COMPUTER SYSTEM VALIDATION & DATA INTEGRITY COMPLIANCE CONGRESS

December 7-9, 2020 | The Wyndham Historic District | Philadelphia, PA

35+ TUTORIALS COVERING
COMPLIANT PROCESSES, ELITE VALIDATION PRACTICE AND INNOVATIVE TECHNOLOGY

**COMPUTER SYSTEMS AND SOFTWARE VALIDATION**
- Understand FDA's CSA Guidance in the Context of Current Regulations and GAMP®
- Conduct a Part 11 Gap Analysis - Create a Checklist
- Steps for CSV Migration to CSA and Modern Testing
- Conduct Periodic Review and Revalidation of Systems
- Qualify SAAS, IAAS and Other Software Services
- Master Risk-based Spreadsheet Validation
- Validation by Design - Manufacturing Automation Systems
- Testing During IQ and OQ for Successful System Turnover
- Perform Risk-based Impact Assessments
- Best-In-Class Master Plans, Templates and Checklists
- Conduct IT Infrastructure and Network Qualification

**DATA INTEGRITY GOVERNANCE AND INSPECTION READINESS**
- Success Factors for Implementing a Corporate Program
- Compliant Processes for Legacy Software Applications
- Reducing Human Errors for Compliance
- Implement Process Mapping to Identify Data Integrity Gaps
- Conduct a Gap Analysis of Your Program
- Use Critical Thinking for Your Approach to Technology
- Understand CSA's Applicability to Data Integrity
- Audit Your Audit Trails – Are We Challenging Status Quo?
- Overcome the Top Challenges of Program Implementation
- Monitor Controls through Process Monitoring
- Understand How Raw Data Files are Generated and Stored
- Prevent Error with Design, Automation and Procedure Control

**ELITE FACULTY BENCHMARK AGAINST INDUSTRY’S LEADING SUBJECT MATTER EXPERTS FROM LEADING ORGANIZATIONS:**
- Sanofi Pasteur • AbbVie • Alcon Laboratories • Bayer Pharmaceuticals
- Johnson & Johnson Vision Care • REGENXBIO • Takeda Pharmaceuticals • Gilead Sciences
- Abbott Laboratories • ICU Medical • And Many More!

**FEATURED REGULATORY KICKOFF – HEAR FROM FDA ADVISORY COMMITTEE MEMBERS**

Understanding FDA's CSA Guidance in the Context of Current Regulations and GAMP®

Senthil Gurumoorthi
Director, IT
Gilead Sciences

Ken Shitamoto
Senior Director, IT
Gilead Sciences

REGISTER BEFORE OCTOBER 30TH AND RECEIVE A $300 DISCOUNT
TEAM DISCOUNT: REGISTER 3 AND THE 4TH ATTENDS FREE

Register Online | www.kenx.org/conferences
Day One - December 7, 2020

10:00 EST Exhibitor Showroom and Virtual Platform
Open House

10:15 EST Chairperson’s Opening Remarks

10:30 EST - 11:00 EST
Understanding FDA’s CSA Guidance in the Context of Current Regulations and GAMP®

Ken Shitamoto, Senior Director, IT and Senthil Gurumoorthi, Director, IT, Gilead Sciences
- Understand the intent and scope of Computer Software Assurance
- Understand CSA's relationship to other existing regulations
- Understand CSA's relationship to GAMP®
- Brass tacks - What can YOU do now?
- Brass tacks - Advice from the trenches”

11:00 EST - 12:00 EST
Applying Computer Software Assurance to Data Integrity

- CSA concepts apply to all validation for intended use of a computerized system
- Automation improves Data Integrity and promotes better use of data for the benefit of the patient safety and product quality
- Risk management and Data Integrity
- CSA is the application of critical thinking and risk-based principles when developing computerized system lifecycle strategy in support of Data Integrity
- Recent intensification of Data Integrity sanction
- The applicability of direct and indirect risks to patient safety and product quality and Data Integrity
- The value of avoiding the mistake of focusing on regulatory risk over patient risk
- How to remediate deficiencies

Takeaway Tools
- Reference to Good Practice Guide – Data Integrity By Design (CSA Appendix)

12:15 EST - 12:45 EST
Exhibitor Showroom & Think Tank Sessions

1:00 EST - 1:30 EST
CSV and Regulatory Enforcement – Current and Future

Eric Henry, Senior Quality Systems and Compliance Advisor, FDA and Life Science Practice, King & Spalding
- Review the current state of CSV-related regulatory enforcement
- Understand how various regulatory bodies and competent authorities emphasize CSV differently
- Learn how new regulatory literature will impact regulatory enforcement
- How will specific technology challenges (e.g. cybersecurity, machine learning, cloud-based services) impact regulatory enforcement?

