Dear Colleague,

With Polymorphism and Crystallisation making the critical foundations of the solid state industry, it is essential that you attend this years conference, to see what critical changes are affecting your business.

This years conference will not only provide you with over 10 industry case studies, but also provide you with information on some of the newest characterisation technique developments, vital for you to gain an unrivalled edge over your colleagues.

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- Terahertz Spectroscopy
- High-Throughput Screening and Initial Physicochemical Characterisation
- Computed Crystal Energy Landscape
- Pharmaceutical Solid State IR

Don't miss this year's focus day on Chiral Crystallisation, the new hot topic providing you with what new opportunities Chiral Crystallisation can bring to your company.

I look forward to welcoming you in March.

S. Haynes

Sarah Haynes
Conference Director
Pharma IQ

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11th – 13th March 2008 • Le Meridien Piccadilly, London UK

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- Uncover the very latest **characterisation technique developments** to drive process efficiency, maintain your competitive edge and move your business forward
- Identify the most appropriate techniques for your business to **cut your research costs**
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- Explore how PAT can be built into your design stage processes in order to **improve your time to market**

NEW FOR 2008:

1) Exclusive Chiral Crystallisation Focus day: 13th March 2008

Your opportunity to explore the importance of Chiral Crystallisation on your Industry.

2) Interactive Evening Workshops

A: **Computational Tools in Pharmaceutical Development:**
Analysis of Powder X-ray Data, Prediction of Crystal Packing Arrangements, and Morphology Analysis
11th March

B: **Polymorphs Behaving Badly**
Use this unique opportunity to explore the detection of polymorphs, process of polymorph discovery, and their analytical characterisation
12th March

3) Don't miss out on the Diamond Drinks Reception

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Chris Frampton, *Chief Scientific Officer,* **Pharmorphix**
Dr. Jan-Olav Henck, *Senior Director,* **Aptuit**
Dr. Rolf Hilfiker, *Director, Head of Department, Solid-State Development,* **Solvias AG**
Peter Kaprinski, *Senior Fellow,* **Novartis Pharmaceuticals Corp**
Dr. Richard Kellogg, *CFO, Senior Executive,* **Syncom**
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Leslie Leiserowitz, *Professor,* **Weizmann Institute**
Dr. Frank Leusen, *Senior Scientist,* **Bradford Institute of Pharmaceutical Innovation**
Dr. Michael Karl Levis, *Head of Process Optimisation Chemistry,* **Seigfried Ltd.**
Dr. Tariq Mahmud, *Senior Lecturer in Chemical Engineering,* **University of Leeds**
Paul Meenan, *Scientist*, **Pfizer**
Max Peterson, *Product Manager, Analytical and Crystallisation Tools,* **Accelrys**
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Dr. Veronica Profir, *Purchasing Manager,* **AstraZeneca**
Dr. Kevin Roberts, *Brotherton Professor of Chemical Engineering and Director of Research for the* **Institute of Particle Science and Engineering (ISPE) University of Leeds**
Featured Representative, **Avantium**
Dr. Michael Quayle, *Principal Crystallisation Specialist,* **AstraZeneca**
Mike Zaworotko, *Professor and Chairperson,* **University of South Florida**
Axel Zeitler, *Research Associate,* **University of Cambridge**

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Day One: 11th March 2008

08:30 Registration and coffee
09:00 Pharma IQ and Chair's welcome

Industry Overview

09.10 **Polymorphism: The Fastest or the Most Stable?**
- Polymorphs as alternative crystallisation outcomes
- When may one expect polymorphism?
- Why does polymorphism occur?

Gautam Desiraju, *Professor,* School of Chemistry, **University of Hyberabad**

09.55 **Transitioning to Development: The Significance of the Solid-Form**

This presentation will cover current approaches to solid-form development including crystallisation, salt-selection polymorphism and co-crystal screening
- The selection of a potential clinical candidate for development is based on many factors and is a decision that will ultimately commit a large amount of resource to a development programme
- There have been numerous examples where a lack of awareness of the solid-state properties of the selected candidate has caused major setbacks in the development programme
- In particular the phenomenon of polymorphism in crystalline materials can have critical implications on the chemical and physical properties of an API and hence it's "developabilty" as a potential candidate
- To minimise the risk to the programme, solid-form investigations should be conducted at a relatively early stage of the drug development process to ensure that reliable and consistent processes and pharmacokinetic data are obtained

