

Program Agenda

ECU 3rd Annual Spring Pharma Conference

May 10-11, 2022

#ECUpharma



Brought to you by the ECU Eastern Region Pharma Center and the Office of Continuing Professional Education

SPRING BREAK 2022 PHARMA CONFERENCE

Day 1

Event Locations ● Lobby ● 1006 ● 1001 ● 3002 ● 4007

8:00am - 8:30am	Check-In	Coffee, Doughnuts
8:30am - 8:45am	Day 1 Welcome	Jack Pender , <i>ECU ERPC</i>
8:45am - 9:30am	The Lab Analyst's Role	Michael DeHart , <i>CMP Pharma</i>
9:30am - 10:00am	Networking Break	Light snacks, Conversation
10:00am - 10:45am	Advanced Modeling from Highly Accelerated Stability Testing (ASAP) to Determine Drug Product Stability	Kenneth C. Waterman , <i>FreeThink Technologies (virtual)</i>
10:45am - 11:00am	Break	

Breakout Session 1 | 11:00am - 11:45am

PHARMA FUNDAMENTALS	METHOD DEVELOPMENT & VALIDATION	QUALITY
The Drug Development Process <small>PRESENTED BY:</small> Wael Elmasri <i>Thermo Fisher Scientific</i>	USP <1220> Analytical Procedure Lifecycle <small>PRESENTED BY:</small> Lucy Botros <i>Thermo Fisher Scientific</i>	Why is Electronic CDS Data a Major Data Concern for Regulators? <small>PRESENTED BY:</small> Emily Cluggish <i>Waters Corporation</i>

11:45am - 1:00pm	Lunch	Sponsored by <i>Sequence, Inc.</i>
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Breakout Session 2 | 1:00pm - 1:45pm

PHARMA FUNDAMENTALS	METHOD DEVELOPMENT & VALIDATION	QUALITY
What makes a Lab GMP? <small>PRESENTED BY:</small> Kimberly Lupo <i>Portrett Pharmaceuticals</i>	Comments and Insights on Draft ICH Q2 (Rev 2) <small>PRESENTED BY:</small> Pierre Lebrun <i>PharmaLex</i>	Quality During a Global Pandemic <small>PRESENTED BY:</small> Wendy Haines <i>PharmEng Technology Inc.</i>

Breakout Session 3 | 2:00pm - 2:45pm

PHARMA FUNDAMENTALS	METHOD DEVELOPMENT & VALIDATION	QUALITY
Stability Programs 101 <small>PRESENTED BY:</small> John Glennon <i>Novo Nordisk</i>	Understanding the Relationship between Total Error and Measurement Uncertainty <small>PRESENTED BY:</small> Pierre Lebrun <i>PharmaLex</i>	What will change with the new Computer Software Assurance Guidance document? <small>PRESENTED BY:</small> Joseph Franchetti <i>JAF Consulting, Inc.</i>

2:45pm - 3:15pm	Networking Break	
3:15pm - 4:00pm	Reflections on a Pharma Career	Tom Wilson , <i>Retired</i>
4:00pm - 6:00pm	Welcome Reception	Sponsored by <i>CMP Pharma</i>

Event Locations ● Lobby ● 1006 ● 1001 ● 3002

8:00am - 8:30am	Check-In	Coffee, Doughnuts
8:30am - 8:45am	Day 2 Welcome	Jack Pender , ECU ERPC
8:45am - 9:30am	Inside the USP: General Chapter Development and Revision Process	Lucy Botros , Thermo Fisher Scientific
9:30am - 10:00am	Networking Break	Light snacks, Conversation
10:00am - 10:45am	Analytical Development within a CDMO - Focus Assay: Capillary Electrophoresis, Sodium Dodecyl Sulfate	Emily Bermes , Thermo Fisher Scientific
10:45am - 11:00am	Break	

Breakout Session 4 | 11:00am - 11:45am

PHARMA FUNDAMENTALS	METHOD DEVELOPMENT & VALIDATION	QUALITY
Dissolution Fundamentals PRESENTED BY: Ken Boda Agilent Technologies	Choosing an HPLC column: Phases Explained PRESENTED BY: Ali Khorasani Phenomenex	Quality 4.0 Future of Quality Technology and Innovation PRESENTED BY: Amy Taylor Novo Nordisk

11:45am - 1:00pm	Lunch
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Breakout Session 5 | 1:00pm - 1:45pm

PHARMA FUNDAMENTALS	METHOD DEVELOPMENT & VALIDATION	QUALITY
What is Data Integrity? PRESENTED BY: Ryan Edgerton Thermo Fisher Scientific	Analytical QbD Practices with FUSION in Method Development PRESENTED BY: Zhimin Liu Thermo Fisher Scientific	How Project Management and Project Planning Contribute to Quality in an Organization PRESENTED BY: Jason Baird PharmEng Technology Inc.

Breakout Session 6 | 2:00pm - 2:45pm

PHARMA FUNDAMENTALS	METHOD DEVELOPMENT & VALIDATION	QUALITY
Understanding HPLC System Suitability: Arts and Crafts Session PRESENTED BY: Jack Pender ECU ERPC	Analytical QbD and Draft ICH Q14: Analytical Procedure Development PRESENTED BY: Pierre Lebrun PharmaLex	Regulatory Expectations for Laboratory Investigations PRESENTED BY: Amy Taylor Novo Nordisk

2:45pm - 3:15pm	Networking Break & Vendor Raffle	
3:15pm - 4:00pm	Survey of Recent Warning Letters	Joseph Franchetti , JAF Consulting, Inc.
4:00pm - 4:30pm	Conference Wrap Up	Jack Pender , ECU ERPC

2022 ECU Spring Pharma Conference

3rd Annual

Thank you to our Program Sponsors and Exhibitors!

GOLD



PURPLE



Conference Patrons: NC Biotech and Thermo Fisher Scientific

Exhibitors: PharmaLex	Brandtech Scientific	Beckman Coulter Life Sciences
Bruker Scientific, LLC	Thermo Fisher Scientific	Lighthouse Worldwide Solutions
JAF Consulting, Inc.	Portrett Pharmaceuticals	Sequence, Inc.
Waters Corporation	Quality Chemical Laboratories	

Pharma Fundamentals

Designed to supplement the practical knowledge early-career professionals use daily with a broader understanding of the pharmaceutical industry and address the "why" behind common pharma approaches.

Method Development & Validation Sessions

Designed to address issues in MD/MV with emphasis on understanding the Analytical Method Lifecycle Approach.

Quality Sessions

Designed for Quality and Advanced Laboratory Professionals to discuss current trends and best practices in pharma quality.