KENX
KNOWLEDGE EXCHANGE NETWORK

Attend Virtually or In-Person

VALIDATION & GMP UNIVERSITY 2021

PROCESS VALIDATION & CONTINUED VERIFICATION

DATA INTEGRITY GOVERNANCE | FDA INSPECTIONS

CHANGE CONTROL | QUALITY RISK MANAGEMENT

August 23 – 25, 2021 | Wyndham Historic District | Philadelphia, PA

50+ TUTORIALS ADDRESSING VALIDATION AND DATA INTEGRITY FROM A TO Z

Process Validation
Quality by Design
Lean Validation
Impact Assessment
Change Control
Cost Management
Validation Master Plans
Quality Culture
Facility and Equipment Qualification
Statistical Process Control
Human Behavior
Cleaning Validation
Supplier Quality Agreements
Sampling Plans
Process Performance Qualification
IQ/OQ/PQ – Fit for Intended Use
Computer Software Assurance
Single Use Systems
Commissioning & Qualification
Critical Process Parameters
FDA Audits and Inspections
Critical Quality Attributes
Process Performance
Audit Checklists
Continued Verification
Critical Utility Qualification
EU Annex 1 - Contamination Control
Process Mapping
Acceptance Criteria and Health Limits
Quality Risk Management
Environmental Monitoring
Performance Qualification
Process Control Charts
Computer Software Assurance
Data Integrity
Process Design
Protocols and Reports
Risk-Based Decision Making
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PLUS! FDA REGULATORY ROUNDTABLE

Compliance Intelligence – Agency Insight, Trends, and A Year in Review

James Mason, PharmD, Compliance Officer, Office of Pharmaceutical Quality Operations, **U.S. Food and Drug Administration** *(Invited)*

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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 & Exhibitor Showroom Open House

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, Office of Pharmaceutical Quality Operations, **U.S. Food and Drug Administration** *(Invited)*

DESCRIPTION TO COME

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**

- Understand how culture is built and reinforced, and how values impact culture
- Understand how human behavior individually and collectively contributes to culture
- Identify critical behaviors to drive and maintain a strong Quality Culture

Takeaway Tools

- Template for behavioral root cause analysis

2:45 ET Exhibitor Showroom & 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**

DESCRIPTION TO COME

4:00 - 4:30 ET Validation Master Plans (VMP), Protocols and Reports - Discover Best in Procedural Templates

JR Humbert, Senior Director Quality, **INCOG Biopharma**

- Define VMPs, protocols, and reports
- Understand the importance of content, acceptance criteria, and summarizing data
- Learn how to "scaffold" risk assessment and engineering design documents into effective protocols and reports
- Build a "wrapper" for COTS software / equipment qualification protocols
- Understand why building a protocol and report template is valuable and efficient for your validation program

4:30 - 5:00 ET Annex 1 Contamination Control – What the Recent Revision Means for Validation

Parsa Famili, President & CEO, **NOVATEK INTERNATIONAL**

- Introduction
- Data Integrity
- Annex 1 and total contamination control strategy
- Review an example of risk-based system
- Optimized manufacturing and validation
- Using the risk-based approach computerized systems in contamination control strategy

Knowledge Exchange

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

Takeaway Tools

- The importance of clear roles and responsibilities
- TCCS starts with proper determination of Maximum Safe Carryover (MSC)
- Process workflow chart

5:00 ET ***Game Night - Trivia Welcome Reception***

Day Two – August 24, 2021

7:30 ET Exhibitor Showroom & 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**

Part 1 – QRM-Based Validation Program Assessment

- Assess application of QRM to requirements specification, risk assessment, and C&Q system delivery

- Assess maturity of Good Engineering Practices (GEP), application to C&Q, and the Engineering Quality Process (EQP)
- Assess application of QRM to system lifecycle, including change management, deviation/CAPA management, continuous improvement, maintaining the state of control, and periodic assessment
- Assess application of QRM to process, cleaning, sterilization, and other validation lifecycles written

Part 2 – Gap Remediation

- Understand the keys to remediating QRM gaps
- Understand the important, and sometimes difficult, paradigm shifts required

Takeaway Tools

- Example validation program assessment tool

2 Supplier Qualification - Create and Maintain Quality Agreements

JR Humbert, Senior Director Quality, **INCOG Biopharma**

- Review regulatory requirements for supplier qualification and quality agreements
- Understand quality agreements and how they can be used for:
  - » Validation contractors / consultants
  - » Software
  - » Contract laboratories
  - » Contract manufacturers
- Understand auditing as a part of supplier qualification
- Requirements for on-boarding and off-boarding suppliers
- Supplier qualification maintenance

3 Single Use Systems (SUSs) - Implementation and Validation

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

Part 1 - Selection of Facility Type for Single-Use Bio-Manufacturing Facility

- Regulatory expectation and requirements
- Facility design options for single-use manufacturing facility
- Facility and utility design, commissioning, and qualification
- Consideration for using contract manufacturing verse design built single-use facilities
- Typically cost and budget requirements for contract manufacturing verse design built single-use facilities

Part 2 – Setup and Operation of Single-Use Options for Both Upstream and Downstream Processing Steps

- Selection of best quality vendor for your manufacturing operations
- Advantages and disadvantages of single-use technologies relative to multi-use equipment
- Process scenarios that offer advantages over traditional multi-use equipment
- Technical limitations to single-use technology and the impact to process design
- Basic cost calculations to provide justification for single-use technologies
- Key validation expectations, including testing of extractables and leachable
- Process validation requirements for single-use manufacturing operations

