



2ND ANNUAL SYMPOSIUM

Chemical & Pharmaceutical Structure Analysis

*Where Technology and Solutions Meet
Where East Meets West*

CPSA SHANGHAI 2011

April 13-16, 2011

Renaissance Shanghai Pudong Hotel
Shanghai

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WELCOME LETTER

Inspiration and Education

Dear Colleague:

On behalf of the organizing committee and our sponsors, we welcome you to the 2nd Annual Shanghai Symposium on Chemical and Pharmaceutical Structure Analysis (CPSA Shanghai 2011). It is a pleasure to host this unique event in Shanghai again.

Parallel to its fast economical growth, China is also among the fastest growing countries in science and technology including pharmaceutical research and development. The goal of CPSA Shanghai is to bring together the scientists from both the East and the West to provide unique, in-depth review of innovative technology and industry practices through open discussions of industry related issues and needs.

The theme of the meeting "Changing Paradigm of Drug Discovery and Development: East Meets West" reflects a new trend in the globalization of the pharmaceutical research and development environment. This starts with offshore outsourcing, integrated research and development capability, and leads to global R&D, registration, and marketing strategies. CPSA Shanghai 2011 will examine this changing paradigm from a unique perspective; drug metabolism/pharmacokinetics and pharmaceutical sciences with a focus on their foundational disciplines - bioanalysis and pharmaceutical analysis.

At CPSA Shanghai 2011, for the first time, we will present the Young Scientist Excellence Award. This award will recognize rising stars in a pharmaceutical related discipline. Also for the first time, we have designed multiple workshops and a special joint session with local discussion groups that will be delivered mostly in Chinese.

We have created a unique meeting format that encourages scientists to openly share their firsthand experiences with specific applications and technologies. Imagination and stimulating discussion are central to each CPSA function and session. Our hope is for attendees to actively participate in the conference and become inspired with new ideas, new contacts, and with practical actions they can apply.

A special thanks is extended to our sponsors who all share the sincere belief that CPSA Shanghai will become the premier international event to meet experts in the field and to discuss our industry's most fundamental challenges. Enjoy the meeting - where technology and solutions meet... and where East meets West!

Sincerely,



Mike S. Lee, Ph.D, Founder CPSA



Jing-Tao Wu, Ph.D, CPSA Shanghai 2011 Program Chair

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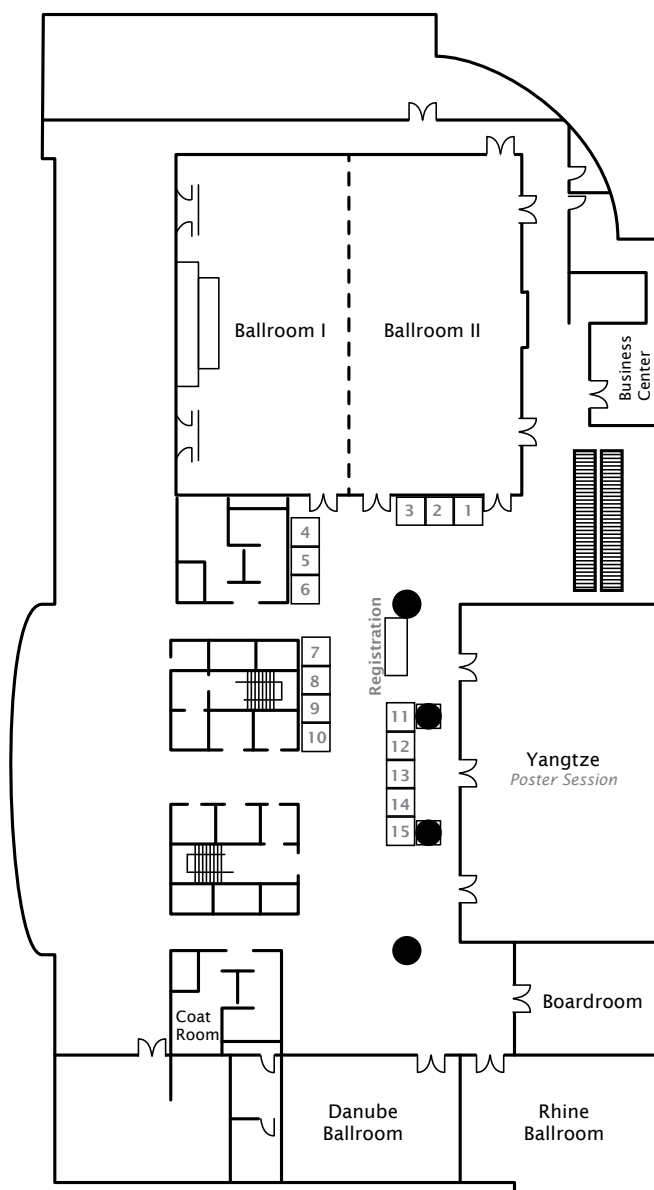
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FLOORPLAN