1:30 EST - 2:00 EST
Pharma 4.0 and Digitalization – Don’t Be Left Behind

Jonathon Thompson, Principal Consultant, CAI
- Define Pharma 4.0
- Define the vision and mission of Pharma 4.0
- Understand the digital maturity index
- Understand some of the challenges and obstacles to a Pharma 4.0 implementation
- Understand how to get started on the Pharma 4.0 journey

Takeaway Tools
- Example digital maturity index
- Example Pharma 4.0 roadmap

3:00 EST - 3:30 EST
How Much Validation is Enough?

Pritam Khade, Director, Global Quality Compliance, and Rae-chelle Ramondo, Executive Director, Global IT Quality, AbbVie; Shana Kinney, Associate Director, Validation, REGENXBIO
- Understand the importance of planning and critical thinking
- Ways to assess risk and use the level of risk to inform the level of assurance required
- Leverage vendor package through effective vendor audits
- Balance speed and quality through effective documentation
- Risk-based testing techniques to assure system quality

THANK YOU TO OUR PLATINUM SPONSOR
3:30 - 4:00 EST  Effective Risk Tools for CSV, DI and Automation

Kevin C. Martin, Senior Director and Managing Partner, Azzur Group

- Describe a risk-based computer validation approach that incorporates Data Integrity
- Provide an overview of risk assessment approaches and how they translate to efficient testing
- Learn the differences between technological and human related Data Integrity issues
- Understand the phases of the CSV life cycle risk assessments are applied
- Improve validation program efficiency by utilizing critical thinking and applying a Computer Software Assurance strategy

Takeaway Tools
- Example risk assessment form
- Computer system life cycle flow diagram showing where risk assessments are performed

4:00 - 4:30 EST  Overcome Top Challenges to Program Implementation

Erik Muegge, M.S., Manager Operations Quality, Abbott Laboratories

Sometimes it is intimidating just trying to figure out where to start with your Data Integrity implementation. In this session, we discuss some of the top challenges and how to overcome them. Key points include:

- Data Integrity awareness
- What is in scope and where to look
- Assess your gaps
- Establish a foundation and building upon it

4:30 EST  Game Night - Trivia Welcome Reception

Day Two – December 8, 2020

7:00 EST  Exhibitor Showroom Opens

7:15 - 8:00 EST  Select Between Knowledge Exchange Sessions (1-3)

1  System Configuration and Change Management

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

- Understand their interrelationship and importance in managing IT systems

2  Educate Personnel on CSV Execution

Robert J. Wherry, MSc, MS –Quality Compliance & Systems, RDQ Data Systems, Takeda Pharmaceuticals

- Understand their interrelationship and importance in managing IT systems
- Use ITIL IT Services Management framework establish effective processes for managing system configuration

Part 2 – Discussion of the Basic Elements of ITIL
- Service strategy
- Service design
- Service transition
- Service operation
- Continual support improvement
- What should we look for in a configuration management tool?

3  DI Compliance for Legacy Software Applications

Sanjay Agrawal, President and CEO, CIMCON Software

- The problems with legacy software applications
- Practical approaches for remediating legacy software applications
- Understand relevant data Integrity and Part 11 requirements
- Learn possible approaches to remediate legacy applications
- Understand how raw data files are generated and stored, and approaches on how these can be secured and managed

THANK YOU TO OUR GOLD SPONSORS

---

REGISTER NOW! www.kenx.org/conferences
A Critical Thinking and Risk-based Approach to CSV

Calvin Kim, Director Digital GxP Compliance Management, Bayer

Part 1 - Understand the Key Topics in Risk Assessment
Validation applicability assessment for systems
- Part 11 regulatory requirement assessment - Security, audit trail and e-signature
- Data integrity assessment including data flow and data life cycle
- Importance of critical thinking in risk management
- Periodic review of risk management
- Emphasis on risk management strategy - Is testing overrated?

