



JBF Annual Report FY2018

(From 1st April 2018 to 31st March 2019)

1. Overview

It has been seven and a half years since the establishment of the Japan Bioanalysis Forum (JBF).

We aim to facilitate discussions on regulated bioanalysis in Japan, to interact with Japanese regulators in the field, and to represent Japan in worldwide bioanalysis communities.

JBF acts with the Steering Committee (SC), two memberships (corporate and supporting memberships), JBF partners and the Discussion Groups (DGs). At the end of FY2018, the corporate and supporting memberships consist of 21 companies and 18 companies, respectively.

The main JBF activities of FY2018 are as indicated below:

1. Convening the 10th JBF symposium
2. Participation in the government working groups
3. Promotion of DG activity
4. Update on BMV guidelines/guidance comparisons between MHLW, EMA and FDA

The 10th JBF symposium was held on 12th to 14th February 2019 in Yokohama in celebration of its 10th anniversary, and over 370 participants from pharmaceutical industries, contractors, academia and regulatory authorities from home and abroad came together. This symposium aimed to not only present diverse bioanalytical topics as has happened in the past but also foster collaboration with the scientists surrounding bioanalysts, according to the theme 'Open to the Public.' The symposium also included a broad range of pioneering programs, such as lectures by speakers from DMPK/metabolomics fields, discussions of future bioanalysis and poster presentations by publicly offered presenters. JBF DGs also presented their outcomes and openly discussed these with participants.

2. Organization and members of the steering committee

The SC consists of the committee members (including a GBC SC member).

The number of the SC members for FY 2018 was 29; 18 from pharmaceuticals, 6 from CROs and other industry, 2 from academia and 3 from regulatory agency.

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 >

Biomarker	Travel accommodation rule
Communication tool	

<Steering Committee Members>

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)
GBC SC	Shinobu Kudoh (Yokogawa Electric Corp.)
Deputy Representative	Noriko Katori (National Institute of Health Sciences), Masanari Mabuchi (Mitsubishi Tanabe Pharma Corp.), Yoshiaki Ohtsu (Astellas Pharma Inc.)

Name	Affiliation
Nozomu Koseki	KYORIN Pharmaceutical Co., Ltd.
Tomoko Arakawa	Pfizer Japan Inc.
Harue Igarashi	GlaxoSmithKline K. K.
Hisanori Hara	Novartis Pharma AG, Switzerland
Hitoshi Uchiyama	Towa Pharmaceutical Co., Ltd.
Jun Hosogi	Kyowa Hakko Kirin Co., Ltd.
Naoaki Murao	Chugai Pharmaceutical Co., Ltd.
Takeru Yamaguchi	Sumika Chemical Analysis Service, Ltd.
Keiko Nakai	LSI Medience Corp.
Kenji Yahata	Sanofi K.K.
Masaaki Kakehi	Takeda Pharmaceutical Co., Ltd.
Yumi Nishiguchi	CMIC Pharma Science Co., Ltd.
Makoto Takahashi	Daiichi Sankyo Co., Ltd.
Yosuke Kawai	Otsuka Pharmaceutical Co., Ltd.
Takahiro Nakamura	Shin Nippon Biomedical Laboratories, Ltd.
Yoshihisa Sano	Eisai Co., Ltd.
Yutaka Yasuda	Toray Research Center, Inc.
Akemi Nagao	Japan Tobacco Inc.
Hiroshi Kamimori	Shionogi & Co., Ltd.
Junji Komaba	Ono Pharmaceutical Co., Ltd.
Akira Nakayama	Ajinomoto Co., Inc.

3. Activities of steering committee

JBF SC Meetings were held monthly (except for February, 2019) on 12th April, 10th May, 14th June, 11th July, 10th August, 12th September, 12th October, 14th November and 14th December in 2018, and

9th January and 8th March in 2019. The minutes were finalized and distributed to the SC members.

- The operational document for SC members was updated.
- JBF has participated in the domestic working group of biomarker measurements, ICH S3A Q&A, ICH M10 (BMV) and regulatory requirements of next-generation medium-sized molecular peptide derugs.
- The communication tool TF was newly launched.

In addition to the activities above, the outcome of SC activities is described in Sections 4 to 7.

4. Task forces and activity of JBF

The AMED biomarker assay validation study group was started in 2018. The JBF Biomarker TF was formed again with expectation of contribution to the AMED study group. This year, the AMED study group decided to write a point to consider document for biomarker assay validation, defined its scope, and started discussion on details. The TF actively joined the whole process. In addition, the reference standard for protein biomarkers was discussed in the TF and the outcome (including comments for papers from US and EU) was presented as an opinion from JBF.

The communication tool TF was newly formed in FY2018 to discuss simple and basic bioanalytical issues with domestic bioanalysts. TF evaluated several communication tools, such as e-BBS, SNS and mailing list, in terms of user friendliness, cost and security. Consequently, mailing list was selected from easy-to-use, accesses limited and free communication tool. It can also divide groups by each discussion subject and was named s-DG (small/short discussion group). s-DG kick-off was announced in the closing remark of 10th JBF symposium.

