

**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](http://www.management-forum.co.uk)**

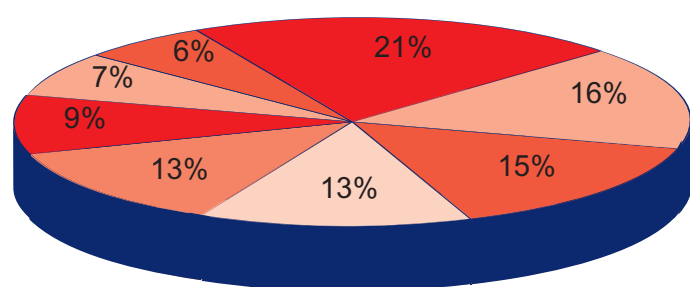
## WHY SHOULD YOU ATTEND?

- Gain an introduction to the fundamental principles of biotechnology
- Improve your understanding of the key techniques used by biotechnologists
- Understand the importance of meeting regulatory requirements and hear about the advances being made
- Learn to recognise potential patents, and why and how they must be protected
- Share knowledge and experiences with fellow attendees from across Europe

## WHO SHOULD ATTEND?

### Personnel from:

- Quality Assurance
- Regulatory Affairs
- Legal and IP
- Business Development
- Sales and Marketing
- Engineering
- Finance
- Training
- Administration
- Management



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

*\*Based on delegate attendance 2003-2010*

## 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** Principal Scientist, BioReliance, UK

**Alison Sykes** Stability and Formulation Manager, Analytical Services, Lonza Biologics plc, UK

**Dr Philip Webber** Dehns, Patent and Trade Mark Attorneys, UK

**Dr Robert Young** Principal Scientist, Cell Culture Process Development, Lonza Biologics plc., UK

## REGISTRATION

You may register by:

Visiting – [www.management-forum.co.uk](http://www.management-forum.co.uk)

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Fax: – + 44 (0) 1483 730008

Please contact [sarah.packham@management-forum.co.uk](mailto:sarah.packham@management-forum.co.uk) with any questions.

## Day One

6 April 2011

- 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
- ▶ **General Discussion**
- 17.00 **Drinks Reception**
- 18.00 ▶ **End of Day One**

## Day Two

7 April 2011

- 08.30 ▶ **Process Optimisation and Scale-Up**
- Scale-up strategies
  - Strain improvement
  - Media improvement
  - Process improvement
- ▶ **Analysis of Biopharmaceuticals**
- Biological 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**
- 17.00 ▶ **End of Day Two**

## Day Three

8 April 2011

- 08.30 ▶ **Patenting of Biotech Inventions**
- What is a patent?
  - What are the 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**
- 16.30 ▶ **End of Seminar**

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