Part 2 - A Practical Implementation of Risk-Based Computerized System Validation
- Common IT supplier audit findings
- Assessment and mitigation of supplier risks in quality clauses in contractual clauses
- Risk assessment 101 - Process, roles and documentation
- Risk mitigation strategy - Technical and procedural controls
- Review an example of a typical risk assessment practice
- Case studies - CSV pitfalls (validation don’ts and more don’ts)

Knowledge Exchange
Two seasoned auditors will present real-life examples of relevant audit findings in computerized system development (IT supplier) and validation (sponsor) practices, to drive emphasis on critical thinking aspects of risk management in computerized system validation

Takeaway Tools
- Checklist for Part 11 regulatory requirement system requirements
- Checklist for IT supplier quality agreements
- A comprehensive risk assessment template
- Template contents for IQ
- Template contents for UAT

Reducing Human Error for Compliance

Cindy Duhigg, Global Validation Steward, Alcon Laboratories

Part 1 - The Elements of Human Error
- What is human error?
- Understanding the role of human error - Regulatory and industry perspectives
- Understanding the types of human error
- Understanding the sources human error
- Human error as a root cause

Part 2 - Controlling Human Error
- The importance of clear roles and responsibilities
- Create the right risk-based culture
- Human error rates and measurement
- Trending and tracking
- Eliminate, replace, facilitate: Process step errors
- Design, automation, and procedural controls for error prevention
- Predictive governance
- CAPA effectiveness

Knowledge Exchange
Attendees take part in an interactive process error review.

Takeaway Tools
- An understanding of the Psychology of Error and Human Error Characteristics
- Poka-Yoke Mistake Proofing

Develop a Process for the End of a Computer System Life Cycle

John Hannon, PE, CPIP, CBCP, Global Principal for Automation and IT, CAI

Implementation Case Study – Overcome the Challenges of Paperless Implementation

Joseph Zec, Associate Director, R&D Data Systems Software Quality Assurance, Takeda Pharmaceuticals

This case study looks at one organization’s journey from a paper-based test execution system to a paperless one and how they overcame the challenges inherent in making the switch.
- Barriers to adopting paperless testing
- Planning the paperless program
- Communication
• Leveraging other efforts
• Training
• Implementation support

Knowledge Exchange – Countering the Arguments
Attendees divide into working groups and strategize the best way to overcome objections to implementing a paperless validation process.

8 Conduct a Part 11 Gap Analysis – Create a Checklist for Compliance

Carlos L. Pereira, Regional Manager of U.S. Midwest and Canada, VTI Life Sciences

Part 1 – Determine the Scope of the Review
• Review the system and application and determine its capabilities, functionality, and configuration
• Review way system / application intended to be used and issues (if any)
• Determine what qualification / validation was performed on the application
• Determine what are the departments and major sponsors using the system / application
• Understand the regulatory requirements for the system/application based on intended use

Part 2 – Perform the Review
• Document use (or intended us) of the system/application by users
• Verify if system/application SOPs exist and if they match the use of system/application
• Review problems/limitations of the system/application
• Review the validation protocols to verify the application validation matches current use
• Review change process and if system / application was maintained in a validated state
• Review control process to verify if the company has the proper procedures in place to qualify / validate system / application

Part 3 – Write the Report
• Report should include the following sections:
  - intro
  - background of system/application
  - major findings
  - recommendations
  - detailed summary of review

Takeaway Tools
• Part 11 GAP Assessment Report template

9 Create a Culture of Quality Throughout Your Organization

Matthew LaPierre, Data Integrity Specialist, Industry Expert

Part 1 – Quality Culture – Why Is It So Hard?
• Identify what makes a good Quality Culture
• Learn the not-so-evident characteristics of a bad Quality Culture – Signs and concerns
• Learn how a bad Quality Culture can impact a company’s integrity - Short term and the long haul
• Understand leadership’s incredible responsibility

Part 2 – How to Make It Better
• Understand why training is not always the answer
• Review real-life examples of how companies have improved Quality Culture
• Learn to shift your thinking when it comes to Quality Culture

Knowledge Exchange
Attendees take part in a round-the-room dialogue, learning from each other actions that have worked and those that have not to improve Quality Culture.

