



The International Society of Pharmacometrics’ Special Interest Group on Quantitative Systems Pharmacology: Developing a Community and Advancing a Field

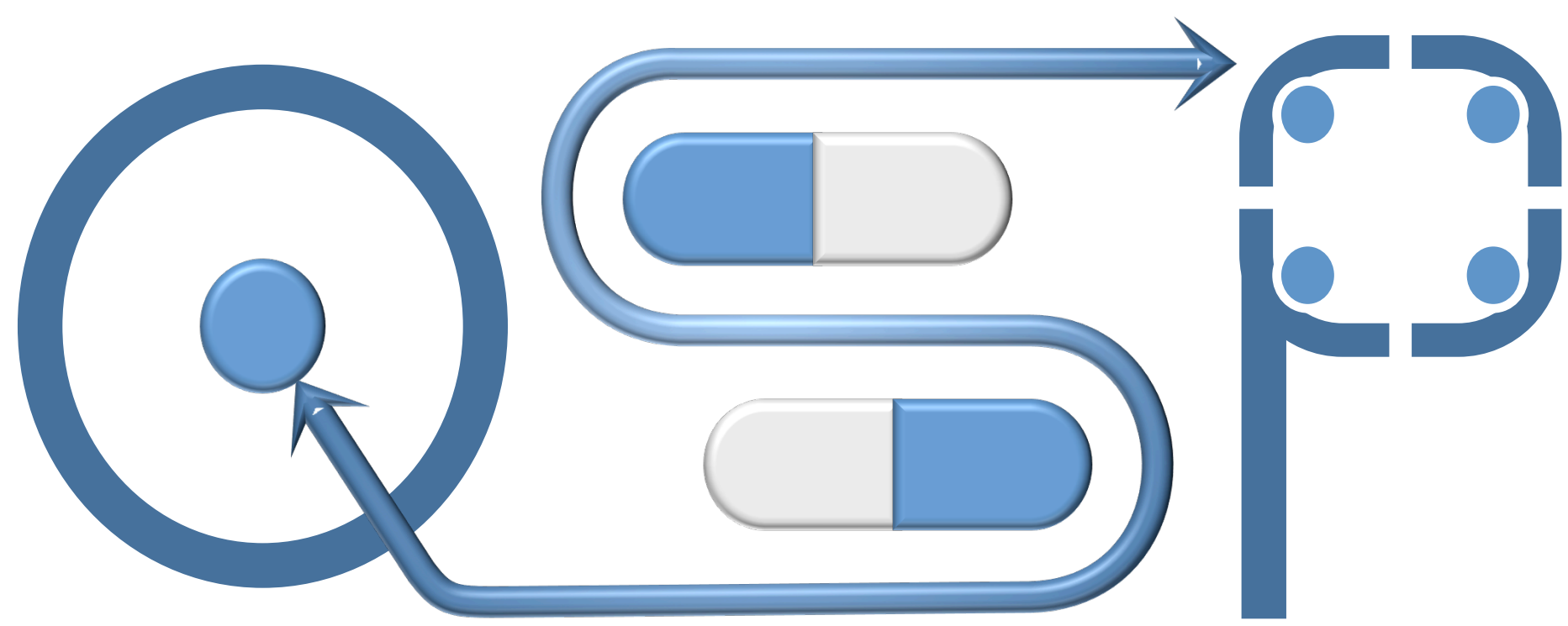
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What is Quantitative Systems Pharmacology?

Quantitative Systems Pharmacology (QSP) has been described as the “quantitative analysis of the dynamic interactions between drug(s) and a biological system that aims to understand the behavior of the system as a whole...” [1].

The field, which has emerged at the interface of engineering, pharmaceutical sciences and systems biology [2], is realizing increased adoption in pharmaceutical research and development with the hope of improving the efficiency of getting new medicines to patients in need. With the evolution of this field, there is greater need for sharing knowledge through sponsored sessions at professional meetings, white papers, discussion groups, and publications.



Quantitative Systems Pharmacology

<http://www.go-isop.org/quantitative-systems-pharmacology>

Our Vision:

To advance the development and utilization of safe and efficacious medicines through the application of QSP

Consistent with this Vision, we will:

- Advance the science of QSP by fostering a community for the exchange of ideas and knowledge;
- Promote the application of QSP in drug development and regulatory decision-making;
- Develop and maintain information resources for its members, including establishment of “best practices;”
- Facilitate communication and advance knowledge through sponsored sessions at professional meetings, white papers, discussion groups, and publications.