CPSA Shanghai Meeting Rooms

CPSA Shanghai symposia and events will be held in the Renaissance Shanghai Pudong Hotel, with the exception of Saturday's joint meeting with local area discussion groups, which will be held at the Shanghai Institute for Materia Medica. A floorplan of the meeting rooms referenced within the program can be found below.

4th Floor



EXPO HOURS

The CPSA Shanghai 2011 Exposition booths will be open on the following schedule:

THURSDAY	11:00 AM - 2:00 PM
FRIDAY	11:00 AM - 2:00 PM

EXHIBITORS

Booth#	Company
1	Antpedia
2	Agela Technologies
3	Instrument.com.cn
4	ASPEC Technologies
5	Covance
6	Agilent Technologies
7	Thermo Fisher Scientific
8	New Objective
9	MS Parts
10	Wuxi AppTec
11	McKinley Scientific
12	Pharmaron
13	Apricot Designs
14	ACD Labs
15	AB Sciex

FOR EXHIBITORS

Move-in: Wednesday, 9:00 am - 10:30 am
 Move-out: Thursday, 2:00 pm - 5:00 pm

Please be sure that a company representative is present at your booth during the posted exposition hours.

SPONSORS

Thank You

The CPSA Shanghai annual symposium is made possible by the broad-based support of industry sponsors. The passion for the analytical sciences and the accelerated discovery and development of pharmaceuticals is shared by each sponsor. As a result, the event is dedicated to promoting awareness and understanding of the issues and needs associated with pharmaceutical R&D in the hopes of inspiring significant advances in the field.



NEW OBJECTIVE



Meeting Management



Media Sponsors



WORKSHOPS

Wednesday April 13

1:00 PM – 5:00 PM

BIOTRANSFORMATION: LEAD OPTIMIZATION AND CLINICAL CANDIDATE SELECTION THROUGH IN VITRO ADME EVALUATION

Workshop Leader: Mingshe Zhu, Bristol-Myers Squibb

- ▶ **Common in Vitro ADME Assays: Methods and Data Interpretation**
Weiqing Chen, ChemPartner
- ▶ **Assessment of Transporter-Mediated Drug-Drug Interactions: Current Strategy and Methodology**
Guangqing Xiao, Biogen Idec
- ▶ **Drug Metabolite Identification in Drug Discovery Using High-Resolution Mass Spectrometry**
Jie Xing, University of Shandong, China
- ▶ **Design Proper in Vitro ADME Studies to Meet Needs in Drug Discovery**
Mingshe Zhu, Bristol-Myers Squibb

1:00 PM - 5:00 PM

BIOANALYSIS: LC-MS/MS BIOANALYSIS FROM DRUG DISCOVERY TO DEVELOPMENT: PROCESSES, TECHNOLOGIES AND REGULATIONS

Workshop Leader: Jian Wang, Bristol-Myers Squibb

- ▶ **Overview of LC-MS/MS Bioanalysis in Pharmaceutical Industry: Processes and Applications**
Danlin Wu, Roche
- ▶ **Technical Fundamentals in LC-MS/MS Bioanalytical Method Development, Validation and Sample Analysis: Procedures, Issues and Solutions**
Yuan-Qing Xia, Bristol-Myers Squibb
- ▶ **Performing Regulated Bioanalysis, Challenges and Case Studies from a CRO Perspective**
Xiaohang Shen, WuXi AppTec
- ▶ **Discovery Bioanalysis**
Jian Wang, Bristol-Myers Squibb