4 Data Integrity Risk Assessments and Process Mapping

Chinmoy Roy, Senior Industry Consultant, **ValGenesis**

- Understand the Data Integrity risk management process
- A compendium on risk assessment
- Differences between process risk and data integrity risk assessment
- QC lab analytical data life cycle and how is it different from Data life cycle
- What are "data verbs"
- How to use data verbs is DI risk assessments
- Using process mapping to assess Data Integrity risk

Takeaway Tools

- Example Data Integrity policy document
- Example Data Integrity risk management report

9:15 - 10:00 ET **Select Between Knowledge Exchange Sessions (5-8)**

5 Supply Chain Validation - Lessons Learned During Covid-19

To Be Announced

DESCRIPTION TO COME

6 FDA Inspection Management - Tips that Impress Investigators

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

- FDA arrival - What to expect on Day 1
  - » Do you have an inspection game plan?
- Learn how to host and manage deliverables in the inspection room

  - » Thinking three steps ahead of the Investigator
- Inspection management – How preparation impacts deliverable turn around time
  - » Inspection Team Roles and Responsibilities
- Close out meeting – do's and don't tips
  - » Understand the findings and response timeline before the Investigator leaves

Takeaway Tools

- Inspection management workflow chart
- Response outline and tips

7 Align Your CSV Program with FDA's Proposed CSA Guidance

Joseph Zec, R&D CSV/Process QA and Compliance Leader, **Takeda**

The soon-to-be-issued FDA Guidance on Computer Software Assurance (CSA) will modernize the discipline of Computer System Validation (CSV). It is the new paradigm for non-product software being developed in partnership with industry. But is your organization ready for it? How will it handle the transition? This workshop aims to help with these growing pains.

Part 1 – How CSA Changes Regulated Software Testing

- Just what is "limited scripted" testing anyway?
- Implement an "Unscripted" (but not undocumented) testing program
- The "ad-hoc" and "basic assurance" approaches
- Just what am I going to do with all those screenshots anyway?

Part 2 – Other SDLC modernization elements:

- More digital, less paper
- More quality, less documentation
- Automation
- The role of the Software-as-a-Service provider in CSA

Knowledge Exchange

Participants work in teams to devise transition strategies for various elements of CSA.

8 Data Integrity Programs - Case Study Examples

Matthew LaPierre, Data Integrity Specialist, **Jackson Scott Consulting**

- Understand the critical elements of a data integrity program: structure, management buy-in, program tools
- Learn what to assess in your program – Hint: it is not just computerized systems
- Review a failed data integrity program case study - What went wrong?
- Review a successful data integrity program case study - What caused its success?
- Understand the importance of communication in a successful program

Takeaway Tools

- Insight and expertise in building a more effective, successful Data Integrity program

10:00 ET Exhibitor Showroom & 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**

Part 1 – Create Nimble Validation Processes

- Learn the main challenges for validation leaders today
  - » What are the common challenges validation leaders face?
  - » Create a nimble approach to validation can resolve those challenges
  - » Create more cost effective and nimble validation processes to meet today's challenges
- Key areas in validation to create efficiency and cost while maintaining compliance:
  - » Cleaning Validation
    - ◊ Effective use of validation and contractors to develop cycles to create efficiency
  - » Standardization of C&Q processes to risk-based approaches and reducing costs
    - ◊ Use risk-based approaches to C&Q to gain efficiencies across the organization and focus on key quality risks
    - ◊ Standardize your C&Q approach globally, to allow for global leveraging of your C&Q processes
  - » Embrace technology to lower your costs and create efficient processes
    - ◊ Use of big data to enhance CPV
    - ◊ Paperless validation systems

Part 2 – Use Paperless Validation Systems to 'Lean-Out' Validation

- Case study on paperless C&Q
  - » Demonstration of risk based approach in paperless validation system for :
    - ◊ Efficient protocol creation
    - ◊ Linking risk assessments to testing
    - ◊ Automation of RTM
    - ◊ Reporting of test execution and deviations
  - » Effective change management
  - » Leveraging test case templates
  - » Inline test execution

- Deviation management
  - Other areas for digitalization
- Laboratory instrument validation
- Computer System Validation
- Facilities, utilities and equipment validation
- Process validation
- Cleaning validation/equipment change over

Takeaway Tools

- Example C&Q adoption tool for standardization
- ROI tool for paperless validation systems
- Business justification template for paperless validation tools
- Demonstration of how a paperless validation system can create efficient C&Q processes

10 Risk-based Cleaning Validation - Key Elements for Success

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

Part 1 – Risks in a Cleaning Validation Program and How Automation can Address These Risks

- Awareness of the regulations for cleaning validation
- Identify risks in the cleaning validation program
- The importance of managing master data
- Understand the correlation between master data tables
- Define risk ranges and risk criteria to use to determine potent vs non-potent products
- Gain Insight into the equations to calculate and select the Maximum Safe Carry (MSC)

Part 2 – Risk-Based Cleaning Validation System – Automation of Processes

- The importance of automating MSC calculations
- Structures for Digitization of your cleaning validation data
- Understand the change process and avoid information silos through electronic means
- Criteria for warning when selecting MSC values
- Trending and process control metrics for results and safety margins
- Recognize the benefit of automation, data integrity, and regulatory compliance for cleaning validation data

Knowledge Exchange

Attendees take part in four polls which relate to the processes used in the industry and the processes they use at their facilities. Results from previous polls are shared and compared to current responses. There is also a brief case study which illustrates issues and solutions when moving from paper to automated, and from PPM or 1/1000th method to the science and risk based HBELs approach.

