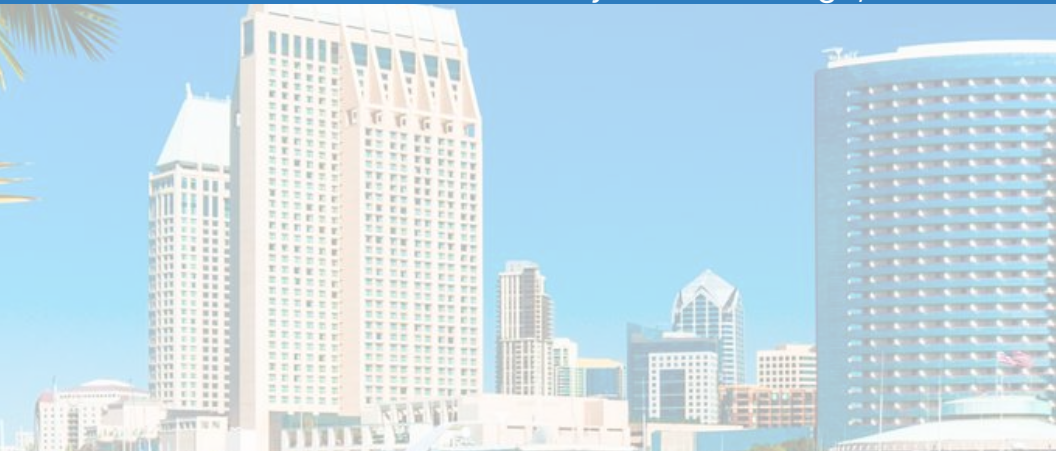# KENX
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Geetanjali Abbi
Global Head of Digital Quality
Alkermes

Bhaskar Aryasomayajula
Director, Global IT Quality Assurance
Bristol-Myers Squibb

Paul Anderson
Senior Organizational
Change Management Lead
DRChange, LLC

Arif Azad
Engineering Validation Manager
Pfizer

Michael Benedict
Robotics / Automation Integrator
Minerva

Sachin Bhandari
Head of CSV and
Qualification Standards
Boehringer Ingelheim

Octavian Boca
CEO and Founder
**Massachusetts Technology
Innovation Corp (MTI)**

David DeLuca
Director, Engineering & Validation
Compliance Group

Brian DiVasta,
Director, CSV
ElevateBio

Amanda Forsythe
Quality Technology Manager
Agilent Technologies

Madhavi Ganesan
Life Sciences Solutions Director
KPMG

Joanne Goldberg
Senior Principal Technical Analyst
Medtronic

Dori Gonzalez-Acevedo
CEO
ProcellaRX

Esra Guven
Associate Director, GIS -
Computer Systems Validation
Apotex, Inc.

Ed Hein
Senior Manager,
Digital Product Excellence
LifeScan Global Corp

Kim Huynh-ba
Managing Director
Pharmalytik

Marc Koetter
Senior Manager
Computer System
Validation & IT Governance
Fresenius Medical Care

Loganathan Kumarasamy
Head – Validation &
Compliance Services
Zifo RnD Solutions

Linda Lagrou
Senior Manager IT Quality
Abbott Laboratories

Matthew LaPierre
Data Integrity Lead
Jackson Scott Consulting

Bill Lee
Director of Information Services
DAP Health

Leslie Lighton-Humphreys
IT CSV & SQA Manager
Cencora

Ian Lucas
Director / Training Manager
SeerPharma

EXCHANGE KNOWLEDGE WITH OUR ELITE FACULTY

Kalpesh Patel
MBA, PMP, CSM,
Associate Director, QA
BeiGene

Carlos Pereira
Regional Manager
VTI Life Sciences

Radha Ramesh
Director, IT Compliance and V&V
Ultragenyx

Rogue Redondo
Senior Technical Consultant
Minerva Knowledge Management, LLC

Nina Ricciardelli
Director of Vault Validation Management
Veeva Systems

Lizzandra Rivera
Director IT Quality
Alexion Pharmaceuticals

Chinmoy Roy
Senior Industry Consultant
ValGenesis, Inc.

