



Purdue University – Burton D. Morgan Center for Entrepreneurship MRGN, Room 121 | 201 W. State Street West Lafayette, IN 47907 West Lafayette, IN 47906, USA

Our planning committee consists of representatives from **Argonne National Laboratory, Excelsus Structural Solutions, Improved Pharma, and Purdue University.**

We are pleased to host the return of this very popular and informative workshop. Following previous workshops held at Purdue in 2018 and the Paul Scherrer Institute in Switzerland in 2019, the workshop returns to Purdue for 2023. Attendees can network with solid-state experts from around the world, learn how synchrotron-XRPD can be used to tackle industrial drug development issues and discuss how synchrotron-XRPD can play a crucial role in patent litigation and intellectual property protection

### SCHEDULE

#### DAY 1 – 19<sup>TH</sup> MAY 2023

|                     |  |
|---------------------|--|
| 8:00 am – 9:00 am   | <b>Get together breakfast &amp; Registration</b>   |
| 9:00 am – 10:30 am  | Background to the workshop (25+5m): <ul style="list-style-type: none"> <li>Polymorphism in Pharmaceutical Applications (<b>Steve Byrn &amp; Pam Smith</b>, Purdue University/Improved Pharma, USA)</li> <li>Synchrotron XRPD (<b>Fabia Gozzo</b>, Excelsus Structural Solutions, Switzerland)</li> <li>Pair Distribution Function in Pharma (<b>Chris Benmore</b>, APS, USA)</li> </ul>  |
| 10:30 am – 11:00 am | <b>Further questions to speakers</b>   |
| 11:00 am – 12:30 am | <b>Networking lunch &amp; real-time Acoustic Levitator demo</b>  |
| 12:30 pm – 12:35 pm | Welcome to the SPS-XRPD workshop   |
| 12:30 pm – 3:00 pm  | Regulatory aspects (25+5m) <ul style="list-style-type: none"> <li>Technical and Regulatory Aspects of Managing Solid Form Transformations in Drug Product (<b>Anisha Patel</b>, Merck &amp; Co., Inc., USA)</li> <li>XRPD Role in Pharma Products Characterization and Control: Quality Frameworks and Guidelines (<b>Matteo Daldosso</b>, Aptuit Verona– Evotec company, Italy)</li> </ul><br>Role of polymorphism in Intellectual property rights (25+5m) <ul style="list-style-type: none"> <li>Patent filing, patent litigation and the Hatch-Waxman Act (<b>Eyal Barash</b>, Barash Law LLC, USA)</li> <li>Patent litigation: The Originator Perspective (<b>Einar Stole</b>, Covington &amp; Burling LLP, USA)</li> <li>Patent Litigation: The Generic Perspective (<b>Carolyn Blessing</b>, Locke Lord LLP, USA)</li> </ul> |
| 3:00 pm – 4:30 pm   | <b>Coffee break &amp; snacks and Round Table Discussion</b><br><b>Further questions to RA and IP speakers – (Moderator: Steve Byrn)</b>  |
| 4:30 pm – 6:30 pm   | Synchrotron advanced instrumentation and applications in Pharma (25+5m) <ul style="list-style-type: none"> <li>The Swiss Light Source and ALBA Powder Diffraction Stations (<b>Mickael Morin</b>, Excelsus Structural Solutions, Switzerland)</li> <li>The industry-oriented powder diffraction and total scattering beamlines P02.1/P25 at PETRA III (<b>Henrik Jeppesen</b>, DESY, Germany)</li> <li>Feasibility of Synchrotron XRD for the Analysis of Mixture Sub-Samples (<b>Ruba Alajlouni</b>, Improved Pharma, USA)</li> <li>Advanced detection and quantification techniques (<b>Mathilde Reinle-Schmitt</b>, Excelsus Structural Solutions, Switzerland)</li> </ul>  |
| 6:30pm –7:30 pm     | <b>Further questions to speakers – Comments from the audience</b>  |
| From 7:30 pm        | <b>Welcome dinner &amp; Networking</b>   |

#### DAY 2 – 20<sup>TH</sup> MAY 2023

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|---------------------|---|
| From 8:15 am        | <b>Breakfast &amp; Networking</b>   |
| 9:00 am – 10:30 am  | Electron Diffraction & SAXS & complementary techniques (25+5m) <ul style="list-style-type: none"> <li>Small Angle Scattering technique: an overview (<b>Jan Ilavsky</b>, APS, USA)</li> <li>Single crystal X-ray and Electron Diffraction experiments for the pharmaceutical industry: From nonstandard crystallization techniques to in-situcrystallization for ED experiments (<b>Gustavo Santiso</b>, Crystallise!, Switzerland)</li> <li>Structure Elucidation Capabilities in the Pharmaceutical Industry: Polymorphs in a Pandemic (<b>Justin Newman</b>, Merck &amp; Co., Inc., USA)</li> </ul>  |
| 10:30 am – 11:00 am | <b>Further questions to speakers and Coffee break</b>   |
| 11:00 am – 12:00 pm | Pair Distribution Function instrumentation and applications – Part 1/2: talks (25+5m) <ul style="list-style-type: none"> <li>APS 11-ID-B PDF-dedicated beamline (<b>Olaf J. Borkiewicz</b>, APS, USA)</li> <li>Acoustic levitation and the Pair Distribution Function: a structural probe of nonequilibrium processes for pharmaceutical products (<b>Stephen Wilke</b>, APS, USA)</li> </ul>   |
| 12:00 pm – 1:00 pm  | <b>Lunch</b>  |
| 1:00 pm – 3:30 pm   | Pair Distribution Function instrumentation and applications – Part 2/2: (25+5m) <ul style="list-style-type: none"> <li>Characterizing amorphous and nanostructured materials with total scattering (<b>Simon Billinge</b>, Columbia University, USA)</li> <li>A Deeper Dive into Amorphous Solid Dispersions: Evaluating Stability and Drug-Polymer Interactions using X-ray Pair Distribution Function (PDF) Analysis (<b>Gabriel de Araujo</b>, University of Sao Paulo, Brasil)</li> <li>Current software options for extracting pair distribution functions from x-ray total scattering data (<b>Leighanne Gallington</b>, APS, USA)</li> <li>What the Pair Distribution Function (PDF) can tell you about amorphous pharmaceuticals. (<b>Chris Benmore</b>, APS, USA)</li> <li>Laboratory-based PDF applied to pharmaceuticals: how far can we go? (<b>Martin Schreyer</b>, Panalytical, Germany)</li> </ul> |
| 3:30 pm –5:30 pm    | <b>Round table on role of polymorphism, S-XRPD and PDF – PDF guidelines, an update (Moderators: P. Smith, F. Gozzo, Ch. Benmore &amp; S. Byrn)</b>  |
| 5:30 pm –5:45 pm    | <b>Final remarks and announcement of the next SPS-XRPD meeting in Switzerland</b>   |