



# CSV & CSA UNIVERSITY EUROPE

**ENSURING COMPLIANCE AND  
INTEGRITY ACROSS TRADITIONAL,  
DIGITAL, AND AI-DRIVEN SYSTEMS**

**CORK, IRELAND | 4-5 JUNE 2025**  
ATTEND VIRTUALLY OR IN-PERSON

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## ELITE FACULTY WITH REPRESENTATION FROM



Nelly Chankovo  
Head of Global Consulting  
**Körber Pharma Software**



Stefan Münch  
VP Validation &  
Qualification  
**Körber Pharma Consulting**



Oisín Curran  
Founder  
**Odyssey VC**



Steven Davy  
Research Centre  
Manager Sustainable  
Digital Technologies,  
**TU Dublin**



Donncadh Nagle  
Commissioning  
Qualification &  
Validation Lead  
**Jacobs Engineering Group Inc.**, Assistant  
Lecturer, **TU Dublin**



Joanne Goldberg  
Senior Principal  
Business Analyst  
**Medtronic**



Ben O'Brien  
Business  
Development Partner  
**ERA Science**



Kir Henrici  
Chief Executive  
Officer - Principal  
**The Henrici Group**



Andy O'Connor  
Executive Director  
**ERA Sciences**



Dr. Ulrich Köllisch  
Partner  
**GXP - CC**



Dave O'Connor  
CQV Digital  
Transformation Manager  
**No Deviation**



Catherine Lunardi  
CEO  
**GenAIz**



Kevin O'Donnell  
Manager Market  
Compliance HPRA;  
Adjunct Professor,  
**TU Dublin** (Invited)



Laurent Martin  
SQA Domain Lead,  
Digital & Regional IT QA,  
Quality & Compliance,  
BTS, **Abbott**



Eustache Paramithiotis  
Vice President,  
Research and  
Development  
**CellCarta**

## ELITE FACULTY WITH REPRESENTATION FROM



William Ryan  
Senior Manager  
OUS SQA Operations  
**Abbott**



Ken Shitamoto  
Executive Director IT  
**Gilead Sciences**



Raul Soto, MSc, CQE,  
MedTech Senior  
Manager, Digital  
Transformation  
Excellence Systems,  
**Johnson & Johnson**



Frederik Thiele  
VP Line Optimizer  
**Körber Pharma  
Consulting**



Pat Tobin  
Project Manager  
Validation  
**Regeneron**



Gaurav Walia  
VP of CSV/CSA/DI and  
Digital Governance,  
Head of PQE Chicago  
Officer and Senior  
Associate Partner,  
**PQE Group**



Sean Walsh  
Associate Director,  
Capital Projects  
Digital Delivery,  
Manufacturing Value  
Team, DMMD  
**MSD**

7:20 - 8:20	<b>Registration - Coffee &amp; Tea</b>
8:20 - 8:30	<b>Chairperson's Opening Remarks</b>
8:30 - 9:00	
Keynote	<b>Revolutionizing CSV: Embracing Critical Thinking, Risk Analysis, and Cutting-Edge Tools in an Evolving Tech Landscape</b> Gaurav Walia, VP of CSV/CSA/DI and Digital Governance, Head of PQE Chicago Officer and Senior Associate Partner, <b>PQE Group</b>
9:00 - 10:00	
Panel	<b>Navigating the Regulatory Maze: Mastering Data Integrity, Annex 11 Draft Update, CSA, GAMP® 5, and Emerging AI Guidance</b> Dr. Ulrich Köllisch, Partner, <b>GXP - CC</b> Stefan Münch, VP Validation & Qualification, <b>Körber Pharma Consulting</b> Ken Shitamoto, Executive Director IT, <b>Gilead Sciences</b> Pat Tobin, Project Manager Validation, <b>Regeneron</b>
10:00 - 10:30	<b>Exhibitor Showroom and Networking Refreshment Break</b>
10:30 - 11:00	
Keynote	<b>Breaking Down Silos: A Collaborative Approach to Risk-Based, Business-Driven Validation Strategies</b> Ken Shitamoto, Executive Director IT, <b>Gilead Sciences</b>
11:00 - 12:00	
Panel	<b>AI and Digital Transformation: Redefining Validation Strategies and Superintelligence Governance</b> Andy O'Connor, Executive Director, <b>ERA Sciences</b> Kevin O'Donnell, Manager Market Compliance HPRC; Adjunct Professor, <b>TU Dublin</b> (Invited) Donncadh Nagle, Commissioning Qualification & Validation Lead, <b>Jacobs Engineering Group Inc.</b> , Assistant Lecturer, <b>TU Dublin</b>
12:00 - 13:00	<b>Roundtable Luncheon - Topics Include:</b>
	<b>Modernizing CSV Training: Leadership Strategies and Innovative SOPs</b> Ken Shitamoto, Executive Director IT, <b>Gilead Sciences</b>
	<b>Data Integrity Beyond ALCOA: Modernizing Your Program</b> Dr. Ulrich Köllisch, Partner, <b>GXP - CC</b>
	<b>Effective Strategies for Network and IT Infrastructure Qualification</b> To Be Announced

