

ECU Spring Break 2019 Pharma Conference

Back to Basics: The Pharmaceutical Industry

March 5th and 6th

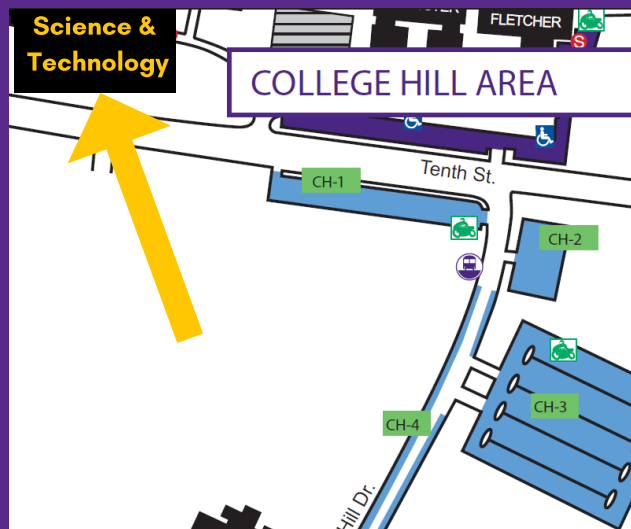
Summary:

During this 2-day conference attendees will participate in lectures and discussions led by regional experts covering an array of topics fundamental to working in the pharmaceutical industry. The presentations are intended to supplement the practical knowledge working professionals use daily with a broader understanding of the pharmaceutical industry and the regulations that govern it. In addition to the formal program, attendees will have substantial time for discussions with experts and peers during breaks, meals, and social times.

Location and Information:

Third floor, Science and Technology Building,
East Carolina University, Room 346.

Beverages, lunch, snacks, lecture slides, and supplemental materials will be provided.



Contact
Dr. Jack Pender
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Attendees should park
in the CH-3 Lot
(no permit required).

ECU Spring Break 2019 Pharma Conference Agenda

March 5th, 2019		
Time	Topic	Presenter
8:30-8:50 am	Check in; coffee, doughnuts, conversation	
8:50-9:05 am	Welcome, Opening Remarks	Jack Pender ECU Chemistry, Pharma Center
9:05-9:50 am	Introduction to the Pharmaceutical Industry; History and Law	Keith Holmes ECU Chemistry, Pharma Center
10:00-10:45 am	Drug Development Process	Wael Elmasri Thermo Fisher Scientific
10:45-11:15 am	Morning Break; light snacks, conversation	
11:15-12:00 pm	Quality Systems	Angela Swain Thermo Fisher Scientific
12:00-12:50 pm	Lunch; Catered, conversation	
1:00-1:50 pm	Electronic Records, Part 11, and Data Integrity	Stacy Southerland Thermo Fisher Scientific
2:00-2:50 pm	Stability Programs	Boyce Johnson Mayne Pharma
2:50-3:15 pm	Afternoon Break; light snacks, conversation	
3:15-4:15 pm	The USP Organization and Compendia Testing	Alan Potts and Martina Jones Thermo Fisher Scientific
4:15-5:00 pm	Social Hour, End of Day 1	
March 6th, 2019		
Time	Topic	Presenter
8:30-8:50 am	Coffee, doughnuts, conversation	
9:00-9:50 am	Introduction to Validation	Jennifer Popovich Mayne Pharma
10:00-10:45 am	The Purpose of Common Pharma Test Methods	Michael Dehart CMP Pharma
10:45-11:15 am	Morning Break; light snacks, conversation	
11:15-12:00 pm	Analytical Methods Validation, Transfer, System Suitability	Richard Vinson Mayne Pharma
12:00-12:50 pm	Lunch; Catered, conversation	
1:00-1:50 pm	Introduction to Regulatory Filings	Kimberly Lupo Mayne Pharma
2:00-2:50 pm	Survey of Recent Warning Letters	Angela Swain Thermo Fisher Scientific
2:50-3:15 pm	Afternoon Break; light snacks, conversation	
3:15-3:45 pm	Finding Guidance....CFR, FDA, USP, PF, Conferences, and Other Resources	Jack Pender ECU Chemistry, Pharma Center
3:45-4:00 pm	Conference Wrap-up, Feedback, and Future Events	

Rates:

Standard Attendee \$199
ECU Faculty/Staff \$99
ECU Student \$39

Registration:

<https://cpe.ecu.edu/course-catalog/arts-sciences/ecu-spring-break-2019-pharma-conference-back-to-basics-the-pharmaceutical-industry/>