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11TH ANNUAL

VALIDATION AND LAB WEEK EUROPE

19-21 MAY 2020 • HILTON DUBLIN • DUBLIN, IRELAND

NEW GLOBAL REGULATIONS, TECHNOLOGY ADVANCES AND INDUSTRY CASE MODELS FOR DEVELOPING, IMPLEMENTING AND DEPLOYING VALIDATION PROCEDURES ENTERPRISE-WIDE

IVT Certificate of Attendance — Earn GMP Training Hours

KEYNOTE PRESENTATIONS

Kevin O'Donnell, Market Compliance Manager, **Health Products Regulatory Authority (HPRA)** (Invited)

Anne Greene, Professor and Head of Pharmaceutical Regulatory Science Team (PRST), **TU Dublin**

Michael Zwitkovits, GMDP, Inspector, **Austrian Medicines and Medical Devices Agency**

DISTINGUISHED FACULTY REPRESENTING:

ASTELLAS IRELAND ★ BEI ROCHE ★ BRISTOL-MYERS SQUIBB ★ CSL BEHRING EIRCHEM ★ FRESENIUS KABI ★ JOHNSON & JOHNSON VISION CARE LEO PHARMA ★ MINAPHARM PHARMACEUTICALS ★ NIBRT ★ TU DUBLIN

EXPLORE THE KEY ISSUES IN VALIDATION:

- Recent Advances in Quality Risk Management — The PIC/S QRM Expert Circle, Inspector Training and Inspectional Deficiencies
- Validation and Data Integrity with Advanced Technologies
- Development of Compliance Culture in Laboratory Operations
- Best Practices for Stability and Forced Degradation Studies
- Lifecycle Approach to Cleaning Validation
- Change Control — Design, Validation and Implementation

CONFERENCE HIGHLIGHTS:

- **TWO INTENSIVE WORKSHOPS**
  - — Annex 1 Validation Readiness
  - — Lifecycle Approach to Validation and Qualification in the Laboratory
- **GAME CHANGER PANEL**
  Update on Regulatory and Industry Collaboration on Computer Software Assurance (CSA)
- **MOCK INSPECTION**
  Prepare for the Rigors of Regulatory Inspection and How to Respond to Regulatory Inspection Findings

Presented by:

IVT NETWORK
INSTITUTE OF VALIDATION TECHNOLOGY
Brought to you by Informa Connect

MEDIA PARTNERS: PHARMA ADVANCEMENT, PharmTech, LCGC north america, BioPharm International

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Conference Participants Representing More Than

25 COUNTRIES

- Austria
- Belgium
- Canada
- Czech Republic
- Denmark
- Egypt
- Finland
- France
- Germany
- India
- Ireland
- Israel
- Italy
- Lithuania
- The Netherlands
- Norway
- Singapore
- South Africa
- South Korea
- Spain
- Sweden
- Switzerland
- Taiwan
- United Kingdom
- USA

IVT's Validation and Lab Week Europe is industry's flagship global event for quality and validation excellence. Backed by over a decade of knowledge-sharing and networking, this conference is the premier forum to gain comprehensive information on new regulations, technology advances and case models for developing, implementing and deploying validation procedures enterprise-wide. By attending, you'll benefit from an end-to-end roadmap for compliance in a complex and highly regulated environment.

The program features customisable learning and networking opportunities, including a unique track dedicated to Validation and another specifically focused on the Laboratory, plus:

- *Two Inclusive Workshops*
- *Twelve Interactive Content Offerings for Peer-to-Peer Knowledge Sharing*
- *Ten Opportunities to Expand Your Validation Network*
- *Eleven In-Depth and Advanced Sessions*

Who Should Attend:

You will benefit from attending this event if you work within the life sciences industry with responsibilities or involvement in the following areas:

★ Validation ★ Engineering ★ Quality / QA / QC ★ Laboratory Operations
★ IT / IS ★ Software ★ Regulatory Affairs ★ Scientist ★ R&D

This conference will also benefit consultants and software vendors providing services in the above areas of validation, laboratories, compliance, documentation management and QMS.