Takeaway Tools
• Real-life examples of how to improve Quality Culture at your organization

12:30 - 1:15 EST Select Between Knowledge Exchange Sessions (10-12)

10 SQA 101 – Introduction to Modern Testing in Preparation for CSA

Ken Shitamoto, Senior Director, IT and Senthil Gurumoorthi, Director, IT, Gilead Sciences

• What is modern testing?
• How is it different than validation?
• How do I get started?
• Static test techniques
• Dynamic test techniques
• How do I introduce it into my validation cycle?
• Automation

11 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

A Compliance Approach for Paper-based and Hybrid Systems
John Hannon, PE, CPIP, CBCP, Global Principal for Automation and IT, CAI
- Understand aspects of Data Integrity in electronic systems
- Discuss mechanisms of effective IT architecture
- Evaluate system effectiveness and architecture
- Discuss elements of data historization
- Apply standards for laboratory system deployment
- Apply network security profiles
- Review cryptographical tools for one-off situations

Takeaway Tools
- Tools for Data Integrity assessment
- Assessments for SIEM tool selection
- Models for laboratory network architecture
- Evaluation tools for lab network effectiveness
- Tool resources for encryption

1:30 - 2:00 EST  Exhibitor Showroom & Think Tank Sessions

2:15 - 3:45 EST  Select Between Knowledge Exchange Sessions (13-15)

13  Planning Steps for Migrating CSV to CSA

Leslie Lighten-Humphreys, IT SQA and CSV Manager, AmerisourceBergan

Part 1 - Learn the key differences between the legacy and future state processes
- Understand what can be migrated to the new operating model
- Know what needs to remain the same
- Understand the implementation timeline

Part 2 - Create a CSV to CSA Migration Implementation Plan
- How are your CSV deliverables managed now?
- Outline your current process for evaluating validation candidate risks
- Policies, procedures, and work instructions that need to change and why
- Determine what policy and procedure elements or entire documents stay the same
- Implementation steps that are required and/or optional
- Learn what artifact migration tracking procedures need to be in place
- Know what metrics should be baselined and tracked through the implementation
- Determine what training will be required and for what audience
- Execute an implementation dry run
- Determine implementation timing, reviewers, approvers, and other stakeholders
- Post-implementation feedback and changes
- What else?

Knowledge Exchange
Attendees reflect on how they might migrate from validation to assurance activities while ensuring existing and future systems under regulatory oversight are maintained in a validated state.

Takeaway Tools
- Checklist
- Sample implementation plan
Conduct Risk-based Impact Assessments

Eric Henry, Senior Quality Systems and Compliance Advisor, FDA and Life Science Practice, King & Spalding

Part 1 - The Criticality of Impact Analysis and Its Relationship to Risk
• What is impact analysis and what does it do?
• When is impact analysis appropriate?
• How does risk management relate to impact analysis?
• How does poor / non-existent impact analysis affect regulatory compliance?
• How does poor / non-existent impact analysis affect the bottom line?

Part 2 - The Elements and Execution of Risk-Based Impact Analysis
• When in the change process should an impact analysis be done?
• What are the key elements of an impact analysis?
• What are some impact analysis methods?
• How does impact analysis of legacy code / systems differ from that of more process-mature and structured code / systems?
• How does impact analysis drive changes to process and system artifacts?

Knowledge Exchange
Attendees review an example system change and discuss how to (1) assess the impact of the change and (2) determine what lifecycle activities must be conducted as an output of the assessment.

