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COMPUTER SYSTEMS VALIDATION & DATA INTEGRITY INSPECTION READINESS

25 - 27 November 2019 | Cork, Ireland | Rochestown Park Hotel

OUR THIRD ANNUAL HIGHLIGHTS INCLUDE:

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Day One – 25 November 2019

12:00 Conference Registration
Coffee and Tea

13:15 Chairperson's Opening Remarks

13:30 Compliance Intelligence – Ensure Your Validation, Quality Risk Management and Data Integrity Programmes are Fit-for-Purpose

Nuala Calnan, Ph.D., Founder & Principal, **BioPharm Excel Ltd.**; Adjunct Research Fellow, **Technological University Dublin**

- UnparallelUpdates on recent regulatory changes across the US, EU and ROW impacting validation, DI and risk management programmes
- Review of recent regulatory actions trends, WLs, SNC, product recalls and shortages
- Track and trend CAPAs, quality defects and product recalls to inform the effectiveness of your risk controls strategies
- Build in formal risk review processes into your Continued Process Verification (CPV) programmes
- What else is new? Gain insight into other key regulatory impacts expected in the coming year

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**

DESCRIPITON TO BE DELIVERED SOON

14:30 Prepare for Validation Inspections and Respond to Regulatory Findings

Milan Kalinic, Validation Lead, **Alexion Pharmaceuticals**

- Organizational behavior and culture
- Presentations for the areas of interest
- SME expertise and readiness
- Documentation flow & from room/back room readiness, runners
- Mock audit
- How to respond specifically on the observation
- Observation examples and responses
- CAPA management for audit responses

15:00 Networking Refreshment Break

15:30 Managing a Data Integrity Programme – Essential Tips for Success

Matthew LaPierre, Specialist – CSV and Data Integrity Compliance

- Understand why a Data Integrity programme is essential in this current regulatory climate
- Realize the importance of the Data Integrity programme scope (not just limited to computerised systems)
- Gain helpful tools in creating and managing a successful programme
- Learn the many ways the human factor component can influence the direction of a DI programme
- Overcome the uphill battles that face DI programmes

16:00 Overcome the Top Five Validation Challenges

Connie Hetzler, Global Head – Validation, **Alcon Laboratories**

The Big Picture:

- Process Validation – The misunderstood function, lost in space
- Process Validation – The linker function in product life cycle risk management

The Top 5 Technical and Business Challenges:

- Cross-functional conflict in managing validation (quality, R&D, manufacturing)
- Project time pressure impact on validation effectiveness
- Resource support for validation in a reduced budget environment
- Maintain focus on addressing high risks versus "validate" everything approach
- Speak to executive level audiences – Convey the importance to the business

16:30 Acquire a Systematic Approach for a Knowledge Management Model

Cliff Campbell B.E., Principal, **Cliff Campbell Consulting Ltd.**

- KM-related FDA and industry activities
- KM from a PV lifecycle perspective
- KM 101 – Self-assessment
- KM definitions and techniques
- KM model essentials

17:15 Networking & Welcome Reception

Day Two – 28 November 2019

7:00 Coffee and Lite Breakfast

7:30 – 8:15 Select Between Knowledge Exchange Sessions (1-4)

1 | Documentation Requirements for Successful Validation

Chinmoy Roy, Data Integrity and CSV SME, **Consultant**

- Understand the validation process and requirements
- A compendium on the elements of validation
- System lifecycle and validation lifecycle – The differences
- Governance documents for validation
- Documentation deliverables for a validation project
- Factors to consider for certifying a system as "fit for use"
- Factors influencing a successful validation project

2 | Implementation of a Risk-based Cleaning Validation Management System

Parsa Famili, President & CEO, **Novatek International**

- Manual systems vs. computerised systems
- Benefits of compliant computerised cleaning validation system
- Components of a compliant cleaning validation system
- Cleaning validation user requirements based on inherent risks
- Supplier qualification
- Implementation, validation and training

2 | Change Control in Validation – Managing Like-for-Like Changes

Alma O'Reilly, Validation Manager, LEO Pharma, Representative, **Technological University Dublin**

Donncadh Nagle, Validation Coordinator, Avara Shannon, Representative, **Technological University Dublin**

- Determine if like-for-like changes should be implemented without a formal impact assessment - Ensure product quality, safety and efficacy
- Classify like-for-like changes
- Understand what happens when parts are redundant:
  - can a new model of the same component be a like-for like change?
  - what does maintenance say?
- Document and justify decisions and assess impact
- Review failures of like-for-like changes

