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December 5 - 7, 2016, **San Francisco**

3rd Annual QSP2016

The Only Conference Exclusively Dedicated to the Successful Application of QSP in Pre-Clinical & Clinical Research

Advancing Your Understanding of Disease & Drug Action

Hear from 19 World Class Scientists Including:

Birgit Schoeberl
Head of Discovery &
Senior Vice President
Merrimack

Valeriu Damian-Iordache
Director - Pharmacokinetics &
Translational Biology
GSK

CJ Musante
Associate Research Fellow
Pfizer Inc.

Tarek Leil
Group Dir, Head of Quantitative Clinical
Pharmacology
BMS

"This was a great meeting bringing together scientists who share a passion in developing and implementing QSP models in the industry."

Merck, QSP Past Attendee

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Welcome to QSP 2016

Harness the Added Value of QSP to Inform Critical Decisions During Drug Discovery & Development

Uniquely focussed on the practical development and applications of QSP models, the **3rd annual QSP meeting will delve deeper into the science** behind the decisions in the development of these next generation models.

At this event, you will discover how leading pharmaceutical companies are applying these models to better understand disease pathogenesis and optimize pharmaceutical development. Gain unprecedented access to the data and outcomes of field defining case studies and enjoy solution led discussions.

This is a great opportunity for you to address your key challenges including **integrating big data, approaches to validating these models, and current and potential methods addressing biological uncertainty and variability.**

Join fellow senior scientists from both industry and academia to shape the pre-competitive culture, and build an interconnected QSP network that will become a revolutionary force in drug discovery and development.

Hear What Previous QSP Attendees Have To Say:

"Great meeting providing an overview on QSP approaches within drug discovery and development and forming a QSP Community."

Sanofi

"A very great meeting with lots of case studies on how to successfully apply QSP in different fields of research and development."

Boehringer Ingelheim

"A good conference with lots of useful information."

UCB Celltech

10 Reasons to Attend QSP 2016

1. Discover the **successful applications of systems pharmacology in drug discovery**, development and pharmacotherapy
2. **Realize the potential of QSP models** over classical modeling and simulation techniques
3. **Overcome computational challenges, including methods for validation**, to unlock the full potential of QSP through solution led sessions
4. Understand how QSP can **optimize clinical dosing regimes to minimize severe adverse events** and cumulative toxicity
5. **Promote and strengthen collaboration with multidisciplinary scientists** to rapidly advance your QSP modeling approach
6. Gain insight into how to approach the design and engineering of these models to **address challenges including biological variability and uncertainty**
7. **Anticipate the evolving regulatory landscape** facing the uses of these models so that you are up to date with the latest discussions from the FDA and worldwide
8. Discover and **shape genuine best practice around data standardization** and the incorporation of a variety of datasets
9. Learn how QSP is informing crucial decisions by **delivering greater predictability** from enhanced drug candidate selection, and improved clinical translation to post marketing analyses
10. **Define the optimal combination regimes between compounds** for enhanced therapeutic responses

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www.qspcongress.com Quantitative Systems Pharmacology (QSP)

Speakers

Valeriu Damia-Iordache Director - Pharmacokinetics & Translational Biology
GSK

Eric Sobie
Associate Professor
Icahn School of Medicine at Mount Sinai

Paul Watkins
Howard J Ferguson Distinguished Professor & Director,
UNC School of Pharmacy Institute for Drug Safety Sciences.

CJ Musante
Associate Research Fellow
Pfizer Inc.

Melissa Hallow
Assistant Professor
University of Georgia

Antje Walz
Senior Principal Scientist, Quantitative Systems Pharmacology
Hoffman La Roche

Lans Taylor
Director - Drug Discovery Institute & Allegheny Foundation Professor
University of Pittsburgh

Kapil Gadkar
Senior Scientist
Genentech

Tarek Leil
Group Dir, Head of Quantitative Clinical Pharmacology
BMS

Birgit Schoeberl
Head of Discovery & Senior Vice President-
Merrimack

Herbert Sauro
Assistant Professor, Bioengineering
University of Washington

Saroja Ramanujan
Principal Scientist
Genentech

Markus Friden
Head of Modelling & Simulation
AstraZeneca

Nathan Price
Associate Director
Systems Biology Institute

Ioannis Androulakis
Professor Biomedical, Chemical & Biochemical Eng.
Rutgers University

Pending Approval
Dhananjay Marathe
Senior Pharmacometric Reviewer
FDA

Bruce Gomes
Executive Director, Pharmacometrics Modeling and Simulation
Novartis

Sergey Ermakov
Principal Scientist Clinical Pharmacology, Modeling & Simulation
Amgen Inc

Scott Q Siler
President
DILIsym Services, Inc.

