

# JBF Annual Report 2011

Period : from 10<sup>th</sup> August 2011 to 31<sup>st</sup> March 2012

## 1. Foundation of the Japan Bioanalysis Forum

### 1.1. Background

Regulated bioanalysis has been discussed in Japan from 1990's. Although there was not any society specialized for regulated bioanalysis in Japan, seminars and ad-hoc symposia were held and several books were published. The first symposium for regulated bioanalysis in Japan was the workshop titled "Discussion on AAPS/FDA White Paper for Bioanalytical method validation" held in 2008 (Tsukuba, Japan), and then the need for a place to discuss regulated bioanalysis was getting higher.

Late of 2010, the Global Bioanalysis Consortium was organized to merge existing or emerging bioanalytical guidances to create one, unified consensus.document. The first Conference in Asia Pacific on Recent Issues in Regulated Bioanalysis held on January 2011 in Shanghai and GBC activities introduced in the workshop knocked the next door and triggered a formation of the first and only association for scientific discussion of regulated bioanalysis in Japan.

### 1.2. Establishment of the Japan Bioanalysis Forum

The Japan Bioanalysis Forum (JBF) is organized by volunteers from industry, government and academia. The forum held the first JBF symposium on 10<sup>th</sup> August 2011 (Tokyo, Japan), and declared the establishment of the forum which enables scientific discussion of regulated bioanalysis in Japan. The committees, task forces and members are listed as follows.

#### <Committees>

F&A	Event execution
Financial auditors	Information management (-Nov 2011)
Website administration	Public relations (Nov 2011-)
Membership	EBF window (Mar 2012-)
Documentation	

#### <Task forces>

GBC SC support (-Oct 2011)	GBC HT support
BMAS/Mass Spectrometry Society support (-Oct 2011)	Small molecule BA method guideline (Nov 2011-)
Membership system startup (Nov 2011-)	

<Steering Committee Members>

Representative	Tatsuo Kurokawa (Prof., Keio Univ.)
Advisors	Jun Haginaka (Prof., Mukogawa Women's Univ.) Tsutomu Masujima (Prof., Hiroshima Univ.)
GBC SC	Tatsuo Kurokawa (Prof., Keio Univ) (-Sep 2011) Shinobu Kudoh (Shimadzu Techno Research, Inc.) (Jul 2011-)
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.
Hisanori Hara	Novartis Pharma AG, Switzerland
Katsuhiko Yamamoto	Kyowa Hakko Kirin Co., Ltd.
Kazutaka Togashi	Sumika Chemical Analysis Service, Ltd.
Keiko Nakai	Mitsubishi Chemical Medience Ltd.
Kenji Yahata	Sanofi-Aventis
Mami Imazato	Novartis Pharma K. K.
Nobuhiro Kobayashi	Daiichi Sankyo Co., Ltd.
Noriko Inoue	JCL Bioassay Co., Ltd.
Takahiko Osumi	Otsuka Pharmaceutical Co., Ltd.
Takehisa Matsumaru	Nippon Boehringer Ingelheim Co., Ltd.
Tomoki Yoneyama	Takeda Pharmaceutical Company Ltd.
Yoshiyuki Minamide	Shimadzu Techno-Research, Inc.

## 2. JBF steering committee meeting

Meetings of the steering committee were held monthly (3<sup>rd</sup> Oct, 11<sup>th</sup> Nov, and 3<sup>rd</sup> Dec in 2011, and 13<sup>th</sup> Jan, 15<sup>th</sup> Feb and 28<sup>th</sup> Mar in 2012). The minutes were finalized and distributed to the SC members.

## 3. Organization of JBF

Name of the forum, the charter for JBF, a bank account and URL of website had been obtained by the declaration of the JBF establishment.

‘The JBF information management guideline’ and ‘the procedures of important decision making’ had been finalized.

The logo and a stamp were prepared, and the website in Japanese version was released.

The Japan Pharmaceutical Manufacturers Association (JPMA) had permitted a link to JBF website.

Discussions about ‘Global vision’, ‘Membership system’, and next representative candidate were started.

