



JBF Annual Report FY2017

(From 1st April 2017 to 31st March 2018)

1. Overview

It has been six 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 FY2017, the corporate and supporting memberships are consisted of 20 companies and 18 companies, respectively.

The main JBF activities of FY2017 are as indicated below:

1. Holding the 9th JBF symposium
2. Participation in the government working groups for regulated bioanalysis of large molecules using MS (LM-MS) and biomarkers
3. Promotion of DG activity

The 9th JBF symposium was held from February 6th to 8th, 2018 in Tokyo. This symposium presented diverse topics as follows by inviting speakers from Japan, the US, and EU: microsampling in nonclinical toxicity studies, sample preparation automation for bioanalysis, perspectives on ICH M10 bioanalytical method validation guideline, recent progress of anti-drug antibodies analysis, bioanalysis of therapeutic antibodies by LC/MS and LBA, validation for quantitative analysis using flow cytometry, Luminex, and qPCR and biomarker measurement and its application to clinical diagnosis. JBF DGs also presented their outcomes and openly discussed these with more than 260 scientists from industry, regulatory agencies and academia.

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 2017 was 27; 16 from pharmaceuticals, 6 from CROs and other industry, 1 from academia and 4 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>

Large molecule LC/MS	Biomarker
Financial strategy	--

<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
Harue Igarashi	GlaxoSmithKline K. K.
Hisanori Hara	Novartis Pharma AG, Switzerland
Hitoshi Uchiyama	Towa Pharmaceutical Co., Ltd.
Jun Hosogi	Kyowa Hakko Kirin Co., Ltd.
Eitaro Nanba	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.
Toshio Teramura	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 in 2018). The dates in 2017 were April 6th, May 9th, June 6th, July 5th, August 1st, September 14th, October 12th, November 9th and December 14th, and the dates for 2018 were January 11th and March 8th. The minutes were finalized and distributed to the SC members.

- The operational document for SC members was updated.
- JBF cooperated with the working group for large molecule analysis based on LC-MS and for biomarker measurements following the previous year.
- JBF has participated in the domestic working group of the ICH S3A Q&A and M10 (BMV).
- The financial strategy 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 BMV study group granted by AMED collaborated with JBF in order to provide documents to ensure the reliability of large molecule analysis based on LC-MS and of biomarker measurements, which are not covered with the existing guidelines.

The LM-LC/MS TF (formed in FY2013) was reorganized in 2016 requested by the BMV study group. The TF discussed topics that are specific to the bioanalysis of therapeutic antibodies by LC/MS to prepare a document which involves strategies for the development of LC/MS methods and suggestions for method validation. The document was submitted to *CHROMATOGRAPHY*, which is a journal published by The Society of Chromatographic Science and was published in February 2018. The activity of LM-LC/MS TF finished this fiscal year and dissolved on March 2018.

The biomarker TF (formed in FY2014) worked with the biomarker working group, formed in the BMV study group, and contributed to develop some sort of “white paper”, which provides an effective strategy of biomarker assay development and analysis, using a survey result of Japanese industries. In 2017, the TF greatly contributed to a publication entitled “Current situation on biomarker validation in Japan” in *Bioanalysis* to introduce a standpoint on biomarker assay from JBF TF’s perspective and encourage stakeholders to make an effort on harmonization on recommendation of biomarker assay validation and study sample analysis. The TF also played a major role to conduct the survey with the biomarker working group. The result of the survey was analyzed and will be publicized in the near future. The activity of biomarker TF also finished this fiscal year and dissolved on March 2018.

The financial strategy TF was newly formed in FY2017 to promote efficient use of income as an internal activity of JBF. This TF proposed a strategy with some practical actions. This TF dissolved in March 2018 and implementation of the strategy was taken over by Membership committee and Event execution committee.

5. Symposium

5.1. The 9th JBF Symposium

We held the 9th symposium on February 6th to 8th, 2018 in Tokyo. The theme was ‘Bioanalysis: Deeper and Broader’, chaired by Junji Komaba (Ono Pharmaceutical Co., Ltd.).

At this symposium, microsampling in nonclinical toxicity studies, sample preparation automation for bioanalysis, perspectives on ICH M10 bioanalytical method validation guideline, recent progress of anti-drug antibodies analysis, bioanalysis of therapeutic antibodies by LC/MS and LBA, validation for quantitative analysis using flow cytometry, Luminex, and qPCR and biomarker measurement and its application to clinical diagnosis were taken up as hot topics, and 23 speakers from Japan, the US,

and EU gave presentations. In addition, 11 poster presentations including the outcomes of 7 diverse topics by the DG, in which daily bioanalytical issues/interests were scientifically discussed, were presented and more than 260 dedicated attendees from industry, agencies and academia openly exchanged their views on a wide range of bioanalytical issues with the DG members. Topics included, ‘Giving consideration to accuracy and precision criteria’, ‘Microsampling (3) – Proposals for planning and method -’, ‘Application of imaging mass spectrometry to drug discovery research’, ‘Quantitative analysis of endogenous large molecule substances by LC-MS’, ‘Automated sample preparation in regulated LC-MS bioanalysis’, ‘Considerations for designing validation for quantitative analysis using qPCR’, and ‘Ligand binding assay using commercial immunoassay kits’.