Takeaway Tools

- Decision tree assessment
- Assessment check sheet

4 | Data Integrity – Navigate the Maze of Regulations

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

- EudraLex Vol. 4 GMP,
- Annex 11 – Computerised Systems, MHRA 'GXP" Data Integrity Guidance and Definitions
- WHO Guidance on Good Data and Record Management Practices
- PIC/S Guidance on Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments
- Review of regulatory findings related to Data Integrity issues
- Management of the programme (internal audits, CAPAs)
- Preparation for Data Integrity based Inspections
- Review of system audit trails

08:30 – 10:00 Select Between Knowledge Exchange Sessions (5-8)

5 | The Validation Master Plan (VMP) – Plans that Impress Regulatory Investigators

Connie Hetzler, Global Head – Validation, **Alcon Laboratories**

Part 1 – What Do the Regulations Require For VMP?

- Compliance Guidance and Formats to Follow
- Who is the audience and what is the purpose of a VMP?
- How is it different from a Project Plan?

Part 2 – Developing a VMP

- Strategic focus or detailed document?
- Advantages and disadvantages of keeping it simple
- How many VMPs should a site have?

Knowledge Exchange

This portion of the session entails an open discussion different companies' approach VMPs. The discussion includes formats for equipment and process inventory as well as various options for populating risk levels, validation requirements and project timeline information.

Takeaway Tools

- Multiple template formats that can be adapted for specific situations

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6 | Risk-Based Cleaning Validation – Key Elements to a Successful Programme

Fergal Giles, Cleaning Validation Lead,
Janssen Sciences Ireland

Part 1 – The Benefits of a Risk-Based Cleaning Validation Approach

- Understand the risk-based cleaning validation approach
- Review an example of generic risk-based cleaning validation flow
- Write a risk-based cleaning validation assessment
- Link risk-based cleaning validation to the process understanding

Part 2 – Successful Implementation of Risk-Based Cleaning Validation Strategy

- Create the right risk-based culture
- Plan the activities and team members
- Resolve issues and deviations
- The importance of change control throughout the risk based cleaning validation process

Knowledge Exchange

Attendees take part in a round-the-room survey of your company's challenges and strategies and evaluate a baseline to where industry is.

Takeaway Tools

- Generic process flow for risk-based cleaning validation approach

7 | Introduction to Statistics in Validation

Raul Soto, Senior Principal Engineer,
Johnson & Johnson Vision Care

Part 1 – Statistics for Non-Statisticians

- The benefit of understanding fundamental statistics for quality assurance
- FDA perspective: regulations and guidance documents that refer to statistics

Part 2 – Process Capability Analysis

- Use process capability analysis to determine if your process is capable
- Are 3 validation lots enough to validate a process?
- Calculate the appropriate sample sizes to ensure the accuracy of your CPKs

Part 3 – Tolerance Intervals

- Use tolerance Intervals to make determine which percentage of your individual units meet process specifications
- Learn how to make a claim about process capability when your data does not follow a normal distribution

Part 4 – Hypothesis Testing

- Use hypothesis tests to support the validation of changes to processes, equipment, raw materials, etc.
- Statistical power vs. statistical confidence – What they are and why they matter
- Use Cohen's d to assess the magnitude of a change

Takeaway Tools

- Examples of real-life validation issues supported by statistics
- Step-by-step instructions Minitab instructions to perform statistical analysis
- Examples of FDA 483 and Warning Letters related to statistics

8 | Implement an Effective and Pragmatic Data Integrity Programme

Chris Reid, Principal Consultant Quality and Compliance,
Integrity Solutions Limited

Part 1 – Identify Data Integrity Risks and Opportunities

- Do you have a Data Integrity problem?
- Understand your company's Data Integrity Risks & Threats?
- Understand techniques and tools for identifying and assessing Data Integrity risks
- Share examples of real Data Integrity issues
- Assess your Data Integrity controls maturity

Part 2 – Successful Implementation of a sustainable Risk-Based Data Integrity Programme

- Define strategies for addressing Data Integrity risks and incidents
- Define the components of an effective risk-based Data Integrity programme
- Integrate Data Integrity controls into the Quality Management System
- Establish effective governance
- Effective investigation of Data Integrity incidents

Knowledge Exchange

Participants evaluate their own company's Data Integrity programme and discuss strategies and approaches to ensure an effective Data Integrity programme that is focused on risk.

