



# JBF Annual Report FY2012

(From 1<sup>st</sup> April 2012 to 31<sup>st</sup> March 2013)

## 1. Overview

It has been passed a year and a half since the establishment of Japan Bioanalysis Forum (JBF), and we are going to the next stage with reorganization and new activities.

The representative of JBF has been changed. The two memberships (corporate and supporting memberships) have been established and the members for them are being recruited. The 'Discussion group (DG)' was proposed for science-based and cross-organizational discussion about broad topics of interest in bioanalysis field as a new activity of JBF. Three trial DGs have been formed to seek good practice towards a full-fledged DG planned to be started in summer 2013. Several processes to administer JBF and to communicate with other scientific societies have been established. We routinely communicate with European Bioanalysis Forum (EBF) and China Bioanalysis Forum (CBF).

The 3<sup>rd</sup> JBF symposium was held on 8<sup>th</sup> August 2012 in Tokyo with the theme 'International Harmonization of Bioanalysis Regulation' accompanying the programs of the invited lectures by three speakers from Global Bioanalysis Consortium (GBC) steering committee members, and the poster presentations by Japanese representatives from all the 20 GBC harmonization teams (HT) followed by a panel discussion. Three hundred or more delegates from industries, regulators and academia participated in the symposium, showing a growing interest in the activities on the international harmonization of bioanalysis.

We are cooperating with the bioanalytical method validation (BMV) study group of MHLW to prepare our own BMV guidelines in Japan. For small molecule chromatographic analyses, we have proposed the final draft of BMV guideline to the study group, and, as a result, 'A draft guideline on Bioanalytical Method Validation in Pharmaceutical Development' has been submitted to MHLW on March 2013. For ligand binding assays, we have proposed a preliminary guideline to the same study group on February 2013.

## 2. Organization and members of steering committee

Dr. Haruhiro Okuda (National Institute of Health Sciences) became the new representative of JBF. Prof. Tatsuo Kurokawa who is the former and the first representative has been appointed an adviser to JBF on 22<sup>nd</sup> June. The names, responsibilities and allocation of task forces and committees of JBF were reviewed and members had been re-located. International vision committee was renamed to be the International Affairs Committee. Each three members were nominated as either of EBF or CBF window person.

The steering committee (SC) is consisted of 27 members; 15 from pharmaceuticals, 7 from CROs, 3 from academia and 2 from regulatory agency as of the end of March 2013. Nine members of SC reached the full-term (2 years), and eight of them have decided to continue for the next 2 years.

<Committees>

F&A	Event execution
Financial auditors	Public relations
Website administration	International affairs
Membership	EBF window persons
Documentation	CBF window persons

<Task forces>

Membership system startup	GBC HT support
Small molecule BMV guideline	Ligand binding assay BMV guideline
Discussion group	

<Steering Committee Members>

Representative	Tatsuo Kurokawa (Prof., Keio Univ.) (-Jun 2012) Haruhiro Okuda (National Institute of Health Sciences) (Jun 2012-)
Advisors	Jun Haginaka (Prof., Mukogawa Women's Univ.) Tsutomu Masujima (Prof., Hiroshima Univ.) Tatsuo Kurokawa (Prof., Keio Univ.) (Jun 2012-)
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
Akira Nakayama	Ajinomoto Pharmaceuticals Co., Ltd.
Harue Igarashi	GlaxoSmithKline K. K.
Hidehisa Tachiki	Towa Pharmaceutical Co., Ltd. (-Sep 2012)
Hisanori Hara	Novartis Pharma AG, Switzerland
Hitoshi Uchiyama	Towa Pharmaceutical Co., Ltd. (Sep 2012-)
Jun Hosogi	Kyowa Hakko Kirin Co., Ltd. (Aug 2012-)
Katsuhiko Yamamoto	Kyowa Hakko Kirin Co., Ltd. (-Aug 2012)
Kazuhiro Miya	Chugai Pharmaceutical Co., Ltd. (Jul 2012-)
Kazutaka Togashi	Sumika Chemical Analysis Service, Ltd.
Keiko Nakai	Mitsubishi Chemical Medience Ltd.
Kenji Yahata	Sanofi K.K.
Mami Imazato	Novartis Pharma K.K.
Masaaki Kakehi	Takeda Pharmaceutical Company Ltd. (Mar 2013-)
Masanori Kawamura	JCL Bioassay Co., Ltd. (Aug 2012-)
Nobuhiro Kobayashi	Daiichi Sankyo Co., Ltd.
Noriko Inoue	JCL Bioassay Co., Ltd. (-Aug 2012)
Takahiko Osumi	Otsuka Pharmaceutical Co., Ltd.
Takahiro Nakamura	Shin Nippon Biomedical Laboratories, Ltd. (Jul 2012-)

