

RDD2024

Respiratory Drug Delivery



**JW Marriott Starr Pass,
Tucson, **Arizona**
May 5 – 9, 2024**



RDD2024

Respiratory Drug Delivery

JW Marriott Starr Pass, Tucson, Arizona

May 5–9, 2024

Conference Supporters



SUNDAY • MAY 5 • 2024

3:00 – 7:00 p.m.

Registration

Tucson Registration Desk

7:30 – 9:30 p.m.

Welcome Reception

Ania Terrace

Sponsored by Our Conference Supporters

7:30 a.m.	Continental Breakfast Registration	<i>Ania Terrace Tucson Registration Desk</i>
8:30 a.m.	Welcome and Introduction Richard N. Dalby, Ph.D. Professor, School of Pharmacy University of Maryland, Baltimore, Maryland	<i>Arizona Ballroom</i>
8:45 a.m.	Presentation of Charles G. Thiel Award Michael Hindle, Ph.D. Professor, School of Pharmacy Virginia Commonwealth University, Richmond, Virginia	<i>Arizona Ballroom</i>
9:00 a.m.	Keynote <i>Sponsored by Our Conference Supporters</i> Moderator: Joanne Peart, Ph.D. <i>Crystal Ribcage: A Platform for Probing Lung Function in Health and Disease</i> Hadi T. Nia, Ph.D., Boston University, Boston, Massachusetts	<i>Arizona Ballroom</i>
10:00 a.m.	REFRESHMENTS	<i>Tucson Ballroom</i>
10:30 a.m. - 12:00 p.m.	SESSION 1: Searching for the Grail: The Path to Aerosol Surfactant Moderator: Peter R. Byron, Ph.D.	<i>Arizona Ballroom</i>
10:30 a.m.	<i>Aerosolized Surfactants for the Treatment of Neonatal Respiratory Distress Syndrome: Challenges and Opportunities</i> Robert DiBlasi, RRT-NPS, FAARC, Seattle Children's Research Institute, Seattle, Washington	
11:00 a.m.	<i>A Dry Powder Route to Effective Aerosol Surfactant Therapy: A Little Can Go a Long Way</i> Worth Longest, Ph.D., Virginia Commonwealth University, Richmond, Virginia	
11:30 a.m.	<i>AeroFact™: A Clinical Path to Inhaled Surfactant Treatment for Infants and Adults</i> Andrew R. Clark, Ph.D. and James B. Fink, Ph.D., Aerogen Pharma, San Mateo, California	
12:00 p.m.	SESSION 1 ENDS • LUNCH	

12:00 p.m. - 2:00 p.m.	Posters and Exhibition “Grab and Go” Lunch	<i>Tucson Ballroom</i>
2:00 p.m. - 3:00 p.m.	SESSION 2: From Bench to Bedside: New Tools and Targets Moderator: John S. Patton, Ph.D.	<i>Arizona Ballroom</i>
2:00 p.m.	<i>Inhaled mRNA Delivery using Polymeric Nanoparticles</i> Laura Rotolo, Ph.D., Emory University, Atlanta, Georgia	
2:30 p.m.	<i>Development of Inhalable Ion Channel Prosthetics for Cystic Fibrosis</i> Jeffrey G. Weers Ph.D., cystetic Medicines, San Carlos, California	
3:00 p.m.	SESSION 2 ENDS • REFRESHMENTS	<i>Tucson Ballroom</i>
3:30 p.m. - 5:00 p.m.	SESSION 3: Posters on the Podium Moderators: Daniela Traini, Ph.D. and Elizabeth R. Bielski, Ph.D. Poster authors chosen by the Editorial Team present their work during a fast-paced podium session.	<i>Arizona Ballroom</i>
3:35 p.m.	<i>Accelerated Stability and Aerosol Performance Assessment for a Spray Dried Nasal COVID-19 Vaccine Candidate</i> John Chen, Ph.D., Access to Advanced Health Institute, Seattle, Washington	
3:45 p.m.	<i>Designing mRNA Lipid Nanoparticles for Tumor Associated Macrophages: Towards Immunotherapies for the Treatment of Osteosarcoma Lung Metastases</i> Raneem Aldaqq, Pharm.D., Virginia Commonwealth University, Richmond, Virginia	
3:55 p.m.	<i>Evaluating Published Artificial Mucus Models for Understanding Predictability of Inhaled Drug Delivery Dynamics</i> Nishant Shah, M.S., University of Michigan, Ann Arbor, Michigan	
4:05 p.m.	<i>Enhancing Nose-to-Brain Drug Delivery: A Comparative Study of Peptide Formulations Using a Multidose Nasal Spray</i> Jerry Wong, Ph.D., Macquarie University, Sydney, Australia	
4:15 p.m.	<i>Tuning the Aerosol Delivery of the RespiMat® Soft Mist Inhaler</i> Moritz Fleischhauer, B.Pharm., Johannes Gutenberg-Universität Mainz, Germany	