Takeaway Tools

- Governance plan for a Data Integrity programme
- Example controls maturity assessment

10:00 Mid-Morning 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**

Part 1 – Current Regulatory Expectations

- Clarify similarities and differences between EU and US expectations
- Establish a three-stage, science and risk-based, lifecycle process validation programme
- impact of ICH Q8, 9, 10, 11 and draft Q12
- The FDA 2011 and EU 2014 and 2016 guidance on process validation and the 2015 EU GMP Annex 15
- The practical expectations for a three-stage approach involving process design, equipment and process qualification and ongoing/continued process verification

Part 2 – How to Gain Process Understanding (FDA Stage 1)

- Identification of critical quality attributes (CQAs) and critical process parameters (CPPs)
- Develop and apply a control strategy for process validation
- Understand how Quality by Design supports process validation

Part 3 – Facility Design and Qualification of Equipment and Utilities (FDA Stage 2.1)

- Write & document a User Requirements Specification (URS)
- Design Qualification (DQ),
- Installation Qualification (IQ),
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Part 3 – Process Validation/Process Performance Qualification (PV/PPQ) (FDA Stage 2.2)

- The importance and content of protocols
- Set acceptance criteria
- When to begin to commercialise (how many batches?)
- Understand residual risk

Part 4 – Continued/Ongoing Process Verification (FDA Stage 3)

- Maintain a state of control over the product lifecycle
- Implications of changes on supply chain

Part 5 – Tools That Enable Effective and Efficient Validation

- Quality Risk Management (QRM) and risk register
- Statistical tools, e.g. control charts, process capability, DoE and multi-variate analysis

Part 6 – Change Management/Process Monitoring Stage

- Focus on routine process monitoring
- Revalidation requirements and expectation for revalidation

10 Establishing Acceptance Criteria and Health-Based Limits in Cleaning Validation

Joe Brady Ph.D., Lecturer, School of Chemical and Pharmaceutical Sciences, **Technological University Dublin**

Part 1 – What is Meant by Acceptable Carryover of residues from One Batch to Another

- What residues need to be cleaned to acceptable levels? What are these acceptable levels?
- Measure and test for clean?
- Establish carryover limits as acceptance criteria?
- Overcome the challenges with the determinations and sampling

Part 2 – Calculate Carryover Calculations for a Hypothetical Scenario

- Calculation based on PDE (permitted daily exposure) as per PDA Technical Report 49
- Calculation based on 1/1000 of daily therapeutic does
- Calculation based on LD50 toxicity
- Calculation based on traditional 10 ppm carryover value (FDA, 1993)

Knowledge Exchange

Attendees participate in calculating and comparing carryover values using a range of formulas.

Takeaway Tools

- Formulae templates for calculating allowable carryover calculations

11 Implement a Risk-Based Computerised System Validation Programme

Chris Reid, Principal Consultant Quality and Compliance, **Integrity Solutions Limited**

Part 1 – Establish the Foundation of a Risk-Based Approach

- How risk factors influence the validation approach
- Busting the validation myths
- Are we doing too much, if so where?
- Implement Q with a small c!
- The role of people in ensuring risk-based approach
- What are the key roles and responsibilities for an effective risk-based approach?

Part 2 – Apply a Risk Based Approach – A Case Study

- Explore examples of how risk-based approach is applied to different systems
- Apply different methodologies, iterative, Agile, V-Model
- Adapt and scale validation according to risks
- Explore ways to get more value from your validation approach
- Use tools to increase efficiency
- Review case studies "What went well", "What could be done better"

Knowledge Exchange

Participants define effective validation approaches for your solutions, share challenges and receive advice on how to overcome them.

Takeaway Tools

- Risk assessment tools
- Example validation plan defining a risk-based approach

12 | Understand Impact of Human Factors on Data Integrity – Create the Culture You Desire

Matthew LaPierre, Specialist – CSV and Data Integrity Compliance

Part 1 – What Are the Human Factors that Cause Data Integrity Lapses?

- Types of human error
- Characteristics and causes of human error
- Cognitive biases and blind spots
- The role of management
- Consequences in the laboratory

Part 2 – Conquer Data Integrity by Minimizing Human Error

- Automation as a solution for mitigating human error risk
- Organised investigations, problem solving and root cause analysis
- Continued method optimization, efficiencies and improvements
- Human error-based training
- Creating a culture of quality and a culture of courage

Knowledge Exchange

Attendees take part in a round-the-room discussion of company challenges with human factors on Data Integrity and brainstorm strategies to overcome them.