1:00 PM - 5:00 PM

PHARMACEUTICAL ANALYSIS

Workshop Leaders: Gang Xue, Pfizer; Yong-Guo "Fred" Li, Roche

- ▶ **High Speed and High Efficiency Method Development**
Gang Xue, Pfizer
- ▶ **ICH Q-Series, Key Points Exploration**
Yong-Guo "Fred" Li, Roche
- ▶ **Dissolution Design and Testing, Critical for Oral Drug**
Mufeng Xie, Shanghai Institute for Food and Drug Control (SIFDC)

SPONSOR'S DINNER

Wednesday April 13

EVENING

SPONSOR'S DINNER

Hosted by Thermo Fisher Scientific

Introduction and Welcome

Iain Mylchreest, Vice President and General Manager, Thermo Fisher Scientific

Applying Proven Proteomic Workflows and Tools for Quantitative Bioanalysis of Large Molecules

Jonathan McNally, Marketing Manager for Bioanalysis, Thermo Fisher Scientific

PROGRAM AGENDA

Thursday April 14

8:30 AM – 10:00 AM

Ballroom 1-2

OPENING REMARKS

Welcome

Mike Lee, Milestone Development Services

Meeting Overview

Jing-Tao Wu, Millennium Pharmaceuticals

PLENARY LECTURE

Challenges and Future Direction of Oncology Drug Development

Pete Smith, Senior Vice President, Millennium Pharmaceuticals

11:00 AM - 2:00 PM

4th Floor Lobby

CPSA SHANGHAI EXPO

See the latest in services and technologies from participating CPSA Shanghai Expo vendors

10:15 AM - 11:45 AM

Ballroom 1

PARALLEL SESSIONS

Track 1: ADME I

Comparison of Regulatory Requirements on DMPK Package

Chair: Jeff Zhang, Novartis

- ▶ **Overview of DMPK Package in China: Regulatory Requirement & Current Practice**
Dafang Zhong, Shanghai Institute of Materia Medica
- ▶ **U.S./Europe Regulatory Requirements on Metabolites in Safety Testing**
Mingshe Zhu, Bristol-Myers Squibb
- ▶ **U.S./Europe Regulatory Requirements on Drug/Drug Interactions**
Lawrence Gan, Biogen Idec

Rhine Ballroom

Track II: Pharmaceutical Sciences

Emerging Trends and Technologies in Pharmaceutical Sciences

Chair: Jack Chen, DSM

- ▶ **PAT Applications in a Quality-by-Design (QbD) Environment**
Kevin Bittorf, Vertex Pharmaceuticals
- ▶ **Enhancing Product Performance Through Innovative Formulation & Manufacturing**
Qun Lu, Merck
- ▶ **New Technology in Polymorph Studies**
Beth Sarsfield, Bristol-Myers Squibb

PROGRAM AGENDA

Thursday April 14

Ballroom 2

Track III: Bioanalytical

Dried Blood Spots and Other Emerging Bioanalytical Technologies

Chair: Naidong Weng, Johnson & Johnson

- ▶ Applications of DBS for Clinical Bioanalysis Support
Tom Verhaeghe, Johnson & Johnson
- ▶ Case Study of Dried Blood Spots Application in Toxicology Study
Luke Bi, Covance
- ▶ High Resolution Accurate Mass Spectrometry in Quantitative Bioanalysis: Effect of Mass Resolution and Extraction Window on Selectivity
Yuan-Qing Xia, Bristol-Myers Squibb
- ▶ High-Throughput Bioanalysis Using an Ultra-fast On-line Extraction System
Wenyang Jian, Johnson & Johnson

11:45 AM - 1:15 PM

LUNCH & ROUNDTABLE DISCUSSION

4th Floor lobby area

12:15 PM - 1:15 PM

SPONSORED ROUNDTABLE WORKSHOPS

Danube Ballroom

Workshop hosted by AB Sciex

- ▶ High Resolution Quantitation for Bioanalysis using AB Sciex 5600 Triple ToF
Hesham Ghobarah, AB Sciex
- ▶ Targeted Peptide Quantitation using MIDAS Workflow
Wenhai Jin, AB Sciex

The Boardroom

Workshop hosted by McKinley Scientific

- ▶ Analytical Equipment and Clinical Systems: New Business Models to Assist Research in Academia, Pharmaceuticals, and Hospitals
Martin Steel, McKinley Scientific