MONDAY • MAY 6 • 2024 continued**SESSION 3 (continued)***Arizona Ballroom*

- 4:25 p.m. ***Measurement of Vapor Pressure and Viscosity of Ethanol in HFA134a, HFA152a, and HFO1234ze(E) Mixtures used in pMDIs***
Swetha Chowdary Vutlapalli, M.Eng.,
Monash University, Melbourne, Australia
- 4:35 p.m. ***The Fluid Dynamics of a Dry Powder Inhaler Assisted with a Zero-Net-Mass-Flux Jet***
Rina Perven, M.Eng.,
Monash University, Melbourne, Australia
- 4:45 p.m. ***Optical Photothermal Infrared Spectroscopic Assessment of Fluticasone/Salmeterol/Lactose Co-Association in Advair Diskus® and Wixela Inhub®***
Dipesh Khanal, Ph.D.,
University of Sydney, Sydney, Australia
- 4:55 p.m. **Presentation of VCU RDD Peter R. Byron Graduate Student Award**

5:00 p.m. SESSION 3 ENDS

- 5:00 p.m. - **Posters and Exhibition Evening Reception** *Tucson Ballroom*
7:00 p.m. ***Bringing Science, Innovation and People Together***

TUESDAY • MAY 7 • 2024

- 7:30 a.m. **Continental Breakfast** *Ania Terrace*
Registration *Tucson Registration Desk*

8:30 a.m. - **SESSION 4: Nasal Spotlight** *Arizona Ballroom*
9:30 a.m..

Moderator: Julie D. Suman, Ph.D.

- 8:30 a.m. ***A Dry Powder Platform for Thermostable, Adjuvanted, Nasal Vaccines***
Reinhard Vehring, Ph.D.,
Access to Advanced Health Institute, Seattle, Washington

- 9:00 a.m. ***Targeting the Brain via Intranasal Delivery: Rationale, Progress and Challenges***
Daniela Traini, Ph.D.,
Macquarie University and Woolcock Institute of Medical Research,
Sydney, Australia

- 9:30 a.m. **SESSION 4 ENDS • REFRESHMENTS** *Tucson Ballroom*

10:00 a.m. - 12:00 p.m.	SESSION 5: Inhalation Innovation: Regulatory Initiatives to Expand the Generic Marketplace	<i>Arizona Ballroom</i>
	Moderator: Martin Oliver, Ph.D.	
10:00 a.m.	<i>Challenging the Relevance of Inhaler Patents in the Orange Book</i>	
	Kurt R. Karst, JD, Hyman, Phelps & McNamara, Washington, D.C.	
10:30 a.m.	<i>FDA Recommendations for the Design and Implementation of In Vitro and In Vivo Alternative Bioequivalence Approaches</i>	
	Elizabeth R. Bielski, Ph.D. and Susan Boc, Ph.D., U.S. Food and Drug Administration, Silver Spring, Maryland	
11:00 a.m.	<i>FDA Recommendations for Alternative Bioequivalence Approaches: Design, Validation, and Use Case for In Silico Studies</i>	
	Ross Walenga, Ph.D., U.S. Food and Drug Administration, Silver Spring, Maryland	
11:30 a.m.	<i>An Industry Perspective on FDA's Alternative Approaches to Comparative Clinical End Point Studies for Generic Inhalation Products</i>	
	Stephen Devereux, Ph.D., Teva Pharmaceuticals, Waterford, Ireland	

12:00 p.m. **SESSION 5 ENDS • LUNCH**

12:00 p.m. - 2:00 p.m.	Posters and Exhibition "Grab and Go" Lunch	<i>Tucson Ballroom</i>
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2:00 p.m. - 5:00 p.m.	SESSION 6: WORKSHOPS	<i>Arizona Ballroom Salons 1-5, 8-12, San Luis and San Pedro</i>
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The following companies will host 45-minute interactive presentations on new technologies related to aerosol drug delivery. Meeting participants may select and attend **THREE** of these sessions.

Refreshments will be available throughout the afternoon.

2:00 p.m.	Workshop Selection #1
3:00 p.m.	Workshop Selection #2
4:00 p.m.	Workshop Selection #3



Empowering the Path to Clinical: Innovative Strategies for De-Risking Product Development

Arizona 5



Manufacturing pMDIs using Ultra-low Global Warming Potential Propellant HFO-1234ze(E)

San Pedro 1 & 2



Build Your Own Soft Mist Inhaler

Arizona 8



Practical Considerations for Development and Scale-up of Spray Dried Inhalation Powders

Arizona 1



Automating Inhaled and Nasal Product Testing: Lower Variability, Higher Productivity

Arizona 12



A Modular Approach to Understand the Design Space of a Capsule-based High-performance DPI

Arizona 2



Nasal Powders: Formulation and Device Integration

Arizona 10



Exploring *In Vitro* Only Bioequivalence Pathways for Generic Nasal Suspensions

Arizona 11



Considering a Green pMDI? Q&A to Navigate an Evolving Regulatory Landscape

San Luis 1 & 2



Integrated Carrier-based Formulation Development: Process and Performance Considerations

Arizona 3



Blending Optimization in Multi-component DPI Formulations

Arizona 4



A New Approach to Optimize Delivery Performance and Treatment Time in Breath-Triggered Nebulizers

Arizona 9

5:00 p.m.

