

A central rectangular image showing a microscopic view of numerous blue, irregularly shaped particles. The particles have a porous, sponge-like appearance with many small holes and irregular edges. They are set against a dark, almost black background, which makes the blue color stand out. The particles are scattered across the frame, with some appearing larger and more detailed than others.

# PROGRAM

## RECENT ADVANCES IN THE DEVELOPMENT OF AMORPHOUS DISPERSIONS

SEPTEMBER 13-15, 2023  
AUSTIN, TX

[www.austinp.com/workshop/](http://www.austinp.com/workshop/)

# **Recent Advances in Amorphous Solid Dispersions:** Formulation and Characterization Strategies

September 13 - 15, 2023 Hosted by AustinPx

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Identifying the appropriate bioavailability enhancement technology in early development is essential to avoiding expensive redevelopment, or worse, clinical failure due to lack of exposure. During this workshop, presenters will share insights into recent advancements in amorphous dispersion development and analytical techniques to overcome solubility and scalability challenges, as well as analytical techniques to assess the performance of ASDs.

## **SPEAKERS**

### **Workshop Chair**

Derek Hennecke, MS, MBA, Biotech and CDMO Entrepreneur

### **Presenters**

- Jim DiNunzio, PhD, Director, Merck
- Dana Moseson, PhD, Senior Principal Scientist, Small Molecule Drug Product Design, Pfizer
- David Kwajewski, Senior Technical Business Consultant, The TIM Company
- Joshua Lomeo, Director, Application Science, DigiM Solutions
- Dave Miller, PhD, CSO, AustinPx
- Justin Keen, PhD, Senior VP, Operations, AustinPx
- Chris Brough, PhD, CTO, AustinPx

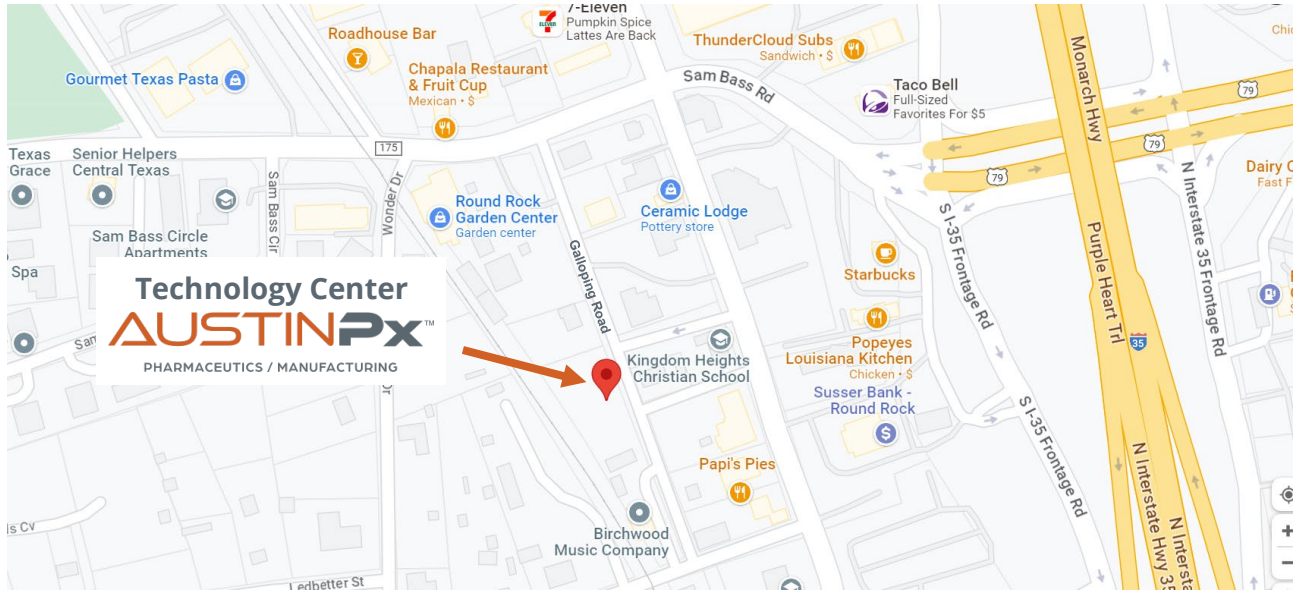
### **Panel Members**

- Feng Zhang, PhD, Associate Professor at The University of Texas at Austin
- Michael Crowley, PhD, President, Theridian Technologies; Adjunct Professor at The University of Texas at Austin; and Co-Founder at Oticara Pharmaceuticals
- Sami Svanbäck, CEO, The Solubility Company Oy



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## DAILY AGENDA & TIMELINE

Day 1: September 13, 2023 Welcome & Dinner	
<b>Location:</b> Sheraton Austin Georgetown Hotel and Convention Center <u>1101 Woodlawn Avenue Georgetown, Texas 78628</u>	
6:00 pm – 7:00 pm	Happy Hour Reception at Jack’s Bar in the Sheraton Hotel
7:00 pm – 8:00 pm	Dinner

