Senior Materials Manager**
- **Training Manager**
- **Director CMC**
- **Scientific Administrator**

CHAIRMAN

Dr Adekunle Onadipe Associate Research Fellow, Bioprocess R&D Cell Line Development, Pfizer Inc., USA

SPEAKERS

Dr Mark Richardson Pharmaceutical & Biotech Regulatory Affairs Consultant, UK

Dr Jon Smith Director, Adjoint R&D Projects, sanofi pasteur, France

Kate Smith Head of Manufacturing, BioReliance, UK

Alison Sykes Stability and Bioanalytics Manager, Analytical Development, Lonza Biologics plc, UK

Dr Philip Webber Frank B. Dehn & Co., Patent and Trade Mark Attorneys, London, UK

Dr Robert Young Principle Group Leader, Cell Culture Process Development, Lonza Biologics plc., UK

REGISTER NOW

Reserve your place and register now:
To register for this course:
www.management-forum.co.uk
Tel: + 44 (0) 1483 730071
Fax: + 44 (0) 1483 730008
Any questions email: ellen.walker@management-forum.co.uk

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

Day One — 23 September 2009

09.00 **Introduction to Biotechnology**
- Historical perspective
- Diversity of biotechnology products
- Impact on society
- Product development overview

Introduction to Molecular Biology
- DNA, RNA, genes, plasmids and vectors
- Protein synthesis - transcription and translation

Re-Expression of Proteins
- Recombinant DNA techniques
- Monoclonal antibodies - from mouse to human
- Transgenic animals and plants

Development of Production Organisms
- Transfection
- Selection
- Preservation

Fermentation Technology and Large Scale Production
- Types of fermenters
- Fermentation basics
- Modes of operation
- Process development

17.00 **General Discussion and Delegate Participation**

17.00- 18.00 **Drinks Reception in the Hotel for Delegates and Speakers**

Day Two — 24 September 2009

08.30 **Process Optimisation and Scale-Up**
- Scale-up strategies
- Strain improvement
- Media improvement
- Process improvement

Analysis of Biopharmaceuticals
- Biology activity
- Physicochemical characterisation
- Purity, impurities and contaminants

Product Recovery and Purification
- Cell harvesting and removal
- Clarification - intracellular and extracellular proteins
- Chromatographic techniques

Formulation Design of Biopharmaceuticals
- Factors affecting degradation
- Choice of excipients
- Prolonging shelf life

Process Economics
- Drug development and bioprocess economics
- Optimising bioprocess economics
- Manufacturing make or buy
- Future manufacturing alternatives

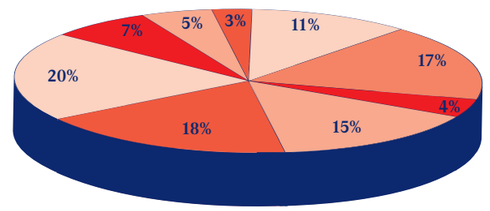
General Discussion and Delegate Participation

17.00 **End of Day Two**

A selection of Companies that have attended this event in the past:

AVECIA LIMITED
BUSINESS MONITOR INTERNATIONAL
CARDINAL HEALTH
CENTRE FOR ENTERPRISE & INNOVATION
D. YOUNG & CO.
EMEA
F. Hoffman-La Roche Ltd
IDIS LTD
JANSSEN PHARMACEUTICA NV
KINESIS PHARMA BV
KPMG
LEO PHARMA A/S
MERIAL SAS
PFIZER GLOBAL R&D
ROCHE PRODUCTS LTD
Shire Pharmaceuticals Dev Ltd
TEFEN EUROPE
WYETH PHARMACEUTICALS

Regulatory Affairs	20%
QC/QA	18%
Production	17%
Project Management	15%
Management & Administration	11%
Business Development	7%
R&D	5%
Patents	4%
Others	3%



Day Three — 25 September 2009

08.30 **Patenting of Biotech Inventions**
- What is a patent
- What are basic criteria for patentability
- What can be patented
- Can you patent genes, proteins, hybridomas, stem cells

Patent Workshop
- How to recognise what is patentable
- Drafting claims to biotech inventions
- Maximising protection for an invention
- Understanding the examination process
- Enforcing patents

Regulatory Considerations
- Genetic characterisation
- Testing for adventitious agents
- Process validation
- Raw material testing
- Cell bank testing

Regulatory Applications and Consequences, Comparability and Equivalence
- Consequences of Manufacturing Process Change
- Assessment of Process Change
- Comparability or Equivalence
- Comparability Strategy
- Biotech Generics

Advances in Regulation: Biosimilars

Current and Future Developments
- Medicine
- Ethics and biotechnology

General Discussion and Delegate Participation

16.30 **End of Seminar**