Ken Shitamoto
Executive Director
Gilead Sciences

Robin Smallwood
Manager of Vault Validation Management
Veeva Systems

Mihir Solanki
Manager, Healthcare and Life Sciences Advisory
KPMG

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

Ivan Soto
Senior Director Quality Assurance Validation
Sarepta Therapeutics

Vignesh Srinivas
Manager – Compliance Services (CSA/CSV)
Zifo Technologies Inc

Brandi Stockton
Co-Founder and Principal Consultant
The Triality Group

Rohit Tyagi
Managing Partner
Sagax Team

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

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

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

Daniel Walter
Policy Analyst, CDRH
U.S. FDA

Elizabeth Warnock
Director, IT Quality and Compliance
Abbott Laboratories

Amy Wilhite
Senior Process Engineer
Kneat

Carolina Zapata
Process Development Manager
Agilent Technologies

Day One	December 5, 2023
9:00 - 10:00 PT	Registration, Exhibitor Showroom, and Refreshments
10:00 - 12:00 PT	Select Between Two Inclusive Workshops
	Implement a CSV & SA Training Program and Measure for Success Dori Gonzalez-Acevedo CEO, **ProcellaRX**
	Develop a Problem Solving Leadership Program Jeffrey G. Soper, Ph.D., Executive Director, **ISBPI INC**
12:00 - 1:00 PT	Exhibitor Showroom and Grab & Go Lunch
1:00 PT	Chairman's Opening Remarks
1:15 - 2:15 PT	**(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**; Rohit Tyagi, CEO, Head of Quality & Compliance, **Sagax Team**; 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**
2:15 - 3:00 PT	**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**
3:00 - 3:30 PT	Exhibitor Showroom and Refreshment Break
3:30 - 4:30 PT	**(Panel) Digitalization, AI/ML, Superintelligence Platforms, and Compliance** David DeLuca Director, Engineering & Validation, **Compliance Group**; Francisco (Cisco) Vicenty, Case for Quality Program Manager, **U.S. FDA**; Bill Lee, Director of Information Services, **DAP Health**
4:30 - 5:00 PT	**Validation of AI/ML and other Superintelligence Platforms** Chinmoy Roy, Senior Industry Consultant, **ValGenesis, Inc.**
5:00 - 5:30 PT	**Industry 4.0 or Validation 4.0 – The Choice is Yours** Ian Lucas, Director / Training Manager, **SeerPharma**
5:15 PT	Welcome Networking Reception

Day Two	December 6, 2023
7:15 PT	Exhibitor Showroom Opens and Lite Breakfast
8:00 - 9:20 PT	Select Between Knowledge Exchange Sessions
	Digitalization Validation Demo Day
9:20 - 10:00 PT	Select Between Knowledge Exchange Sessions
	Software Fundamentals - Writing Test Scripts to Support CSA Vignesh Srinivas, Manager – Compliance Services (CSA/CSV), **Zifo Technologies Inc.**
	T Qualifying SaaS, IaaS - Create a Quality Agreement with Cloud Providers Sachin Bhandari, Head of CSV and Qualification Standards, **Boehringer Ingelheim**
	Implement Data Integrity Controls that Minimize Error Matthew LaPierre, Data Integrity Lead, **Jackson Scott Consulting**
10:00 -10:30 PT	Exhibitor Showroom and Refreshment Break
10:30 - 11:10 PT	Select Between Knowledge Exchange Sessions
	T How Has the Industry Adopted CSA a Year After the FDA Guidance? Madhavi Ganesan, Life Sciences Solutions Director
	Cyber Compliance with the Software Lifecycle Elizabeth Warnock, Director, IT Quality and Compliance, **Abbott Laboratories**
	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
	T Validation and Change Control for Software Upgrades Lizzandra Rivera, Director IT Quality, **Alexion Pharmaceuticals**
	Data Integrity Process Mapping - Identify and Mitigate Gaps Kim Huynh-ba, Managing Director, **Pharmalytik**
	ALM Tools Add Value to Software Validation Marc Koetter, Senior Manager Computer System Validation & IT Governance, **Fresenius Medical Care**
12:00 PT	Exhibitor Showroom and Networking Luncheon
1:30 - 2:10 PT	Select Between Knowledge Exchange Sessions
	Qualifying Network and IT Infrastructures Radha Ramesh, Director, IT Compliance and V&V, **Ultragenyx**
	Cultivate a CSV Quality Culture Lizzandra Rivera, Director IT Quality, **Alexion Pharmaceuticals**
	T A Roadmap to Successful CSA Implementation - Case Study Brian DiVasta, Director, CSV, **ElevateBio**

