Pharma a division of IQPC iQ **Presents the 3rd Annual**

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Amorphous Pharmaceutical Materials 2009

"Excellent talks. All presentations were interesting, detailed & well explained. Extremely valuable-I've learned a lot about amorphous characterisation, generation & control."
Caitriona Cashell, GlaxoSmithKline

Translating Amorphous Research Concepts into Commercial Success

21st – 23rd September 2009 • Mövenpick Hotel, Amsterdam, The Netherlands
Main conference 21st – 22nd September 2009 • Workshops 23rd September 2009

Featuring Innovative Insights from:

Dr Steve Cosgrove, Associate Principal Scientist, Solid State Characterisation, *AstraZeneca*

Dr Rolf Hilfiker, Vice President, Head of Department Solid-State Development, *Solvias AG*

Dr Peter Van Hoof, Director Solid State Characterisation, *Schering Plough*

Dr Geert Verreck, Head of Solid, Early Development, Principal Scientist, *Johnson and Johnson Pharm. R&D*

Dr Sigrid Stokbroekx, Head of Laboratory, *Johnson and Johnson*

Associate Professor Nair Rodriguez-Horendo, Department of Pharmaceutical Sciences, *University of Michigan*

Dr Filipe Gaspar, R&D Particle Design Director, *Hovione*

Dr Marco Gil, R&D Particle Design Senior Engineer, *Hovione*

Dr Carsten Timpe, Fellow, *Novartis Pharma AG*

Senior Representative, *European Patent Office*

Dr David Elder, Director, Externalisation Group, *GlaxoSmithKline*

Dr Wayne Sinclair, Senior Scientist and Laboratory Head, *Bristol Myers Squibb*

Dr Peter Kaprinski, Principal Fellow and Leader of US Salt, Polymorphism Particle Engineering Networks, *Novartis*

- Incorporating amorphous forms as a solution to compounds that won't crystallise to **ensure continued development,** demonstrated by ***Schering Plough***
- **Improve the solubility of compounds** by developing the amorphous form, results shown by ***Solvias***
- Equip yourself with the latest techniques to **ensure stability of your amorphous compound to accelerate drug development,** key insights from ***AstraZeneca***
- **Fast track your drug development** by effectively characterising your amorphous form for first time patent approval, interactive session with the ***European Patent Office***
- **Streamline your decision making criteria** for outsourcing within the development process with key insights from ***GSK's*** externalisation group
- **Ensure effective scale up** and development of your compound, understand the practicalities of changing from lab to commercial scale, examples from ***Hovione***

NEW FOR 2009!

1. 9 brand new case studies from leading industry speakers
2. Gain access to joint networking with the Pharmaceutical Co-Crystals meeting, visit www.iqpc.com/nl/cocrystals for more details
3. GSK assess the options for outsourcing within Amorphous Materials

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Solid State Series

www.iqpc.com/nl/amorphous

08.15 Registration and Coffee

08.45 Chair's Opening Address

08.55 **Pairwise Distribution Function to Rank and Characterise Amorphous Materials: As Applied within the Pharmaceutical Industry**

CASE STUDY

- Explanation of PDF's new application within the pharmaceutical industry and the successful use in characterising an amorphous form
- How improving the speed and quality of decision making with amorphous materials can impact your company's results
- Applicability to single phase API as well as mixed phase amorphous formulations such as solid dispersions
- Dangers and pitfalls identified within our implementation and how to avoid them

Dr Steve Cosgrove, Associate Principal Scientist, Solid State Characterisation, *AstraZeneca*

09.40 **Amorphous Content: Quantification in Drug Substance and Drug Product**

If a substance can exist in several different solid forms – and this is the case for just about every substance considering that the amorphous form also has to be included in these considerations – it is essential that the "right" solid form is chosen for development. This naturally implies that it is necessary to develop methods which can quantify impurities of undesired solid forms in the desired one. Depending on the nature of the substance, various methods such as X-ray diffraction, Raman, DSC, solid state NMR, etc. may be optimal.