SESSION 6 ENDS

5:00 - 7:00 p.m.

Posters and Exhibition Evening Reception
Bringing Science, Innovation and People Together

Tucson Ballroom

7:30 - 9:30 p.m.

AAPS Inhalation & Nasal Community
The Inhalation-based Biopharmaceuticals Classification System: What the iBCS can do with a little help from all of you?

Arizona 1 & 2



Jayne Hastedt, Ph.D.,
JDP Pharma Consulting

8:00 a.m. **Continental Breakfast** *Ania Terrace*

NETWORKING AND RECREATION BREAK

Participants can play golf, tennis, take an excursion, visit the spa, or relax.

2:00 p.m. - **SESSION 7: Aqueous Advances:** *Arizona Ballroom*
 3:00 p.m. **Next Generation Aqueous Products**

Moderator: Paul M. Young, Ph.D.

2:00 p.m. ***Sorting through Soft Mists: Generics, Biologics and Beyond***

Darragh Murnane, Ph.D.,
 University of Hertfordshire, Hatfield, United Kingdom

2:30 p.m. ***From Liquid to Aerosol: Exploring Droplet Formation in Vibrating Mesh Nebulizers***

Benjamin Heine, Dr.-Ing.,
 PARI Pharma, Starnberg, Germany

3:00 p.m. **SESSION 7 ENDS • REFRESHMENTS** *Tucson Ballroom*

3:30 p.m. - **SESSION 8: High Dose Lung Delivery:** *Arizona Ballroom*
 5:00 p.m. **Changing the Treatment Paradigm for Lung Diseases**

Moderator: Paul J. Atkins, Ph.D.

3:30 p.m. ***The Evolving Unmet Need for High Dose Inhaled Therapies in Orphan Lung Diseases***

Thomas Hofmann, MD Ph.D.,
 Aumapharma, Doylestown, Pennsylvania

4:00 p.m. ***Overcoming Biological and Technical Challenges to Achieve High Dose Lung Delivery***

Anthony J. Hickey, Ph.D. Sc.D.,
 Astartein and University of North Carolina, Chapel Hill, North Carolina

4:30 p.m. ***Patient Focused Device Design for High Payload Therapies***

Hugh D. C. Smyth, Ph.D.,
 The University of Texas at Austin, Austin, Texas

5:00 p.m. **SESSION 8 ENDS**

6:30 p.m. **Cocktail Reception** *Ania Terrace*

7:30 p.m. **Dinner and Dancing** *Tucson Ballroom*

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7:30 a.m.	Continental Breakfast Registration	Ania Terrace Tucson Registration Desk
9:00 a.m. - 12:00 p.m.	SESSION 9: MDIs in Transition: A Regulatory Roadmap to Market	Arizona Ballroom
	Moderator: Joanne Peart, Ph.D.	
9:00 a.m.	Generic Symbicort: Navigating the Regulatory Hurdles for Budesonide / Formoterol Fumarate pMDI	
	Stephen W. Stein, M.Sc., Kindeva Drug Delivery, Woodbury, Minnesota	
9:30 a.m.	U.S. Regulatory Considerations for Low Global Warming Potential Propellant Transition for Brand and Generic MDIs	
	Bryan Newman, Ph.D. and Markham C. Luke, MD, Ph.D., U.S. Food and Drug Administration, Silver Spring, Maryland	
10:00 a.m.	A Regulatory Roadmap for the Transition to Low GWP pMDIs: A Proposal for Discussion	
	Richard Lostritto, Ph.D., Lostritto Consulting LLC, Maitland, Florida	
10:30 a.m.	REFRESHMENTS	Ania Terrace
11:00 a.m.	Explore with Experts: Panel Discussion A Regulatory Roadmap to Market	
12:00 p.m.	SESSION 9 ENDS	
12:00 p.m. - 2:00 p.m.	Luncheon <i>Sponsored by Our Conference Supporters</i>	Ania Terrace
	   	
2:00 p.m.	END OF RESPIRATORY DRUG DELIVERY 2024	




November 19-21, 2024
Grand Hyatt Kochi • Kerala, INDIA

Speaker Proposals: June 1, 2024	Workshop Proposals June 1, 2024	Poster Abstract Deadline: August 1, 2024
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