



THE 14TH JBF SYMPOSIUM PROGRAM

Date: Wed, 1st Mar. – Fri, 3rd Mar. 2023

Venue: Tower Hall FUNABORI (Tokyo) and Virtual meeting

Day 1: Wednesday, 1st Mar.

12:10-12:30 Opening Remarks

- Executive Committee Chair of the 14th JBF Symposium
Tomoko ARAKAWA [Pfizer R&D Japan]
- JBF Representative
Yoshiro SAITO [National Institute of Health Sciences]

12:30-14:30 Towards Implementation of the ICH M10 Guideline

- Latest Discussion in Bioanalytical Communities -

Chair: Masayo HASHIMOTO [Sumitomo Pharma Co., Ltd.]
Masanari MABUCHI [Mitsubishi Tanabe Pharma Corp.]

- Introduction and Overview of ICH M10 Guideline
[Akiko ISHII-WATABE • National Institute of Health Sciences]
- ICH M10: JBF Workshop Report
[Makoto TAKAHASHI • Japan Bioanalysis Forum (Daiichi Sankyo Co., Ltd.)]
- AAPS Feedback and Discussions Regarding ICH M10 Guidance and Implementation
[Chad BRISCOE • Celerion on behalf of AAPS]
- Feedback from the EBF Workshop on Harmonised Implementation of the ICH M10 Guideline
[Philip TIMMERMAN • European Bioanalysis Forum]

14:45-16:15 JBF-JPMA Collaboration Session

Chair: Noriyuki KOYAMA [Otsuka Pharmaceutical Co., Ltd.]
Makoto NIWA [Nippon Shinyaku Co., Ltd.]

- Questionnaire Survey on Development Strategy of Drug Concentration Analysis and Analytical Methods in Biological Samples
[Kairi NAKAMURA, Miyuki TAMURA • Non-Clinical Evaluation Expert Committee, Drug Evaluation Committee, Japan Pharmaceutical Manufacturers Association]

17:00-18:30 Electronization in Bioanalysis

Chair: Takeru YAMAGUCHI [Sumika Chemical Analysis Service, Ltd.]
Ryosuke YOSHINAGA [Toray Research Center, Inc.]

- Application of LIMS in the Field of Bioanalysis
[Kazuo TOKUDA • Chugai Pharmaceutical Co. Ltd.]
- Current Utilization Status and Future Perspective of LIMS in SNBL Bioanalysis Operations
[Katsunori IEKI • Shin Nippon Biomedical Laboratories, Ltd.]
- Digitalization and Automation for Bioanalysis [Katsutomo HATA • Shionogi & Co., Ltd.]

10:30-11:40 Basic lecture

- Basic Lecture of LC/MS on Biomarker Analysis [Koji ARAI • LSI Medience Corporation]
- Basic Lecture on Analytical Method Development for ADA in LBA
[Tatsuki NOMURA • Shin Nippon Biomedical Laboratories, Ltd.]



Day 2: Thursday, 2nd Mar.

9:00-11:00 Bioanalysis of Oligonucleotides: Various Approaches and Advancements

Chair: Yuki TAKAMATSU [Takeda Pharmaceutical Co., Ltd.]

Makoto NIWA [Nippon Shinyaku Co., Ltd.]

- A Case Study for Visualizing Oligonucleotide Therapeutics by Using Imaging Mass Spectrometry [Hiroaki AIKAWA • LSI Medience Corporation]
- Points to Note in Bioanalysis of Therapeutic Oligonucleotides by Ion-Pair LC-MS/MS [Suguru FUKUDA • Shin Nippon Biomedical Laboratories, Ltd.]
- Comparison of Bioanalytical Methods for the Oligonucleotide Therapeutics [Yoshiharu HAYASHI • CMIC Pharma Science Co., Ltd.]
- Bioanalysis of Oligonucleotides: Challenges and Solutions [Eric Thomas • Labcorp Drug Development]

11:00-12:30 Poster Presentation

- DG2022-55 Bioanalysis Using Columns Other than ODS
- DG2022-56 Lifecycle management of ligand binding assays
- DG2022-57 Digital transformation in the field of bioanalysis
- DG2022-58 Effective instruction for the bioanalyst career path

12:40-13:40 Luncheon

- Introducing Sciex's Mass Spectrometer Technology, the Next Level Quantitative/Quantitative Analysis [SCIEX]
- Extracellular Vesicles & Circulating Tumor Cells: Recent Studies on Liquid Biopsy Techniques for Biomarker Detection [Sumika Chemical Analysis Service, Ltd.]
- The Latest LC-MSMS Systems and Informatics to Achieve Reliable Bioanalysis of Middle-Molecule Drugs. [Waters]
- Application of the TimsTOF Series to Biopharmaceutical Analysis [Bruker Japan K.K.]

13:50-15:50 Bioanalysis of Biomarkers and Application to Translational Research

Chair: Junji KOMABA [Ono Pharmaceutical Co., Ltd.]

Masayo HASHIMOTO [Sumitomo Pharma Co., Ltd.]

