



# Disso China 2020 International Symposium

TBA (originally 2020.3.26-3.27) CHINA•NANJING

## [Organizer]



CFDA Magazine



Society for Pharmaceutical  
Dissolution Science (SPDS)

## [Co-Organizer]



SHENGJIE(Shanghai) Business Management & Consulting Co., Ltd.

## [Partners]

<Chinese Journal of Pharmaceutical Analysis>

<Drug Standards of China>

## [Supporter]

Xinxiao China Co., Ltd.



Note: <Chinese Journal of Pharmaceutical Analysis> is an academic journal founded by National Institutes for Food and Drug Control. <Drug Standards of China> is a professional authoritative publication of national drug standards founded by China Food and Drug Administration and Chinese Pharmacopoeia Commission.



## Background

At present, the Pharmaceutical Industry field is facing the urgent need of innovation and quality improvement both at home and abroad. Dissolution is a key factor in determining the bioavailability and quality control of drug products. Dissolution research is of great significance for New Drugs, Improved New Drugs and Generic Drugs. It is one of the important quality parameter to accelerate the research and development speed and improve the success rate. Since 1975, when the United States Pharmacopoeia first included dissolution and established the dissolution standard for a few varieties, the research on dissolution has gone deep into the development and production of New Drugs, Improved New Drugs and Generic Drugs, involving related laws and regulations, pharmaceutical formulations, apparatus and equipments etc. This symposium will invite relevant experts at home (China) and abroad to conduct in-depth interpretation of the application of dissolution in Pharmaceutical Industry field, including the interpretation of relevant regulations, the application of new-generation apparatus, and the application of dissolution method in the development and production of New Drugs, Improved New Drugs and Generic Drugs. Guest speakers will share application cases in order to bring greater inspiration and benefits to participants.

## Objectives

Disso China 2020·International Symposium is an international professional dissolution academic conference first time held in China, organized by CFDA Magazine, Society for Pharmaceutical Dissolution Science (SPDS) and co-organized by SHENGJIE(Shanghai) Business Management & Consulting Co., Ltd.. Industry Experts, academia and official regulator authorities in dissolution field from [home\(China\)](#) and [abroad \(US, France, Switzerland, Germany, India, Malaysia, etc.\)](#), will discuss cutting-edge issues in the world-class dissolution field with the Chinese Pharmaceutical industry field in Nanjing in 2020, sharing and exchanging knowledge and experience in dissolution field.

This seminar shall provide deep insights into role of dissolution in:



### Formulation development



### Novel drug delivery systems



### Regulatory aspects of dissolution

- 1.Dissolution as key solution Strategy considering China’ s Generic consistency evaluation (GCE)
- 2.Solutions on significant, long-lasting impacts on the market landscape, drug pricing and generic competition
- 3.Drug dissolution a vital parameter to understand batch-to-batch consistency.
- 4.Importance of discrimination media and its role on Kinetic modeling.
- 5.In-vitro- in-vivo correlation and Similarity factors.
- 6.Material and process attribute on robust Dissolution method development.
- 7.Dissolution testing its vital role in the decision-making process.
- 8.Advancement and automation in dissolution apparatus.

## Who will Attend

The programme is designed to benefit-Product development scientist, Pharma QA/QC/R&D/Regulatory Managers and executives, CRO's, CMO's, Lab managers/supervisors, Regulators, Academia, Graduates, Ph.D students/Scholars, Instrument manufactures, Marketing executives, application specialists, etc.

## Disso China 2020 Cooperative Partners

### Exclusive VIP Sponsor

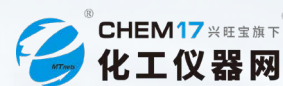


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## Disso China 2020 Scientific Committee

**Bill Wei, Ph.D.**

Beijing Innovaco Pharmaceutical Inc, Beijing- Chair.

**Vinod P. Shah, Ph.D., FAAPS, FFIP**

Ex-US FDA (Food and Drug Administration), USA- Co-chair.

**Arvind K. Bansal, M.Pharm, Ph.D., FAAPS**

National Institute of Pharmaceutical Education and Research (NIPER), India- Co-Chair.



# Guest Speakers

## 国际演讲嘉宾阵容



**Dr. Vinod P. Shah**

Ex-USFDA,  
Consultant, USA.



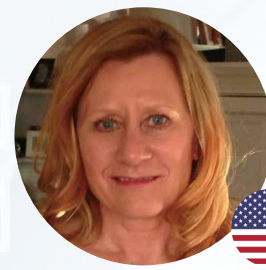
**Dr. Bao-Ming Ning**

Deputy Director,  
Chemical Department,  
China National Institutes for Food  
and Drug Control.



