



Oral Drug Delivery (ODD) 2018

***in vivo* Predictive Dissolution (iPD),
formulation Predictive Dissolution (fPD)**

March 4-9, 2018

Harrah's Lake Tahoe Resort

Lake Tahoe, NV

Organizers:

Gordon L. Amidon (University of Michigan, USA)

Gregory E. Amidon (University of Michigan, USA)

Peter Langguth (University of Mainz, DE)

Raimar Löbenberg (University of Alberta, CA)

Shinji Yamashita (Setsunan University, JP)

Lawrence Yu (FDA, USA)

(Draft 10-1-17)

Program Overview:

Day 1 March 5, 2018 (Monday): Integrating GI Physiology and Oral Drug Absorption from Product

Day 2 March 6, 2018 (Tuesday): Human *in vivo* GI + Plasma Results

Day 3 March 7, 2018 (Wednesday AM, 1/2 day lecture), Formulation Predictive Dissolution (fPD)
Evening 7:00-10:00 PM Exhibitors + Posters):

Day 4 March 8, 2018 (Thursday): Integrating GI Physiology and Predictive Dissolution

Day 5 March 9, 2018 (Friday): Evolution of Product Development and Regulatory Standards

Full Day (Mon, Tues, Thurs): 8:00 am - 5:30 pm (9 hrs., not including lunch, breaks)

Half day (Wed, Fri): 8:00 am - 11:30 am. (Approx. 3 1/2 hrs. each day)

Evening (Wednesday): Open Exhibitor and Poster Presentations/Conference Open Session (Approx. 4 hrs.)

Invited Faculty:

Gordon L. Amidon (University of Michigan, USA)

Gregory E. Amidon (University of Michigan, USA)

Marival Bermejo (Miguel Hernandez University, ES)

James Brasseur (University of Colorado, USA)

Jack Cook (Pfizer, USA)

Jianghong Fan (FDA, USA)

Ping Gao (Abbvie, USA)

Peter Langguth (University of Mainz, DE)

Sue Chih Lee (FDA, USA)

Hans Lennernäs (Uppsala University, Sweden)

Raimer Löbenberg (University of Alberta, CA)

Luca Marciani (University of Nottingham, UK)

Deanna Mudie (Capsugel, USA)

Paulo Paixao (University of Lisbon, PT)

David Sperry (Lilly, USA)

Duxin Sun (University of Michigan, USA)

Yasuhiro Tsume (University of Michigan, USA)

Shinji Yamashita (Setsunan University, Japan)

Lawrence Yu (FDA, USA)

Program Outline

Day 0 – March 4, 2017:

7-10 PM Participant + Faculty Reception: Harrah's Lake Tahoe Resort

Day 1 - March 5, 2018 (Monday): Integrating GI Physiology and Drug Absorption

Moderator: GLA

8:00	Introduction: The New Science of Mechanistic Oral BE	Gordon Amidon
8:30	Measurement of Gastrointestinal luminal and plasma drug concentrations	Duxin Sun
9:15	European OrBiTo: Experience and Results from a large Pharma-Academic collaboration	Hans Lennernäs
10:15	Break	
10:45	Oral Biopharmaceutics Japan: PET Imaging Results	Shinji Yamashita
12:00	Lunch	
1:30	MRI of the GI Tract: Recent Fluid and Motility Results	Luca Marciani
2:30	Fluid Motions in the GIT Fasted/Fed Computational Fluid Dynamics (CFD) Results and Insights	James Brasseur
3:30	Break	
4:00	Development of GI Sampling Capsule	Duxin Sun
4:30	Question & Answer	All
5:30	Conclude	

Day 2 - March 6, 2018 (Tuesday): Human in vivo GI + Plasma Results

8:00	Manometry/motility of the GIT	Gordon Amidon
9:15	Gastrointestinal, Plasma Levels and motility: Ibuprofen Fasted	Marival Bermejo
10:00	Break	
10:30	Gastrointestinal, Plasma Levels and motility: Ibuprofen Fed	Paulo Paixao
11:15	Bicarbonate Buffer: the <i>in vivo</i> Buffer	Gordon Amidon/Greg Amidon
12:00	Lunch	
1:30	Gastrointestinal Simulator (GIS) and Dissolution Methodology	Deanna Mudie
2:15	Analysis of GI Non Absorbable Drug (Marker): Gastric Modeling	Marival Bermejo
3:00	Break	
3:30	Drug-Drug Interactions and Gastrointestinal pH: BCS Class IIb	Jianghong Fan
4:30	GIS/ASD with BCS Class IIb (bases)	Hiro Tsume
5:30	Conclude	

