



# BIOTECHNOLOGY FOR THE NON-BIOTECHNOLOGIST



## APPLICATION TO REGISTER

22-24 September 2010, Conf. No. M9-6010

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.

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk  
If you do not wish to receive selected third party mailings please contact nick@management-forum.co.uk

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

## REGISTRATION INFORMATION

Dates 22-24 September 2010

Times 22 September 2010 Start 09.00 – Finish 17.00

Drinks Reception Start 17.00 – Finish 18.00

23 September 2010 Start 08.30 – Finish 17.00

24 September 2010 Start 08.30 – Finish 16.30

Registration & Coffee

22 September 2010 08.30

Venue

NH Constanza Hotel, Barcelona, Spain

Carrer de Déu i Mata, 99

08029 Barcelona, Spain

Accommodation

A limited number of bedrooms have been reserved at

NH Constanza Hotel, Barcelona, Spain

Carrer de Déu i Mata, 99

08029 Barcelona, Spain

Hotel Tel: +34 93 281 15 00

Hotel Fax: +34 93 410 03 35

Reservation email: d.ghossein@nh-hotels.com

All bookings should be made directly with the hotel

quoting Management Forum and your credit card

number

Conference Fee

GBP £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. M9-6010

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

registrations@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.



# BIOTECHNOLOGY FOR THE NON-BIOTECHNOLOGIST



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

## Companies that have previously attended this event:

ACTELLION  
PHARMACEUTICALS LTD  
ALLERGAN LTD  
ASTELLAS PHARMA  
EUROPE BV  
ASTRAZENECA AB  
AVECIA LTD  
BAYER SA  
BD MEDICAL  
PHARMACEUTICAL SYSTEMS  
BIOGEN IDEC LTD  
BOEHRINGER INGELHEIM  
PHARMACEUTICALS INC.  
CENTOCOR BV  
CSL BEHRING  
EISAI LTD  
F. HOFFMAN-LA ROCHE LTD  
FERRIN PHARMACEUTICALS  
A/S  
GENZYME EUROPE BV  
GLAXOSMITHKLINE  
BIOLOGICALS SA  
INTERVET PHARMA R&D  
JANSSEN  
PHARMACEUTICA NV  
LABORATORIES LET SL  
LEEK PHARMACEUTICALS D.D.  
MERCK KGaA  
MERCK SERONO SpA  
MERIAL SAS  
MUREX BIOTECH LTD  
MYLAN  
PHARMACEUTICALS SL  
NOVARTIS PHARMA SA  
NOVO NORDISK AS  
NOVOZYMES A/S  
PAREXEL INTERNATIONAL LTD  
PFIZER GLOBAL R&D  
PLIVA CROATIA LTD  
SHIRE PHARMACEUTICALS  
SYNGENTA CROP  
PROTECTION  
UCB SA

## 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

### Day Two

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

### 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

Chairman:

**Dr Adekunle Onadipe**

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

Please see inside for full panel of speakers

A highly  
successful  
training course!

For personnel  
new to working with  
Biotechnology  
products

Anyone  
requiring an  
overview



22-24 September 2010  
NH Constanza Hotel, Barcelona, Spain

INTRODUCTION

The purpose of this training course is to provide Scientists and Non-Scientists 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
  - Anyone who needs to gain a broad understanding of Biotechnology
- Information Technology
  - Engineering
  - Sales and Marketing
  - Health and Safety
  - Risk Management

RECENT ATTENDEES

- Qualified Person Executive
  - 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
  - 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

**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 Scientist, 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](http://www.management-forum.co.uk)  
Tel: + 44 (0) 1483 730071  
Fax: + 44 (0) 1483 730008  
Any questions email: [ellen.walker@management-forum.co.uk](mailto: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

22 September 2010

- 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

23 September 2010

- 08.30

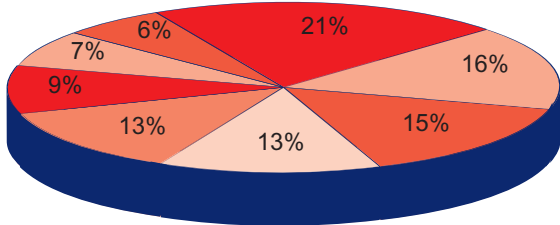
- ▶ **Process Optimisation and Scale-Up**
    - Scale-up strategies
    - Strain improvement
    - Media improvement
    - Process improvement
  - ▶ **Analysis of Biopharmaceuticals**
    - Biology activity
    - Physicochemical characterisation
    - Purity, impurities and contaminants
  - ▶ **Product 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:

ACTELLION PHARMACEUTICALS LTD	CSL BEHRING	MERIAL SAS
ALLERGAN LTD	EISAI LTD	MUREX BIOTECH LTD
ASTELLAS PHARMA EUROPE BV	F. HOFFMAN-LA ROCHE LTD	MYLAN PHARMACEUTICALS SL
ASTRAZENECA AB	FERRIN PHARMACEUTICALS A/S	NOVARTIS PHARMA SA
AVECIA LTD	GENZYME EUROPE BV	NOVO NORDISK AS
BAYER SA	GLAXOSMITHKLINE BIOLOGICALS SA	NOVOZYMES A/S
BD MEDICAL PHARMACEUTICAL SYSTEMS	INTERVET PHARMA R&D	PAREXEL INTERNATIONAL LTD
BIOGEN IDEC LTD	JANSSEN PHARMACEUTICA NV	PFIZER GLOBAL R&D
BOEHRINGER INGELHEIM PHARMACEUTICALS INC.	LABORATORIES LET SL	PLIVA CROATIA LTD
CENTOCOR BV	LEEK PHARMACEUTICALS D.D.	SHIRE PHARMACEUTICALS
	MERCK KGaA	SYNGENTA CROP PROTECTION
	MERCK SERONO SpA	UCB SA

Senior Management & Administration	21%
Regulatory Services	16%
Research & Development	15%
QC/QA/Quality	13%
Engineering & Production	13%
Legal & Patent	9%
Project Management	7%
Business Dev., Finance, Sales	6%



Day Three

24 September 2010

- 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**