Takeaway Tools

- Solutions to minimize human factors on Data Integrity
- Human error-based training examples for training presentations

12:00 TU Poster Session & Networking Luncheon DUBLIN

13:15 – 14:45 Select Between Knowledge Exchange Sessions (13-16)

13 | Key Considerations for Process Validation and Successful Tech Transfer

Derek Foley, Senior Validation Engineer, **Janssen Sciences Ireland**

Part 1 – The Benefits of a Structured Approach to Product Tech Transfers

- Initial process flow vs. new process flow
- Identify stakeholders and core team members
- Set out clear achievable objectives – The importance of clear roles and responsibilities
- Early assessment of process capability
- Identify risks and potential mitigations
- Implementation of work cells, communication and progress evaluation
- Lesson Learned and continuous improvement of the process

Part 2 – Integration of Process Validation into the Structured Tech Transfer process

- Progression of the NPI Process to support process validation
- Integrated sampling plan
- Batch planning and scheduling
- Process validation project management
- On the floor execution

Knowledge Exchange

Attendees take part throughout the session with questions, feedback of experiences and tips or options for various topics discussed.

Takeaway Tools

- Generic process flow for a technical transfer management process

14 | Effective Continuous Cleaning Process Verification – Key Elements to a Successful Programme

Sunil Patel, Senior Global Technical Leader, **Ecolab Life Sciences**

DESCRIPITON TO BE DELIVERED SOON

15 | Implementation of a Risk-based Verification Strategy for CQV

Alice Redmond, Vice President European Operations, **Commissioning Agents Inc.**

DESCRIPITON TO BE DELIVERED SOON

16 | Data Integrity Risk Assessments – Using Process Flow Charts

Chinmoy Roy, Industry Consultant, **ValGenesis Inc.**

Part 1 – Understanding the Risk Management Process

- A compendium on risk assessment
- Differences between process and Data Integrity assessment
- What are "data verbs" and how are they used is DI risk assessments
- Using Data Integrity Maturity model to assess system/organizational risk
- Using process mapping to assess Data Integrity risk

Part 2 – Implementing the Risk Assessment

- Conducting risk assessment in the Laboratory
- Risk assessment for clinical trials
- Risk assessment for manufacturing control system

Knowledge Exchange

Attendees take part in a round-the-room discussion of challenges and success factors in conducting and implementing risk assessment.

14:45 Afternoon Refreshment Break

15:15 – 16:45 Select Between Knowledge Exchange Sessions (17-20)

17 | Risk-based IQ/OQ/PQ Development & Execution

Cliff Campbell B.E., Principal, **Cliff Campbell Consulting Ltd.**

Part 1 – Prevailing Guidance's

- Regulatory requirements
- ISPE vs. ASTM models
- Risk vs. criticality

Part 2 – Strategy Recommendations

- C&Q matrix & schedule
- Executable specifications
- Leveraging – Facts & fallacies

Part 3 – Knowledge Exchange

- Participant best-practice
- IQ/OQ/PQ failures and gaps
- IQ/OQ/PQ budget and resource

Takeaway Tools

- 1-page IQ/OQ/PQ template co-designed by participants

18 | Implement and Validate Single Use Systems (SUSs) in Biopharmaceutical Manufacturing

Aidan Sexton, Process Validation Support Lead, **Janssen Sciences Ireland**

Part 1 – Sourcing Single Use Systems (SUSs)

- Differences between "traditional" and SUSs
- Design and prototyping/specifications
- Supply chain considerations
- Vendor audits
- Addressing extractables and leachables risks

Part 2 – Successful Implementation & Validation of SUSs

- Plan the Commissioning & Qualification activities
- Operational testing:
  - mixing studies
  - hold studies
  - filter validation, etc.
- Product specific E&L assessments

Knowledge Exchange

Attendees take part in a discussion of their companies' challenges and C&Q strategies and discuss their own experiences.

Takeaway Tools

- Family approach to qualifying:
  - mixing studies
  - hold studies
- Risk-based approach to extractables and leachables
- BPOG approach to leachables evaluation

19 | Validation of Mobile Applications

Raul Soto, Senior Principal Engineer,
Johnson & Johnson Vision Care

The validation of mobile devices, apps and software have refueled the need for regulatory guidance. Many challenges come with today's rapidly changing technology. Are apps considered a medical device? How do you validate mobile systems? These issues are discussed in this session.

Part 1 – Introduction to Mobile Device and Software Validation

- What's the difference between validating a mobile app vs other type of GXP software?
- Types of mobile apps
  - informational apps
  - apps that support GxP operations or quality systems
  - apps that are considered medical devices
- Data Integrity challenges for mobile apps and devices

Part 2 – Informational Apps

- Examples
- Applicable regulations

Part 3 – Apps that support GxP operations and quality systems

- Examples
- Applicable regulations
- Mobility-specific issues for validation
- SDLC validation approach
- Validation deliverables
- Design, development, and testing
- Going live! User support and change control

Part 4 – Apps that are considered Medical Devices

- Examples
- Is your mobile app or device a "Medical Device"?
- Applicable regulations
- Design control & design review
- Remote access

20 | Data Integrity Master Class

Rashida Ray, President, **Array Validation Quality and Compliance (AVQC), Inc.**

This master class is for senior-level professionals who have a deep understanding of Data Integrity processes and technology. The session is constructed from participants experiences in which key issues are addressed and best practices are exchanged:

- What is your greatest regulatory concern?
- What is your greatest challenge?
- What innovative process or technology can you share with your peers?
- What CQV technique you excel in and can share with the group?

