



# THE 15<sup>TH</sup> JBF SYMPOSIUM PROGRAM

Date: Mon, 5<sup>th</sup> Feb. – Wed, 7<sup>th</sup> Feb. 2024

Venue: Miyako Messe (Kyoto) and Virtual meeting

## **Day 1: Monday, 5<sup>th</sup> Feb.**

- 12:00-12:20 Opening Remarks (Main venue and Web / Japanese)**
- [Executive Committee Chair of the 15<sup>th</sup> JBF Symposium](#)  
Makoto NIWA [Nippon Shinyaku Co., Ltd.]
  - [JBF Representative](#)  
Yoshiro SAITO [National Institute of Health Sciences]
- 12:20-13:20 Recent Trend and Concerns on the Document-based Inspection in the Japanese New Drug Approval (Main venue and Web / Japanese)**
- Chair: Noriyuki KOYAMA [Otsuka Pharmaceutical Co., Ltd.]  
Yoshiaki OHTSU [Kyowa Kirin Co., Ltd.]
- [About the Checklist for Reliability Standard Studies](#)  
[Mutsumi SUZUKI • Non-Clinical Evaluation Expert Committee, Drug Evaluation Committee, Japan Pharmaceuticals Manufactures Association]
  - [Assurance of Study Reliability from the Perspective of Bioanalysis](#)  
[Noriyuki KOYAMA • Japan Bioanalysis Forum, Otsuka Pharmaceutical Co., Ltd.]
- 13:20-14:20 Poster / Booth Viewing (Poster & Booth Exhibition venue)**
- To facilitate efficient discussions and interactions, viewing time will be provided on the first day.
- 14:20-16:20 Method Development and Standardization for qPCR (Main venue and Web / Japanese and English)**
- Chair: Masaaki KAKEHI [Takeda Pharmaceutical Co., Ltd.]  
Yuu MORIYA [Takeda Pharmaceutical Co., Ltd.]
- [Points to Consider Document on Analytical Method Development and Validation of qPCR Methods for Nucleic Acid Biomarkers](#)  
[Yoshiro SAITO • The National Institute of Health Sciences]
  - [Understanding qPCR Bioanalysis Issues before Validation Planning \(DG2017-33\) -Update-](#)  
[Takeshi HANADA • Daiichi Sankyo Co., Ltd.]
  - [Validation of PCR Assays for Preclinical Studies with Real-World Data](#)  
[Haruka INOUE • Shin Nippon Biomedical Laboratories, Ltd.]
  - [PCR Methods for Bioanalysis in Cell and Gene Therapies](#)  
[Mikael KUBISTA • Czech Academy of Sciences and MultiD Analyses]
- 16:30-17:30 Basic Lecture (Main venue and Web / Japanese)**
- Basic lecture targeting early career scientists will be provided.
- Chair: Koji ARAI [Mediford Corporation]  
Ken-ichi YAMAMOTO [Shin Nippon Biomedical Laboratories, Ltd.]
- [Basic Course on the Development of Analytical Methods Using LC/MS/MS](#)  
[Takeshi Okuzono • Sekisui Medical Co., Ltd.]
  - [Basic Lecture on Analytical Method Development for ADA in LBA](#)  
[Tamiki Mori • Mediford Corporation]



## **Day 2: Tuesday, 6<sup>th</sup> Feb.**

**9:00-11:00**

### **Challenges in Setting Cut Points for Anti-Drug Antibody (ADA) Assays (Main venue and Web / English)**

Chair: Hiroyuki SHIMIZU [Mitsubishi Tanabe Pharma Corporation]  
Ken-ichi YAMAMOTO [Shin Nippon Biomedical Laboratories, Ltd.]

- [Practical Advice on Immunogenicity Cut-Point Evaluations and Demo of an Excel-based Tool](#)  
[Viswanath DEVANARAYAN • Eisai, Inc., and University of Illinois Chicago]
- [Establishing Appropriate Immunogenicity Assay Cut Points in Oncology Disease Indications](#)  
[Michael A PARTRIDGE • Regeneron Pharmaceuticals Inc.]

**11:10-12:10**

### **Poster Presentation (Poster & Booth Exhibition venue)**

**12:20-13:20**

### **Luncheon (Main venue, Sub venue, Luncheon C, Luncheon D / Basically Japanese, English speaker can present in English)**

- [LS2-A] Introduction to Analysis Data with 7500 System and Function of SCIEX OS Including Data Integrity (in Japanese)  
[Toshifumi TOHDA • SCIEX]
- [LS2-B] M10 Implementation and Its Impact on Method Validation  
[Luke BI • Labcorp]
- [LS2-C] “Glycoanalysis of Biopharmaceuticals” presented by CIL/Otsuka (in Japanese)  
[Izumi SAKAMOTO • GlyTech, Inc.]
- [LS2-D] A Complete Solution for Accelerating Oligonucleotide Analysis - From Preprocessing to Detection - (in Japanese)  
[Hiroko IWASAKI • Nihon Waters K.K.]

**13:40-15:10**

### **Program A: Next-generation AI Utilization in Day-to-day Operations (Main venue and Web / Japanese)**

Chair: Yoshiaki OHTSU [Kyowa Kirin Co., Ltd.]  
Makoto NIWA [Nippon Shinyaku Co., Ltd.]

