

Thursday, October 11

08:50 Opening remarks

Maria do Céu Machado, Ph.D. (President of INFARMED)
Shinji Yamashita, Ph.D. (Setsunan University, Japan)

PLENARY LECTURE

09:00 **The Human Gastrointestinal Tract: Do we know (?) or just think we know.** Gordon L. Amidon, Ph.D. (University of Michigan, USA)

SPECIAL LECTURE 1

09:40 **Application of biorelevant dissolution testing in drug development.** Jennifer B. Dressman, Ph.D. (Goethe University,

10:20 – 10:30 SHORT BREAK

SESSION 1

IN VIVO PERFORMANCE OF ORAL DRUG
PRODUCTS - PREDICTION FROM IN VITRO

10:30 **In vitro dissolution methodologies to predict in vivo dissolution: Case study with BCS class IIb and IIc drugs.** Yasuhiro Tsume, Ph.D. (University of Michigan, USA)

11:00 **In vivo evaluation of supersaturation.** Patrick Augustijns, Ph.D. (The University of Leuven, Belgium)

11:30 **Integrating in vitro solubility, dissolution and permeability data into PBPK Models to impact clinical studies and drug labels.** Tycho Heimbach, Ph.D. (Novartis, USA)

12:00 **Applied presentation 1**

12:15 **Applied presentation 2**

12:30 **Wrap up**

12:40 – 14:00 LUNCH

SESSION 2

MODEL AND SIMULATION OF ORAL DRUG ABSORPTION

14:00 **Oral absorption models.** Kiyohiko Sugano, Ph.D. (Rutsumekan University, Japan)

14:30 **Physiologically based pharmacokinetic absorption modeling for BE.** Xinyuan Zhang, Ph.D. (FDA, USA)

15:00 **M & S in industry: when and how.** Amitava Mitra, PhD (Sandoz, Inc. USA)

15:30 **Applied presentation 1**

15:45 **Applied presentation 2**

16:00 **Wrap up**

16:10 – 16:30 BREAK

SPECIAL LECTURE 2

16:30 **Impact of Orbito.** Bertil Abrahamsson, Ph.D. (AstraZeneca, Sweden)

Poster Session

17:10 - 18:10 **Poster presenters**

18:30 - 20:30 **BANQUET DINNER**

Friday, October 12

SPECIAL LECTURE 3

09:00 **Harnessing lipid processing pathways to enhance drug absorption and intestinal lymphatic transport.**

Chris Porter Ph.D. (Monash University, Australia)

09:40 – 09:50 SHORT BREAK

SESSION 3

FORMULATION TECHNOLOGIES ACCELERATING DRUG
DISCOVERY AND DEVELOPMENT

09:50 **Solubilization and formulation development based on its physicochemical properties.**

Lynne Taylor, Ph.D. (Purdue University, USA)

10:20 **Phase separation of supersaturated solutions and its impact on oral absorption.** Kohsaku Kawakami, Ph.D. (National Institute of Materials Science, Japan)

10:50 **Positive impact of biopharmaceutics on oral formulation development.** Yihong Qiu, Ph.D. (Abbvie Inc., USA)

11:20 **Applied presentation 1**

11:35 **Applied presentation 2**

11:50 **Wrap up**

12:00 – 13:30 LUNCH

SESSION 4

INNOVATION IN ORAL DRUG DELIVERY

13:30 **Controlled release technologies for oral drug delivery.** Sheri Shamblin, Ph.D. (Pfizer, USA)

14:00 **Oral Peptide delivery.** Bruno Sarmento, Ph.D. (University of Porto, Portugal)

14:30 **Nanoformulation for oral delivery.** Kunikazu Moribe, Ph.D. (Chiba University, Japan)

15:00 **Applied presentation 1**

15:15 **Applied presentation 2**

15:30 **Wrap up**

15:40 – 16:00 BREAK

SESSION 5

REGULATORY STANDARDS FOR ORAL DRUG PRODUCTS

16:00 **The impact of in vivo predictive dissolution on generic drug development and review.** Liang Zhao, Ph.D. (FDA, USA)

16:25 **Use of dissolution for drug approval at EMA.** Jan Welling, Ph.D. (EMA)

16:50 **ICH for BCS based Biowaiver of human BE study : Japanese aspects.** Ken-ichi Izutsu, Ph.D. (National Institute of Health Sciences, Japan)

17:10 **The Regulatory Quality Lab for post-approval market control.** Maria João Portela, Ph.D. (INFARMED, Portugal)

17:35 - 17:45 **Closing remarks**

José Morais, Ph.D. (University of Lisbon, Portugal)