1:15 PM – 5:00 PM

PARALLEL SESSIONS

Ballroom 1

Track I: ADME II

1:15 pm - 2:45 pm

Drug-Drug Interactions

Chairs: Cindy Xia, Millennium; Angela Wong, Merck Serono

- ▶ DDI of Herbal Medicines
Yan Sun, Shanghai Institute of Materia Medica

PROGRAM AGENDA

Thursday April 14

- ▶ Application of In-Vitro Data to Predict Clinical PK and Drug-Drug Interaction by Simcyp
Jing Lin, Pfizer

- ▶ Pharmacogenetics in Drug Discovery and Development
Renke Dai, South China University of Technology

3:00 pm - 5:00 pm

ADME Optimization to Advance CNS and Oncology Drug Discovery & Development: Industry Case Studies

Chairs: Zack Cheng, GlaxoSmithKline; Haojing Rong, Pfizer

- ▶ Blood-Brain Barrier Transporters: Friend or Enemy for CNS Drug Discovery & Development?
Zack Cheng, GlaxoSmithKline
- ▶ Human CNS Penetration: Can It Be Predicted from Preclinical Data?
Haojing Rong, Pfizer
- ▶ ADME Support of Oncology Programs: Risk Management vs. Pursuit of Appropriate Drug-Like Properties
Hongjian Zhang, PharmaResources
- ▶ Predictive Toxicology Approaches for Small Molecule Oncology Drugs
Vic Kadambi, Millennium Pharmaceuticals

Ballroom 2

Track II: Pharmaceutical Analysis Summit

1:15 am – 2:45 pm

High-Speed, High-Resolution Techniques for Pharmaceutical Analysis

Chairs: Anne-Françoise Aubry, Bristol-Myers Squibb; Xiaoyi Gong, Merck

- ▶ Chromatographic Methodology and Technology for Developing TCM
Xinmiao Liang, Dalian Institute of Chemical Physics
- ▶ Mass Spectrometry and Ion Mobility-Based Techniques for Rapid Pharmaceutical Analysis: No Sample Preparation?
Zhongli Zhang, Pfizer
- ▶ GC-MS and Flow-Modulated GCXGC-FID/MS for the Analysis of Fatty Acids in Bacteria and Marine Biota Using Polar and Ionic Liquid Columns
Qun Gu, Dalian Institute of Chemical Physics

3:00 pm - 5:00 pm

Analytical Approaches for the Determination of Low-Level Impurities to Comply with International Regulations

Chairs: Todd Gillespie, Eli Lilly and Company; Roman Szucs, Pfizer

- ▶ Analytical Strategy for Quantifying Low-Level Genotoxic Impurities
Todd Gillespie, Eli Lilly and Company

PROGRAM AGENDA

Thursday April 14

- ▶ Quantitation of API Impurities Near the Qualification Level
Tianmin Zhu, Hisun Pharmaceuticals
- ▶ High-throughput Chiral Analyses
Xiaoyi Gong, Mercks
- ▶ Bioanalytical ICP-MS in Drug Development
Jaap Wieling, QPS Netherlands

Rhine Ballroom

Track III: Workshop

Absolute Quantification of Peptides and Proteins: From Sample Preparation and Chromatography to ESI-MS/MS

Leaders: Gary Valaskovic, New Objective; Nalini Sadagopan, Agilent Technologies

5:00 PM - 6:00 PM

POSTER SESSION

Yangtze Ballroom

Poster authors will be available for discussion and review

6:00 PM - 9:00 PM

RECEPTION & KEYNOTE LECTURES

Ballroom 1-2

Hosted by Agilent Technologies

Welcome Toast

Keynote Lectures

- ▶ Stable and Reactive Metabolites in Drug Research
Scott Obach, Pfizer
- ▶ Simultaneous Determination of the PK Profile of Clozapine and its Metabolites in Rat Plasma Using a High-Resolution 6540 QTOF Instrument
Lester C. Taylor, Shane Tichy, and Na Pi of Agilent Technologies