Takeaway Tools

- Example of MSC equations for batch and sample point carry over
- Example of risk ranges for potent products
- Examples of trends for cleaning validation

11 Critical Thinking and Change Management - Lessons Learned from the CSA Movement

Ken Shitamoto Senior Director, IT **Gilead Sciences**

Part 1 – Critical Thinking and CSA

- CSA overview
- Critical thinking
- Principles of CSA and how critical thinking can be applied
- Defining your CSA approach

Part 2 – Change Management and CSA

- Organizational change management
- Our CSA Journey – Oh the places you'll go and the things you'll see
  - How we got started
  - What we did
  - What we learned
  - What we would do differently with 20-20 hindsight
- CSA movement and your part

Knowledge Exchange

Open discussion on your challenges implementing CSA and an exchange of knowledge from the speaker and peers.

12 Data Integrity - Assessment, Implementation, and Maintenance

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

Part 1 – Critical Impact of Data Integrity in the Drug Development and Manufacturing

- Understand the regulatory requirements of documentation management system
- How to prioritize data and establish different types of procedures
- Explore systems to secure and protect data quality requirements
- Develop a consistent approach to record, maintain and secure analytical data.
- Understand the impact of the audit trail.

Part 2 – Lifecycle Management of Data Integrity

- Establish systems to document changes and how it impacts data quality
- Understand requirements to record deviations and investigations
- How to manage multiple formats of data generated.
- Explore different ways to communicate data across sites and platforms
- Exploring how to perform periodic reviews using a risk-based approach

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**

- Understand the validation and qualification requirements along the product lifecycle
- Understand the different types of validation and qualification and their dependencies along the Validation Lifecycle (VLC)
- Learn about the top five (5) challenges encountered during validation and qualification
- Identify proactive ways to overcome the five (5) challenges in validation
- Identify reactive (undesirable, yet sometimes unavoidable) ways to minimize impact should you encounter any of the top five (5) challenges in validation

Takeaway Tools

- Case studies (2) of challenges encountered during validation projects; the challenge, the solution, and the final outcome
- Generic checklist for a successful validation program
- Validation and qualification process flow chart

14 Common Gaps in Cleaning Validation and Their Solutions - From Pain to Optimization

TJ Woody, Director of Cleaning Validation, **Azzur Group**

- Replace tedious equipment cleaning processes with streamlined compliant approaches
- Understand how to take lab cleaning trial results to develop and optimize manufacturing equipment cleaning
- Recognize the value of existing data and use it to improve and simplify cleaning processes
- Use product and equipment grouping approaches to reduce cleaning and testing requirements
- Understand the best approach to reducing cleaning efforts is by "not cleaning" and how to implement
- Learn how your recent overhaul of the cleaning validation program may be for naught without this process/procedure in place
- Recognize a common regulatory gap with Total Organic Carbon compendial testing and how to fix

Takeaway Tools

- FDA Questions and Answers on Current Good Manufacturing Practices – Equipment
- Cleaning development SOP

15 Learn How to Use Effective Risk-based Decision Making in Validation

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

- Concepts, methods, and tools for reducing risk in decision making
- Understand and use relationships between process variation and process understanding to reduce decision making risk and improve compliance
- Use a systematic approach to identify the critical few variables that have a major impact on the process
- Create a process control strategy to increasing process stability, capability, and robustness
- Improvement of test method repeatability, reproducibility, and robustness
- Tips, traps, and guidelines for successful continued process verification

Takeaway Tools

- "Adjust, Adapt and Advance: An Enhanced Version of Quality by Design – A Risk-Based, Dynamic Approach to Designing Improving Products and Processes", Quality Progress, May 2016, 34-41.

16 Ensure Data Integrity by Design (DIbD) - The Right Data, Right from the Start

Steve Thompson, Director Industry Solutions, **ValGenesis**

- Understand the data hierarchy
- Get to know the flow – Process mapping and data flow diagrams
- Apply critical thinking and identify risk
- Develop a Data Integrity by Design (DIbD) practice
- Monitor controls (alerts, analytics, and dashboards)

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**

Part 1 – Benchmark with FDA's 3-Stage Process Validation Approach

- Deep dive into FDA's 3-stage approach
  - » Stage 1 – Process design
    - ◊ Capture process knowledge and understanding
    - ◊ Develop a strategy for process control
  - » Stage 2 – Process Qualification
    - ◊ Facility design and utility qualification
    - ◊ Process Performance Qualification (PPQ)

- Protocols, execution, and reports
  - » Stage 3 – Continued Process Verification (CPV)
    - ◊ Revalidations and periodic reviews
    - ◊ Develop a strategy for CPV

Part 2 – Master the Critical Elements of a Risk-based, 3-Stage Approach

- Learn risk-based approaches to validation
- The interrelationship between effective process validation and drug quality
- Implement an integrated team approach
- Learn how to handle variation
- Create and write a Validation Master Plan (VMP)
- Understand documentation requirements and how much validation is enough
- Ensure analytical methods used are scientifically sound
- Understand FDA's focus on statistics
- Conduct a gap analysis of your program

Knowledge Exchange

Participants discuss their unique approach to process validation and create a check list of best-in-class procedures.

