THE 10TH ANNIVERSARY JBF SYMPOSIUM PROGRAM (as of Dec. 2018)

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.

9:00-10:30 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)

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

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

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 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 31 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)］
- ➢ TBD

'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 JSOT]**

     'Practicing Microsampling'

- ➢ Commentary on the ICH S3 Q&A document -Jihei NISHIMURA (PMDA)
- ➢ Status of microsampling application in foreign countries/region -Yoshiro SAITO (NIHS)
- ➢ The microsampling in toxicokinetics -time course sampling and sparse sampling -Hirohiko OHTSUKA (Axcelead)
- ➢ Toxicity evaluation and TK -blood sampling site and device -Yui AKAGAWA (LSI Medience)

-Panel Discussion-

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

     'Collaboration in Early Clinical Trial'

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

-Panel Discussion-

3.   **[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)