KENX
KNOWLEDGE EXCHANGE NETWORK

ONLINE TRAINING

VALIDATION DOCUMENTATION

Implement Best-in-Class Processes for Efficiency, Compliance and ROI

October 28, 2021 | 10:15am - 4:45pm ET

TOP REASONS TO ATTEND:

- Understand Documentation Requirements and How Much Validation is Enough
- Review Current Trends in FDA Regulatory Observations/Focus
- Learn Risk-based Documentation Practice for Commissioning & Qualification (C&Q)
- Incorporate Vendor Testing and Documentation into Verification Strategy
- Manage Vendors and the Engineering Quality Process
- Understand the QRM-based Integrated Process and Ensure Value-Added Documentation
- Implement Best Practice to Support Documentation System and Process Validation Lifecycle
- Learn How to Implement Paperless Validation and Integrate ExistingCompany Templates/Protocols
- Prepare the Organization and Overcome Resistance of e-Validation Solutions
- Leverage URS as Documentation Scope Driver
- Understand FDA's Inspection Strategy Shiftand Critical Elements for a Successful Validation Documentation Review
- Implement an Inspection Readiness Strategy for Processes, Equipment, and Systems
- CreateBest in Class Validation Master Plans, Protocols, Reports, SOPS, and Data Integrity SOPS
- Identify and Prepare Change Controls, Deviations/CAPA with Validation Impact
- Use an Audit App Tools to Streamline Regulatory Inspections
- Receive Validation Documentation, an Inspection Readiness Checklistand a Validation Master Plan Template

Delivered By Industry Leaders

Philip Jarvis
EU C&Q Lead
Abbvie

Chip Bennett
Associate Director
Global C&Q
CAI

Nathan Temple
Global Director
C&Q
CAI

Siobhan Ashmore
Associate Director
QCR
CAI

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10:15 am EDT **Webinar Host Opening Remarks**
Howard Wilensky, Executive Director, **KENX**

10:30am – 11:15 am ET

Understand Documentation Requirements and How Much Validation is Enough

Chip Bennett, Associate Director, Global C&Q
CAI

Part 1 – C&Q Documentation Requirements

- ISPE Baseline Guide 5 – C&Q process documentation
- URS as documentation scope driver
- Risk assessment as documentation rigor driver
- Design Review as documentation acceptance criteria driver
- C&Q plan as role and responsibility driver
- Verification testing documentation – Efficiency, effectiveness, and the differences between integrated and leveraged approaches

Part 2 – Vendor Verification Testing and Documentation

- Getting the right documentation from vendors
- Incorporate vendor testing and documentation into C&Q verification strategy
- Vendor management and the engineering quality process

11:15 am – 11:30pm ET Break

11:30 pm – 1:00 pm ET

Learn Risk-based Documentation Practice for Commissioning & Qualification (C&Q)

Chip Bennett, Associate Director, Global C&Q
CAI

Part 1 – Applying Quality Risk Management to C&Q

- 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 2 – Effective C&Q – Best Practices for Key C&Q Process Deliverables

- User Requirements Specification (URS)
- System Risk Assessment (SRA)
- Design Review (DR)

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- Design Qualification (DQ)
- Verification Testing
- Requirements Traceability Matrix (RTM)
- Acceptance and Release

Part 3 –Efficient C&Q – Best Practices to Ensure Value-Added C&Q Documentation

- Understand the differences between integrated and leveraged approaches
- Understand roles and responsibilities in QRM-based integrated C&Q
- Best practices for Good Engineering Practice (GEP) and the Engineering Quality Process (EQP) to enable and facilitate integrated C&Q
- Best practices for vendor testing, documentation, and management

Part 4 –Implement C&QBest Practice to Support Documentation System and Process Validation Lifecycles

- Change Management
- Deviation Management, Investigations, and CAPA
- Continuous Improvement
- Maintaining State of Control/Qualified State
- Periodic System Assessment
- Process Validation
- Cleaning Validation
- Sterilization Validation
- Environmental Monitoring / EM PQ

1:15pm – 1:30 pm ET Break

1:30pm – 3:00 pm ET

Lean Validation – Tips for Transitioning to Paperless Validation

Philip Jarvis, EU C&Q Lead, **AbbVie**
Nathan Temple, Global Director C&Q, **CAI**

Part 1 – Define the Scope and Advantages

- Getting started - IT, process, or equipment
- Deployment - Project, site and global
- Process focus & data mapping
- eValtool selection
- ROI - Justify paperless tools to stakeholders

Part 2 – Successful Implementation of Paperless Validation

- Planning for a successful implementation
- Creating efficient tools
- Integration of existing company templates/protocols
- Preparing the organization & overcoming resistance
- Boundaries and validating eVal tool for max efficiency

Knowledge Exchange

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

3:00 pm –3:15 pm Break

3:15 pm – 4:45 pm ET

Is Your Validation Documentation Inspection Ready? Prepare NOW for FDA's Remote Interactive Evaluations!

