



JBF Annual Report FY2016

(From 1st April 2016 to 31st March 2017)

1. Overview

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

We aim to facilitate a discussion 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 Group (DG). At the end of FY2016, the corporate and supporting memberships are consisted of 19 companies and 17 companies, respectively.

The main JBF activities of FY2016 are as indicated below:

1. Holding of 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 8th JBF symposium was held on February 8th and 9th, 2017 in Tokyo. This symposium presented the challenges regarding immunogenicity of biopharmaceuticals, ICH S3A Q&A on microsampling, ICH M10 bioanalytical method validation, large molecule analysis by liquid chromatography-mass spectrometry (LC-MS), audit activities for bioanalysis and biomarker bioanalysis by inviting speakers from Japan, the US, and EU. JBF DGs also presented their outcomes and openly discussed these with more than 300 scientists from industry, regulatory agencies and academia.

2. Organization and members of steering committee

The SC consists of the committee members, GBC SC members and the TF members.

The number of the SC members for FY 2016 was 28; 15 from pharmaceuticals, 7 from CROs, 3 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>

Large molecule LC/MS	Biomarker
Incorporation	--

<Steering Committee Members>

Representative	Haruhiro Okuda (National Institute of Health Sciences) (-Sep, 2016) Yoshiro Saito (National Institute of Health Sciences) (Sep, 2016-)
Advisors	Jun Haginaka (Mukogawa Women's Univ.) Tsutomu Masujima (RIKEN) Tatsuo Kurokawa (Japan Self-Medication Industry) (-Sep, 2016) Haruhiro Okuda (National Institute of Health Sciences) (Sep, 2016-)
Honorary Advisor	Tatsuo Kurokawa (Japan Self-Medication Industry) (Sep, 2016-)
GBC SC	Shinobu Kudoh (Shimadzu Techno Research, Inc.)
Deputy Representative	Noriko Katori (National Institute of Health Sciences), Masanari Mabuchi (Mitsubishi Tanabe Pharma Co.), 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 Co.
Kenji Yahata	Sanofi K.K.
Masaaki Kakehi	Takeda Pharmaceutical Company Ltd.
Toshio Teramura	CMIC Pharma Science Co., Ltd.
Makoto Takahashi	Daiichi Sankyo Co., Ltd.
Takehisa Matsumaru	Otsuka Pharmaceutical Co., Ltd.
Takahiro Nakamura	Shin Nippon Biomedical Laboratories, Ltd.
Yoshihisa Sano	Eisai Co., Ltd./Sunplanet Co., Ltd.
Kazuhiro Takegami	Toray Research Center, Inc.
Yoshiyuki Minamide	Shimadzu Techno-Research, Inc.
Akemi Nagao	Japan Tobacco Inc.
Hiroshi Kamimori	Shionogi & Co., Ltd.
Junji Komaba	Ono Pharmaceutical Co., Ltd.

3. Activities of steering committee

JBF SC Meetings were held monthly (except for July and February). The dates in 2016 were April 4th, May 12th, June 9th, August 4th, September 8th, October 6th, November 10th and December 8th, and

the dates for 2017 were January 12th and March 9th. The minutes were finalized and distributed to the SC members.

- The operational document for SC members was updated.
- JBF cooperated with the documents for large molecule analysis based on LC-MS and for biomarker measurements following the previous year.
- JBF has participated in the implementation working group of the ICH to develop a S3A Q&A document.
- As the expectation on ICH M10 (BMV), SC members discussed what items should be harmonized, and presented them at the 8th JBF symposium.
- The Incorporation 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. Large molecule (LM)-LC/MS TF and biomarker TF were formed in FY2013 and FY 2014, respectively. The activities of these TFs are still ongoing.

On the other hand, as an internal activity of JBF, the incorporation TF was newly launched in FY2016.

The LM-LC/MS TF (formed in FY2013) was reorganized in 2016 requested by the BMV study group. The TF discussed topics specific to the bioanalysis of therapeutic antibodies by LC-MS to prepare the document which include the strategies for the development of LM-LC/MS method and the suggestions for the method validation.

The biomarker TF (formed in FY2014) worked with Biomarker working group, formed in the BMV study group, and contributed to develop some sort of “white paper”, which hopefully provides the effective strategy of biomarker assay development and analysis, using a survey result of Japanese industries. In 2016, TF played a major role to generate the draft survey with biomarker working group.

