

COMPUTER & SOFTWARE VALIDATION DATA INTEGRITY COMPLIANCE CONGRESS

December 7-9, 2020 | Wyndham Historic District | Philadelphia, PA

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President and CEO
CIMCON Software



Holly Baldwin
Manager, Quality Validation, CSV
Sanofi Pasteur



April Bunje
Data Integrity Compliance Manager
Sanofi Pasteur



Harsha Chulki
Head of Global IT Quality, Compliance & CSV
ICU Medical Inc.



Stephen J. Cook
VP, Validation and Compliance
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Dan Grill
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Senthil Gurumoorthi
Director, IT
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John Hannon, PE, CPIP, CBCP
Global Principal for Automation and IT
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Senior Quality Systems and Compliance Advisor
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Shana Kinney
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Loganathan Kumarasamy
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Data Integrity Specialist
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Chinmoy Roy
Data Integrity and CSV SME, Industry Consultant
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Ken Shitamoto
Senior Director, IT
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Raul Soto
Senior Principal Engineer
Johnson & Johnson Vision Care



Teri Stokes, Ph.D.
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Jonathon Thompson
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Steve Thompson
Director of Industry Solutions
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David W. Vincent, MPH, Ph.D.
CEO
VTI Life Sciences



Robert J. Wherry, MSc, MS
Quality Compliance & Systems, RDQ Data Systems
Takeda Pharmaceuticals



Joseph Zec
Associate Director, R&D Data Systems Software
Quality Assurance
Takeda Pharmaceuticals

DAY ONE		DECEMBER 7, 2020
9:30 EST		Exhibitor Showroom and Virtual Platform Open House
9:45 EST		Chairperson's Opening Remarks
10:00 - 10:30 EST	COMPLIANCE INTELLIGENCE	T Understanding FDA's CSA Guidance in the Context of Current Regulations and GAMP® Ken Shitamoto, Senior Director, IT and Senthil Gurumoorthi, Director, IT, Gilead Sciences
10:30- 11:30 EST	COMPLIANCE INTELLIGENCE	T Applying Computer Software Assurance to Data Integrity Stephen J Cook, VP - Validation and Compliance and Khaled Moussally - EVP - Regulatory and Client Relations, Compliance Group, Inc.; Harsha Chulki: Head of Global IT Quality, Compliance & CSV - ICU Medical, Inc.
11:30 - 12:00 EST	COMPLIANCE INTELLIGENCE	T The Impact of Data Integrity on Digital Transformation / Knowledge Management Zahid Muhammad, Director CSV, Quality Systems and Compliance Lead, Merck and John V. DeRosier, Jr., Senior IT / Quality Compliance Consultant, Azzur Group
12:15- 12:45 EST		Exhibitor Showroom and Think Tank Sessions
1:00 - 1:30 EST	COMPLIANCE INTELLIGENCE	T CSV and Regulatory Enforcement – Current and Future Eric Henry, Senior Quality Systems and Compliance Advisor, FDA and Life Science Practice, King & Spalding
1:30 - 2:00 EST	COMPLIANCE INTELLIGENCE	T Pharma 4.0 and Digitalization – Don't Be Left Behind Jonathon Thompson, Principal Consultant, CAI
2:00 - 2:30 EST	SOFTWARE	T Assessing GxP SaaS Vendors - Maximize Application Utility, Performance and Compliance Stephen R. Ferrell, CISA CRISC CDPSE - Managing Director, CompliancePath
2:45- 3:15 EST		Exhibitor Showroom and Think Tank Sessions
3:30 - 4:00 EST	CSV	T How Much Validation is Enough? Pritam Khade, Director, Global Quality Compliance, and Raechelle Raimondo, Executive Director, Global Systems Assurance, AbbVie; Shana Kinney, Associate Director, Validation, REGENXBIO
4:00 - 4:30 EST	RISK MANAGEMENT	T Effective Risk Tools for CSV, DI and Automation Kevin C. Martin, Senior Director and Managing Partner, Azzur Group
4:30 - 5:00 EST	DATA INTEGRITY	T Overcome Top Challenges to Program Implementation Erik Muegge, M.S., Manager Operations Quality, Abbott Laboratories
5:00 EST		Game Night - Trivia Welcome Reception
DAY TWO		DECEMBER 8, 2020
7:00 EST		Exhibitor Showroom Opens
7:15 - 8:00 EST		Select Between Knowledge Exchange Sessions (1-3)
1	CHANGE CONTROL	T System Configuration and Change Management Raul Soto, Senior Principal Engineer, Johnson & Johnson Vision Care
2	PERSONNEL TRAINING	Educate Personnel on CSV Execution Robert J. Wherry, MSc, MS - Quality Compliance & Systems, RDQ Data Systems, Takeda Pharmaceuticals
3	DATA INTEGRITY	DI Compliance for Legacy Software Applications Sanjay Agrawal, President and CEO, CIMCON Software
8:15 - 9:45 EST		Select Between Knowledge Exchange Sessions (4-6)
4	CSV	T A Critical Thinking and Risk-based Approach to CSV Calvin Kim, Director Digital GxP Compliance Management, Bayer

