The 8th JBF Symposium Program

Date: 8th -9th February 2017

Venue: Tower Hall Funabori, Tokyo, Japan

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

Chairperson: Takehisa Matsumaru (Otsuka Pharmaceutical)

8th February (Wed.) (Reception : 9:00～, Opening : 9:30～)

10:00-10:05 Opening remarks of 8th JBF symposium

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

10:05-11:45 1. Immunogenicity testing of biopharmaceuticals

Chairs: Takahiro Nakamura (Shin Nippon Biomedical Laboratories, LTD.)
Jun Hosogi (Kyowa Hakko Kirin Co., Ltd.)

1.1 Points to consider in anti-drug antibody analysis used for immunogenicity assessment of biopharmaceuticals
Akiko Ishii-Watabe (Division of Biological Chemistry and Biologicals, National Institute of Health Sciences)

1.2 United States FDA Guidance for Immunogenicity Assay Development
William Hallett (U.S. Food and Drug Administration)

1.3 The revised EU immunogenicity guidance on therapeutic proteins
Meenu Wadhwa (Biotherapeutics Group, National Institute for Biological Standards and Control)

1.4 Current Challenges in the Analysis of Immunogenicity and the Regulatory Landscape: Feedback from the EBF Focus Workshop
Jo Goodman (MedImmune, on behalf of the EBF)

11:55-12:55 Luncheon seminars

Tou-gen (2F): K.K. AB Sciex Japan
Hou-rai (2F): Nihon Waters K.K.
406 (4F): ELGA LabWater
407 (4F): SCRUM Inc.

12:00-20:00 Poster viewing (Zui-un, Hei-an, Fuku-ju, 2F)

13:45-15:30 2. ICH S3A microsampling and ICH M10 bioanalytical method validation

Chairs: Shinichi Miura (On behalf of Japan Pharmaceutical Manufacturers Association [JPMA] / Daiichi Sankyo Co., Ltd.)
Stephen White (GlaxoSmithKline, on behalf of the EBF)

2.1 Recent progress on topics of bioanalysis at ICH: S3A and M10
Yoshiro Saito (National Institute of Health Sciences)

2.2 Expectation on ICH M10 – from JBF's viewpoint -
Yoshiaki Ohtsu (Astellas Pharma Inc., Japan Bioanalysis Forum)

2.3 UTOPIA: THE SCIENCE OF A MODERN GUIDELINE Feedback from the EBF.
Philip Timmerman (Janssen R&D, on behalf of the EBF)

2.4 ICH M10 bioanalytical method validation, from AAPS perspective
Faye Vazvaei (Roche)

15:30-15:50 Break

15:50-17:05 3. Advancement of large molecule analysis by LC-MS

Chairs: Toshio Teramura (CMIC Pharma Science Co., Ltd.)
Takehisa Matsumaru (Otsuka Pharmaceutical Co., Ltd.)

3.1 Quantification of therapeutic proteins in biological samples by liquid chromatography/mass spectrometry
Noritaka Hashii(Division of Biological Chemistry and Biologicals, National Institute of Health Sciences)

3.2 Paradigm shift for the antibody drug pharmacokinetics by LCMS: CDR-peptide selective proteolysis nSMOL
Takashi Shimada(Leading Technology of Bioanalysis and Protein Chemistry, SHIMADZU Corporation)

3.3 Protein quantification by various LC/MS systems
Sumio Ohtsuki (Faculty of Life sciences, Kumamoto Universiry)

17:05-18:05 4. Brief introduction of JBF Discussion Group (DG) activities

Chair: Yoshihisa Sano (Sunplanet Co.,Ltd.)

4.1 DG2016-20 : Giving Consideration to Scientific Validation (2)
Makoto Niwa (Nippon Kayaku Co., Ltd.)

4.2 DG2016-21 : Microsampling (2) -Investigation of technical problems
Katsunorti Ieki (Shin Nippon Biomedical Laboratories, Ltd.)

4.3 DG2016-22 : Application of imaging mass spectrometry to drug discovery research
Yukari Tanaka (Shionogi & Co., Ltd.)

4.4 DG2016-23 : The Pharma-CRO relationship with a focus on method transfer.
Yoshitaka Hashimoto (Ono Pharmaceutical Co., Ltd.)

4.5 DG2016-24 : Questions and Challenges in Bioanalysis – Find the Loadstar (Stability) –
Yuya Hosokawa (Ono Pharmaceutical Co., Ltd.)

