The 9th JBF Symposium Program

Date: 6th -8th February 2018

Venue: Tower Hall Funabori, Tokyo, Japan

(Oral presentation: Small Hall on 5F, Poster session: Event Hall on 2F）

6th February (Tue.) (Reception：12:00～, Opening：13:30～)

13:30-13:35 **Welcome greeting**

Junji Komaba (Chairperson / Ono PHARMACEUTICAL CO., LTD.)

13:35-13:45 **Opening remarks of 9th JBF symposium**

Yoshiro Saito (JBF Representative / National Institute of Health Sciences [NIHS])

13:45-15:45 **1. Toward Proper Inclusion of Microsampling in Nonclinical Toxicity Study**

Chairs: Noriko Katori (NIHS)
Keiko Nakai (LSI Medience Corporation)

1.1 ICH S3A Q&A focusing on microsampling
Yoshiro Saito (NIHS)

1.2 Effects of blood microsampling in a rodent toxicity study
- current status and future issues -
Akio Kobayashi (JAPAN TOBACCO INC.)

1.3 Points to consider in TK analysis using microsampling
Yoichiro Nihashi (Shionogi & Co., Ltd.)

1.4 Usefulness and considerations in toxicological evaluations using microsampling methods
Jihei Nishimura (Pharmaceuticals and Medical Devices Agency)

15:45-16:15 **Break**

16:15-17:40 **2. Application of sample preparation automation for bioanalysis**

Chairs: Hiroshi Kamimori (Shionogi & Co., Ltd.)
Takumi Noda (Ono PHARMACEUTICAL CO., LTD.)

2.1 LabDroid：all purpose humanoid robot for life science
Tohru Natsume (National Institute of Advanced Industrial Science and Technology)

2.2 Automation of sample preparation in ADME screening
Takumi Orikasa (Axcelead Drug Discovery Partners)

2.3 Laborato automation system under the GLP regulations
Toshikazu Horiuchi (Shin Nippon Biomedical Laboratories, Ltd.)

7th February (Wed.)

9:15-10:45 **3. Perspectives on ICH M10 Bioanalytical Method Validation**

Chairs: Yoshiaki Ohtsu (Astellas Pharma)
Masanari Mabuchi (Mitsubishi Tanabe Pharma)

3.1 Perspective on international harmonisation of bioanalytical method validation by the establishment of ICH M10
Akiko Ishii-Watabe (NIHS)
Yoshiro Saito (NIHS)

3.2 Building consensus on Bioanalytical Guidance in Weehawken
Lindsay Ewan King (Pfizer Inc.)

3.3 Harmonization of Bioanalysis Guidelines: delivering on promise!
Philip Timmerman (European Bioanalysis Forum)

10:45-11:00 **Break**

11:00-12:25 **4. Recent progress of anti-drug antibodies analysis in drug development**

Chairs: Jun Hosogi (Kyowa Hakko Kirin)
Takahiro Nakamura (Shin Nippon Biomedical Laboratories)

4.1 Technical requirements for immunogenicity assessments using ligand binding assay
Kazuko Nishimura (NIHS)
Akiko Ishii-Watabe (NIHS)

4.2 ADA Assay Life-Cycle Management During Clinical Development: A Case Study
Sally Saeger (Bristol-Myers Squibb)

4.3 Challenges to improve the drug tolerance of clinical/pre-clinical ADA assays
Maiko Adachi (Kyowa Hakko Kirin Co., Ltd.)

12:40-13:40 **Luncheon seminars**

Tou-gen (2F): K.K. AB Sciex Japan
Hou-rai (2F): Thermo Fisher Scientific K.K.
406 (4F): Future Science Group
407 (4F): SEKISUI MEDICAL CO., LTD.

14:00-15:30 **5. Bioanalysis of therapeutic antibodies by LC/MS and LBA**

Chairs: Takeru Yamaguchi (Sumika Chemical Analysis Service, Ltd.)
Makoto Takahashi (Daiichi Sankyo Co., Ltd.)