Takeaway Tools
• Impact assessment outline
• List of impact assessment methods

Implement Process Mapping to Identify Data Integrity Gaps

William Honeck, Vice President, VTI Life Sciences

Part 1 - Create a Data Process Map
• The importance of data flow and process mapping for Data Integrity
• Understand the system data lifecycle
• Key elements of a system data process map
• Tools to interview the process “players” and stay in the swim lane
• Case Study 1 - Instrument Data Process Map
• Case Study 2 - Manufacturing System Data Process Map

Part 2 – Risk Analysis
• The importance of audit trail components
• Data process flow and identification of Data Integrity risks/ gaps
• Develop risk mitigation strategies

Knowledge Exchange
Attendees take part in a practical exchange of experiences utilizing data process maps to establish appropriate system and process controls.

Takeaway Tools
• Data process map template

Senior Level Think Tank – Bring and Solve Your Challenge

Joseph Zec, Associate Director, R&D Data Systems Software Quality Assurance, Takeda Pharmaceuticals

This CSV master class is for senior-level professionals who have a deep understanding of CSV processes and innovative technology. The session is constructed from participants experiences in which key issues are addressed, best practices are exchanged, and challenges overcome:
• What is your greatest regulatory concern?
• What is your greatest challenge on your desk today?
• What innovative process or technology in which you excel can you share with your peers?
• Do you have any SOPs, templates or checklists you can share with the group?
17 | Supplier Management – A Path to Build Trusted Partnerships

Pritam Khade, Director, Global Quality Compliance, and Vishal Kadakia, Senior QA Specialist, Global Quality, AbbVie

**Part 1 - Early Planning Critical for Success**
- Learn how to identify suitable suppliers
- Why vendor management is critical
- When do you start engaging with supplier?
- How do you determine scope of audit?

**Part 2 - Focused Supplier Evaluation**
- Determine risk associated with supplier
- Learn how to audit effectively

**Part 3 - Ongoing Compliance**
- Establish Quality Agreements to ensure continued partnership
- Manage periodic monitoring of suppliers

**Knowledge Exchange**
- Struggles and challenges in supplier management

18 | Success Factors for Developing a Corporate DI Program

Chinmoy Roy, Data Integrity and CSV SME, Industry Consultant, ValGenesis

**Part 1 - Understand factors that Influence Data Integrity**
- Data Integrity regulatory guidance overview
- Review of elements important to maintaining Data Integrity
- Understanding Data Integrity as a business process
- Understanding Data Management: Governance, data quality, data operations

**Part 2 - Developing the Data Integrity Program**
- The role of executive management
- Identifying the 6 steps to developing the program
- Maintaining program relevance
- Case Study: Using process maps to establish a laboratory Data Integrity controls program

**Knowledge Exchange**
Attendees get their application specific questions answered by the presenter during the Q&A session

**Takeaway Tools**
- Sample Data Integrity Policy
- Sample Laboratory Controls SOP (21 CFR Part 211.160)

Day Three – December 9, 2020

7:00 EST Exhibitor Showroom Opens

7:15 - 8:00 EST Select Between Knowledge Exchange Sessions (19-21)

19 | Auditing Your Audit Trails – Are We Really Challenging the Status Quo?

April Bunje, Data Integrity Compliance Manager, Sanofi Pasteur

- Define audit trails in business terms
- Understand the importance of the audit
- Audit findings in relation personal and business
- Vetting audit businesses for intended purposes
- Defining new approaches

**Takeaway Tools**
- Paper to electronic centric - Regulatory documents
- Example of audit findings - Nexus audit report
- Understanding of data about data - GMQA webinar takeaways

20 | Combatting Malicious Threats to Systems

Kevin C. Martin, Senior Director and Managing Partner and Michael Kazakevich, General Manager, Azzur Group

To Be Announced

6:15 EST Close of Day Two
21  Inspection Readiness – Conduct a Gap Analysis of Your Program

Robert J. Wherry, MSc, MS - Quality Compliance & Systems, RDQ Data Systems, Takeda Pharmaceuticals

Part 1 – Tools for Inspection Preparation
• Gain a regulatory inspector/auditor perspective
• Develop the gap assessment checklists
• Prioritize assessments
• Maintain a “ready” state

Part 2 – Conduct the Gap Assessment
• Motivators for discovering gaps
• Management support, involvement & oversight
• Interim measures & ultimate CAPAs
• Plan, prioritize, budget & schedule
• Practical considerations

Part 3 – Handling Inspections
• Reasonable do’ & don’ts
• Inspection logistics
• Steps for remediation when issues are found

Knowledge Exchange
Attendees discuss how to identify potential CSV & Data Integrity gaps.