2:20 - 3:00 PT	Select Between Knowledge Exchange Sessions
	Key Components to Consider when Transitioning to CSA Ken Shitamoto, Executive Director, **Gilead Sciences**
	🏛 **Conduct Risk-based Impact Assessments of Computer Systems** Rohit Tyagi, CEO, Head of Quality & Compliance, **Sagax Team**
	Automate Decision Making to Accelerate Process – Use Case from Company Spin off Geetanjali Abbi, Director Validation, Alkermes; **Brandi Stockton**
3:00 - 3:30 PT	Exhibitor Showroom and Refreshment Break
3:30 - 4:10 PT	Select Between Knowledge Exchange Sessions
	Elevate Your Tech Game: The CSV Op Model Deciphered Joanne Goldberg, Senior Principal Technical Analyst, **Medtronic**; Paul Anderson, Senior Organizational Change Management Lead, **DRChange, LLC**
	Maximize the Benefits of CSA for Test Driven Agile Validation Jacob Hodovsky, Computer System Validation Engineer, **CAI**
	🏛 **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**
	Robotics, Automation & Process Improvement in the Life Sciences Industry Michael Benedict, Robotics / Automation Integrator, **Minerva**
	🏛 **Conduct a GAMP® 5 Assessment - Use a Customized Checklist** Keith Ulrich, Global Director, Computer System Validation, **Ashfield Engage an Inizio Company**
	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**
5:00 - 5:40 PT	Select Between Knowledge Exchange Sessions
	Agile Development with Software Assurance Suarabh Joshi Shripad, Director for Solutions Engineering, **ValGenesis, Inc.**
	🏛 **Computerized System Validation (CSV) Process Innovation (PI) - Modernization Your Approach** Marc Koetter, Senior Manager Computer System Validation & IT Governance, **Fresenius Medical Care**
	Leverage Vendor Testing Under CSA Amy Wilhite, Senior Process Engineer, **Kneat**
5:40 PT	**Close of Day Two**

Day Three	December 7, 2023

7:15 PT	Exhibitor Showroom Opens, DEI Roundtable, and Lite Breakfast
7:55 - 8:35 PT	Select Between Knowledge Exchange Sessions
	🏛 **Risk-based Spreadsheet Validation** Arif Azad, Engineering Validation Manager, **Pfizer**
	Configuration and Change Management of Computer Systems Amanda Forsythe, Quality Technology Manager, **Agilent Technologies** Carolina Zapata, Process Development Manager, **Agilent Technologies**
	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**
	🏛 **Establish Effective Data Governance Maturity Model** Leslie Lighton-Humphreys, IT CSV & SQA Manager, **Cencora**
	Awareness of Risks and Mitigation Strategies Throughout CS Lifecycle Geetanjali Abbi, Director Validation, **Alkermes**; Brandi Stockton, Co-Founder and Principal Consultant, **The Triality Group**
	A Model for Conducting Digitalization Validation Sachin Bhandari, Head of CSV and Qualification Standards, **Boehringer Ingelheim**
10:15 - 10:45 PT	Exhibitor Showroom and Refreshment Break
10:45 - 11:25 PT	Select Between Knowledge Exchange Sessions
	Taking the CSV Leap: Adopt, Adapt, Achieve! Joanne Goldberg, Senior Principal Technical Analyst, **Medtronic**; Paul Anderson, Senior Organizational Change Management Lead, **DRChange, LLC**
	Use Cases in Conducting Risk Assessments Brian DiVasta, Director, CSV, **ElevateBio**
	🏛 **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
	Scripted vs. Unscripted Testing – Requirements Criticality Assessments Keith Ulrich, Global Director, Computer System Validation, **Ashfield Engage an Inizio Company**
	Your Guide to CSV Modernization - An End to End Approach Nina Ricciardelli, Director of Vault Validation Management; Robin Smallwood, Manager of Vault Validation Management, **Veeva Systems**
	🏛 **Inspection Readiness - Ensuring Systems are Fit for Purpose** Kalpesh Patel, MBA, PMP, CSM, Associate Director, QA, **BeiGene**

Day Three	December 7, 2023

12:15 PT	Exhibitor Showroom and Networking Luncheon
1:00 - 1:40 PT	Select Between Knowledge Exchange Sessions
	🏛 **Effective Collaboration - Streamline Validation Across Validation, Quality, and IT** Ed Hein, Senior Manager, Digital Product Excellence, **LifeScan Global Corp**
	Discover Best in Class SOPs, Templates, Checklists and Master Plans Esra Guven, Associate Director, GIS - Computer Systems Validation, **Apotex, Inc.**
	Validation of Manufacturing Execution Systems (MES) Carlos Pereira, Regional Manager, **VTI Life Sciences**
1:50 - 2:30 PT	Select Between Knowledge Exchange Sessions
	Developing a Quality Process for AI/ML Based GxP System Loganathan Kumarasamy, Head – Scientific Informatics & Compliance Services, **Zifo Technologies Inc.**
	Easy-GxP - Automating Compliance with Regulations and Industry Guidance Octavian Boca, CEO and Founder, **Massachusetts Technology Innovation Corp (MTI)**
	🏛 **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	Refreshment Break
2:45 - 3:25 PT	Select Between Knowledge Exchange Sessions
	🏛 **Using Audit Trails to Support Data Integrity Compliance** Kim Huynh-ba, Managing Director, **Pharmalytik**
	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
	How to Use Factory Talk in Historian for Production Data to Meet FDA Compliance Carlos Pereira, Regional Manager, **VTI Life Sciences**
	🏛 **Learn How to Validate Big Data - Ensure Quality in Complex Platforms** Ivan Soto, Senior Director Quality Assurance Validation, **Sarepta Therapeutics**
4:15 PT	Close of Conference

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