5	DECOMMISSIONING	Develop a Process for the End of a Computer System Life Cycle John Hannon, PE, CPIP, CBCP, Global Principal for Automation and IT, CAI
6	DATA INTEGRITY	Reducing Human Error for Compliance Cindy Duhigg, Global Validation Steward, Alcon Laboratories
10:00 - 10:30 EST		Exhibitor Showroom and Think Tank Sessions
10:45 - 12:15 EST		Select Between Knowledge Exchange Sessions (7-9)
7	LEAN VALIDATION	Implementation Case Study – Overcome the Challenges of Paperless Implementation Joseph Zec, Associate Director, R&D Data Systems Software Quality Assurance, Takeda Pharmaceuticals
8	21 CFR PART 11	Conduct a Part 11 Gap Analysis - Create a Checklist for Compliance Carlos Pereira, Regional Manager, VTI Life Sciences
9	DATA INTEGRITY	Create a Culture of Quality throughout Your Organization Matthew LaPierre, Data Integrity Specialist, Industry Expert
12:30 - 1:15 EST		Select Between Knowledge Exchange Sessions (10-12)
10	CSA	SQA 101 - Introduction to Modern Testing in Preparation for CSA Ken Shitamoto, Senior Director, IT and Senthil Gurumoorthi, Director, IT, Gilead Sciences
11	MOBILE APPS	Validation of Mobile Applications Raul Soto, Senior Principal Engineer, Johnson & Johnson Vision Care
12	DATA INTEGRITY	A Compliance Approach for Paper-based and Hybrid Systems John Hannon, PE, CPIP, CBCP, Global Principal for Automation and IT, CAI
1:30 - 2:00 EST		Exhibitor Showroom and Think Tank Sessions
2:15 - 3:45 EST		Select Between Knowledge Exchange Sessions (13-15)
13	CSA	Planning Steps for Migrating CSV to CSA Leslie Lighton-Humphreys, IT SQA and CSV Manager, AmerisourceBergen
14	IMPACT ASSESSMENTS	Conduct Risk-based Impact Assessments Eric Henry, Senior Quality Systems and Compliance Advisor, FDA and Life Science Practice, King & Spalding
15	DATA INTEGRITY	Implement Process Mapping to Identify Data Integrity Gaps William Honeck, Vice President, VTI Life Sciences
4:00 - 4:30 EST		Exhibitor Showroom and Think Tank Sessions
4:45 - 6:15 EST		Select Between Knowledge Exchange Sessions (16-18)
16	CSV MASTER CLASS	Senior Level Think Tank - Bring and Solve Your Challenge Joseph Zec, Associate Director, R&D Data Systems Software Quality Assurance, Takeda Pharmaceuticals
17	SUPPLIER AUDITS	Supplier Management – A Path to Build Trusted Partnerships Pritam Khade, Director, Global Quality Compliance, and Vishal Kadakia, Senior QA Specialist, Global Quality, AbbVie
18	DATA INTEGRITY	Success Factors for Developing a Corporate DI Program Chinmoy Roy, Data Integrity and CSV SME, Industry Consultant, ValGenesis
6:15 EST		Close of Day Two
DAY THREE		
DECEMBER 9, 2020		
7:00 EST		Exhibitor Showroom Opens
7:15 - 8:00 EST		Select Between Knowledge Exchange Sessions (19-21)
19	AUDIT TRAILS	Auditing Your Audit Trails – Are We Really Challenging the Status Quo? April Bunje, Data Integrity Compliance Manager, Sanofi Pasteur
20	CYBER SECURITY	CyberSecurity – Addressing Malicious Threats in Our Modern Landscape Christopher Robitaille, Chief Technology Officer, and Irving Bruckstein, Advisory Board, Azzur Solutions

