The 5th JBF Symposium Program

Date： March, 6-7th, 2014
Venue: Tower Hall Funabori, Tokyo, Japan
(Oral presentation：Small hall on 5F, Poster session : Exhibition hall on 1F)
Chair: Kobayashi, Nobuhiro (DaiichiSankyo)

March 6th (Thu.)

10:00-10:10 **Opening remarks** Okuda, Haruhiro（National Institute of Health Sciences）

10:10-10:20 **1. JBF activity report** Mabuchi, Masanari（Mitsubishi Tanabe Pharma）

10:20-11:40 **2. BMV guidance/guideline (with a focus on small molecules)**

Chair : Arnold, Mark（Bristol-Myers Squibb）,
Matsumaru, Takehisa（Nippon Boehringer Ingelheim）

2.1 Overview and update of Japan BMV guideline
Katori, Noriko（National Institute of Health Sciences）

2.2 The FDA drafted guidance (Webinar)
Booth, P. Brian （U.S. Food and Drug Administration）

2.3 Open discussion

12:40-12:50 **Luncheon Seminar**

Hourai Nihon Waters
Zui-un ThermoFisher Scientific
Hei-an AB Sciex

12:50-13:30 **3. BMV guidance/guideline (with a focus on LBA)**

Chair : Van Amsterdam, Peter (EBF, Abbott), Yahata, Kenji（Sanofi）

3.1 FDA draft Guidance on Bioanalysis: LBA perspectives and Discussion at the Crystal City V conference DeSilva, Binodh S.(AAPS, Bristol-Myers Squib)

3.2 The EMA guideline – LBA requirements Golob, Michaela（EBF, Merck Serono)

13:30-14:30 **4. Japan BMV guideline**

Chair : Taniguchi, Yoshitaka (Toray Research Center),
Togashi, Kazutaka (Sumika Chemical Analysis Service)

4.1 Summary of the Draft Japanese BMV Guideline for Ligand Binding Assay
Ishii, Akiko（National Institute of Health Sciences）
Nakamura, Takahiro（Shin Nippon Biomedical Laboratories）

4.2 Regulatory compliance to Japanese BMV guideline for small molecule in pharmaceutical companies Miyai, Hiroko（Wakamoto Phama）

14:30-15:30 **5. Panel discussion（Theme：Harmony-"All we have to do is dream"）**

Coordinator：Kudoh, Shinobu（Shimadzu Techno-Research）

5.1. Current status of Regulated Bioanalysis and contribution of Indian bioanalytical community to global harmonization efforts Yadav, Manish (APA-India, ALKEM Labs)

5.2. Perspectives on the harmonization of regulated bioanalysis in general

5.3. LC-MS based approaches for bioanalysis of bio-pharmaceuticals

GBC 2014, time for status update Van Amsterdam, Peter (EBF, Abbott)

（Break 15:30-16:00）

16:00-18:00 **6. Challenge of JBF Discussion Group (DG)**

Chair&Introduction ： Sano, Yoshihisa (Eisai)

6.1 DG2013-01：Preparation of calibration standards and QC samples

Igarashi, Harue (GlaxoSmithKline)

6.2 DG2013-02：Recommendation to prepare standard solutions Osumi, Takahiko (Otsuka)

6.3 DG2013-03：Tiered approach for bioanalytical method of metabolites

Niwa, Makoto (Nippon Kayaku)

6.4 DG2013-04：Partial validation (change in matrix) Nagao, Akemi (Japan Tobacco)

6.5 DG2013-05：LBA topics (critical reagents, ADA, etc.) Miya, Kazuhiro (Chugai)

18:30-20:00 **Banquet（Zui-un, 2F）**

March 7th (Fri.)

9:00-11:30 **7. Poster session**

7.1. DG poster presentation and open discussion

7.1.1 DG2013-01：Preparation of calibration standards and QC samples

7.1.2 DG2013-02：Recommendation to prepare standard solutions

7.1.3 DG2013-03：Tiered approach for bioanalytical method of metabolites

7.1.4 DG2013-04：Partial validation (change in matrix)

7.1.5 DG2013-05: LBA topics (critical reagents, ADA, etc.)

7.2. BMV Guideline/Guidance Comparison for Small Molecule

7.3. Draft Japanese BMV guideline for ligand binding assay

11:30-11:45 **Closing Remark（Small hall, 5F）**

Question for EMA