JBF Annual Report FY2013

(From 1st April 2013 to 31st March 2014)

1. Overview

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

We aim to facilitate a discussion on regulated bioanalysis in Japan, to interact with Japanese regulators in the field of bioanalysis, and to represent Japan in worldwide bioanalysis community.

JBF acts with the Steering Committee (SC), two memberships (corporate and supporting memberships), JBF partner, Discussion Group (DG), and GBC Harmonization Teams (HT) members/supporter community about broad topics of interest in bioanalysis field. At the end of FY2013, the corporate and supporting memberships are 16 and 15 companies, respectively.

Main JBF activities of FY2013 are as indicated below.

1. Holding of JBF symposium
2. Contribution to preparation of bioanalytical method validation (BMV) guideline for Ligand Binding Assay (LBA)
3. Participation in a government working group for regulated bioanalysis of large molecules using LC/MS
4. Comparison of BMV guideline/guidance among Japanese Ministry of Health, Labour and Welfare (MHLW), EMA and FDA in terms of chromatographic assays
5. Promotion of DG activity

JBF symposium has been held twice in FY2013.

The 4th JBF symposium was held on 2nd August 2013 in Tokyo with the theme, 'Current status of Japanese guidelines on bioanalytical method validation and the latest activities of discussion group within the Japanese bioanalyst community'. At this symposium, the outline of the MHLW LC guideline, which was just published in July 2013, and that of the JBF draft version of Japanese LBA guideline, were presented. In addition, the outcomes of discussion on three typical bioanalysis issues were introduced to the attendees as newly started JBF DGs, and the entries to the members/supporters of upcoming DGs were called for.

The 5th JBF symposium was held on 6th and 7th March 2014 in Tokyo with the theme, 'Bridging for a Global Harmonization'. At this symposium, distinguished bioanalytical scientists from government and industry commentated on the BMV guidelines/guidance issued by their own regions including the draft MHLW LBA guideline. Comparison of BMV guideline/guidance (chromatographic assays only) among MHLW, EMA and FDA was also presented. Additionally, five JBF DGs were scientifically discussed, and the attendees openly exchanged their views on a wide range of bioanalytical issues with DG members.

2. Organization and members of steering committee

The SC is consisted of the committee members, GBC SC members and the TF members.

The number of the SC members for FY 2013 is 27; 15 from pharmaceuticals, 7 from CROs, 3 from academia and 2 from regulatory agency.

The committees, task forces and SC members are listed below.

<Committees>

F&A	Event execution
Financial auditors	Public relations
Website administration	International affairs
Membership (-Mar. 2014)	EBF window persons
Documentation	CBF window persons
Discussion group promotion (Mar. 2014-)	Charge of membership (Mar. 2014-)

<Task forces>

Membership system startup (-Mar. 2014)	GBC HT support
Small molecule BMV guideline (-Mar. 2014)	Ligand binding assay BMV guideline
Discussion group (DG) (-Mar. 2014)	Large molecule MS guideline (Mar. 2014-)
Small molecule BMV guideline handbook (Dec. 2013-)	

<Steering Committee Members>

Representative	Haruhiro Okuda (National Institute of Health Sciences)
Advisors	Jun Haginaka (Prof., Mukogawa Women's Univ.) Tsutomu Masujima (Prof., Hiroshima Univ.) Tatsuo Kurokawa (Prof., Keio Univ.)
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. (-Aug. 2013)
Motoki Onishi	Towa Pharmaceutical Co., Ltd. (Sep. 2013-)
Jun Hosogi	Kyowa Hakko Kirin Co., Ltd.
Kazuhiro Miya	Chugai Pharmaceutical Co., Ltd.
Kazutaka Togashi	Sumika Chemical Analysis Service, Ltd.
Keiko Nakai	Mitsubishi Chemical Medience Ltd.
Kenji Yahata	Sanofi K.K.