Takeaway Tools

- Example CPV report/protocol
- Example Validation Master Plan (VMP)

18 | Process Validation Statistics for Non-statisticians

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

This session illustrates the common statistics tools and techniques used in validation. Through real world examples and interactive exercises, we demonstrate the basic concepts of statistics and how to apply them to your validation projects.

Part 1 – Introduction and The Concept of Variance (and why it is important)

- What is statistics?
- Why do you need statistics for validation?
- Regulatory expectations
- Sources of variance
- Measuring variance
- Normal and non-normal distributions
- Measuring Variance

Part 2 – Expressing Variance

- Variance
- Standard deviation
- Coefficient of variation

Part 3 – Process Capability

- Can your system do what you want (need) it to do?
- Measuring capability
- Using capability to set acceptance criteria for validation

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**

Part 1 – SaaS & Clouds

- Understand the difference players and their responsibilities when migrating applications to the Cloud / Saas vs hosting applications inhouse
- Advantages of applications being hosted on Cloud / Saas
- Disadvantages of using Cloud / Saas
- The increased importance of Vendor Audit and understanding all players involved
- Transfer of IT responsibility ex (disaster recovery, backup and restore, and IT security)
- Software upgrades expectations
- Validation Responsibilities

Part 2 – Spreadsheets

- Proper definition of what data may be entered on spreadsheets and use of that data
- Validated spreadsheet vs spreadsheet used for information purposes
- Review of procedures and practices to verify that data from unvalidated spreadsheets not being used to make GMP decisions
- Risks and Benefits of using Spreadsheets in labs
- How to validate spreadsheets (simple overview)

Part 3 – Network Qualifications

- The need to maintain control over IT network, define structure and procedures
- Regulatory requirements for maintaining validated applications in a validated state and how IT plays a role
- How IT and Network controls are centerpiece in a companies Periodic Review of applications
- Ability to leverage IT network qualification protocols when validating applications (disaster recovery, IT security, backup and restore)

Part 4 – Mobile Technology and Digitalization

- Utilizing mobile technology with validated applications
- What are the requirements to validate and qualify?
- How to define the risk of using mobile technology to limited scope of qualification and validation
- Current trends towards digitization along with the risk and advantages
- Understanding the Predicate Rules and applying them accordingly when using digitization
- IT considerations (security, backup and restore and disaster recovery)
- Regulatory requirement and limiting the scope of qualification/validation

20 Cultivate the Culture of Integrity in Data Management

Roque Redondo, VP Automation and Business Development USA Operations, **mirus**

On December 2018, the FDA published the Final Guide for Data Integrity in the regulated industry. But in addition to the FDA, PIC/S Organization also published a guideline related to Data Integrity. Saying that, the Worldwide Healthcare Organization (WHO) also published a guideline in Data Integrity. However, and to make this a real maze, GAMP® decided to also publish a Guide for Records and Data Integrity.

It is clear then, that there are two concepts that all Regulatory Agencies are placing a lot of emphasis due to its criticality and importance in our industry. Those two concepts are Data Integrity and Data Management. Therefore, it is even clearer that both concepts need to be intrinsically embedded in our daily routine at our job. So, how we make that this happens? How Integrity is combined to our daily job routines? Can data be managed to avoid difficulties in the integrity of the information to avoid regulatory risks?

- Understanding human behavior
- Implementing Data Integrity assessments
- The role of senior management
- Technical and non-technical methods to support a Data Integrity environment
- Understanding the importance of the human behavior in a Data Integrity environment
- Determining the role of the senior management

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**

Part 1 – Review of Medical Device Design Controls

- Review of the Standards based on anticipated markets, focus on US and EU
- Does ISO 13485 cover everything?
- When to incorporate risk management into the design process
- When to verify vs. validate design requirements?
- Key differences to include in the Design History File (DHF) between FDA and CE mark submissions
- How / when to incorporate contract manufacturing and suppliers into the design process

Part 2 – Successful Design to Manufacture and the role of Verification and Validation (V&V)

- Key V&V for every device (labeling, shipping, packaging)
- Build the right team to maximize the development window.
- The importance of statical analysis in reports and protocols
- Documentation, how much is really needed?
- What is the role of Test Method Validations (TMV's)?
- How to incorporate Design Changes post V&V activities

Knowledge Exchange

Attendees discuss opportunities for performing V&V testing in parallel and mitigating project risk.

Takeaway Tools

- FDA 820 Part 11 and ISO 13485 as the drivers to a proper DHF and submissions
- Typical stage gates and deliverables from concept to commercialization
- QMS needs for a successful DHF
- Design risk assessment template

22 Statistical Process Control and the Use of Control Charts

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

This session introduces the concept and need for process capability and continued process verification using statistics as a tool for quality control. The development of a system to monitor and control processes and procedures assists with enhancing product conformity, reduction in waste, and identifying product drift and potential loss of system control. A primary focus for process control is to ensure that the behavior of validated processes and procedures has not changed and is continuing to perform as previously described.

Part 1 – Process Capability Approach and Process Improvements

- Define process capability
- Identify / understand various process improvements

Part 2 – Statistical Process Control (SPC)

- Define statistical process control and its use
- What are the benefits for using SPC?
- Typical tools and process control techniques

Part 3 – Control Charting Basics Using Microsoft Excel

- Control chart structure, fundamental concepts, key terms, and features
- Types of control charts
- Setting control charting limits
- Establishing warning zones and out-of-control limit flags

Knowledge Exchange

Attendees discuss how to employ statistical process control to their specific system and be able to identify when their processes or procedures begin to drift toward.