COMPLIANCE group

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DAY ONE TUESDAY 19 MAY 2020

7:00 *Registration and Networking Breakfast*

8:00 *Conference Chair's Welcome and Opening Remarks*
Karen Ginsbury, B.Pharm., M.Sc., MRPharmS., President and CE,
PCI Pharmaceutical Consulting Israel Ltd.

8:15 **Recent Advances in Quality Risk Management – The PIC/S QRM Expert Circle, Inspector Training and Inspectional Deficiencies**

- The December 2012 PIC/S Recommendation document on "Evaluating and Demonstrating the Effectiveness of the Pharmaceutical Quality System with regard to Risk-based Change Management"
- The activities of the PIC/S Expert Circle on QRM
- Inspector training in relation to QRM
- Recent inspectional deficiencies in relation to QRM and tips on how to avoid those same issues arising in your company
- Thoughts on how QRM should develop beyond 2020

Kevin O'Donnell, Market Compliance Manager,
Health Products Regulatory Authority (HPRA) *(invited)*

9:15 **The Role of Academia in Embedding Science and Knowledge into the PQ**

Moderator: *Anne Greene, Professor and Head of Pharmaceutical Regulatory Science Team (PRST),* **TU Dublin**

Presentations and Speakers:

- **Developing a Model for Demonstrating the Practical Effectiveness of QRM within the PQS**

Valerie Mulholland, Senior Consultant GMP Services/Researcher,
Technical University Dublin

- **An Exploration of Industry 4.0 in Pharmaceutical Manufacturing**

Luke Kiernan, B.Sc., M.Sc., Technical Services Director, **Innopharma Labs**

- **Development of a Knowledge Management Tool to Access the Regulatory Readiness Level of Innovative Treatments**

Eamonn McGowran, B.Sc., M.Sc., QA &Regulatory Manager, **Klox Tech**

10:15 *Networking and Refreshment Break*

10:45 **Non-Compliance Reports — A Regulator's Perspective on Corrective Actions in the Wake of Regulatory Citations**

A non-compliance report can quickly derail commercial and clinical operations. Learn to identify common root causes that have resulted in violations and better understand how to quickly mitigate the impact of non-compliance.

- Understand common issues that have led to violations
- Explore strategies to address regulatory observations

Michael Zwitkovits, GMDP Inspector,
Austrian Medicines and Medical Devices Agency

11:45 **Quality Risk Management in a Virtual Quality Oversight Environment**

The application of Quality Risk Management (QRM) principles can bring significant value to pharmaceutical operations and quality systems. This session will examine the application of QRM methodologies in an external manufacturing environment; applying risk criteria for external vendors, executing risk mitigation plans, performing risk review and measuring the effectiveness of the QRM process.

Lynsey Grehan, Associate Director of Quality Services, **Bristol-Myers Squibb**

12:30 *Networking Luncheon*

13:45 CHOOSE BETWEEN TWO WORKSHOPS*

A Lifecycle Approach To Validation and Qualification in The Laboratory

This uniquely tailored workshop will arm newcomers and seasoned laboratory and QC managers with the tools to properly monitor existing control programmes and implement current best practices. QA operations personnel will have a chance to benchmark and better understand the need for laboratory governance. Use case studies, real inspection findings, warning letters and audit findings to identify critical control points in the laboratory to enhance the integrity of your laboratory operations. The session will conclude with interactive mock audit scenarios.

Detailed information on the following topics:

- Introduction to QC relevant EU legislation, including ICH guidelines
- Differences between audits and inspections and types of audits/inspections
- Aide memoire
- Types of questions asked by auditors/inspectors and how to address them
- Laboratory Data Governance
- Audit trail review
- Electronic laboratory notebook best practices
- How to conduct effective internal audits and CAPA
- How to ensure an "always ready" status for regulatory inspections
- Validation case studies
- Mock audit scenarios

Shada Warreth, Senior Bioprocessing Trainer,
National Institute for Bioprocessing Research and Training

B Annex 1 Validation Readiness — Developing and Validating a Robust Contamination Control Strategy

A second draft of EU Annex 1 — Manufacture of Sterile Medicinal Products will be issued in early 2020, with the final version later in the year. Regulators have warned industry — the grace period will be short and rapid implementation and enforcement is planned. One of the biggest additions is the concept of a formal contamination control strategy. This workshop will allow participants to interactively learn and develop a strategy for implementation in their facilities using current risk assessments. A contamination control strategy is the outcome of a systematic risk assessment and mitigation plan incorporating validation as a major element in checking effectiveness. This workshop will address detailed information on the following topics:

- PLAN — New and legacy facility design and upgrade
  - * address ambiguity with personnel materials airlocks
  - * explore why barrier systems are a key risk management element
  - * contamination control strategy: craft a personalized checklist for your facility, process(es) and product(s)
- DO — Construction and ongoing lifecycle monitoring and maintenance of facility and equipment = managed CapEx is planned obsolescence rather than waiting for deviations
- CHECK — Validate your Contamination Control Strategy: craft a personalized VMP for your strategy, your facility, process(es) and product(s) — Demonstrate the effectiveness of YOUR company's strategy
- ACT — Fix what doesn't work
  - * Embed and continue to monitor and improve what works
  - * Manage change and validation of process and product over lifecycle using big data

Karen Ginsbury, B.Pharm., M.Sc., MRPharmS., President and CE,
PCI Pharmaceutical Consulting Israel Ltd.

*There will be a 30 minute networking break at 15:00.

17:15 *Close of Day One*

Networking, Wine and Cheese Reception
immediately following the final session on day one

DAY TWO WEDNESDAY 20 MAY 2020

7:30 *Networking Breakfast*

8:00 *Conference Chair's Review of Day One*
Karen Ginsbury, B.Pharm., M.Sc., MRPharmS., President and CE,
PCI Pharmaceutical Consulting Israel Ltd.

8:15 **Game Changer! Update on Regulatory and Industry Collaboration on Computer Software Assurance (CSA)**

Although FDA Title 21 CFR Part 11 was introduced in 1997 to regulate the use of computerised systems, many life sciences companies still struggle with the complexities and cost to comply, and remain using paper-based, manual tools for documentation and quality management. In an effort to harmonise with international standards, the FDA (CDRH) announced in their FY 2019 Proposed Guidance Development list to release a new draft guidance, "Computer Software Assurance for Manufacturing, Operations, and Quality System Software," that aligns with the current quality systems regulation ISO 13485. Hear directly from a member of the FDA/industry collaborative team on the scope of what this guidance may entail.

- Discuss industry recommendations for anticipated FDA draft guidance
- Hear success stories of implementing the guidance and the resulting benefits
- Analyse the challenges and solutions to automating non-product CSV

Khaled Moussally, EVP Clients & Regulatory Relations,
Compliance Group

9:15 **The Audit Trail Conundrum**

GMP-mandated audit trail review poses logistical and regulatory challenges for today's data integrity programmes. Discuss technical controls for the review and documentation of data touchpoints through the full lifecycle of regulated data sets during this technical analysis of audit trail best practices.

- Define what is an audit trail and how are they used
- Learn to configure and validate audit trail functionality
- Demonstrate technical controls to aid audit trail review

Morcos Loka, Training Manager and GMP Advisor,
Minapharm Pharmaceuticals

10:15 *Networking and Refreshment Break*

10:45 **INTERACTIVE SESSION — How to Respond to Regulatory Inspection Findings**

During this unique extended session, attendees benefit from an opportunity to learn from previous regulatory observations. Use this time to study, simulate and discuss how to properly react and respond to the questions and observations of regulators. The content for the session will be curated by regulatory experts, well-versed in corrective action, risk mitigation and compliance.

- Understand common issues that have led to violations
- Explore strategies to address regulatory observations

Karen Ginsbury, B.Pharm., M.Sc., MRPharmS., President and CE,
PCI Pharmaceutical Consulting Israel Ltd.
Willis Thomas, Ph.D., PMP, CPT, Editorial Advisory Board Member,
Journal of Validation Technology *and* **Journal of GXP Compliance**

12:00 *Networking Luncheon*

13:00-15:00 CUSTOMISE YOUR LEARNING EXPERIENCE AND CHOOSE BETWEEN TWO INTENSIVE CONTENT TRACKS (1-2)

1 Validation Strategies

13:00 **The PQS Effectiveness Workshop**

- Explore how the effective implementation of risk management in the PQS can be demonstrated
- Discuss the challenges with implementing appropriate risk controls in manufacturing environments
- Compare the role of management review in an effective QRM programme

Valerie Mulholland, Senior Consultant
GMP Services/Researcher, **Technical University Dublin**

13:50 **The Importance and Evolving Nature of Data Traceability**

As the volume of R&D and production data grows, the tools and techniques used in data capture, traceability and validation must evolve in parallel. Join peers and industry experts to discuss the evolution of data management and best practices for implementation.

