

COMPUTER SYSTEMS VALIDATION & SOFTWARE ASSURANCE UNIVERSITY

December 5-7 Attend Virtually or in San Diego, CA



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EXCHANGE KNOWLEDGE WITH OUR ELITE FACULTY

	Geetanjali Abbi Global Head of Digital Quality Alkermes		Ed Hein Senior Manager, Digital Product Excellence LifeScan Global Corp
	Bhaskar Ayasomayajula Director, Global IT Quality Assurance Bristol-Myers Squibb		Saurabh Joshi Director for Solutions Engineering ValGenesis, Inc.
	Paul Anderson Senior Organizational Change Management Lead DRChange, LLC		Kim huynh-Ba Managing Director Pharmalytik
	Arif Azad Engineering Validation Manager Pfizer		Marc Koetter Senior Manager Computer System Validation & IT Governance Fresenius Medical Care
	Michael Benedict, Ph.D. Robotics and Automation Advisor Minerva Knowledge Management		Loganathan Kumarasamy Head - Validation & Compliance Services Zito Technologies Inc
	Sachin Bhandari Head of CSV and Qualification Standards Boehringer Ingelheim		Linda Lagrou Senior Manager IT Quality Abbott Laboratories
	Octavian Boca CEO and Founder Massachusetts Technology Innovation Corp (MTI)		Matthew LaPierre Data Integrity Lead Jackson Scott Consulting
	David DeLuca Director, Engineering & Validation Compliance Group		Bill Lee Director of Information Services DAP Health
	Brian Divasta Director, CSV ElevateBio		Leslie Lighton-Humphreys IT CSV & SQA Manager Cencora
	Amanda Forsythe Quality Technology Manager Agilent Technologies		Ian Lucas Director/Training Manager SeerPharma
	Madhavi Ganesan Life Sciences Solution Director KPMG		Jonathan Meuzelaar Director, Quality Systems Compliance Group
	Joanne Goldberg Senior Principal Technical Analyst Medtronic		Meher Muttanapalli Senior Manager - Digital & CSV/CSA Intuitive Surgical
	Dori Gonzales-Acavado CEO ProcellaRX		Kalpesh Patel MBA, PMP, CSM, Associate Director, QA BeiGene
	Esra Guven Associate Director, GIS - Computer System Validation Apotex, Inc.		

EXCHANGE KNOWLEDGE WITH OUR ELITE FACULTY



Carlos Pereira
Regional Manager
VTI Life Sciences



Brandi Stockton
Co-Founder and
Principal Consultant
The Triality Group



Radha Ramesh
Director, IT Compliance and V&V
Ultragenyx



Rohit Tyagi
Managing Partner
Sagax Team



Roque Redondo
Senior Technical Consultant
Minerva Knowledge Management, LLC



Keith Ulrich
Global Director, Computer
System Validation
**Ashfield Engage
an Inizio Company**



Nina Ricciardelli
Director of Vault
Validation management
Veeva Systems



Francisco (Cisco) Vincey
Case for Quality Program
Manager
U.S. FDA



Lizzandra Rivera
Director IT Quality
Alexion Pharmaceuticals



Hong Wa Leong
QA Manager, Computer System,
Validation
Neurocrine Biosciences, Inc.



Chinmoy Roy
Senior Industry Consultant
ValGenesis, Inc.