Name	Affiliation
Mami Imazato	Novartis Pharma K.K. (-Mar. 2014)
Masaaki Kakehi	Takeda Pharmaceutical Company Ltd.
Masanori Kawamura	JCL Bioassay Co., Ltd. (-Mar. 2014)
Noriko Inoue	JCL Bioassay Co., Ltd. (Mar. 2014-)
Nobuhiro Kobayashi	Daiichi Sankyo Co., Ltd. (-Mar. 2014)
Yoko Urasaki	Daiichi Sankyo Co., Ltd. (Mar. 2014-)
Takahiko Osumi	Otsuka Pharmaceutical Co., Ltd.
Takahiro Nakamura	Shin Nippon Biomedical Laboratories, Ltd.
Takehisa Matsumaru	Nippon Boehringer Ingelheim Co., Ltd. (-Mar. 2014)
Yoshihisa Sano	Eisai Co., Ltd.
Yoshitaka Taniguchi	Toray Research Center, Inc.
Yoshiyuki Minamide	Shimadzu Techno-Research, Inc.
Kazuhiko Sasaki	Taisho Pharmaceutical Co., Ltd. (May 2013-)

3. Activities of steering committee

JBF SC Meetings were held monthly (4th Apr, 9th May, 6th Jun, 24th Jul, 5th Sep, 3rd Oct, 7th Nov and 25th Dec in 2013, and 17th Jan, 20th Feb in 2014). The minutes were finalized and distributed to the SC members.

- The operational document for SC members was updated.
- JBF annual reports FY2011 and FY2012 in English were released.
- International Affairs Committee had discussions with Dr. Tang (CBF) and Dr. Yadav (APA-India) to enhance cooperative relations among China, India and Japan.
- International Affairs Committee prepared Comparison of BMV guideline/guidance among MHLW, EMA and FDA in terms of chromatographic assays
- Documentation Committee has shared the electric files on JBF with SC members and stored by Dropbox.
- The handbook on MHLW LC guideline was decided to be published.

In addition to the activities above, the outcome of SC activities is described in Sections 4 to 9.

4. New organization and activity of JBF

- Membership System Startup TF was combined with Membership Committee into Charge of Membership Committee. This committee takes a new role concerning the corporate and supporting memberships, involved in the original role of Membership Committee.
- DG was founded under JBF to provide opportunities for discussing issues raised from daily bioanalytical work among Japanese scientists. After trials of which outcomes were presented at the 4th JBF symposium, over 120 DG supporters were enrolled and five DGs, which leaders/ members were recruited from DG supporters, have been officially initiated and activated. The outcomes were presented at the 5th symposium. To expand DG activity, DG-TF was dissolved,

and DG Promotion Committee has been newly formed.

- Small Molecule BMV Guideline TF was dissolved, because they completed the planned tasks. As a new TF regarding the BMV guideline, Small Molecule BMV Guideline Handbook TF was formed.
- Large molecule MS guideline TF was formed. The TF would provide any deliverables, which are not limited to guidelines, with the large molecular LC-MS working group.
- The way of contribution to biomarker analyses is under discussion.
- The contact point for JP regulatory agencies and Japan Pharmaceutical Manufacturers Association (JPMA) was set up.
- The official name of 'JBF supporter' was determined as 'JBF partner'.

5. Symposium

5.1. The 4th JBF Symposium

We held the 4th symposium on 2nd August 2013 in Tokyo as part of the 26th Symposium on Biomedical-Analytical Sciences (BMAS). The theme was 'Current status of Japanese guidelines on bioanalytical method validation and the latest activities of DG within the Japanese bioanalyst community', organized by Akira Nakayama (Ajinomoto Pharmaceuticals Co., Ltd.).

At this symposium, the outline of MHLW LC guideline, which was just published in July 2013, and that of the JBF draft version of Japanese LBA guideline, were presented to about 250 attendees from industry, government and academia. In addition, the outcomes of three trial DGs, 'Preparation of standard solutions', 'Partial validation' and 'LBA', were also presented and discussed with the symposium attendees. Over 120 DG supporters were enrolled for discussion on future DG topics.

The conference report of the symposium was prepared by Nakayama and accepted by the journal.

5.2. The 5th JBF Symposium

We held the 5th symposium on 6th and 7th March 2014 in Tokyo. The theme was "Bridging for a Global Harmonization", organized by Nobuhiro Kobayashi (Daiichi-Sankyo Co., Ltd.).

At this symposium, distinguished bioanalytical scientists from government and industry commentate on the BMV guidelines/guidance issued by their own regions including the draft MHLW LBA guideline. Dr. Brian Booth (Office of Clinical Pharmacology, FDA) presented FDA draft guidance focused on their philosophy on the revision and their feedback.

Comparison of BMV guideline/guidance among MHLW, EMA and FDA (chromatographic assays) was presented.

