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28 - 30 June 2021 | Hilton Grand Canal | Dublin, Ireland

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DAY ONE	28 JUNE 2021
11:00 IST	Exhibitor Showroom and Virtual Platform Open House
11:30 IST	Chairperson's Opening Remarks
11:45 - 12:15 IST	**Effective Risk-based Decision Making** Nuala Calnan, Ph.D., Founder & Principal, **BioPharm Excel Ltd.**; Adjunct Research Fellow, **Technological University Dublin**
12:15 - 12:45 IST	**FDA Insight – Agency Updates and Compliance Trends** James Mason, PharmD, Compliance Officer, OPQO, **U.S. FDA**
12:45 - 13:15 IST	**Validation Audit Preparation** Phil Jarvis, Global C&Q lead for EU, **AbbVie**
13:15 IST	Exibitor Showroom and Afternoon Stretch
13:45 - 14:15 IST	**Examine Validation Training Effectiveness** Danielle Duran, Director, GxP Compliance and Training, **Aimmune Therapeutics, a Nestle Health Sciences Company**
14:15 - 14:45 IST	**Detecting the Lack of Data Integrity** Ronald D. Snee, Ph.D., Founder and President, **Snee Associates, LLC**
14:45 - 15:15 IST	**Remote FAT Execution – Best Practices** Alice Redmond, Vice President European Operations, **CAI**
15:15 IST	Exibitor Showroom and Afternoon Stretch
15:45 - 16:15 IST	**Assessing GxP SaaS Vendors – Maximize Application Utility, Performance and Compliance** Stephen R. Ferrell, CISA CRISC CDPSE – Managing Director, **CompliancePath**
16:15 - 16:45 IST	**Annex 1 Contamination Control – What the Recent Revision Means for Validation** Parsa Famili, President and CEO, **NOVATEK INTERNATIONAL**
16:45 - 17:30 IST	**FDA's Proposed Computer Software Assurance Guidance** Kevin Martin, General Manager & Managing Partner, **Azzur Group** LLC and Ken Shitamoto, Senior Director, **Gilead Sciences**
17:30 IST	*Game Night - Trivia Welcome Reception*
DAY TWO	**29 JUNE 2021**
8:00 IST	Exhibitor Showroom Opens
8:30 - 9:15 IST	Select Between Knowledge Exchange Sessions (1-2)
1	**Emerging Technologies in the Pharma and Life Sciences Industry – Mixed Reality Case Study** Donncadh Nagle, CQV Lead, **Jacobs Engineering Group**; & Researcher, **TU Dublin**; Michael Egan, Lead Validation Engineer I, **Alkermes Pharma Ireland**
2	**Create an Effective Supplier Quality Agreement** Elizabeth Rivera, Technical Services Manager, **STERIS**
9:30 - 11:00 IST	Select Between Knowledge Exchange Sessions (3-5)
3	**Implement a Risk-Based Process Validation Programme** Phil Jarvis, Global C&Q lead for EU, **AbbVie**
4	**Contamination Control Strategy – An Implementation Approach** Walid El Azab, Senior Manager Technical Services, **STERIS**
5	**Mapping CQA, CPP, CA – Methodology, Risk Assessment, Sustaining Operations and Change Control** Alice Redmond, Vice President European Operations, **CAI**
11:10 - 11:50 IST	Exhibitor Showroom and Think Tank Sessions