**Dr. Qi-Ming Zhang**

Deputy Director,  
Member of Expert Committee,  
Chinese Pharmacopoeia Commission,  
China National Institutes for Food  
and Drug Control.



**Prof. Dr. Diane J. Burgess**

Board of Trustees Distinguished Professor  
of Pharmaceutics,  
Pfizer Distinguished Chair  
of Pharmaceutical Technology,  
University of Connecticut,  
Department of Pharmaceutical Sciences.



**Dr. Umesh Banakar**

Professor of Pharmaceutics,  
Independent Consultant/Advisor,  
Pharmaceutical Industry and  
Academia worldwide.



**Dr. Jia-Sheng Tu**

Professor, Department of Pharmacy,  
China Pharmaceutical University,  
Committee Member,  
Chinese Pharmacopoeia Commission.



**Dr. Chen Yao**

Director, Medical Statistics Office,  
China Peking University First Hospital,  
Deputy Director,  
China Peking University  
Clinical Research Institute.



**Dr. Shi-Feng Wei**

Co-Founder and CEO,  
Innovaco Pharmaceutical Inc.



**Dr. Xu-Jin Lv**

Research Fellow,  
Pharmaceutical Science And  
Technology Department,  
Bristol-Myers Squibb (BMS).



**Dr. Yan Lou**

Senior Vice President,  
Shanghai Xihua Scientific,  
General Manager,  
Xihua Pharmaceuticals Co., Ltd.



**Dr. Samir Haddouchi**

President,  
SPS Pharma Services, France.



**Dr. Sandra Klein**

Professor,  
Department of Pharmacy,  
Institute of Biopharmaceutics and  
Pharmaceutical Technology,  
Ernst-Moritz-Arndt-Universität Greifswald.



**Dr. Arvind K. Bansal**

Professor and Head,  
Department of Pharmaceutics,  
National Institute of Pharmaceutical  
Education and Research (NIPER).



**Dr. Grahame Woollam**

Scientific Lead Technical Research  
& Development (TRD),  
Global Drug Development,  
Novartis, Switzerland.



**Dr. Leong Chuei Wuei**

Independent Consultant/Advisor,  
Malaysia,  
Pharmaceutical Industry and  
Academia worldwide.



**Dr. L. Ramaswamy**

Managing Director,  
SOTAX India Pvt Ltd.



**Mr. Michel Magnier**

Product Manager & Application  
Specialist in Dissolution Testing,  
SOTAX, AG, Switzerland.



**Mr. Vijay Kshirsagar**

CEO,  
TRAC, India.

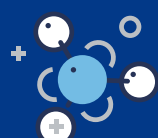


# DISSO CHINA 2020

## International Symposium

Theme: 'Significance of Dissolution Science  
in Pharmaceutical Product Development and Product life cycle'

### Day 1 Morning Session

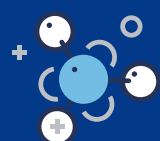


**Theme: The Dissolution Technique & Apparatus.**

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|--------------------|---|
| <b>8:30-9:00</b>   | <b>Inaugural Session of Disso China 2020.</b>   |
| <b>9:00-9:40</b>   | <b>Importance of dissolution in drug product quality.</b><br><b>Dr. Vinod P. Shah, (Ex-USFDA)</b><br>Consultant, USA.   |
| <b>9:40-10:20</b>  | <b>Dissolution testing of non-conventional dosage form.</b><br><b>Dr. Samir Haddouchi,</b><br>President,<br>SPS Pharma Services, France.  |
| <b>10:20-10:35</b> | <b>Tea Break</b>  |
| <b>10:35-11:15</b> | <b>Bioequivalence (BE) design: Challenges and Solutions.</b><br><b>Dr. Chen Yao,</b><br>Director, Medical Statistics Office,<br>China Peking University First Hospital,<br>Deputy Director,<br>China Peking University Clinical Research Institute. |
| <b>11:15-11:55</b> | <b>Principles and benefits of Dissolution Automation.</b><br><b>Mr. Michel Magnier,</b><br>Product Manager & Application Specialist in Dissolution Testing,<br>SOTAX, AG, Switzerland.  |
| <b>11:55-13:00</b> | <b>Lunch</b>  |



