

**IWPCPS®- 11**  
**Eleventh International Workshop on Physical Characterization of  
Pharmaceutical Solids**  
**Stamford, CT; USA**  
**June 14 - 18, 2009**

**Sunday June 14, 2009**

Registration

16:00 - 18:00

**Monday June 15, 2009**

9:00 - 9:10	assa® welcome	A. Rehfeldt, assa® Inc.; USA
9:10 - 10:00	The Changing Face of the Pharmaceutical Industry	R. L. Mueller, former Director, Physical Properties & Developability - PA, GlaxoSmithKline; USA

**Polymorphs and Solvates**  
**Session Chair: Cornelia Field, Boehringer Ingelheim Pharmaceuticals; USA**

10:00 - 10:15	Session Introduction	C. Field, Boehringer Ingelheim; USA
10:15 - 10:45	From Solid Form Screen to Crystallization Development: Case Studies	B. S. Yang, Boehringer Ingelheim; USA
10:45 - 11:15	API Process Development of a Polymorphic System	C. Wang, Bristol-Myers Squibb; USA
11:15 - 11:45	API and Water - A Good Team!	U. Werthmann, Boehringer Ingelheim; Germany
11:45 - 12:15	<b>Coffee Break</b>	
12:15 - 12:45	Concepts for Successful Co-Crystal Screening of Pharmaceutical Compounds	B. Baumgartner, Sanofi-Aventis; Germany
12:45 - 13:10	Validation of the Quantification of Polymorphism by Spectroscopic Methods Combined with Partial Least Square Methods	M. Scarzello, Schering Plough; The Netherlands
13:10 - 13:35	Identification and Quantification of Polymorphs and Amorphous Material Using Solid State NMR Spectroscopy	T. Offerdahl, Boehringer Ingelheim; USA
13:35 - 14:00	Near Infrared Spectroscopy as a Tool to Guide Formulation Development for a Drug Molecule Prone to Polymorph and Solvate Conversion	C. T. John, L. Sharon, L. Li, R. Maus, R. Suomela, M. Cruanes, and M. Mowery, Merck & Co; USA

**14:00 - 15:30 Lunch**

<b>15:30 - 15:55</b>	Quantitative Analysis of Phases with Partial or No Known Crystal Structure	A. Kern, Bruker-AXS; Germany
<b>15:55 - 16:20</b>	Simultaneous X-Ray Diffraction and Differential Scanning Calorimetry in the Drug Discovery Process	J. D. Ferrara <sup>1</sup> , P. U. Pennartz <sup>2</sup> , A. Kishi <sup>3</sup> <sup>1</sup> Rigaku Americas Corp.; USA <sup>2</sup> Rigaku European Headquarters; Germany <sup>3</sup> Rigaku Corporation; Japan
<b>16:20 - 16:45</b>	The Importance of Diversity in Accomplishing Successful Comprehensive Solid State Screening Programs	A. Winkler, Avantium; USA
<b>16:45 - 17:15</b>	Discussion Round	

**WELCOMING RECEPTION**

**Tuesday June 16, 2009**

**Thermal Methods in Pharmaceutical Characterization  
Session Chair: Dr. Gabriele Kaiser, Netzsch GmbH; Germany**

<b>8:30 - 9:15</b>	Characterization of Hydrates by Means of Thermal Analysis	G. Kaiser, Netzsch GmbH; Germany (1,2) (2)
<b>9:15 - 9:40</b>	Introducing Large Sample Sized Scanning Calorimetry in Pharmaceutical Studies	P. Ralbovsky, Netzsch Instruments; Germany
<b>9:40 - 10:05</b>	New Solid State Properties of Drugs by Dielectric and Calorimetric Analysis	A. T. Riga and K. S. Alexander <sup>1</sup> Cleveland State University; USA <sup>2</sup> University of Toledo; USA
<b>10:05 - 10:30</b>	Spontaneous Salt Dissociation & Effect of Crystallinity on Form Conversion	R. J. Behme, Eli Lilly & Company; USA
<b>10:30 - 11:05</b>	Thermodynamic Stability Relationship of Polymorphs and Hydrates of an Investigational Drug	Y.- H. Kiang, Amgen; USA
<b>11:05 - 11:30</b>	Discussion Round	

**11:30 - 13:00 Lunch break**

**Solid State Characterization of Lyophiles and the Lyophilization Process**  
**Session Chair: Dr. Paul Luner, Pfizer R&D; USA**