Professor Chris Frampton, *Chief Scientific Officer,* **Pharmorphix Ltd**

10.30 Coffee

Case Study Updates

10.50 **The Control of Structure and Mechanical Properties of Crystalline Forms**
- Processes at the molecular level and the structural aspects of crystallisation associated
- Parameters required to obtain the desired structure and related properties of a material during crystallisation processes

Paul Meenan, *Scientist,* **Pfizer**

11.35 **Update to Solution Phase Nucleation: Cluster Size and Shape and its Correlation with Crystallisation Kinetics and Polymorph Selection**

Physical and chemical properties denoted by cluster structure, size and shape affect the rate of crystallisation and therefore influence the polymorph selection process. Within this presentation we will examine the above effects in solution phase nucleation, topics will include:
- Using iso- and poly-thermal turbidometric analysis to examine solution phase nucleation kinetics measurements
- Predicting nucleation cluster structure as a function of it's size and shape through molecular modelling techniques
- Manipulating solution chemistry to ensure a particular solid form is produced exploring the interplay of kinetics and structure in polymorphic systems

Dr. Kevin Roberts, *Brotherton Professor of Chemical Engineering and Director of Research for the Institute of Particle Science and Engineering (IPSE),* **University of Leeds**

12.20 **Solid Forms as Drug Delivery Tools**
- Polymorphs, hydrate, cocrystals, amorphous materials and their impact on solubility/bioavailability
- What does "stability" of these solid forms mean?
- Practical considerations of these solid forms in terms of API and drug formulation development and production

Dr. Jan-Olav Henck, *Senior Director,* **Aptuit**

12.55 Networking Lunch

PAT and its Implications for Polymorphism and Crystallisation

14.10 **Process ATR-FTIR Spectroscopy for Monitoring and Controlling Crystallisation Processes: From Lab to Industrial Plant**
- Discussion of a closed-loop feedback control system, with *in-situ* measurements of solute concentration using ATR-FTIR spectroscopy coupled with a multivariate chemometric calibration model has been developed for monitoring and control of supersaturation in batch cooling crystallisation of L-glutamic acid
- How the supersaturation monitoring and control system has been scaled up via laboratory-scale trials in 20L stirred tank crystalliser and implemented on a 250L industrial pilot-plant crystalliser

Dr. Tariq Mahmud, *Senior Lecturer in Chemical Engineering,* **University of Leeds**

14.55 **Development of Crystallisation Processes in Process Research and Development**
- Design and optimisation of crystallisation processes
- Use of PAT within the laboratory and pilot plants
- Case studies of challenging crystallisations

Dr. Michael Quayle, *Principal Crystallisation Specialist,* **AstraZeneca**

15.40 Coffee

Trouble Shooting

16.10 **Trouble Shooting in Crystallisation**
- Optimising or stabilising of "old" crystallisation processes
- Crystallisation optimisation to solve process issues in downstream processes such as filtration
- Differences or preferenecs in Crystallisation or drying
- Meeting historical particle size requirements

Dr. Michael Karl Levis, *Head Process Optimisation Chemistry,* **Siegfried Ltd.**

17.00 Chair's Closing Remarks end of Day One

17.15 **Workshop**
Computational Tools in Pharmaceutical Development: Analysis of Powder X-ray Data, Prediction of Crystal Packing Arrangements, and Morphology Analysis.
See later in brochure for further details

From 19.15 Luxury Champagne & Diamond Reception Followed by Gala Dinner
From the comfort of Le Meridien Hotel, London, join your colleagues and peers for a spot of champagne, a chance to network and the opportunity to win a real diamond.

Day Two: 12th March 2008

08:30 Registration and Coffee
09.00 Pharma IQ and Chair's Welcome

Characterisation Techniques

09.10 **Induced Alignment of Self-Assembled Molecules**
- Induced alignment at the air-water interface via pulsed linearly polarised IR light
- Aligned monolayer Crystals

Leslie Leiserowitz, *Professor,* **Weizmann Institute**

09.55 **Automation of Powder X-ray Data**
- Amorphous content characterisation and refinement techniques, including QPA
- Hydrogen bond topologies and polymorph prediction
- Applications of morphology prediction

Max Peterson, *Product Manager, Analytical and Crystallisation Tools,* **Accelrys**

10.40 Coffee

New Screening Techniques

11.00 **Spectroscopic Measurements of Crystal Structure - Terahertz Spectroscopy, an Ideal Tool to Characterise Pharmaceutical Solids**
- What is terahertz spectroscopy? An introduction to measurement principles and spectral information in this frequency range
- Characterisation of crystalline solid state modifications by terahertz time-domain spectroscopy
- Characterisation of amorphous materials
- What unique advantages terahertz spectroscopy can offer: time resolved measurements of dynamic processes (phase transitions, crystallisation processes), direct measurement of the absorption coefficient and refractive index