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

5.2. The 10th JBF Symposium

We have decided to hold the 10th JBF symposium in 2019 from February 12th to 14th in Yokohama (as a memorial symposium). Yoshihisa Sano (Eisai Co., Ltd.) will organize the symposium.

6. Publication and presentation

6.1. Publication

Nozomu Koseki, et al.: “Giving Consideration to Scientific Validation in Japanese Drug Application by Japan Bioanalysis Forum Discussion Group.” *Bioanalysis*, Vol. 9 No. 13, 963-968, 2017

Takehisa, Matsumaru: “The 8th Japan Bioanalysis Forum symposium.” *Bioanalysis*, Vol. 9 No. 22, 1733-1737, 2017

Noboru Tanaka, et al.: “Overview of Topics and Issues for Anti-Drug Antibody Assay in Drug Development” *Pharmaceutical and medical device regulatory science*, Vol. 48 No. 5, 282-291, 2017

Noritaka Hashii, et al.: “Bioanalytical Quantification of Therapeutic Antibodies by Liquid Chromatography/mass Spectrometry (Japanese)” *Chromatography*, Vol. 39 No. 1, 7-19, 2018

6.2. Presentation

Takumi Noda: 85th Hokuriku-area Colloquium / Lecture Meeting on 17 Jun 2017 (Fukui, Japan)

Kozo Omichi, et al.*: 44th Annual Meeting of the Japanese Society of Toxicology on 10 -12 Jul 2017 (Yokohama, Japan)

Katsunori Ieki: 30th Symposium on Biomedical-Analytical Sciences on 28-29 Aug 2017 (Tokyo, Japan)

Nozomu Koseki: 30th Symposium on Biomedical-Analytical Sciences on 28-29 Aug 2017 (Tokyo, Japan)

Yoshiaki Ohtsu: AAPS/EBF/JBF joint ICH M10 Workshop on 13-15 Sep 2017 (Weehauken, NJ, USA)

Hisanori Hara: AAPS/EBF/JBF joint ICH M10 Workshop on 24-26 Sep 2017 (Lisbon, Portugal)

Masanari Mabuchi: 10th EBF Open Symposium on 15-17 Nov 2017 (Barcelona, Spain)

Yoichiro Nihashi, et al.*: 10th EBF Open Symposium on 15-17 Nov 2017 (Barcelona, Spain)

Yutaka Yasuda, et al.*: 32nd JSSX Annual Meeting on 29 Nov -1 Dec 2017 (Tokyo, Japan)

Yukari Tanaka, et al.*: 32nd JSSX Annual Meeting on 29 Nov -1 Dec 2017 (Tokyo, Japan)

*: Poster

7. External Circumstances

- The Workshop for the ICH M10 was held by AAPS (13-15 Sep 2017, at Weehawken, NJ).
- The Focus Workshop for the ICH M10 was held by EBF (24-26 Sep 2017, in Lisbon).
- The draft ICH S3A Q&A document reached Step 4 of the ICH process, and the final draft was recommended for adoption to the regulatory bodies of ICH regions (16 Nov 2017). The Q&A translated in Japanese and answer document for public comments are being prepared by the regulatory parties.

JBF activities in 2017(April 2017 to March 2018)

	Symposium/ Social meeting/ Guideline/ Publication	JBF Steering committee meeting/ JBF Organization
April 2017	<ul style="list-style-type: none"> ➤ The planning of the 9th JBF symposium ongoing ➤ The planning of the 10th JBF symposium initiated 	<ul style="list-style-type: none"> ➤ Steering committee (SC) meeting (6th April) ➤ LM-LC/MS TF prepared draft document (in Japanese)
May	<ul style="list-style-type: none"> ➤ The organizer and the outline of the 9th JBF symposium decided ➤ EMEA: “Guideline on Immunogenicity assessment of therapeutic proteins” was issued (18th May 2017) 	<ul style="list-style-type: none"> ➤ SC meeting (9th May) ➤ Seven discussion groups were launched, and recruiting of DG members started ➤ The operational document for SC members released
June	<ul style="list-style-type: none"> ➤ Publication: Noboru Tanaka, et al.: “Overview of Topics and Issues for Anti-Drug Antibody Assay in Drug Development” <i>Pharmaceutical and medical device regulatory science</i>, Vol. 48 No. 5, 282-291, 2017 ➤ Presentation: Takumi Noda: 85th Hokuriku-area Colloquium / Lecture Meeting (17 Jun 2017, Fukui, Japan) 	<ul style="list-style-type: none"> ➤ SC meeting and plenary assembly (6th June) ➤ Approval of revenue and expenditure settlement of FY2016, JBF business plan and budget of FY2017