<b>13:00 - 13:45</b>	Physical Characterization of Formulations in Frozen and Freeze-Dried Solid States: An Overview	J. Liu, Abraxis BioScience; USA
<b>13:45 - 14:30</b>	Relaxation Dynamics in Amorphous Pharmaceuticals	M. Pikal, University of Connecticut; USA
<b>14:30 - 14:55</b>	Usefulness and Limitation of NMR Relaxation Time as an Indicator of Stability-Related Molecular Mobility in Freeze-Dried Formulations	S. Yoshioka, University of Connecticut; USA
<b>14:55 - 15:20</b>	<b>Coffee Break</b>	
<b>15:20 - 15:45</b>	Calorimetric Assessment of Enthalpy Relaxation in Lyophilized Glasses	S. Luthra, Pfizer; USA
<b>15:45 - 16:10</b>	Characterization of Mannitol Polymorphic Forms in Lyophilized Protein Formulations	Y. Xie, Amgen; USA
<b>16:10 - 16:35</b>	Potential Application of Pair Distribution Function Analysis to Measure Phase Separation in Freeze-Dried Solids	D. Engers, Aptuit/SSCI; USA
<b>16:35 - 17:00</b>	Discussion Round	
<b>17:30 - 19:00</b>	<b>Seminar: Effect of Surface Properties on Granulation Performance</b>	<b>Surface Measurement Systems; USA</b>

**Wednesday June 17, 2009**

**Patent and Litigation Support for Pharmaceutical Solids**  
**Session Chair: Dr. Robert Whittock, Freshfields Bruckhaus Deringer LLP; UK**

<b>8:00 - 8:45</b>	Pharmaceutical Patents: From Invention to Validation	R. Whittock, Freshfields Bruckhaus Designer LLP; UK
<b>8:45 - 9:30</b>	Invention Strategies from the Laboratory to Litigation	M. Feldstein, Finnegan, Henderson, Farabow, Garrett and Dunner, LLP; USA
<b>9:30 - 10:15</b>	Novelty and Inherent Anticipation as Criteria for a Patentability of Crystalline Forms	A. Raphael, O'Brien Jones PLLC; USA
<b>10:15 - 10:35</b>	<b>Coffee Break</b>	

<b>10:35 - 11:20</b>	Lessons from U.S. Case Law to Guide Preparation, Prosecution, and Enforcement of Patents Covering Pharmaceutical Solid Forms	L. Hymel, Weingarten, Schurgin, Gagnebin & Lebovici LLP; USA
<b>11:20 - 12:05</b>	Pharmaceutical Patent Litigation in the UK: Recent Trends, Including Solid Form Pharmaceutical Patents	J. Ball, Norton Rose; UK
<b>12:05 - 12:50</b>	Impact of the European Commission Pharmaceutical Sector Inquiry	M. Engelman, Hardwicke Building; UK
<b>12:50 - 13:15</b>	Discussion Round	
<b>13:15 - 14:30</b>	<b>Lunch Break</b>	

**Solid State Characterization Methods and Physical Stability of API Dispersions**  
**Session Chair: Dr. Eric Munson, University of Kansas; USA**

<b>14:30 - 15:15</b>	Applications of Solid-State NMR Spectroscopy to Complex Matrices: Drugs, Excipients, and Formulations	E. Munson, University of Kansas; USA
<b>15:15 - 15:40</b>	Solid State NMR Spectroscopy for the Examination of Drug Substance and Drug Product	T. Offerdahl, Boehringer Ingelheim; USA
<b>15:40 - 16:05</b>	Terahertz Pulsed Imaging as an Analytical Tool for Tablet Film Coating	T. Rades, University of Otago; New Zealand
<b>16:05 - 16:30</b>	Some Experiences Utilizing a Wide-Area Illumination (WAI) Raman Probe in Form Selection and Quantitation Studies	P. Isbester, AMRI; USA
<b>16:30 - 16:55</b>	Characterization of Phase Separation by SSNMR	A. Medek, Vertex Pharmaceuticals Inc.; USA
<b>16:55 - 17:25</b>	Discussion Round	
<b>18:00 - 19:30</b>	<b>Seminar: X-Ray Characterization Methods in the Pharmaceutical Industry - A World of Applications</b>	<b>PANalytical; The Netherlands</b>

Thursday June 18, 2009

**Amorphous Pharmaceutical Materials: Where Are We And What's Next?  
Session Chair: Dr. Rama Shmeis, Sanofi-Aventis; USA**

