



OSP Community Conference 2024 Agenda

Day 1 – Monday October 7, 2024

11:30 - 12:45	Registration & Networking & Snacks (finger food lunch)
12:45 - 12:50	Welcome & Keynote
12:45 - 12:55	Birgit Schoeberl (Novartis): Welcome from the Host
12:55 - 13:00	Stephan Schaller (ESQlabs): Welcome from the OSP Management Team
13:00 - 13:30	KEYNOTE: Jörg Lippert (Bayer) & Stephan Schaller (ESQlabs): The Roots and the Leaves of the OSP Suite
13:30 - 14:30 (15' + 5' Q&A)	Session I: Physiologically Based Biopharmaceutics Modelling Chairs: André Dallmann (Bayer), Erik Sjögren (Pharmetheus)
13:30 - 13:50	Mariana Guimaraes Sa Correia (ESQlabs): Qualification of an OSP-R IVIVC and vBE workflow
13:50 - 14:10	Paul Vrenken (National and Kapodistrian University of Athens): Development of Novel Formulation Release Functions for PK-Sim
14:10 - 14:30	Fabian Winter (AbbVie): Industrial Applications of PK-Sim for PBBM
14:30 - 15:00	NETWORKING Coffee
15:00 - 16:00 (15' + 5' Q&A)	Session II: In Vitro-In Vivo Extrapolation Chairs: Donato Teutonico (Sanofi), Tobias Kanacher (Pharmetheus)
15:00 - 15:20	Susana Proença (ESQlabs): Towards an OSP IVIVE Toolbox
15:20 - 15:40	Behnam Amiri (MPSlabs) & Choi Siak-Leng (Sanofi): Digital Twins for Organ-on-Chips
15:40 - 16:00	Denise Feick (Sanofi): Prediction of human fraction absorbed from in vitro Caco-2 permeability – are we there yet?
16:00 - 17:30 (15' + 5' Q&A)	Session III: Perspectives on the use of PBPK in regulatory submission Chairs: Stephan Schaller (ESQlabs), Ibrahim Ince (Boehringer Ingelheim)
16:00 - 16:20	Flora Musuamba (EMA, U Namur): Risk-based approach for model assessment

16:20 – 16:40	Masanobu Sato (Boehringer Ingelheim): Exploring PBPK Application Trends and Regulatory Conversations in New Drug Approvals in Japan
16:40 – 17:00	Pieter J Colin (EMA, UMC Groningen): EMA review of assessments of PBPK models from regulatory submissions
17:00 – 17:20	Hao Zhu (Private, Key Opinion Leader in Mechanistic Modeling): Use of mechanistic modeling to support new drug development and decision-making
17:20 – 17:30	Regulatory Applications with OSP: Open Discussion & Exchange
17:30 – 18:00 (20' + 10' Q&A)	Session IV: Integrated PBPK-PD/QSP modeling Chairs: Henrik Cordes (Sanofi), Lars K�pfer (University Clinic Aachen)
17:30 – 18:00	Pavel Balazki (ESQlabs): PBPK-QSP: Model Modularization and Qualification with OSP Suite v12 – aka “OSMOSES”
18:30 – 24:00	Dinner @ Volta Br�u (open end, INCLUDED IN REGISTRATION)

Day 2 – Tuesday October 8, 2024

08:30 – 09:10 (15' + 5' Q&A)	Session V: Drug-Drug Interaction modeling Chairs: Stephan Schaller (ESQlabs), Alexander Staab (Boehringer Ingelheim)
08:30 – 08:50	Thomas Wendl (Bayer): PBPK DDI Network Qualification and Regulatory Application
08:50 – 09:10	Sheila Peters (Boehringer Ingelheim): Optimal Use of Static and Dynamic Models for DDI Assessment along the Value Chain
09:10 – 10:10 (15' + 5' Q&A)	Session VI: PBPK Best Practice & Introduction to the ICH MIDD Guidance Chairs: Rolf Burghaus (Bayer), Jan Schlender (Novartis)
09:10 – 09:30	Nicolas Frey (Roche): ICH M15 Model Informed Drug Development – Steps Toward Harmonized Guidance
09:30 – 09:50	Jan Schlender (Novartis): Best Practices in PBPK for the OSP Suite Community
09:50 – 10:10	Abdullah Hamadeh (University of Waterloo): The FDA Model Master File: Standardization of M&S practices to support the development and approval of dermatological products
10:10 – 10:40	NETWORKING Coffee
10:40 – 11:40	Session VII: Large Molecules modeling Chairs: Wilbert de Witte (ESQlabs), Christoph Niederal (Bayer)
10:40 – 11:00	Wilbert de Witte (ESQlabs): PBPK-QSP of FcRn Inhibitors and the use of the PK-Sim FcRn Model
11:00 – 11:40	Erik Sj�gren (Pharmetheus) & Salih Benamara (Sanofi): Modeling SC Absorption & Immunogenicity of Large Molecules
11:40 – 12:40	Session VIII: Special populations in the OSP Suite Chairs: Ibrahim Ince (Boehringer Ingelheim), Andr� Dallmann (Bayer)
11:40 – 12:00	Andr� Dallmann (Bayer): Modeling Motherhood I: Pregnancy PBPK in the Era of Personalized Medicine

12:00 – 12:20	Kathleen Job (University of Utah): Modeling Motherhood II: Pregnancy PBPK for Asthma
12:20 – 12:40	Julia Macente & Nina Nauwelaerts (KU Leuven): Modeling Motherhood III: Lactation PBPK modeling
12:40 – 13:00	Annika Schneider (Bayer): PBPK Modeling for Hepatically Impaired Patients
13:00 – 14:00	NETWORKING & Lunch
14:00 – 15:00	Session IX: Community Engagement – OSP Suite Qualification & Release Chairs: Donato Teutonico (Sanofi), Rolf Burghaus (Bayer)
14:00 – 14:20	Stephan Schaller (ESQlabs): OSP Community Engagement & Dissemination
14:20 – 15:00	Juri Solodenko (Bayer): OSP Software Release Management and (Re-)Qualification Framework
15:00 – 15:30	NETWORKING coffee
15:30 – 16:00	Session X: OSP community building, funding, and management Chairs: Alexander Staab (Boehringer Ingelheim), Andreas Kovar (Sanofi)
15:30 – 15:45	Stephan Schaller (ESQlabs): Building and Funding a sustainable community for the OSP Suite
15:45 – 16:00	Open Discussion & Exchange
16:00 – 16:30	Participant Feedback on Conference, Evaluation
16:30 +	Departure

Location

Novartis Campus:

Frank O. Gehry building, Fabrikstrasse 15, 4056 Basel, Switzerland

Hotel Recommendations

Near Novartis Campus:

The Novartis Campus is right at the French border and, hence, hotels in Saint Louis are a budget option. Here are a few options in walking distance:

Aparthotel Adagio Access Saint Louis Bâle, Saint-Louis – 700 m

Hôtel et Spa La Villa K – Basel Airport, Saint-Louis – 1.7 km

HÔTEL D, Blumenrain 19, 4051 Basel (via Tram 11) – 1.8 km

Ibis Aéroport Bâle Mulhouse, Saint-Louis – 2 km

Organizing Committee

Henrik Cordes,
Sanofi

Donato Teutonico,
Sanofi

Stephan Schaller,
ESQlabs

Ibrahim Ince,
Boehringer
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Wilbert de Witte,
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