Takeaway Tools 📊
• A checklist for a laboratory gap assessment or inspection plan

23  Qualify SAAS, IAAS and Other Software Services

Steve Thompson, Director of Industry Solutions, ValGenesis

Part 1 – Understand the Technology Stack
• Challenges we face with cloud-computing, and how to deal with them
• Infrastructure as a Service (IaaS)
• Platform as a Service (PaaS)
• Software as a Service (SaaS). Shouldn’t this be validated?

Part 2 – Qualifying SaaS, IaaS and Other Software Services (collectively XaaS)
• XaaS Policies and procedures
• XaaS Standards & framework
• XaaS Planning
• XaaS Execution
• XaaS Maintenance
• XaaS Decommissioning / retirement

Knowledge Exchange
Open discussion and Q&A with attendees. Live poll to be analyzed by all at end of presentation.

Takeaway Tools 📊
• On-line survey during presentation
• XaaS Qualification Concepts (PDF)

22  Continuous Monitoring – Periodic Review and Revalidation of Computer Systems

Stephen J Cook, VP - Validation and Compliance, Khaled Moussally - EVP - Regulatory and Client Relations, Compliance Group, Inc.

Part 1 – Overview of What a Monitoring Program Looks Like
• The value of tracking issues in production
• Learn how to ensure change management reviews are practical and achievable
• Ensure success with good procedures

Part 2 – Executing Continuous Monitoring
• What to review
• The value of a great checklist for assessment
• How to remediate deficiencies
• Learn when revalidation might be required

Knowledge Exchange
Attendees learn what goes into a robust monitoring program, what artifacts to include during a periodic review and when to revalidate.

Takeaway Tools 📊
• Periodic review checklist

24  Critical Thinking – Rethinking Your Approach to Technology

April Bunje, Data Integrity Compliance Manager, Sanofi Pasteur

Part 1 – Critical Thinking Skills and Challenging Ways of Working
• Start with why, law of diffusion of innovation
• Data Integrity and digital adoption together
• A paradigm shift in the ways of business and personal adoption
• New digital reality
• Understand the difference between traditional Data Integrity and old Data Integrity methodologies
• EU blockchain observatory and forum
• FDA & Data Integrity
• Mapping your process, a foundation approach
• What does Data Integrity adoption look like?
• What are the risks?
Part 2 – Executing
• The importance of clear roles and responsibilities
• Evaluating and project sandboxes
• The plan (short and long term)
• Resolve
• The importance of mindset throughout processes
• Technology brings traceability for every circumstance leverage your capabilities and hedge for the future

Takeaway Tools ❧
• Article, Is Your Technology Ready for the New Digital Reality?
• IMI Call 15, topic 2, “Blockchain Enabled Healthcare”
• EU Blockchain Observatory Forum
• FDA Data Integrity and Compliance with CGMP Questions and Answers Guidance for Industry
• Simon Sinek TEDx video, Start with Why

10:00 - 10:30 EST Exhibitor Showroom & Think Tank Sessions

10:45 - 12:15 EST Select Between Knowledge Exchange Sessions (25-27)

Part 3 – Available Technology
• Identify available technology to aid in maintaining control over validated spreadsheets
• Understand and establish processes needed to use technology

Knowledge Exchange
Participants discuss common pitfalls in spreadsheet validation, overcoming challenges, and Warning Letter trends.

25 | IT Infrastructure and Network Qualification

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

• Network infrastructure software – Qualification vs. validation
• Understand the scope of network infrastructure qualification
  - layered software
  - infrastructure software tools
  - software-defined infrastructure
• Discover the roles and responsibilities involved in IT network software qualification
• Learn the main phases of IT network software qualification
• Know what kind of documentation to produce
  - per phase
  - project documentation vs system documentation - living documents

Part 2 - Risk-based Validation
• Identify what is most critical - Patient safety/ product quality impact
• Apply Quality Risk Management principles to manage the risks associated with spreadsheets
• Focus on assurance rather than documentation
• Create effective validation package
• Maintain spreadsheets in a validated state

