Timetable

Day 1 (November 17, 2022): Past to Present

9:00 – 9:20 **Opening Remarks**

Ikumi Tamai (Kanazawa University, Japan)

Elke Lipka (TSRL, USA)

Plenary lecture

Chairperson: Ikumi Tamai (Kanazawa University, Japan)

Elke Lipka (TSRL, USA)

9:20 – 9:45 **Mechanistic Oral Bioequivalence (BE) A Modern Approach.**

Gordon L. Amidon (University of Michigan, USA)

9:45 – 10:10 **Are In Vitro Dissolution Predictions In Vivo Relevant? A Physical Model Approach.**

Gregory E. Amidon (University of Michigan, USA)

10:10 – 10:35 **For What, So What?**

Shinji Yamashita (Setsunan University, Japan)

10:35 – 10:50 Short Break

Special lecture

Chairperson: Marival Bermejo (Miguel Hernandez University, Spain)

James E. Polli (University of Maryland, USA)

10:50 – 11:10 **Physiologically Based Pharmacokinetic Modeling of Nonlinear Pharmacokinetics by Cluster Gauss-Newton Method: A Novel Top-down and Middle-out Approach.**

Yuichi Sugiyama (Josai International University, Japan)

11:10 – 11:30 **Predicting Pharmacokinetics of Multisource Acyclovir Oral Products Through Physiologically Based Biopharmaceutics Modeling.**

Peter Langguth (Johannes Gutenberg University, Germany)

11:30 – 11:50 **Direct Measurement of Drug Dissolution, Bile Salts, and Microbiome in Human GI Tract Using Intubation and Wireless Sampling Capsule.**

Duxin Sun (University of Michigan, USA)

11:50 – 13:00 Lunch

Session 1: What was done in the past

Chairperson: Shinji Yamashita (Setsunan University, Japan)

Yasuhiro Tsume (MSD, USA)

13:00 – 13:20 **BCS as a Tool for Industrial Drug Development.**

Jack Cook (Pfizer, USA)

13:20 – 13:40 **Oral Drug Delivery of Drugs and Hormones – Importance of Release Rates.**

Hans Lennernäs (Uppsala University, Sweden)

13:40 – 14:00 **Industrial Use of Physiologically Based Biopharm Modelling in BA/BE.**

Bertil Abrahamsson (AstraZeneca, Sweden)

14:00 – 14:20 **Challenges Faced in Assessing In Vitro Bioequivalence of a Drug that is not Systemically Absorbed**

Ismael J. Hidalgo (Absorption Systems, USA)

14:20 – 14:40 **'Commission for Species Difference Problem on DDS Formulation Design' Supported by APSTJ.**

Hiroshi Kikuchi (DDS Strategy Firm, Japan)

14:40 – 15:00 **Application of Microphysiological System Models to Study Intestinal Drug Disposition.**

Kenneth E. Thummel (University of Washington, USA)

15:00 – 15:20 Short Break

Session 2: What is going on now

Chairperson: Peter Langguth (Johannes Gutenberg University, Germany)

Duxin Sun (University of Michigan, USA)

15:20 – 15:40 **In Vivo Predictive Dissolution (iPD) and Modeling as Tool in Generic Development**

Marival Bermejo (Miguel Hernandez University, Spain)

15:40 – 16:00 **Prediction of Oral Drug Absorption and Biopharmaceutic Risk Using a Dissolution-Hollow Fiber Membrane (D-HFM) System.**
James E. Polli (University of Maryland, USA)

16:00 – 16:20 **Oral Drug Therapy Following Bariatric Surgery: Where Pharm Sci Meets the Patient.**
Arik Dahan (Ben-Gurion University of the Negev, Israel)

16:20 – 16:40 **Organoclay-Based Nanocomposites as the Non-Invasive Delivery Systems of Biomacromolecules.**
Hyo-Kyung Han (Dongguk University, South Korea)

16:40 – 17:00 **Formulation Design and Evaluation of In Vivo Bioavailability of Drugs with Poor Water Solubility and Limited Oral Absorption Windows.**
Beom-Jin Lee (Ajou University, Korea)

17:00 – 17:20 **How We Get Here and Where We Go from Here - In Vivo Predictive Dissolution (iPD) and Modeling?**
Yasuhiro Tsume (MSD, USA)