Name	Affiliation
Takehisa Matsumaru	Nippon Boehringer Ingelheim Co., Ltd.
Tomoki Yoneyama	Takeda Pharmaceutical Company Ltd. (-May 2012)
Yoji Kuze	Takeda Pharmaceutical Company Ltd. (May 2012-Mar 2013)
Yoshihisa Sano	Eisai Co., Ltd. (Aug 2012-)
Yoshitaka Taniguchi	Toray Research Center, Inc. (Jun 2012-)
Yoshiyuki Minamide	Shimadzu Techno-Research, Inc.

### 3. Activities of steering committee

JBF SC Meetings were held monthly (12<sup>th</sup> Apr, 15<sup>th</sup> May, 22<sup>nd</sup> Jun, 1<sup>st</sup> Aug, 10<sup>th</sup> Sep, 5<sup>th</sup> Oct, 1<sup>st</sup> Nov and 6<sup>th</sup> Dec in 2012, and 10<sup>th</sup> Jan, 7<sup>th</sup> Feb, 7<sup>th</sup> Mar in 2013). .

- The term of SC members have been decided to be 2 years and the process at the expiration of member's term has been established.
- The procedures of preparing annual and monthly reports of SC activities and of sending information to the representative and advisors have been fixed.
- The operational document for SC members has been updated.
- The web site in English version has been released.
- International Affairs Committee received an offer from CBF to hold TC to discuss Asia pacific Bioanalytical Consortium and the discussion is ongoing. The committee started routine communication with EBF and CBF.
- The process for cooperation proposed by other scientific societies has been fixed.
- The way of cooperation with academia or pharmaceutical society of Japan is under discussion.
- The way of contribution to biomarker analyses is under discussion

In addition to the activities above, the outcome of SC activities is described in Sections 4, 5, 6, 7, 8 and 9.

### 4. New organization and activity of JBF

The corporate and supporting membership systems have been established, and then the member recruitment has been started from February 2013 for their FY2013 memberships. Personal membership system is under discussion.

'Discussion Group (DG)' was proposed for science-based and cross-organizational discussion about broad topics of interest in bioanalysis field as a new activity of JBF, and the topics to be discussed were collected from SC members as the first step. The DG task-force has been formed before setting up DGs. Three topics were selected and trial DGs have been formed. DG task-force held monthly TCs to share the progress of each topic team and facilitate successful discussion for their goals.

## **5. Symposium**

### **5.1. The 3<sup>rd</sup> JBF Symposium**

We held the 3<sup>rd</sup> symposium on 8<sup>th</sup> August 2012 in Tokyo as part of the 25<sup>th</sup> Symposium on Biomedical-Analytical Sciences (BMAS). The theme was International Harmonization of Bioanalysis Regulation with a running title, Discussion in GBC Harmonization Teams, organized by Mami Imazato (Novartis Pharma K. K.). Division of Physical Science, The Pharmaceutical Society of Japan cooperated with the symposium. The forum presented the updates in JBF activities and the latest updates in GBC activities accompanying the programs of the invited lectures by three speakers from GBC SC members, and poster presentations by Japanese representatives from all the 20 GBC HTs followed by a panel discussion. Three hundred or more delegates from industries, regulators and academia participated in the symposium, showing a growing interest in the activities on the international harmonization of bioanalysis. The conference report of the symposium was published by Imazato.

### **5.2. The 4<sup>th</sup> JBF Symposium**

We have decided to hold the 4<sup>th</sup> JBF symposium on 2<sup>nd</sup> August 2013 in Tokyo as part of the 26<sup>th</sup> Symposium on BMAS. Akira Nakayama (Ajinomoto Pharmaceuticals Co., Ltd.) would organize the symposium.

### **5.3. The 5<sup>th</sup> JBF Symposium**

We have decided to hold the 5<sup>th</sup> JBF symposium on 6<sup>th</sup> and 7<sup>th</sup> March 2014 in Tokyo. Nobuhiro Kobayashi (Daiichi-Sankyo Co., Ltd.) would organize the symposium.