23 Take a Risk-based Approach to Audit Trail Reviews

Joseph Zec, R&D CSV/Process QA and Compliance Leader, **Takeda**

Data Integrity is a key factor in gaining the confidence of regulatory authorities that data submitted to or investigated by the agency is trustworthy. One key ingredient in assuring Data Integrity is maintaining and reviewing audit trails for that data. This is also a regulatory expectation as detailed in 21 CFR Part 11. But audit trails can be expensive to maintain and review. How much is enough? How much is too much? This session helps attendee apply risk-based thinking to reviewing audit trails in a least-burdensome yet still compliant manner.

- Audit trails – Components
- FDA and industry perspective
- Apply risk-based audit trail review strategies

Knowledge Exchange

Participants will work in teams to apply risk-based audit trail review strategies to various scenarios.

24 Build Your Custom Audit Checklist – Master Class

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

- Understand what your Client or "Customer" expect to learn from the audit
- Plan for the audit
  - » understanding your Auditee
  - » audit purpose (qualification, for-cause, routine, etc.)
  - » application of regulations and standards that will dictate your audit checklist
- Review examples of types of Audit Checklists
  - » generic GMP checklist
  - » scoring checklist
  - » custom checklist
- Pitfalls to avoid when using an audit checklist
- Building your custom audit checklist

Knowledge Exchange

Attendees take part on an interactive discussion on building custom GMP checklists based on examples of various types of manufacturers and/or regulations for medical devices and drug products.

Takeaway Tools

- Template of generic GMP audit checklist
- Template of scoring checklist
- Best practices and tips
- Benchmarking with colleagues
- Logistics
- Remediation when issues are found (because no one is perfect)

Knowledge Exchange

Attendees take part in an exercise in preparing for an Agency inspection.

Takeaway Tools

- Checklists for a laboratory inspection plan, including extensive Data Integrity topics

5:00 ET Close of Day Two

Day Three – August 25, 2021

7:30 ET Exhibitor Showroom and Lite Breakfast

8:20 - 9:05 ET Select Between Knowledge Exchange Sessions (25-28)

25 Risk-based Commissioning & Qualification - Successful Development and Execution

Donncadh Nagle, Commissioning, Qualification & Validation Lead, **Jacobs Engineering Group**; and **Researcher, TU Dublin**

Part 1 – Plan and Prepare for Success

- Regulatory guidance available – Why we need an effective qualification phase
- C&Q planning – What is the approach? – Develop a plan
- Highlight the role Quality Risk Management plays in helping design a robust C&Q plan
- Explore how to apply Quality Risk Management to C&Q
- Review an example of generic risk-based protocols
- Look at efficient use of a change management process to support C&Q
- Link risk-based verification to the process understanding – What is high risk?
- Don't forget about the commissioning activities and team members (FAT/SAT)

Part 2 – Successful Execution

- The importance of clear roles and responsibilities
- Prerequisites are the foundation to the protocols
- Discrepancy management – Resolving issues and deviations
- The importance of change control throughout the risk-based verification process
- Is a risk-based verification strategy the right approach for every circumstance?.

Knowledge Exchange

Attendees take part in a round-the-room survey of your company's challenges and C&Q strategies.

Takeaway Tools

- Generic risk-based protocols
- Risk assessments templates

26 Validation Statistics - Strategies to Graph, Analyze, and Present Data

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

Charts and graphs are extremely effective communication tools – when they are used correctly. They can be used for exploratory data analysis – to uncover trends and relationships in your data – and to present your results and conclusions in a powerful, effective manner. In this session, attendees learn how to make your charts and graphs make your point for you.

- How human perception affect the way our brains interpret different kinds of graphs
- Common types of errors in graphs, and how to avoid them
- Select the most effective visualization for various types of data in various scenarios:
  - » Comparisons of two or more data sets: boxplots
  - » Frequency-based data: histograms
  - » Proportional data
  - » Display error bars and p-value comparisons
  - » Trends: data as a function of time
  - » Contour, surface, and radar / spider plots to display and analyze multi-variable / multidimensional data
  - » Scatter diagrams and SPLOM matrices to discover correlations between multiple variables
  - » Color-based heat maps

27 Cleaning Validation Hot Topics - Documentation, Acceptance Criteria and Health Limits

Cindy Duhigg, Global Validation Steward, **Alcon Laboratories**

Part 1 – Documenting a Risk-Based Cleaning Process

- What is QbD, and why should you care?
- How to recognize a "validatable" cleaning process
- Microbial risk-busting

Part 2 – Acceptance Criteria and Health Limits

- The dirty truth about cleaning validation limits
- Making sense of the alphabet soup
- A rational 5-step process for deriving and justifying limits

Knowledge Exchange

- Attendees discuss a case study on risk management around "new" regulatory requirements.