Siobhan Ashmore, Associate Director, QCR, **CAI**

With shift in FDA Inspection focus and increased validation activities during the Covid19, the following points are why you need to have your Validation Documentation inspection ready.

Part 1 – FDA Inspection Strategy Shift

On April 14th, 2021, the FDA released the immediately-in effect guidance "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities". As per this guidance, the FDA intends to request records and any other information under section704 (a)(4) of the FDCA, prior to initiating a remote interactive evaluation. The guidance states that the records or any other information provided to the FDA upon request, may be used to:

- Rank or prioritize a facility for an inspection, particularly a surveillance GMP inspection based on documentation provided and reviewed
- Support a regulatory meeting, warning letter, import alert, recall activities, or enforcement action
- Justify a follow-up or compliance inspection or any other surveillance

Part 2 –Critical Elements for Successful Validation Documentation Inspection

Inspection Readiness for Validation is often overlooked, with most companies typically focusing on Inspection readiness for manufacturing and quality management systems and quality control. Covid19 has led to increased validation activity in the pharmaceutical Industry globally due to the need for the industry to pivot in the direction of process, system, equipment optimization to meet supply demands whilst working with a remote workforce. This session covers:

- IdentifyingGxP processes, equipment, systems in relation to validation
- Current trends in Regulatory Observations/Focus of FDA in relation to validation
- Implementing an Inspection Readiness Strategy for GxP processes, equipment, systems
- Creating and preparingbest in class, Validation Master Plans, protocols, reports, SOPS, Data Integrity SOPS for GXP processes
- Identify and prepare change controls, deviations/CAPA with validation impact
- Create best in the class Validation Master Plans, SOPs, protocols, summary reports
- IdentifyingGxP processes, equipment, systems in relation to validation
- Audit app tools used to streamline regulatory inspections

Takeaway Tools

- Validation documentation
- Inspection Readiness Checklist
- Validation master plan template

Personnel in the Following Environments Should Attend:

- Validation
- QA/QC
- Documentation
- Risk Management
- Engineering
- Data Integrity
- Regulatory Affairs
- Compliance
- Manufacturing
- Laboratory

Personnel in the Following Environments Should Attend:

Validation
IT
Scientist, Chemist
Regulatory Affairs
Manufacturing Manager
Data Integrity
QA/QC
Engineering
Compliance
Laboratory Manager

Pricing: $595

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About the Instructors:

Chip Bennett, Associate Director, Global C&Q, **CAI**

Chip is a Project Manager and Senior Validation Engineer, and a PMI® Certified Project Management Professional (PMP) with over 20 years of experience in the pharmaceutical and regulated non-pharmaceutical industries and with expertise in risk-based verification, aseptic manufacturing, cleaning validation, quality systems, and owner project management. Chip is responsible for developing and implementing Quality Risk Management (QRM) based Commissioning and Qualification programs and projects, with a focus on assessing and training clients regarding development, implementation, and transition to risk-based approaches.

Philip Jarvis, EU C&Q Lead, **Abbvie**

Mr. Jarvis is an experienced team leader with over ten years of experience in all areas of validation including; process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation. Through strategic thinking, he has success in steering and managing complex validation projects within the medical device and pharmaceutical industries.

Nathan Temple, Global Director C&Q, **CAI**

Nathan Temple serves as the CAI CQV Business Area Lead,is a PMI® Certified Project Management Professional (PMP) and licensed Professional Engineer with 20 consecutive years of experience in the fields of start-up, maintenance, commissioning, and qualification. Nathan has extensive engineering, test execution, and project management experience with a wide variety of systems and equipment. Nathan is a computer system validation subject matter expert providing project consulting and support. He is a member of the ISPE C&Q Community of Practice Steering Committee.

Siobhan Ashmore, Associate Director, QCR, **CAI**

Siobhan Ashmore has over 25 years of International Experience in the Pharmaceutical, Medical Device, Biopharmaceutical Industry. Siobhan has vast experience as an auditor with 15 years in Manufacturing Validation, Quality, Regulatory Compliance Management positions, 7 years as a Consultant QA Auditor. She has led Inspection Readiness Teams for organizations globally during FDA, TGA, EU Regulatory Audits. Siobhan is on the Audit Board of the American Society of Quality (ASQ). She is currently involved in supporting organizations in their Software Validation and Software Supplier Evaluation activities for GxP processes. Her passion is supporting organizations in their "Inspection Readiness" endeavors. She is a proud ambassador of the CAI Audit App developed to streamline Inspection Readiness activities.

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