

# 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**