<b>8:00 - 8:45</b>	Kinetics and Thermodynamics of Amorphous Pharmaceutical Solids	L. Yu, University of Wisconsin; USA
<b>8:45 - 9:30</b>	Chemical Reaction Kinetics & Mechanisms in Amorphous Solids	B. Anderson, University of Kentucky; USA
<b>9:30 - 10:05</b>	Different Measures of Molecular Mobility and Relevance to Physical Stability: Comparison Between Calorimetric and Thermally Stimulated Current Measurements	R. A. Shmeis, Sanofi-Aventis; USA
<b>10:05 - 10:25</b>	<b>Coffee Break</b>	
<b>10:25 - 11:10</b>	Can Milling Really Amorphize a Compound? Can It Also Induce Recrystallization?	M. Descamps, J.-F. Willart, University of Lille1; France
<b>11:10 - 11:35</b>	Terahertz Pulsed Spectroscopy and Other Spectroscopic Techniques to Investigate Amorphous Pharmaceutical Solids	T. Rades, University of Otago; New Zealand
<b>11:35 - 12:00</b>	X-Ray Scattering Studies on Nano Crystalline and Amorphous Materials Using High-Energy X-Rays on a Laboratory System	D. Beckers, M. Gateshki and J. te Nijenhuis, PANalytical B.V., Almelo; The Netherlands
<b>12:00 - 12:30</b>	Discussion Round	
<b>12:30 - 14:00</b>	<b>Lunch</b>	

**Detecting Process Induced Transformations in Solid State Formulations  
Chair: Dr. Thomas Rades, University of Otago; New Zealand**

<b>14:00 - 14:10</b>	Detecting Process Induced Transformations in Solid State Formulations	T. Rades, University of Otago; New Zealand
<b>14:10 - 14:55</b>	Detecting Process Induced Transformations in Crystallisation	T. Rades, University of Otago; New Zealand
<b>14:55 - 15:20</b>	Detecting Process Induced Transformations in Drying	C. Strachan, University of Otago; New Zealand

<b>15:20 - 16:05</b>	Detecting Process Induced Transformations in Milling	T. Rades, University of Otago; New Zealand
<b>16:05 - 16:30</b>	<b>Coffee Break</b>	
<b>16:30 - 17:15</b>	Detecting Process Induced Transformations During Dissolution	M. Savolainen, University of Copenhagen; Denmark
<b>17:15 - 17:40</b>	Imaging of Solid State Dosage Forms During Dissolution Using Coherent Anti-Stokes Raman Scattering (CARS) Microscopy	C. Strachan, University of Otago; New Zealand
<b>17:40 - 18:00</b>	Characterization and Stabilization of Amorphous Pharmaceuticals Solids	F. Zhang, University of Otago; New Zealand
<b>18:00 - 18:30</b>	Discussion Round	

**Friday June 19, 2009**

**Morphology and Surface Characterization  
Session Chair: Prof. Dr. K. Terada, Toho University; Japan**

This session had to be cancelled due to travel restriction of Japanese scientists.  
We apologize for any inconvenience.

## Poster Presentations

Characterization of Polymorphs and API-Excipient Cocrystals Using Vibration Spectroscopy and Solid-State NMR

J. Jampilek<sup>1</sup>, Z. Oktavec<sup>2</sup>, T. Pekarek<sup>2</sup>,  
J. Havlicek<sup>2</sup>, J. Dohnal<sup>1,2</sup>, V. Kral<sup>2,3</sup>  
<sup>1</sup>University of Veterinary and  
Pharmaceutical Sciences; Czech Republic  
<sup>2</sup>Zentiva a.s.; Czech Republic  
<sup>3</sup>Faculty of Chemical Engineering;  
Czech Republic

Challenges in Thermal Method Development and Validation of Amorphous Materials

M. Davidovich, Bristol Meyers Squibb; USA

Application of Novel Meltsonocrystallization Technique for the Induction of Polymorphism in Progesterone

Rahul Tripathi<sup>1,2</sup>, Shailesh V. Biradar<sup>1</sup>,  
B. Mishra<sup>2</sup>, Anant R. Paradkar<sup>1,3</sup>  
<sup>1</sup>Poona College of Pharmacy and  
Research Centre; India  
<sup>2</sup>Institute of Technology; India  
<sup>3</sup>University of Bradford West Yorkshire;  
UK

Recent Advances in Understanding the Influence of Mechanical Processed Crystal Powders on the Physico-Chemical Characteristics

I. Takanori, Mitsubishi Tanabe  
Pharma Co.; USA

---

### Notes

---

---

---

---

---

---

---

---

---

---



**Twelfth International Workshop  
on Physical Characterization  
of Pharmaceutical Solids**

**IWPCPS®-12**

**June 21 – 24, 2010**

**Lille, France**

- Advance Your Career Through Learning About Cutting-Edge Pharmaceutical Sciences
- Get Answers For Your Questions
- Network

**The Most Advanced Workshop  
In Pharmaceutical Sciences.**

*Space is limited!*

*Early Bird registration discounts are available!*

*For more information please check  
[www.assainternational.com](http://www.assainternational.com)*



**Eleventh International Workshop  
on Physical Characterization  
of Pharmaceutical Solids**

**IWPCPS®-11**

**PROGRAM  
GUIDE**

**June 14 – 18, 2009**

**Stamford, CT; USA**

*[www.assainternational.com](http://www.assainternational.com)*



**assa  
international  
workshops**

