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 10th 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.

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-)
2. **JBF steering committee meeting**

Meetings of the steering committee were held monthly (3rd Oct, 11th Nov, and 3rd Dec in 2011, and 13th Jan, 15th Feb and 28th 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 1st JBF Symposium
The JBF held the first symposium on 10th 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 2nd JBF Symposium
The JBF held the second symposium on 8th 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 3rd JBF symposium
The JBF had decided that the third JBF symposium would be held on 8th August 2012 in Tokyo as part of the 25th 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)
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 11th 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 30th 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 19th 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 9th March 2012 (next day of the 2nd 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 24th symposium on BMAS was held from 31th August to 2nd September 2011 in Tottori, Japan.
The 4th 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 6th 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.
<table>
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<tr>
<th>Month</th>
<th>Activities</th>
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| **Aug 2011** | - The 1st JBF symposium (10th August)  
   Announce the inauguration of the Japan Bioanalysis Forum (JBF) |
| **Sep** | - Complete the takeover of a GBC steering committee member from Prof. Kurokawa to Kudoh  
   - Presentation: Noriko Katori, The 24th Symposium on Biomedical Analytical Sciences (BMAS), Tottori  
   - Press report: PHARM TECH JAPAN, 27(10), 36 (2011) |
| **Oct** | - Steering Committee meeting (3rd Oct)  
   - Reorganization of the steering committee commenced: The GBC backup task force and the BMAS/Mass Spectrometry Society of Japan task force dissolved.  
   - Organization of JBF: JBF logo provided  
   - 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) |
| **Nov** | - Steering Committee meeting (11th Nov)  
   - 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  
   - Organization of JBF: The JBF information handling guidelines finalized  
   - JBF was asked by BMV Working Group to draft out the BMV guidelines of Japan  
   - Presentation: Yoshiaki Ohtsu: Waters seminar (Tokyo)  
   - Shinobu Kudoh: 4th EBF Open Symposium (Barcelona, Spain) |
| **Dec** | - Steering Committee meeting (3rd Dec)  
   - Activities of Regulated bioanalysis in Japan researched and summarized |
### JBF activities in 2011

| Jan 2012 | ➢ Steering committee meeting (13th Jan)  
            ➢ HT member-supporter community established  
            ➢ JBF Website (Japanese version) released  
            ➢ Organization of JBF : Make stamp  
            ➢ Publication  
                Yoshiaki Ohtsu : Bunseki, 1, 52 (2012) |
|----------|----------------------------------------------------------------------------------|
| Feb      | ➢ Steering committee meeting (15th Feb)  
            ➢ Organization of JBF : 'JBF Important decision making method’ finalized  
            ➢ Publication :  
                Tatsuo Kurokawa : PHARM TECH JAPAN, 28(3), 7 (2012)  
                Shinobu Kudoh (translation) : PHARM TECH JAPAN, 28(3), 9-20 (2012)  
| March    | ➢ The 2nd JBF symposium (8th March)  
            ➢ Closed meeting with EBF (9th March)  
            ➢ Steering committee meeting (28th March)  
            ➢ Draft guideline on Bioanalytical method validation in Japan provided by JBF submitted to BMV working group |