THE 10TH ANNIVERSARY JBF SYMPOSIUM PROGRAM

Date: Tue, 12th Feb. – Thu, 14th Feb. 2019
Venue: PACIFICO YOKOHAMA, Yokohama, Japan
http://www.pacifico.co.jp/english/tabid/500/Default.aspx

Day 1: Tuesday, 12th Feb.

12:45-14:15 PM Future of Bioanalysis Part I

- Crawling marks of bioanalysis -Shinobu KUDOH (Yokogawa Electric)
- Innovation in technologies and services in bioanalysis (Panel Discussion)

14:30-15:30 **Special Lecture**
"Recent Trends and Future Challenges of Metabolome Analysis" -Prof. Takeshi BAMBA (Kyushu University)

16:30-18:30 Update on the Validation of Analytical Methods for Biomarkers

- Development of points to consider document on biomarker assay validation in Japan -Yoshiro SAITO (NIHS)
- Proposed selection strategy of an appropriate surrogate matrix for the successful quantitation of targeted endogenous substances, based on discussions by a Japan Bioanalysis Forum discussion group (DG2015-15) -Akira WAKAMATSU (GSK)
- Clinical biomarker assay platform for drug development -Takashi MIYAYAMA
- Case study of the analytical validation of biomarker assay using immunoassay platform in non-clinical and clinical studies - Akihide TSUJIMOTO (Mitsubishi Tanabe)

-Panel Discussion-

Day 2: Wednesday, 13th Feb.

9:00-10:10 AM Hot Topics in Bioanalysis of Antibody Drug

- Challenges and opportunities in developing a sound bioanalytical strategy for PK assessment of antibody drug conjugate therapeutic -Boris GOROVITS (Pfizer)
- Technical challenges for the quantitation of total and free therapeutic antibodies -Ichio ONAMI (Chugai)
- Achievement of the anti-drug antibody assays in the Chugai's antibody drug development over the last decade and current perspectives -Kazuhiro MIYA (Chugai) (This presentation is moved to 'Technologies Supporting Bioanalysis' session at 11:20 on Day 3.)

10:45-11:45 Future of Bioanalysis Part II

- Challenges for the 21st Century Bioanalyst - Philip TIMMERMAN (EBF)
- Future of bioanalysis -Yoshiaki OHTSU (JBF)

10:15-11:15 Sponsored Seminar

12:00-13:00 PM Luncheon

13:15-15:15 [JBF-JSSX Joint Session]

Utilizing Endogenous Biomarkers for Drug-drug Interaction Evaluation and its Bioanalytical Method Validation.

- Assessment of drug-drug interaction risks using endogenous substrates of drug transporters -Hiroyuki KUSUHARA (University of Tokyo)
- Evaluation of CYP3A activity in patients with kidney failure using endogenous substances - Yosuke SUZUKI (Meiji Pharmaceutical University)
- Bioanalysis of endogenous biomarkers for transporters-mediated DDI evaluation – method development, validation and implementation consideration -Jianing ZENG (BMS)
- Development and validation of an LC-MS/MS method for determination of biomarker of CYP3A activity -Yuri TAKEDA (Shionogi)

-Panel Discussion-

15:15-16:00 Update of ICH M10 and FDA Guidance

- ICH M10 and FDA 2018 BMV Guideline: Feedback from the EBF - Stephen WHITE (GSK)

15:45-17:00 **Poster Presentation by JBF DGs / Public Offering Speakers (Part I)**

- DG2018-35 Giving consideration to accuracy and precision criteria (2)
- DG2018-36 Quantitative analysis of oligonucleotide therapeutics by LC-MS
- DG2018-37 Automated sample preparation in LC-MS bioanalysis
- DG2018-38 Parallelism in ligand binding assay
- DG2018-39 Failure & trouble cases and their solutions of LBA

Also 33 public offering presentations are nominated.

17:15-18:15 **Keynote Lecture**

"New Horizon of Drug Discovery and Development: Quantitative Proteotyping accelerated by reliable Peptide Search (rPS) engine" -Tetsuya TERASAKI (Tohoku University)

18:30-20:30 Banquet

Day 3: Thursday, 14th Feb.

09:00-10:15 AM **Poster Presentation by JBF DGs / Public Offering Speakers (Part II)**

Same program as Part I on Day 2

10:30-11:45 **Technologies Supporting Bioanalysis [Parallel Session]**

'Bioanalysis of Macromolecular Drugs by LC/MS'

- Development of bioanalytical method for antisense therapeutics and challenge on its standardization -Yuchen SUN (NIHS)
- Hybrid immunoaffinity LC-MS/MS pharmacokinetic assays in the development of biologic protein drugs -Surinder KAUR (Genentech)]
- **Hot Topics in Bioanalysis of Antibody Drug** (continued): Achievement of the anti-drug antibody assays in the Chugai's antibody drug development over the last decade and current perspectives -Kazuhiro MIYA (Chugai)

'Advanced Technology of Bioanalysis in Drug Discovery Stage'

- Early phase ADME evaluation using high-resolution mass spectrometer -Junya KATO (Ono)
- Quantification of nucleic acid molecule by enzyme-linked oligosorbent assay (ELOSA) -Yosuke KOTANI (SNBL)
- Simple quantitative imaging mass spectrometry for drug distribution analysis in tissues -Yukari TANAKA (Shionogi)

12:00-13:00 PM Luncheon

13:15-16:45 **Synergy with Surrounding Scientific Areas [Parallel Session]**

1. **[Collabo Session with Clinical Pharmacology]**

'Collaboration in Early Clinical Trial'

- Leverage of Bioanalysis in Early Clinical Trials -Yuji KUMAGAI (Kitasato University Hospital)

-Panel Discussion-

2. **[Collabo Session with JSQA]**

'Proposal of Electronic Operation of Raw Data using LC-MS/MS as a Theme -from the Perspective of Data Integrity-'

- Practical operation of equipment and system in a GLP Laboratory (the main focus on LC-MS/MS) -Yoshihisa KUSAKAWA (CMIC)
- Point of view to assure the analytical data -Misae ITO (Chugai)

3. **[Collabo Session with Toxicity Evaluation]**

'Practicing Microsampling'

- Commentary on the ICH S3 Q&A document -Jihei NISHIMURA (PMDA)
- Status of microsampling application in foreign countries/region -Yoshiro SAITO (NIHS)

- Toxicity evaluation and TK -time course sampling and sparse sampling -HirohikoOHTSUKA (Axcelead)
- Toxicity evaluation and TK -blood sampling site and device -Yui AKAGAWA (LSI Medience)

-Panel Discussion-