

VALIDATION WEEK

EUROPE

INDUSTRY'S LEADER IN GLOBAL VALIDATION
13-15 MARCH 2018 • BRUSSELS, BELGIUM

DAY ONE — TUESDAY, 13 MARCH 2018

12:00	Main Conference Registration
13:15	Chairman's Welcome and Opening Remarks
13:30	KEYNOTE ADDRESS REGULATORY PULSE ON EMERGING ENFORCEMENT TRENDS AND RECENT WARNING LETTERS
14:15	GLOBAL REGULATORY SHOWCASE VALIDATION BEYOND BORDERS — NAVIGATE GUIDING PRINCIPLES AND REGULATIONS ACROSS THE WORLD
15:00	<i>Networking and Refreshment Break</i>
15:30	DATA INTEGRITY SPOTLIGHT A NEW WAVE OF RISK — PROACTIVE STRATEGIES FOR THE PREVENTION AND REMEDIATION OF DATA INTEGRITY NON-COMPLIANCE
16:15	INNOVATIVE INSIGHTS PHARMA 4.0 — INNOVATIVE PARADIGM TRANSFORMING MANUFACTURING
17:00	<i>Close of Day One Networking, Wine and Cheese Reception</i>

DAY TWO — WEDNESDAY, 14 MARCH 2018

8:00	Continental Breakfast	
8:30	CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (1-3)	
	Session 1 Validation Boot Camp — A Lifecycle Approach to Validation Examining Principles, Implementation, Documentation Requirements and Practice	Session 2 CSV Playbook — An Agile Program in an Increasingly Electronic Environment
	Session 3 Robust Cleaning Validation Program — Deep-Dive into Aseptic Processing and Environmental Processing	
10:00	<i>Networking and Refreshment Break</i>	
10:30	CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (4-6)	
	Session 4 Change Control — Optimal Management and Revalidation	Session 5 Critical Components of a Master Validation Plan (MVP)
	Session 6 Conduct a Gap Analysis of Your Process Validation Program	
12:00	<i>Networking Luncheon</i>	
13:00	CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (7-9)	
	Session 7 Align Validation with FDA's Quality Metrics Guidance — What You Need to Know	Session 8 Utilize Statistics to Design Sampling Plans that Align with Global Regulatory Expectations
	Session 9 Continued Process Verification (CPV) — A Systems Approach	
14:30	<i>Networking and Refreshment Break</i>	

VALIDATION WEEK *Cont.*

15:00 **CHOOSE BETWEEN THREE 90-MINUTE SESSION (10-12)**

Session 10
Understand, Detect and Control Variation

Session 11
Equipment Qualification — Ensure Fit for Intended Use

Session 12
Integrate Quality by Design (QbD) into Process Validation

16:30 *Close of Day Two*

DAY THREE — THURSDAY, 15 MARCH 2018

8:00 *Continental Breakfast*

8:30 **CHOOSE BETWEEN TWO IN-DEPTH AND INCLUSIVE WORKSHOPS (I-II)**

WORKSHOP I:
Product Complaints and Recalls—Best Practices and Industry Playbook for Effective Processing, Handling, Trending and Analysis

WORKSHOP II:
Develop and Implement Risk-Based Approaches for Data Integrity

**There will be a Networking Refreshment Break at 10:00*

12:00 *Networking Luncheon*

13:00 **CHOOSE BETWEEN TWO 90-MINUTE SUMMITS (A-B)**

SUMMIT A:
Learn How to Conduct Effective Supplier Audits

SUMMIT B:
Qualify Cloud and Network Infrastructures

14:30 *Networking Refreshment Break*

15:00 **CHOOSE FROM TWO 60-MINUTE SUMMITS (C-D)**

SUMMIT C:
Leading Validation Frameworks for OTC and Consumers Products

SUMMIT D:
Think Tank for Pharma's Top Challenges within a Highly Regulated Industry

16:00 *Close of Conference*

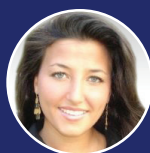
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