The 6th JBF Symposium Program
"Challenge of Regulated Bioanalysis"

Date: 25th -26th February 2015

Venue: Tower Hall Funabori, Tokyo, Japan

Overall host: Harue Igarashi (GlaxoSmithKline)

25th February (Wed.)

1. JBF activity update — Masanari Mabuchi (Mitsubishi Tanabe Pharma)

2. Global BMV guideline/recommendation — Chair: Noriko Inoue (JCL Bioassay)

2.1 FDA guidance update — Brian Booth (U.S. Food and Drug Administration)

2.2 GBC update — Shinobu Kudoh (Shimadzu Techno-Research, GBC-SC)

3. JBF's first session on biomarkers — Chair: Noriko Katori (National Institute of Health Sciences), Takehisa Matsumaru (Otsuka Pharmaceutical)

3.1 An overview of the draft concept paper on quantitative measurements of endogenous biomarkers for drug developments; regulatory importance and future directions — Takayoshi Suzuki (National Institute of Health Sciences)

3.2 Fit-for-purpose biomarker assay validation: from concept to practices — Jean W. Lee (BioQualQuan, LLC)

3.3 Biomarker assay development based on drug R&D strategy — Nobuhiro Kobayashi (DaiichiSankyo)

3.4 Comparison of biomarker assay between bioanalysis and laboratory test — Keiko Nakai (LSI medience)

3.5 Panel discussion

4. Best practices in Asia-pacific CRO — Chair: Shinobu Kudoh (Shimadzu Techno-Research), Kenji Yahata (Sanofi)

4.1 Cross validation and matrix effect – two critical factors in ensuring successful regulated bioanalysis — Bi Luke (Covance)

4.2 Bioanalytical best practice in Australia — Andrew Dinan (CPR Pharma)

4.3 Bioanalytical Current Circumstances in Korea — Masahiro Taniguchi (SBB)

26th February (Thu.)

5. Poster presentation and open discussion

5.1 Outcomes and recommendations from JBF Discussion Group

5.1.1 DG2014-06: "The Study of Failure" in analytical studies

5.1.2 DG2014-07: Development of analysis method

5.1.3 DG2014-08: Quantitative analysis of endogenous substance

5.1.4 DG2014-09: Tiered approach for the quantitative assay method

5.1.5 DG2014-10: Partial validation (3)

5.1.6 DG2014-11: Anti-Drug Antibody (ADA) Assay

5.1.7 DG2014-12: Quantitative analysis by LBA (PK/Biomarker)

5.1.8 DG2013-01: Recommendation to prepare calibration standards and QC samples

5.2 Achievement of the JBF task force for large molecule MS

LMMS task force [Masaki Hoshino (LSI medience) and all]

5.3 Achievement of the JBF task force for biomarker — Biomarker task force

6. Bioanalysis of large molecule pharmaceuticals using LC-MS

Chair: Masahiro Utoh (Shin Nippon Biomedical Laboratories),
Hisao Shimizu (Takeda)

6.1 Meaning of large molecule bioanalysis using mass spectrometory — Rieko Goto (JCL Bioassay)

6.2 Outcomes from large molecule MS Task force team — Ryoya Goda (Daiichi-Sankyo)

6.3 LC-MS-based bioanalysis in support of protein biotherapeutics development: current challenges and emerging opportunities — Rand Jenkins (PPD)

6.4 Panel discussion

Short presentation: Recommendations for validation of LC-MS/MS bioanalytical methods for protein biotherapeutics — Jean W. Lee

Panel discussion:

7. MHLW BMV guidelines — Chair: Masanari Mabuchi (Mitsubishi Tanabe Pharma), Kazutaka Togashi (Sumika Chemical Analysis Service)

7.1 LC guideline, Implementation for a year

7.1.1 Evaluation of bioanalysis in regulatory review in Japan — Daisuke Iwata (PMDA)

7.1.2 Implementation of the BMV guideline for generic drug development in Japan

Hidehisa Tachiki (Towa, JGA)

7.2 LBA guideline

7.2.1 Guideline/guidance comparison on large molecule bioanalysis (ligand binding assay)

Jun Hosogi (Kyowa Hakko Kirin)

7.2.2 Issues on method validation/ sample assay after application of LBA guideline

Yoshiyuki Minamide (Shimadzu Techno-Research)

8. Panel discussion — Chair: Masanari Mabuchi, ,Kazutaka Togashi