Axel Zeitler, *Research Associate,*
University of Cambridge

11.45 **High-Throughput Screening and Initial Physicochemical Characterisation of Pharmaceutical Salts, Co-crystals and Polymorphs**
- The advantages of the use of automated and robotic systems in salt, co-crystal, and polymorph screening in solution, and in early crystallisation development experimentation over manual only route
- Increasing the number of experimental conditions that may be tested to enhance the probability of salt/co-crystal/polymorph discovery
- It is essential that this enhanced throughput extends beyond the generation of salts/co-crystals/polymorphs, to their initial characterisation
- Ensure correct design of the crystallisation/co-crystallisation device and address the new need for automated data evaluation
- In this presentation, the author will share his experiences on conducting an effective salt/Co-Crystal/polymorph screening

Peter Kaprinski, *Senior Principal Fellow,*
Novartis Pharmaceuticals Corp.

12.30 **Case Study Update**
- Industry case depicting how we use polymorphism and crystallisation
- Which analytical techniques we used to characterise
- Problems encountered by Avantium and solutions implemented
- Scientific update into strategies implemented and techniques applied

Avantium representative
For further detail please visit the website www.iqpc-pharma.com/uk/poly

13.15 Networking Lunch

14.30 **How the Computed Crystal Energy Landscape can Complement Experimental Polymorph Screening**
Although the computational goal of predicting all the polymorphs of a molecule is still a long way off, current methods of searching for the low energy crystal structures already can provide a useful complement to polymorph screening in conforming that the most thermodynamically stable structure is known and providing insight into the possible complexities of the solid state
- Case studies where genuine predictions of the crystal structure have been made, and later verified
- Case studies where the energy landscape rationalises polymorphism and solvate formation
- An overview of how the crystal energy landscape can provide insight into the factors that control polymorphism or generate problems in controlling the crystallisation process

Sarah L. Price, *Professor of Chemistry,* **University College London**

15.15 **Case Study: Carbamazepine: Hydrate or Anhydrate?**
- Hydrates in the solid form space-solubility/ absorption
- Concept of water activity

Dr Rolf Hilfiker, *Director, Head of Department, Solid-State Development,* **Solvias AG, Basel, Switzerland**

16.00 Coffee

16.20 **Crystal Structure Prediction: Current Status and Challenges**
- Introduction to Crystal Structure Prediction
- Force fields, electrostatics, lattice energy calculations
- Overview of the CCDC blind tests in Crystal Structure Prediction
- Results of the latest (2007) blind test
- Focus on the one, novel method that predicted all four structures correctly in the latest blind test
- Implications of crystal structure prediction for pharmaceutical development
- Discussion of limitations and remaining challenges
- Future outlook

Dr. Frank Leusen, *Senior Scientist,*
Bradford Institute of Pharmaceutical Innovation

What is the next stage for Polymorphism and Crystallisation?

17.05 **Interactive Discussion Session: Where is the industry headed?**
- What is important in the industry now
- How we see the industry moving forward
- How we can get there

17.50 **Chair's Closing Remarks end of Day Two**

18.15 **Workshop**
Polymorphs Behaving Badly
This workshop will outline detection of polymorphs, process of polymorph discovery, and their analytical characterisation
See later in brochure for further details

"Extremely informative, a must for every Chemist"

Himanshu Godbole, *Principal Chemist,*
Lupin Pharmaceuticals

11th March 2008

17.15 -19.15 Computational Tools in Pharmaceutical Development: Analysis of Powder X-ray Data, Prediction of Crystal Packing Arrangements, and Morphology Analysis

This workshop introduces some key techniques that complement and enhance experimental activity within pharmaceutical development.

- First, techniques for analysing powder X-ray data are reviewed with particular emphasis on amorphous content characterisation, form identification, and form quantification. Approaches for automation of repetitive task are introduced, namely scripting approaches and deployment as web services.
- The second part of the workshop explores virtual experimentations using modelling and simulation techniques. Particular emphasis is given on exploring interactions of solid APIs with excipients as well as virtual polymorph screening efforts.

Key aspects of each area will be illustrated and reinforced by means of hands-on exercises.