Karim Azer
Senior Director Clinical Pharmacology
Sanofi

Conference Day One | Tuesday, December 6, 2016

07.30 **Registration**

08.30 **Chair's Opening Remarks**

Bringing Quantitative Systems Pharmacology into Drug Development

Karim Azer, Senior Director Clinical Pharmacology, **Sanofi**

08.40 **Driving the Adoption of Innovative Pre-Clinical & Clinical Designs: Advanced Quantitative Systems Models in Drug Development**

- Reflecting on recent highlights and advances since the 2015 QSP meeting
- Evaluating state of the art computational models supporting the systems biology approach
- Exploring case studies to demonstrate the impact of QSP on the drug discovery process
- Defining QS: Strengths and shortcomings of the current approach

Dhananjay Murathe, Senior Pharmacometric Reviewer, **FDA**

09.10 **Creating the Environment to Drive Innovation: The Roadmap to Regulatory Acceptance**

- Addressing the context of use for QSP models as well as the current regulatory paradigms for QSP modeling
- An insight into how we can begin to bridge the gap between industry early adopters and the mainstream
- Understanding what can be done to overcome the regulatory hurdles and approval standards for the clinical applications of QSP models

09.40 **Morning Refreshments & Speed Networking**

Comparing QSP Approaches

Bruce Gomes, Executive Director, Pharmacometrics Modeling and Simulation **Novartis**

10.40 **The Use of QSP Modeling to Aid in Design of Antibody Drug Conjugates**

- How to effectively utilize knowledge gained from mathematical modeling of tumor-immune interactions to accurately forecast response to treatment
- Exploring the use of QSP modeling for drug discovery of Antibody Drug Conjugates
- Accelerating the development of safe, targeted anticancer therapeutics using cutting edge techniques
- Identifying the correct design parameters to match affinity to receptor target density, understand the tumor properties that effect performance and aid in choice of the best tumor type to use for ADC approach

Saroja Ramanujan, Principle Scientist, **Genentech**

11.10 **Systems Pharmacology in Translational Cancer Immunotherapy: From Preclinical Data to Clinical Predictions**

- Marrying mechanistic and data-driven approaches in systems modeling and addressing population variability
- Establishing confidence in translational predictions
- Informing diverse clinical questions and considerations through the iterative development of the model

"Very invigorating conference! Bringing a group of like minded people together to share common stories"

Eli Lilly

Karim Azer, Senior Director Pharmacology, **Sanofi**

Kapil Gadkar, Scientist, **Genentech**

Bruce Gomes Executive Director, Pharmacometrics Modeling and Simulation **Novartis**

11.40 **Panel Discussion: Balancing Complexity vs. Functionality: Engineering Predictive Models & Qualifying Their Use in Drug Discovery & Development**

- Highlighting the importance of mimicking the heterogeneity of tumors and other disease states to improve clinical outcomes
- Reviewing the key characteristics that can be modeled for future applications in drug testing
- Exploring the best approaches to designing and engineering a QSP Model
- Understanding the need to develop fully integrated models vs. smaller more focused ones
- Understanding the importance of robust parameter estimation in systems modeling
- Leveraging a diversity of physiological information in combination with diverse in vitro and in vivo data
- Where QSP can and should be applied in the context of discovery, toxicology and wider drug development
- Assessing the current utility and limitations of QSP in the discovery of next generation therapies
- Identifying where we should be investing our time and resources for QSP R&D

12.35 **Lunch & Networking**

Challenges & Opportunities for QSP in Drug Discovery & Development

Ioannis Androulakis, Professor Biomedical, Chemical & Biochemical Eng., **Rutgers University**

1.35 **Comparing QSP Approaches – Mathematical Models of Different Complexities**

Historically, QSP models tend to be "cell"-centric describing in great detail the complexities of signal transduction

The next frontier for systems-based approaches will be to extend and expand the operating envelope and slowly approach the host level, and beyond (environment, society etc.)