26 | Risk-based Spreadsheet Validation – An Organized, Effective Approach for GxP Environments

Pritam Khade, Director, Global Quality Assurance, and Vishal Kadakia, Senior Specialist, Global Quality Assurance, AbbVie

Part 1 – Planning and Identification of What to Validate – The Key to Success
• Understand your environment and spreadsheets in use
• Determine GxP applicability of those spreadsheets
• Identify owners and users of spreadsheets

Part 2 – GAMP®5 Guidance and IQ / OQ Testing Sections
• GAMP®5 recommended testing sections for CSV
• Installation Qualification testing dos and don’ts for the following
  - drawing verification
  - hardware environment and utilities
  - hardware specifications
  - software specifications
  - data historian point verification
• Operational Qualification testing dos and don’ts for:
  - security
  - alarm testing
  - HMI screen verification
  - start up, shut down, power loss and recovery
  - boundary limit testing
  - system functional testing (aka sequence of operations)

Knowledge Exchange
Attendees take part in a round-the-room survey of your company’s challenges and CSV testing strategies.

Takeaway Tools ❧
• Recommended list of testing sections for CSV protocols
• Example test cases
• Template written test cases
12:30 - 1:15 EST
Select Between Knowledge Exchange Sessions (28-30)

28
Develop a Cohesive Relationship Between QA and IT

Pritam Khade, Director, Global Quality Compliance, and Raechelle Ramondo, Executive Director, Global IT Quality, AbbVie; Ken Shitamoto, Senior Director, IT and Senthil Gurumoorthi, Director, IT, Gilead Sciences

- Partnering to drive quality culture
- Engage right stakeholders
- Drive efficiencies through collaboration
- Keep an open mind & strive for continuous improvement
- Embrace new tools and technologies

29
GDPR Compliance Considerations for SAAS and Cloud Services

Holly Baldwin, Manager, Quality Validation, CSV, Sanofi Pasteur

- What is GDPR and why does my company need to comply?
- Steps to add GDPR compliance into your IT supplier audit process
- Questions to ask SaaS / CSP on their commitment to GDPR
- Scrutinize the SaaS / CSP answers to GDPR audit - What’s behind their talk?
- Enhancing your IT validation approach to include privacy by design

Takeaway Tools 🤖
- Example of SaaS/CSP GDPR whitepaper
- Example of Data Privacy Impact Assessment (DPIA)

30
Transitioning from Manual Processes to Process Automation

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

Part 1 - The Planning and Identification of Key Participants for Success

- You are the product/process expert - Are you an automation expert?
  - assess your organizational state
  - GAMP® 5
- The importance of TQM to your project?
- Selection of an Automation Architect
- Accelerate the translation layer between owner and automation contractor
- Determine RACI for VMP, URS, FRS, DDS, FAT, SAT, EIOQ, software V&V, PPQ, and regulatory submission documentation

Part 2 - Process Automation - Case Study

- Manual process in R&D state
- Retain a consultant to qualify manual process and translate to Automation Architect
- Apply Quality Risk Management principles to define CQA and CPP
- Focus on assurance rather than documentation
- Create effective documentation package
- URS strategy - System level and cell level
- Communicate conduit between client and Automation Architect via URS

Part 3 - Assembly Automation - Case Study

- Automate manual process and scale prototype automated process to high volume production system
- Understand, document, and establish processes needed to define automation, C&Q plan
- Know the best use of your regulated automation consultant
- customers “eyes and ears” at multiple North American automation integrators
- FAT during COVID
- continuous on-site presence
- knowledge transfer

- Minimum viable equipment
- Risk-based testing strategies

1:30 - 2:00 EST Exhibitor Showroom & Think Tank Sessions

2:15 - 3:45 EST
Select Between Knowledge Exchange Sessions (31-33)

31
Validation Case Study – Using Mixed Reality Technology for C&Q of Pharmaceutical Equipment and Systems

Donncadh Nagle, Validation Lead, Eirchem Pharma & 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 showcases the results of a recently recorded real-life 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
- Executed 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 will get to hear from several industry SME’s and experts about the merits of using mixed reality technology.