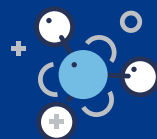
## Day 1 Afternoon Session



**Theme: Dissolution Regulation and Method Development Strategy.**

- 13:00-13:40**     **Development of dissolution experiment in Chinese Pharmacopoeia and related progress of new pharmacopoeia.**  
**Dr. Qi-Ming Zhang,**  
Deputy Director,  
Member of Expert Committee, Chinese Pharmacopoeia Commission,  
China National Institutes for Food and Drug Control.
- 13:40-14:20**     **Initial QbD set up for dissolution method development: Practical considerations and regulatory hurdles.**  
**Dr. Leong Chuei Wuei,**  
Independent Consultant/Advisor, Malaysia,  
Pharmaceutical Industry and Academia worldwide.
- 14:20-15:00**     **Role and Unique Applications [Case Studies] of IVIVC in Generic Drug Program.**  
**Dr. Umesh Banakar,**  
Professor of Pharmaceutics,  
Independent Consultant/Advisor,  
Pharmaceutical Industry and Academia worldwide.
- 15:00-15:15**     **Tea Break**
- 15:15-15:55**     **Use of dissolution for Bio-waiver: Regulatory perspective.**  
**Dr. Vinod P. Shah, (Ex-USFDA)**  
Consultant, USA.
- 15:55-16:35**     **Dissolution method qualification. (Drafted)**  
National Institutes for Food and Drug Control.
- 16:35-17:15**     **Q&A session for dissolution panel discussion**
- 18:00-21:00**     **Disso Night-Gala Dinner**

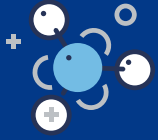
## Day 2 Morning Session



**Theme: Material properties / Formulation aspects of Dissolution for New Drugs and Generic products.**

- |                    |   |
|--------------------|---|
| <b>8:30-9:10</b>   | <b>Role of material property in dissolution.</b><br><b>Dr. Arvind K Bansal,</b><br>Professor and Head,<br>Department of Pharmaceutics,<br>National Institute of Pharmaceutical Education and Research (NIPER), India.                                     |
| <b>9:10-9:50</b>   | <b>Solid-state characterization and dissolution properties of poorly soluble drugs (with case study).</b><br><b>Dr. Grahame Woollam,</b><br>Scientific Lead Technical Research & Development (TRD),<br>Global Drug Development,<br>Novartis, Switzerland. |
| <b>9:50-10:30</b>  | <b>Enabling technology for dissolution enhancement. (Drafted)</b><br>Center for Drug Evaluation, CFDA.  |
| <b>10:30-10:45</b> | <b>Tea Break</b>  |
| <b>10:45-11:25</b> | <b>Effect of excipient change on dissolution of Amorphous Solid Dispersions (ASDs).</b><br><b>Dr. Xu-Jin Lv,</b><br>Research Fellow,<br>Pharmaceutical Science And Technology Department,<br>Bristol-Myers Squibb (BMS).                                  |
| <b>11:25-12:05</b> | <b>The Effect of the Manufacture Process Parameter on the Dissolution Profiles.</b><br><b>Dr. Yan Lou,</b><br>Senior Vice President Shanghai Xihua Scientific,<br>General Manager of Xihua Pharmaceuticals Co., Ltd.                                      |
| <b>12:05-13:00</b> | <b>Lunch</b>  |

## Day 2 Afternoon Session



**Theme: Practical approaches for dissolution studies of Drug Delivery System.**

- |                    |  |
|--------------------|--|
| <b>13:00-13:40</b> | <b>Development of IVIVCs for parenteral products such as microspheres / Real time and accelerated in vitro testing of complex and long acting parenteral product.</b><br><b>Prof. Dr. Diane J. Burgess,</b><br>Board of Trustees Distinguished Professor of Pharmaceutics,<br>Pfizer Distinguished Chair of Pharmaceutical Technology,<br>University of Connecticut,<br>Department of Pharmaceutical Sciences. |
| <b>13:40-14:20</b> | <b>The use of biorelevant media in successfully predicting in vivo performance.</b><br><b>Prof. Dr. phil. nat. Sandra Klein,</b><br>Professor, Department of Pharmacy,<br>Institute of Biopharmaceutics and Pharmaceutical Technology,<br>Ernst-Moritz-Arndt-Universität Greifswald.   |
| <b>14:20-15:00</b> | <b>Significance and Role of dissolution from early development to Life cycle management (MAH and QCE).</b><br><b>Dr. Shi-Feng Wei,</b><br>Co-Founder and CEO,<br>Innovaco Pharmaceutical Inc.  |
| <b>15:00-15:15</b> | <b>Tea Break</b>   |
| <b>15:15-15:55</b> | <b>Factors influencing release rate of biodegradable microspheres.</b><br><b>Dr. Jia-Sheng Tu,</b><br>Professor, Department of Pharmacy,<br>China Pharmaceutical University,<br>Committee Member,<br>Chinese Pharmacopoeia Commission.   |
| <b>15:55-16:35</b> | <b>Q&amp;A session for dissolution panel discussion</b>  |
| <b>16:35-17:00</b> | <b>Vote of thanks.</b>   |

