2020 Pharmaceutical Crystallization Summit

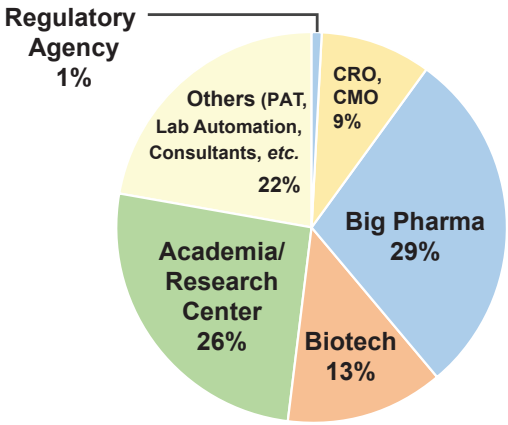
October 7 & 8
Online (live)

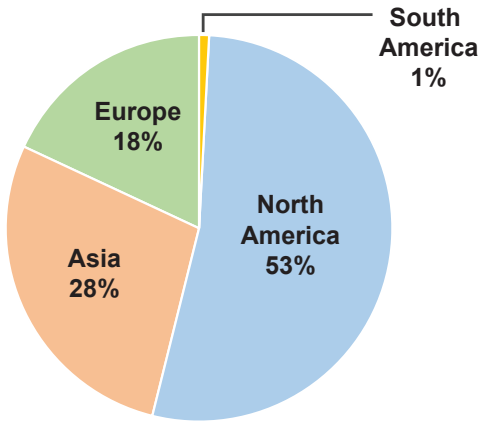
Breaking Drug Development Bottlenecks via Enabling Technologies

EVENT OVERVIEW 01

Crystallization technologies are bridges between drug substances (DS) and drug products (DP) enabling consistent and robust safety and efficacy profiles of small molecule based medicines. In an effort to fully utilize existing tools and develop better new methodlogies for solving bottleneck problems in drug development, the Center for Pharma Crystallization (CfPC) at J-Star Research launched its first annual conference, jointly with XtalPi.

The 2-day online event was attended by 203 experts, scientists and researchers from large and small pharma companies, CROs, CDMOs and academia in 22 countries.





12 Keynote Speakers from 3 Continents

Session 1
Smarter Solid State Research via Prediction and Simulation

Dr. Qi Gao (Moderator), J-Star
Prof. Tonglei Li, Purdue U
Dr. Yuriy A. Abramov, XtalPi
Dr. Shanming Kuang, J-Star

Session 2
Physical Property Based Crystallization Process Development

Dr. Jian Wang (Moderator), J-Star
Prof. Kevin J. Roberts, U of Leeds
Dr. Bing-Shiou Yang, BI
Mr. Don Kientzler, J-Star

Session 3
Particle Engineering and DS-DP Co-Processing

Dr. San Kiang (Moderator), J-Star
Prof. Rajesh N Dave, NJIT
Dr. Deniz Erdemir, BMS
Prof. Saif A. Khan, National U of Singapore

Session 4
Partnering for Addressing Challenges of Today and the Future

Dr. Joanne Johnson (Moderator), Porton
Dr. Fang Wang, Global Blood Therapeutics
Dr. William Glauser, XtalPi
Dr. Jian Wang, J-Star

J-STAR RESEARCH, Inc. CfPC XtalPi PORTON

SESSION OVERVIEW 02

Session 1 Smarter Solid State Research via Prediction and Simulation

Self-assembling nucleation mechanism in crystallization was demonstrated by **Prof. Li** with molecular conformation and local intermolecular interactions, such as H-bonding and aromatic stacking, using a series of structurally similar diarylamines as the model compounds. Furthermore, computational tools to facilitate solid state research were presented by **Dr. Abramov** for selection of stable crystalline form, in-silico cocrystal coformer screening, and rational solvent selection for crystallization process development and impurity rejection. A case study was presented by **Dr. Kuang** for a crystallization process wherein a wrong solvent selection caused enormous pain during commercialization and how computation assisted solvent selection can prevent such mishaps in the future.

Session 2 Physical Property Based Crystallization Process Development

A step-wise multi-technique examination encompa-ssing both computational modeling and experi-mental studies to control desired crystal parame-ters was presented by **Prof. Roberts** using para amino benzoic acid as model compound. Molecular confor-mational stability and energetics using DFT QM modeling was demonstrated as well. The importance of solid form understanding was emphasized by **Dr. Yang** using case studies to facilitate proper crystalli-zation design, resolve process challenges, and achieve better control of product critical quality attributes. The development of an integrated process via controlled pH swing crystallization with salt remo-val by diafiltration was described by **Mr. Kientzler**, with basic data, a good demonstration of continuous processing for better control of API quality attributes.

Session 3 Particle Engineering and DS-DP Co-Processing

Predictive capabilities were examined by **Prof. Dave** to engineer particle surface via dry coating process. Mechanistic particle contact models allowed selection of flow aid type and amount, and prediction for enhanced bulk power properties. **Dr. Erdemir** summarized currently available co-processing technology platforms and the existence of an IQ committee to promote interactions with regulatory bodies. She presented a case study on using the CPT (Co-precipitation) platform approach, which demonstrated that a poor flow API can be improved in density and flow properties reproducibly across lab and plant scales. Microfluidics-based methods were described by **Prof. Khan** to allow for crystallization and formulation of drug substances being carried out in one step, leading to mono-disperse spherecal granules with unprecedented control over crystal attributes such as shape, size and polymorphism.

Session 4 Partnering for Addressing Challenges of Today and the Future

A case study given by **Dr. Fang Wang** illustrated strategies for addressing the challenges in delivering high quality therapy to patients quickly and cost effectively, which include an effective model of partnership with CROs. Solutions via integrating physics-based and AI-based approaches were elaborated by **Dr. Glauser** to de bottleneck issue associated with polymorphic instability and growing insoluble drug candidates, which requires creative partnerships among pharma companies, CROs and academia. Diverse crystallization challenges encountered and addressed by CfPC were highlighted by **Dr. Jian Wang**, which offered insights into bottleneck problems with drug development programs and exemplified the critical roles of technology application and synergetic partnerships in providing effective and timely solutions to the challenges of today and the future.

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R&D Services offered by J-Star & XtalPi

- Intelligent Digital Drug Design and Development
- API Synthesis and Material Delivery
- Solid Form Screen & Studies
- Crystallization Process Development
- Pre-Formulation Evaluations
- Particle Engineering & Co-Processing
- Analytical Development and QC
- Catalysis screening and enabling technology
- Flow chemistry and continuous manufacturing
- DS/DP process development and production
- Potent Compound Development and Production

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