THE 11TH JBF SYMPOSIUM PROGRAM (as of Dec. 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 (Japan Pharmaceutical Manufacturers Association)
- 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 its evaluation as a biomarker in Mucopolysaccharidosis VII (MPSVII)
  - Julie TAYLOR (Ultragenyx)
- Biomarker assay validation - Feedback from EBF discussions on today's challenge of connecting science and regulations - Joanne GOODMAN (AstraZeneca)
- Validation of Biomarker Quantification in Japan (DG2019-44)
  - Yoshitaka HASHIMOTO (Ono Pharmaceutical)

Translation service for English to/from Japanese will be provided in the “Practical biomarker measurements in drug development” session.

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 - Mayur MITRA (Genentech)
- ADA assessment for therapeutic oligonucleotides - Hideo TAKAKUSA (Daiichi Sankyo)
- Immunogenicity assessment of gene therapies: Current and future concepts
  - Lydia MICHAUT (Bioagilytix Europe)

9:15-10:40 AM Closed Session: Let's talk to each other about bioanalysis ［Parallel Session］

Additional registration is required to attend this session.

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-WATABE and Yoshiro SAITO (National Institute of Health Sciences)
- ICH-M10: JBF Workshop Report - Proposals from JBF
  - Takeru YAMAGUCHI (Sumika Chemical Analysis Service)
- Industry (EBF) Feedback on ICH M10 draft Guideline
  - 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

Translation service for English to/from Japanese will be provided in "Anti-drug antibodies in new modality drugs" session and "ICH M10 Guideline / Draft" session.

Day 3: Thursday, 27th Feb.

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

- DG2019-40 Accuracy and precision criteria of method validation for bioequivalence studies
- 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
How can Industry Clinical Pharmacologists and Bioanalysts Work Together?

- Expectations to Bioanalysts for Each Measurement Item - Ryoko TAKUBO (Chugai Pharmaceutical)
- Analytical Issues in Clinical Studies - Risa FUKUSHI (Astellas Pharma)

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

- Overview of tiered metabolite quantification: Japan Bioanalysis Forum (JBF) 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