5.1 Revisiting the AAPS Recommendations Paper on Validating LC-MS Bioanalytical Methods for Protein Therapeutics: 3 Years of Progress.
Steve Loews (Q2 Solutions)

5.2 EBF view and future perspective of free/total large molecule drug quantification
Roland Staack (Roche, on behalf of the European Bioanalysis Forum)

5.3 Commentaries and Proposals on Bioanalytical Quantification of Therapeutic Antibodies by LC/MS
Nozomu KATO (Mitsubishi Tanabe Pharma Corp.)

5.4 Various approaches to antibody drug measurement - comparison of analytical methods -
Noriyuki Danno (CMIC Pharma Science Co., Ltd.)

16:00-18:15 **Poster presentation and open discussion 1 (Zui-un, Hei-an, and Fuku-ju, 2F)**

Outcomes and recommendations from JBF Discussion Group

P.1 DG2016-28 : Giving consideration to accuracy and precision criteria

P.2 DG2016-29 : Microsampling (3) –Proposals for planning and method

P.3 DG2016-30 : Application of imaging mass spectrometry to drug discovery research

P.4 DG2016-31 : Quantitative analysis of endogenous large molecule substances by LC-MS

P.5 DG2016-32 : Automated sample preparation in regulated LC-MS bioanalysis

P.6 DG2016-33 : Considerations for designing validation for quantitative analysis using qPCR

P.7 DG2016-34 : Ligand binding assay using commercial immunoassay kits

Activities of JBF/DG

P.8 JBF/AAPS/EBF ICH-M10 Joint Meeting (Oral Presentation)
Regulatory Reflections on the BMV Guideline/Guidance Harmonization

P.9 EBF 10th Open Symposium (Oral Presentation)
Relationship between Pharma and CRO in method development and transfer - based on the survey by JBF Discussion Group

P.10 DG activities on 10th EBF Open Symposium (Poster Presentation)
Current Situation of Microsampling in Japan: Report from the Japan Bioanalysis Forum Discussion Group

Audit activities for bioanalysis study by Joint Special Project Group 2, Japan Society of Quality Assurance (JSQA)

P.11 Discussion on the temperature management of the biological samples and reference standards for bioanalyses in clinical trials

18:30-20:00 Banquet (Fuku-ju, Tou-gen, 2F)

8th February (Thu.)

09:00-10:45 Poster presentation and open discussion 2 (Zui-un, Hei-an, and Fuku-ju, 2F)

11:00-12:20 6. Validation for quantitative analysis using flow cytometry, luminex, and qPCR

Chairs: Takahiro Nakamura (Shin Nippon Biomedical Laboratories)
Jun Hosogi (Kyowa Hakko Kirin)

6.1 Considerations for designing validation for quantitative analysis using flow cytometry and Luminex
Yoshitaka Hirasawa (Ina Research Inc.)

6.2 Considerations for designing validation for quantitative analysis using qPCR
Asako Uchiyama (Shin Nippon Biomedical Laboratories, Ltd.)

12:30-13:30 Luncheon seminars

Tou-gen (2F): Nihon Waters K.K.
401 (4F): Meso Scale Discovery
406 (4F): Agilent Technologies Japan, Ltd.
407 (4F): Biotage Japan Ltd.

13:45-15:45 **7. Current practice of biomarker measurement and its application to clinical diagnosis**

Chairs: Harue Igarashi (GlaxoSmithKline K.K.)
Masaaki Kakehi (Takeda Pharmaceuticals Co., Ltd.)

7.1 Current status of biomarker measurement and regulatory issues
Noriko Katori (NIHS)

7.2 Challenges in developing Biomarker Assays for patient selection and Companion Diagnostic (CDx) Assays in early and late stage of drug development
Kenji Nakamaru (Daiichi Sankyo Co.)

7.3 The current issues on development of companion diagnostics
Hirohisa Matsushita (NICHIREI BIOSCIENCES INC.)

7.4 High Accuracy and precision analysis for Amino Acid as Biomarker
－What kind of data should be acquired in the sight of Regulated Bioanalysis？－
Akira Nakayama (Ajinomoto Co., Ltd.)

15:45-15:50 **Closing remarks**

Yoshiaki Ohtsu (Astellas Pharma Inc., Japan Bioanalysis Forum)

Note:

- The program might be changed without prior notice due to the circumstances of the speaker.