THE 11TH JBF SYMPOSIUM PROGRAM (as of Oct. 2019)

Date: Tue, 25th Feb. – Thu, 27th Feb. 2020
Venue: TOWER HALL FUNABORI, Tokyo, Japan

Day 1: Tuesday, 25th Feb.

12:30-12:45 PM   Opening Remarks

12:45-14:05   Introduction of AI to bioanalysis and pharmacokinetics

> ➢ Isn't machine learning difficult if you think it's just a tool?
> - Tatsuya KANEYAMA (Sumitomo Dainippon Pharma)

> ➢ HPLC method development using AI: current practice and recent trend
> - Masaaki SUZUKI (ChromSword Japan)

> ➢ Approach for the prediction of ADME parameters using machine learning
> - Koichi HANDA (Teijin Pharma)

12:45-14:05   Failure & Trouble Cases and these Solutions of LBA   〔Parallel Session〕

> ➢ Failure & Trouble Cases and these Solutions of LBA
> - Yohei HAYATA (Shin Nippon Biomedical Laboratories)

14:20-15:50   Poster Presentation Part I

14:20-15:20 Core-time for public offering presentations (odd number posters)

16:00-18:00   Practical biomarker measurements in drug development

> ➢ Draft of points to consider document on biomarker assay validation in Japan
> - Yoshiro SAITO (National Institute of Health Sciences)

> ➢ "Case study: Validation of an LC-MS method for measuring urinary glycosaminoglycans and it's evaluation as a biomarker in MPSVII" - Julie TAYLOR (Ultragenyx)

> ➢ Biomarker assay validation - FB from EBF discussions on today's challenge of connecting science and regulations - Joanne GOODMAN (AstraZeneca)

> ➢ DG2019-44 Validation of Biomarker Quantification in Japan (tentative)
> - Yoshitaka HASHIMOTO (Ono Pharmaceutical)

Day 2: Wednesday, 26ᵗʰ Feb.

9:00-10:40 AM   Anti-drug antibodies in new modality drugs

- ➤ Immunogenicity assessment of biosimilar: FKB327's case
  - Katsuhiko YAMAMOTO (Fujifilm Kyowa Kirin Biologics)
- ➤ Immunogenicity assessment of peptide therapeutics - Mayurranjan MITRA (Genentech)
- ➤ ADA assessment for therapeutic oligonucleotides - Hideo TAKAKUSA (Daiichi Sankyo)
- ➤ Immunogenicity assessment of gene therapies: Current and future concepts
  - Lydia MICHAUT (Bioagilytix Europe)

10:55-11:25   Poster Presentation Part II

10:55-11:55 Core-time for public offering presentations (even number posters)

12:35-13:35 PM   Luncheon

13:45-15:00   ICH M10 Guideline / Draft

- ➤ ICH M10 draft guideline and future perspectives
  - Akiko ISHII and Yoshiro SAITO (National Institute of Health Sciences)
- ➤ ICH-M10: JBF Workshop Report - Proposals from JBF
  - Takeru YAMAGUCHI (Sumika Chemical Analysis Service)
- ➤ Feedback from ICH M10 discussions in Europe
  - Philip TIMMERMAN (European Bioanalysis Forum)

15:30-17:00   Bioanalysis for development of DDS drugs

- ➤ A corporate pharmaceutical researcher's expectations for the bioanalysis technologies
  - Hideo KOBAYASHI (Daiichi Sankyo RD Novare)
- ➤ Case study of bioanalysis in the development of DDS products
  - Masayoshi SAITO (Mitsubishi Tanabe Pharma)
- ➤ Characterization of Nano-DDS Formulations in Drug Discovery Stage
  - Eiichi YAMAMOTO (National Institute of Health Sciences)

17:10-18:10   Keynote Lecture

Prof. Yasuhiro Matsumura (National Cancer Center)

18:30-20:30   Banquet

Day 3: Thursday, 27th Feb.

9:00-11:00 AM   Poster Presentation Part III (JBF Discussion Groups)

- ➢ DG2019-40   Accuracy & Precision Criteria on BE study (tentative)
- ➢ DG2019-41   Bioanalysis of Unbound Drug
- ➢ DG2019-42   Current situations and issues of multiplex LBA
- ➢ DG2019-43   Guide to ADA Analysis: Considerations in Developing Analytical Methods and Conducting Nonclinical/Clinical Studies
- ➢ DG2019-44   Validation of Biomarker Quantification in Japan

11:15-12:15   Collaboration Session with Clinical Pharmacology

- ➢ TBD - Risa FUKUSHI (Astellas Pharma)
- ➢ TBD - Ryoko TAKUBO (Chugai Pharmaceutical)

11:15-12:15   Collaboration Session with JSQA ［Parallel Session］
How to use computerised system without support data integrity validation by SOP?

- ➢ Best practice of operation management under data-integrity guidelines - A case study using stand-alone HPLC - Yoshikazu MASAKI (Otsuka Pharmaceutical Factory)

12:30-13:30 PM   Luncheon

13:45-15:45   Application of large molecule analytical technologies to new drug development

- ➢ Utilization of LC/MS analysis on the immunogenicity research of therapeutic antibodies - Nobuo SEKIGUCHI (Chugai Pharmaceutical)
- ➢ Biotransformation evaluation of therapeutic monoclonal antibody using LC-MS - Kazuhiro KOBAYASHI (Kyowa Kirin)
- ➢ Quantitative analysis of Collategene by Q-PCR - Takao KOMATSUNO (Anges)
- ➢ Application of quantitative proteomic analysis in drug discovery research - Tomohiro ANDO (Axcelead)

16:00-17:00   Metabolite evaluation in clinical development

- ➢ Application of Tiered Metabolite Quantification Reviewed by Japan Bioanalysis Forum Discussion Group - Makoto NIWA (Nippon Shinyaku)
- ➢ Investigation of metabolites and assessment of metabolite exposure in human matrices at the clinical stage - Takahiro GOTO (Mitsubishi Tanabe Pharma)
- ➢ Tiered Approach for Assessment of Human Metabolites without Authentic Standards - Satoru KOBAYASHI (Japan Tobacco)

17:00-17:15   Closing Remarks