16:45 Day Two Closing Session

17:15 Close of Day Two

Validating Cloud Solutions – Learn How to Mitigate Risk

Michal Timler, Senior Validation Consultant, **ecvalidation**

Do you?

- use cloud services in your organization or do you consider to start using them?
- have difficulty in defining the most important criteria for selecting a Cloud Solution supplier?
- want to learn more about potential risks associated with the cloud and how to effectively control them?

If you answered yes to the above questions, you will certainly benefit from this presentation by getting acquainted with the following topics:

- What is a Cloud Solution?
- Advantages and disadvantages of cloud solutions' usage
- Computer System Validation methodology for cloud solutions
- Risk related to Validation of cloud solutions
- Case study – Risk management for a cloud-based data exchange system

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For More Information Contact:

Howard Wilensky, *Director of Business Development*
Phone: 609 707 0135
Email: Howard.wilensky@kenx.org

Day Three – 27 November 2019

7:00 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**

The presentation discuses key auditing approach for medical device organisations. The Medical Device Single Audit Programme (MDSAP) allows a single audit of a medical device manufacturer's QMS which satisfies the requirements of multiple regulatory jurisdictions:

- Develop, implement and manage an internal audit programme
- Examine MDSAP as a system audit, compliance audit, product audit, and process audit
- Identify requirements for auditing technical documentation and sterilisation processes
- Review MDSAP processes, tasks, outcomes, linkages and nonconformity grading
- Analyse device regulations in MDSAP jurisdictions: Australia, Brazil, Canada, Japan, Europe and the U.S.
- Review the intent and guidance for ISO 13485:2016 interpretation
- Evaluate objective evidence using a case study approach to simulate an MDSAP internal audit
- Apply a risk-based approach to designing the internal audit programme
- Evaluate strategies for aligning the internal audit programme to MDSAP

22 | Latest Developments in the Qualification of Water Systems, Clean Steam Systems and Process Gasses

Mark Thompson, Managing Director, **MTL Projects Ltd.**

Part 1 – Understand How Has Risk-Based Verification Approach Impacted Critical Utilities

- Examples of the Quality Critical Attributes (QCA's) and Critical Process Parameters (CPP's) for Water, Steam and Process Gases. Typical examples
- Learn how to leverage data from the pre installation stages of the project.

Part 2 – Top 10 Common Failures on Critical Utilities

- Water system POU errors, installation problems
- Failure modes associated with biofilm in critical utilities
- Steam system design for dryness value compliance
- Steam quality testing
- Materials of construction in process gas systems

Knowledge Exchange

Recent inspections findings will be shared with the group as well as group discussion/benchmarking,

Takeaway Tools

- Example QCA and CPP assessment sheets completed.
- Example wrap around protocols including data leveraging.

23 | Conduct Risk-Based Revalidations and Periodic Reviews of Systems

Donncadh Nagle, Validation Coordinator, **Avara Shannon,** Representative, **Technological University Dublin**

A key fundamental of any pharmaceutical Quality System is that companies must fully understand how their critical data is performing. This presentation shows 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 presents 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 & large molecule)

Takeaway Tools

- Periodic review template for CSV
- Periodic review template for equipment and utilities

24 | Learn How to Use Testing as a Risk Mitigation Tool

Kamila Sitkiewicz, Senior Validation Consultant, **ecvalidation**

Do you?

- perform tests for your validated IT tools?
- wonder what kind of test should be executed for specific requirement?
- want to learn more about potential risks associated with the testing strategy and how to effectively control them?

If you answered yes to the above questions, you will certainly benefit from our presentation by getting acquainted with the following topics:

- What is a testing strategy for validated IT systems?
- Determine when testing strategy should be created
- How to estimate test rigor
- Risk related to testing strategy
- Case study – Testing management for a cloud-based data exchange system

08:30 – 10:00 Select Between Knowledge Exchange Sessions (25-28)

25 Continued Process Verification (CPV) – Maintain the Validation State

Philip Jarvis, C&Q lead, **Abbvie (EU)**

Part 1 –Understand the Requirements for CPV

- Understand Annex 15 and FDA regulations
- Considerations for the CPV plan
  - what and how to trend
- Create your CPV report

Part 2 – What Can CPV Give Your organisation?

