

3rd JBF Symposium

International Harmonization of Bioanalysis Regulation
-Discussion in GBC Harmonization Teams-

8 August 2012, 9:30-17:50

Venue: Keio University (Tokyo, Japan)

Opening remarks	9:30-9:40
Haruhiro Okuda, Ph.D. (JBF Representative: National Institute of Health Sciences)	
1. Updates in JBF Activity	9:40-10:00
Yoshiaki Ohtsu (Astellas Pharma Inc.)	
2. Invited lecture	Session Chair: Shinobu Kudoh (Shimadzu Techno-Research, Inc.)
- Current topics on regulated bioanalysis in the Ligand Binding Assay area, such as the EMA guideline	10:00-10:30
Dr. Michaela Golob (Merck-Serono, GBC-SC)	
- Updates on Global Harmonization of Bioanalytical Guidance/Guidelines and Current Hot Topics in Regulated Bioanalysis:	
“Impact of Hemolysis on Drug Stability”	10:45-11:15
Dr. Fabio Garofolo (Algorithme Pharma, GBC-SC)	
- Regulated Bioanalysis in China	11:15-11:45
Dr. Daniel Tang (Icon Development Solutions, APAC, GBC-SC)	
Lunch break	
3. GBC Discussion Update	13:10-13:55
Keiko Nakai (Mitsubishi Chemical Medience Corporation)	
Takahiko Osumi (Otsuka Pharmaceutical Co., Ltd.)	
Yoshitaka Taniguchi (Toray Research Center, Inc.)	
Break	
4. Poster presentation by Japanese GBC HT members	14:10-16:20
5. General discussion	16:30-17:40
Session Chair: Masanari Mabuchi (Mitsubishi Tanabe Pharma Corporation)	
Takehisa Matsumaru, Ph.D. (Nippon Boehringer Ingelheim Co., Ltd.)	
Closing remarks	17:40-17:50
Jun Haginaka, Ph.D. (Professor, Mukogawa Women's Univ.)	

Chair: Mami Imazato (Novartis Pharma K.K.)

This document is a translation of the official handout for the 3rd JBF Symposium.