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<b>Day 2: September 14, 2023</b> <b>Workshop &amp; Baseball Game</b>	
<b>Location: Dell Diamond, United Heritage Center</b> <b>3400 E Palm Valley Blvd, Round Rock, TX 78665</b>	
7:45 am	<b>Shuttle departure from Sheraton Hotel – Speakers Only</b>
8:00 am	<b>Shuttle departure from Sheraton Hotel – All Others</b>
<b>WORKSHOP</b>	<b>8:30 am – 9:00 am</b> <b>Workshop Check-in</b> United Heritage Center at the Dell Diamond
	<b>9:00 am – 9:15 am</b> <b>Derek Hennecke</b> <i>Welcome &amp; Introductions</i>
	<b>9:15 am – 10:15 am</b> <b>Dana Moseson, PhD, Pfizer</b> <i>Critical Quality Attributes of Amorphous Solid Dispersions (ASDs)</i> ASD formulations rely on the creation and maintenance of supersaturation to enhance bioavailability over formulations using their crystalline counterparts. In this presentation, fundamental aspects of ASD formulations will be presented, highlighting the interplay of material and manufacturing process attributes on ASD properties, critical quality attributes, and product performance. Crystallinity will be specifically considered by understanding its origins and impact of dissolution performance. Crystallinity can be found within an ASD from one of two pathways: (1) incomplete amorphization, or (2) crystal creation (nucleation and crystal growth). While nucleation and crystal growth is the more commonly considered pathway, where crystals originate as a physical stability failure upon accelerated or prolonged storage, manufacturing-based origins of crystallinity are possible as well. Detecting trace levels of crystallinity is a significant analytical challenge, and orthogonal methods should be employed to develop a holistic assessment of sample properties. Probing the impact of crystallinity on release performance which may translate to meaningful clinical significance is inherently challenging, requiring optimization of dissolution test variables to address the complexity of ASD formulations, in terms of drug physicochemical properties (e.g. crystallization tendency), level of crystallinity, crystal reference material selection, and formulation characteristics. The complexity of risk presented by crystallinity to product performance will be illuminated through several case studies, highlighting that a one-size-fits-all approach cannot be used to set specification limits, as the risk of crystallinity can vary widely based on a multitude of factors. Risk assessment considerations surrounding drug physicochemical properties, formulation fundamentals, physical stability, dissolution, and crystal micromeritic properties will be discussed.

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## Continued - Day 2: September 14, 2023 Workshop & Baseball Game

**Location:** Dell Diamond, United Heritage Center

3400 E Palm Valley Blvd, Round Rock, TX 78665

### WORKSHOP

10:15 am - 11:15 am

**David Kwajewski, TIM Company**

*Understanding the Available Suite of Tools Available to Characterize ASD Drug Release in Different Stages of Drug Development*

The use of novel tools in the early stages drug development space has become standard in most formulation development labs for the characterization of drug release. With process-stabilized amorphous formulations becoming commonplace using techniques like spray drying, hot melt extrusion, and Kinetisol, the complexity of characterization and risk assessment has increased. Systems like the MicroDiss have penetrated the CDMO space and pharma alike, meaning most oral drugs in development get measured on these novel platforms at some point in their development life cycle. Services on novel systems like The TIM Company allow for further investigation into the performance of the drug under more physiologically relevant test conditions. Yet, despite the availability of such tools, knowing where, how, and when to apply them continues to be a challenge. This talk will provide an overview of the problem statement around characterizing drug release for ASD formulations, investigate the available suite of in vitro tools, and reference applications where these tools have been successfully implemented to predict in vivo exposure.

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Continued - Day 2: September 14, 2023

Workshop & Baseball Game

**Location:** Dell Diamond, United Heritage Center

3400 E Palm Valley Blvd, Round Rock, TX 78665

<b>WORKSHOP</b>	<b>11:30 am - 12:30 pm</b>	<p><b>Dave Miller, PhD, AustinPx</b></p> <p><i>Why KinetiSol® is Disrupting Spray Drying</i></p> <p>This talk will start by showcasing two case studies of commercial spray dried dispersions replicated with KinetiSol and eliminating toxic solvents, manufacturing complexity, and improving drug product properties. Springboarding off of these case studies, the talk will then focus on the facility, utilities, and down stream processing requirements for SDDs and contrast those with the same for KinetiSol. The second half of the talk will then dive into the biopharmaceutical performance benefits achievable with KinetiSol over spray drying. This will be demonstrated by a series of case studies and explained with rigorous analytical data. At the end of the lecture, the audience will understand that KinetiSol is a commercially ready process not only capable of reproducing SDDs with far less manufacturing complexity and environmental impact, but also with the capability to out design and outperform spray drying.</p>
	<b>12:30 pm - 1:30 pm</b>	<b>Lunch</b>



