



RESEARCH & DEVELOPMENT FOUNDATION  
of PHARMACEUTICAL INDUSTRY , TURKEY

MANAGEMENT FORUM LTD., UK

## BIOPHARMACEUTICALS IN THE DRUG INDUSTRY

28-29 February 2008, Sheraton Istanbul, Turkey

### Day 1

Thursday, 28 February 2008

09.00- 09.15 h

#### Opening remarks

**Mr. Kaya Turgut, President,**

Research & Development Foundation of Pharmaceutical Industry (İKEV)

**Dr. Orhan Gümrükçüoğlu**

Undersecretary of Ministry of Health

#### MORNING SESSION

09.15- 10.15 h

#### Introduction to Biotechnology – Dr. Kunle Onadipe/ Dr. Jon Smith

- Historical perspective
- Diversity of biotechnology products
- Impact on society
- Product development overview
- Biopharmaceuticals in development stages

10.15- 11.00 h

#### Introduction to Molecular Biology – Dr. Robert Young

- DNA, RNA, genes, plasmids and vectors
- Protein synthesis – transcription and translation

11.00- 11.15 h

#### Coffee Break

11.15- 12.30 h

#### Re-Expression of Proteins – Dr. Robert Young

- Recombinant DNA techniques
- Monoclonal antibodies – from mouse to human
- Transgenic animals and plants

12.30- 13.30 h

#### Lunch

#### AFTERNOON SESSION

13.30- 14.30 h

#### Development of Production Organisms – Dr. Jon Smith

- Transfection
- Selection
- Preservation

14.30- 15.30 h

#### Fermentation Technology and Large Scale Production – Dr. Jon Smith

- Types of fermenters
- Fermentation basics
- Modes of operation
- Process development

15.30- 15.45 h

#### Coffee Break

15.45- 16.45 h

#### Process Optimization and Scale-up – Dr. Kunle Onadipe

- Scale-up strategies
- Strain improvement
- Media improvement
- Process improvement

16.45- 17.30 h

#### General Discussion and Delegate Participation



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**Day 2**                      **Friday, 29 February 2008**

### **MORNING SESSION**

09.00– 10.00 h    **Analysis of Biopharmaceuticals - Alison Sykes**

- Biological activity
- Physicochemical characterisation
- Purity, impurities and contaminants

10.00 - 11.00h    **Product Recovery and Purification - Suzanne Aldington**

- Cell harvesting and removal
- Clarification – intracellular and extracellular proteins
- Chromatographic techniques

11.00– 11.15 h    **Coffee Break**

11.15- 12.00 h    **Formulation Design of Biopharmaceuticals - Alison Sykes**

- Factors affecting degradation
- Choice of excipient
- Prolonging shelf life

12.00- 13.00 h    **Lunch**

### **AFTERNOON SESSION**

13.00- 14.00 h    **Regulatory Considerations: Quality and Safety – Dr. Mark Richardson**

- Preclinical safety
- Genetic characterization
- Raw material testing
- Process validation

14.00- 15.00 h    **Application of Regulatory Principles: Specification and Comparability – Dr. Mark Richardson**

- Control of biotech drug substance/product
- Specification vs. validation
- Consequences of Manufacturing Process Change

15.00- 15.15 h    **Coffee Break**

15.15- 16.15 h    **Advances in Regulation: Biosimilars – Dr. Mark Richardson**

- Legal status
- Comparability or Equivalence?
- Biosimilar Development Strategy

16.15- 16.45 h    **Current and Future Developments – Dr. Kunle Onadipe**

- Medicine (Gene therapy, DNA vaccines etc.)
- Ethics and biotechnology

16.45- 17.30 h    **General Discussion and Delegate Participation**

\* Simultaneous translation (English/Turkish) will be available.



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### Speakers and programme provided by:

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

Tel. +44 (0) 1483 730071  
Fax. +44 (0) 1483 730008  
www.management-forum.co.uk

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### For Information :

Phone: (0212) 353 11 20  
Fax: (0212) 353 11 41  
Web: [www.ikev.org](http://www.ikev.org)