Takeaway Tools

- Stepwise procedure for deriving health-based limits

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**

Part 1 – Planning

- Why do mock audits?
- Process elements for conducting mock audits
- Establish roles and staffing (internal and external)
- Set up the front room and back room
- The audit risk heat map
- Storyboards for those tricky topics
- Selecting appropriate tools for supporting the QMS and managing the mock audit
- Scheduling

Part 2 – Execution

- One-on-one front room and SME drills
- Full mock audit execution
- Remote vs. in-person audits
- Escalating tension by transitioning from coaching to adversarial
- Capturing the results
- Improving execution
- Don't overdo it

Takeaway Tools

- Mock audit preparation checklist
- Audit roles and responsibilities list
- Sample audit risk heat map

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.**

- Diagnose the strengths and limitations of current approaches to quality monitoring
- Use of process stability and capability methods and indices
- Develop a systematic approach to quality monitoring, control, and improvement:
  - » What it is, why it is needed and how to implement the approach
- How to sustain process stability and capability - Periodic management review
- Successful deployment, getting started and sustaining the initiative
- Tips, traps, and guidelines for successful continued process verification

Takeaway Tools

- Quality monitoring publication - "Crucial Considerations in Monitoring Process Performance and Product Quality"

30 Validation Case Study - Using Mixed Reality Technology in C&Q in Equipment and Systems

Donncadh Nagle, Commissioning, Qualification & Validation Lead, **Jacobs Engineering Group**; and **Researcher, TU Dublin**

This presentation evaluates the benefits of using mixed reality technology (augmented and virtual reality) to assist validation teams with their day-to-day activities within the pharmaceutical industry. The presentation assesses if there are significant time, cost and efficiency savings to be realized as a result of using mixed reality technology.

The presenters discuss the pros and cons of using mixed reality headsets and technology within pharmaceutical facilities today to aid GMP and non-GMP activities and showcase the results of a recently recorded reallife pilot study conducted within a pharmaceutical facility using VR headset and mixed reality technology. The pilot study:

- Conduct virtual Factory Acceptance Test (FAT) within a
- pharmaceutical plant
- Execute an equipment qualification test script within a GMP
- plant using a mixed reality headset
- Conduct a virtual audit of a Pharmaceutical facility using a
- mixed reality headset

Knowledge Exchange

- Attendees watch a pre-recorded video presentation of these pilot studies and get to hear from several industry SME's and experts about the merits of using mixed reality technology

31 Leverage Digital Validation for Streamlined Risk-Based Testing

Dori Gonzalez-Acevedo, VP of Strategic Solutions, **Tx3 Services**

- Define risk-based testing in the context of a CSV program
- Understand and overcome the perceived challenges of leveraging risk-based testing for regulated systems
- The benefits of risk-based testing over and application's lifecycle
- Where and how to start a risk-based testing Program
- What is digital validation and how it further enables a streamlined Risk-Based Testing program in CSV
- Utilize digital validation to fully incorporate test automation in risk-based testing

Takeaway Tools ⚒

- CSV and SDLC Modernization Assessment – Workshop
- Digital Validation: A Dynamic Approach to Regulatory Compliance – White Paper
- CIO Spotlight: A Strategic Test Automation that Won't Fail Before You Start – White Paper

32 Learn How to Use Risk in Change Control Processes

Roque Redondo, VP Automation and Business Development USA Operations, **mirus**

Part I – Concepts around Risk Assessment

- What are the basis and guides related to risk assessment?
- Review an example of a typical risk assessment flow diagram
- Link the risk-based approach to the knowledge of the processes where it will be implemented
- What are the essentials parts in a Quality Risk Management approach?

Part 2 – Change Control and How to Integrate Risk Assessment

- Understand the concept of change
- What is change control?
- Risk when using like-to-like parts or replacement parts
- Importance of change control throughout the risk-based approach process

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**

Part 1 – Critical Utility Qualification

- Understand the benefits of a quality-centric qualification approach
- Learn how to integrate commissioning and qualification activities
- Identify Critical Quality Attributes (CQA) and Critical Process Parameters (CPP) for critical utilities
- Utilize a qualification summary report to accept the critical utility and release it for Performance qualification (PQ)
- Select sampling locations and develop a phased PQ
- Understand the requirements for ongoing monitoring and how to reduce sampling of critical utilities following PQ completion
- Link critical utility qualification and impact to follow-on validation efforts such as environmental monitoring performance qualification (EMPQ)

Part 2 – Environmental Monitoring Performance Qualification

- Learn the basics of EM – Scope and types of monitoring
- Understand the pre-requisites before EMPQ activities may commence
- Identify sample locations based on risk assessment and in accordance with regulations and standards

- Use a phased approach to execute EMPQ
- Utilize EMPQ data to establish ongoing monitoring locations and frequencies
- Link EMPQ and ongoing EM data to a site's contamination control program
- Identify key components to an EM trend report and how feedback may impact the EM program

Knowledge Exchange

Attendees participate in a round table discussion on your company's critical utility and EM qualification strategy. Understand how changes to EU GMP Annex 1 may impact your site.

Takeaway Tools

- Trend evaluation tool
- Generic risk assessment template

34 Apply Quality by Design (QbD) for all Validation Types - QbD for All

Steve Thompson, Director Industry Solutions, **ValGenesis**

Part 1 – Laying the QbD Foundation

- The big picture of Validation
- Process, Method, Cleaning, Equipment, Instrument, and CSV Software
- The composition of QbD
- Foreseeing the impact of change on your organization
- How to attain a Quality Focused Culture

Part 2 – Implementing QbD for Validatioon in your Organization

- Assess the legacy litany of Validation (manual processes and hardcopy outputs)
- Design your controls (procedurally and technically)
- Implement your systems (manual and automated)
- Measure and monitor results (alerts, dashboards, and analytics)
- Continuously improve your processes