- Identify common stumbling blocks to effective data governance
- Explore scale-out and how to bring existing systems into compliance with good data management standards
- Collaborate with peers to identify a strategy to reduce risk and eliminate human error related to data traceability

Michael Zwitkovits, GMDP Inspector,
Austrian Medicines and Medical Devices Agency

2 Best Practices for Laboratory Validation Management

Documentation Practices for Successful Operations

- Integrate data integrity into your quality management system
- Understand how to implement documentation trainings and maintain data integrity standards
- Learn steps to document and investigate data integrity issues

John O'Neill, MS, R.Ph., Stability Information Specialist, **StabilityHub**

Quality by Design (QbD) – Build Quality into Pharmaceutical Products for Patient Safety

QbD principles necessitate a robust understanding of a process before optimising it. This session will explore how to best use the philosophy of QbD within product development, including analytical methods.

- Examine the pillars of the QbD philosophy
- Learn how analytical methods validation can be connected to the QbD requirements given
- Apply QbD case studies found in literature to enhance your laboratory qualification practices

Anita Persson, Ph.D., Director of Analytical Development, **Fresenius Kabi**

14:40 *Networking and Refreshment Break*

15:10-16:00 CUSTOMISE YOUR LEARNING EXPERIENCE AND CHOOSE BETWEEN TWO COMPREHENSIVE BREAKOUT SESSIONS (1-2)

BREAKOUT 1.

15:10

Quality-Risk Management for Shared Facilities

Eroding profit margins and drug shortages are driving manufacturing economies. Yet the use of shared/multi-purpose facilities seems to represent a disproportionate level of risk for the manufacturer. In particular, product changeover and cleaning validation practices become complicated, costly and time-consuming. Understand how to execute effective risk assessments and resource mitigation measures.

- Learn how to select a team of SMEs able to accurately identify process and product related risks
- Understand EMA's Health-Based Exposure Limit (HBEL) Guidance and Q&As
- Explore tools for hands-on, time-limited risk management, communication, implementation and monitoring

Maximilian Augustin, Validation Engineer, **BEI Roche**

BREAKOUT 2.

Safeguarding Data in The Lab — Risk-based Cybersecurity

Cyber crime is sweeping the globe at an alarming rate. It is crippling business operations and paralyzing research and development operations. Life sciences companies are striving to protect their intellectual property and implement practical methods to safeguard data in the lab while maintaining compliance with regulatory agencies. This presentation discusses traditional and emerging approaches in safeguarding operations.

- Convey the importance of safeguarding data in the laboratory environment
- Identify potential vulnerabilities with documentation and systems in the laboratory environment that needs safeguarding
- Describe risk-based approaches to cyber security
- Discuss how the laboratory is becoming increasing electronic in its creation and transmission of data
- Review case studies in cyber security implemented in laboratory environments

Willis Thomas, Ph.D., PMP, CPT, Editorial Advisory Board Member, **Journal of Validation Technology** *and* **Journal of GXP Compliance**

16:00-16:50 CUSTOMISE YOUR LEARNING EXPERIENCE AND CHOOSE BETWEEN TWO COMPREHENSIVE BREAKOUT SESSIONS (3-4)

16:00

BREAKOUT 3.

Change Control — Design, Validation and Implementation

Change is often the only constant in the life sciences industry. Learn with real case studies how effective change control process keeps your operations current and compliant with minimal interruption to day-to-day operations. Understand how to classify and validate a process change.

- How change control is important to maintain validation status and regulatory compliance
- When change control is required to be initiated
- How to classify change and assess its impact
- What are the success factors in change control planning, implementation and follow up?
- How to measure effectiveness of change
- What are change control process Key Performance Indicators?

Morcos Loka, Training Manager and GMP Advisor, **Minapharm Pharmaceuticals**

BREAKOUT 4.

