SPRING BREAK **2020** PHARMA CONFERENCE | Day 1

Session Locations 430 C309 440 Atrium

8:30-8:50	**Check-in**	**Coffee, Doughnuts**
8:50-9:05	**Welcome, Opening Remarks**	**Jack Pender,** *ECU Chemistry Pharm Ctr*
9:05-9:50	**Drug Development Process from Discovery to Market**	**Wael Elmasri,** *Thermo Fisher Scientific*
10:00-10:45	**It's Not Working! What Will Work?** The Lifecycle Approach for Methods	**Jane Weitzel,** *Independent Consultant*
10:45-11:15	**Morning Break**	**Light Snacks, Conversation**

Breakout Session 1 | 11:15-12:00

Stability	Method Development/Validation	Quality
Stability Programs 101 **PRESENTED BY:** Boyce Johnson *Mayne Pharma*	**HPLC Method Development Part 1:** Overview, Traditional Approaches and Tools **PRESENTED BY:** Michael Dong *MWD Consulting*	**Quality Management System Review** **PRESENTED BY:** John Suedbeck *Merck*

12:00-12:50	**Lunch**	**Catered, Olive Garden**

Breakout Session 2 | 1:00-1:45

Stability Study Design by Phase of Clinical Development **PRESENTED BY:** Geoff Carr *Patheon by Thermo Fisher Scientific (Ontario)*	**HPLC Method Development Part 2:** Easier Approaches for Early-Phase Methods **PRESENTED BY:** Michael Dong *MWD Consulting*	**"Know Thy Data"** Statistical Techniques for Analyzing Data **PRESENTED BY:** Tammy Triplett *Mayne Pharma*

Breakout Session 3 | 2:00-2:45

Adulterated to Misbranded – When Stability Gets a Warning Letter **PRESENTED BY:** Jennifer Alligood *CMP Pharma*	**Analytical Quality By Design:** aQbD for Analytical Methods **PRESENTED BY:** Jane Weitzel *Independent Consultant*	**ASQ Programs, Certifications, and Your Local Chapter** **PRESENTED BY:** John Suedbeck *ASQ Chapter 1126*

2:45-3:45	**Special Afternoon Break - Social Hour**	**Sponsored by Distek**
3:45-4:30	**Test Methods in Common:** An "Analytical Formulator's" Prospective*	**Michael DeHart,** *CMP Pharma*
4:30-Until	**Optional Gathering Uptown Greenville**	

*2019 Conference Favorite

SPRING BREAK **2020** PHARMA CONFERENCE | Day 2

Session Locations 430 C309 440 Atrium

8:30-9:00	**Morning Welcome**	**Coffee, Bagels**
9:00-9:45	**Quality Standard Setting Process –** A Perspective of USP's Role*	**Alan Potts,** *Thermo Fisher Scientific*
10:00-10:45	**Biopharmaceuticals –** An Overview of Process Manufacturing and Analytical Testing	**Janet Davis,** *Thermo Fisher Scientific*
10:45-11:15	**Morning Break**	**Light Snacks, Conversation**

Breakout Session 4 | 11:15-12:00

Stability	Method Development/Validation	Quality
Stability Data Evaluation and Shelf-life Projection **PRESENTED BY:** Craig Hamilton *H&A Scientific*	**Forced Degradation Studies** **PRESENTED BY:** Geoff Carr *Patheon by Thermo Fisher Scientific (Ontario)*	**Effective Root Cause Analysis** **PRESENTED BY:** Tammy Triplett *Mayne Pharma*

12:00-12:50	**Lunch**	**Catered, GK Café**

Breakout Session 5 | 1:00-1:45

Special Purpose Studies **PRESENTED BY:** Vonda Sheppard *Mayne Pharma*	**HPLC Method Validation:** Overview, Methodologies, and Case Studies **PRESENTED BY:** Michael Dong *MWD Consulting*	**Corrective and Preventative Actions** **PRESENTED BY:** Jerry Zemble *Purdue Pharma*

Breakout Session 6 | 2:00-2:45

Packaging Configuration and Product Type Impact on Stability Testing Requirements **PRESENTED BY:** Kristi Pittman *Fresenius Kabi*	**Uncertainty and Statistics for Method Validation** **PRESENTED BY:** Jane Weitzel *Independent Consultant*	**Sampling Types and Plans Used in the Pharmaceutical Industry** **PRESENTED BY:** Dan Carlson *ASQ Chapter 1126*

2:45-3:15	**Afternoon Break & Raffle**	
3:15-4:00	**What's Hot?** A Survey of Recent Warning Letters	**Angela Corbin,** *Thermo Fisher Scientific*
4:00-4:30	**Discussion and Conference Wrap up**	**Jack Pender,** *ECU Chemistry Pharm Ctr*