Day 2 (November 18, 2022): Present to Future

Session 3: Understanding gastrointestinal physiologies in human

Chairperson: Kazuki Matsui (Sawai Pharmaceutical Co., Ltd., Japan)
Yoshihisa Shitara (Sanofi K.K., Japan)

9:00 – 9:30 **Insights in Gastrointestinal Physiology Using MRI.**
Werner Weitschies (University of Greifswald, Germany)

9:30 – 10:00 **Surface pH of Drug Particles and Its Dissolution, How to Predict In Vivo Performance with PBBM.**
Bart Hens (Pfizer, United Kingdom)

10:00 – 10:30 **Biorelevant Dissolution Testing Coupled with an In Silico Modeling to Predict In Vivo Performance of Oral Dosage Forms.**
Atsushi Kambayashi (Astellas Pharma, Japan)

10:30 – 11:00 **Use of Human- and Animal-Derived Cultured Intestinal Epithelial Cells for the Evaluation of Intestinal Absorption and Drug-Induced Toxicity.**
Kazuya Maeda (Kitasato University, Japan)

11:00 – 11:15 **<P-35> Quantitative Analysis of the Impact of Controlled-Release Formulation on Oral Absorption and Bioavailability of P-gp/CYP3A4 Substrates.**

Yoshiyuki Shirasaka (Kanazawa University, Japan)

11:15 – 11:30 **<P-37> Intestinal precipitation of weak base drugs simulated by population balance model.**

Hibiki Yamamoto (Ritsumeikan University, Japan)

11:30 – 12:30 Lunch

Session 4: Innovation in formulation technologies

Chairperson: Toshiro Fukami (Meiji Pharmaceutical University, Japan)
Yusuke Tanaka (Hiroshima International University, Japan)

12:30 – 13:00 **Methodology of Oral Formulation Selection in the Pharmaceutical Industry.**

René Holm (University of Southern Denmark, Denmark)

13:00 – 13:30 **Oral Absorption of BCS Class II Drugs from Cocrystals: Evaluation and Control of In Vivo Cocrystal Dissolution Based on Physicochemical Properties of Cocrystals.**

Makoto Kataoka (Setsunan University, Japan)

13:30 – 14:00 **Introducing cPAD: Leveraging Amorphous Solid Dispersions and a Hierarchical Particle Approach to Improve Delivery of High Drug Loadings.**

Jasmine Rowe (MSD, USA)

14:00 – 14:30 **Importance of Evaluating Drug Amorphous Solubility in the Development of Supersaturated formulations.**

Keisuke Ueda (Chiba University, Japan)

14:30 – 14:45 **<P-06> Characterization of drug-rich phase formed by liquid-liquid phase separation and its significance on intestinal absorption of drug.**

Shiryu Takemoto (Chiba University, Japan)

14:45 – 15:00 **<P-07> Drastic dissolution enhancement by co-crystallization enables to develop Ensitrelvir as an oral formulation for COVID-19.**

Tetsuya Miyano (Shionogi & Co., Ltd., Japan)

15:00 – 16:00 **Poster (Q & A by Presenters)**

Session 5: How to evaluate in vivo performance of oral drug products

Chairperson: Takashi Mano (Ono Pharmaceutical Co., Ltd. Japan)
Kazutaka Higaki (Okayama University, Japan)

16:00 – 16:30 **Generation and Integration of Paediatric Gastrointestinal Physiological Data into PBPK Software.**

Hannah Batchelor (University of Strathclyde, UK)

16:30 – 17:00 **How to Design and Evaluate Potential Oral Drug Products Based on Drug Absorption Variance in Different Species.**

Hiromu Kondo (University of Shizuoka, Japan)

17:00 – 17:30 **Assessment and Prediction of Bioequivalence of Oral Drug Products in Variable Physiological Conditions Using a Newly Developed In Vitro System.**

Toshihide Takagi (Setsunan University, Japan)

17:30 – 18:00 **In Vitro-In Silico Predictions of Amorphous Solid Dispersion Bioperformance.**

Deanna Mudie (Lonza, USA)

18:00 – 18:15 **<P-13> Bicarbonate buffering action at interfaces: Mass transport analysis and application in in vivo-predictive dissolution method design.**