The participation assist rule TF was formed in 2017 aiming to set travel expense rules when attending (mainly) overseas conferences/symposia representing JBF. The taskforce consisted of 4 SC members (Nanba [leader], Sano, Komaba, and Nakai) and exchanged opinions for more than a year, resulting in 'JBF Travel Expense Rules' made effective as of March 2019. In brief, SC or DG members could request reimbursement of travel expenses including a conference fee in full, as well as meals, transportation, and accommodation fee, and other actual expenses up to 300,000 yen, with pre-application to and approval by JBF SC.

5. Symposium

5.1. The 10th JBF Symposium

We held the 10th anniversary symposium on 12th to 14th February 2019 in Yokohama. The theme was 'Open to the Public', chaired by Yoshihisa Sano (Eisai Co., Ltd.).

At this symposium, recent trends and future challenges of metabolome analysis, update on the validation of analytical methods for biomarkers, hot topics in bioanalysis of antibody drug, utilizing endogenous biomarkers for drug-drug interaction evaluation and its bioanalytical method validation, update of ICH M10 and FDA guidance, quantitative proteotyping accelerated by reliable peptide search engine, bioanalysis of macromolecular drugs by LC/MS, advanced technology of bioanalysis in drug discovery stage were taken up as hot topics, and 28 speakers from Japan, the US, and EU gave presentations. In particular, collabo sessions with related fields such as DMPK, clinical pharmacology, quality assurance, and toxicity evaluation were memorable events of this symposium towards

breakthrough in drug development. Public offering presenters were invited to participate in the poster session for the first time, and as a result, 38 poster presentations including the outcomes of 5 diverse topics by the DG, in which daily bioanalytical issues/interests were scientifically discussed, were presented and more than 370 dedicated attendees from industry, agencies and academia openly exchanged their views on a wide range of bioanalytical issues with the poster presenters and the DG members. Topics of DGs included ‘Giving consideration to accuracy and precision criteria (2)’, ‘Quantitative analysis of oligonucleotide therapeutics by LC-MS’, ‘Automated sample preparation in LC-MS bioanalysis’, ‘Parallelism in ligand binding assay’, and ‘Failure & trouble cases and their solutions of LBA’. In addition, a big chronology panel (200 × 80 in²) was prepared and displayed in the hall of the poster sessions and the 8-year history of JBF was commemorated by participants. Among publicly offered presentations, three excellent ones were awarded by JBF. Participants also enjoyed the so-called stamp-rally: they went around the booths of the symposium sponsors and received fabulous gifts from the sponsors. Meanwhile, two basic lectures on quantitative LC–MS/MS and LBA, convened prior to the formal symposium programs, were welcomed by young scientists and new practitioners.

The conference report of the symposium was prepared under management by Yoshihisa Sano and accepted by the journal, *Bioanalysis*.

5.2. The 11st JBF Symposium

We have decided to hold the 11th JBF symposium from 25th to 27th February 2020 in Tokyo. Jun Hosogi (Kyowa Kirin Co., Ltd.) will organize the symposium.

6. Publication and presentation

6.1. Publication

- Mochizuki A., et al. "Proposal for risk-based scientific approach on full and partial validation for general changes in bioanalytical method" *Bioanalysis*, Vol. 10 No. 8, 577-586, 2018
- Saito Y., et al. "Current situation on biomarker validation in Japan." *Bioanalysis*, Vol. 10 No. 12, 901-903, 2018
- Wakamatsu A, et al. "Proposed selection strategy of surrogate matrix to quantify endogenous substances by Japan Bioanalysis Forum DG2015-15" *Bioanalysis*, Vol. 10 No. 17, 1349-1360, 2018
- Komaba J., et al. "The ninth Japan Bioanalysis Forum symposium" *Bioanalysis*, Vol. 10 No. 18, 1467-1471, 2018
- Niwa M., et al. "Evaluating exposure using confidence intervals: implication in tiered quantitation of metabolites for safety risks" *Bioanalysis*, Vol. 10 No. 19, 1553-1556, 2018
- Ohtsu Y., et al. "Biomarker assay validation for clinical trials: a questionnaire survey for the pharmaceutical companies in Japan." *Bioanalysis*, Vol. 11 No. 2, 55-60, 2019
- Igarashi H., et al. "The Japan Bioanalysis Forum (JBF): the past 8 years and future perspective" *Bioanalysis*, Vol. 11 No. 7, 611-617, 2019

6.2. Presentation

- Yoichiro Nihashi, et al.: 45th Annual Meeting of the Japanese Society of Toxicology on 18th Jul

2018 (Osaka, Japan)

- Yoshinobu Yokota: 11th EBF Open Symposium on 21st-23rd Nov 2018 (Barcelona, Spain)
- Asako Uchiyama: 11th EBF Open Symposium on 21st-23rd Nov 2018 (Barcelona, Spain)
- Yoshiaki Ohtsu: 11th EBF Open Symposium on 21st-23rd Nov 2018 (Barcelona, Spain)

7. External Circumstances

- The BMV guidance was finalized and issued by FDA (May 2018).
- The 11th EBF Open Symposium was held (21st-23rd Nov 2018, in Barcelona).
- The ADA assay guidance was finalized and issued by FDA (Jan 2019).
- The draft ICH M10 (Step 2b) was published on ICH web site (Feb 2019).
- The ICH S3A Q&A document (Japanese version) was published by MHLW (15th Mar 2019).

