VALIDATION UNIVERSITY

PROCESS VALIDATION & CONTINUED PROCESS VERIFICATION

CLEANING VALIDATION & CRITICAL CLEANING PROCESSES

COMPUTER SYSTEMS VALIDATION & DATA INTEGRITY INSPECTION READINESS

25 - 27 November 2019 | Cork, Ireland

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DAY ONE	25 November 2019
12:00	**Conference Registration** *Coffee and Tea*
13:15	**Chairperson's Welcome and Opening Remarks**
13:30	**Ensure Your Validation, QRM and DI Programmes are Fit-for-Purpose** Nuala Calnan, Ph.D, Founder & Principal, **BioPharm Excel Ltd.** Researcher, **Technological University Dublin**
14:00	**Data Integrity Inspection Readiness – An Up-to-the-Minute Update** Tracy Moore, GMDP Operations Manager and Senior Inspector, Inspection Enforcement & Standards Division, **MHRA (Invited)**
14:30	**Prepare for Validation Inspections and Respond to Regulatory Findings** Milan Kalinic, Validation Lead, **Alexion Pharmaceuticals**
15:00	**Networking Refreshment Break**
15:30	**Managing a Data Integrity Programme – Essential Tips for Success** Matthew LaPierre, Specialist – CSV and Data Integrity Compliance
16:00	**Overcome the Top Five Validation Challenges** Connie Hetzler, Global Head – Validation, **Alcon Laboratories**
16:30	**Conduct Risk-Based Revalidations and Periodic Reviews of Systems** Donncadh Nagle, Validation Coordinator, **Avara Shannon** Researcher, **Technological University Dublin**
17:15	*Networking & Welcome Reception*

DAY TWO	26 November 2019
07:00	**Coffee and Lite Breakfast**
07:30–08:15	**Select Between Knowledge Exchange Sessions (1-4)**
1	**Documentation Requirements for Successful Validation** Chinmoy Roy, Data Integrity and CSV SME, **Consultant**
2	**Implementation of a Risk-based Cleaning Validation Management System** Parsa Famili, President & CEO, **Novatek International**
3	**Change Control in Validation – Managing Like-for-Like Changes** Donncadh Nagle, Validation Coordinator, **Avara Shannon**, Alma O'Reilly, Validation Manager, **LEO Pharma**, Researchers, **Technological University Dublin**
4	**Data Integrity – Navigating the Maze of Regulations** David W. Vincent, Ph.D., CEO, **VTI Life Sciences**
08:30-10:00	**Select Between Best-In-Class Case Studies (5-8)**
5	**The Validation Master Plan (VMP) – Plans that Impress Investigators** Connie Hetzler, Global Head – Validation, **Alcon Laboratories**
6	**Risk-Based Cleaning Validation – Key Elements to a Successful Programme** Fergal Giles, Cleaning Validation Lead, **Janssen Sciences Ireland**
7	**Introduction to Validation Statistics for Non-Statisticians** Raul Soto, Senior Principal Software Engineer, **Johnson & Johnson Vision Care**
8	**Implement an Effective and Pragmatic Data Integrity Programme** Chris Reid, Managing Director, **Integrity Solutions, Inc.**
10:00	**Networking Refreshment Break**