Additionally, JBF DG, in which daily bioanalytical issues/interests were scientifically discussed, picked up five topics, and more than 200 attendees openly exchanged their views on a wide range of bioanalytical issues with DG members. Topics of these were 'Preparation of calibration standard and QC samples', 'Recommendation to prepare standard solutions', 'Tiered approach for bioanalytical method of metabolites', 'Partial validation', and 'LBA'.

Each leader of five DGs presented an overview in the oral session, while all DG members showed their outcomes and held active discussion with attendees in the poster session. Most of DGs have plans to submit their deliverables to relevant scientific articles in the near future.

The conference report of the symposium was prepared by Kobayashi.

5.3. The 6th JBF Symposium

We have decided to hold the 6th JBF symposium at the end of the FY2014 in Tokyo. The organizer and the outline of the symposium are under consideration.

6. BMV Guideline in Japan

- The draft BMV guideline for LC-MS/MS and HPLC was released by MHLW in April 2013 for invitation of public comments.
- The BMV guideline for LC-MS/MS and HPLC and the Q&A were issued in July 2013 and those in English in September 2013.
- The draft BMV guideline for LBA was released by MHLW in January 2014 for invitation of public comments. The BMV guideline for LBA would be issued in April 2014.

7. GBC related

GBC HT has prepared white papers to describe their best practice and/or recommendations based on their scientific discussion in each HT. The first white paper was published in the AAPS Journal on November 2013, and then has followed one after another.

The conclusions and recommendations from the HT are available on the GBC Website and were published as GBC Webinars on May 2013.

At the 5th JBF symposium, Peter van Amsterdam presented a status update on GBC, and showed the achievement of GBC.

8. Publication and presentation

8.1. Publication

Noriko Katori: Bioanalysis, 5(11), 1321-1323 (2013) (in English)
Noriko Katori: The archives of practical pharmacy, 73(5), 296-301 (2013) (in Japanese)
Takeru Yamaguchi: Pharm Stage, 13(10), 4-9 (2014) (in Japanese)

8.2. Presentation

Noriko Katori: 7th WRIB in April 2013 (Long beach, US)
Dr. Daniel Tang (on behalf of Yoshiaki Otsu): CPSA Shanghai 2013 (Shanghai, China)
Noriko Katori: 20th Chromatography symposium (Kobe, Japan)
Akira Nakayama: 20th Chromatography symposium (Kobe, Japan)
Kazutaka Togashi: 20th Chromatography symposium (Kobe, Japan)
Noriko Katori: The Japanese Society for the Study of Xenobiotics (JSSX) 2013 (Tokyo, Japan)
Nobuhiro Kobayashi: JSSX2013 (Tokyo, Japan)
Keiko Nakai: JSSX2013 (Tokyo, Japan)
Noriko Katori：AAPS/FDA Crystal City V Workshop (Baltimore, MD, US)
Noriko Katori: 8th WRIB in March 2014 (LA, US)

9. Other activities

Mini symposium was held as a part of the 28th Japanese Society for the Study of Xenobiotics Annual meeting in 2013. Nobuhiro Kobayashi chaired a session with the theme, ‘Developing

bioanalysis and contribution to pharmacokinetics in Japan' and several members of JBF SC were invited there as key speakers.

Small molecule BMV guideline TF exchanged views on the BMV guideline with JPMA (Japan Pharmaceutical Manufacturers Association) on April 2013.

The cooperation between the BMAS2014 and JBF has been agreed. Program review committee for BMAS 2014 was established in JBF.

10. External Circumstances

- 20th Chromatography symposium was held in Kobe, Japan. JBF members presented about a current status of Japanese BMV guidelines.
- FDA draft BMV guidance was issued on September 2013. Comments on the draft guidance were submitted to FDA by International affairs committee.
- Crystal City V meeting was held in Baltimore, US, on December 2013.
- The draft Chinese BMV guideline was up on the CBF Website.
- The draft Japanese guideline, "Drug Interactions Guidelines for Drug Development and Appropriate Information Provision" for public comments was issued by MHLW on December 2013.

