

Programme

09:30 Arrivals and Refreshments

10:00 Chair's Welcome, Elaine Stone (APS)

10:15 Hidden dangers in determining small amorphous contents in pharmaceutical powders by thermal methods
Professor Simon Gaisford (UCL)

10:45 Looking back at challenges encountered with amorphous materials
Gerry Steele (Pharmacryst)

11:15 Dr John Murphy (Particology Ltd)

11:45 Building better dispersions: Analytical tools guiding ASD development
Dr Luis Sousa (Hovione)

12:15 Lunch and posters

13:20 Chairs welcome, Laura Waters (JPAG)

13:30 Analysis of Materials
Dr Kofi Asare-Addo (University of Huddersfield)

14:00 Shane Cullen (Veranova)

14:30 Refreshment break

15:00 Covering Case Studies from M2M Pharmaceuticals
Dr Mridul Majumder (M2M Pharmaceuticals)

15:30 Cracking the Glass: From Risk to Reward in Amorphous APIs - Opportunities with Amorphous Glasses
Dr Andy Robbins (AstraZeneca)

16:00 Closing remarks

Abstracts

Dr Kofi Asare-Addo - University of Huddersfield

Title TBC: Analysis of materials.

Dr Shane Cullen - Veranova

Amorphous solid dispersions (ASDs) are a well-established strategy for stabilising the amorphous form of an API, improving dissolution and bioavailability. The most common techniques for generating ASDs are spray drying and hot-melt extrusion, each offering distinct advantages and limitations. This talk focusses on coprecipitation as an alternative approach. This robust and versatile method can be performed using conventional reaction vessels that are widely available in most laboratories and manufacturing environment for preparation of drug substance. While challenges such as poor filtration can arise, these can be effectively addressed through careful control of critical process parameters, enabling manipulation of particle morphology.

The talk will focus on a process which was successfully scaled from milligram-scale vial experiments to a 2 L jacketed reaction vessel, demonstrating its suitability for development. Finally, the ASD material produced by coprecipitation was benchmarked against material generated by spray drying, with comparisons made using a range of analytical techniques.

Prof Simon Gaisford - University College London

Determining the percent amorphous content of a pharmaceutical powder is often very important, especially if it is to be formulated for use in a dry powder inhaler. There are many thermal methods that may be used (for instance, isothermal microcalorimetry, solution calorimetry and DSC) and they are all excellent – however, all will give incorrect values if the user doesn't understand the subtleties of each method and, especially, if the fact that amorphous materials can relax is not considered. Here we will explore these potential problems using real examples from the author's own laboratory.

Dr Mridul Majumder - M2M Pharmaceuticals Ltd

Amorphous Materials (Intentional or Unintentional): Have you got all covered?

Milling induced disordered material, amorphous, is highly energetic and these particles significantly influence the cohesive and adhesive balance of micronised particles. This behaviour results in varying fine particle fraction which ultimately affects dry powder inhaler performance. This presentation will discuss methods to detect amorphous content of powders for inhalation.

Dr John Murphy - Particology Ltd

Everything but Quantification

Understanding the dynamics of pharmaceutical glass formers, how they relate to stability and devising control strategies based on minimising risk.

Dr Andy Robbins - AstraZeneca

Cracking the Glass: From Risk to Reward in Amorphous APIs — Opportunities with

Dr Luis Sousa - Hovione

Amorphous solid dispersions (ASDs) present a unique set of challenges due to their inherent complexity. Thermodynamically, while these high-energy systems offer significant solubility advantages, they are counterbalanced by the difficulty of maintaining their metastable state. From a kinetic perspective, the inclusion of polymers to enhance dissolution can lead to excessive supersaturation, increasing the risk of drug crystallization in solution.

Given these complexities, a well-defined formulation strategy supported by robust analytical tools is essential throughout the development process. This presentation will explore the application of analytical techniques at key stages of ASD development, including formulation screening, process optimization, batch characterization, and stability assessment.

Dr Gerry Steele - Pharmacryst

Amorphous to Crystalline

This talk will discuss the transition from the amorphous to crystalline state and other solid phases in between, e.g. mesophases and also touch on polyamorphism. The business and scientific drivers for choosing an amorphous API for development will be discussed in terms of pros and cons. Examples of marketed drugs formulated with amorphous APIs will be presented (not amorphous solid dispersions). A brief outline of some of the manufacturing processes involved in the production of amorphous APIs will be given. The glass transition temperature is discussed. A short case study involving the solid-state characterisation of an amorphous API and the determination of the quantity of amorphous in crystalline, using various solid-state analytical techniques, will be delivered.