35 What to Do When Things Go Wrong - Implement an Effective CAPA Program

Shannon Chesterfield, Senior Director of Consulting, **Azzur Group**

Part 1 – What Makes an Effective CAPA Program

- Review the regulatory requirements for the CAPA system and
- Understand the typical CAPA Lifecycle
- Learn the importance of the CAPA program in your quality system
- Writing effective problem statements
- Evaluate risk and determine root cause
- Understand containment, Corrective and Preventive Actions
- Develop a strong CAPA Plan that addresses the root cause
- Create strong effectiveness verification
- Tracking and Trending CAPA Metrics

Part 2 – Hands on CAPA Workshop

- Participate in the development of CAPAs based on real life examples
  - » Create the problem statement and assess risks
  - » Investigate and determine root cause and contributing factors
  - » Develop the CAPA Plan
  - » Develop an effectiveness verification plan

Knowledge Exchange

Attendees take part in an interactive workshop to create effective CAPA documentation based on real life examples

Takeaway Tools

- Generic process flow for CAPA systems
- Examples of strong CAPA documentation
- Templates for problem statements, investigations, CAPA plans and Effectiveness verification

36 Mastering the Critical Elements of a Quality Risk Management (QRM) Program

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

Part 1 – Understand QRM as the Driver for Process and System Lifecycles

- Understand C&Q within the process validation lifecycle
- Understand QRM incorporation and benefits to C&Q and process validation

Part 2 – Applying Quality Risk Management to System Design and Delivery

- Understand the QRM-based integrated C&Q process
- Understand engineering and quality roles and responsibilities
- Understand the supporting processes for QRM-based C&Q
- Apply ICH Q8 and ASTM E2500 principles to use CQAs, CPPs, and CAs as the C&Q basis
- Apply ICH Q9 and ICH Q10 principles to define the risk control strategy
- Use design review to determine Critical Design Elements (CDEs)
- Use CAs and CDEs to support QbD, DQ, and Qualification strategy

Part 3 – Applying Quality Risk Management to System Operational Lifecycle

- QRM-Based change management
- QRM-Based deviation management, Investigations, and CAPA

- QRM-Based continuous improvement
- QRM as the basis for maintaining state of control/qualified state
- QRM as the basis for periodic system assessment

Part 4 – Applying Quality Risk Management to the Process Validation Lifecycle

- QRM-Based process validation
- QRM-Based cleaning validation
- QRM-Based sterilization validation
- QRM-Based environmental monitoring / EM PQ

Knowledge Exchange

Attendees take part in a round-the-room survey of companies' challenges, strategies, and successes implementing a holistic QRM program.

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**

Part 1 – The Benefits of Making Great Personnel Choices and Focused Training to Set-up for Success

- An employee is optimistic for their new role – AND they expect to be trained by their employer to some degree that starts them on their road to success
- Employees deserve to be trained well so they can reach their full potential
- Companies owe it to themselves to invest in training for their employees
- Discuss the pros and cons to training new vs. seasoned employees – The one-size-fits-all approach does not always work
- Do you need a formal training program for every job?
- The classroom and on-the-job matrix design for successful training
- The choice of trainers can make or break the training program
- The importance of a proper transition from training to work
- Expectation of managers and supervisors during and after the formal training process

Part 2 – Successful Implementation of the Training Program

- Establish a baseline for every job that will be involved in the program
- Consider how the training will be administered. – what will success look like?
- Will the trainer(s) be part-time, full-time, or just an available subject matter expert?
- If an employee is not successful in their role, is it based on training or other factors? How can this downward spiral be corrected?
- Are training tests strong evidence that an employee will be successful in their job over the long term?

Knowledge Exchange

Attendees take part in a round-the-room survey of your company's challenges and training programs to determine a baseline as to where industry is:

Takeaway Tools

- Example of a Customized training worksheet based on a specific role
- List of key attributes that are common for successful employees
- Example of how to assess the depth of a training program
- A roadmap for success - setting expectations for new employees

38 Use Validation Sampling Plans for Critical Decisions

Cindy Duhigg, Global Validation Steward, **Alcon Laboratories**

Part 1 – The Validation Sampling Plan

- The role of sampling in validation
- Validation sampling versus lot acceptance sampling
- Statistical sampling for validation
- Five-Step method

Part 2 – Critical Validation Decisions

- Critical Process Parameters (CPP)
- Critical Product Attributes (CPA)
- Acceptance criteria
- Process Capability and process stability
- Statistical Process Control (SPC) and maintaining a validated state

Knowledge Exchange

Attendees discuss a case study on deriving a statistical sampling plan for a real-life process validation.

Takeaway Tools

- Stepwise procedure for deriving a statistical sampling plan for process validation

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)**

Part 1 – Analytical Method Validation and The Fit-For-Purpose Acceptance

- Understand the regulatory requirements of analytical procedures
- The use of analytical testing to support pharmaceutical quality systems

- Establish design of method expectations using Quality-by-Design
- Understand the validation lifecycle for analytical procedures
- Assure that evaluation aim to fit-for-purpose.
- Review acceptance criteria based on the intended use of the procedures

Part 2 – Establish critical attributes of analytical procedures

- Evaluate critical changes that could impact the validity of the analytical testing
- Discuss handling of failures and how to establish CAPA
- Explore different ways to assure methods stay in compliance
- Establish system to measure method performance
- Exploring how to perform periodic reviews using a risk-based approach

Takeaway Tools

- Method validation review checklist
- Analytical procedure planning checklist

40 Change Control - Conduct System Criticality and Impact Assessments

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

Part 1 – Impact Assessment as A Part of Change Control

- The ability to assess the impact of a change is integral to the process of change control
- Must be an integral part of your change control procedure
- Not an option

Part 2 – Why Do an Impact Assessment as Part of Change Control?