PROGRAM AGENDA

Friday April 15

8:30 AM – 9:15 AM

Ballroom 1-2

PLENARY LECTURE

Multi-dimensional Chromatography-Mass Spectrometry for Protein Analysis

Xiangmin Zhang, Fudan University

9:30 AM - 11:00 AM

Ballroom 1

PARALLEL SESSIONS

Track I: Novel Drug Delivery Technologies

Chair: Nick Zhang, Novartis

▶ **Antibody Drug Conjugates: A General Review**

Boahua Gu, Novartis

▶ **Drug Targeting and Nanotechnology**

Jianxin Wang, Fudan University

▶ **Liposome Drug Delivery System**

Zhixuan Wang, Novartis

Ballroom 2

Track II: Biomarker Analysis in Drug Discovery, Development and the Clinic

Chairs: Scott Fountain, Pfizer; Nalini Sadagopan, Agilent

▶ **Application of Target and Mechanism Biomarkers in Advancing Biotherapeutics and Pharmatherapeutics**

Scott Fountain, Pfizer

▶ **Implementing Biomarkers into Clinical Trials on a Global Scale**

Tom Turi and LiBin Ma, Covance

▶ **Proteomics Approaches to the Development of Plasma Markers for Predicting Pre-Term Birth**

Kevin P. Rosenblatt, The Brown Foundation Institute of Molecular Medicine

Rhine Ballroom

Track III: Comparison of Regulations for Pharmaceutical Sciences

Chair: Gang Xue, Pfizer

▶ **Reviews of CMC Requirements for Drug Development, Registration and Post Approval**

Yanyun Chen, Pfizer

▶ **CMC Requirements for Analytical/QC**

Wenfang Miao, Pharmaron

11:00 AM - 12:00 PM

Yangtze Ballroom

POSTER SESSION

Poster authors will be available for discussion and review

PROGRAM AGENDA

Friday April 15

11:00 AM - 2:00 PM

4th Floor Lobby

CPSA SHANGHAI EXPO

See the latest in services and technologies from participating CPSA Shanghai Expo vendors

12:00 PM - 1:30 PM

LUNCH / ROUNDTABLE DISCUSSION

12:30 PM - 1:30 PM

Danube Ballroom

SPONSORED ROUNDTABLE WORKSHOPS

Workshop hosted by Thermo Fisher Scientific

- ▶ Identification and Screening for Drug Impurities, Leachables, and Extractables Using New Software and High Resolution Mass Spectrometry
Kate Comstock, Marketing Specialist for Drug Metabolism, Thermo Fisher Scientific

The Boardroom

Workshop hosted by New Objective

- ▶ The Application of Nanospray Techniques and Methods for Product Development
Todd Gillespie, Eli Lilly and Company
- ▶ Ultra-low-flow Nanospray for Low-Level Biomarkers, Metabolites, and Beyond: Addressing Needs for Sensitivity, Selectivity, and Throughput
Gary Valaskovic, New Objective, Inc.

Rhine Ballroom

Workshop hosted by Agela Technologies

- ▶ What is the Most Convenient and General Approach for Plasma Sample Clean-up?
Jerry Wang, Agela Technologies

1:30 PM – 5:15 PM

Ballroom 1

PARALLEL SESSIONS

Track I: ADME III

1:30 am – 3:00 pm

Development of Biologics as Therapeutics

Chair: Lawrence Gan, Biogen Idec; Haojing Rong, Pfizer

- ▶ Introduction of Biologics
Jennifer Visich, Genentech
- ▶ Biologics Drug-Drug Interaction
Lewis Klunk, Biogen Idec
- ▶ PK/PD of Biologics
Anup Zutshi, Pfizer

PROGRAM AGENDA

Friday April 15

3:15 pm - 5:00 pm

PK/PD in Drug Discovery & Development

Chairs: Jenny Zheng, Pfizer; Zhuohan Hu, Research Institute for Liver Diseases

- ▶ **The Myths of PK/PD - Empirical? Mechanistic? Or System?**
Jenny Zheng, Pfizer
- ▶ **A Mechanistic-Based PK/PD Modeling for Drug Metabolism by CYP3A in Rat**
Wei Lu, Peking University, China
- ▶ **Case History: Use of PK/PD in Drug Candidate Selections**
Ellen Rohde, Biogen Idec
- ▶ **Application of PBPK and In-Vitro Hepatocyte Models to Accurately Predict Human PK**
Yurong Lai, Pfizer