JBF activities in 2018(April 2018 to March 2019)

	Symposium/ Social meeting/ Guideline/ Publication	JBF Steering committee meeting/ JBF Organization
April 2018	<ul style="list-style-type: none"> ➤ The planning of the 10th JBF symposium ongoing ➤ Publication: Ayumi Mochizuki, et al.: “Proposal for risk-based scientific approach on full and partial validation for general changes in bioanalytical method” <i>Bioanalysis</i>, Vol. 10 No. 8, 577-586, 2018 	<ul style="list-style-type: none"> ➤ Steering committee (SC) meeting (12th April) ➤ JBF Biomarker TF was formed.
May	<ul style="list-style-type: none"> ➤ FDA: “Bioanalytical Method Validation Guidance for Industry” was issued (12th May 2018) 	<ul style="list-style-type: none"> ➤ SC meeting and plenary assembly (10th May) ➤ Recruiting of DG members started ➤ Approval of revenue and expenditure settlement of FY2017, JBF business plan and budget of FY2018
June	<ul style="list-style-type: none"> ➤ Publication: Yoshiro Saito, Noriko Katori, and Yoshiaki Ohtsu. "Current situation on biomarker validation in Japan." <i>Bioanalysis</i> 10(12) 901-903, 2018 	<ul style="list-style-type: none"> ➤ SC meeting (14th June)
July	<ul style="list-style-type: none"> ➤ Presentation Yoichiro Nishashi, et al.: 45th Annual Meeting of the Japanese Society of Toxicology on 18th Jul 2018 (Osaka, Japan) 	<ul style="list-style-type: none"> ➤ SC meeting (11th July)
August	N/A	<ul style="list-style-type: none"> ➤ SC meeting (10th August) ➤ The comparison table between FDA guidance, MHLW guideline and EMA guideline has been revised.

September	<ul style="list-style-type: none"> ➤ Publication: Akira Wakamatsu, et al: “Proposed selection strategy of surrogate matrix to quantify endogenous substances by Japan Bioanalysis Forum DG2015-15” <i>Bioanalysis</i>, Vol. 10 No. 17, 1349-1360, 2018 Junji Komaba, et al: “The ninth Japan Bioanalysis Forum symposium” <i>Bioanalysis</i>, Vol. 10 No. 18, 1467-1471, 2018 	<ul style="list-style-type: none"> ➤ SC meeting (12th September)
October	<ul style="list-style-type: none"> ➤ Publication: Makoto Niwa, et al: “Evaluating exposure using confidence intervals: implication in tiered quantitation of metabolites for safety risks.” <i>Bioanalysis</i>, Vol. 10 No. 19, 1553-1556, 2018 	<ul style="list-style-type: none"> ➤ SC meeting (12th October) ➤ The communication tool TF was formed.
November	<ul style="list-style-type: none"> ➤ Upload to JBF website: 1st draft program and link to the online registration for participation of the 10th JBF symposium ➤ Presentation Yoshinobu Yokota, Yoshiaki Ohtsu, Asako Uchiyama: 11th EBF Open Symposium on 21st-23rd Nov 2018 (Barcelona, Spain) 	<ul style="list-style-type: none"> ➤ SC meeting (14th November)
December	<ul style="list-style-type: none"> ➤ Upload to JBF website: 2nd draft program of the 10th JBF symposium 	<ul style="list-style-type: none"> ➤ SC meeting (14th December) ➤ Draft JBF business plan of FY2019 finalized
January 2019	<ul style="list-style-type: none"> ➤ Upload to JBF website: Draft Abstracts of the 10th JBF symposium Draft JBF business plan of FY2019 	<ul style="list-style-type: none"> ➤ SC meeting (9th January)

	<ul style="list-style-type: none"> ➤ Publication: Yoshiaki Ohtsu, et al: "Biomarker assay validation for clinical trials: a questionnaire survey for the pharmaceutical companies in Japan" <i>Bioanalysis</i>, Vol. 11 No. 2, 55-60, 2019 	
February	<ul style="list-style-type: none"> ➤ Upload to JBF website: N/A Final draft program and abstracts of the 10th JBF symposium ➤ The 10th JBF symposium (12th to 14th February, Yokohama, Japan) ➤ Closed meeting among the DG members 	
March	<ul style="list-style-type: none"> ➤ Upload to JBF website: Presentation slide on the 10th JBF symposium ➤ Publication: Igarashi H. et al. " The Japan Bioanalysis Forum (JBF): the past 8 years and future perspective" <i>Bioanalysis</i>, Vol. 11 No. 7, 611-617, 2019 	<ul style="list-style-type: none"> ➤ SC meeting (8th March)