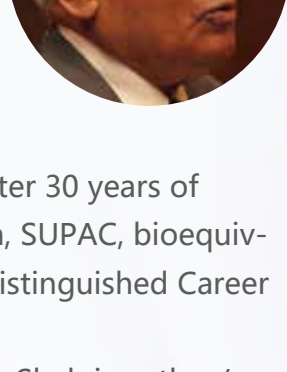




## 部分专家简介

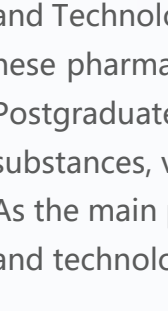
### Dr. Vinod P. Shah

Ex-USFDA,  
Consultant, USA.



Dr. Shah is a pharmaceutical consultant. He retired from US FDA (Food and Drug Administration) as a Senior Research Scientist after 30 years of service in July 2005. At FDA, he has developed several Regulatory Guidances for Pharmaceutical Industry in the area of dissolution, SUPAC, bioequivalence and biopharmaceutics. He has received several FDA Awards including Award of Merit, Scientific Achievement Award and Distinguished Career Service Award.

Dr. Shah is an Honorary Member of Indian Pharmaceutical Association (2003), a recipient of IDMA and SPDS Excellence Award. Dr. Shah is author/co-author of over 300 scientific papers and a co-editor of four books. He was the President of American Association of Pharmaceutical Scientists (AAPS) in 2003. He is a Fellow of AAPS and International Pharmaceutical Federation (FIP). Dr. Shah is a recipient of FIP Lifetime Achievement Award in Pharmaceutical Sciences, Honorary Doctorate from Semmelweis University, Budapest, Hungary and from University of Medicine and Pharmacy Carol Davila Bucharest, Romania, AAPS Distinguished Pharmaceutical Scientist Award, AAPS Global Leader Award and Marquis Who's Who Albert Nelson Marquis Lifetime Achievement Award.



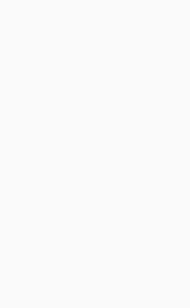
### Dr. Bao-Ming Ning

Deputy Director,  
Chemical Department,  
China National Institutes for Food  
and Drug Control.

Dr. Bao-Ming Ning, Deputy Director of Chemical Department in China National Institutes for Food and Drug Control, Evaluation Expert of International Chemical Reference in WHO, Committee Member of Chinese Pharmacopoeia Commission, Evaluation Expert of major projects of Ministry of Science and Technology, Evaluation Expert of Innovative Drug. Dr. Ning is the Editorial Board Member of Chinese edition of American pharmacopoeia and Chinese pharmacopoeia in English. He is also the visiting scholar of American Pharmacopoeia Commission and European Pharmacopoeia Commission, Postgraduate advisor of China Pharmaceutical University and Yantai University. Dr. Ning is engaged in quality research of chemical drugs, standard substances, vitro quality and in vivo correlation study of sustained release dosage forms, study on quality control technology of inhaled formulations. As the main person in charge or technical expert, Dr. Ning has participated in more than 10 scientific research projects, such as major national science and technology projects, consistency evaluation of generic drugs, and improvement of standards of Chinese Pharmacopoeia Commission.

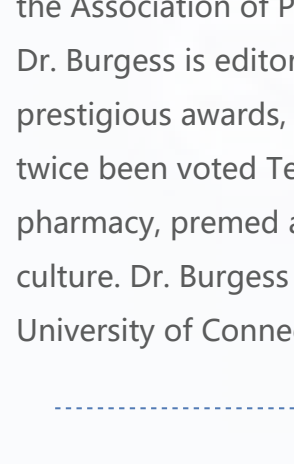
### Dr. Qi-Ming Zhang

Deputy Director,  
Member of Expert Committee,  
Chinese Pharmacopoeia Commission,  
China National Institutes for Food and Drug Control.



Dr. Qi-Ming Zhang has been engaged in pharmaceutical quality research in China National Institutes for Food and Drug Control for more than 30 years, mainly engaged in drug quality research and other aspects of the work. He served as the director of Chemical Drug office and director of Drug Inspection Department in China National Institutes for Food and Drug Control.