- Development of Biomarker of Microglial Activation [Tatsuya IKEHARA • Shionogi & Co., Ltd.]
- Diversity of Biomarker Analysis - Case of qPCR, FCM and IHC - [Makoto YAMAZAKI • Mitsubishi Tanabe Pharma Corp.]
- Utilization of Sphingolipids as Translational Biomarkers [Youhei KOSUGI • Takeda Pharmaceutical Co., Ltd.]
- Strategy to Select Fit-for-Purpose Bioanalytical Methods for Successful Measurement of Translational Biomarkers [Motohiko MORIHARA • Ono Pharmaceutical Co., Ltd.]



16:05-17:05 Data Integrity

Chair: Takahiro NAKAMURA [Shin Nippon Biomedical Laboratories, Ltd.]

- Considerations When Implementing a Computerized System
-Based on the Description in the OECD GLP Data Integrity Guidance-
[Tomoharu SHIMOKAWA • Toray Research Center, Inc., Japan Society of Quality Assurance GLP Division]

16:05-17:05 t-DG (temporal DG)

Additional Registration is Required to Attend this Session

17:20-18:20 What's New in Immunogenicity Assessment

Chair: Takahiro NAKAMURA [Shin Nippon Biomedical Laboratories, Ltd.]

Tetsu SAITO [Sunplanet Co., Ltd.]

- Immunogenicity Profile of the Port Delivery System with Ranibizumab in Patients with nAMD
[Mauricio Maia • Genentech/Roche]
- Feedback from the EBF Workshop on Points to Consider on Cut Points for Immunogenicity
[Joanne Goodman • European Bioanalysis Forum]



Day 3: Friday, 3rd Mar.

9:00-10:00

Patient Centric Sampling

Chair: Makoto TAKAHASHI [Daiichi Sankyo Co., Ltd.]
Yoshiaki OHTSU [Kyowa Kirin Co., Ltd.]

- [Using Patient Centric Sampling for PK to Support COVID Oral Therapies - Method Validation, Bridging and Implementation \[Katty Wan • Pfizer\]](#)
- Empowering the Clinical Trial Subject through Self Collection of Blood Samples [Sharin ROTH • Otsuka Pharmaceutical Development & Commercialization, Inc.]

10:00-11:00

Development Strategy of Antibody-Drug Conjugates

Chair: Takahiro NAKAMURA [Shin Nippon Biomedical Laboratories, Ltd.]
Tetsu SAITO [Sunplanet Co., Ltd.]

- Bioanalytical Approaches to Evaluate in Vivo Behavior of ADCs [Hideo TAKAKUSA • Daiichi Sankyo Co., Ltd.]
- [Bioanalysis of ADC Drugs \(PADCEV, as an example\) \[Masanori NAGATA • Astellas Pharma Inc.\]](#)

11:00-12:30

Poster Presentation

12:40-13:40

Luncheon

- 1. Introduction of Thermo Scientific™ Orbitrap™ Mass Spectrometer for Quantitative Analysis.
2. The Benefits of Ion Mobility (Thermo Scientific™ FAIMS Pro Duo interface) System for Bioanalysis.
3. Seamless Output of MS Quantitative Data Reduce Repetitive Checking by Utilizing the New Report Templates for Analytical Method Validation.
[Thermo Fisher Scientific]
- Patient-Centric Sample Collection Enables Denser and More Reliable Data Collection in Clinical Trials [Tasso, Inc.]
- 1. Development of Analytical Methods for Nanomedicines Using HPLC
2. The Role of Global CRO in Drug R&D Bioanalysis
[Pharmaron Japan LLC]
- Benefit/Advantage of Conducting Clinical Sample Analysis at Labcorp Shanghai (Why Labcorp?) [Labcorp Drug Development]

13:50-15:55

Update of Public-Private Joint Research: Bioanalytical Researches on Development and Standardization of Analytical Methods for Pharmacokinetic Evaluation of Four New Modality Drugs

Chair: Yuki TAKAMATSU [Takeda Pharmaceutical Co., Ltd.]
Junji KOMABA [Ono Pharmaceutical Co., Ltd.]

- [Public-Private Joint Research on Bioanalytical Methods for Four New Modality Drugs : Objectives and Overview \[Yoshiro SAITO • National Institute of Health Sciences\]](#)
- [Development and Standardization of Bioanalytical Methods for Oligonucleotide Therapeutics \[Yuchen SUN • National Institute of Health Sciences\]](#)
- Standardization of Advanced Peptide Drug Bioanalysis: Research Concepts and Prospects [Kosuke SAITO • National Institute of Health Sciences]
- Analysis of Drug-to-Antibody Ratio Distribution of ADC in Blood Samples by Intact Mass Analysis [Noritaka HASHII • National Institute of Health Sciences]
- Development and Standardization of Methods for Measurement of Drug Concentrations in Gene Therapy Products [Yoichi TANAKA • National Institute of Health Sciences]

15:55-16:05

Closing Remarks

- Executive Committee Chair of the 15th JBF Symposium
Makoto NIWA [Nippon Shinyaku Co., Ltd.]