Facilitated by **Max Peterson,** *Product Manager, Analytical and Crystallisation Tools,* **Acclerys**

12th March 2008

18.15 -19.15 Polymorphs Behaving Badly

This interactive workshop will include;

SCOPE

- Statistically, 85% of active pharmaceutical ingredients (APIs) exhibit (pseudo)poly-morphism, and 50% of APIs have multiple (pseudo)polymorphs, the production of specific stable polymorphs being an integral part of the API development process.
- This cannot be done without a thorough and systematic process involving the polymorph discovery stage and analytical determination of their properties

METHODS

- Various approaches (manual vs. automated high-throughput) and analytical techniques (XRD, Raman, DSC, TGA/DTA, DVS, and others) were used and the necessity of so doing constitutes the very point of this presentation.

RESULTS

- *The paper will outline detection of polymorphs, process of polymorph discovery, and their analytical characterisation. –case study examples.*
- *Although these examples focus on 'polymorphs behaving badly', they will be of interest to both experienced polymorphism scientists and those new to the subject.*

APPLICABILITY

- Whilst confusing results are standard the ultimate goal is to select the most thermodynamically stable form and be able to manufacture it consistently.
- The preferential nucleation and growth of specific (pseudo)polymorphs over others is possible through careful control of environmental conditions, such as temperature, supersaturation, rate of crystallization, seeding, type of solvent(s).

Facilitated by **Peter Kaprinski,** *Senior Principal Fellow,* **Novartis Pharmaceuticals Corp**

Exclusive Chiral Crystallisation Focus Day: 13th March 2008

09.00 Registration and Coffee

09.15 Chairs Introduction

09.30 **Chiral Resolution via Crystallisation.**

- Pasteurian resolution and variants
- Preferential crystallisation
- Preferential nucleation
- Stereo selective: Host guest inclusions

Gerard Coquerel, *Professor,* **University of Rouen**

10.15 Coffee

10.45 **Towards Predictive Models for Racemate Resolution**

- Introduction to chirality and the need for racemate resolution
- Thermodynamics of spontaneous and classical resolutions
- Overview of methodology: crystal structure prediction
- Application examples on the prediction of spontaneous resolution: racemic solids versus enantiomorphs
- Application example on the prediction of racemate resolution through the selective crystallisation of diastereomeric salts
- Current limitations and future directions

Dr. Frank Leusen, *Senior Scientist,* **Bradford Institute of Pharmaceutical Innovation**

11.30 **Co-Crystals involving Chiral Co-Crystal Formers**

- Crystal engineering strategies for design of pharmaceutical co-crystals
- Co-crystals from racemic co-crystal formers
- Co-crystals from homochiral co-crystal formers

Mike Zaworotko, *Professor and Chairperson,* **University of South Florida**

12.15 Lunch

13.45 **Tailor-Made Auxiliaries for Crystallisation**

- General Stereochemical method for the control of crystal nucleation, growth and dissolution
- Examples illustrating the compromise and the control of crystal polymorphism and the resolution of racemates by the process of crystallisation
- Describing an industrially feasible kinetic process for the conversion of D,L-racemic mixtures, crystalline in the form of conglomerates, into optically pure materials
- Including consideration of the presence of single-enantiomer polymer that causes crystals that match it in chirality to lag behind their enantiomers both in growth and in dissolution
- The phase lag exploited in a repeated cycle of growth and dissolution to collect crystals of one kind of partial growth and of the other before complete dissolution.
- The method of "tailor- made" auxiliaries, extended by Dutch researchers for the resolution of enantiomers via the formation of diasteroisomeric crystals.

Meir Lahav, *Professor,* **Weizmann Institute**

14.30 **Dutch Resolution and Chiral Crystallisation**

Update to Chiral Separation via Dutch Resolution

- The process of separating enantomers through Dutch Resolution
- Why this is important and how it helps Chiral crystallisation

Dr. Richard M. Kellogg, *CFO, Senior Executive,* **Syncom**

15.15 Coffee

15.45 **Strategies for Separating Enantiomers by Crystallisation.**

- Different types of racemates
- Different methods for separation by crystallisation
- Which method applied to which type of racemate
- Practical examples (influence of process parameters on purity, polymorphism, e.t.c.)

Dr. Veronica Profir, Sales Manager, **AstraZeneca**

16.15 Discussion Session:
How is Chiral Crystallisation Important to you?

- How does Chiral Crystallisation fit in with Polymorphism and Crystallisation as a whole
- What new issues do we see arising here
- Which areas of the industry is it going to affect the most
- Why its important to you

17.00 Chairs Closing Remarks

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