- Using CPV to optimize and understand processes
- Document your process knowledge
- How can CPV be used in the product lifecycle?

Knowledge Exchange

Participants take an interactive poll of room on CPV methodologies and challenges.

Takeaway Tools

- Example templates for CPV plan and reports
- Example justification for number of PPQ runs
- Example tech transfer plan

26 Industry and Regulatory Trends in the Development and Qualification of Vapour Phase Hydrogen Peroxide for Decontamination and Sterilisation

Mark Thompson, Managing Director, **MTL Projects Ltd.**

Part 1 – Current Understanding on VPHP Mechanism and Efficacy

- Discuss the regulatory interest in the efficacy of VPHP
- Benchmark current industry response and practices for VPHP application in decontamination and sterilisation applications

Part 2 – Qualification of VPHP Systems

- Qualification of surface decontamination
- Qualification of VPHP for surfaces required to be sterile
- Ongoing monitoring and requalification requirements

Part 3 – Current Regulatory and Audit Challenges Knowledge Exchange

This lecture is all about current benchmarking and industry trends and is an open discussion on general various approaches / issues used.

Takeaway Tools

- Example qualification approach
- Evidence for VPHP sterilisation

27 Improper Use of Statistics – The Misuse, Misinterpretation and Bias of Analytical Assay Data

Douglas B. Brown, Ph.D., Senior Scientist, Methods Development and Validations, **Charles River Laboratories, Inc.**

Part 1 – Introduction to the Use of Statistics in Scientific Research

- Establish and understand the definition of defining statistics
- The importance of statistics during research and the use for determining conclusions

Part 2 – Misuse – When Statistical Arguments Assert Falsehoods

- Faulty Analogy – Comparing things that are not comparable
- Over-complexity – Creating graphs & data visualizations that are too complex
- Data dredging – Data mining where extremely large volumes of data are analyzed

Part 3 – Misinterpretation - Lack of Understanding or Unwittingly Arriving at the Wrong Conclusion

- Correlation versus causation – Assuming a correlation implies causation
- Flawed correlation – Linking two variables that have to practical association
- Garbage in, garbage Out – Meaningful data must be analysed by appropriate statistical methods

Part 4 – BIAS – Prejudice in Data Collection Leading to Skewed Conclusions

- Misleading data visualization – Displaying data in a manner that over-emphasizes or de-emphasizes results
- Biased scaling – Altered scaling may demonstrate a significant change when there is actually very little change
- Biased labelling – Axis labels and/or caption causing the reader to be inappropriately leading toward a conclusion
- Faulty polling – Specific wording patterns have a persuasive effect & induce predictable answers
- Sampling bias – Sampling systematically favors certain outcomes over others

Knowledge Exchange

Attendees discuss how to employ (and not to employ) statistics in evaluating data, drawing conclusions, and making go/no go decisions.

28 IT Infrastructures and Cloud Environments - Don't Get Caught with Your Head in the Clouds

Oisín Curran, CEO, **CompliantCloud.com**

Part 1 – GxP IT Strategic View – Where is the Market Going?

- Macro market trends and preparing for the changes
- Define your operating deployment model and/or consumption model – IaaS: PaaS: SaaS
- Agile software project delivery – What does a compliant delivery model look like?
- Vendor auditing – The essentials in making sure your vendors are aligned
- Understand the regulations as they relate/apply to outsourced activities
- Use case – What is the vendor audit like and what to audit?
- Understand the macro trend impact on your strategy
- Put in place a flexible qualification strategy

Part 2 – Understand your business need – Why do we need to Qualify IT Infrastructures or Be Concerned about Data Integrity

- What is your business IT strategy, and have you identified the risks?
- Is the GxP impact of your IT decisions fully understood?
- Organisation impact on your IT strategy
- Outsourcing versus insourcing -- Your infrastructure or someone else's?
- The hidden overhead – Insourcing and outsourcing may not be the silver bullet you hoped for if you're not structured correctly
- Data flow design, record identification and impact
- Outsourcing contract structures?
- Use Case – Moving legacy applications to the cloud

Knowledge Exchange

Attendees take part in interactive discussions concerning the macro IT trends that impact your IT strategic decisions and your quality and compliance decisions as a result. Attendees see real-world use cases of dealing with some of these challenges

Takeaway Tools

- An adaptation of the classic V-model for application deployment
- A data-flow template for GxP architectures
- A sample contract template for outsourced IT hosting

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**

Part 1 – Data Infrastructure, Contextualization and Transformation

- Data connectivity infrastructure for present and future advanced analytics projects
- Data contextualization and readiness for MVA & APC
- Marry data systems such as MES, OSI PI, SAP by Implementing Microsoft Azure Solution as a one stop data hub.