The Incorporation TF (formed in FY2016) was formed for the discussion and execution of acquiring the corporation number and included the corporation of JBF. It was concluded that the corporation number is necessary for taxes and JBF accounts. JBF acquired the “Corporation Number” in Jan 2017 and paid the tax for profit-earning business in consultation with an accounting firm. On the other hand, JBF decided not to be a corporation at the present time because JBF organization is not mature, and to work on arranging a system and operation allowed for corporate response in the future. This TF has dissolved on March 2017.

5. Symposium

5.1. The 8th JBF Symposium

The 8th JBF symposium was chaired by Takehisa Matsumaru (Otsuka Pharmaceutical Co., Ltd).

At this symposium, immunogenicity of biopharmaceuticals, ICH S3A Q&A on microsampling, ICH M10 bioanalytical method validation, large molecule analysis by liquid chromatography-mass

spectrometry (LC-MS), audit activities for bioanalysis and biomarker bioanalysis were taken up as hot topics, and 24 speakers from Japan, the US, and EU gave presentations. In addition, the outcomes of eight diverse topics by the DG, in which daily bioanalytical issues/interests were scientifically discussed, were presented and more than 300 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 scientific validation (2)', 'Microsampling (2) - investigation of technical problems -', 'Application of imaging mass spectrometry to drug discovery research', 'The Pharma-CRO relationship with a focus on method transfer', 'Questions and challenges in bioanalysis - Find the Loadstar (Stability) -', 'Quantitative analysis of endogenous substance (LC-MS) - surrogate analyte & large molecule endogenous substance -', 'Quantitative analysis of endogenous substances (LBA) - validation of LBA for the analysis of endogenous substances -' and 'Quantitative analysis of endogenous substance - other analytical methods for endogenous substances: flow cytometry, luminex, and PCR -'.

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

5.2. The 9th JBF Symposium

We have decided to hold the 9th JBF symposium in 2018 on February 6th and 8th in Tokyo. Junji Komaba (Ono Pharmaceutical Co., Ltd.) will organize the symposium.

6. Publication and presentation

6.1. Publication

Takahiro Nakamura: *Bioanalysis*, Vol. 8 No. 20, 2097-2102, 2016

Noboru, Tanaka, et al. "Overview of Topics and Issues for Anti-Drug Antibody Assay in Drug Development." *Pharmaceutical and medical device regulatory science*, 48(5), 282-291, 2017

6.2. Presentation

Eitaro Nanba, et al.: 43rd JSOT Annual Meeting on 29 Jun-1 Jul 2016 (Nagoya, Japan)

Eitaro Nanba: 31st JSSX Annual Meeting on 13-15 Oct 2016 (Matsumoto, Japan)

Junji Komaba: AAPS Annual Meeting and Exposition on 13-17 Nov 2016 (Denver, CO, USA)

Yoshiaki Ohtsu: 9th EBF Open Symposium on 16-18 Nov 2016 (Barcelona, Spain)

Harue Igarashi, et al.*: 9th EBF Open Symposium on 16-18 Nov 2016 (Barcelona, Spain)

Akira Wakamatsu, et al.*: 9th EBF Open Symposium on 16-18 Nov 2016 (Barcelona, Spain)

*: Poster

7. External Circumstances

- The draft ICH S3A Q&A document reaches Step 3 of the ICH process.
- The concept paper and business plan of ICH M10 (BMV) are uploaded.
- FDA MIST guidance was revised on November 2016.
- The outcomes of 10th WRIB, the white papers on recent issues in bioanalysis: focus on biomarker assay validation (BAV) (Part 1 to 3) were published in *Bioanalysis*, Vol. 8 No. 22 and 23.

JBF activities in 2016(April 2016 to March 2017)

	Symposium/ Social meeting/ Guideline/ Publication	JBF Steering committee meeting/ JBF Organization
April 2016	<ul style="list-style-type: none"> ➤ Notification by MHLW: Briefing session on draft ICH S3A Q&A document held next month (30th May) ➤ The organizer and the outline of the 6th JBF symposium decided 	<ul style="list-style-type: none"> ➤ Steering committee (SC) meeting (7th April) ➤ The membership regulations of JBF revised
May	<ul style="list-style-type: none"> ➤ Notification by MHLW: Briefing session on draft ICH S3A Q&A document held 	<ul style="list-style-type: none"> ➤ SC meeting (12th May) ➤ Eight new topics and the leaders of FY2016 DGs decided ➤ For 2 DGs, recruiting DG members started
June	<ul style="list-style-type: none"> ➤ Notification by MHLW: Public comments for draft ICH S3A Q&A document recruited ➤ The ICH endorsed a new topic on the validation of bioanalytical methods and study sample analyses in non-clinical and clinical studies. ➤ Presentation: Nanba Eitaro: 43rd JSOT Annual Meeting (29th June-1st July, Nagoya, Japan) 	<ul style="list-style-type: none"> ➤ SC meeting and plenary assembly (9th June) ➤ Approval of income and expenditure settlement of FY2015, JBF business plan and budget of FY2016 ➤ The operational document for SC members released ➤ For 6 DGs, recruiting DG members started