Jozef Al-Gousous (Johannes Gutenberg University, Germany)

18:15 – 18:30 **<P-19> How the postprandial Magenstrasse (gastric water-pathway) is formed? : challenge to reproduce the pathway in the in vitro chamber.**

Ryosuke Sakai (Kanazawa University, Japan)

19:00 – 21:00 Banquet

Day 3 (November 19, 2022): Future and Regulation

Session 6: Cutting-edge technologies for oral drug delivery

Chairperson: Yuriko Higuchi (Kyoto University, Japan)
Noriyasu Kamei (Kobe Gakuin University, Japan)

9:00 – 9:30 **In-Blister 3D-Printing: Accelerating Drug Development and Optimizing Commercial Success with Minimal Scale-up.**

Don Wetherhold (Aprecia Pharma, USA)

9:30 – 10:00 **Microphysiological System (MPS) Platforms with High Operability for Commercialization.**

Hiroshi Kimura (Tokai University, Japan)

10:00 – 10:30 **Mucoadhesive Versus Mucopenetrating Nanoparticles for Enhanced Oral Delivery of Insulin.**

Shirui Mao (Shenyang Pharmaceutical University, China)

10:30 – 11:00 **Oral Peptide Technologies | Perspectives on Formulation and Delivery Strategies.**

Stephen T. Buckley (Novo Nordisk, Denmark)

11:00 – 11:15 **<P-31> Investigation of the region-specific functional expression of transporters and enzyme induction in human intestinal spheroid-derived differentiated enterocytes.**

Kazuyoshi Michiba (University of Tokyo, Japan)

11:15 – 11:30 **<P-32> Fabrication of 3D printed gummy formulations for pediatric patients in hospital setting.**

Tatsuaki Tagami (Nagoya City University, Japan)

11:30 – 13:00 Lunch & Poster

Session 7: Regulatory standards towards harmonization

Chairperson: Ken-ichi Izutsu (National Institute of Health Sciences, Japan)
Susumu Takeuchi (Ono Pharmaceutical Co., Ltd., Japan)

13:00 – 13:30 **Moving Forward to Harmonization on Bioequivalence: the European Perspective.**

Paulo Paixão (University of Lisbon, Portugal)

13:30 – 14:00 **Bioequivalence Studies Recommended for Generic Drug Approval from US FDA: Potential Areas for Harmonization.**

Partha Roy (U.S. Food and Drug Administration, USA)

14:00 – 14:30 **Modernisation and Strengthening of BE Guidelines in Japan.**

Toru Yamaguchi (Pharmaceuticals and Medical Devices Agency, Japan)

14:30 – 15:00 **Cloud-based Regulatory Assessment: ICH M4Q(R2) and FDA KASA Initiative.**

Lawrence Yu (U.S. Food and Drug Administration, USA)

15:00 – 15:15 **Closing Remarks**

Peter Langguth (Johannes Gutenberg University, Germany)

Program of Poster Presentation

Presentation number marked * was selected for young researcher oral presentations.

P-01 Effect of hydrophobic hydration on the intermolecular interaction of acidic and basic drugs: Diffusion coefficient of Fick's law determined by diffusion ordered spectroscopy and electrochemical impedance spectroscopy

Ryotaro Koga[1], Satoru Goto[1], Takatoshi Kinoshita[1], Hikaru Kataoka[1], Momoko Fujita[1], Takehisa Hanawa[1], Isao Shitanda[2], Hideshi Yokoyama[1]

([1]Faculty of Pharmaceutical Sciences, Tokyo University of Science, [2]Faculty of Science and Technology, Tokyo University of Science)

P-02 Determination of crystal polymorph entropy of indomethacin and quantitative effect of hydrotrope on solubility of indomethacin

Kanji Hasegawa, Hideshi Yokoyama, Satoru Goto

(Faculty of Pharmaceutical Sciences, Tokyo University of Science)

P-03 Effects of wet granulation process variables on the quantitative assay model of transmission Raman spectroscopy for pharmaceutical tablets

Ryo Ohashi [1,2], Tatsuo Koide [3], Toshiro Fukami [1]