#### **4. Symposium**

##### **4.1. The 1<sup>st</sup> JBF symposium**

The JBF held the first symposium on 10<sup>th</sup> August 2011 in Tokyo to declare the JBF establishment. The chairman was Takahiko Osumi (Otsuka Pharmaceutical Co., Ltd.). The participants were 200 or more by delegates from industry, regulators and academia. Division of Physical Science, The Pharmaceutical Society of Japan cooperated to the symposium.

##### **4.2. The 2<sup>nd</sup> JBF Symposium**

The JBF held the second symposium on 8<sup>th</sup> March 2011 in Tokyo, having approximately 200 participants. The chairman was Kazutaka Togashi (Sumika Chemical Analysis Service, Ltd.). The latest topics related to BMV, European Medicines Agency (EMA) guidance, GBC-HT discussions and development status of Japan BMV guideline, were discussed with two guest speakers from EBF and GBC. Division of Physical Science, The Pharmaceutical Society of Japan cooperated to the symposium.

##### **4.3. The 3<sup>rd</sup> JBF symposium**

The JBF had decided that the third JBF symposium would be held on 8<sup>th</sup> August 2012 in Tokyo as part of the 25<sup>th</sup> Symposium on Biomedical-Analytical Sciences (BMAS). Mami Imazato (Novartis Pharma K. K.) would organize the JBF symposium.

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

##### **5.1. Press report**

PHARM TECH JAPAN, 27(10), 36 (2011)

##### **5.2. Publication**

Yoshiaki Ohtsu : Bunseki, 1, 52 (2012)

Tatsuo Kurokawa : PHARM TECH JAPAN, 28(3), 7 (2012)

Shinobu Kudoh (translation) : PHARM TECH JAPAN, 28(3), 9-20 (2012)

Noriko Katori : PHARM TECH JAPAN, 28(3), 21-24 (2012)

Hidehisa Tachiki : PHARM TECH JAPAN, 28(3), 25-27 (2012)

Keiko Nakai : Bunseki, in printing

##### **5.3. Presentation**

Noriko Katori : BMAS (Tottori, September 2011)

Yoshiaki Ohtsu : Waters seminar (Tokyo, November 2011)

Shinobu Kudoh : EBF Open Symposium (Spain Barcelona, November 2011)

## **6. Others**

### **6.1. GBC related**

GBC SC takeover, to Shinobu Kudoh from Prof. Tatsuo Kurokawa was completed around September including the approval of the GBC.

Japanese representatives assigned for all Harmonization Team (HT) in GBC by supporting from GBC SC and GBC HT support TF.

The JBF created a HT member-supporter community which shares the GBC discussion and discusses topics domestically to support all Japanese HT members in the GBC. The scientific discussion is ongoing. The social gathering of HT member-supporter community would be held on 11<sup>th</sup> April 2011, in Kansai area.

### **6.2. Japanese Guideline on BMV**

The JBF received a request to prepare a draft Japanese guideline on BMV from a study group established by MHLW on November 2011. The JBF prepared a draft Japanese guideline on BMV, and then submitted to the study group on 30<sup>th</sup> March 2012. The scope of the draft guideline covers LC and GC analyses and combined those with mass spectrometry.

### **6.3. Others**

The JBF decided to cooperate to the session of bioanalysis in 19<sup>th</sup> International Mass Spectrometry Conference (IMSC) would be held on September 2012, Kyoto.

The information related to bioanalysis in Japan were gathered from books, paper, conferences and seminars, and then summarized.

The closed meeting between JBF and EBF was held on 9<sup>th</sup> March 2012 (next day of the 2<sup>nd</sup> JBF symposium).

Toshinari Mitsuoka (MHLW) would participate in the working dinner of CVG in the U.S. San Antonio in March 2012; JBF volunteer had prepared the answers for the questionnaires provided in advance.

## **7. External Circumstances**

The 24<sup>th</sup> symposium on BMAS was held from 31<sup>th</sup> August to 2<sup>nd</sup> September 2011 in Tottori, Japan.

The 4<sup>th</sup> EBF symposium was held on November 2011 in Spain.