ROUNDTABLE DISCUSSION — Development of Compliance Culture in Laboratory Operations

Bio/pharmaceutical and medical device compliance is often complicated through the observation of regulatory minutia. Truly successful compliance programmes have built a culture of compliance down from the level of senior leadership. During this collaborative session, learn how to begin transforming your operations and grow an effective culture of compliance.

- Discuss how to effectively negotiate buy-in from senior leadership
- Explore strategies to modify staff behavior to enhance the compliance profile of your laboratory operations
- Leverage the collective intelligence of all conference attendees to increase the integrity of your compliance programme

Moderator:

John O'Neill, MS, R.Ph., Stability Information Specialist, **StabilityHub**

16:50

Like for Like Equipment Changes – A Hidden Risk?

Change is evitable within the pharmaceutical industry. 'Like-for-Like' changes to equipment have long been considered as normal practice within the industry, but do we fully understand what the true definition is for a 'Like-for-Like' change?

- Explore the question: Is there an inherent risk or are there sufficient controls in place within our Quality Management Systems to manage Like-for-Like equipment changes?
- Present a decision making tool which aims to reduce the risk

Bonus Material:

- A decision-making tool (Like-4F-Like) for assessing like-for-like changes

Alma O'Reilly, Validation Manager, Technical Services, **LEO Pharma**

Donnacha Nagle, Validation Lead, **Eirchem Pharmaceutical Services Limited;** *also representing* **Technological University Dublin**

17:40 *Close of Day Two*

DAY THREE THURSDAY 21 MAY 2020

7:30 *Networking Breakfast*

8:00 *Conference Chair's Review of Day Two* • *Karen Ginsbury, B.Pharm., M.Sc., MRPharmS., President and CE,* **PCI Pharmaceutical Consulting Israel Ltd.**

8:15-10:15 CUSTOMISE YOUR LEARNING EXPERIENCE AND CHOOSE BETWEEN TWO INTENSIVE CONTENT TRACKS (3-4)

3 Validation Strategies

8:15

Lifecycle Approach to Cleaning Validation

The FDA Process Validation Guidance outlines principles and approaches for manufacturing process validation of drugs and API. Its concepts are also being utilised in other validated processes, equipment/facilities/utilities qualification, quality systems management and other applications.

- Describe a lifecycle approach to cleaning validation
- Review cleaning-related activities during each stage of cleaning validation
- Discuss technical problems associated with stage activities are discussed
- Propose internal audit questions for site cleaning validation programme evaluations

Paul L. Pluta, Ph.D., Editor-in-Chief, **Journal of Validation Technology** *and* **Journal of GXP Compliance, Informa Connect**, *Managing Director,* **Lifecycle Compliance Systems;** *Adjunct Faculty,* **College of Lake County**

9:15

Validation of Computerized Instruments

- Discuss a systems development lifecycle approach
- Harmonize the U.S. Pharmacopoeia model with the GAMP model
- Outline 21 CFR Part 11 and data integrity aspects

Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

4 Best Practices for Laboratory Validation Management

Best Practices for Stability and Forced Degradation Studies

Stability testing is a major resource commitment in the QC laboratory. Explore what must be achieved in order to establish and then maintain GMP compliance.

- Discuss best practices for stability study initial start up
- Understand how to reduce resource commitments while maintaining compliance and knowledge of product safety
- Explore the importance of "stability indicating" tests
- Learn best practices for the reporting and documentation of stability tests

Jeremiah Hayes, Quality Control Manager, **Astellas Ireland**

Statistics in Validation for Non-Statisticians

In this programme, we will discuss the common statistics tools and techniques used in validation. Through real-world examples and interactive exercises, we will demonstrate the basic concepts of statistics and how to apply them to your validation projects. Learn to incorporate risk in sampling strategies.