([1]Department of Molecular Pharmaceutics, Meiji Pharmaceutical University, [2]Formulation R&D Laboratory, R&D Division, SHIONOGI & CO., LTD., [3]Division of Drugs, National Institute of Health Sciences)

P-04 Exploration of Pioglitazone Complexes for Improved Solubility

Naoki Shimada[1], Tomoki Takayama[1], Varin Titapiwatanakun[2], Toshiro Fukami[1]

([1]Meiji pharmaceutical university, [2]Chulalongkorn University, Thailand)

P-05 Formulation development of water-insoluble Cu-ATSM nanoparticles to enhance oral absorption

Nayuta Oike[1], Taiki Akashi[1], Hideyo Takahashi[2], Kiyomi Ito[3], Toshiro Fukami[1]

([1]Meiji Pharmaceutical University, [2]Tokyo University of Science, [3]Musashino University)

P-06* Characterization of drug-rich phase formed by liquid-liquid phase separation and its significance on intestinal absorption of drug

Shiryu Takemoto, Keisuke Ueda, Kenjirou Higashi, Kunikazu Moribe

(Graduate School of Pharmaceutical Sciences, Chiba University**)**

P-07* Drastic dissolution enhancement by co-crystallization enables to develop Ensitrelvir as an oral formulation for COVID-19

Tetsuya Miyano, Shigeru Ando, Daiki Nagamatsu, Yui Watanabe, Hiroshi Ueda

(Physical chemistry, Laboratory for medicinal chemistry, Shionogi & Co., Ltd.)

P-08 Development of pH responsive polymer-coated mRNA-LNP for oral delivery of mRNA medicine

Koki Ogawa, Hamid Alghurabi, Tohma Shinkai, Tatsuaki Tagami, Tetsuya Ozeki

(Graduate School of Pharmaceutical Sciences, Nagoya City University)

P-09 Formulation design of three-component solid dispersion particles with using hydroxy propyl-β-yclodextrin and their drug release profiles

Noriko Ogawa, Ayumi Nishikata, Kosuke Fujita, Ryohei Yasue, Toshiya Yasunaga, Hiromitsu Yamamoto

(Department of Pharmaceutical Engineering, School of Pharmacy, Aichi Gakuin University)

P-10 Characterization of the viscoelasticity of disintegrants by dynamic rheological analysis

Takayuki Terukina, Takanori Kanazawa, Hiromu Kondo

(Department of Pharmaceutical Engineering and Drug Delivery Science, Graduate School of Pharmaceutical Sciences, University of Shizuoka)

P-11 Analysis of the Effect of Surface Area/Volume (SA/V) Ratio on Drug Absorption for Supersaturated Solutions

Haruki Higashino, Chie Higashino, Corey Develin, Tyler Lim, Robert Strab, and Ismael J. Hidalgo

(Absorption Systems, A Pharmaron Company, Exton, PA, USA)

P-12 *In Vitro* Digestion-Diffusion Model for Predicting *In Vivo* Performance of Lipid-Based Formulations

Haruki Higashino, Chie Higashino, Corey Develin, Tyler Lim, Andrew Martin, Feng Zhou, Robert Strab, and Ismael J. Hidalgo

(Absorption Systems A Pharmaron Company, USA)

P-13* Bicarbonate buffering action at interfaces: Mass transport analysis and application in *in vivo*-predictive dissolution method design

Jozef Al-Gousous[1,2], Niloufar Salehi[3], Mauricio Garcia[1], Michael Hofmann[1], Robert M Ziff[3],Gregory E Amidon[2], Peter Langguth[1], Gordon L Amidon[2].

([1]Institute of Pharmaceutical and Biomedical Sciences, Johannes Gutenberg University, Germany; [2]College of Pharmacy, University of Michigan, USA, [3]Dept. of Chemical Engineering, University of Michigan, USA)

P-14 The Impact of Oral Dose of Lipid-Based Formulations with Different Compositions on the *In Vivo* Performance of Ritonavir

Yusuke Tanaka, Hirotaka Doi, Takeru Katano, Satoshi Kasaoka

(Laboratory of Pharmaceutics, Faculty of Pharmaceutical Sciences, Hiroshima International University)

P-15 Simple bicarbonate buffer system for dissolution test: Floating lid method and its application