13:00 - 13:40	Select Between Knowledge Exchange Sessions
	<b>Risk-Based Approach to CSV: Simplifying Compliance</b> Stefan Münch, VP Validation & Qualification, <b>Körber Pharma Consulting</b>
	<b>Qualifying SaaS and IaaS: Building Reliable Cloud Validation Processes and Quality Agreements</b> Ben O'Brien, Business Development Partner, <b>ERA Science</b>
13:50 - 14:30	Select Between Knowledge Exchange Sessions
	<b>CSA Implementation 101 – Industry Case Studies That Inspire Success</b> William Ryan, Senior Manager OUS SQA Operations, <b>Abbott</b>
	<b>Ensuring Trust in AI-Assisted Line Clearance: How to Validate AI-powered Systems</b> Frederik Thiele VP Line Optimizer, <b>Körber Pharma Consulting</b>
14:30 - 15:30	Speed Networking
15:30 - 16:10	Select Between Knowledge Exchange Sessions
	<b>Modern Risk-Based Approaches to Spreadsheet Validation</b> Joanne Goldberg, Senior Principal Business Analyst, <b>Medtronic</b>
	<b>AI in Action! Quality Management Use Cases</b> Gaurav Walia, VP of CSV/CSA/DI and Digital Governance, Head of PQE Chicago Officer and Senior Associate Partner, <b>PQE Group</b>
16:20 - 17:00	Select Between Knowledge Exchange Sessions
	<b>Application of ISPE™ Good Practice Guide® on Digital Validation</b> Dave O'Connor, CQV Digital Transformation Manager, <b>No Deviation</b>
	<b>Integrating AI Innovation in GxP: Use Cases and a Practical Approach for CSA</b> Catherine Lunardi, CEO, <b>GenAlz</b>
	Networking Cocktail Reception

7:30 - 8:30	<b>Exhibitor Showroom Opens and Lite Breakfast</b>
8:30 - 9:10	<b>Select Between Knowledge Exchange Sessions</b>
	<b>Risk-Based Validation Strategies for Software Upgrades</b> Billy Ryan, Senior Manager OUS SQA Operations , <b>Abbott</b>
	<b>Effective Approaches to CSA for Streamlined Validation</b> Ken Shitamoto, Executive Director IT, <b>Gilead Sciences</b>
9:20- 10:00	<b>Select Between Knowledge Exchange Sessions</b>
	<b>Developing SOPs, Templates, and Master Plans for Validation Success</b> Joanne Goldberg, Senior Principal Business Analyst, <b>Medtronic</b>
	<b>Ensuring Compliance for AI-Driven SaaS and Cloud Systems</b> Oisín Curran, Founder, <b>Odyssey VC</b>
10:00 - 10:30	<b>Exhibitor Showroom and Refreshment Break</b>
10:30 - 11:10	<b>Select Between Knowledge Exchange Sessions</b>
	<b>Risk-based Impact Assessments – Scripted vs. Unscripted Testing for Criticality</b> Gaurav Walia, VP of CSV/CSA/DI and Digital Governance, Head of PQE Chicago Officer and Senior Associate Partner, <b>PQE Group</b>
	<b>Validate Big Data Effectively to Ensure Quality Across Complex Platforms</b> Andy O'Connor, Executive Director, <b>ERA Sciences</b>
11:20 - 12:00	<b>Select Between Knowledge Exchange Sessions</b>
	<b>Configuration and Change Management Best Practices</b> Pat Tobin, Project Manager Validation, <b>Regeneron</b>
	<b>Leveraging Vendor Testing for Digitized Validation Success</b> Stefan Münch, VP Validation & Qualification, <b>Körber Pharma Consulting</b>
12:00 - 1:00	<b>Networking Luncheon - Topics Include:</b>
	<b>Data Integrity Mapping: Identifying Risks and Building Robust Systems</b> Kir Henrici, Chief Executive Officer - Principal, <b>The Henrici Group</b>
	<b>Managing Risks in Decommissioning Legacy Systems</b> Joanne Goldberg, Senior Principal Business Analyst, <b>Medtronic</b>