Speaker biographical details



Dr Kofi Asare-Addo - University of Huddersfield

Kofi is a Reader in Pharmaceutics at the University of Huddersfield. Kofi completed his PhD at the Medway School of Pharmacy, University of Kent in 2012. His PhD was an Industrial CASE studentship with the University and the polymer company Colorcon. His research work which specifically focused on the development of an in-vitro testing method to investigate drug release from hypromellose matrix tablets under fed and fasted conditions. He has extensive expertise in UV imaging of dissolution processes and has >80 peer reviewed publications. Kofi also became a Fellow of the Higher Education Academy in 2014. Kofi successfully collaborates with other universities and several pharmaceutical industries.



Dr Shane Cullen - Veranova

Shane Cullen is a scientist at Veranova (Cambridge) working as a member of the Pharmorphix® team. He has extensive experience in coamorphous and amorphous solid dispersion screening, complemented by broad experience across polymorphism, salt and cocrystal screening, crystallization development, and kilo-lab manufacture. His work spans the full spectrum of solid form development, from early-stage screening through to process scale-up, enabling the delivery of robust solutions for complex pharmaceutical compounds. Before joining Pharmorphix, Shane completed his PhD at Queen's University Belfast, focusing on process development for lipid nanoparticle manufacture using twin-screw extrusion technology.



Prof Simon Gaisford - University College London

Simon is Professor of Pharmaceutics and Vice-Dean Impact & External Engagement for the Faculty of Life Sciences at University College London. He runs a large research group looking at the characterisation of pharmaceutical materials with thermal methods (calorimetry in particular). He has previously been Chair of the Thermal Methods Group (RSC) and a Board Member of the US Calorimetry Conference. He has published more than 240 papers and has featured on the Clarivate Highly Cited Research List continuously since 2019.



Dr Mridul Majumder - M2M Pharmaceuticals Ltd

Mridul is a pharmaceutical professional with 15 years of experience in drug development in innovative R&D. He leads a successful solid-state group which grew organically and achieved significant milestones. He works with large-medium-small pharmaceutical/biotech companies around the Globe. M2MPharma was the King's Award for Enterprise 2024 Winner



Dr John Murphy - Particology Ltd

John is the Chief Operating Officer at Particology, Ltd. This relatively new company delivers expertise in particle technology and materials science. John was over 16 years at Pfizer and has a PhD from Queen's University entitled 'Thermal Analysis of Amorphous and Partially Amorphous Salbutamol Sulphate'.



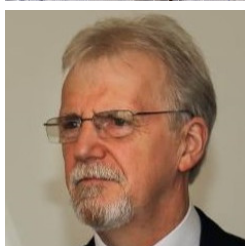
Dr Andy Robbins - AstraZeneca

Andy is an Associate Principal Scientist in Pharmaceutical Sciences at AstraZeneca, with 16 years spanning early- and late-stage development in solid-state chemistry and crystallisation. They have contributed to compound nominations, commercial launches, and are a named inventor on multiple solid-form patents. Recently, their work leverages amorphous materials to address poorly soluble compounds. Andy holds a PhD from Durham University, supervised by Prof. Paul Hodgkinson.



Dr Luis Sousa - Hovione

Dr. Luis Sousa is a Senior Analytical Scientist working in the R&D Analytical Development area, at Hovione. He is a pharmacist by training and holds a PhD in Thermal Analysis and Pharmaceutics from the UCL School of Pharmacy, London, UK. After his PhD, Dr. Sousa did a two-year post-doc in Prof. Lynne Taylor's lab at Purdue University, West Lafayette, USA, before joining Hovione in 2015.



Dr Gerry Steele - Pharmacryst

Gerry graduated with an Honours degree in Chemistry from Paisley College of Technology in 1978. After working in the food industry for a year, he continued his studies at the University of Strathclyde, Glasgow where he gained an MSc in Applied Colloid and Interface Science (1981) and a PhD in colloidal drug delivery (1984) from the Departments of Pure and Applied Chemistry and Pharmacy respectively. After a further year as a research associate in the Pharmacy Department, where he constructed an instrument to measure drug-membrane interactions using quasi-elastic laser light scattering, he joined Fisons Pharmaceuticals in Loughborough in 1985.

From 1985-2002 he worked as the Preformulation team manager in the Pharmaceutical and Analytical R&D Department of AstraZeneca R&D Charnwood. In this role, he led a team that conducted physicochemical characterisation and selection studies of candidate drugs for development. During 2002 he transferred to the Process Engineering function of Process R&D in AZ where, as a Principal Scientist, he built a team concentrating on the development, scale up and trouble-shooting of active pharmaceutical ingredient (API) crystallisation processes. During this time he also significantly increased the process analytical technology (PAT) capability of the department. In April 2011, Gerry elected for early retirement due to AZ's exit from its Loughborough site. Since 2012, he has worked as an independent consultant (PharmaCryst Consulting Ltd) to the pharmaceutical and other industries. In addition, he is also a Visiting Professor to the Dept. of Chemical Engineering of Loughborough University.

Delegate information

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Fee for members of JPAG ** £195

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