QSP can provide the foundations for developing an integrated framework for the assessment of drugs and their impact on disease within a broader context expanding the envelope to account in great detail to account for physiology, environment and prior history

- With a focus on inflammation and anti-inflammatory drugs, explore some of the critical enablers, major obstacles and opportunities towards the development of extended and expanded QSP models

Markus Friden, Section Head, Modelling and Simulation, **AstraZeneca**

2.05 **PKPD 'versus' QSP: Case Studies of Impact Across AstraZeneca´s Drug Discovery Project Portfolio**

- How embedding of PKPD modeling capability in drug discovery project teams has leveraged real-time delivery of predictions and mechanistic insight into the biology and pharmacokinetics
- An insight into how AstraZeneca has implemented modeling in discovery and identifying the requirements of their success
- Differentiated impact of modeling to iteratively build datasets / knowledge: Case studies from AstraZeneca´s therapeutic areas: Cardiovascular, metabolic, respiratory/immunity, oncology and safety

Herbert Sauro, Assistant Professor, Bioengineering, **University of Washington**

2.40 **The Importance of Standards in Model Exchange, Reuse & Reproducibility of Simulations**

- Exemplifying the necessity for standards within QSP
- Exploring the current challenges and paradigms to approaching model exchange, reuse, and reproducibility of simulations
- Key success stories

Herbert Sauro, Assistant Professor, Bioengineering, **University of Washington**

Markus Friden, Section Head of Modelling & Simulation, **AstraZeneca**

CJ Musante, Associate Research Fellow, **Pfizer Inc.**

3.10 Panel Discussion: Debating Approaches to Validating Systems Models

- What constitutes a validated model from a regulatory standpoint?
- What is best practice when applying complex models to the translational and pre-clinical landscape to increase the confidence rationale of drug targets
- Can we employ open target libraries across industry to begin standardizing models and more importantly data sources across the board?
- What are the requirements from regulatory agencies to help facilitate further success?
- How can we begin to utilize genomic/epigenomic determinants and network analyses integrated with dynamical models?

3.55 Afternoon Refreshments & Poster Presentations

Mechanistic Physiological-Based Models Informing Drug Development

Scott Q Siler President **DILIsym Services, Inc.**

4.30 NAFLDsym™: A New QSP model for Accelerating Drug Development for NAFLD & NASH

- NAFLDsym™ is a mechanistic, mathematical, quantitative systems pharmacology (QSP) model
- NAFLDsym™ has been constructed to support clinical development of NAFLD treatments
- NAFLDsym™ is derived from DILIsym®, the gold standard QST mathematical model for predicting DILI risk

Birgit Schoeberl, Head of Discovery & Senior Vice President, **Merrimack**

4.40 From Systems Biology to Systems Medicine

- A comprehensive analysis of phenotypic and signaling responses of a panel of colorectal cancer cell lines to a single growth factor
- Analyzing a pairwise combination of growth factor treatments in the presence and absence of signaling inhibitors
- Demonstrating the use of phenotypic screening and computational modeling to reveal unexpected behaviors, identify positive and negative biomarkers, and guide novel treatment strategies in Merrimack's pipeline

Kapil Gadkar, Senior Scientist, **Genentech**

5.10 A QSP Model for Evaluating Potential Drugs for the Treatment of Asthma

- How to support clinical and biomarker development strategies for novel interventions of asthma utilizing a mechanism-based systems model representing different cellular and molecular contributors to disease
- Demonstrating the ability of the model to predict changes in clinical readouts and biomarker endpoints for novel therapeutic interventions
- Reviewing a case study demonstrating model based evaluation of biomarkers for anti-ST2 program

5.40 Chair's Closing Remarks

5.45 Close of Day One

See the latest agenda at:
www.qspcongress.com/agenda

"Strong program, great speakers and a genuine focus on identifying solutions"
Novartis

Conference Day Two | Wednesady, December 7, 2016

08.00 Chair's Opening Remarks

Applying QSP to Cardiovascular & Metabolic Disease

CJ Musante, Associate Research Fellow, **Pfizer Inc.**

08.10 The Future's So Bright: Leveraging Advances in Supercomputing & Machine-Learning for Next Gen QSP

- Identifying what the future can hold for QSP and the roadmap to achieving it
- Looking at the advances in scientific computation that can drive the next generation of QSP models and methods
- Identifying the recent advances in cardiovascular and metabolic diseases' efficacy and safety applications

Antje Walz Senior Principal Scientist, Quantitative Systems Pharmacology **Hoffman La Roche**

08.40 How to Increase Confidence in Compound Selection & Human Dosage Predictions?

- Understanding how QSP model approaches help to identify and close knowledge gaps
- Improving predictions from animals to humans by combining experimentation with modeling
- Assessing current utility and limitations of QSP models to make predictions regarding the cardiac toxicity potential in humans