Gaurav Walia
Senior Global director
Principal SME in DI/CSV/CSA
PQE Group



Ken Shitamoto
Executive Director
Gilead Sciences



Daniel Walter
Policy Analyst, CDRH
U.S. FDA



Robin Smallwood
Manager of Vault
Validation Management
Veeva Systems



Elizabeth Warnock
Director, IT Quality and
Compliance
Abbott Laboratories



Mihir Solanki
Manager, Healthcare and
Life sciences Advisory
KPMG



Amy Wilhite
Senior Process Engineer
Kneat



Jeffrey G., Soper, Ph.D.
Executive Director
ISBPI INC



Carolina Zapata
Process Development Manager
Agilent Technologies



Ivan Soto
Senior Director Quality
Assurance Validation
Sarepta Therapeutics



Jason Spiegler
SVP Strategy & Customer
Experience
Compliance Group



Vignesh Srinivas
Manager - Compliance
Services (CSA/CSV)
Zito Technologies Inc

<p>9:00 - 09:45 PT Mission Foyer</p>	<p>Registration, Exhibitor Showroom, and Refreshments</p>
<p>9:45 - 10:00 PT Mission I</p>	<p>Chairman's Opening Remarks</p>
<p>10:00 - 12:00 PT</p> <p>Mission I</p> <p>Mission II</p>	<p>Select Between Two Inclusive Workshops</p> <p> Modernize CSV & CSA Training Programs - Throw Out Your Read and Understand SOP Playbook Dori Gonzalez-Acevedo CEO, ProcellaRX</p> <p>Develop a Problem Solving Leadership Program Jeffrey G. Soper, Ph.D., Executive Director, ISBPI INC</p>
<p>12:00 - 1:15 PT Mission Terrace</p>	<p>Exhibitor Showroom and Networking Luncheon</p>
<p>1:15 - 2:15 PT Mission I/II</p>	<p> (Panel) CSA - The Foundation for Digital Transformation David DeLuca Director, Engineering & Validation, and Jason Spiegler, SVP Strategy & Customer Experience, Compliance Group; Francisco (Cisco) Vicenty, Case for Quality Program Manager, U.S. FDA; Bill Lee, Director of Information Services, DAP Health; Ken Shitamoto, Executive Director, Gilead Sciences</p>
<p>2:15 - 3:00 PT Mission I/II</p>	<p> Computer Software Assurance (CSA) Implementation with Focus on Industry Case Study Linda Lagrou, Senior Manager IT Quality, Abbott Laboratories; Gaurav Walia, Senior Global Director, Principal SME in DI/CSV/CSA, PQE Group</p>
<p>3:00 - 3:30 PT Mission III</p>	<p>Exhibitor Showroom and Refreshment Break</p>
<p>3:30 - 4:30 PT Mission I/II</p>	<p> (Panel) CSA Update - The Impact on Part 11, Risk Analysis, Critical Thinking and Test Scripts Francisco (Cisco) Vicenty, Case for Quality Program Manager, U.S. FDA; Daniel Walter, Policy Analyst, CDRH, U.S. FDA; Meher Muttanapalli, Senior Manager - Digital & CSV/CSA, Intuitive Surgical; Radha Ramesh, Director, IT Compliance and V&V, Ultragenyx; Gaurav Walia, Senior Global Director, Principal SME in DI/CSV/CSA, PQE Group; Ian Lucas, Director / Training Manager, SeerPharma</p>
<p>4:30 - 5:00 PT Mission I/II</p>	<p> Validation of AI/ML and other Superintelligence Platforms Chinmoy Roy, Senior Industry Consultant, ValGenesis, Inc.</p>
<p>5:00 - 5:30 PT Mission I/II</p>	<p> Industry 4.0 or Validation 4.0 – The Choice is Yours Ian Lucas, Director / Training Manager, SeerPharma</p>
<p>5:15 PT Mission III</p>	<p>Welcome Networking Reception</p>

7:15 PT Mission III	Exhibitor Showroom Opens and Lite Breakfast
8:00 - 9:20 PT Mission Terrace	Digitalization Validation Demo Day
9:20 - 10:00 PT	Select Between Knowledge Exchange Sessions
Mission I	Software Fundamentals - Writing Test Scripts to Support CSA Vignesh Srinivas, Manager – Compliance Services (CSA/CSV), Zifo Technologies Inc.
Mission II	 Qualifying SaaS, IaaS - Create a Quality Agreement with Cloud Providers Sachin Bhandari, Head of CSV and Qualification Standards, Boehringer Ingelheim
Belmont	Implement Data Integrity Controls that Minimize Error Matthew LaPierre, Data Integrity Lead, Jackson Scott Consulting
10:00 - 10:30 PT Mission III	Exhibitor Showroom and Refreshment Break
10:30 - 11:10 PT	Select Between Knowledge Exchange Sessions
Mission I	 How Has the Industry Adopted CSA a Year After the FDA Guidance? Madhavi Ganesan, Life Sciences Solutions Director, KPMG
Mission II	Cyber Compliance with the Software Lifecycle Elizabeth Warnock, Director, IT Quality and Compliance, Abbott Laboratories
Belmont	The Interrelationship between CSV and the Secure Supply Chain (SSC) and the Drug Supply Chain Security Act (DSCSA) Leslie Lighton-Humphreys, IT CSV & SQA Manager, Cencora
11:20 - 12:00 PT	Select Between Knowledge Exchange Sessions
Mission I	 Validation and Change Control for Software Upgrades Lizzandra Rivera, Director IT Quality, Alexion Pharmaceuticals
Mission II	Data Integrity Process Mapping - Identify and Mitigate Gaps Kim Huynh-ba, Managing Director, Pharmalytik
Belmont	ALM Tools Add Value to Software Validation Marc Koetter, Senior Manager Computer System Validation & IT Governance, Fresenius Medical Care
12:00 PT Mission Terrace	Exhibitor Showroom and Networking Luncheon
1:30 - 2:10 PT	Select Between Knowledge Exchange Sessions
Belmont	Qualifying Network and IT Infrastructures Radha Ramesh, Director, IT Compliance and V&V, Ultragenyx
Mission I	Cultivate a CSV Quality Culture Lizzandra Rivera, Director IT Quality, Alexion Pharmaceuticals
Mission II	 A Roadmap to Successful CSA Implementation - Case Study Brian DiVasta, Director, CSV, ElevateBio

