



# ***Bioequivalence, Dissolution, Biosimilarity***

***From the "Chain Bridge" to other Bridges of  
the Pharmaceutical World***

**25 April 2015**

**Akra Barut Hotel,  
Antalya, Türkiye**

## PROGRAMME

- 09:00-10:00 **Registration**
- 10:00-10:15 **Opening**  
*Nevin Çelebi*, TÜFTAD President, Gazi University  
Turkey  
*Atilla Hıncal*, İDE Pharmaceutical Consultancy Ltd  
Co, Turkey  
*Laszlo Endrenyi*, University of Toronto, Canada  
*Vinod Shah*, VPS Consulting, LLC, USA
- 10:15-10:35 **Story of the Hungarian bioequivalence workshop series**  
*Imre Klebovich*, Semmelweis University, Hungary
- 10:35-10:55 **The legal basis for applications: an issue of understated importance in the EU**  
*Tamás Paál*, University of Szeged, Hungary
- 10:55-11:15 **Points to consider during the development of a generic modified-release dosage form**  
*Vinod Shah*, VPS Consulting, LLC, USA
- 11:15-11:35 **Requirements of various regulatory authorities for the bioequivalence of modified-release drug products**  
*Laszlo Endrenyi*, University of Toronto, Canada
- 11:35-11:55 **Coffee break**
- 11:55-12:15 **In vitro-in vivo correlations: an update**  
*José Morais*, Unversidade de Lisboa, Portugal
- 12:15-12:35 **In vitro-in vivo correlations: traditional approach**  
*Nikoletta Fotaki*, University of Bath, UK
- 12:35-14:00 **Lunch**
- 14:00-14:20 **Formulation of drug-loaded microfiber based solid dosage forms for in vitro dissolution enhancement of poorly soluble drugs**  
*Romána Zelkó*, Semmelweis University, Hungary

## PROGRAMME

- 14:20-14:40 **Biowaiver applications in the European scenario**  
*Carla Caramella, University of Pavia, Italy*
- 14:40-15:00 **Tyrosine kinase inhibitors (TKIs) -Challenges for anticancer therapy and regulatory perspectives**  
*Milena Jadrijevic-Mladar Takac, University of Zagreb, Croatia*
- 15:00-15:20 **The place of capillary electrophoresis among bioanalytical separation techniques (Joint presentation with Tamás Tabi)**  
*Éva Szökő, Semmelweis University, Hungary*
- 15:20-15:40 **Tea break**
- 15:40-16:00 **Emerging technologies: Milk based formulations**  
*Panos Macheras, University of Athens, Greece*
- 16:00-16:20 **Biosimilars: The challenge of making an informed decision in therapy**  
*Clive Wilson, Strathclyde Institute of Pharmacy & Biomedical Sciences, UK*
- 16:20-16:40 **Developing biosimilars biobetters & development in Turkey**  
*Atilla Hincal, İDE Pharmaceutical Consultancy Ltd Co, Turkey*
- 16:40-17:00 **Similar of nonbiological complex drugs (NBCDs): challenges for a regulatory approach**  
*Stefan Mühlebach, Vifor Pharma, Glattbrugg, Switzerland*
- 17:00-17:20 **Uncertainties in the analysis of clinical trials**  
*Constantin Mircioiu, Carol Davila University, Romania*
- 17:20 **Closing**  
*Atilla Hincal, TÜFTAD Honorary President, İDE Pharmaceutical Consultancy Ltd Co, Turkey*
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## KAYIT FORMU

Formu doldurduktan sonra kayıt ücretinin ödendiğine dair dekont ile birlikte aşağıdaki iletişim adresine gönderiniz.

Son Kayıt Tarihi: 20 Nisan 2015

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Kayıt Ücreti: 300 TL

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