Melissa Hallow, Assistant Professor, **University of Georgia**

09.10 Renal & Cardiovascular QSP: Understanding Unexpected & Unintuitive Reno- & Cardioprotective Mechanisms of SGLT2 Inhibition

- Demonstrating and quantifying the unintuitive renoprotective mechanisms of SGLT2 inhibition
- Generating clinically testable hypotheses of mechanisms of cardiovascular protection using a QSP model of renal and cardiovascular function
- Using QSP models to quantify the impact of disease stage and patient baseline characteristics on response: Maximizing benefit and minimizing risk
- How to reuse a QSP model over different disease areas and phases of development

Tarek Leil, Group Dir, Head of Quantitative Clinical Pharmacology, **BMS**

09.40 Cross Functional Development & Application of a Metabolic Disease Systems Pharmacology Model

- Importance of cross functional development of QSP disease models applied to exploratory clinical development
- Integration of data and knowledge on glucose and lipid physiology and the effects of various interventions for development of a metabolic diseases QSP model
- Application of the metabolic diseases model for generation of hypotheses in exploratory clinical development

10.10 Morning Refreshments & Networking

Lans Taylor, Director - Drug Discovery Institute & Allegheny Foundation Professor, **University of Pittsburgh**

Saroja Ramanujan, Principal Scientist, **Genentech**

Sergey Ermakov, Principal Scientist Clinical Pharmacology, Modeling & Simulation, **Amgen Inc**

10.55 Panel Discussion: Defining QSP & More Importantly What it is Not!

Following the NIH white paper in 2011, QSP has become an umbrella term for a variety of modeling approaches that integrate a mathematical representation of a biological system within pharmaceutical development. As its popularity grows and the field evolves, the divides within QSP are becoming more evident, and key questions remain to be answered.

- Where on the continuum of ADME tox to modeling disease progression should QSP be utilized?
- Can the rationale of applying QSP from the patient through to drug development to clinical trials truly be accomplished?
- Is an integrated and mechanistic approach the correct approach?
- Where should the boundaries be drawn with systems biology?

11.40 Round Tables

Exploring the QSP regulatory landscape

Adapting Machine learning to a QSP approach to enhance the drug discovery process

Integrating diverse data sets from a variety of models for the development of diverse product types

Challenges and opportunities for Big Data integration in system pharmacology

Herbert Sauro, Assistant Professor, Bioengineering, **University of Washington**

CJ Musante, Associate Research Fellow, **Pfizer Inc.**

Dhananjay Marathe, Senior Pharmacometric Reviewer, **FDA**

12.40 Lunch & Networking

Development of Quantitative System Toxicology (QST) Approaches

Paul Watkins, Howard J Ferguson Distinguished Professor & Director, **UNC School of Pharmacy Institute for Drug Safety Sciences.**

1.40 QSP Modeling of Hepatotoxicity: Understanding & Predicting Dose Dependent & Idiosyncratic Events

- Analyzing the current utility and limitations of QSP models as predictive tools
- Incorporating mechanistic and translational biomarkers to improve predictions
- Exploring examples of QSP modeling of hepatotoxicity included in regulatory submissions and an FDA Ad Com presentation
- Understanding the best use of metabolically competent systems to incorporate metabolite effects and to direct modeling efforts

Eric Sobie, Associate Professor, **Icahn School of Medicine at Mount Sinai**

2.10 QSP Approaches to Improve Early Detection of Adverse Events

- Understanding how simulations of drug effects in cardiac myocytes can correctly produce adverse effects such as drug-induced proarrhythmia
- Discovering how simulations of dynamics combined with machine learning approaches can improve identification of potentially dangerous drugs
- Demonstrating how extensions of existing QSP approaches can help to streamline drug toxicity testing

Valeriu Damian-Iordache Director, Pharmacokinetics & Translational Biology, **GSK**

Eric Sobie, Associate Professor, **Icahn School of Medicine at Mount Sinai**

Paul Watkins, Howard J Ferguson Distinguished Professor & Director, **UNC School of Pharmacy Institute for Drug Safety Sciences.**

2.40 **Panel Discussion: Combining QSP with Systems Toxicology**

- Is there scope to put these two disciplines together?
- Can we understand the likely mechanisms of toxicity and perhaps target toxicity during drug development?
- Utilizing QSP & QST to model therapeutic index and understanding the therapeutic window
- From drug discovery to late phase patient identification: When is the right time to use these models?
- How can we take what we know in terms of mechanisms of toxicology and apply it to the discovery process?