2:20 - 3:00 PT	Select Between Knowledge Exchange Sessions
Mission I	Key Components to Consider when Transitioning to CSA Ken Shitamoto, Executive Director, Gilead Sciences
Mission II	 Agile Computer Software Assurance (CSA) in a Low-Code Environment - Building Quality with Efficiency Daniel Walter, Policy Analyst, CDRH, U.S. FDA ; Jonathan Meuzelaar, Director, Quality Systems, Compliance Group
Belmont	Automate Decision Making to Accelerate Process – Use Case from Company Spin off Geetanjali Abbi, Director Validation, Alkermes; Brandi Stockton
3:00 - 3:30 PT Mission III	Exhibitor Showroom and Refreshment Break
3:30 - 4:10 PT	Select Between Knowledge Exchange Sessions
Mission I	Elevate Your Tech Game: The CSA Op Model Deciphered Joanne Goldberg, Senior Principal Technical Analyst, Medtronic ; Paul Anderson, Senior Organizational Change Management Lead, DRChange, LLC
Mission II	 Conduct Risk-based Impact Assessments of Computer Systems Rohit Tyagi, CEO, Head of Quality & Compliance, Sagax Team ; Meher Muttanapalli, Senior Manager - Digital & CSV/CSA, Intuitive Surgical
Belmont	CSV ROI for Business Sake - Balancing Quality vs. Cost Management Ed Hein, Senior Manager, Digital Product Excellence, LifeScan Global Corp
4:20 - 5:00 PT	Select Between Knowledge Exchange Sessions
Mission I	Robotics and Automation in Life Sciences - Transitioning for Maximum Benefit in Advanced Therapies Michael Benedict, Ph.D., Robotics and Automation Advisor, Minerva Knowledge Management
Mission II	 Conduct a GAMP® 5 Assessment - Use a Customized Checklist Keith Ulrich, Global Director, Computer System Validation, Ashfield Engage an Inizio Company
Belmont	Use Cases: How has CSA been Applied to Advanced Technologies? Bhaskar Aryasomayajula, Director, Global IT Quality Assurance, Bristol-Myers Squibb ; Mihir Solanki, Manager, Healthcare and Life Sciences Advisory, KPMG
5:10 - 5:40 PT	Select Between Knowledge Exchange Sessions
Belmont	Agile Development with Software Assurance Saurabh Joshi, Director for Solutions Engineering, ValGenesis, Inc.
Mission I	 Computerized System Validation (CSV) Process Innovation (PI) - Modernization Your Approach Marc Koetter, Senior Manager Computer System Validation & IT Governance, Fresenius Medical Care
Mission II	Leverage Vendor Testing Under CSA Amy Wilhite, Senior Process Engineer, Kneat
5:50 PT	Close of Day Two