## **6. BMV Guideline in Japan**

For small molecule bioanalysis using chromatography techniques, the draft guideline provided by JBF was handed out to the related three associations, Japan Pharmaceutical Manufacturers Association (JPMA), Japan Generic Medicines Association (JGA) and Japan Association of Contract Laboratories for Safety Evaluation (JACL) for seeking comments. More than 400 comments were gathered from these associations. Most of the comments were related to practical procedure being contained in the draft. On the basis of these comments, the guideline task-force prepared draft Q &A texts which would be released along with the BMV guideline. The final draft of the guideline and Q&A texts were proposed to the BMV study group in November, and resulted in the submission of 'A draft guideline on Bioanalytical Method Validation in Pharmaceutical Development' to MHLW on March 2013.

Another task-force has been formed for large molecule analysis in JBF (LBA-TF). A working group for ligand binding analyses (LBA-WG) was inaugurated under the BMV study group, and LBA-WG asked JBF to propose a draft BMV guideline for ligand binding assay. The first meeting between LBA-TF and LBA-WG was held on 21<sup>st</sup> September. The scope of the guideline was not large molecules, but the analytical technique (ligand binding assay), which should include small molecules. The draft of scope and items of the guideline were proposed to LBA-WG at the end of 2012. Consequently, the texts of preliminary guideline have been prepared and submitted to LBA-WG on February 2013.

## **7. GBC related**

GBC SC continues to notify the latest information of GBC to HT members and JBF. Webinar and Linked-In programs were provided by GBC to spread them broadly to HT-members/supporters.

HT members have contributed to prepare white papers to describe their best practice and/or recommendations based on their scientific discussion in each HT.

The closed meeting with three GBC SC members attending the 3<sup>rd</sup> JBF symposium was held on 9<sup>th</sup> August 2012 (the next day of the 3<sup>rd</sup> symposium).

The social event of HT-member/supporter community was held in Kansai area on 11<sup>th</sup> April 2012. The operational document for HT-member/supporter community was revised and distributed to the community members.

## **8. Press report, publication and presentation**

### **8.1. Press report**

PHARM TECH JAPAN 28(7), 141 (2012)

### **8.2. Publication**

Keiko Nakai: Bunseki, 7, 399 (2012) (in Japanese)

Kazutaka Togashi: CHROMATOGRAPHY, 33 (2), 107-112(2012) (in Japanese)

Kazutaka Togashi: CHROMATOGRAPHY, 33 (2), 117-121(2012) (in Japanese)

Yoneyama et al: Pharmaceutical and medical device regulatory science, 43 (8), 750-760 (2012) (in Japanese)

Mami Imazato: Bioanalysis, 5(3), 281-283 (2013) (in English)

Noriko Katori: Bioanalysis, 5(11), 1321-1323 (2013) (in English)

Noriko Katori: Yakuzaigaku, 73(5), 296-301 (2013) (in Japanese)

### **8.3. Presentation**

Tatsuo Kurokawa: 19<sup>th</sup> International Mass Spectrometry Conference (IMSC) 2012, Kyoto, Japan)

Noriko Katori: IMSC 2012 (Kyoto, Japan)

Shinobu Kudoh (session organizer): IMSC 2012 ( Kyoto, Japan)

Keiko Nakai: Waters seminar at IMSC 2012 (Kyoto, Japan)

Noriko Katori : 5<sup>th</sup> EBF Open Symposium (Barcelona, Spain)

## **9. Other activities**

Noriko Katori has been invited to the 7<sup>th</sup> WRIB in the US, long beach in April 2013. JBF SC members have prepared the answers for the questionnaires about ISS provided in advance.

Mini symposium will be held as a part of the 28<sup>th</sup> Japanese Society for the Study of Xenobiotics Annual meeting in 2013. Nobuhiro Kobayashi will chair a session with the theme, 'Developing bioanalysis and contribution to pharmacokinetics in Japan' and several members of JBF SC have been invited there as key speakers.

The cooperation between the Society for Chromatographic Sciences and JBF has been agreed.

## **10. External Circumstances**

The guidance for bioanalysis had been updated and released by ANVISA on May 2012.

The draft documents, "Technical Guidelines for Nonclinical Pharmacokinetic Studies" and "Technical Guidelines for Drug Toxicokinetic Studies" were issued by SFDA on August 2012.

The draft document, "Guidance for Industry Immunogenicity Assessment for Therapeutic Protein Products" was issued by FDA on February 2013.

