Nov 16-17, 2022

A quest for biowaiver, including next generation dissolution characterization and modeling

virtual workshops

Areas covered

How and on what ground the biowaivers are to be obtained?
What are modern trends in the search for surrogates of clinical trials?
What is next generation dissolution modeling?

To whom?

Pharmaceutical industry
Academia
Everyone who is interested in the dissolution technologies, modeling and simulations

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Free of charge registration

Organizers:

JAGIELLONIAN UNIVERSITY
MEDICAL COLLEGE

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Workshops agenda

Chair: Vivian Gray (AAPS), Aleksander Mendyk (JUMC)

Co-chair: Nikoletta Fotaki (AAPS), Jie Shen (AAPS), Jakub Szlęk (JUMC)

Day 1, Nov 16th

2 pm to 4 pm CEST (8 to 10 am EST) & 5 pm to 7 pm CEST (11 am to 1 pm EST)

Session 1: Regulatory aspects and expectations (Moderator: Aleksander Mendyk, Ph.D.)

2 to 2:10 pm	**Introduction** Vivian Gray, Dissolution Technologies Aleksander Mendyk, Ph.D., Jagiellonian University – Medical College
2:10 to 2:40 pm	**Biopharmaceutics Classification System- Based Biowaivers ICH M9** James Mann, Ph.D., AstraZeneca Xavier Pepin, Ph.D., Simulation Plus
2:40 to 3:10 pm	**Performance Tests in the U. S. Pharmacopeia** Margareth R. C. Marques, Ph.D., U.S. Pharmacopeia
3:10 to 3:40 pm	**Dissolution method development - European perspective** Aleksander Mendyk, Ph.D., Jagiellonian University – Medical College
3:40 to 4 pm	**Q&A session** All speakers and participants

Session 2: Basics and best practices on dissolution testing (Moderator: Jie Shen, Ph.D.)

5 to 5:30 pm	**Challenges when developing a discriminatory dissolution method** Vivian Gray, Ph.D., Dissolution Technologies
5:30 to 6 pm	**Current Challenges of Dissolution Testing in support of Postapproval Changes for Oral Drugs** Andreas Abend, Ph.D., Merck
6:00 to 6:30 pm	**A statistical approach on generic development** Aleksander Mendyk, Ph.D., Jagiellonian University – Medical College
6:30 to 7 pm	**Q&A session** All speakers and participants

Workshops agenda

Day 2, Nov 17th

2 pm to 4 pm CEST (8 to 10 am EST) & 5 pm to 7 pm CEST (11 am to 1 pm EST)

Session 3: Next generation characterization for dissolution testing (Moderator: Nikoletta Fotaki, Ph.D.)

2:00 to 2:20 pm	**Drug dissolution in a snapshot - visualization of mass transport in pharmaceutical systems** Prof. Przemysław Dorożynski, Warsaw Medical University
2:20 to 3:05 pm	**Biopredictive testing as a tool supporting rational development of oral medicines** Dr Habil. Grzegorz Garbacz, Physiolution GmbH
3:05 to 3:35 pm	**Novel approaches on dissolution methods for microsystems; Case study: Liposomes** Nikoletta Fotaki, Ph.D., Centre of Therapeutic Innovation (CTI), Department of Life Sciences, University of Bath
3:30 to 4 pm	**Q&A session** All speakers and participants

Session 4: Modeling and artificial intelligence approaches (Moderator: Vivian Gray, Ph.D.)

5 to 5:30 pm	**IVIVC based on artificial intelligence** Aleksander Mendyk, Ph.D., Jagiellonian University – Medical College
5:30 to 6 pm	**The Application of Physiologically Based Biopharmaceutics Modeling (PBBM) in Support of Formulation, Manufacturing and Controls Changes via Safe Space Biowaivers** Sandra Suarez, Ph.D., Simulation Plus
6:00 to 6:30 pm	**3D printing combined with biopredictive dissolution and PBPK/PD modeling for the personalized therapy optimization - are we there yet?** Prof. Sebastian Polak, Certara UK, Jagiellonian University – Medical College
6:30 to 6:55 pm	**Q&A session** All speakers and participants
6:55 to 7 pm	**Closing remarks** Vivian Gray, Dissolution Technologies Aleksander Mendyk, Ph.D., Jagiellonian University – Medical College

Our speakers

Dr. Margareth R. C. Marques

is currently Senior Principal Scientist at USP, where she manages several documentary standards on dissolution, disintegration, drug release, ophthalmic products and products applied to the skin. In addition, she manages the databases on reagents, chromatographic columns and dissolution/disintegration tests. She is an editor and contributor to the Dissolution Technologies journal. She has a bachelor's degree in Pharmacy, a M.Sc. in Pharmacy, both by the University of Sao Paulo, Brazil, and a Ph.D. in Analytical Chemistry by the State University of Campinas, Brazil. She has more than 20 years of experience in Quality Control and Quality Assurance both for active pharmaceutical ingredients as well as for pharmaceutical dosage forms.

