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** *(PBBM)* Chairs: André Dallmann (Bayer), Erik Sjögren (Pharmetheus)
13:30 – 13:50	**Mariana Guimaraes Sa Correia (ESQlabs):** Leveraging OSP for developing dissolution safe-space through IVIVC and VBE workflows: a qualification perspective
13:50 – 14:10	**Paul Vrenken (National and Kapodistrian University of Athens):** Extending the OSP Oral Absorption Toolbox: An End-to-End PBBM Approach
14:10 – 14:30	**Fabian Winter (AbbVie):** Combination of in-vitro and in-silico tools for biopharmaceutical risk assessment in drug product development
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	**Choi Siak-Leng (Sanofi):** Organ-on-a-Chip (OoC) Digital Twins for Estimating Small Molecules' Human Hepatic Clearance and PK Profiles
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 Recent Trends in PBPK Applications in New Drug Approvals in Japan: Regulations and Reviews by PMDA
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 Küpfer (University Clinic Aachen)
17:30 – 18:00	**Pavel Balazki (ESQlabs):** Introducing OSMOSES: Modularization and Qualification of complex PB-QSP models with OSP version 12
18:30 – 24:00	Dinner @ Volta Bräu (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 Niederalt (Bayer)
10:40 – 11:00	**Wilbert de Witte (ESQlabs):** PBPK-QSP modelling of FcRn Inhibitors and the use of the PK-Sim FcRn Model
11:00 – 11:40	**Erik Sjögren (Pharmetheus) & Salih Benamara (Sanofi):** Modeling Subcutaneous Absorption & Immunogenicity of Large Molecules

11:40 – 12:40	**Session VIII: Special populations in the OSP Suite** Chairs: Ibrahim Ince (Boehringer Ingelheim), André Dallmann (Bayer)
11:40 – 12:00	**André 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

<u>Novartis Campus:</u>
Frank O. Gehry building, Fabrikstrasse 15, 4056 Basel, Switzerland

Hotel Recommendations

<u>Near Novartis Campus:</u>
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 Ingelheim
Wilbert de Witte, ESQlabs	Lars Kupfer, RWTH Aachen	André Dallmann, Bayer	Jan Schlender, Novartis

Sponsors

Gold ⭐ ⭐ ⭐ ([Become a sponsor](#))

Boehringer Ingelheim

NOVARTIS

Silver ⭐ ⭐ ([Become a sponsor](#))

eSQlabs
we empower life sciences

Bronze ⭐ ([Become a sponsor](#))

BioNotus®
BioAnalysis &
Pharmacometrics

Pharmetheus®

Allucent™
Helping bring new therapies to light

Contact

info@clsfoundation.org

COMPUTATIONAL LIFE SCIENCES FOUNDATION
Advancing Computational Life Sciences through Open Collaboration