

PROGRAM

Thursday, May 31

08:00-09:00 **Registration**

09:00-9:30 **Greetings / Welcome and Opening Address**

Fusun Acartürk, Ph.D., Course Director, TUFTAD, Turkey

Daan Crommelin, Ph.D., Course Director, EUFEPS, Netherlands

A. Atilla Hincal, Ph.D., President of TUFTAD, Turkey

Saim Kerman, M.D., Vice-Head of General Directorate of Pharmaceuticals
Ministry of Health, Turkey

9:30-12:30 **SESSION I Scientific Aspects**

Chair: Vinod P. Shah, Ph.D., FIP, USA

09:30-10:00 Global Perspectives on Biotechnology Based Therapeutic Products
Selçuk S. Özceada, Ph.D., Bosfor Bioscience Partners, Turkey

10:00-10:30 Delivery of Pharmaceutical Proteins
Daan Crommelin, Ph.D., Utrecht University, Netherlands

10:30-11:00 **COFFEE BREAK**

11:00-11:30 Immunogenicity of Biotech Products
Daan Crommelin, Ph.D., Utrecht University, Netherlands

11:30-12:00 Special Aspects of Approved Recombinant Drugs with Respect to
Pharmacodynamics and Pharmacokinetics
Theo Dingermann, Ph. D., Johann Wolfgang Goethe University, Germany

12:00- 12:30 Issues Related to the Formulation of Pharmaceutical Proteins
Daan Crommelin, Ph.D., Utrecht University, Netherlands

12:30-14:00 **LUNCH**

14:00-17:30 **SESSION II Case Studies and Regulatory Aspects**
Chair: Daan Crommelin, Ph.D., Utrecht University, Netherlands

14:00-14:30 Case Study: Quality and Potential Safety of Biosimilar Epoetins – An
International Survey
Suresh Aravind , Johnson & Johnson, Executive Director for Eprex, USA

14:30-15:00 Case study: Production Systems for Pharmaceutical Proteins
Wolfgang Buchinger, Ph.D., Boehringer Ingelheim, Austria

15:00-15:30 **COFFEE BREAK**

15:30-16:00 Regulatory Considerations for Biotech Products
Vinod P. Shah, Ph.D., FIP, USA

- 16:00-16:30 The European Regulatory System for the Approval of Biosimilars
Teresa Pepper, Amgen, Cambridge, UK
- 16:30-17:00 Comparison of EMEA and FDA views on Regulatory Aspects of Biosimilar Products
Ajaz S. Hussain, Ph.D., Sandoz, USA
- 17:00-17:30 Discussion
- 19:30 **GALA DINNER**
Complimentary to all registrants

Friday, June 1

- 09:00-10:15 **SESSION III Scientific and Regulatory Aspects in Turkey**
Chair: Füsün Acartürk, Ph.D., Course Director, TUFTAD, Turkey
- 09:00-9:30 Biotechnological Products Used in Targeted Therapeutical Systems
Emin Kansu, Ph.D., Hacettepe University, Turkey
- 09:30-10:00 Scientific Aspects of the Biotechnology Revolution in Turkey: Biotechnology Now and in the Future
Beyazıt Çırakoğlu, Ph.D., Marmara University, Turkey
- 10:00-10:15 Regulatory Procedure of Biotechnological Products in Turkey
Asuman Bozkır, Ph.D., Ankara University & Member of the Advisory Committee of Biotechnological Products to the Ministry of Health, Turkey
- 10:15-10:45 **COFFEE BREAK**
- 10:45-12:15 **SESSION IV Panel Discussion on Regulatory Importance of Biotech and Biosimilar Products**
Moderators: Daan Crommelin, Ph.D., Utrecht University, The Netherlands
A. Atilla Hıncal, Ph.D., TUFTAD, Turkey
Ajaz S. Hussain, Ph.D., Sandoz, USA
Emin Kansu, Ph.D., Hacettepe University, Turkey
Teresa Pepper, Amgen, Cambridge, UK
Vinod P. Shah, Ph.D., FIP, USA
- 12:15-12:30 **CONCLUDING REMARKS**
Vinod P. Shah, Ph.D., FIP, USA
Füsün Acartürk, Ph.D., TUFTAD, Turkey
- Meeting Adjourns**