- Regulatory guidance talks to ensuring all changes are reviewed, verified and/or validated as appropriate
- Determination of "appropriate" is a little vague.
- Regulatory guidance does not provide much guidance on how to do an impact assessment
- The process and procedure must be part of internal SOPs

Part 3 – Quick Review of the Elements of a Change Description

- The change, reason, and justification

Part 4 – Low Impact Changes

- Not all changes require a comprehensive impact assessment
- There should be a predefined list of changes or change types that do not require a full impact assessment to justify
- This list of changes or change types should be part of an SOP, fairly short, and well defined

Part 5 – Impact Assessment Team

- If it is determined that a full impact assessment is needed a team to do the assessment should be put together
- Can be permanent group or put together as needed
- Need someone to drive the change
- Other functional areas depending on the nature of the change

Part 6 – Creating a Change Control Roadmap

- The use of forms and decision trees is essential to success
- Team needs to have guidance and a place to record impact decisions
- Examples of decision tree and change impact assessment form
- Understanding of risk management impact and regulatory impact is critical

3:00 ET Exhibitor Showroom & Refreshment Break

3:15 – 4:45 ET Select Between Knowledge Exchange Sessions (41-43)

41 Assay Transfer, Qualification, Validation – Are We Living in a 'Land of Confusion'?

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

The objective of this session is to discuss the definition of terms (e.g., transfer, verification, qualification, validation), their respective concepts and meaning, and understanding when, if, and how they should be employed as products are targeted for marketplace distribution. The main objective of a qualification and validation of an analytical procedure is to demonstrate that the procedure is suitable for its intended purpose. Due to the complex nature, analytical procedures for biological and biotechnological products, in some cases, the approach may be quite different. This session will aid in understanding what, when and how to utilize these steps and clarify what is often seen as a muddling sea of terms and confusing requirements.

- Understand how to transfer, verify, qualify, and validation assay methods
- Link regulatory guidelines to the tasks needed for 'compliance'
- Definition of terms, concepts, structure of analytical processes/evaluation
- Outline and structure for various process requirements
- Learn how the concepts fit together with regulatory guidelines and recommendations
- Determine what is needed and when to perform certain processes to be in alignment with various regulatory guidelines

Knowledge Exchange

Attendees are encouraged to participate in a discussion throughout the presentation focusing on the understanding of terms like verification, qualification, and validation; knowing the differences between the terms; and recognizing when (if and how) these items should be employed during the process of getting a product to the marketplace.

42 | Qualification of Temperature Mapping and Storage Chambers

Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**

Part 1 – Temperature Mapping

- Low to map all kinds of chambers from incubators to warehouses
  - » Understand what needs to be mapped
    - ◊ Temperature alone may not be enough
  - » Learn what you need to plan your mapping
  - » Know What regulations do you need to follow
    - ◊ Some needs are not regulations, but common sense will dictate them

Part 2 – Qualifying Stability Chambers

- There are stability chambers and stability chambers
  - » Do not simply accept manufacturer's assurances
    - ◊ The responsibility is yours
- Map is just a snapshot in time, it needs to be monitored
- Plan for different products and monitoring of existing products

Knowledge Exchange

Attendees discuss examples of different data loggers.

Takeaway Tools

- Copy of ICH Q1(R2)
- Copy of Guidance for Industry: Container and Closure System Integrity Testing in Lieu of Sterility Testing as a Component of the Stability Protocol for Sterile Products.

43 | Validation and Change Control - Null Hypothesis Significant Testing

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

Null-hypothesis significance testing (NHST) can be used, among other things, to determine if there is a statistically significant difference between the means two data sets, or between the mean of a data set and a fixed value. This can be extremely useful in some validation and change control exercises.

In this session, attendees learn:

Part 1 – How to use NHST

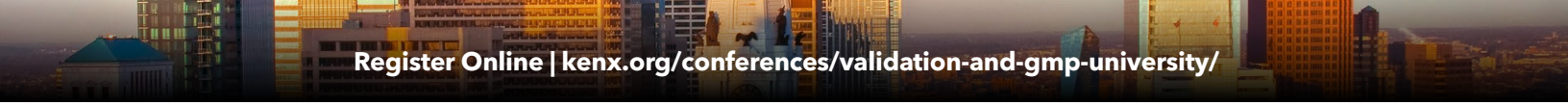
Test if a process improvement or material change has a significant impact on your product's critical quality characteristics.

- Determine if a drug or treatment has higher effect than placebo, or than another treatment
- Test if raw materials from two vendors are indeed functionally equivalent
- Demonstrate that an equipment change does not have unintended product impact
- Compare machines, raw material vendors, tooling sets, methods, etc.
- Determine if your process has shifted

Part 2 – Use a Two-Sample T-Test to Perform NHST With Quantitative (Variables) Data, and Fisher's Exact Test for Qualitative (Binary, Attributes) Data

- Use power analysis to determine the sample size required to detect a given difference between two data sets
- Use confidence intervals to estimate the magnitude of a detected difference
- Use Cohen's d to determine the real-life significance of a detected difference
- Interpret Minitab's hypothesis test results and write a conclusion for your test protocol
- What are Type-S errors, Type-M errors, p-Hacking … and how to avoid them?

4:45 ET Close of Conference



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