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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Fax: +90 212 353 11 41
E-mail: Ms. Burcu Imdat (burcu.imdat@ieis.org.tr)

For Information :

Phone: (0212) 353 11 20
Fax: (0212) 353 11 41
Web: www.ikev.org