Our Leadership Team

Chair,
Soroja
Ramanujan

Chair Elect
Michael
Zager

Vice Chair,
Valeriu
Damian

Secretary,
Michael
Weis

Past Chair,
C.J.
Musante

Past
Secretary,
Jeffrey
Woodhead

Our Steering Committee

| | |
|--------------------------------|---------------------------------|
| Darrell Abernethy | Stephan Schmidt (FIP QSP chair) |
| Masoud Jamei (AAPS SP Chair) | Vikram Sinha |
| Rukmini Kumar | Craig Thalhauser |
| Mark Peterson | Piet van der Graaf |
| Matthew Riggs (ASCPT SP chair) | Paolo Vicini |
| Julio Saez-Rodriguez | Don Mager (ISoP) |

Our Membership

- 100+ members
- Free with ISoP membership (<http://www.go-isop.org/membership>)

Our Activities

Member-Led Working Groups

| Working Group | Chair(s) | Goal | Near-Term Deliverables & Related Efforts |
|---|--|---|--|
| GPS for QSP (follow-on from ACoP6 symposium) | • CJ Musante • Michael Zager | Develop and implement multi-year plan for advancement of QSP in the following areas: <ul style="list-style-type: none">• Building effective QSP teams• Building mutually beneficial academic, industry, and nonprofit/regulatory partnerships• Building a community | • Perspectives paper (in preparation) <ul style="list-style-type: none">• Update at ACoP7 SIG event• Formalize multi-year goals |
| Workflows and Methods for QSP (follow-on from ACoP6 tutorial) | • Kapil Gadkar | Identify, collect, & share useful info on workflows and methodologies for executing QSP projects and analyses of various kinds | • YouTube video ACoP6 tutorial (in preparation) <ul style="list-style-type: none">• Tutorial pub on workflow ✓• Publication on virtual populations ✓• Tutorial pub on qualification ✓• Start resource and lit repositories• Whitepaper on trends/needs |
| Software and Tools for QSP (follow-on from ACoP6 tutorial) | • Craig Thalhauser • Sergey Ermakov | Identify and describe software packages (proprietary and freeware) that enable QSP modeling efforts | • YouTube software tutorials ✓ (more in progress) <ul style="list-style-type: none">• Software/tools survey (in progress) & summary publication |
| Integration of QSP & Pharmacometrics | • Mirjam Trame • CJ Musante | Identify, collect, & share useful info on best practices, examples, and approaches for integrating QSP & PMx | • Create/seed resource and lit repositories <ul style="list-style-type: none">• Perspectives paper• 2017 scientific programming submission ✓ |
| QSP in Regulatory Interactions | • Ananth Kadambi | Assess opportunities for QSP in facilitating sponsor-regulatory discussions and propose strategies to facilitate increased adoption in these areas | • White paper on opportunities , needs, and examples <ul style="list-style-type: none">• 2017 scientific programming submission (in progress) |

Scientific Programming

ACoP6 (co-sponsored by the AAPS SP Focus Group)

Symposium: “GPS for QSP: Where We’ve Been, Where We Are, and Where We’re Heading”

ASCPT 2016 (co-sponsored by the ASCPT SP Community)

Workshop: “QSP: A Case for Disease Models”

ACoP 6 (co-sponsored by the AAPS SP Focus Group)

Workshop: “A Robust Workflow, Technical Approaches, and Software Tools for Application of QSP in Model-Based Drug Development”

AAPS 2015 (organized by the AAPS SP Focus Group and co-sponsored by the ISoP QSP SIG)

Symposium: “When and why to focus on QSP in drug development: A question-based approach with vignettes”



Bellevue, Washington, October 23rd to October 26th, 2016

- Meet the QSP SIG session
- Dinner symposium with panel discussion on “*Making QSP Happen: Strategies and Lessons Learned from Experts Who’ve Done It*”
- New QSP Student Award!
 - \$1000 prize for best abstract;
 - Sponsored by the generous support of Genentech, J&J, Pfizer, and Rosa & Co

ACKNOWLEDGMENTS

We would like to thank our past Steering Committee Members and the ISoP Executive Committee and Board of Directors for their support.

REFERENCES

[1] van der Graaf PH, Benson N. Systems pharmacology: bridging systems biology and pharmacokinetics-pharmacodynamics (PKPD) in drug discovery and development. Pharm Res. 2011 Jul;28(7):1460-4. doi: 10.1007/s11095-011-0467-9. Epub 2011 May 11.

[2] Sorger, PK, et al. Quantitative and Systems Pharmacology in the Post-genomic Era: New Approaches to Discovering Drugs and Understanding Therapeutic Mechanisms. An NIH White Paper, QSP Workshop Group R. Ward, Editor. 2011.