- Why you need statistics for validation
- Outline the regulatory expectations for validation
- Understand the concept of variance, such as normal and non-normal distributions, how to measure variance
- Explore how to measure process capability and set acceptance criteria for validation

Alan Golden, Principal, **Design Quality Consultants**

10:15 *Networking Refreshment Break* 10:45 *Plenary Sessions Resume*

Previous Attendee Acclaim:

> "Interesting topics and valuable interaction with other attendees."
>
> **— Validation Engineer, Intersurgical**

> "Absolutely loved the mock inspection."
>
> **— Ajinomoto Bio-Pharma Services**

10:45 **Periodic Reviews of Validated Systems**

Periodic review of validated systems has come more into the spotlight within the pharmaceutical industry in recent years with the additional level of focus that companies have had to put on data integrity. A key fundamental of any pharmaceutical quality system is that companies must fully understand how their critical data is performing. This presentation will show that there is evidence to suggest that most companies have reasonable periodic review strategies in place for CSV and process validation — however, the challenge now exists to ensure periodic review procedures also assess equipment, cleaning and analytical validation. This presentation will present on the results and findings from the following research methodologies adopted:

- Literature review of the current regulations and guidelines relating to periodic review
- An interview with a regulator from the Irish competent body, the Health Products Regulatory Authority (HPRA) to get an insight into what the competent authorities have observed in industry to date with respect to Periodic Review of Validated Systems, and to gain insight into regulatory expectations
- An industry study conducted with ten pharmaceutical companies (small molecule and large molecule)
- Review ISPE's latest industry guidance on Periodic Review for pharmaceutical manufacturing facilities, systems, utilities and equipment (Ref. ISPE Baseline® Guide: Commissioning and Qualification (Second Edition) June 2019)

Takeaway Tools

- Periodic review template for computer system validation
- Periodic review template for equipment and utilities

Donnacha Nagle, Validation Lead,
Eirchem Pharmaceutical Services Limited;
also representing **Technological University Dublin**

11:30 **Next Generation Therapeutics — ATMPs**

Advanced therapy medicinal products (ATMPs) hold promise as treatments for formerly untreatable and high-burden diseases. They aim to treat causes of the diseases rather than symptoms only and offer major clinical and economic potential. However, their specific nature which is based on biological materials raises certain challenges on how the regulatory landscape should frame biomedical innovation for society's benefit. Explore the topic along with the current state and uncertainties that these therapies bring. The following topics will be included:

- Types of ATMPs
- How they compare to current biopharmaceuticals
- Why is there special legislation for ATMPs
- Regulation (EC) No 1394/2007
- Potential manufacturing and testing challenges

Shada Warreth, Senior Bioprocessing Trainer, **National Institute for Bioprocessing Research and Training**

12:15 *Networking Luncheon*

13:15 **INTERACTIVE SESSION — IVT's Widely Acclaimed and Highly Popular Mock Inspection**

IVT's team of experts promises you a dynamic and animated session to prepare you for the rigors of a regulatory inspection. Facilitated by experienced professionals who have been through inspections, test your skills in responding to questions and practice showcasing your quality system in the shortest and most professional way. It is no longer sufficient to be in compliance, you must be able to present your subject clearly and concisely while answering the questions asked. This session not only challenges your knowledge base but shows how you can improve your compliance profile to have a smooth, observation-free outcome.

- Understand common issues that have led to violations
- Explore strategies to address regulatory observations

Morcos Loka, Training Manager and GMP Advisor,
Minapharm Pharmaceuticals

14:15 **Enhancing Risk Management Capability Across the Biopharmaceutical Sector — Introducing a QRM Professional Certification Scheme**

Regulatory expectations regarding the application of risk-based approaches have been evolving across the life science sector for almost 20 years. However, lack of rigor for justifications offered, lack of evidence of science-backed decision making, issues related to subjectivity and bias in calculating risk ratings and a tendency towards retrospective rather than proactive risk assessments continue to appear in regulatory actions and audit findings. Discuss a new assessment and curriculum framework for the provision of professional competency-based certification for Quality Risk Management (QRM) proficiencies across the biopharmaceutical and life science sectors. Introduce the following concepts:

- A new academically-backed professional certification scheme for QRM competencies
- Understand the importance of enhancing QRM proficiency within their organisations to sustainably reduce patient and business risk
- Outline the continued professional development benefits for the individual in developing QRM skills and capabilities accessible through a tiered certification scheme

Dr. Nuala Calnan, Adjunct Research Fellow – Pharmaceutical Regulatory Science Team, **TU Dublin**

15:00 *Close of Conference*