

# 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	<b>KEYNOTE ADDRESS</b> REGULATORY PULSE ON EMERGING ENFORCEMENT TRENDS AND RECENT WARNING LETTERS
14:15	<b>GLOBAL REGULATORY SHOWCASE</b> VALIDATION BEYOND BORDERS — NAVIGATE GUIDING PRINCIPLES AND REGULATIONS ACROSS THE WORLD
15:00	<i>Networking and Refreshment Break</i>
15:30	<b>DATA INTEGRITY SPOTLIGHT</b> A NEW WAVE OF RISK — PROACTIVE STRATEGIES FOR THE PREVENTION AND REMEDIATION OF DATA INTEGRITY NON-COMPLIANCE
16:15	<b>INNOVATIVE INSIGHTS</b> 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	<b>CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (1-3)</b>		
	<b>Session 1</b> Validation Boot Camp — A Lifecycle Approach to Validation Examining Principles, Implementation, Documentation Requirements and Practice	<b>Session 2</b> CSV Playbook — An Agile Program in an Increasingly Electronic Environment	<b>Session 3</b> Robust Cleaning Validation Program — Deep-Dive into Aseptic Processing and Environmental Processing
10:00	<i>Networking and Refreshment Break</i>		
10:30	<b>CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (4-6)</b>		
	<b>Session 4</b> Change Control — Optimal Management and Revalidation	<b>Session 5</b> Critical Components of a Master Validation Plan (MVP)	<b>Session 6</b> Conduct a Gap Analysis of Your Process Validation Program
12:00	<i>Networking Luncheon</i>		
13:00	<b>CHOOSE BETWEEN THREE 90-MINUTE SESSIONS (7-9)</b>		
	<b>Session 7</b> Align Validation with FDA's Quality Metrics Guidance — What You Need to Know	<b>Session 8</b> Utilize Statistics to Design Sampling Plans that Align with Global Regulatory Expectations	<b>Session 9</b> 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, 30 MARCH 2017

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*

## 3 EASY WAYS TO REGISTER

**WEBSITE:**  
[cbinet.com/valweekeu](http://cbinet.com/valweekeu)

**PHONE**  
800.817.8601

**EMAIL**  
[cbireg@cbinet.com](mailto:cbireg@cbinet.com)

## WANT TO GET INVOLVED?



**SPEAKING OPPORTUNITIES**

Caitlin Murgia  
E: [caitlin.murgia@cbinet.com](mailto:caitlin.murgia@cbinet.com)  
P: 339.298.2104



**SPONSORSHIP OPPORTUNITIES**

Hunter Gates  
E: [hunter.gates@ivtnetwork.com](mailto:hunter.gates@ivtnetwork.com)  
P: 339.298.2108



**REGISTER YOURSELF OR YOUR TEAM**

Michael Berube  
E: [michael.berube@cbinet.com](mailto:michael.berube@cbinet.com)  
P: 339.298.2185