JBF activities in 2016(April 2016 to March 2017)

July	<ul style="list-style-type: none"> ➤ Notification by MHLW: Public comments for draft ICH S3A Q&A document shut up recruitment ➤ The meeting of the AMED/BMV study group granted by MHLW held (6th July, Tokyo, Japan) ➤ Conference report of the 7th JBF symposium accepted by Bioanalysis 	
August	<ul style="list-style-type: none"> ➤ Publication: Workshop Report: Crystal City VI—Bioanalytical Method Validation for Biomarkers in <i>the AAPS journal</i>, Vol. 18 No. 6, 1366-1372, 2016 ➤ Draft concept paper of bioanalysis of the large molecule MS by Large molecule MS TF preparing (until April, 2017) 	<ul style="list-style-type: none"> ➤ SC meeting (4th August)
September	<ul style="list-style-type: none"> ➤ Publication: Nakamura Takahiro: <i>Bioanalysis</i>, Vol. 8 No. 20, 2097-2102, 2016 	<ul style="list-style-type: none"> ➤ Change of representative of JBF From Haruhiro Okuda to Yoshiro Saito ➤ Inauguration of advisor and honorary advisor of JBF Advisor: Haruhiro Okuda Honorary advisor: Tatsuo Kurokawa ➤ SC meeting (8th September) ➤ JBF Biomarker TF

JBF activities in 2016(April 2016 to March 2017)

October	<ul style="list-style-type: none"> ➤ Presentation: Nanba Eitaro: 31st JSSX Annual Meeting (13th-15th October 2016, Matsumoto, Japan) ➤ Draft questionnaire prepared by JBF Biomarker TF discussed by working group for biomarker granted by MHLW 	<ul style="list-style-type: none"> ➤ SC meeting (6th October) ➤ Draft questionnaire prepared by JBF Biomarker TF
November	<ul style="list-style-type: none"> ➤ Presentation Junji Komaba: AAPS Annual Meeting and Exposition (13th-17th November 2016, Denver, CO, USA) Yoshiaki Ohtsu: the 9th EBF Open Symposium (16th-18th November 2016, Barcelona, Spain) ➤ Poster: Harue Igarashi et al.: 9th EBF Open Symposium (16th-18th Nov 2016, Barcelona, Spain) Akira Wakamatsu et al.: 9th EBF Open Symposium (16th-18th Nov 2016, Barcelona, Spain) 	<ul style="list-style-type: none"> ➤ SC meeting (10th November) ➤ Draft questionnaire by JBF Biomarker TF preparing
December	<ul style="list-style-type: none"> ➤ Working group for biomarker granted by MHLW discussed final draft questionnaire ➤ Upload to JBF website: 1st draft program and link to the online registration for participation of the 8th JBF symposium 	<ul style="list-style-type: none"> ➤ SC meeting (8th December) ➤ Draft JBF business plan of FY2017 finalized

JBF activities in 2016(April 2016 to March 2017)

January 2017	<ul style="list-style-type: none"> ➤ Upload to JBF website: Abstracts and 2nd draft program of the 8th JBF symposium ➤ The organizer and the outline of the 9th JBF symposium decided 	<ul style="list-style-type: none"> ➤ SC meeting (12th January) ➤ JBF acquired the “Corporation Number”
February	<ul style="list-style-type: none"> ➤ Upload to JBF website: Final version of abstracts and program of the 8th JBF symposium ➤ The 8th JBF symposium (8th and 9th February, Tokyo, Japan) ➤ Closed meeting with the foreign guests (EBF and AAPS) on the 8th JBF symposium ➤ Closed meeting among the DG members 	<ul style="list-style-type: none"> ➤ Upload to JBF website: Draft JBF business plan of FY2017 and recruitment for corporate member and supporting member of JBF
March	<ul style="list-style-type: none"> ➤ Upload to JBF website: Presentation slide on the 8th JBF symposium ➤ The meeting of the AMED/BMV study group granted by MHLW held (1st March, Tokyo, Japan) 	<ul style="list-style-type: none"> ➤ SC meeting (9th March)