- [Use of Generative AI in Creating Staff Training Materials](#)  
[Makoto NIWA • Nippon Shinyaku Co., Ltd.]
- The Use of Artificial Intelligence in Medical Publication: an Agency’s Perspective  
[Mami HIRANO • Cactus Communications]
- Providing New-age Behavior Analysis Solutions with Human Sensing Technology and LLM  
[Atom SONODA • Lightblue K.K.]

### **Program B: Career Visions of Bioanalysts (Sub venue / Japanese)**

Chair: Koji ARAI [Mediford Corporation]  
Hitoshi UCHIYAMA [Towa pharmaceutical Co., Ltd.]

- [Report of 2022-DG58 "Effective Instruction for the Bioanalyst Career Path"](#)  
[Shinsuke UCHIHASHI • Maruho Co., Ltd.]
- [Survey Results on the Career of Bioanalysts](#)  
[Eiichi SHIMADA • Japan Bioanalysis Forum, Ono Pharmaceutical Co., Ltd.]
- Panel Discussion  
Presenters / Panelists:
  - Shinsuke UCHIHASHI (Maruho Co., Ltd.)
  - Eiichi SHIMADA (Ono Pharmaceutical Co., Ltd.)
  - Yoshihisa SANO (Eisai Co., Ltd.)
  - Hideo MATSUMOTO (JAC Recruitment)



**15:20-16:20 Program A: Data Integrity / JSQA Collaboration Session (Main venue and Web / Japanese)**

Chair: Noriyuki KOYAMA [Otsuka Pharmaceutical Co., Ltd.]

- [Ensuring the Integrity of Electronic Data in Non-Clinical studies - A Case Study of Electronic Notebook Data -](#)  
[Tadahiro YOSHIYAMA • Japan Society of Quality Assurance GLP Division,  
Chugai Pharmaceutical Co., Ltd.]

**Program B: t-DG (temporal Discussion Group) (Sub venue etc. / Japanese)**

Participants will be divided into small groups to engage in discussions on topics they have selected. Additional registration is required to attend this session.

**16:30-17:30 ICH M10 Implementation Insights: Experiences and Lessons Learned from Bioanalytical Communities (1) (Main venue and Web / English and Japanese)**

Chair: Masayo HASHIMOTO [Sumitomo Pharma Co., Ltd.]  
Katsutomo HATA [Shionogi & Co., Ltd.]

- [Toward Implementation of ICH M10 Guideline](#)  
[Akiko ISHII-WATABE • National Institute of Health Sciences]
- [One Year into ICH M10: Feedback and Learnings from the Recent EBF Workshop 'Keeping the Finger on the Pulse'](#)  
[Philip TIMMERMAN • European Bioanalysis Forum]

**18:00-19:30 Banquet (Poster & Booth Exhibition venue)**



### **Day 3: Wednesday, 7<sup>th</sup> Feb.**

- 9:00-10:00 ICH M10 Implementation Insights: Experiences and Lessons Learned from Bioanalytical Communities (2) (Main venue and Web / English and Japanese)**  
Chair: Masayo HASHIMOTO [Sumitomo Pharma Co., Ltd.]  
Katsutomo HATA [Shionogi & Co., Ltd.]
- [Feedback from the JBF Workshop for ICH-M10 Guideline in 2023](#)  
[Yuki TAKAMATSU • Japan Bioanalysis Forum, Takeda Pharmaceutical Co., Ltd.]
  - [Experiences and Lessons Learned from the AAPS Bioanalytical Community One Year after the Implementation of ICH-M10](#)  
[Faye VAZVAEI • MSD]
- 10:10-11:10 Poster Presentation (Poster & Booth Exhibition venue)**
- 11:30-12:30 Luncheon (Main venue, Sub venue, Luncheon C, Luncheon D / Basically Japanese, English speaker can present in English)**
- [LS3-A] Watson LIMS for Bioanalysis Workflow and Recent DI Trends and Implementation Examples (in Japanese)  
[Takayuki MATSUNUMA • Thermo Fisher Scientific K.K.]
  - [LS3-B] Precautions and Know-how in Using Ultrapure Water for LCMS (in Japanese)  
[Yoshifumi KUROKI • ELGA LabWater]
  - [LS3-C] Reducing Timelines in Biomarker Development  
[Leonard COX • Meso Scale Diagnostics, LLC.]
  - [LS3-D] Bioanalytical Strategies and Considerations for Antibody Drug Conjugate Development  
[Lynn KAMEN • BioAgilytix]
- 12:50-14:50 Issues and Solutions for LC/MS Analysis of Peptides (Main venue and Web / Japanese)**  
Chair: Yuki TAKAMATSU [Takeda Pharmaceutical Co., Ltd.]  
Takeru YAMAGUCHI [Sumika Chemical Analysis Service, Ltd.]
- [Research in Development and Standardization of LC-MS/MS Based Peptide Bioanalysis](#)  
[Kosuke SAITO • National Institute of Health Sciences]
  - Introduction of Analytical Tips and Examples of Analysis When Quantitatively Measuring Peptides Using LC/MS  
[Chie INAGAKI • SCIEX]
  - [Various Approaches to Some Challenges in Peptides Bioanalysis](#)  
[Ryoma YAMAMOTO • Thermo Fisher Scientific K.K.]
  - [Basics of LC/MS and Tips in Peptide Analysis](#)  
[Junna NAKAZONO • Shimadzu Corporation]
- 14:50-15:10 Poster Award and Closing Remarks**
- Poster Award
  - Closing Remarks  
Executive Committee Chair of the 16<sup>th</sup> JBF Symposium  
Naohito YAMADA [Japan Tobacco Inc.]