Part 2 – Multivariate Analysis, Model Building, SIMCA & Operational Implementation

- Types of MVA models and real-life use cases
- Techniques and constructions of MVA models
- Use of SIMCA & SIMCA Online
- Connecting Azure cloud-based solution to SIMCA
- Implementing MVA tools to support manufacturing

Takeaway Tools

- Data infrastructure required for advanced analytics
- Best practices for MVA model construction
- Operational implementation for advanced analytics into manufacturing

30 Defining Critical Cleaning Process Parameter and Critical Quality Attributes, Using a Risk-Based Approach – A Case Study

Philip Jarvis, C&Q lead, **Abbvie (EU)**

Part 1 – Background to The Case Study/And What to Consider When Revalidating Cleaning Processes to Current Cleaning Regulations

- Understand the background to the case study
- Overview of current applicable regulations
- Define the revalidation plan, and CQA's
- Considerations for cycle development
- Implement a lean approach to cleaning validation by using experienced vendors

Part 2 – Understand Cleaning CPP's and Designing an Optimal Cleaning Cycle

- Understand operational constraints before cycle development
- The importance of coupon studies, and creating representative soils for cycle development
- Understand development data and defining optimal ranges for CPP's
- Key equipment qualification considerations and there impacts to cleaning cycles
- Discuss the conclusion of case study data

Knowledge Exchange

Participants review of cleaning development data, and discussion of setting cycle ranges based on data

Takeaway Tools

- Cleaning assessment template

31 The Use of Wireless Dataloggers for Thermal Validation – From Freezers to Autoclaves

Chris Maughan, Managing Director, **Thermal Compliance Ltd.**

Part 1 – Thermal Validation Using Wireless Dataloggers

- Introduction to wireless dataloggers
- Sensor Selection and positioning
- Calibration procedures for wireless dataloggers
- Optimization of thermal mapping processes
- Buffering and datalogger response time
- Risk assessment of thermal processes
- Writing a URS for a thermal validation system
  Insights into the criticality of response time of validation sensors

Part 2 – Benefits of Using Wireless Dataloggers for Autoclave, Lyophilization and Steam In Place Systems

- Regulatory overview
- Sensor Selection and Positioning
- Pros and cons of thermocouple and dataloggers for validation
- Optimizing validation timelines around production demands
- Advanced reports and calculations in validation software – Data Analysis and Review
- Benefits of paper and electronic bowie dick tests

Knowledge Exchange

Attendees take part in a round room discussion focusing on the challenges of thermal validation.

Takeaway Tools

- Calibration matrix for wireless dataloggers
- Risk assessment template
- Using wireless dataloggers for autoclave validation – article
- Using wireless dataloggers for thermal validation – article
- Autoclave cycle design template for porous load steriliser

32 Conducting an Audit and Gap Analysis of Computerised Systems

Matthew LaPierre, Specialist – CSV and Data Integrity Compliance

Part 1 – Conducting the Audit and Gap Analysis

- The why – Regulation, requirements and benefits
- Developing the audit team
- Resource allocation
- Specific Data Integrity considerations for gap analysis
- Recommendations for audit of Empower

Part 2 – After the Audit – Actions & Plans

- Classification of deficiencies
- Developing risk assessments
- Objectives and content of a remediation plan
- Corrective and preventative actions to address system vulnerabilities
- Verification of effectiveness

Knowledge Exchange

Attendees take part in a round-the-room discussion of Data Integrity computerised system assessments at their sites, what works, what does not.

Takeaway Tools

- Computerised system/Enterprise assessment tool

12:00 Networking Luncheon

13:15 – 14:45 Select Between Knowledge Exchange Sessions (33-35)

33 Equipment Qualification – Fit for Intended Use

Milan Kalinic, Validation Lead, **Alexion Pharmaceuticals**

(This session discusses a case study for the qualification of an aseptic line equipped with a VHP isolator used for aseptic filling of an ultra-rare disease medicine in pre-sterilised containers.)

Part 1 – Qualification Lifecycle

- Project initiation
- Key vendor selection criteria
- Design phase
- Build and testing phase
- Benefits of risk-based approach used against old traditional methods
- RBV process flow including all phases and responsibilities
- QA Vs SME approvals during RBV qualification lifecycle
- Real-life example of release document

Part 2 – Decontamination Cycle (VHP) and Non-Touch Technology Tub Transfer

- Can VHP be considered to provide sterilisation or it should be claimed only as decontamination?
- High level overview of VHP cycle
- Cycle development
- Biological indicator qualification strategy. rouge BI and way how to address these phenomena
- Requalification requirements
- Good isolator practices – Regulatory feedback and requirements
- Autoclaving direct/indirect contact parts and aseptic practices
- Utilization of non-touch technology during vial tub transfer without e-beam
- FDA/HPRA observations and findings and responses
- Lessons learned

Knowledge Exchange

Attendees discuss current hot topics in Good Isolator Practices, MHRA/HPRA observations and recommendations. In addition, FDA/HPRA observations, findings and responses are shared.