7:15 PT Mission III	Exhibitor Showroom Opens, DEI Roundtable, and Lite Breakfast
7:55 - 8:35 PT	Select Between Knowledge Exchange Sessions
Mission I	 Risk-based Spreadsheet Validation Arif Azad, Engineering Validation Manager, Pfizer
Mission II	Configuration and Change Management of Computer Systems Amanda Forsythe, Quality Technology Manager, Agilent Technologies Carolina Zapata, Process Development Manager, Agilent Technologies
Belmont	Conduct a 21 CFR Part 11 Gap Analysis Jacob Hodovsky, Computer System Validation Engineer, CAI
8:45 - 10:15 PT	Select Between Knowledge Exchange Sessions
Belmont	 Establish Effective Data Governance Maturity Model Leslie Lighton-Humphreys, IT CSV & SQA Manager, Cencora
Mission I	Awareness of Risks and Mitigation Strategies Throughout CS Lifecycle Geetanjali Abbi, Director Validation, Alkermes ; Brandi Stockton, Co-Founder and Principal Consultant, The Triality Group
Mission II	Digitizing Validation Framework Sachin Bhandari, Head of CSV and Qualification Standards, Boehringer Ingelheim
10:15 - 10:45 PT Mission III	Exhibitor Showroom and Refreshment Break
10:45 - 11:25 PT	Select Between Knowledge Exchange Sessions
Mission I	Taking the CSA Op Model Leap - Plan, Build and Deliver Joanne Goldberg, Senior Principal Technical Analyst, Medtronic ; Paul Anderson, Senior Organizational Change Management Lead, DRChange, LLC
Mission II	Use Cases in Conducting Risk Assessments Brian DiVasta, Director, CSV, ElevateBio
Belmont	 How to Use Risk in Decommissioning of Computer Systems and Software Applications Ivan Soto, Senior Director Quality Assurance Validation, Sarepta Therapeutics
11:35 - 12:15 PT	Select Between Knowledge Exchange Sessions
Mission I	Scripted vs. Unscripted Testing – Requirements Criticality Assessments Keith Ulrich, Global Director, Computer System Validation, Ashfield Engage an Inizio Company
Mission II	Your Guide to CSV Modernization - An End to End Approach Nina Ricciardelli, Director of Vault Validation Management and Robin Smallwood, Manager of Vault Validation Management, Veeva Systems ; Hong Wa Leong, QA Manager, Computer System Validation, Neurocrine Biosciences, Inc.
Belmont	 Inspection Readiness - Ensuring Systems are Fit for Purpose Kalpesh Patel, MBA, PMP, CSM, Associate Director, QA, BeiGene

12:15 PT Mission Terrace	Exhibitor Showroom and Networking Luncheon
1:00 - 1:40 PT	Select Between Knowledge Exchange Sessions
Mission I	 Effective Collaboration - Streamline Validation Across Validation, Quality, and IT Ed Hein, Senior Manager, Digital Product Excellence, LifeScan Global Corp
Mission II	Using Audit Trails to Support Data Integrity Compliance Kim Huynh-ba, Managing Director, Pharmalytik
Belmont	Validation of Manufacturing Execution Systems (MES) Carlos Pereira, Regional Manager, VTI Life Sciences
1:50 - 2:30 PT	Select Between Knowledge Exchange Sessions
Mission I	Developing a Quality Process for AI/ML Based GxP System Loganathan Kumarasamy, Head – Scientific Informatics & Compliance Services, Zifo Technologies Inc.
Mission II	Easy-GxP - Automating Compliance with Regulations and Industry Guidance Octavian Boca, CEO and Founder, Massachusetts Technology Innovation Corp (MTI)
Belmont	 Impact Assessments - Know Which Test Approach to Use During Validation Amanda Forsythe, Quality Technology Manager, and Carolina Zapata, Process Development Manager, Agilent Technologies
2:30 PT Mission III	Exhibitor Showroom and Refreshment Break
2:45 - 3:25 PT	Select Between Knowledge Exchange Sessions
Mission I	 Discover Best in Class SOPs, Templates, Checklists and Master Plans Esra Guven, Associate Director, GIS - Computer Systems Validation, Apotex, Inc.
Mission II	Modernize Your 21 CFR Part 11 Program - CSA, Two Factor Authentication, AI/ML Roque Redondo, Senior Technical Consultant, Minerva Knowledge Management, LLC
3:35 - 4:15 PT	Select Between Knowledge Exchange Sessions
Mission I	 How to Use Factory Talk in Historian for Production Data to Meet FDA Compliance Carlos Pereira, Regional Manager, VTI Life Sciences
Mission II	Conduct a 21 CFR Part 11 Gap Analysis To Be Announced
4:15 PT	Close of Conference

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