MHLW founded a study group related to regulated bioanalysis, 'Research and validation study for global harmonization on the process to ensure the quality, efficacy and safety of drugs' (alias, Ohno study group). The kick-off meeting was held on 6<sup>th</sup> October 2011. The first meeting between the study group and the JBF GL TF was held on December 2011.

GBC HT discussion is ongoing. GBC SLT meetings were held twice (Jan. 2012 and Mar. 2012).

FDA might release draft guidance around July to August 2012, related conference (Crystal City 4) might be held around autumn. Schedule of global meeting in GBC might be changed.

<b>JBF activities in 2011</b>	
Aug 2011	<ul style="list-style-type: none"> <li>➤ The 1<sup>st</sup> JBF symposium (10<sup>th</sup> August)</li> <li>Announce the inauguration of the Japan Bioanalysis Forum (JBF)</li> </ul>
Sep	<ul style="list-style-type: none"> <li>➤ Complete the takeover of a GBC steering committee member from Prof. Kurokawa to Kudoh</li> <li>➤ Presentation : Noriko Katori, The 24<sup>th</sup> Symposium on Biomedical Analytical Sciences (BMAS), Tottori</li> <li>➤ Press report : PHARM TECH JAPAN, 27(10), 36 (2011)</li> </ul>
Oct	<ul style="list-style-type: none"> <li>➤ Steering Committee meeting (3<sup>rd</sup> Oct)</li> <li>➤ Reorganization of the steering committee commenced : The GBC backup task force and the BMAS/Mass Spectrometry Society of Japan task force dissolved.</li> <li>➤ Organization of JBF : JBF logo provided</li> <li>➤ Circumstances : BMV working group at MHLW founded 'Research and validation study for global harmonization on the process to ensure the quality, efficacy and safety of drugs' (alias, Ohno study group)</li> </ul>
Nov	<ul style="list-style-type: none"> <li>➤ Steering Committee meeting (11<sup>th</sup> Nov)</li> <li>➤ Reorganization of the steering committee completed : Takeover the job of information management committee to HP and PR committees The membership committee task force, The guideline task force, EBF contacts established</li> <li>➤ Organization of JBF : The JBF information handling guidelines finalized</li> <li>➤ JBF was asked by BMV Working Group to draft out the BMV guidelines of Japan</li> <li>➤ Presentation Yoshiaki Ohtsu : Waters seminar (Tokyo) Shinobu Kudoh : 4<sup>th</sup> EBF Open Symposium (Barcelona, Spain)</li> </ul>
Dec	<ul style="list-style-type: none"> <li>➤ Steering Committee meeting (3<sup>rd</sup> Dec)</li> <li>➤ Activities of Regulated bioanalysis in Japan researched and summarized</li> </ul>

<b>JBF activities in 2011</b>	
<b>Jan 2012</b>	<ul style="list-style-type: none"> <li>➤ Steering committee meeting (13<sup>th</sup> Jan)</li> <li>➤ HT member-supporter community established</li> <li>➤ JBF Website (Japanese version) released</li> <li>➤ Organization of JBF : Make stamp</li> <li>➤ Publication Yoshiaki Ohtsu : Bunseki, 1, 52 (2012)</li> </ul>
<b>Feb</b>	<ul style="list-style-type: none"> <li>➤ Steering committee meeting (15<sup>th</sup> Feb)</li> <li>➤ Organization of JBF : 'JBF Important decision making method' finalized</li> <li>➤ Publication : Tatsuo Kurokawa : PHARM TECH JAPAN, 28(3), 7 (2012) Shinobu Kudoh(translation) : PHARM TECH JAPAN, 28(3), 9-20 (2012) Noriko Katori : PHARM TECH JAPAN, 28(3), 21-24 (2012) Hidehisa Tachiki : PHARM TECH JAPAN, 28(3), 25-27 (2012)</li> </ul>
<b>March</b>	<ul style="list-style-type: none"> <li>➤ The 2<sup>nd</sup> JBF symposium (8<sup>th</sup> March)</li> <li>➤ Closed meeting with EBF (9<sup>th</sup> March)</li> <li>➤ Steering committee meeting (28<sup>th</sup> March)</li> <li>➤ Draft guideline on Bioanalytical method validation in Japan provided by JBF submitted to BMV working group</li> </ul>