13:00 - 13:40	Select Between Knowledge Exchange Sessions
	<b>From Paper to Digital: Best Practices for Paperless Validation Programs</b> Donncadh Nagle, Commissioning Qualification & Validation Lead, <b>Jacobs Engineering Group Inc.</b> , Assistant Lecturer, <b>TU Dublin</b>
	<b>Enhancing Validation Efficiency with AI-Driven Automation</b> Oisín Curran, Founder, <b>Odyssey VC</b>
13:50 - 14:30	Select Between Knowledge Exchange Sessions
	<b>Building Cyber-Resilient Validation Systems: Integrating IT Security into CSV</b> Joanne Goldberg, Senior Principal Business Analyst, <b>Medtronic</b>
	<b>Validating Agentic AI: Ensuring Compliance, Integrity, and Value of Large Language Models in Pharmaceutical Manufacturing</b> Steven Davy, Research Centre Manager Sustainable Digital Technologies, <b>TU Dublin</b>
14:30 - 14:45	Exhibitor Showroom and Networking Refreshment Break
14:45 - 15:25	Select Between Knowledge Exchange Sessions
	<b>Lean Validation: Driving Efficiency and Reducing Costs in Complex Projects</b> Sean Walsh, Associate Director, Capital Projects Digital Delivery, Manufacturing Value Team, DMMD, <b>MSD</b>
	<b>Ensuring Compliance in Manufacturing Execution Systems (MES)</b> Nelly Chankovo, Head of Global Consulting, <b>Körber Pharma Software</b>
15:35 - 16:15	Select Between Knowledge Exchange Sessions
	<b>AI-Driven Data Integrity &amp; Governance in GxP: Best Practices and Ensuring Compliance</b> Catherine Lunardi, CEO, <b>GenAlz</b>
	<b>Ensuring Compliance on the Go: Validating Mobile Devices and Applications</b> Raul Soto, MSc, CQE, MedTech Senior Manager , Digital Transformation Excellence Systems, <b>Johnson &amp; Johnson</b>
	Close of Day Two

# REGISTRATION

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	<b>March 26-27</b> Philadelphia, PA		<b>Validation University</b> Driving Excellence in Modern Validation & Qualification Processes
	<b>May 14-15</b> San Diego, CA		<b>Laboratory University</b> Mastering Analytical Methods, Stability Testing, and QC Excellence
	<b>June 4-5</b> Cork, Ireland		<b>CSV &amp; CSA University Dublin</b> Ensuring Compliance and Integrity Across Traditional, Digital, and AI-Driven Systems Conference
	<b>June 10-11</b> Philadelphia, PA		<b>Harness the Power of AI in GxP</b> Use Cases, Process Optimization, and Validation
	<b>August 5-6</b> Philadelphia, PA		<b>Advancing Sterility &amp; Safety Summit</b> Cleaning, Contamination Control & Microbiology
	<b>September 18-19</b> Philadelphia, PA		<b>Medical Device Validation &amp; Verification University</b> Integrating Compliance, Design, and Post Market Success
	<b>October 7</b> San Diego, CA		<b>GMP Bootcamp</b> Building a Framework for GMP Success
	<b>October 8-9</b> San Diego, CA		<b>GMP University</b> Modernizing GMP Processes from Risk to Inspections
	<b>October 21-22</b> Philadelphia, PA		<b>Pharmaceutical Engineering Summit</b> Integrating Process, Automation, and Facility Excellence
	<b>November 19-20</b> Dublin, Ireland		<b>Validation University Dublin</b> Driving Excellence in Modern Validation & Qualification Processes
	<b>December 9-10</b> San Diego, CA		<b>CSV &amp; CSA University</b> Ensuring Compliance and Integrity Across Traditional, Digital, and AI-Driven Systems

 Temple Tracks  Virtual Option

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