The following issues will be addressed:

- Suitable methods to detect crystalline impurities in the desired form
- Ways to trace amorphous content in crystalline solids
- Micronisation and amorphisation
- Impact on drug substance properties

Dr Rolf Hilfiker, Vice President, Head of Department Solid-State Development, *Solvias AG*

10.25 Networking Coffee

10.55 **Development and Validation of a Drug Product Solid State Method for a NDA (New Drug Applications) - Gaining Approval**

CASE STUDY

- Background on why solid method had to be developed and validated
- FDA following ICH Q6A on polymorphism
- Solid state method development
- Validation of solid state methods
- Gaining first time approval

Dr Peter Van Hoof, Director Solid State Characterisation, *Schering Plough*

11.40 **Effective Methods of Amorphous Particle Engineering and Downsizing the Amorphous Form**

CASE STUDY

Advantages and pitfalls of the following methods will be discussed along with specific examples of how these have been used to accelerate drug development as well as the practicalities in downsizing through the development process.

- Spray Drying
- Hot melt Extrusion
- Super Critical Fluids
- Grinding

Dr Geert Verreck, Head of Solid, Early Development, Principal Scientist, *Johnson & Johnson Pharm. R&D*

12.25 Networking Lunch

13.30 **Automated Screening for Excipients that have the Ability to Act as Precipitation Inhibitors**

CASE STUDY

To overcome the poor solubility and dissolution properties of drug candidates, these may be converted into the amorphous state. First of all, excipients are used to ensure the long term stability of the amorphous phase. In addition, the selected excipients need to attain and sustain a supersaturated condition for drug candidates in order to obtain enhanced drug absorption.

Following topics will be addressed within the presentation:

- The approach to automate and miniaturise the search for precipitation inhibitors
- Preparation of amorphous films
- Evaluation of amorphous systems

Dr Sigrid Stokbroekx, Head of Laboratory, *Johnson and Johnson*

14.15 **The Importance of Solution Chemistry and Amorphous Phases on Co-Crystal Formation**

Co-crystals and amorphous phases offer the advantage of generating solid forms of active pharmaceutical ingredients (APIs) and produce materials with higher aqueous solubility.

This talk will present liquid and solid-state driven methods for co-crystal formation. The phase transformation of API to co-crystal is shown to depend on solution and co-crystal chemistry where nonstoichiometric concentrations of co-crystal reactants lead to thermodynamically favourable conditions for co-crystallisation. This concept is extended to high-throughput screening by solution-based methods which include the use of green solvents, and explains the mechanisms by which moisture generates co-crystals. The role of amorphous phases on co-crystal formation by solid-state processes will also be discussed.

Associate Professor Nair Rodriguez-Horendo, Department of Pharmaceutical Sciences, *University of Michigan*

15.00 Networking Coffee

15.30 **From Lab Scale Development to Commercial Manufacturing**

CASE STUDY

This dual presentation will encapsulate how efficiently Hovione have managed to produce stable amorphous materials using spray drying technology. This session will be supported by case study examples and address the issues of:

- Amorphous technology update: what has helped us through our process
- Spray drying, the positive impact on our development process
- Development of amorphous materials by spray drying at laboratorial scale
- Scale up from laboratory scale to commercial scale

Dr Filipe Gaspar, R&D Particle Design, Director, *Hovione*
Dr Marco Gil, R&D Particle Design, Senior Engineer, *Hovione*

16.15 **Biopharmaceutical Aspects of Amorphous Materials: Stabilising Oversaturation**

CASE STUDY

While physicochemical and manufacturing aspects of amorphous materials (e.g. solid dispersions, nanoparticles) increasingly understood, the factors that would better stabilize targeted oversaturation under in-vivo conditions in the gut require further research and investigations of underlying principles to develop improved drug products for the market. The presentation tries to give a short introduction into solid dispersion and nanoparticle formulation principles in industrial drug development and will then focus more on the biopharmaceutical aspects in the second part.