Takeaway Tools

- Site acceptance release report template

34 Cleanroom Validation, Disinfection and Environmental Monitoring

To Be Announced

DESCRIPITON TO BE DELIVERED SOON

35 Machine Learning (ML) Validation and the future of Computer Systems

Rosalind Beasley, Digital Transformation Leader, **Healthcare & Life Sciences, ROQMetrics, Inc.**

Part 1 – Machine Learning (ML) Overview

- What is Artificial Intelligence (AI)?
- What is Machine Learning (ML)?
- 5 AI/ML trends on Life Science
- Why is validating ML different from traditional validation?
- The new workforce required to validate AI/ML

Part 2 – Broad Framework for ML Computer Systems Validation

- Kick off the ML validation process
- Prepare data for ML
- Define test harness methods
- Manage ML algorithm change
- Develop validation deliverables

Part 3 – Validate ML in Software as a Medical Device (SaMD)

- Good Machine Learning Practices (GMLP)
- Three broad risk categories for ML change management
- Pre-Specifications (SPS)
- Algorithmic change protocols

Knowledge Exchange

Attendees take part in an interactive discussion of your company's use-cases for Machine Learning and challenges with validation.

Takeaway Tools

- General ML validation framework
- Insights into SaMD ML validation
- ML validation deliverables checklist

14:30 Afternoon Refreshment Break

15:00 – 16:30 Select Between Knowledge Exchange Sessions (36-37)

36 Statistical Process Controls – Construct and Analyse Control Charts

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

Part 1 – What are Control Charts?

- Construct and analyse control charts to detect "special cause" variation in your validation runs and in regular production
- Quantitative vs. qualitative product quality characteristics – Select the correct control chart for your process
- Use run charts to quickly and effectively detect the presence of special cause variation before implementing SPC
- Estimate process capability and percent non-conforming from your control charts

Part 2 – How Effective are your Control Charts?

- Use Average Run Length (ARL) to evaluate the performance of your control charts

Part 3 – Advanced Control Charts

- Use CuSum and EWMA charts to detect small shifts in your process average

37 Overcome the Challenges of MS Excel Spreadsheet Validation

To Be Announced

DESCRIPITON TO BE DELIVERED SOON

16:30 Close of Conference

ABOUT THE VENUE

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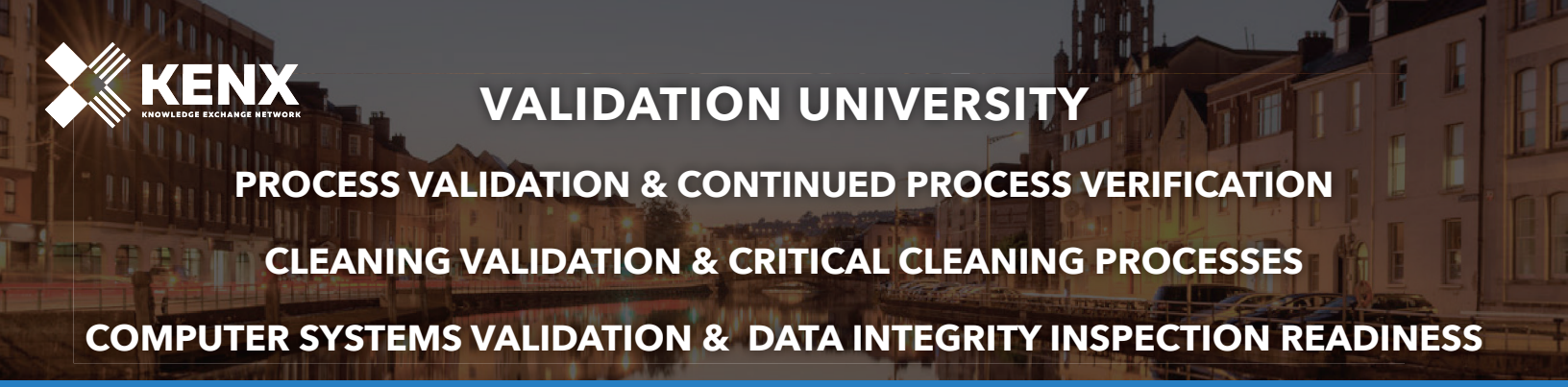

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