



## OSP Community Conference 2024 Agenda

### Day 1 – Monday October 7, 2024

11:30 – 12:45	<b>Registration &amp; Networking &amp; Snacks</b> (finger food lunch)
12:45 – 12:50	<b>Welcome &amp; Keynote</b>
12:45 – 12:55	<b>Birgit Schoeberl (Novartis):</b> Welcome from the Host
12:55 – 13:00	<b>Stephan Schaller (ESQlabs):</b> Welcome from the OSP Management Team
13:00 – 13:30	<b>KEYNOTE: Jörg Lippert (Bayer) &amp; Stephan Schaller (ESQlabs):</b> The Roots and the Leaves of the OSP Suite
13:30 – 14:30 (15' + 5' Q&A)	<b>Session I: Physiologically Based Biopharmaceutics Modelling (PBBM)</b> Chairs: André Dallmann (Bayer), Erik Sjögren (Pharmetheus)
13:30 – 13:50	<b>Mariana Guimaraes Sa Correia (ESQlabs):</b> Leveraging OSP for developing dissolution safe-space through IVIVC and VBE workflows: a qualification perspective
13:50 – 14:10	<b>Paul Vrenken (National and Kapodistrian University of Athens):</b> Extending the OSP Oral Absorption Toolbox: An End-to-End PBBM Approach
14:10 – 14:30	<b>Fabian Winter (AbbVie):</b> Combination of in-vitro and in-silico tools for biopharmaceutical risk assessment in drug product development
14:30 – 15:00	<b>NETWORKING Coffee</b>
15:00 – 16:00 (15' + 5' Q&A)	<b>Session II: In Vitro-In Vivo Extrapolation</b> Chairs: Donato Teutonico (Sanofi), Tobias Kanacher (Pharmetheus)
15:00 – 15:20	<b>Susana Proença (ESQlabs):</b> Towards an OSP IVIVE Toolbox
15:20 – 15:40	<b>Choi Siak-Leng (Sanofi):</b> Organ-on-a-Chip (OoC) Digital Twins for Estimating Small Molecules' Human Hepatic Clearance and PK Profiles
15:40 – 16:00	<b>Denise Feick (Sanofi):</b> Prediction of human fraction absorbed from in vitro Caco-2 permeability – are we there yet?

<b>16:00 – 17:30</b> (15' + 5' Q&A)	<b>Session III: Perspectives on the use of PBPK in regulatory submission</b> Chairs: Stephan Schaller (ESQlabs), Ibrahim Ince (Boehringer Ingelheim)
16:00 – 16:20	<b>Flora Musuamba (EMA, U Namur):</b> Risk-based approach for model assessment
16:20 – 16:40	<b>Masanobu Sato (Boehringer Ingelheim):</b> Exploring Recent Trends in PBPK Applications in New Drug Approvals in Japan: Regulations and Reviews by PMDA
16:40 – 17:00	<b>Pieter J Colin (EMA, UMC Groningen):</b> EMA review of assessments of PBPK models from regulatory submissions
17:00 – 17:20	<b>Hao Zhu (Private, Key Opinion Leader in Mechanistic Modeling):</b> Use of mechanistic modeling to support new drug development and decision-making
17:20 – 17:30	<b>Regulatory Applications with OSP: Open Discussion &amp; Exchange</b>
<b>17:30 – 18:00</b> (20' + 10' Q&A)	<b>Session IV: Integrated PBPK-PD/QSP modeling</b> Chairs: Henrik Cordes (Sanofi), Stephan Schaller (ESQlabs)
17:30 – 18:00	<b>Pavel Balazki (ESQlabs):</b> Introducing OSMOSES: Modularization and Qualification of complex PB-QSP models with OSP version 12
<b>18:30 – 24:00</b>	Dinner @ Volta Bräu (open end, <b>INCLUDED IN REGISTRATION</b> )