Dr. Qi-Ming Zhang is the member of the eighth, ninth, tenth and eleventh Chinese Pharmacopoeia Commission, and Vice Chairman of the tenth and eleventh Expert Committee. Dr. Zhang is the editorial board of many professional magazines, having published more than 200 professional papers, and having participated in the compilation or translation of many monographs. He has cultivated more than 20 graduate students.



### Prof. Dr. Diane J. Burgess

Board of Trustees Distinguished Professor of Pharmaceutics,  
Pfizer Distinguished Chair of Pharmaceutical Technology,  
University of Connecticut,  
Department of Pharmaceutical Sciences.

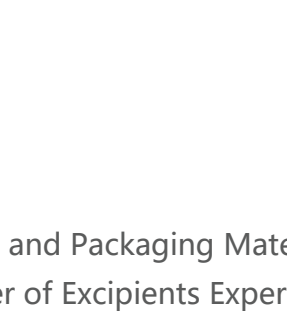
Dr. Burgess is Board of Trustees Distinguished Professor of Pharmaceutics, at the University of Connecticut. She has over 160 publications, over 420 research presentations at major scientific meetings, over 210 invited lectures, and has presented 15 keynote addresses. Her research efforts focus on gene and drug delivery: microspheres, emulsions, liposomes, hydrogels, as well as interfacial chemistry and implantable biosensors for glucose monitoring.

Dr. Burgess was the 2010 President of the Controlled Release Society (CRS), the 2002 President of the American Association of Pharmaceutical Scientists (AAPS) and is an AAPS, CRS and an American Institute for Medical and Biological Engineering (AIBE) fellow. She is also an international fellow of the Association of Pharmaceutical Science and Technology Japan (APSTJ).

Dr. Burgess is editor of the International Journal of Pharmaceutics and serves on the editorial boards of nine international journals. Among other prestigious awards, she is the 2011 recipient of the Nagai APSTJ International Woman Scientist Award. Dr. Burgess is an outstanding teacher and has twice been voted Teacher of the Year by her students. She designed and coordinates a summer Study Abroad Program for University of Connecticut pharmacy, premed and other science majors to go to China to learn about Traditional Chinese Medicine and immerse themselves in a different culture. Dr. Burgess has recently been appointed to the University of Connecticut Academic Vision Committee (a committee that will draft the next University of Connecticut academic plan 2014-2020).

### Dr. Umesh Banakar

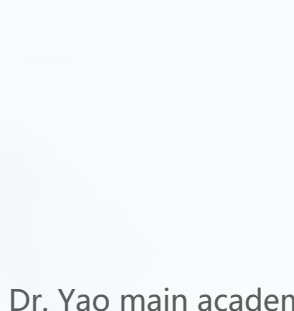
Professor of Pharmaceutics,  
Independent Consultant/Advisor,  
Pharmaceutical Industry and Academia worldwide.



Umesh V. Banakar, Ph.D. is Professor of Pharmaceutics and an Independent Consultant/Advisor to Pharmaceutical Industry and Academia worldwide with extensive contribution in drug product development and evaluation (in vitro and clinical).

During his academic career, he has served as Professor of Pharmaceutics, Director of Research, Chairperson of Department of Pharmaceutical Sciences and Head/Dean of Graduate School at 3 Universities in the US.

He is on the International Scientific Advisory Board of several pharmaceutical corporations worldwide. Of date, he has successfully completed several Pharmaceutical Product Development Technology Transfer through education assignments sponsored by the UN/IESC and other pharmaceutical corporations worldwide. Additionally, he has planned and executed the development, both in vitro and clinical, of several NDAs (including 505(b)(2)) and ANDAs (both IR and MR products).



### Dr. Jia-Sheng Tu

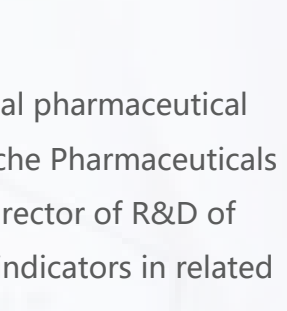
Professor, Department of Pharmacy,  
China Pharmaceutical University,  
Committee Member,  
Chinese Pharmacopoeia Commission.

Dr. Jia-Sheng Tu is the member of Chinese Pharmacopoeia Commission, executive member (Chairman of Pharmaceutical Excipients and Packaging Materials Committee), expert in Center for Drug Evaluation, NMPA, executive member of American Pharmacopoeia Commission, member of Excipients Expert Committee, Chairman of American Pharmacopoeia Registration Standards East Asia (MCEA) Committee, member of Formulation Committee of Chinese Pharmaceutical Association.