Following topics will be addressed within the presentation:

- Amorphous materials: solid dispersions and nanoparticle solid oral forms - principles, stabilisation and manufacturing technologies
- Precipitation robustness of amorphous materials under in-vitro and in-vivo conditions
- IVIVC aspects

Dr Carsten Timpe, Fellow, *Novartis Pharma AG Basel*

17.00 Chairperson's Closing Remarks

17.15 Close of Conference Day One

Sponsorship and Exhibition Opportunities

Why Now?

Is all you're hearing "Faster, quicker, better properties, improve your ROI?" The pressure is on for everyone in the current economic climate to push compounds into the next stages of development, faster than the competition and in an efficient cost-effective way. Pharmaceutical companies are focusing on speeding up the development process, in order to do this they need to employ the latest technology and services available from within the market. In a saturated market Amorphous materials provides a unique platform to identify those most actively seeking assistance in these challenging times.

Networking at the Event

Gain unparalleled networking opportunities, with a large number of senior decision makers, with unrivalled discussion session, extended breaks and in-depth workshops. Spend critical face to face time with academic industry experts; utilise this time to help find solutions to your challenges. Attend dedicated networking activities to cement the relationships you will build throughout the conference in a more relaxed environment – from informal networking to organised dinners.

What Pharmaceutical Amorphous Materials Offers…

Pharmaceutical Amorphous Materials will provide you with direct access to an elite audience of senior decision makers from department heads to group leaders. The event is carefully structured and designed to provide valuable opportunities for you to showcase your capabilities and develop valuable new business relationships. This event is unique, as Amorphous Materials runs alongside our Pharmaceutical Co-Crystals meeting there are joint networking sessions, providing you with access to double the audience!

For sponsorship and exhibition opportunities contact Gal Cohen on +44 (0) 207 368 9300 or email sponsorship@iqpc.co.uk

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Day Two: 22nd September 2009

08.00 – 10.30 **Interactive Session One – Ensuring First Time Patent Approval**

Gaining first time patent approval has become more pertinent than ever in the current climates, with generic companies pushing harder to find new routes to market and an increasing amount of litigation, ensuring complete patent coverage of your compound is essential. With supplementary patent certificates, patenting polymorph forms and further options to extend your patent life this is not a straight forward issue.

This meeting will address the following Issues:

- Peculiarities of the amorphous forms inventions
- Characterisation of an amorphous form in a claim
- Typical objections of an EP patent examiner
- Hints and tips for drafting amorphous form patent applications

Applicants within the session will be asked in groups to analyse particular patent claims, assess whether they think they were approved and if not why not. Then after feedback to the group as a whole, you will discuss whether these patents were approved and the reasons for their rejection if necessary.

Senior Representative, *European Patent Office*

Please visit www.iqpc.com/nl/amorphous for more details

10.30 – 10.55 **Networking break**

10.55 – 14.30 CASE STUDY **Interactive Session Two - Assessing Outsourcing Opportunities within the Solid State Arena**

- Qualifying external sources for quality services
- Balancing cost vs. increased efficiency
- Coping with resource restraints
- Previous experiences with solid state vendors
- Standard decision making criteria

Confirmed: Dr David Elder, Director, Externalisation Group, *GSK*

12.25 – 13.30 **Networking Lunch**

14.30 – 15.30 **Networking Break**

15.00 – 15.45 CASE STUDY **Physicochemical Stability and Crystallisation Kinetics of the Amorphous Form in a Low Dose Drug Product by Chemometric Molecular Spectroscopy**

The identification, characterization and quantification of the amorphous form in the final dosage form is an essential part of the development process to confirm sufficient physical stability over the extended shelf life of the product such that it can be utilized to improve dissolution performance. Such analysis is considerably challenging, particularly when the drug is at relatively low levels in a multiple excipient component formulation. Specific examples will be given to demonstrate the following:

- Application of chemometric molecular spectroscopic tools to characterize and quantify low dose amorphous forms during drug product development.
- Evaluating the effect of temperature and humidity stress testing conditions on the physical stability of the amorphous form and the impact on physiochemical quality attributes
- How the use of kinetic modelling can enhance the fundamental mechanistic understanding of the crystallization process and assist in the rational design and development of a suitable formulation.