3.25 **Afternoon Refreshments**

QSP & Personalized Medicine

D. Lansing Taylor, Director - Drug Discovery Institute & Allegheny Foundation Professor, **University of Pittsburgh**

4.25 **Harnessing QSP in Parallel with Phenotypic Assays for Drug Discovery & the Advancement of Personalized Medicine**

- Identifying mechanisms of disease progression to test predicted therapeutic strategies likely to achieve clinical validation for appropriate subpopulations of patients
- Using the model as a platform to address biological heterogeneity and anticipate the evolution of resistance mechanisms
- Gaining an understanding of mechanism(s) of disease progression to enable the identification of novel therapeutic strategies as well as repurposing drugs
- Assessing the impact of this type of QSP approach on future of precision medicine

Nathan Price, Director, **Systems Biology Institute**

4.55 **Big Data Analyses for Optimizing Wellness & Minimizing Disease**

- Analyzing new approaches providing new paths to quantitative systems pharmacology and building data-informed quantitative models for disease and health
- An insight into new technologies enabling the gathering of unprecedented amounts of health-relevant data for the analysis of the manifestation of genetic risk in the body
- Utilizing dense, dynamic, personal data clouds to provide a means to discover candidate preventive and even treatment strategies for disease

5.25 **Chair's Closing Remarks & Close of Day Two**

End of Conference

"The talks were high quality and the interaction among participants was excellent."

Genentech

Act now to reserve your place at QSP 2016 Register online at: *www.qspcongress.com/register*

Pre-Conference Workshop A

Lessons Learnt From Pre-Competitive Consortia & Other Open Innovation Partnerships to Bridge Drug Discovery & Development

Date: December 5, 2016 | Time: 9am-12pm

QSP promises an increased level of predictivness that can inform decisions by identifying the statistical likelihood of successes and failures during the drug development process.

Since the field's inception, QSP's ability to bridge scientific gaps between disciplines has resulted in Pharma quickly realizing the potential in this technology. Several consortia have been created with the objective of developing, validating and sharing pre-competitive QSP models.

But what have been the key success factors to these consortia?

Join this workshop to discover where we now need to build our efforts to continue to drive the science within these open partnerships, and maximize the pre competitive culture.

QSP modeling of Hepatoxicity - The Experience of the DILIsim Public-Private Partnership

Drug-induced liver injury remains a major adverse drug event leading to termination of drug development programs, expanding and lengthening clinical trials, and labelling restrictions. Three major mechanisms have emerged as underlying dose-dependent hepatotoxicity:alterations in bile acid homeostasis, oxidative stress, and impairment in mitochondrial respiration. It is now possible to quantitatively assess these liabilities *in vitro*. QPS enables integration of these liabilities, together with PBPK estimates to predict dose dependent hepatoxicity in simulated patient populations. The DILIsim Initiative is a public-private partnership that has had success in using QSP not only to predict dose-dependent hepatoxicity but also rare, or idiosyncratic, liver events.

Workshop leader

Paul Watkins, Howard J Ferguson Distinguished Professor, Schools of Pharmacy, Medicine and Public Health, **University of North Carolina Chapel Hill. Director of the UNC School of Pharmacy Institute for Drug Safety Sciences**

Dr. Paul B. Watkins is director of the University of North Carolina Institute for Drug Safety Sciences. Dr. Watkins is a trained clinical hepatologist and also an accomplished basic and translational investigator in the fields of drug metabolism and hepatotoxicity. He serves as the chair of both the Steering and Genetics Committees for the U.S. Drug-Induced Liver Injury Network (DILIN) (U01DK065201). He also directs the DILIsim Initiative, which is a public-private partnership involving scientists from 12 major pharmaceutical companies and the FDA.

Pre-Conference Workshop B

A Six-Stage Workflow for Robust Application of Systems Pharmacology

Date: December 5, 2016 | Time: 1pm-4pm

One factor critical to the ultimate success of QSP is the establishment of commonly accepted language, technical criteria, and workflows. We present a robust workflow that, in its entirety or in sections, has been successfully applied in QSP-based efforts to address many of the novel challenges these efforts face.

In this workshop, key steps in this workflow are described, bridging conceptual objectives of each of them with technical methodologies to support their execution.

