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VALIDATION & GMP UNIVERSITY 2021

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

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ELITE FACULTY

Chip Bennett
Associate Director, Global C&Q, SME, CQV Program Development, **CAI**

Elizabeth Brockson
Senior Validation Scientist
CAI

Melissa Brookshier
Director
Azzur Group

Douglas B. Brown Ph.D.
Senior Scientist and Manager
Charles River

Javier Cardenas, Ph.D.
Senior Consultant, Technical Lead
Azzur Group

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Business Development Manager
H&A Scientific

Shannon Chesterfield
Senior Director of Consulting
Azzur Group

Mony Clark
Senior Manager, QA Compliance
Genmark Dx - Roche Diagnostics

Susan B. Cleary, B.Cs, M.B.A.
Director of Product Development
NOVATEK INTERNATIONAL

Cindy Duhigg
Global Validation Steward
Alcon Laboratories

Danielle Duran
Director, GxP Compliance and Training
Aimmune Therapeutics,
a Nestle Health Sciences Company

Parsa Famili
President & CEO
NOVATEK INTERNATIONAL

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Principal
Design Quality Consultants, LLC

Gerardo Gomez Ph.D.
Director QMC-US
Pharmalex

Dori Gonzalez-Acevedo
VP of Strategic Solutions
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Eric Henry
Senior Quality Systems and Compliance Advisor
FDA and Life Science Practice
King & Spalding

Connie Hetzler
Global Head – Validation
Alcon Laboratories

JR Humbert
Senior Director Quality
INCOG Biopharma

Kim Huynh-Ba
Managing Director, **Pharmalytik LLC**
Adjunct Professor, Regulatory Compliance
Illinois Institute of Technology (IIT)

Phil Jarvis
Global C&Q lead for EU
AbbVie

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)*

Donncadh Nagle
Commissioning, Qualification & Validation 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 Operations, **mirus**

Chinmoy Roy
Senior Industry Consultant
ValGenesis

Ken Shitamoto
Senior Director, IT
Gilead Sciences

Ronald D. Snee Ph.D.
Founder and President
Snee Associates, LLC.

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** Donncha Nagle, Commissioning, Qualification & Validation 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)** Donncha Nagle, Commissioning, Qualification & Validation 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, Senior Validation Specialist, **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	**T 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	**T 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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Mark Your Calendar for Other 2021 Conferences

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

Computer Systems Validation & Software Assurance University
December 6-8 , 2021 • San Diego, CA