10:30–12:00	**Select Between Knowledge Exchange Sessions (9-12)**
9	**Successful Implementation of a 3-Stage Process Validation Programme** David W. Vincent, Ph.D., CEO, **VTI Life Sciences**
10	**Establish Acceptance Criteria and Health-Based Limits in Cleaning Validation** Joe Brady, Lecturer, **School of Chemical and Pharmaceutical Sciences**
11	**Implement a Risk-Based Computer Systems Validation Programme** Chris Reid, Managing Director, **Integrity Solutions, Inc.**
12	**Impact of Human Factors on Data Integrity** Matthew LaPierre, Specialist – CSV and Data Integrity Compliance
12:00	**DUBLIN** Poster Session & Networking Luncheon
13:15–14:45	Select Between Knowledge Exchange Sessions (13-16)
13	**Risk-based IQ/OQ/PQ Development and Execution** Cliff Campbell, **Cliff Campbell Consulting Ltd.**
14	**Implementation and Validation of Single Use Systems (SUSs) in Biopharmaceutical Manufacturing** Aidan Sexton, Process Validation Support Lead, **Janssen Sciences Ireland**
15	**Implementation of a Risk-based Verification Strategy for CQV** Alice Redmond, Vice President European Operations, **Commissioning Agents Inc.**
16	**Effective Continuous Cleaning Process Verification – Key Elements to a Successful Programme** Sunil Patel, Senior Global Technical Leader, **Ecolab Life Sciences**
14:45	Afternoon Refreshment Break
15:15–16:45	Select Between Knowledge Exchange Sessions (17-20)
17	**Key Considerations for Process Validation and Successful Tech Transfer** Derek Foley, Senior Validation Engineer, **Janssen Sciences Ireland**
18	**Cleanroom Validation, Disinfection and Environmental Monitoring** Sunil Patel, Senior Global Technical Leader, **Ecolab Life Sciences**
19	**Validation of Mobile Applications** Raul Soto, Senior Principal Software Engineer, **Johnson & Johnson Vision Care**
20	**Data Integrity Master Class** Rashida Ray, President, **Array Validation Quality and Compliance (AVQC), Inc.**
16:45	Day Two Closing Session **Validating Cloud Solutions – Learn How to Mitigate Risk** Michal Timler, Senior Validation Consultant, **ecvalidation**
DAY THREE	**27 November 2019**
07:00	Coffee and Lite Breakfast
07:30–08:15	Select Between Knowledge Exchange Breakfasts (21-24)
21	**Build an Effective Medical Device Single Audit Programme** David W. Vincent, Ph.D., CEO, **VTI Life Sciences**
22	**Latest Developments in the Qualification of Water Systems, Clean Steam Systems and Process Gasses** Mark Thompson, Managing Director, **Mark Thompson Life Sciences Ltd.**
23	**Acquire a Systematic Approach for a Knowledge Management Model** Cliff Campbell B.E., Principal, **Cliff Campbell Consulting Ltd.**
24	**Learn How to Use Testing as a Risk Mitigation Tool** Kamila Sitkiewicz, Senior Validation Consultant, **ecvalidation**

08:30-10:00	**Select Between Knowledge Exchange Sessions (25-28)**
25	**Continued Process Verification (CPV) – Maintain the Validation State** Philip Jarvis, Global C&Q, **Abbvie**
26	**Development and Qualification of Vapour Phase Hydrogen Peroxide for Decontamination & Sterilisation** Mark Thompson, Managing Director, **Mark Thompson Life Sciences Ltd.**
27	**Qualification and Data Integrity Strategies for IT Infrastructures** Oisín Curran, CEO, **CompliantCloud.com**
28	**Manage Data Integrity Inspections and Respond to Inspectional Findings** To Be Announced
10:00	**Mid-Morning Refreshment Break**
10:30-12:00	**Select Between Knowledge Exchange Sessions (29-32)**
29	**Data Contextualization, Modelling (Multi Variate Analysis) and Advanced Process Control** Patrick T. O'Sullivan Multivariate Analysis Lead, **Janssen Sciences Ireland**
30	**Critical Cleaning Process Parameters and Critical Quality Attributes** Philip Jarvis, Global C&Q, **Abbvie**
31	**The Use of Wireless Dataloggers for Thermal Validation** Chris Maughan, Managing Director, Thermal Compliance Ltd.
32	**Conducting an Audit and Gap Analytical of Computerised Systems** Matthew LaPierre, Specialist – CSV and Data Intvegrity Compliance
12:00	**Networking Luncheon**
	Insights from a Cleanroom Validation Case Study Sunil Patel, Senior Global Technical Leader, **Ecolab Life Sciences**
13:00-14:30	**Select Between Knowledge Exchange Sessions (33-35)**
33	**Equipment Qualification – Fit for Intended Use** Milan Kalinic, Validation Lead, **Alexion Pharmaceuticals**
34	**Cleanroom Validation, Disinfection and Environmental Monitoring** To Be Announced
35	**Machine Learning (ML) Validation and the Future of CSV** Rosalind Beasley, Digital Transformation Leader, **ROQMetrics, Inc.**
14:30	**Afternoon Refreshment Break**
15:00-16:30	**Select Between Knowledge Exchange Sessions (36-37)**
36	**Statistical Process Controls – Construct and Analyze Control Charts** Raul Soto, Senior Principal Software Engineer, **Johnson & Johnson Vision Care**
37	**Overcome the Challenges of MS Excel Spreadsheet Validation** To Be Announced
16:30	**Close of Conference**