Aoi Sakamoto, Kiyohiko Sugano

(Molecular Pharmaceutics Lab., College of Pharmaceutical Sciences, Ritsumeikan University)

P-16 Development of floating lid bicarbonate buffer flow-through cell dissolution test and its application to bioequivalence prediction of enteric-coated tablets

Shotaro Ikuta[1,2], Hidetoshi Nakagawa[2], Toshiya Kai[2], Kiyohiko Sugano[1]

([1]Molecular Pharmaceutics Lab., College of Pharmaceutical Sciences, Ritsumeikan University, [2]Pharmaceutical Research Laboratories, Pharmaceutical Department, Nipro corporation)

P-17 Disintegration time of enteric-coated tablets in bicarbonate buffer system

Fumiya Matsui, Kiyohiko Sugano

(Ritsumeikan University)

P-18 Localization of Janus nanoparticles around adherence junction in Caco-2 monolayer

Akihiro Matsumoto[1], Takeo Kitazawa[2], Yuta Hatori[2], Chie Watanabe[3], Tomoya Takashima[1], Masahiro Murakami[1]

([1]Osaka Ohtani University, [2]Yasuda Women's University, [3]Josai University)

P-19* How the postprandial Magenstrasse (gastric water-pathway) is formed? : challenge to reproduce the pathway in the *in vitro* chamber

Ryosuke Sakai[1], Toshihide Takagi[2], Keiko Minami[2], Makoto Kataoka[2], Yoshiyuki Shirasaka[1], Ikumi Tamai[1], Shinji Yamashita[2]

([1]Faculty of Pharmaceutical Sciences, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University; [2]Faculty of Pharmaceutical Sciences, Setsunan University)

P-20 *In vitro* evaluation on bioequivalence of orally disintegrating tablet (ODT) using BE-checker (1) : for dosing with water

Yoshiemon Shiono, Toshihide Takagi, Keiko Minami, Makoto Kataoka, Shinji Yamashita
(Faculty of Pharmaceutical Sciences, Setsunan University)

P-21 *In vitro* evaluation on bioequivalence of orally disintegrating tablet (ODT) using BE-checker (2) : for dosing without water

Mana Mizutani, Yuki Nakano, Takato Masada, Toshihide Takagi, Keiko Minami, Makoto Kataoka, Shinji Yamashita
(Faculty of Pharmaceutical Sciences, Setsunan University)

P-22 Development of bioequivalence evaluation method for fed conditions using BE checker

Mana Kadoguchi, Toshihide Takagi, Keiko Minami, Makoto Kataoka, Shinji Yamashita
((Faculty of Pharmaceutical Sciences, Setsunan University)

P-23 Drug Absorption Process from Oral Jelly Formulations: Correlation between *in vitro* Dissolution and *in vivo* Absorption

Junko Nakamura[1], Keiko Minami[2], Makoto Kataoka[2], Yukari Kakino[1], Yoshihiro Hishikawa[1], Shinji Yamashita[2]
([1]Ohkura Pharmaceutical Co., Ltd., [2]Setsunan University)

P-24 Development of oral mucus-penetrating PEGylated liposomes to improve peptide drug absorption

Eriko Yamazoe, Takaaki Ito, Kohei Tahara
(Laboratory of Pharmaceutical Engineering, Gifu Pharmaceutical University)

P-25 Potential of OATP2B1-mediated prodrug approach for improving absorption

Naomi Fukazawa, Tomohiro Nishimura, Saki Noguchi, Masatoshi Tomi
(Faculty of Pharmacy, Keio University)

P-26 Effect of cyclodextrin complex formation on the solubility change of each drug due to intermolecular interactions between acidic drug NSAIDs and basic drug H2 blockers

Chihiro Tsunoda, Ryosuke Hiroshige, Takahiro Kasai, Satoru Goto
(Faculty of Pharamaceutical Science, Tokyo University of Science)

P-27 Effects of local anesthetics on liposomes determined by the inhibitory activity to lipid peroxidation

Yusuke Horizumi, Miwa Takatsuka, Satoru Goto
(Faculty of Pharmaceutical Sciences, Tokyo University of Science)

P-28 Improvement of cell-cell interaction by site-directed modification of antibody to the cell membrane using non-natural amino acid

