



JBF Annual Report FY2023

(From 1st April 2023 to 31st March 2024)

1. Overview

It has been twelve and a half years since the Japan Bioanalysis Forum (JBF) was first established.

Purpose of the JBF is to facilitate discussions on regulated bioanalysis in Japan, to interact with Japanese regulators in the field, and to represent Japan in global bioanalysis communities.

Activities of JBF include the Steering Committee (SC), two memberships (corporate and supporting memberships), and JBF partners and Discussion Groups (DGs). By the end of FY2023, 25 companies and 22 companies took part in the corporate and supporting memberships, respectively.

The followings are the main activities implemented by the JBF in FY2023.

1. Held the 15th JBF symposium as a hybrid conference (both on-site and online)
2. Organized the ICH M10 Workshop
3. Participated in the AMED working groups
4. Promoted the DG activities

The 15th JBF symposium was held as a hybrid symposium with both a face-to-face conference at a venue in Kyoto and online, from 5th to 7th February 2024. The theme of the 15th JBF symposium was "Toward the New World: Science as a Universal Endeavor," symbolizing the ongoing exploration of the essence of bioanalysis, which involves the quantification of biological samples, and the continuation of scientific advancements in the past and future. Over 370 participants from pharmaceutical industries, contractors, academia, regulatory authorities, and other sectors attended the symposium. The event featured lectures and discussions on various topics, including trends in regulatory dossier assessments, development of qPCR analysis methods, ADA evaluation, data integrity, ICH M10 guideline, and LC/MS analysis of peptides. Many participants joined the symposium in person, leading to fruitful discussions.

2. Organization and Members of the Steering Committee

The SC consists of the committee members.

Twenty-nine members participated as SC members in FY 2023; 14 members from pharmaceutical companies, 8 members from CROs, 1 member from academia, 5 members from regulatory agencies, and 1 member of private consultant.

The details of the committees, task forces and SC members are listed below:

<Committees>

Finance and accounting (F&A)	Event execution
Financial auditors	Public relations
Website administration	Documentation
Membership	Discussion group (DG) promotion

<Task forces (TF)>

Biomarker	Information dissemination through publication
ICH M10 guideline handbook	ICH M10 guideline workshop 2023
Immunogenicity guideline	LC-MS educational materials

<Board & Steering committee>

Representative	Yoshiro Saito (National Institute of Health Sciences)
Advisors	Jun Haginaka (Mukogawa Women's Univ.) Haruhiro Okuda (National Institute of Health Sciences)
Honorary Advisor	Tatsuo Kurokawa (The Japan Biosimilar Association)
Deputy Representatives	Noriko Katori (National Institute of Health Sciences), Yoshiaki Ohtsu (Kyowa Kirin Co., Ltd.) Makoto Takahashi (Daiichi Sankyo Co., Ltd.)

Name	Affiliation
Koji Arai	LSI Medience Corp. (-October, 2023) Mediford Corp. (November, 2023-)
Tomoko Arakawa	Pfizer R&D Japan
Hitoshi Uchiyama	Towa Pharmaceutical Co., Ltd.
Yohei Ohashi	Kyorin Pharmaceutical Co., Ltd.
Takeshi Okuzono	Sekisui Medical Co., Ltd. (May, 2023-)
Ryosuke Ochiai	ShimadzuTechno-Research, Inc.
Noriyuki Koyama	Otsuka Pharmaceutical Co., Ltd.
Kosuke Saito	National Institute of Health Sciences
Tetsu Saito	Axcelead Drug Discovery Partners Inc.
Eiichi Shimada	Ono Pharmaceutical Co., Ltd.
Hiroyuki Shimizu	Mitsubishi Tanabe Pharma Corp.
Yuki Takamatsu	Takeda Pharmaceutical Co., Ltd.
Yumi Nishiguchi	CMIC Pharma Science Co., Ltd.
Makoto Niwa	Nippon Shinyaku Co., Ltd.
Masayo Hashimoto	Sumitomo Pharma Co., Ltd.
Katsutomo Hata	Shionogi & Co., Ltd.
Hisanori Hara	RW Bioanalysis Consulting
Takashi Miyayama	Chugai Pharmaceutical Co., Ltd.
Takeru Yamaguchi	Sumika Chemical Analysis Service, Ltd.

Name	Affiliation
Naohito Yamada	Japan Tobacco Inc.
Ken-ichi Yamamoto	Shin Nippon Biomedical Laboratories, Ltd.
Ryosuke Yoshinaga	Toray Research Center, Inc.

3. Activities of Steering Committee

JBF SC Meetings were held on a monthly basis (6th April, 8th May, 7th June, 14th July, 2nd August, 8th September, 3rd October, 10th November, and 6th December of 2023, and 12th January, 14th February, and 8th March of 2024). The minutes were finalized and shared with the SC members.

- The operational documents for SC members were updated.
- JBF has kept participating in the domestic working group for biomarker measurements in FY2023 as well.
- On 18th May 2023, the plenary assembly was held for approval of revenue and expenditure settlement of FY2022, the JBF business plan and budget of FY2023.

