

7th Japanese Safety Pharmacology Society (JSPS) Annual Meeting

Program (FINAL)

Date: February 19 (Fri) -20 (Sat), 2016 Venue: The University of Tokyo, Yayoi Auditorium, Ichijo Hall / Annex Seihoku Gallery President: Seiji Hayashi (Nippon Shinyaku Co., Ltd.)

Day 1 (February 19th)

10:00 - 17:00 Poster Sessions (Annex Seihoku Gallery)

9:50 - 10:00 Opening

Opening remarks (Seiji Hayashi, President of 7th Annual Meeting)

10:00 - 11:50 Symposium 1 [Biologics] (Yayoi Auditorium, Ichijo Hall)

Current challenges and future prospects in preclinical safety/safety pharmacology assessment of innovative biologics

Moderator: Katsuyoshi Chiba (Daiichi Sankyo Co., Ltd.), Tetsuya Kitayama (Kyowa Hakko Kirin Co., Ltd.)

- 1. Recent Considerations on the Preclinical Assessment of Oligonucleotide Therapeutics Kazushige Maki (Office of New Drug III, Pharmaceuticals & Medical Devices Agency)
- Safety evaluation of biologics
 Mutsumi Suzuki (R&D Division, Kyowa Hakko Kirin Co., Ltd.)
- Approaches to develop safe and effective biologics
 Yasuo Tsutsumi (Laboratory of Toxicology and Safety Science, Graduate School of Pharmaceutical Science, Osaka University)

12:10 - 13:10 Luncheon Seminar 1 (Faculty of Agriculture, building number 1st) New Methods in Pre-Clinical Arrhythmia Prediction William J. Crumb Jr. (Cytocentrics Inc.) (Sponsored by Drug Safety Testing Center Co., Ltd.)





13:30 -14:30 Special Lecture (Yayoi Auditorium, Ichijo Hall)

Moderator: Seiji Hayashi (Nippon Shinyaku Co., Ltd.)

Acute poisoning of CNS acting drug: Clinical situation and its problems

Manabu Sugita (Department of Emergency and Critical Care Medicine, Juntendo University Nerima Hospital)

15:00 - 16:30 Oral Session (Yayoi Auditorium, Ichijo Hall)

Moderator: Hiroyuki Ando (Ono Pharmaceutical Co., Ltd.), Yuji Tsurubuchi (Biolin Scientific K.K.)

 Physiological maturation and drug responses in long-term culture of human induced pluripotent stem cell-derived cortical neurons

Ikuro Suzuki (Department of Electronics, Tohoku Institute of Technology)

 Assessment of premonitory electroencephalographic (EEG) changes of drug-induced seizure using a non-human primate EEG telemetry model

Motohiro Shiotani (Global Drug Safety, Biopharmaceutical Assessments Core Function Unit, Eisai Co., Ltd.)

3. Detection of drug-induced torsade de pointes arrhythmias *in vivo* using a new rabbit model of acute atrioventricular block

Mihoko Hagiwara (Department of Pharmacology and Therapeutics, Faculty of Pharmaceutical Sciences, Toho University)

Moderator: Harushige Ozaki (Takeda Pharmaceutical Co., Ltd.), Kiyotaka Hoshiai (CMIC BIORESEARCH CENTER Co., Ltd.)

- 4. Promising advantages of left ventricular pressure-volume relationship analysis compared with standard left ventricular pressure measurement for the assessment of cardiac contractility in monkeys Tomomichi Ishizaka (Medicinal Safety Research Laboratories, Daiichi Sankyo Co., Ltd.)
- 5. The efficacy and limitation of *microminipig* as an experimental model for assessing the drug-induced change in QT-interval

Takeshi Wada (Department of Pharmacology, Faculty of Medicine, Toho University)

 Assessment of electropharmacological effects of amantadine on cardiovascular system: Net balance between inward and outward current modifications *in vivo* Xin Cao (Department of Pharmacology, Faculty of Medicine, Toho University)



16:50 - 17:50 Overseas Invited Speakers (Yayoi Auditorium, Ichijo Hall)

Moderator: Kohei Sawada (Eisai Co., Ltd.)

Translational research in safety pharmacology

William S Redfern (AstraZeneca, R&D Innovative Medicines, Drug Safety & Metabolism)

18:30 - Banquet Party (Sanjo Conference Hall)





Day 2 (February 20th)

9:00 - 15:00 Poster Sessions (Annex Seihoku Gallery) Poster Discussion (11:00 - 12:20)

9:00 - 10:50 Symposium 2 [in silico] (Yayoi Auditorium, Ichijo Hall) Current status and future prospects of *in silico* research

Moderator: Takashi Yoshinaga (Eisai Co., Ltd.), Taeko Kubo (Sumitomo Dainippon Pharma Co., Ltd.)

- 1. Current status and usage of *in silico* drug discovery in drug industry Megumi Ikemori (Next Generation Systems CFU, Eisai Co., Ltd.)
- *in silico* analysis for cardiac safety from basic to clinical medicine: implications for the application of human induced pluripotent stem cell-derived cardiomyocytes to safety pharmacology Takashi Ashihara (Department of Cardiovascular Medicine, Shiga University of Medical Science)
- Vision of virtual thorough QT testing Jun-ichi Okada (UT-Heart Inc.)

12:30 - 13:30 Luncheon Seminar 2 (Faculty of Agriculture, building number 1st)

Using CiPA studies to boost the drug discovery pipeline Christopher Mathes (Ion Channel Services, Charles River Laboratories) (Sponsored by Charles River Laboratories Japan, Inc.)

14:00 - 15:30 Workshop (Yayoi Auditorium, Ichijo Hall)

Activity report from J-ICET and iSMART working group in JSPS

Moderator: Mitsuyasu Tabo (Chugai Pharmaceutical Co., Ltd.), Nobuyuki Baba (Mitsubishi Tanabe Pharma Corporation)

- J-ICET_ECG : Advanced approach to assessment of QT and proarrhythmic potential in monkeys toward the early clinical QT assessment <Interim report> Ryuichi Komatsu (Research Division, Chugai Pharmaceutical Co., Ltd.)
- J-ICET_BP/HR : Preclinical hemodynamic assessment in non-rodents by considering the physiological variation range <Interim report> Toshiki Kagawa (Safety Research Laboratories, Research Division, Mitsubishi Tanabe Pharma Corporation)
- iSMART: *in silico* assessment of drug-induced arrhythmogenic risk using human ventricular cell model <Goals and progress>

Keiichi Asakura (Pharmacokinetics and Safety Assessment Dept., R&D Labs., Nippon Shinyaku Co., Ltd.)



16:00 - 17:00Safety Pharmacology Q&A (Yayoi Auditorium, Ichijo Hall)Moderator: Chieko Kasai (Astellas Pharma Inc.), Hiroshi Yokoyama (Nippon Kayaku Co., Ltd.)

17:00 - Closing (Yayoi Auditorium, Ichijo Hall) JSPS award ceremony (Seiji Hayashi, Selection Chairman) Closing remarks (Takashi Yoshinaga, President of 8th Annual Meeting)