The 7th JBF Symposium Program
－Regulated Bioanalysis, To a New Stage－

Date: 9th -10th March 2016

Venue: Tower Hall Funabori, Tokyo, Japan

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

Chair: Takahiro Nakamura (Shin Nippon Biomedical Laboratories)

9th March (Wed.)

10:00-10:05 **Opening remarks** Haruhiro Okuda (National Institute of Health Sciences [NIHS])

10:05-12:00 **1. Open discussion with regulatory authorities**

Chairs: Noriko Katori (NIHS),
Kenji Yahata (Sanofi)

Part 1: - Q&A session -

Panelists: Daisuke Iwata (Pharmaceuticals and Medical Devices Agency [PMDA])
Toru Yamaguchi (PMDA)
Webinar: Brian Booth (U.S. Food and Drug Administration)
Pre-answered: Jan Welink (European Medicines Agency)

Part 2: - How should we insure the reliability in drug application? -

Panelists: Daisuke Iwata (PMDA)
Toru Yamaguchi (PMDA)
Yoshinobu Yamai
(Taisho Pharmacetutical, Japan Society of Quality Assurance [JSQA] KT-2)

12:10-13:10 **Luncheon seminar**

Fuku-ju (2F): SCIEX

Tou-gen (2F): Shin Nippon Biomedical Laboratories

403 (4F): Veolia Water Solutions & Technologies, ELGA LabWater

13:00-20:00 **Poster viewing（Zui-un and Hei-an, 2F）**

14:00-15:00 **2. Antibody drug conjugates**

Chair: Jun Hosogi (Kyowa Hakko Kirin)

Bioanalysis of Antibody-Drug Conjugates (ADCs): an overview of current approaches and case studies illustrating the challenges presented by hybrid biotherapeutic molecules

Rand Jenkins (Pharmaceutical Product Development)

15:00-16:00 **3. Brief introduction of JBF Discussion Group (DG) activities**

Chair: Yoshihisa Sano (Sunplanet)

3.1 DG2015-13: Questions and Challenges in Bioanalytical Study- Find the Loadstar -,
Naohito Yamada (Japan Tobacco)

3.2 DG2015-14: Carry-over, Takumi Noda (Ono Pharmaceutical)

3.3 DG2015-15: Quantitative analysis of endogenous substances (2),
Kazuaki Sakai (Teijin Pharma)

3.4 DG2015-16: Giving consideration to scientific validation,
Makoto Niwa (Nippon Kayaku)

3.5 DG2015-17: Microsampling –Implementation status and operational issues–
Eitaro Nanba (Chugai Pharmaceutical)

3.6 DG2015-18: Analysis of anti-drug antibody,
Tatsuki Nomura, (Shin Nippon Biomedical Laboratories)

3.7 DG2015-19: Quantitative analysis by ligand binding assay (method development),
Hiroyuki Shimizu (Toray Research Center)

(Break 16:00-16:15)

16:15-17:45 **4. Collaboration of EBF and JBF** (Panel discussion of biomarker assay)

Chair: Takehisa Matsumaru (Otsuka Pharmaceutical)

Theme: What are necessary in biomarker assay for drug development?

Panelist: Philip Timmerman (European Bioanalysis Forum [EBF])
Marianne Scheel-Fjording (EBF)
Kousuke Iijima (Kyowa Hakko Kirin)
Yoshiaki Ohtsu (Astellas Pharma)
Toshihiro Oguma (Daiichi Sankyo)
Takashi Miyayama (Chugai Pharmaceutical)

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

10th March (Thu.)

09:00-12:00 **5. Poster presentation and open discussion (Zui-un and Hei-an, 2F)**

Outcomes and recommendations from JBF Discussion Group

DG2015-13: Questions and Challenges in Bioanalytical Study- Find the Loadstar -

DG2015-14: Carry-over

DG2015-15: Quantitative analysis of endogenous substances (2)

DG2015-16: Giving consideration to scientific validation

DG2015-17: Microsampling –Implementation status and operational issues–

DG2015-18: Analysis of anti-drug antibody

DG2015-19: Quantitative analysis by ligand binding assay (method development)

Audit perspective for bioanalysis assay

Survey results of bioanalysis methods in JSQA

10:00-11:00 **6. Round table talks of biomarker assay (Fuku-ju, 2F)**

Facilitator: Takehisa Matsumaru (Otsuka Pharmaceutical)

Guest: Noboru Nakayama (Biosys Technologies)

12:05-13:05 **Luncheon seminar (Fuku-ju and Tou-gen, 2F; Rooms 402 and 403, 4F)**

Fuku-ju (2F): Thermo Fisher Scientific

Tou-gen (2F): Nihon Waters

402 (4F): Biotage Japan

403 (4F): Sumika Chemical Analysis Service

13:15-14:00 **7. Audit perspective for bioanalysis assay**

Chair: Akira Nakayama (Ajinomoto)

7.1 Follow Up Activity for Japanese BMV Guideline

～Relationship between JSQA and JBF～

Akira Nakayama (Ajinomoto)

7.2 Common Special Project Group 2,

Japan Society of Quality Assurance: Audit Perspective for Bioanalysis Assay

Yoshinobu Yamai (Taisho Pharmacetutical, JSQA KT-2)

14:00-14:45 **8. Current status and perspective of mass spectrometry imaging in drug development.**

Chairs: Masanari Mabuchi (Mitsubishi Tanabe Pharma, JBF)
Seiji Tanaka (Aska Pharmaceutical, Japan Pharmaceutical Manufacturers Association [JPMA] Non-Clinical Evaluation Expert Committee, Drug evaluation Committee KT4)

8.1 Drug distribution analysis using mass spectrometry imaging in cancer research
Mitsuhiro Hayashi (National Cancer Center)

8.2 Introduction of JPMA activities for mass spectrometry imaging
Yuuya Houjyou (Kyorin Pharmaceutical, JPMA Non-Clinical Evaluation Expert Committee, Drug Evaluation Committee KT4)

8.3 PMDA perspective on mass spectrometry imaging
Shintaro Nakano (PMDA)

(Break 14:45-15:00)

15:00-16:30 **9. Microsampling – ICH S3A Q&A and panel discussion -**

ICH S3A Q&A update: Noriko Katori (NIHS)

Survey results: Kozo Omichi (Kowa)

Panel discussion

Facilitator: Noriko Katori (NIHS)
Keiko Nakai (LSI Medience)

Panelists: Yoshiro Saito (NIHS),
Shin-ichi Kanzawa (PMDA),
Kazuhiro Taniyama (Toa Eiyo)
Eitaro Nanba (Chugai Pharmaceutical)

Closing remarks