Ballroom 2

Track II: Regulated Bioanalysis Summit

1:30 pm - 3:30 pm

Regulated Bioanalysis: State of the Art

Chair: Danlin Wu, Roche

- ▶ **Perspectives on Regional Differences in Bioanalytical Regulations**
Mark Arnold, Bristol-Myers Squibb
- ▶ **Strategies to Avoid Pitfalls in Developing and Validating High-quality Quantitative Bioanalytical Methods to Support Regulated Studies**
Jinsong Xing, Wuxi AppTec
- ▶ **Importance of Reagent Quality for Ligand Binding Assay Development**
Roland Staak, Roche
- ▶ **Validation and Application of Ligand Binding Assays for Protein Therapeutics Quantitation and Immunogenicity Testing: A GLP Bioanalytical Lab Perspective**
Eginhard Schick, Roche

3:45 pm – 5:15 pm

Current Issues in Regulated Bioanalysis

Chair: Anne Françoise-Aubry, Bristol-Myers Squibb

- ▶ **Unexpected Event Investigations in the Bioanalytical Laboratory**
Anne Françoise-Aubry, Bristol-Myers Squibb
- ▶ **Bioanalytical Method Transfer: Challenges & Opportunities**
Naidong Weng, Johnson & Johnson
- ▶ **Harmonization of Regulated Bioanalytical Operation at Both U.S. and China Sites**
XinPing Fang, XenoBiotic Laboratories

PROGRAM AGENDA

Friday April 15

Rhine Ballroom

Track III: Workshop

Pharmacokinetic Applications in Drug Discovery and Development: Human PK and Efficacious Dose Prediction

Workshop Leaders: Frances Wang, Astra Zeneca; Xingmei Han, Novartis

6:00 PM - 9:30 PM

CPSA SHANGHAI SOCIAL

Ballroom 1-2

Held in conjunction with local bioanalytical and metabolism discussion groups

6:00 pm - 7:00 pm

Social Hour

7:00 pm - 7:30 pm

Awards & Announcements

7:30 PM - 9:00 PM

POINT/COUNTERPOINT DISCUSSIONS

Future Direction of Pharmaceutical R&D in China and the Role of ADME Science

Chair: Jeff Zhang, Novartis

Panel: Chunlin Chen, Medicilon; Jenny Zheng, Pfizer; Jinsong Xing, Wuxi AppTec;

Su Zeng, Zhejiang University; Dafang Zhong, Shanghai Institute of Materia Medica

- ▶ Current Drug Discovery Models
- ▶ Program-based vs. Study-based Outsourcing
- ▶ One-stop Shop vs. Core Expertise

PROGRAM AGENDA

Saturday April 16

10:00 AM - 12:00 PM

JOINT SESSION WITH LOCAL BIOANALYTICAL & METABOLISM DISCUSSION GROUPS

Held at The Shanghai Institute of Materia Medica

- ▶ Application of PK/PD in Drug Discovery and Development
Li Yu, Hoffmann-La Roche
- ▶ Overview of DMPK Process in Drug Discovery and Development
Jeff Zhang, Novartis
- ▶ Application of Radioisotopes in Drug Absorption, Distribution, Metabolism, and Excretion Studies
Zhe-ming Gu, XenoBiotic Laboratories

Directions to The Shanghai Institute for Materia Medica

From the Renaissance Shanghai Pudong Hotel, take a taxi to The Shanghai Institute of Materia Medica (中国科学院上海药物研究所) located at 555 Zu Chong Zhi Road, Zhang Jiang Hi-Tech Park, Pudong, Shanghai (上海市浦东张江祖冲之路555号). The cost of the taxi is around RMB 18 (\$3.00).

To take public transportation, walk to Shanghai Science and Technology Museum and take Subway Line #2 towards the airport. Get off at Zhang Jiang Hi-Tech Park (third stop). The Shanghai Institute of Materia Medica is directly across the street from the subway station.



Program Chair

Roger Hayes

Cetero Research

Workshops

New Technologies in
Separation Sciences

Dried Blood Spot Summit

High Performance Nanospray

14th Annual Symposium on
Chemical & Pharmaceutical Structure Analysis

Make plans now to attend CPSA 2011! This annual meeting began in 1998 and has evolved into the premier industry-led event dedicated to promoting awareness of issues and needs associated with research and development.

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