Open Systems Pharmacology Management Team

Charter

Table of Content:

Open Systems Pharmacology - Introduction

Open Systems Pharmacology (OSP) is an open science community focussing on systems pharmacology with a strong emphasis on physiology based pharmacokinetics (PBPK).

Vision & Mission

Vision

Robust and reliable, easy-to-use modeling & simulation tools, processes and models for pharmaceutical and other life-sciences applications qualified and accepted by a scientific community from academia, regulatory agencies and industry available and open to everyone.

Mission

Provide a platform for joint development, review & qualification, and application of state-of-the-art tools for PBPK and Systems Pharmacology modeling and an open library of models for application as well as method & tool qualification purposes. Promote the idea of pre-competitive open collaboration for the advancement of modeling & simulation sciences in pharmaceutical and life science.

Scope

Quality & Certification

OSP puts a focus on quality and respective certification. It is developing, providing and maintaining best practices for systems pharmacology and its applications. OSP intends to provide sustainable content packages to proof and document the qualification of the technical OSP platform for various relevant applications (such as PBPK based assessment of drug-drug interactions) when used according to applicable best practices. The organization establishes a framework to provide OSP quality and release certificates. Quality certificates might relate to e.g. models, population data bases, or application qualification packages. The community provides a means for scientific consultation.

Tools

OSP is developing, maintaining and providing the OSP suite. It consists of the versatile PBPK tool PK-SIM®, the general purpose systems pharmacology model building tool MoBi®, and associated Matlab® and R toolboxes. OSP is also providing further modeling and simulation as well as auxiliary tools. A dedicated simulation and reporting engine facilitates setting up a validated system to fulfill GxP requirements. A technical qualification verification engine is used to perpetuate simulation packages to future releases of the OSP platform.

Beyond software the OSP repository is used as a basis to share scientific content, models and data, such as a PBPK compound library, a library of (non-PBPK) systems pharmacology models, data bases for model parameters and data bases for experimental data.

Community

The OSP community essentially is about two elements, scientific interaction and education. Scientific interaction primarily takes place in the internet based discussion forum. In addition, there are workshops organized, which can be held in a face to face manner or virtually. The community is a marketplace for open science projects in the areas of development of methods, tools, models and best practices. Respective activities can be organized using web based project management tools. The community provides educational material such as manuals, tutorials, training material, Q&A compilations, and references.

Roles

Within the OSP community, a couple of distinct roles can be distinguished.

Users

Users do apply the OSP content and the software platform for their systems pharmacology applications. Beyond application, they interact with the community by providing feedback such as reporting observations, needs, or issues when doing systems pharmacology work using the OSP platform. Users exchange experience and actively provide contributions, e.g. via Q&A, through the OSP forum.

Members

Members develop the open systems pharmacology content. This covers in particular models, data, software requirements, methods, best practices, qualification packages and training material. Members also engage in development and testing of the OSP software platform and tools, which in particular executes the agreed OSP development roadmap. They work on the qualification of systems pharmacology applications as well as the technical validation of the OSP platform. Members engage in experience exchange and actively provide contributions to the OSP forum.

Management Team

The OSP management team manages the community and its membership. It is responsible for regular review, endorsement and publication of the OSP development roadmap. The management team provides certification of the software platform, models and other systems pharmacology content such as qualifications and trainings. It releases certified platform versions. The team organizes contributions to the scientific and regulatory community and publishes white papers.

Sounding Board

The management team's sounding board is a group of community members with a consistent history of relevant contributions. It reviews scientific and technical content provided by the community. The sounding board identifies scientific and regulatory trends and proposes elements for the roadmap of future OSP development. It provides scientific and technical consultancy to the management team, which may be the basis for certification by the management team.

OSP Management Team - Rules of Procedure

The Open Systems Pharmacology Management Team is a project group of the AGAH.

Membership in the OSP Management Team

Candidates for membership in the OSP Management Team (OSP MT) are nominated by a member of the OSP MT. They get elected by unanimous vote of all OSP MT members. Members leave by active resignment. Exclusion can only be achieved by unanimous vote of the members of the MT.
Founding members of the OSP MT represent stakeholders from pharmaceutical industry, academia, CROs and software providers.

Chair of the OSP Management Team

The chair of the OSP MT is a member of the OSP MT. He/she is elected by the MT via majority vote of all members of the OSP MT. The chair is mandated for 2 years. He/she represents the OSP MT at AGAH. The chair organizes and leads OSP MT meetings and decision processes.

OSP Management Team Decision Rules

OSP MT decisions are taken by majority vote of all MT members in general. Documentation of OSP MT decisions are published through OSP community channels. Changes to the rules of procedure are decided by unanimous vote of all members of the OSP MT. Implementation rules are decided by majority vote of all MT members.

Implementation Rules

Implementation rules for the rules of procedure are developed and put effective by the OSP MT. They are laid down in separate documents outside of the rules of procedure. Implementation rules are published through OSP community channels.
Implementation rules might cover the definition and rules for the sounding board, procedures for the OSP MT meetings such as meeting frequency and establishment of the agenda, roadmap release management, OSP certification procedures, and rules and procedures for community and OSP membership management.

OSP Sounding Board

The OSP management team's sounding board is a non-voting group. Candidates for membership in the sounding board are community members with a consistent history of relevant contributions. They are nominated by OSP MT members and elected by unanimous vote of all OSP MT members. OSP sounding board members leave by active resignment.