ECU 3rd Annual Spring Pharma Conference

May 10-11, 2022
#ECUpharma
8:00am - 8:30am  
Check-In

Coffee, Doughnuts

8:30am - 8:45am  
Day 1 Welcome

Jack Pender, ECU ERPC

8:45am - 9:30am  
The Lab Analyst’s Role

Michael DeHart, CMP Pharma

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, FreeThink Technologies (virtual)

10:45am - 11:00am  
Break

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

PHARMA FUNDAMENTALS

The Drug Development Process  
PRESENTED BY: Wael Elmasri  
Thermo Fisher Scientific

METHOD DEVELOPMENT & VALIDATION

USP <1220> Analytical Procedure Lifecycle  
PRESENTED BY: Lucy Botros  
Thermo Fisher Scientific

QUALITY

Why is Electronic CDS Data a Major Data Concern for Regulators?  
PRESENTED BY: Emily Cluggish  
Waters Corporation

11:45am - 1:00pm  
Lunch

Sponsored by Sequence, Inc.

1:00pm - 1:45pm  
Breakout Session 2

PHARMA FUNDAMENTALS

What makes a Lab GMP?  
PRESENTED BY: Kimberly Lupo  
Portrett Pharmaceuticals

METHOD DEVELOPMENT & VALIDATION

Comments and Insights on Draft ICH Q2 (Rev 2)  
PRESENTED BY: Pierre Lebrun  
PharmaLex

QUALITY

Quality During a Global Pandemic  
PRESENTED BY: Wendy Haines  
PharmEng Technology Inc.

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

PHARMA FUNDAMENTALS

Stability Programs 101  
PRESENTED BY: John Glennon  
Novo Nordisk

METHOD DEVELOPMENT & VALIDATION

Understanding the Relationship between Total Error and Measurement Uncertainty  
PRESENTED BY: Pierre Lebrun  
PharmaLex

QUALITY

What will change with the new Computer Software Assurance Guidance document?  
PRESENTED BY: Joseph Franchetti  
JAF Consulting, Inc.

2:45pm - 3:15pm  
Networking Break

3:15pm - 4:00pm  
Reflections on a Pharma Career  
Tom Wilson, Retired

4:00pm - 6:00pm  
Welcome Reception  
Sponsored by CMP Pharma
## Day 2

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

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**PRESENTED BY:**  
- Ken Boda  
  Agilent Technologies

**PRESENTED BY:**  
- Ali Khorasani  
  Phenomenex

| Coffee, Doughnuts |

### Breakout Session 5  1:00pm - 1:45pm

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**PRESENTED BY:**  
- Ryan Edgerton  
  Thermo Fisher Scientific

**PRESENTED BY:**  
- Zhimin Liu  
  Thermo Fisher Scientific

| Analytics and Draft ICH Q14: Analytical Procedure Development |

**PRESENTED BY:**  
- Pierre Lebrun  
  PharmaLex

| Regulatory Expectations for Laboratory Investigations |

**PRESENTED BY:**  
- Amy Taylor  
  Novo Nordisk

| 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

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Thank you to our Program Sponsors and Exhibitors!

Conference Patrons: NC Biotech and Thermo Fisher Scientific

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

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.

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