### JBF activities in 2012 (April 2012 to March 2013)

	Symposium/ Social meeting/ Guideline/ Publication	JBF Steering committee meeting/ JBF Organization
<b>April 2012</b>	<ul style="list-style-type: none"> <li>➤ The social gathering of HT member/supporter community</li> </ul>	<ul style="list-style-type: none"> <li>➤ Steering committee (SC) meeting (12<sup>th</sup> April)</li> <li>➤ The next representative of JBF nominated</li> <li>➤ The membership regulations of JBF released</li> <li>➤ Preparation of BMV guideline for large molecule analysis started</li> </ul>
<b>May</b>	<ul style="list-style-type: none"> <li>➤ Press report: PHARM TECH JAPAN 28(7), 141 (2012)</li> </ul>	<ul style="list-style-type: none"> <li>➤ SC meeting (15<sup>th</sup> May)</li> <li>➤ The term of a SC member fixed to be 2 years</li> </ul>
<b>June</b>		<ul style="list-style-type: none"> <li>➤ SC meeting (22<sup>nd</sup> June)</li> <li>➤ Takeover of JBF representative from Prof. Kurokawa to Dr. Okuda</li> <li>➤ The operational document for SC members released</li> </ul>
<b>July</b>	<ul style="list-style-type: none"> <li>➤ Publication: Keiko Nakai: Bunseki, 7, 399 (2012)</li> </ul>	<ul style="list-style-type: none"> <li>➤ Discussion group (DG) taskforce formed</li> <li>➤ JBF website in English version released</li> </ul>
<b>August</b>	<ul style="list-style-type: none"> <li>➤ The 3<sup>rd</sup> JBF symposium (8<sup>th</sup> August, Tokyo, Japan)</li> <li>➤ Closed meeting with GBC SC members (9<sup>th</sup> August)</li> <li>➤ Publication: Kazutaka Togashi: CHROMATOGRAPHY, 33 (2), 107-121(2012) Yoneyama et al: Pharmaceutical and Medical Device Regulatory Science, 43 (8), 750-760 (2012)</li> </ul>	<ul style="list-style-type: none"> <li>➤ SC meeting (1<sup>st</sup> August)</li> </ul>
<b>September</b>	<ul style="list-style-type: none"> <li>➤ Kick off meeting with working group for ligand binding assay (21<sup>st</sup> Sep)</li> <li>➤ Presentation :</li> </ul>	<ul style="list-style-type: none"> <li>➤ SC meeting (10<sup>th</sup> September)</li> </ul>

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<p>Tatsuo Kurokawa: 19<sup>th</sup> International Mass Spectrometry Conference (IMSC2012, Kyoto, Japan)          Noriko Katori: IMSC2012 (Kyoto, Japan)          Shinobu Kudoh(session organizer): IMSC2012 ( Kyoto, Japan)          Keiko Nakai: Waters seminar at IMSC 2012 (Kyoto, Japan)</p>	
<b>October</b>	<ul style="list-style-type: none"> <li>➤ SC meeting (5<sup>th</sup> Oct)</li> <li>➤ The operational document for SC members updated (v2)</li> </ul>
<b>November</b>	<ul style="list-style-type: none"> <li>➤ Presentation Noriko Katori : 5<sup>th</sup> EBF Open Symposium (Barcelona, Spain)</li> <li>➤ SC meeting (1<sup>st</sup> Nov)</li> </ul>
<b>December</b>	<ul style="list-style-type: none"> <li>➤ SC meeting (6<sup>th</sup> Dec)</li> <li>➤ Trial DG official announcement distributed</li> </ul>
<b>January 2013</b>	<ul style="list-style-type: none"> <li>➤ SC meeting (10<sup>th</sup> Jan)</li> </ul>
<b>February</b>	<ul style="list-style-type: none"> <li>➤ Draft guideline on BMV for ligand binding assay provided by JBF submitted to BMV working group</li> <li>➤ Publication : Mami Imazato: Bioanalysis, 5(3), 281-283</li> <li>➤ SC meeting (7<sup>th</sup> Feb)</li> <li>➤ The operational document for SC members updated (v3)</li> <li>➤ The membership regulations of JBF updated (v2)</li> <li>➤ The process on expiration of term of steering committee members fixed</li> <li>➤ The process for cooperation with other scientific societies fixed</li> <li>➤ Recruiting corporate member and supporting member started</li> </ul>
<b>March</b>	<ul style="list-style-type: none"> <li>➤ 'A draft guideline on Bioanalytical Method Validation in Pharmaceutical Development' for LC/small molecule provided by BMV working group submitted to MHLW (14<sup>th</sup> March)</li> <li>➤ SC meeting (7<sup>th</sup> March)</li> <li>➤ Term of 9 SC members expired, 8 members decided to continue</li> <li>➤ Trial DG started</li> </ul>