Dr. Jia-Sheng Tu has hosted and participated in NIH targeted design and synthesis of peptides, Ministry Of Science And Technology support plan "Safety And Quality Of Medicinal Materials For Injection", Natural Science fund project "Design And Evaluation Of SIRNA Delivery Carrier Of Tumor Targeting", National 115 Pharmaceutical Formulation Innovation Platform, National 125 Major Special Projects, Chinese Pharmacopoeia Commission Pharmaceutical Excipients Standards Improvement Plan, CDE Technical Support Plan, Major National Special Projects For The Creation And Production Of New Drugs "Consistency Of Oral Formulation Quality And Efficacy" and so on. Dr. Tu has led the development of many new drugs and new dosage forms. He has published 80 SCI papers.

### Dr. Chen Yao

Director, Medical Statistics Office,  
China Peking University First Hospital,  
Deputy Director,  
China Peking University Clinical Research Institute.



Dr. Yao main academic achievements: Chairman of Evidence-Based Medicine Expert Committee of Chinese Medical Doctor Association, Vice Chairman of Statistical Theory And Methods Expert Committee of Chinese Health Statistics Association, Guest Professor of Advanced Research Institute of CFDA, committee member of Expert Advisory Committee on Drug/Device Evaluation, and Doctoral supervisor of clinical research (methods).

Dr. Yao is committed to the research of data management and application of statistical analysis methods in clinical research, and carries out the education and training of clinical research design. He has worked with clinicians on numerous new drugs, medical devices, and investigator-initiated clinical research projects.



### Dr. Shi-Feng Wei

Co-Founder and CEO,  
Innovaco Pharmaceutical Inc.

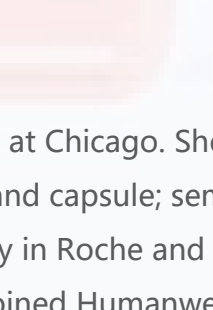
Dr. Wei has more than 20 years of experience in developing innovative products for formulations and management in multinational pharmaceutical companies as well as pharmaceutical technology enterprises in United States. Dr. Wei served successively as senior scientist of Roche Pharmaceuticals co., LTD., director scientist of Johnson & Johnson co., LTD., senior academician of Novartis Pharmaceuticals co., LTD., and senior director of R&D of NexMed, Inc. As the leader, Dr. Wei has developed several major innovator drug products, and many of them have become gold indicators in related therapeutic areas.

Dr. Wei is a recognized expert in American pharmaceutical industry. He has participated in industry standards established by USFDA, such as the guidelines for manufacturing change of sustained-release pharmaceuticals - SUPAC-MR. As WHO's pharmaceutical industry consultant, He has trained officials of ASEAN FDA for the production technology transfer/validation.

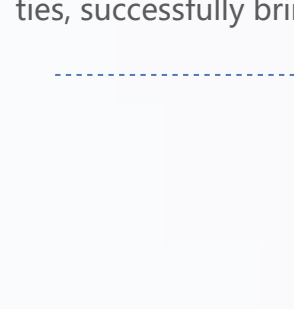
Dr. Wei was the President of Sino-American Pharmaceutical Professionals Association (SAPA) from 1996 to 1997. He was also a member of Overseas New Drug R&D Consulting Committee of Shanghai Municipal Science & Technology Commission, BMSTC and MOST (Ministry of Science and Technology).

### Dr. Xu-Jin Lv

Research Fellow,  
Pharmaceutical Science And Technology Department,  
Bristol-Myers Squibb (BMS).



Dr. Xu-Jin Lv, Master in Analytical Chemistry of Dalian Institute Of Chemical Physics of CAS (Chinese Academy of Sciences), Ph.D. in Analytical Chemistry of University of Georgia, Post-Doctoral of University of Illinois - Urbana Champagne. He has 28 years of experience in pharmaceutical formulation R&D and pharmaceutical analysis, including the establishment of pharmaceutical analysis and process analysis methods, drug release and dissolution, as well as biorelated in vitro testing and pharmaceutical risk assessment in prescription and pre-prescription studies. Dr. Lv is the member of American Association of Pharmaceutical Scientists (AAPS), American Chemical Society, Society For Applied Spectroscopy and The Cobbler Institute. He is the Ex-Chairman(2013 - 2015) of In Vitro Release And Dissolution Techniques (IVRDT) Focus Group of AAPS, member of Drug Performance Testing Expert Group of USP, and Editorial Board Member of Dissolution Technologies Periodicals. Dr. Lv chaired the first and second AAPS/NIFDC Drug Dissolution Symposium as chairman (Tianjin City 2016, Yantai City 2019).