The three primary focus areas for the workshop will include:

1. Considerations and strategies for QSP model scoping to prepare an optimal roadmap for subsequent execution to develop and apply "fit for purpose" QS models
2. Technical tools for calibration of QSP models to be consistent to diverse data ranging from *in-vitro*, preclinical and clinical data
3. Methodologies for exploration of underlying biological uncertainty and variability using a virtual population approach to ensure robust predictions from the QSP models

Join this workshop for:

- An understanding of the different stages of a robust workflow for the development and application of QSP models
- Familiarity with the key concepts and technical methodologies applicable at each stage of the workflow; appreciation of the value addition of the same for robust QSP efforts
- Familiarity with existing literature wherein some of these concepts and methods have been successfully applied

Genentech

Workshop leader

Kapil Gadkar, Senior Scientist, **Genentech**

Dr. Gadkar received a Ph.D. in Chemical Engineering from UCal Santa Barbara and is currently a Senior Scientist in the Translational & Systems Pharmacology Group at Genentech. His research focuses on developing Systems Pharmacology models to support drug development efforts at Genentech. Prior to joining Genentech, Kapil was a Biosystems Engineer at Entelos.

Sponsorship Opportunities

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DILIsym Services, Inc. (DSS) improves the safety and efficacy of new therapeutics by applying their proprietary DILIsym® software to address liver safety concerns, as well as applying their proprietary NAFLDsym™ software to explore and validate molecular targets for the treatment of non-alcoholic fatty liver disease (NAFLD) . Objectives for use of simulation results include informing the candidate selection process, providing information regarding the risk versus benefit question often debated as large investments are considered, and identifying and/or substantiating personalized medicine approaches.

Why sponsor

With a pressing need to address attrition rates, **leading drug developers are investing heavily into more effective mathematical models** that can inform critical decisions across pharmaceutical development.

Realizing the potential for QSP, **these companies are seeking external expertise** to help them develop and integrate these models into their drug development pipeline.

We are inviting vendors to help these organizations in developing effective quantitative systems approaches that can streamline drug development and regulatory interactions.

- **Differentiate yourself** from your peers by demonstrating your specific expertise and/or technologies in this market that can provide credible insights and enable confident decision making
- **Present alongside industry leaders** to establish credibility among key decision makers from the pharmaceutical industry
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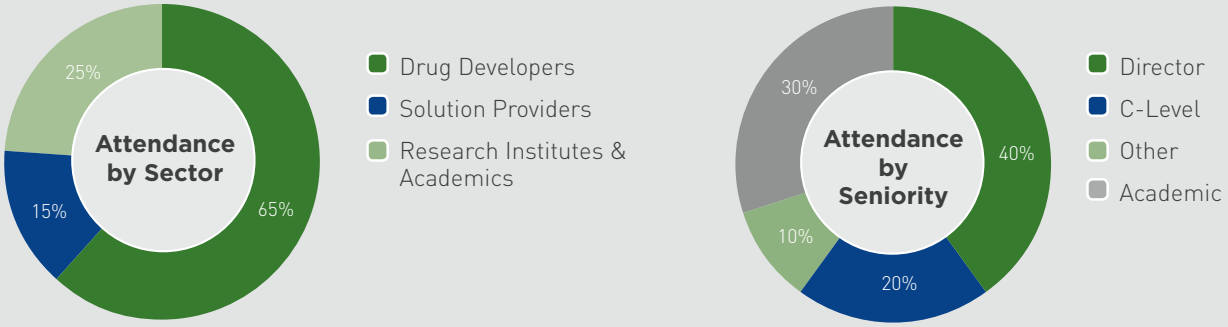

Figures based on attendance of QSP 2015 and research during 2016

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Top 3 Benefits of Attending

1. **Shape genuine best practice for the use of these models in industry**
2. **Strengthen collaborations within a pre-competitive climate**
3. **Accurately inform crucial decisions within your drug pipeline**

Industry			
	Register & Pay before Friday September 30, 2016	**Register & Pay before Friday October 28, 2016**	**Standard Prices**
Gold Package Conference + 2 workshops	$3397 **(save $700)**	$3597 **(save $500)**	$3797 **(save $300)**
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Bronze Package Conference only	$2799 **(save $200)**	$2899 **(save $100)**	$2999
Workshops (each)	$899		

Venue

Hotel Kabuki
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www.jdvhotels.com

Please note: Overnight accommodation and travel are not included in the registration fee.

"It was very interesting to discuss the QSP present and future"

Pfizer

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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