Prof. Dr. Habil. Przemysław Dorożyński

is an expert in pharmaceutical technology, drug delivery and industrial pharmacy. His main area of interest is focused on analysis of spatial and temporal changes occurring during mass transport within controlled release polymeric matrix systems e.g. tablets, gastroretentive drug delivery systems. During last two decades, he initialized a number of scientific collaborations with Polish and international scientific organizations (i.e. Canadian, Spanish, Italian, etc.), concerning applications of advanced imaging techniques (MRI, microCT) for pharmaceutical purposes.
Professional experience of prof. Dorożyński stems from academia, where he serves as scientist, teacher and lecturer, an industry where he was employed as Chair of Department in National Medicines Institute, Scientific Director and Managing Director of Pharmaceutical Research Institute.
Currently, prof. Dorożyński is involved in scientific projects and grants concerning novel methodologies of drug dissolution testing, theranostics, pulmonary drug delivery and 3D printing of personalized oral dosage forms.

Dr. Vivian Gray

has spent the last 40+ years involved in all aspects of dissolution testing and evaluating new dissolution technology. At the United States Pharmacopeia, she enjoyed a long career serving first as a bench chemist, supervisor and lastly as a liaison to various expert USP committees, including the Biopharmaceutics and Dissolution Expert Committee. In 1997, Vivian joined the DuPont-Merck Pharmaceuticals Company Analytical Research and Development Section as the Head of the Dissolution Group.
Vivian has been an invited speaker for conferences on 70 occasions (28 of these were international invitations), lecturing especially in the areas of dissolution method development and validation, FDA requirements in dissolution testing, troubleshooting dissolution method problems, and new dissolution technology and dosage forms. She is a proactive participant in the field as demonstrated by 60 publications, including 7 book chapters. Vivian has co-authored a book on dissolution testing called "Handbook of Dissolution Testing", Third Edition, published in 2004. In 2002, she formed her own consulting business in dissolution testing and related areas. The company name is V. A. Gray, Consulting, Inc, www.vagrayconsulting.net. In June of 2003, she became Managing Director of *Dissolution Technologies*, a peer-reviewed journal dealing specifically with dissolution testing issues, www.dissolutiontech.com.
Email: vagray@rcn.com

Our speakers

James Mann, Ph.D.

is a principal scientist of in vitro product performance at AstraZeneca in the UK. An experienced analytical scientist with more than 15 years' experience in pharmaceutical industry specializing in all aspects of dissolution testing. At AstraZeneca, James is the global lead for the in vitro product performance scientific community with oversight of all dissolution related activities in product development. Additionally, James co-leads the International Consortium for Innovation & Quality (IQ) in Pharmaceutical Development Dissolution working group. Prior to joining AZ, James was with Merck in the UK where he jointly led the global in vitro predictive technologies team as well as supervising a small team of product development analysts and more recently was the analytical manager at Molecular Profiles. James received his first degree from University of Strathclyde, followed by a PhD from the University of East Anglia.

Prof. Sebastian Polak

holds tenure position at the Faculty of Pharmacy Jagiellonian University Medical College, Cracow, Poland (Professor in Biopharmacy) where he leads a multidisciplinary team of scientists and engineers working on applying various modelling and simulation approaches in drug development. Dr. Polak is also a Senior Scientific Advisor in Certara UK, part of an international Certara company leading team developing non-oral in silico absorption models.
Always late, lacks assertiveness, likes motorcycles theoretically and even more in real life.