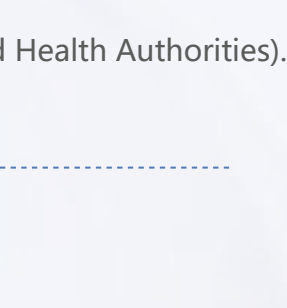
### Dr. Yan Lou

Senior Vice President,  
Shanghai Xihua Scientific,  
General Manager,  
Xihua Pharmaceuticals Co., Ltd.

An Entrepreneurial pioneer the Sino-US pharmaceutical industry. Dr. Lou received her Ph.D. in Pharmaceutical at University of Illinois at Chicago. She worked mainly in the pre-formulation and formulation areas with different kinds of dosage forms which include: IR, ER ODT tablets and capsule; semi-solid/liquid soft gelatin capsules; IR/ER combination tablets and capsule. Dr. Lou worked for over a decade in the US Pharma Industry in Roche and the then Barr Laboratories before its acquisition by Teva. She then joined Zhejiang Hisun Pharmaceuticals as the VP of R&D. Later she joined Humanwell of Purac in US, for the position of VP of R&D. At both position she was responsible for all technical aspects of R&D from development to manufacture. Afterword she founded her own company, Westlake Pharmaceuticals, Inc., and was the CEO leveraging her unique network of industry contacts for several big pharma partners in China. Providing them with crucial technical expertise and consulting services allowing them to update their facilities, successfully bring their products to market, and navigate the ever changing regulatory landscape both in China and in the USA.

### Dr. Samir Haddouchi

President,  
SPS Pharma Services, France.



Prior to joining SPS Pharma Services in 2005, Samir spent more than 10 years in the pharmaceutical industry. As a chemist, he started working on the analytical development of agrochemical compounds at Sandoz Agro in the region of Basel (Switzerland). During the Novartis merger, he moved to Orléans (France) in 1998 to join the analytical group in the technical development department where he became responsible for dissolution.

In 2005, he resigned from Novartis to create SPS Pharma Services in Clermont Ferrand which is the first and only CRO specialized in Dissolution and Release Testing. Since then, Samir manages SPS facility and is in charge of projects management.

In April 2013, SPS Pharma Services moved to a new larger facility in Orleans (France) in order to ensure better efficiency and provide a broader range of services to its clients, including cGMP routine testing. The facility has been successfully inspected by US FDA and is registered as Pharmaceutical Establishment for both US and Europe.

Fields of interest and expertise: analytical development (LC), in vitro dissolution and release testing (all techniques from USP1 to USP7), in vitro-in vivo correlations (IVIVC), formulation development, laboratory automation.

Samir is regularly invited as speaker in international conferences as well as expert for various organizations (scientific societies and Health Authorities).



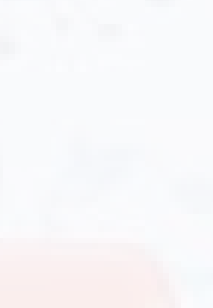
### Prof. Dr. phil. nat. Sandra Klein

Professor, Department of Pharmacy,  
Institute of Biopharmaceutics and Pharmaceutical Technology,  
Ernst-Moritz-Arndt-Universität Greifswald.

After working in the pharmaceutical industry for 4 years, Sandra Klein studied pharmacy and got her pharmacist's license and her Ph.D. from the Goethe University of Frankfurt. Subsequently, she was a postdoctoral fellow at Eastman Chemical Company in Kingsport/TN, USA and returned to the Goethe University of Frankfurt a senior research associate. Since many years she is working in the field of biorelevant dissolution testing, focusing on the development of test methods addressing essential gastrointestinal parameters relevant to in vivo drug release and is (co-) author of various original manuscripts and book chapters on this topic. Her current research is focused on developing predictive dissolution methods and dosage forms for special patient groups, particularly the paediatric and geriatric population. Beside this, she is developing predictive in vitro test methods for lozenges, vaginal delivery systems and accelerated drug release methods for a number of non-oral drug-delivery systems. Another focus of her research is the enhancement of bioavailability of poorly soluble drugs with different polymer- and cyclodextrin-based approaches. Prof. Klein is a board member of APV, an EuPFI associate and a member of AAPS, CRS, DPhG. Moreover, she is a member of the editorial board of several scientific journals and editor-in-chief of DiePharmazie, an international peer-reviewed journal of pharmaceutical sciences.