6	**Wired vs. Wireless - Risk and Benefits of Thermal Validation** Dennis Plante, Senior Validation Market / Product Manager, **Amphenol - Kaye**
7	**Personnel Training – Hiring People that Make Validation Great** Gerardo Gomez, Ph.D., Director of Validation Services, **PharmaLex**
12:00 - 12:45 IST	Select Between Knowledge Exchange Sessions (8-10)
8	**Process Validation Statistics for Non-statisticians** Alan Golden, MS, Principal, **Design Quality Consultants, LLC**
9	**Optimize Your Validation Efforts Using QRM** William T. Drummond Jr., MSCS, Senior Director, Global Quality Systems, **Charles River Laboratories**
10	**Navigate the Maze of Data Integrity Regulations** Roque Redondo, VP Automation & Business Development, **Mirus Consulting Group**
12:55 - 13:35 IST	Exhibitor Showroom and Think Tank Sessions
11	**Build Your Custom Audit Checklist – Master Class** Dawn Marshall, Senior Director Global Quality, **Sanofi Pasteur**
12	**Align Your CSV Programme with FDA's Proposed CSA Guidance** Kevin Martin, Senior Director & Managing Partner, **Azzur Group**
13:45 - 15:15 IST	Select Between Knowledge Exchange Sessions (13-15)
13	**Risk-Based Cleaning Validation – Applying CQAs and CPPs Throughout the Cleaning Process Validation Lifecycle** Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, **CAI**
14	**Cultivate the Culture of Integrity in Data Management** Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**
15	**Learn How to Use Statistics as a Risk Tool** Tara Scherder, Partner, and Katherine Giacoletti, Partner, **SynoloStats**
15:25 - 16:05 IST	Exhibitor Showroom and Think Tank Sessions
16	**HANDS-FREE Validation Using Augmented Reality** Steve Thompson, Director Industry Solutions, **ValGenesis, Inc.**
17	**Inspection Management – Root Cause Analysis and Corrective Action (CAPA)** Gerardo Gomez, Ph.D., Director of Validation Services, **PharmaLex**
16:15 - 17:45 IST	Select Between Knowledge Exchange Sessions (18-20)
18	**Validation Statistics with Confidence and The Arts of Charts** Ronald D. Snee, Ph.D., President, **Snee Associates, LLC**
19	**Manage Data Integrity Inspections and Respond to Findings** Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**
20	**Mastering the Critical Elements of a QRM Programme** Roque Redondo, VP Automation & Business Development, **Mirus Consulting Group**
17:45	Close of Day Two
DAY THREE	**30 JUNE 2021**
8:00 IST	Exhibitor Showroom Opens
8:30 - 9:15 IST	Select Between Knowledge Exchange Sessions (21-22)
21	**The Big Reshuffle – Impact Assessment and System Criticality** Donncadh Nagle, CQV Lead, **Jacobs Engineering Group**; and Researcher, **TU Dublin**; Laura Butchart, Validation Lead, **ParagonV**; Philip Jarvis, Global Commissioning & Qualification Lead (EU), **AbbVie**
22	**Conduct a Change Control Impact Assessment** Dawn Marshall, Senior Director and Sterility Assurance SME, **Sanofi**

9:30 - 11:00 IST	Select Between Knowledge Exchange Sessions (23-25)
23	**Lean Validation - Ensure Quality While Reducing Costs** Phil Jarvis, Global C&Q lead for EU, **AbbVie**; Jerry Quirke, Lead Process Engineer, **Kneat Solutions**
24	**Qualify Utilities – Water Systems, Clean Steam and Process Gases** David W. Vincent, MPH, Ph.D., CEO, **VTI Life Sciences**
25	**Advanced Cleaning Validation – How Much Validation is Enough and Green Your Clean** Dr. Kenneth Pierce, Cleaning Validation SME, **Hyde Engineering + Consulting**
11:10 - 11:50 IST	Exhibitor Showroom and Think Tank Sessions
26	**Legacy Software Applications and Spreadsheets - Data Integrity and Compliance** Sanjay Agrawal, President and CEO, **CIMCON Software, LLC**
27	**Build a Streamlined Audit Trail Review Process** Matthew LaPierre, Data Integrity Specialist, **Jackson Scott Consulting**
12:00 - 12:45 IST	Select Between Knowledge Exchange Sessions (28-30)
28	**Cleaning Validation – Documents, SOPs and Checklists** Fred Ohsiek, Senior Cleaning Validation Specialist, **Novo Nordisk**
29	**Create Validation Strategy for Intelligent Automation** Steve Thompson, Director Industry Solutions, **ValGenesis, Inc.**
30	**Integrate Risk Management into Change Control Processes** Raul Soto, Senior Principal Engineer, **Johnson & Johnson Vision Care**
12:55 - 13:35 IST	Exhibitor Showroom and Think Tank Sessions
31	**Equipment Qualification – A Risk-based Approach to Ensure Fit for Intended Use** Chip Bennett, Associate Director, Global C&Q, **CAI**
32	**Overcome the Top Challenges of Data Integrity Implementation** Matthew LaPierre, Data Integrity Specialist, **Jackson Scott Consulting**
13:45 - 15:15 IST	Select Between Knowledge Exchange Sessions (33-35)
33	**Process Validation and Successful Tech Transfer** David W. Vincent, MPH, Ph.D., CEO, **VTI Life Sciences**
34	**The Validation Master Plan (VMP) – Plans that Impress Investigators** Connie Hetzler, Global Head – Validation, **Alcon Laboratories**
35	**Computer Software Assurance Deep Dive** Ken Shitamoto, Senior Director, **Gilead Sciences**
15:30 - 15:45 IST	Exhibitor Showroom and Afternoon Stretch
15:45 – 17:15	Select Between Knowledge Exchange Sessions (36-38)
36	**Medical Device Validation & Verification Master Class** Alan Golden, MS, Principal, **Design Quality Consultants, LLC**
37	**Right Size Sampling and Statistics for PPQ** Tara Scherder, Partner and Katherine Giacoletti, Partner, **SynoloStats**
38	**Data Integrity Risk Assessment Across the Data Lifecycle** Chinmoy Roy, Senior Industry Consultant, **Valgenesis**
17:45 IST	Close of Conference