JBF activities in 2013 (April 2013 to March 2014)		
	Symposium/ Social meeting/ Guideline/ Publication	JBF Steering committee meeting/ JBF Organization
April 2013	➢ Draft guideline on Bioanalytical Method Validation in Pharmaceutical Development (chromatographic assays) for public comments released by MHLW ➢ Presentation: Noriko Katori: 7th WRIB (Long beach, USA) ➢ Kick off meeting of the program review committee for 5th JBF symposium ➢ TC with EBF (European Bioanalysis Forum) and International affairs committee ➢ TC with CBF (China Bioanalysis Forum) and International affairs committee ➢ Presentation: Dr. Daniel Tang (on behalf of Yoshiaki Otsu): CPSA Shanghai 2013	➢ Steering committee (SC) meeting (4th April)
May		➢ SC meeting (9th May) ➢ Publication of the handbook on MHLW LC guideline decided
June	➢ Publication: Noriko Katori: Bioanalysis, Vol. 5 (11), 1321-1323, 2013 ➢ Presentation: Noriko Katori, Akira Nakayama and Kazutaka Togashi: 20th Chromatography symposium (Kobe, Japan) ➢ TC with EBF and International affairs committee ➢ TC with CBF and International affairs committee	➢ SC meeting (6th June) ➢ The operational document for SC members released ➢ JBF annual report FY2011 in English released ➢ Storage of the electric files on JBF by Dropbox started

JBF activities in 2013 (April 2013 to March 2014)		
July	➢ Notification by MHLW: BMV guideline for chromatographic assays, the Q&A and the answers for public comments (11th July) Effective date: 1st April, 2014	➢ SC meeting (24th July)
August	➢ The 4th JBF symposium（2nd August, Tokyo, Japan） ➢ Introduction of DG at the 4th JBF symposium	➢ Recruiting Large molecule/LC-MS TF members started
September	➢ Notification by MHLW: BMV guideline for chromatographic assays and the Q&A in English （13th September) ➢ Notification by FDA: Draft BMV guidance (revised) ➢ Publication: Noriko Katori: The archives of practical pharmacy, 73 (5), 296-301	➢ SC meeting (5th September) ➢ Large molecule/LC-MS TF members decided ➢ 2014 DGs started with 5 new topics
October	➢ Presentation: Noriko Katori, Nobuhiro Kobayashi and Keiko Nakai: JSSX2013 (Tokyo, Japan)	➢ SC meeting (3rd October)
November		➢ SC meeting（7th November） ➢ Comments on FDA draft BMV guidance invited by International Affairs Committee ➢ The official name of 'JBF supporter' determined as 'JBF partner

JBF activities in 2013 (April 2013 to March 2014)		
December	➢ Presentation Noriko Katori：AAPS/FDA Crystal City V Workshop (Baltimore, MD, USA) ➢ Comments on FDA draft BMV guidance submitted to FDA by International affairs committee	➢ Ad hoc SC meeting（25th December） ➢ JBF annual report FY2012 in English released ➢ Reform recommendation for Membership system startup TF approved ➢ New name of DG TF decided to ”DG promotion committee” ➢ Small molecule BMV guideline handbook TF formed ➢ Comparison of BMV guideline/guidance among MHLW, EMA and FDA prepared and fixed by International Affairs Committee (chromatographic assays)
January 2014	➢ Draft BMV guideline for LBA for public comments released by MHLW ➢ Upload to JBF website: Comparison with Japanese BMV Guideline , EMA guideline and draft FDA guidance (2013) (chromatographic assays)	➢ SC meeting（17th January）
February	➢ Kick off meeting of the large molecule/LC-MS Working group for Japanese BMV Guideline ➢ Upload to JBF website: Comparison with Japanese BMV Guideline , EMA guideline and draft FDA guidance (2013) revised (chromatographic assays) ➢ Conference report of the 4th JBF symposium accepted by *Bioanalysis*	➢ SC meeting（20th February）

JBF activities in 2013 (April 2013 to March 2014)		
March	➢ The 5th JBF symposium（6th and 7th March, Tokyo, Japan） ➢ International Affairs Committee had F2F discussions about the future cooperative system with Dr. Tang (CBF) and Dr. Yadav (APA-India). ➢ Presentation Noriko Katori: 8th WRIB (CA, USA) ➢ Program review committee for BMAS 2014 determined ➢ Closed meeting among the DG members	➢ Small molecule BMV guideline TF dissolved ➢ Large molecule MS guideline TF formed ➢ MHLW LC guideline handbook under discussion of the overview and the author ➢ “Membership system startup TF” integrated with “Member committee” ➢ “DG TF” altered to ”DG promotion committee”