21	DATA INTEGRITY	Inspection Readiness – Conduct a Gap Analysis of Your Program Robert J. Wherry, MSc, MS -Quality Compliance & Systems, RDQ Data Systems, Takeda Pharmaceuticals
8:15 - 9:45 EST		Select Between Knowledge Exchange Sessions (22-24)
22	CONTINUOUS MONITORING	Continuous Monitoring – Periodic Review and Revalidation of Computer Systems Stephen J Cook, VP - Validation and Compliance, Khaled Moussally - EVP - Regulatory and Client Relations, Compliance Group, Inc.
23	CLOUD QUALIFICATION	 Qualify SAAS, IAAS and Other Software Services Steve Thompson, Director of Industry Solutions, ValGenesis
24	DATA INTEGRITY	Critical Thinking - Rethinking Your Approach to Technology April Bunje, Data Integrity Compliance Manager, Sanofi Pasteur
10:00 - 10:30 EST		Exhibitor Showroom and Think Tank Sessions
10:45 - 12:15 EST		Select Between Knowledge Exchange Sessions (25-27)
25	NETWORK QUALIFICATION	IT Infrastructure and Network Qualification Raul Soto, Senior Principal Engineer, Johnson & Johnson Vision Care
26	SPREADSHEETS	 Risk-based Spreadsheet Validation – An Organized, Effective Approach for GxP Environments Pritam Khade, Director, Global Quality Assurance, and Vishal Kadakia, Senior Specialist, Global Quality Assurance, AbbVie
27	AUTOMATION	Testing During Installation and Operational Qualification for Successful System Turnover Dan Grill, Operations Manager & CSV Lead, Azzur Group
12:30 - 1:15 EST		Select Between Knowledge Exchange Sessions (28-30)
28	CSV	Develop a Cohesive Relationship Between QA and IT Pritam Khade, Director, Global Quality Compliance, and Raechelle Raimondo, Executive Director, Global Systems Assurance, AbbVie ; Ken Shitamoto, Senior Director, IT and Senthil Gurumoorthi, Director, IT, Gilead Sciences
29	GDPR	 GDPR Compliance Considerations for SAAS and Cloud Services Holly Baldwin, Manager, Quality Validation, CSV, Sanofi Pasteur
30	AUTOMATION	Transitioning from Manual Processes to Process Automation David W. Vincent, MPH, Ph.D., CEO, VTI Life Sciences
1:30 - 2:00 EST		Exhibitor Showroom and Think Tank Sessions
2:15 - 3:45 EST		Select Between Knowledge Exchange Sessions (31-33)
31	VIRTUAL VALIDATION	Validation Case Study – Using Mixed Reality Technology for C&Q of Pharmaceutical Equipment and Systems Donnacha Nagle, Validation Consultant & Academic Researcher, TU Dublin
32	MEDICAL DEVICE	A Common Sense Approach to CSV and CSA – Implementing New Data Technology in the Device Environment Teri Stokes, Ph.D., Director & Senior Consultant, GXP International
33	AUTOMATION	 Validation by Design of a Manufacturing Automation System Chinmoy Roy, Data Integrity and CSV SME, Industry Consultant, ValGenesis
4:00 - 5:30 EST		Select Between Knowledge Exchange Sessions (34-36)
34	CSV	 Best-in-Class Documentation, SOPs, Templates and Checklists Stephen J Cook, VP - Validation and Compliance, Compliance Group, Inc.
35	GMP LABORATORY	Instrument Qualification and Data Integrity Considerations Loganathan Kumarasamy, Head - US Validation & Compliance, Zifo RnD Solutions
36	AUTOMATION	Validation of Robotic Process Automation (RBA) Steve Thompson, Director of Industry Solutions, ValGenesis
5:30 EST		Close of Conference