## Day 2 – Tuesday October 8, 2024

<b>08:30 – 09:10</b> (15' + 5' Q&A)	<b>Session V: Drug-Drug Interaction Modeling</b> Chairs: Alexander Staab (Boehringer Ing.), Marylore Chenel (Pharmetheus)
08:30 – 08:50	<b>Thomas Wendl (Bayer):</b> PBPK DDI Network Qualification and Regulatory Application
08:50 – 09:10	<b>Sheila Peters (Boehringer Ingelheim):</b> Optimal Use of Static and Dynamic Models for DDI Assessment along the Value Chain
<b>09:10 – 10:10</b> (15' + 5' Q&A)	<b>Session VI: PBPK Best Practice &amp; Introduction to the ICH MIDD Guidance</b> Chairs: Rolf Burghaus (Bayer), Jan Schlender (Novartis)
09:10 – 09:30	<b>Nicolas Frey (Roche):</b> ICH M15 Model Informed Drug Development – Steps Toward Harmonized Guidance
09:30 – 09:50	<b>Jan Schlender (Novartis):</b> Best Practices in PBPK for the OSP Suite Community
09:50 – 10:10	<b>Abdullah Hamadeh (University of Waterloo):</b> The FDA Model Master File: Standardization of M&S practices to support the development and approval of dermatological products
<b>10:10 – 10:40</b>	<b>NETWORKING Coffee</b>
<b>10:40 – 11:40</b>	<b>Session VII: Large Molecules Modeling</b> Chairs: Wilbert de Witte (ESQlabs), Christoph Niederalt (Bayer)
10:40 – 11:00	<b>Wilbert de Witte (ESQlabs):</b> PBPK-QSP modelling of FcRn Inhibitors and the use of the PK-Sim FcRn Model
11:00 – 11:40	<b>Erik Sjögren (Pharmetheus) &amp; Salih Benamara (Sanofi):</b> Modeling Subcutaneous Absorption & Immunogenicity of Large Molecules

<b>11:40 – 12:40</b>	<b>Session VIII: Special Populations in the OSP Suite</b> Chairs: Ibrahim Ince (Boehringer Ingelheim), André Dallmann (Bayer)
11:40 – 12:00	<b>André Dallmann (Bayer):</b> Modeling Motherhood I: Pregnancy PBPK in the Era of Personalized Medicine
12:00 – 12:20	<b>Kathleen Job (University of Utah):</b> Modeling Motherhood II: Pregnancy PBPK for Asthma
12:20 – 12:40	<b>Julia Macente &amp; Nina Nauwelaerts (KU Leuven):</b> Modeling Motherhood III: Lactation PBPK modeling
12:40 – 13:00	<b>Annika Schneider (Bayer):</b> PBPK Modeling for Hepatically Impaired Patients
<b>13:00 – 14:00</b>	<b>NETWORKING &amp; Lunch</b>
<b>14:00 – 15:00</b>	<b>Session IX: Community Engagement – OSP Suite Qualification &amp; Release</b> Chairs: Donato Teutonico (Sanofi), Rolf Burghaus (Bayer)
14:00 – 14:20	<b>Stephan Schaller (ESQlabs):</b> OSP Community Engagement & Dissemination
14:20 – 15:00	<b>Juri Solodenko (Bayer):</b> OSP Software Release Management and (Re-)Qualification Framework
<b>15:00 – 15:30</b>	<b>NETWORKING coffee</b>
<b>15:30 – 16:00</b>	<b>Session X: OSP community building, funding, and management</b> Chairs: Alexander Staab (Boehringer Ingelheim), Andreas Kovar (Sanofi)
15:30 – 15:45	<b>Stephan Schaller (ESQlabs):</b> Building and Funding a Sustainable Community for the OSP Suite
15:45 – 16:00	<b>Open Discussion &amp; Exchange</b>
<b>16:00 – 16:30</b>	<b>Participant Feedback on Conference, Evaluation</b>
<b>16:30 +</b>	<b>Departure</b>

## **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  
Ingelheim

Wilbert de Witte,  
ESQlabs

Lars Kupfer,  
RWTH Aachen

André Dallmann,  
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Jan Schlender,  
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## Contact

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