

VALIDATION & GMP UNIVERSITY 2021

PROCESS VALIDATION & CONTINUED VERIFICATION DATA INTEGRITY GOVERNANCE | FDA INSPECTIONS CHANGE CONTROL | QUALITY RISK MANAGEMENT

August 23 - 25, 2021 | Wyndham Historic District | Philadelphia, PA

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Program Development, **CAI**



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Associate Director, Global Quality Control
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a Nestle Health Sciences Company**



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Global C&Q lead for EU
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Steven S. Kuwahara Ph.D.
Principal Consultant
GXP BioTechnology



Matthew LaPierre
Data Integrity Specialist
Jackson Scott Consulting



James Mason PharmD
Compliance Officer, OPQO
U.S. FDA (Invited)



Donncahd Nagle
Commissioning, CQV Lead
Jacobs Engineering Group and Researcher
TU Dublin



Carlos Pereira
Regional Manager of U.S. Midwest and Canada,
VTI Life Sciences



Jerry Quirke
Lead Process Engineer
Kneat Solutions



Roque Redondo, VP
Automation and Business Development USA
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Ken Shitamoto
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Ronald D. Snee Ph.D.
Founder and President
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Raul Soto
Senior Principal Software Quality Engineer
Johnson & Johnson Vision Care



David W. Vincent, MPH, Ph.D.
CEO
VTI Life Sciences



TJ Woody
Director of Cleaning Validation
Azzur Group



Joseph Zec
R&D CSV/Process QA and Compliance Leader
Takeda

DAY ONE		AUGUST 23, 2021
12:00 ET		Registration and Exhibitor Showroom Openhouse
1:00 ET		Chairperson's Opening Remarks
1:15 - 2:15 ET		FDA Regulator Roundtable: Compliance Intelligence – Agency Insight, Trends, and a Year in Review James Mason, PharmD, Compliance Officer, OPQO, U.S. FDA (Invited)
2:15 - 2:45 ET		Understanding Human Behavior and Quality Culture in Validation and GMP Operations Danielle Duran, Director, GxP Compliance and Training, Aimmune Therapeutics, a Nestle Health Sciences Company
2:45 ET		Exhibitor Showroom and Refreshment Break
3:15 - 4:00 ET		Process Validation and Continued Verification – A Risk-based Implementation Case Study Javier Cardenas, Ph.D., Senior Consultant, Technical Lead, Azzur Group
4:00 - 4:30 ET		Validation Master Plans (VMP), Protocols and Reports - Discover Best in Procedural Templates JR Humbert, Senior Director Quality, INCOG Biopharma
4:30 - 5:00 ET		Annex 1 Contamination Control – What the Recent Revision Means for Validation Parsa Famili, President & CEO, NOVATEK INTERNATIONAL
5:00 ET		Game Night - Trivia Welcome Reception
DAY TWO		AUGUST 24, 2021
7:30 ET		Exhibitor Showroom and Lite Breakfast
8:20 - 9:05 ET		Select Between Knowledge Exchange Sessions (1-4)
1		Conduct a Gap Analysis of Your Validation Program Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, CAI
2		Supplier Qualification – Create and Maintain Quality Agreements JR Humbert, Senior Director Quality, INCOG Biopharma
3		Single Use Systems (SUSs) – Implementation and Validation David W Vincent, MPH, Ph.D., CEO, VTI Life Sciences
4		Data Integrity Risk Assessments and Process Mapping Chinmoy Roy, Senior Industry Consultant, ValGenesis
9:15 - 10:00 ET		Select Between Knowledge Exchange Sessions (5-8)
5		Supply Chain Validation - Lessons Learned During Covid-19 To Be Announced
6		FDA Inspection Management – Tips that Impress Investigators Mony Clark, Senior Manager, QA Compliance, Genmark Dx - Roche Diagnostics
7		Align Your CSV Program with FDA's Proposed CSA Guidance Joseph Zec, R&D CSV/Process QA and Compliance Leader, Takeda
8		Data Integrity Programs – Case Study Examples Matthew LaPierre, Data Integrity Specialist, Jackson Scott Consulting

10:00 ET	Exhibitor Showroom and Refreshment Break
10:30 - 12:00 ET	Select Between Knowledge Exchange Sessions (9-12)
9	Lean Validation – Ensure Quality While Reducing Costs Phil Jarvis, Global C&Q lead for EU, AbbVie Jerry Quirke, Lead Process Engineer, Kneat Solutions
10	📄 Risk-based Cleaning Validation - Key Elements for Success Susan B. Cleary, B.Cs, M.B.A., Director of Product Development, NOVATEK INTERNATIONAL
11	Critical Thinking and Change Management – Lessons Learned from the CSA Movement Ken Shitamoto Senior Director, IT Gilead Sciences
12	Data Integrity – Assessment, Implementation, and Maintenance Kim Huynh-Ba, Managing Director, Pharmalytik LLC ; Adjunct Professor, Regulatory Compliance, Illinois Institute of Technology (IIT)
12:00 ET	Grab & Go Lunch and Think Tank Sessions
12:30 - 1:15 ET	Select Between Knowledge Exchange Sessions (13-16)
13	Overcome the Top 5 Validation Challenges Gerardo Gomez, Ph.D., Director QMC-US, Pharmalex
14	Common Gaps in Cleaning Validation and Their Solutions – From Pain to Optimization TJ Woody, Director of Cleaning Validation, Azzur Group
15	Learn How to Use Effective Risk-based Decision Making in Validation Ronald D. Snee, Ph.D., Founder and President, Snee Associates, LLC.
16	📄 Ensure Data Integrity by Design (DIBD) – The Right Data, Right from the Start Steve Thompson, Director Industry Solutions, ValGenesis
1:30 - 3:00 ET	Select Between Knowledge Exchange Sessions (17-20)
17	Case Study – Implementing a Risk-based Process Validation Life Cycle Approach Connie Hetzler, Global Head - Validation, Alcon Laboratories
18	📄 Process Validation Statistics for Non-statisticians Alan Golden, MS, Principal, Design Quality Consultants, LLC
19	CSV Hot Topics – SaaS, Spreadsheets, Network Qualification, Clouds, Mobile Technology and Digitalization Carlos Pereira, Regional Manager of U.S. Midwest and Canada, VTI Life Sciences
20	Cultivate the Culture of Integrity in Data Management Roque Redondo, VP Automation and Business Development USA Operations, mirus
3:00 ET	Exhibitor Showroom and Refreshment Break
3:30 - 5:00 ET	Select Between Knowledge Exchange Sessions (21 -24)
21	Validation & Verification – A Medical Device Master Class Melissa Brookshier, Director, Azzur Group
22	Statistical Process Control and The Use Of Control Charts Douglas B. Brown, Ph.D., Senior Scientist and Manager, Charles River