### Dr. Arvind K. Bansal

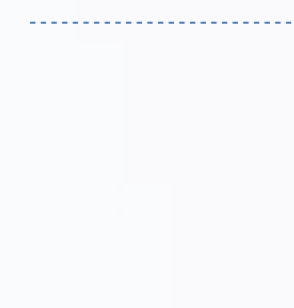
Professor and Head,  
Department of Pharmaceutics,  
National Institute of Pharmaceutical Education and Research (NIPER).



Dr Arvind Kumar Bansal is currently Professor and Head, department of Pharmaceutics at National Institute of Pharmaceutical Education and Research (NIPER) - SAS Nagar, Punjab, India. He earned his M Pharm (Pharmaceutics) (1988) and Ph.D. (1993) from University of Delhi, India. Prof Bansal worked as Senior Scientist and Group Leader in JK Pharmaceuticals and Ranbaxy Research Laboratories, for 8 years. Therein he conceptualised, evolved formulation strategies, developed and transferred the technology to production shop floor, for NCEs and generic drug products.

Prof Bansal joined NIPER in 2000 and has developed expertise in areas of pre-formulation and formulation development encompassing characterization and stabilization of the amorphous form, polymorphism, pseudo-polymorphism, particle engineering, screening salt forms, improvement of oral bioavailability and lyophilization. His research group works with the mission statement - 'developing science based industrially viable pharmaceutical technologies' and works closely with pharmaceutical industry to create opportunities for commercial exploitation of the products.

Dr Bansal was conferred prestigious Fellow of American Association of Pharmaceutical Scientists in 2016. He is the only Indian working India being awarded this Fellow status. He has won prestigious awards like AAIPS Distinguished Educator and Researcher Award, Innocentive Award and OPPI Award. Prof Bansal's research group has completed more than 550 industry sponsored projects, granted 8 patents, filed 27 patents, and published 180 research articles and 26 review articles. He is an editorial board member of Journal of Excipients and Food Chemicals and Pharmaceutics. He is also an Advisor to the editorial board of Journal of Pharmaceutical Sciences and on Editorial Board of Molecular Pharmaceutics. Recently his lab has out-licensed a platform technology on "Nano crystalline solid dispersions - NanoCrySP.



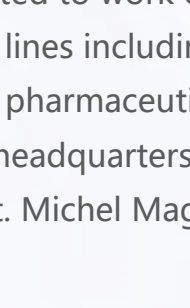
### Dr. Grahame Woollam

Scientific Lead Technical Research & Development (TRD),  
Global Drug Development,  
Novartis, Switzerland.

Dr. Grahame is currently working as Scientific Lead, Solid State Chemistry/Senior fellow in Technical Research & Development (TRD), a Global Drug Development function within Novartis Pharmaceuticals AG, Switzerland, focused on solid form selection (salt, co-crystal, and polymorphism). He earned his degree and master from University of Liverpool and PhD from University of Manchester in 2017. He is Member of Royal Society of Chemistry: London, London, GB. Working to develop methods and strategies to expand the platform to cover the development process using empirical and ab initio tools. Over fourteen years' experience in the pharmaceutical industry spanning chemical and pharmaceutical development divisions, at various locations and companies like Astra Zenica, GSK across the UK and Europe.

### Dr. Leong Chuei Wuei

Independent Consultant/Advisor, Malaysia,  
Pharmaceutical Industry and Academia worldwide.



Dr. Leong Chuei Wuei is a qualified Professional Pharmacist from the University of London, with a PhD in Pharmaceutical Technology. She has over 20 years of industrial working experience in both Asia and Europe and has her own consultancy company, offering consulting services to pharmaceuticals, biotechnology and medical devices companies on strategic positioning as well as technical know-how in pipeline development, technical troubleshooting, global clinical trials management and regulatory challenges.



### Mr. Michel Magnier

Product Manager & Application Specialist in Dissolution Testing,  
SOTAX, AG, Switzerland.

After completing a Master degree in Biochemistry/Organic Chemistry at the University of Paris XI Orsay, Michel Magnier started to work on scientific instrumentation at Fisher Scientific Group as Product Manager France for seven years developing different product lines including UV-Vis spectrophotometry and climatic chambers. End of 1999, Michel Magnier joined the SOTAX Group to specialize in pharmaceutical testing market covering this specific field for SOTAX France. After six successful years, Michel Magnier moved to SOTAX AG headquarters in Switzerland. Since 2005, he has held different positions in Marketing, Business Development as well as Product Management. Michel Magnier is now Product Manager & Application Specialist in Dissolution Testing for SOTAX Business Unit Europe & Asia-Pacific.