In addition to the details of the activities listed above, the outcomes of SC activities are described in Sections 4 to 6.

4. Task Forces and Activity of JBF

The AMED study group completed the preparation of a points to consider document for biomarker assay validation (qPCR) in English and Japanese. The summary was presented at the 15th JBF symposium in Feb 2024. The TF actively participated in the AMED study group throughout the process.

Information Dissemination by Publication TF was formed in 2022 to enhance the dissemination of information from Japan through scientific publication. After initial publication of commentary article last year, further publication plan was discussed. The TF is going to encourage presenters in the JBF symposium to disseminate their thoughts by scientific articles.

ICH M10 guideline handbook TF made the concept of the ICH M10 handbook and held a kick-off meeting with its writers. The TF planned to publish the handbook early 2025.

The ICH-M10 workshop 2023 TF was formed in July 2023 to hold a workshop which gives Japan bioanalysts a place to have discussions of the update on ICH M10 implementation made after the workshop last year. At the workshop (2nd-3rd October 2023, Yokohama), participants were limited to supporting members and corporate members, and a roundtable discussion was held in three groups (2 groups for chromatography, 1 group for LBA). 78 members participated in the workshop in total. The TF team responded to a questionnaire from EBF based on the contents discussed at the JBF workshop. The responses were introduced at the EBF workshop (November 2023) and published on the EBF website. The discussions at the JBF workshop were introduced at the 15th JBF symposium and published on the JBF website after the symposium. As a result, ICH-M10 workshop 2023 TF has completed its activities and was dissolved in February 2024.

The LC-MS Educational Materials TF was established and worked for creating a single material allows the easier access to the number of LC-MS-related information available on the Internet. The

TF focused on the materials regarding LC and MS on the websites of the equipment manufacturers (5 companies) belonging to JBF as supporting members, and created a link collection of such materials posted on their web site as of the end of July 2023. The information in the collection of links were categorized into (1) LC: from basics to applications, (2) Basics of MS and basics to applications of LC-MS, (3) troubleshooting, (4) small molecules, (5) biomarkers, (6) biotherapeutics, (7) proteins, peptides and amino acids, (8) proteomics, (9) metabolomics and lipidomics, and (10) gene therapy products and nucleic acids. TF completed its role and disbanded after launching the created collection of links on the JBF website in September 2023.

When the AMED immunogenicity guideline working group was started in 2023, the JBF immunogenicity TF was formed in an effort to make a contribution to this working group. This working group discussed immunogenicity guideline and prepared draft guideline. The TF actively participated in the AMED immunogenicity guideline working group throughout the process.

Some of the JBF members made contribution to ICH M10 study group in Japan.

5. Symposium

5.1. The 15th JBF Symposium

Due to the continued pandemic of COVID-19 at the planning phase, the 15th JBF symposium was planned as hybrid (online and in-person) conference at a spacious venue, Miyako Messe Kyoto, which enables to keep a certain physical distance. The symposium was held from 5th to 7th February 2024, hosted by the chairpersons Makoto Niwa (Nippon Shinyaku Co., Ltd.) and Tomoko Arakawa (Pfizer R&D Japan G.K.). Over 370 participants joined the symposium online or in-person during the conference.

The symposium was held under the theme of "Toward the New World – Science as a Universal Endeavor", covering a wide range of discussion topics on bioanalysis including ICH M10, qPCR, immunogenicity, peptide LC-MS, e-notebook, artificial intelligence, reliability standards, and carrier development. A total of 20 speakers from Japan, US and EU gave presentations and discussed with the audiences online and in the venue. Poster session presentations (posters submitted from general public and the outcomes of the discussion by the JBF discussion groups (DG) available on the venue) were also a great success, and two excellent posters won the award.

The conference report of the symposium was prepared by the chairpersons and accepted by the journal, *Bioanalysis*.

5.2. The 16th JBF Symposium

It was decided to hold the 16th JBF symposium from 3rd to 5th March 2025 in Hyogo. Naohito Yamada (Japan Tobacco Inc.) and Makoto Niwa (Nippon Shinyaku Co., Ltd.) will organize the symposium.

6. Publication and presentation

- Yuchen Sun, et al. "Development and validation of qPCR methods for nucleic acid biomarkers as a drug development tool: points to consider" *Bioanalysis* (2023) 15(17): 1069-1081.
- Makoto Takahashi "Bioanalyst' Discussions and Opinions on ICH M10 Guideline at 2022 JBF

Workshop” Pharmaceutical and Medical Device Regulatory Science (2024) 55 (1), 18-23

- “Feedback on General items from a recent JBF meeting on ICH M10 “ on EBF website

7. External Circumstances

- The 17th WRIB Virtual Event (19th to 23rd June 2023)
- The 16th EBF Open Symposium (15th to 17th November 2023)

JBF activities in 2023 (April 2023 to March 2024)