23	 Take a Risk-based Approach to Audit Trail Reviews Joseph Zec, R&D CSV/Process QA and Compliance Leader, Takeda
24	Build Your Custom Audit Checklist – Master Class Mony Clark, Senior Manager, QA Compliance, Genmark Dx - Roche Diagnostics
5:00 ET	Close of Day Two
DAY THREE	AUGUST 25, 2021
7:30 ET	Exhibitor Showroom Opens
8:20 - 9:05 ET	Select Between Knowledge Exchange Sessions (25-28)
25	 Risk-based Commissioning & Qualification – Successful Development and Execution Donnacha Nagle, Commissioning, CQV Lead, Jacobs Engineering Group and Researcher, TU Dublin
26	Validation Statistics – Strategies to Graph, Analyze, and Present Data Raul Soto, Senior Principal Software Quality Engineer, Johnson & Johnson Vision Care
27	Cleaning Validation Hot Topics – Documentation, Acceptance Criteria and Health Limits Cindy Duhigg, Global Validation Steward, Alcon Laboratories
28	Learn How to Conduct a Mock Inspection in Preparation for an Audit Eric Henry, Senior Quality Systems and Compliance Advisor, FDA and Life Science Practice, King & Spalding
9:15 - 10:00 ET	Select Between Knowledge Exchange Sessions (29-32)
29	Optimize Process Performance - Implement an Effective Quality Monitoring System Ronald D. Snee, Ph.D., Founder and President, Snee Associates, LLC.
30	Conduct Remote Virtual Factory Acceptance Testing (FAT) Donnacha Nagle, Commissioning, CQV Lead, Jacobs Engineering Group and Researcher, TU Dublin
31	Leverage Digital Validation for Streamlined Risk-Based Testing Dori Gonzalez-Acevedo, VP of Strategic Solutions, Tx3 Services
32	 Learn How to Use Risk in Change Control Processes Roque Redondo, VP Automation and Business Development USA Operations, mirus
10:00 ET	Exhibitor Showroom and Refreshment Break
10:30 - 12:00 ET	Select Between Knowledge Exchange Sessions (33-36)
33	 Critical Utility Qualification and Environmental Monitoring Performance Qualification Elizabeth Brockson, Associate Director, Global Quality Control, CAI
34	Apply Quality by Design (QbD) for all Validation Types – QbD for All Steve Thompson, Director Industry Solutions, ValGenesis
35	What to Do When Things Go Wrong – Implement an Effective CAPA Program Shannon Chesterfield, Senior Director of Consulting, Azzur Group
36	Mastering the Critical Elements of a Quality Risk Management (QRM) Program Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, CAI

12:00 ET	Grab & Go Lunch and Think Tank Sessions
1:30 - 3:00 ET	Select Between Knowledge Exchange Sessions (37-40)
37	Personnel Training – Hiring People that Make Validation Great Mark Chesire, Business Development Manager, H&A Scientific
38	Use Validation Sampling Plans for Critical Decisions Cindy Duhigg, Global Validation Steward, Alcon Laboratories
39	Analytical Method Validation – What Quality and Process Professionals Need to Know Kim Huynh-Ba, Managing Director, Pharmalytik LLC ; Adjunct Professor, Regulatory Compliance, Illinois Institute of Technology (IIT)
40	Change Control - Conduct System Criticality and Impact Assessments Alan Golden, MS, Principal, Design Quality Consultants, LLC
3:00 ET	Exhibitor Showroom and Refreshment Break
3:15 - 4:45 ET	Select Between Knowledge Exchange Sessions (41-44)
41	Assay Transfer, Qualification, Validation – Are We Living in a ‘Land of Confusion’? Douglas B. Brown, Ph.D., Senior Scientist and Manager, Charles River
42	Qualification of Temperature Mapping and Storage Chambers Steven S. Kuwahara, Ph.D., Principal Consultant, GXP BioTechnology
43	Validation and Change Control – Null Hypothesis Significant Testing Raul Soto, Senior Principal Software Quality Engineer, Johnson & Johnson Vision Care
4:45 ET	Close of Conference

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Biopharmaceutical Manufacturing University
November 9-11, 2021 • San Diego, CA

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