4.6 DG2016-25 : Quantitative analysis of endogenous substance - LC-MS - Surrogate analyte & Large molecule endogenous substance-
Akira Wakamatsu (GlaxoSmithKline K.K., Ltd.)

4.7 DG2016-26 : Quantitative analysis of endogenous substances (LBA) -Validation of LBA for the analysis of endogenous substances-
Satomi Sasahara (Towa Pharmaceutical Co., Ltd.)

4.8 DG2016-27 : Quantitative analysis of endogenous substance - Other analytical methods for endogenous substances: Flow cytometry, Luminex, and PCR -
Takahiro Nakamura (Shin Nippon Biomedical Laboratories, Ltd.)

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

9th February (Thu.)

09:00-12:00 Poster presentation and open discussion (Zui-un, Hei-an, and Fuku-ju, 2F)

Outcomes and recommendations from JBF Discussion Group

P.1 DG2016-20 : Giving Consideration to Scientific Validation (2)

P.2 DG2016-21 : Microsampling (2) -Investigation of technical problems

P.3 DG2016-22 : Application of imaging mass spectrometry to drug discovery research

P.4 DG2016-23 : The Pharma-CRO relationship with a focus on method transfer.

P.5 DG2016-24 : Questions and Challenges in Bioanalysis – Find the Loadstar (Stability) –

P.6 DG2016-25 : Quantitative analysis of endogenous substance - LC-MS - Surrogate analyte & Large molecule endogenous substance-

P.7 DG2016-26 : Quantitative analysis of endogenous substances (LBA) -Validation of LBA for the analysis of endogenous substances-

P.8 DG2016-27 : Quantitative analysis of endogenous substance - Other analytical methods for endogenous substances: Flow cytometry, Luminex, and PCR -

Activities of JBF/DG

P.9 DG activities on 9th EBF Open Symposium
DG2013-01 : Recommendations from JBF discussion group, DG2013-01 on the preparation of calibration standards and QC samples for bioanalysis of small molecular drugs

P.10 DG activities on 9th EBF Open Symposium:
DG2015-15 : Recommendation for alternative matrix in the quantitative assay method of endogenous substance in biological samples - Selection and evaluation of appropriate matrix - by JBF discussion group (DG2015-15)

P.11 2016 AAPS Annual Meeting and Exposition: AAPS/EUFEPS/JBF/USP Joint Symposium: Global Perspectives on Quality and Regulatory Challenges in Drug DevelopmentRegulatory challenges related to bioanalysis in global filings: From a JBF perspectives

P.12 Questionnaires survey about storage aliquots of matrix stability samples in Japan

P.13 9th EBF Open Symposium (Oral Presentation)
Scientific Validation: Feedback from JBF Discussion Group

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

P.14 Japan Society of Quality Assurance: Survey results on the audit of bioanalysis.

P.15 Japan Society of Quality Assurance: Audit perspective for bioanalysis in clinical trials.

12:10-13:10 Luncheon seminars

Tou-gen (2F): Thermo Fisher Scientific K.K.
Hou-rai (2F): Sumika Chemical Analysis Service, Ltd.
406 (4F): Agilent Technologies Japan, Ltd.
407 (4F): Biotage Japan Ltd.

13:25-14:00 5. Discussion about the Audit activities for Bioanalysis study

Chairs: Takehisa Matsumaru (Otsuka Pharmaceutical Co., Ltd.)
Takahiro Nakamura (Shin Nippon Biomedical Laboratories, Ltd.)

5.1 Joint Special Project Group 2, Japan Society of Quality Assurance: Discussion about the audit activities for bioanalysis study.
Tomoyoshi Taniguchi (Eisai Co., Ltd.)
Yoshinobu Yamai (Taisho Pharmaceutical Co., Ltd.)

14:00-15:30 6. Biomarker bioanalysis and its application to drug development

Chairs: Junji Komaba (Ono Pharmaceutical Co., Ltd.)
Makoto Takahashi (Daiichi Sankyo Co., Ltd.)

6.1 The method validation for the determination of endogenous biomarkers in the clinical trial of the drug candidate for dermatitis
Shinya Horita (Kyowa Hakko Kirin Co., Ltd.)

6.2 Biomarker Research Using Mass Spectrometry in Non-Clinical Studies
Makoto Yamazaki (Mitsubishi Tanabe Pharma Corporation)

6.3 Particular attention at the Quantitative analysis of endogenous substance -Further discussion on DG2015-15: Quantitative analysis of endogenous substance (2)-
Kazuaki Sakai (Teijin Pharma)

15:30-15:35 Closing remarks

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