Dr Wayne Sinclair, Senior Scientist, Analytical Research and Development, *Bristol Myers Squibb*

15.45 – 16.30 CASE STUDY

Round table Discussion: Streamlining Your Development Processes

This discussion session will enable participants to discuss issues surrounding:

- Process and pre-formulation difficulties, identification and potential solution implementation
- The potential positive effects on your bottom line

16.30 **Chairperson's Closing Remarks**

16.45 **Close of Conference Day Two**

Amorphous Pharmaceutical Materials Workshop Day: 23rd September 2009

07.45 – 08.00 **Registration and Coffee**

08.00 – 08.30

Transport to Avantium Technology

Please note attendance maybe restricted. Please call for more information

08.30 – 12.30 **Workshop One – Co-Crystallisation with the Crystalline™, A New Bench Top Reactor for Solid State Research**

The Crystalline™ is a small scale parallel crystalliser with particle visualisation capabilities in combination with programmable temperature control and transmission analytics. The instrument operates on a milliliter scale (1-5 ml working volume) and incorporates through the vial analytics, making it possible to scan many conditions for possible habit changes, enabling rapid screening during process development. During the workshop you have the opportunity to become familiar with the capabilities of the Crystalline™. You will see how you can optimise your co-crystallisation process.

Dr Ir. J.H. Ter Horst, Intensified Reaction and Separation Systems, *Delft University of Technology*
Dr. A. Coetzee, Director, Product Development Systems, *Avantium Technologies*

13.00 – 15.30 **Workshop Two – Characterisation of Co-Crystals**

Whilst this is a topic which has been addressed in numerous papers and reports globally it is one essential to get right, the correct understanding and essential techniques to characterise a co-crystal are necessary for further development. Incorrect characterisation can be detrimental to the whole project, which is why we have organised a discussion forum where top tips and best practices can be shared for you to ensure you are using the most suitable techniques in the most effective way.

(Including networking coffee break)

Facilitated by: Dr Peter Kaprinski, Principal Fellow and Leader of US Salt and Polymorphism and Particle Engineering networks, *Novartis*

Session sponsors

Solvias provides comprehensive physical chemistry services for the identification and selection of polymorphs, salts and co-crystals, including method development for polymorphic purity/amorphous content and optimization of crystallization processes. With years of drug development exp?erience as a former research group of a major pharmaceutical company, we can help you crystallize your ideas.

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Exhibitor

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Amorphous Pharmaceutical Materials 2009

Mövenpick Hotel, Amsterdam, The Netherlands
Main conference: 21st-22nd September 2009
2009 Workshops: 23rd September 2009

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My registration code is PDFW

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Further details of workshops to follow, please see the website www.iqpc.com/nl/amorphous for the latest details

For Separately Bookable Options, Please Call Customer Services on +44 (0) 2073 689 300 who will be happy to assist you

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Please photocopy for each additional delegate

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Mövenpick Hotel Amsterdam City Centre
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ACCOMMODATION:

Overnight accommodation is not included in the registration fee. To book accommodation at Mövenpick Hotel Amsterdam City Centre, Tel: + 31 20 519 12 00. Always quote booking reference IQPC. Rates from: €205.00 exclusive 5% city tax room only. All rooms are subject to availability so it is advisable to book early. For a further selection of nearby hotels please visit www.cityhotelaccommodation.com/amsterdam.html

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