Dr. Habil. Grzegorz Garbacz

was born in 1980 in Nysa, Poland. In the years 1999-2004 he studied Pharmacy at the Medical University of Wroclaw in Poland. In the year 2004 he joined the group of Prof. Werner Weitschies and started to work on the construction and optimization of bio-relevant test models for simulation of mechanic and physical parameters of the gastro-intestinal tract. Working on this highly interesting topic he graduated from his studies in Pharmaceutical Sciences in 2005 and received his Ph.D. in 2010 and habilitation in 2020. In the year 2009 he co-founded the pharmaceutical company Physiolution GmbH and in the year 2017 the polish branch - Physiolution Polska. He is the CEO of both companies. His research is focused on the development of test devices capable of simulating the GI transit conditions, bio-predictive dissolution testing of oral drugs as well as the development of analytical methods and innovative medicines.

Xavier Pepin, Pharm.D, Ph.D

is a pharmacist (University Paris XI). He has a Ph.D. in granulation technology where he studied powder surface energy and liquid bridges during wet high-shear granulation. He has more than 25 years' experience in the pharmaceutical industry and has occupied several positions from preformulation, clinical and commercial formulation development, industrial transfer, regulatory CMC and biopharmaceutics. He's worked in biopharmaceutics for 15 years using in vitro, in silico, and in vivo tools to support evaluation of drugs along the development value chain and post marketing. He was the co-leader of WP4 in silico tools for the OrBiTo IMI project 2012-2018. He has joined SimulationsPlus in May 2022 and supports the regulatory strategy focusing on PBBM to support product quality.
He has 50 publications in the field of powder surface energy, granulation technology and biopharmaceutics modeling and simulation.

Our speakers

Andreas Abend, Ph.D.

received his PhD degree in Organic Chemistry from the University of Karlsruhe in Germany. Prior to joining MSD, he was a Post-Doctoral Fellow at the University of Wisconsin's Enzyme Institute in Madison, Wisconsin, USA. He is currently a Senior Principal Scientist in the Biopharmaceutical Sciences group in MRL's Development Sciences and Clinical Supply Department. Throughout his career at MSD, he provided analytical support to small and large molecule API and drug product development spanning all clinical phases. Andreas is a member of MSD's Biopharmaceutical Advisory Team, co-chair of Product Quality Research Institute's Biopharmaceutics Tech Committee (PQRI BTC), and a member of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ) Analytical Leadership Group, and a member of FIP. He presented at many national and international meetings, published several manuscripts on Clinically Relevant Dissolution specifications and co-organized workshops at the Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI).

Dr. Nikoletta Fotaki, Pharmacist, MSc, Ph.D., FAAPS

is a Reader in Biopharmaceutics at the University of Bath, UK. She graduated in Pharmacy from the National and Kapodistrian University of Athens in Greece and she holds an MSc in Toxicology and a PhD in Biopharmaceutics-Pharmacokinetics. Her expertise and research are focused on PBPK modeling, in vitro and in silico tools for predicting absorption in normal populations and in special populations, dissolution methods, IVIVCs and biowaivers. Her scholastic work includes 87 peer reviewed publications, one book, 10 book chapters, 87 published conference contributions and 2 patents. She is an AAPS Fellow and a member of the AAPS Board of Directors with leading roles in the OBAM and IVRDT AAPS Communities. She is also the chair of the Biopharmaceutics Group of APS and she is a member of a USP expert panel and of several scientific societies and has been an invited speaker at several conferences.

Dr. Sandra Suarez-Sharp

is currently Vice President of Regulatory Affairs at Simulations Plus. Prior to joining Simulations Plus, Dr. Suarez-Sharp was a master reviewer and scientific advisor to the Division of Biopharmaceutics, Office of Product Quality/FDA in areas such as in vitro-in vivo correlation, biowaivers, RTRT dissolution models, and Physiologically based biopharmaceutics modeling (PBBM). She has a large number of publications related to the areas of dissolution, in vitro-in vivo correlation, establishment of specifications with clinical relevance, physiology-based biopharmaceutics modeling (PBBM).

Aleksander Mendyk, Ph.D., DSc.

is an expert in application of artificial&computational intelligence methods in pharmaceutical technology&biopharmacy, in vitro in vivo correlation (IVIVC) and bioequivalence, Author of over 100 publications. A pharmacist and programmer both in Open Source and commercial applications. Currently Acting Head of the Chair of Pharmaceutical Technology and Biopharmaceutics Jagiellonian Univeristy-Medical College, Kraków, Poland.

Organizing comitee:

JUMC: Aleksander Mendyk, Jakub Szlęk, Justyna Srebro, Natalia Czub

AAPS: Vivian Gray, Nikoletta Fotaki, Jie Shen