Day 3 - March 7, 2018 (Wednesday, 1/2 day): formulation Predictive Dissolution (iPD-fPD)

8:00	iPD-fPD and GIS: Introduction to UM Progress on predictive Dissolution Device	Gregory Amidon
9:00	Dissolution Permeation System: Product Development	Shinji Yamashita
10:00	ASD: Utility in Product Development	David Sperry
10:45	Super saturation: Two- Phase Dissolution System	Ping Gao
11:30	Mass Transport Analysis of Two-Phase System	Deanna Mudie

Afternoon Free

7:00-9:00 pm	Posters & Exhibitor Presentations	All
9:00-10:00 pm	Discussion	All

Potential Invited Exhibitors (12):

Agilent	PSE
Erweka	SimCyp
Hansen	SimulationsPlus
PHAST	Sirius (now part of plon)
Physiolution	Sotax
plon	Vankel

Day 4 – March 8, 2018 (Thursday): Integrating GI Physiology and Product Development

8:00	Gastrointestinal Simulator Examples: BCS Class IIb	Yasuhiro Tsume
9:00	Optimizing Predictive Dissolution During Clinical Development	Jack Cook
10:00	Break	
10:30	Mass Transport Analysis (MTA): GIS System	Gregory Amidon
11:30	Disintegration and Dissolution Methodology in Product Development	Peter Langguth
12:30	Lunch	
2:00	GIS, PAT, and QbD: A Mechanistic Product Development	Raimar Löbenberg
3:00	Industry Utility of ASD in Formulation Development	David Sperry
4:00	Integrating Clinical and Formulation Development Plans	Jack Cook
5:00	Micro-macro Fluid Motions: 2 & 3D from Computational Fluid Dynamics (CFD) Results	James Brasseur
5:45	Conclude	
7:00-10:00	Banquet and Game	Faculty & Participants

Day 5 - March 9, 2018 (Friday): Evolution of Product Development and Regulatory Standards

8:00	Delayed Release Products	Peter Langguth
9:00	Product BE Regulation, NDA and ANDA	Lawrence Yu
9:45	Dissolution, Permeability, 1 st -Pass Metabolism: Challenges for MR Products	Sue Chih Lee
10:30	Mechanistic IVIVC	Raimar Löbenberg
11:00	Conclude; BE Bright Future	Gordon Amidon

References:

Educational CD:

Modern Biopharmaceutics (distributed with registration)

Scientific References:

[1-8]

1. Matsui, K., et al., *The Evaluation of In Vitro Drug Dissolution of Commercially Available Oral Dosage Forms for Itraconazole in Gastrointestinal Simulator With Biorelevant Media*. J Pharm Sci, 2016.
2. Tsume, Y., et al., *In vitro dissolution methodology, mini-Gastrointestinal Simulator (mGIS), predicts better in vivo dissolution of a weak base drug, dasatinib*. Eur J Pharm Sci, 2015. **76**: p. 203-12.
3. Matsui, K., et al., *In Vitro Dissolution of Fluconazole and Dipyridamole in Gastrointestinal Simulator (GIS), Predicting in Vivo Dissolution and Drug-Drug Interaction Caused by Acid-Reducing Agents*. Mol Pharm, 2015. **12**(7): p. 2418-28.
4. Tsume, Y., et al., *The Biopharmaceutics Classification System: subclasses for in vivo predictive dissolution (IPD) methodology and IVIVC*. Eur J Pharm Sci, 2014. **57**: p. 152-63.
5. Talattof, A., J.C. Price, and G.L. Amidon, *Gastrointestinal Motility Variation and Implications for Plasma Level Variation: Oral Drug Products*. Mol Pharm, 2016.
6. Krieg, B.J., et al., *In Vivo Predictive Dissolution: Comparing the Effect of Bicarbonate and Phosphate Buffer on the Dissolution of Weak Acids and Weak Bases*. J Pharm Sci, 2015. **104**(9): p. 2894-904.
7. Mudie, D.M., et al., *Quantification of Gastrointestinal Liquid Volumes and Distribution Following a 240 mL Dose of Water in the Fasted State*. Mol Pharm, 2014. **11**(9): p. 3039-47.
8. Krieg, B.J., et al., *In Vivo Predictive Dissolution: Transport Analysis of the CO₂ Bicarbonate In Vivo Buffer System*. J Pharm Sci, 2014.