	Symposium/ Social meeting/ Guideline/ Publication	JBF Steering committee meeting/ JBF Organization
April 2023	<ul style="list-style-type: none"> ➤ The planning of the 15th JBF symposium ongoing ➤ The new groups of the immunogenicity TF and the LC-MS educational materials TF were established. ➤ Uploaded the following items to JBF website: <ul style="list-style-type: none"> • Updated JBF SC members • JBF Annual Report FY2021 • Posted oral presentations of the 14th JBF symposium 	<ul style="list-style-type: none"> ➤ Steering committee (SC) meeting (6th April) ➤ Implemented accounting audit ➤ Appointed to SC: Kosuke Saito, Hiroyuki Shimizu, Eiichi Shimada and Ken-ichi Yamamoto ➤ Appointed to deputy representative: Makoto Takahashi
May	<ul style="list-style-type: none"> ➤ The planning of the 15th JBF symposium ongoing ➤ Uploaded the following items to JBF website: <ul style="list-style-type: none"> • Updated oral presentations of the 14th JBF symposium 	<ul style="list-style-type: none"> ➤ SC meeting and plenary assembly (8th May) ➤ Approval of revenue and expenditure settlement of FY2022, JBF business plan and budget of FY2023 ➤ Appointed to SC: Takeshi Okuzono ➤ Recruiting members for newly established topic of DG
June	<ul style="list-style-type: none"> ➤ The planning of the 15th JBF symposium ongoing: Dedicated website of the symposium launched ➤ Uploaded the following items to JBF website: <ul style="list-style-type: none"> • Updated JBF SC members • Updated JBF business plan • Updated oral presentations of the 14th JBF symposium 	<ul style="list-style-type: none"> ➤ SC meeting (7th June) ➤ Review and finalization of JBF scope ➤ Seven new DGs launched

JBF activities in 2023 (April 2023 to March 2024)

July	<ul style="list-style-type: none"> ➤ The planning of the 15th JBF symposium ongoing ➤ Uploaded the following items JBF website: <ul style="list-style-type: none"> • Opened the 15th JBF symposium website • Announcement of ICH M10 Workshop 2023 ➤ The new group of the ICH M10 guideline workshop 2023 TF was established. 	<ul style="list-style-type: none"> ➤ SC meeting (14th July)
August	<ul style="list-style-type: none"> ➤ The planning of the 15th JBF symposium ongoing ➤ The planning of the ICH M10 guideline workshop 2023 	<ul style="list-style-type: none"> ➤ SC meeting (2nd August)
September	<ul style="list-style-type: none"> ➤ Uploaded the following items to the 15th JBF symposium website: <ul style="list-style-type: none"> • Draft program of the 15th JBF symposium • Submission of presentation posters by general public started. 	<ul style="list-style-type: none"> ➤ SC meeting (8th September)
October	<ul style="list-style-type: none"> ➤ The ICH M10 Guideline Workshop 2023 was held. ➤ The 14th JBF symposium conference report published on Bioanalysis ➤ Uploaded the following items to JBF website: <ul style="list-style-type: none"> • Publish a collection of links to educational materials about LC-MS ➤ The planning of the 15th JBF symposium ongoing ➤ The discussion on the 16th JBF symposium started 	<ul style="list-style-type: none"> ➤ SC meeting (3rd October) ➤ Hold ICH M10 Workshop (2nd and 3rd October)
November	<ul style="list-style-type: none"> ➤ Uploaded the following items to the 15th JBF symposium website: <ul style="list-style-type: none"> • The online registration for participation of the 15th JBF symposium started 	<ul style="list-style-type: none"> ➤ SC meeting (10th November) ➤ Collected concerns and questions regarding bioanalysis (6th to 20th November)
December	<ul style="list-style-type: none"> ➤ The planning of the 15th JBF symposium ongoing 	<ul style="list-style-type: none"> ➤ SC meeting (6th December)

JBF activities in 2023 (April 2023 to March 2024)

- The planning of the 16th JBF symposium ongoing
- Uploaded the following items to the 15th JBF symposium website:
 - Submission of presentation posters by general public closed (18th December)

January 2024

- Uploaded the following items to the 15th JBF symposium website:
 - The abstract of 15th JBF symposium
 - The final program of the 15th JBF symposium
- The planning of the 16th JBF symposium ongoing
- SC meeting (12th January)

February

- The 15th JBF symposium (5th to 7th February)
- The planning of the 16th JBF symposium ongoing
- Uploaded the following items to JBF website:
 - Discussion Contents from the ICH M10 Guideline Workshop 2023
- SC meeting (14th February)
- Posted the feedback on the concerns and questions regarding bioanalysis collected in November 2023 on the JBF website

March

- Uploaded the following items to the JBF website:
 - Posted oral presentations of the 15th JBF symposium
- The planning of the 16th JBF symposium ongoing
- SC meeting (8th March)
- Retired from SC: Noriko Katori, Ryosuke Ochiai, Tetsu Saito and Ryosuke Yoshinaga