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## Continued - Day 2: September 14, 2023 Workshop & Baseball Game

**Location:** Dell Diamond, United Heritage Center

3400 E Palm Valley Blvd, Round Rock, TX 78665

<b>WORKSHOP</b>	<b>1:30 pm – 2:30pm</b>	<p><b>Joshua Lomeo, DigiM</b></p> <p><i>Role of Microstructures in Processing, Scale Up, &amp; Performance of ASDs</i></p> <p>The structural properties of amorphous solid dispersions (ASDs) go far beyond particle size. Aspects like porosity, internal and external surface area, and particle wall thickness can have significant impact on the downstream processing and manufacturability of the dispersion at different scales. These structural factors also impact the corresponding structures within the final dose form, and its disintegration and dissolution properties. In this talk, the use of advanced imaging techniques and AI analysis to quantify critical quality attributes of ASDs and final doses will be covered. Case studies from industry will explore how advanced microstructures characterization can guide manufacturing science, troubleshoot scale up challenges, and determine the most ideal ASD manufacturing method. Implications for formulation selection, process development, product quality and regulatory submissions are reviewed.</p>
	<b>2:45 pm – 3:45 pm</b>	<p><b>Justin Keen, PhD, AustinPx</b></p> <p><i>KinetiSol® Technology: Scale Up Approach</i></p> <p>Phase appropriate process development objectives will be reviewed as they relate to scale and mode changes as product development evolves to deliver clinical trial material and develop the process design space. Process parameter and quality attribute relationships, including those for typical pre and post KinetiSol unit operations, will be explored in context of real examples.</p>

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Continued - Day 2: September 14, 2023 Workshop & Baseball Game		
Location: Dell Diamond, United Heritage Center 3400 E Palm Valley Blvd, Round Rock, TX 78665		
<b>WORKSHOP</b>	4:00 pm – 5:00 pm	<p><b>Jim DiNunzio, PhD, Merck</b> <i>Industry Approaches to Solubility Enhancement</i></p> <p>This presentation will discuss industry approaches for managing low solubility compounds in a stage appropriate manner. Covering topics from early identification of solubility issues to approaches for managing challenging compounds from first in human studies through commercialization. It will also highlight opportunities for pivoting dispersion technologies during development and how to manage amorphous control strategies for compounds where crystallization may be a risk.</p>
	5:00 pm – 5:45 pm	<p><b>Panel Discussion</b></p> <ul style="list-style-type: none"> <li>Feng Zhang, PhD, Associate Professor at UT Austin</li> <li>Michael Crowley, PhD, President, Theridian Technologies</li> <li>Sami Svanbäck, CEO, The Solubility Company</li> </ul>
	5:45 pm – 6:00 pm	<b>Workshop Closing</b>
<b>DINNER &amp; GAME</b>	6:00 pm – 7:00 pm	<p><b>Dinner</b> Dell Diamond, United Heritage Center</p>
	7:05pm	<p><b>Round Rock Express Game @ The Dell Diamond</b> Karbach Ranch Water Suite at the Dell Diamond</p>
	TBD – at end of game	Shuttle departure from Dell Diamond to Sheraton Hotel

# Recent Advances in Amorphous Solid Dispersions: Formulation and Characterization Strategies

September 13 - 15, 2023 Hosted by AustinPx

Day 3: September 15, 2023 KinetiSol Demonstrations	
Location: AustinPx Technology Center 8 Galloping Rd, Round Rock, TX 78681	
8:30 am	Shuttle departure from Sheraton Hotel
9:00 am – 9:30 am	<b>Chris Brough, PhD, AustinPx</b> KinetiSol Origin Story & Technology Center Facility Tour
9:30 am – 11:00 am	<b>KinetiSol Demonstrations</b>
11:00 am	Shuttle transportation back to airport

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### HOTEL

#### Sheraton Austin Georgetown Hotel & Conference Center

AustinPx has partnered with Sheraton to provide discounted rates of \$179/night during the event. To be eligible for the discounted rate, please book your room no later than **August 23rd**. [Click here](#) to reserve your room.

### DRESS CODE

Austin is a laid-back place where we value a person's brains more than their clothes. The dress code for the event is business casual and casual.

#### Thursday, September 14<sup>th</sup> Evening

While September in Austin is typically in the 80's, this summer has been unusually HOT for even Texas. While we will have an indoor escape in our hospitality suite, you may want to be outside for the best view, so we recommend **casual clothing** for the baseball game. But we have a saying in Texas, "If you don't like the weather, stick around, it will change." So, check the weather forecast before you leave.

#### Friday, September 15<sup>th</sup>

KinetiSol Technology demonstrations will be held at our Technology Center where we build our KinetiSol equipment. Due to the presence of heavy machinery, **closed toe shoes** are best.

### CONTACTS

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