Yuriko Higuchi, Fumiyoshi Yamashita

(Graduate School of Pharmaceutical Sciences, Kyoto University)

P-29 Liposomes as an oral formulation: process and mechanism of enhanced absorption of poorly water-soluble drugs

Keiko Minami[1], Makoto Kataoka[1], Toshihide Takagi[1], Tomohiro Asai[2], Naoto Oku[3], Shinji Yamashita[1]

([1] Faculty of Pharmaceutical Sciences, Setsunan University, [2]School of Pharmaceutical Sciences, University of Shizuoka, [3]Faculty of Pharma-Science, Teikyo University)

P-30 Development of a Novel Booster with Antedrug Characteristics to Improve Oral Bioavailability of CYP Substrates

Shota Fujii, Sae Takenaka, Keiko Minami, Toshihide Takagi, Shinji Yamashita, Kentaro Kawai, Masaaki Omote, Makoto Kataoka

(Faculty of Pharmaceutical Sciences, Setsunan University)

P-31* Investigation of the region-specific functional expression of transporters and enzyme induction in human intestinal spheroid-derived differentiated enterocytes

Kazuyoshi Michiba[1], Kazuya Maeda[1,2], Osamu Shimomura[3], Yoshihiro Miyazaki[3], Shinji Hashimoto[3], Yusuke Ohara[3], Tsuyoshi Enomoto[3], Tatsuya Oda[3] and Hiroyuki Kusuhara[1]

([1]The University of Tokyo, [2]Kitasato University, [3]University of Tsukuba)

P-32* Fabrication of 3D printed gummy formulations for pediatric patients in hospital setting

Tatsuaki Tagami[1], Erina Ito[1], Risako Kida[1], Kiyomi Hirose[2], Tekehiro Noda[1], Koki Ogawa[1], Tetsuya Ozeki[1]

([1]Graduate School of Pharmaceutical Sciences, Nagoya City University, [2]Department of Hospital Pharmacy, Nagoya University Hospital)

P-33 Osmotically active excipients-mediated pharmacokinetic interaction in pediatric polypharmacy

Kazuki Matsui, Tomoya Nakagawa, Tomonori Okumura, Miki Yamane, Yuji Tokunaga, Shoji Yokota

(Research and Development Division, Sawai Pharmaceutical Co. Ltd.)

P-34 CREB is a potential marker associated with drug-induced liver injury: Identification and validation through transcriptome database analysis

Qiyue Zhang[1], Shiori Taniguchi[1], Kanako So[2], Masahiro Tsuda[2], Yuriko Higuchi[1], and Fumiyoshi Yamashita[1,2]

([1]Department of Drug Delivery Research, Graduate School of Pharmaceutical Sciences, Kyoto University, [2]Department of Applied Pharmaceutics and Pharmacokinetics, Graduate School of Pharmaceutical Sciences, Kyoto University)

P-35* Quantitative Analysis of the Impact of Controlled-Release Formulation on Oral Absorption and Bioavailability of P-gp/CYP3A4 Substrates

Yoshiyuki Shirasaka[1], Emika Murayama[1], Yugo Yasugi[1], Satoru Suzuki[1], Peter Langguth[2], Ikumi Tamai[1]

([1]Faculty of Pharmacy, Institute of Medical, Pharmaceutical and Health Sciences, Kanazawa University, [2]Institute of Pharmacy and Biochemistry, Johannes Gutenberg-University, Germany)

P-36 Prediction of liquid-liquid phase separation on the salt particle surface

Taiga Uekusa, Kiyohiko Sugano

(Molecular Pharmaceutics Lab., College of Pharmaceutical Sciences, Ritsumeikan University)

P-37* Intestinal precipitation of weak base drugs simulated by population balance model

Hibiki Yamamoto, Kiyohiko Sugano

(Ritsumeikan University)

P-38 Effect of food viscosity on drug dissolution rate

Rika Hirose, Kiyohiko Sugano

(Molecular Pharmaceutics Lab., College of Pharmaceutical Sciences, Ritsumeikan University)

P-39 Bile micelle binding of zwitterionic drugs

Rie Takeuchi, Kiyohiko Sugano

(Molecular Pharmaceutics Lab., College of Pharmaceutical Sciences, Ritsumeikan University)