32 A Common Sense Approach to CSV and CSA - Implementing New Data Technology in the Device Environment

Teri Stokes, Ph.D., Director & Senior Consultant, GXP International

Part 1 - A Common Sense Approach to Sorting Computer System Validation (CSV) and Computer Software Assurance (CSA) practices for Patient Safety and Product Integrity

• Describe the intended role of the new technology in your work process
• Identify inputs/outputs from the intended role activities
• Identify possible errors, omissions, or other risks/issuses that could disrupt inputs/outputs from other factors in the work process or work environment
• Assess the impact of identified risks on potential patient safety using your medical device
• Assess the impact of identified risks on product-related data integrity or physical integrity
• Define Risk Analysis decision analysis for your product decision for CSV or CSA

Part 2 – Auditable Implementation of CSA Strategy Testing

• Standardize the approach to assurance (CSA) Testing with SOP
• Define concise documentation for describing risk analysis, testing strategy, and results obtained
• Identify tester credentials and test witness
• Define CSA Acceptance criteria for your product

Knowledge Exchange
Attendees participate in a group survey of company challenges strategies and experiences with CSV/CSA choices past and present for introducing new IT technologies into their medical device manufacturing and distribution process.

Takeaway Tools
• MHRA - GXP Data Integrity Guidance and Definitions - March 2018
• FDA - General Principles of Software Validation; Final Guidance for Industry and Staff (2002) (Medical Devices)
• FDA - Data Integrity and Compliance with Drug CGMP Question and Answers Guidance for Industry (2018)

33 Validation by Design of a Manufacturing Automation System

Chinmoy Roy, Data Integrity and CSV SME, Industry Consultant, ValGenesis


• A compendium on CSA (Computerized Systems Assurance)
• What is USFDA’s Case for Quality and where does CSA fit in?
• A compendium on the architecture and design of a manufacturing automation system
• Data dependency and data flow diagrams of a typical manufacturing automation system

Part 2 – Implementing CSA in a Manufacturing Automation System

• Control software design using functional modularity
• Testing strategy for software designed by using functional modularity
• Design as an enabler of agile testing during installation and commissioning
• Manufacturing flexibility and agility

Takeaway Tools
• Test Plan using CSA Test techniques

4:00 - 5:30 EST Select Between Knowledge Exchange Sessions (34-36)

34 Best-in-Class Documentation, SOPs, Templates and Checklists

Stephen J Cook, VP - Validation and Compliance, Compliance Group, Inc.

Part 1 – Develop High Quality Documentation

• The value of consistency
• Pre-writing content to remove poor writing and subjectivity
• Using styles and good formatting
• Documentation as defense

Part 2 – Use High Quality Documentation

• Use instructional text
• Use blue text (sample) and black text (required)
• Create logical structures for SOPs to templates, checklists and forms
• Understand the difference between a form and a template

Knowledge Exchange
Attendees learn foundational concepts for creating best-in-class documents, formatting tips using styles and how to use checklists, forms and templates to ensure concepts are fully addressed and deliverables are consistent.
Instrument Qualification and Data Integrity Considerations

Loganathan Kumarasamy, Validation Consultant, Zifo RnD Solutions

- Review the current state of CSV-related regulatory enforcement
- Understand how various regulatory bodies and competent authorities emphasize CSV differently
- Learn how new regulatory literature will impact regulatory enforcement
- How will specific technology challenges (e.g. cybersecurity, machine learning, cloud-based services) impact regulatory enforcement?

Validation of Robotic Process Automation (RBA)

Steve Thompson, Director of Industry Solutions, ValGenesis

Part 1 - Robotic Process Automation Overview
- What is Robotic Process Automation (RPA)?
- Why is it becoming more prevalent today?
- How is it different from other technologies?
- Is it new, old, or a fad?

Part 2 - Validating RPA
- Do we really need to validate RPA differently?
- RPA validation planning
- RPA validation execution
- Maintaining RPA technologies

Knowledge Exchange
Open discussion and Q&A with attendees. Live poll to be analyzed by all at end of presentation.

Takeaway Tools
- On-line survey during presentation
- RPA Validation Concepts (PDF)

5:30 EST Close of Conference