JBF activities in 2017(April 2017 to March 2018)

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| July | <ul style="list-style-type: none"> ➤ Working group for biomarker granted by MHLW conducted the survey on bioanalysis for biomarker through Japan Pharmaceutical Manufacturers Association ➤ Publication:
Nozomu Koseki, et al.: “Giving Consideration to Scientific Validation in Japanese Drug Application by Japan Bioanalysis Forum Discussion Group.” <i>Bioanalysis</i>, Vol. 9 No. 13, 963-968, 2017 ➤ Poster Presentation:
Kozo Omichi, et al: 44th Annual Meeting of the Japanese Society of Toxicology on 10 -12 Jul 2017 (Yokohama, Japan) | <ul style="list-style-type: none"> ➤ SC meeting (5th July) |
| August | <ul style="list-style-type: none"> ➤ Presentation:
Katsunori Ieki: 30th Symposium on Biomedical-Analytical Sciences on 28-29 Aug 2017 (Tokyo, Japan)
Nozomu Koseki: 30th Symposium on Biomedical-Analytical Sciences on 28-29 Aug 2017 (Tokyo, Japan) | <ul style="list-style-type: none"> ➤ SC meeting (1st August) |
| September | <ul style="list-style-type: none"> ➤ Presentation:
Yoshiaki Ohtsu: AAPS/EBF/JBF joint ICH M10 Workshop on 13-15 Sep 2017 (Weehauken, NJ, USA)
Hisanori Hara: AAPS/EBF/JBF joint ICH M10 Workshop on 24-26 Sep 2017 (Lisbon, Portugal) | <ul style="list-style-type: none"> ➤ SC meeting (14th September) ➤ The financial strategy TF was formed |

JBF activities in 2017(April 2017 to March 2018)

October		➤ SC meeting (12 th October)
November	<ul style="list-style-type: none"> ➤ Publication: Takehisa, Matsumaru: “The 8th Japan Bioanalysis Forum symposium.” <i>Bioanalysis</i>, Vol. 9 No. 22, 1733-1737, 2017 ➤ Presentation Masanari Mabuchi: 10th EBF Open Symposium on 15-17 Nov 2017 (Barcelona, Spain) ➤ Poster: Yoichiro Nihashi, et al.: 10th EBF Open Symposium on 15-17 Nov 2017 (Barcelona, Spain) Yutaka Yasuda, et al.: 32nd JSSX Annual Meeting on 29 Nov -1 Dec 2017 (Tokyo, Japan) Yukari Tanaka, et al.: 32nd JSSX Annual Meeting on 29 Nov -1 Dec 2017 (Tokyo, Japan) 	➤ SC meeting (9 th November)
December	<ul style="list-style-type: none"> ➤ Upload to JBF website: 1st draft program, abstracts and link to the online registration for participation of the 9th JBF symposium JBF Annual Report FY2016 	➤ SC meeting (14 th December)
January 2018	<ul style="list-style-type: none"> ➤ Publication: contribution of LM-LC/MS TF Noritaka Hashii, et al.: “Bioanalytical Quantification of Therapeutic Antibodies by Liquid Chromatography/mass Spectrometry (Japanese)” <i>Chromatography</i>, Vol. 39 No. 1, 	<ul style="list-style-type: none"> ➤ SC meeting (11th January) ➤ Draft JBF business plan of FY2018 finalized

JBF activities in 2017(April 2017 to March 2018)

7-19, 2018

- Upload to JBF website:
2nd draft program and abstracts of the 9th JBF symposium

February

- The 9th JBF symposium (6th to 8th February, Tokyo, Japan)
- Closed meeting with foreign guests (EBF and AAPS) on the 9th JBF symposium
- Closed meeting among the DG members
- The questionnaire for the 9th JBF symposium was conducted with participants
- Upload to JBF website:
Recruitment for corporate member and supporting member of JBF

March

- Upload to JBF website:
Presentation slide on the 9th JBF symposium
Notice of the 10th JBF symposium and recruitment of participants for general presentation
- The organizer and the outline of the 10th JBF symposium decided
- SC meeting (8th March)
- JBF Biomarker TF and LM-LC/MS TF have dissolved in March 2018
- New JBF Biomarker TF planning