

2024

MEMBERSHIP PRODUCT CATALOG



Conferences | Trainings | Webinars
Articles | Tools, Templates & SOPs
Membership

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About KENX

Making the life science industry a safer place through the exchange of knowledge.

We have spent the past three decades on an epic ride through the life science industry. With early beginnings in the FDA and globally-regulated environment, we understand the importance of sharing knowledge to make better, safer drugs and devices using sound scientific procedures. Working together, we can not only improve lives, but also save them.

Knowledge Exchange Network (KENX), provides webinars, one-day trainings, and hybrid conferences in the life sciences industry with a focus on GMP and Validation. Whether it is updated guidance from the FDA, new technologies, or validation strategies, it is our goal to ensure your team has the training they need to be compliant, efficient, and effective.

This product catalog gives you an idea of the high quality content you can expect from KENX across our training offerings.

Conference Session Recordings

VALIDATION (CLEANING)

Cleaning Cycle Efficiency and Environmental Footprint – How Much Can You Save?

Kenneth Pierce, Ph.D., Technical SME, Cleaning Science & Validation; Fearghal Downey, Ph.D., Vice President, Engineering & Project Delivery; and Colm O'Flynn, Senior Design Engineer, [Hyde Engineering + Consulting](#)

Integrate Risk Management into Change Control Procedures

Connie Hetzler, Global Head – Validation, [Alcon Laboratories](#)

Compliance Trends, Metrics, and the Cost of Non-quality and Validation

Karen Ginsbury, MSc, BPharma, CEO, [PCI Pharmaceutical Consulting Israel](#)

Project Management Intelligence for Delivering Pharmaceutical CQV Capital Projects

David Egan, Managing Director, [WiiPlan](#)

Guidance for Industry: Sterile Drug Products Produced By Aseptic Processing - Current Good Manufacturing Practice

Neal Schmidt, Senior Manager of Validation, [Resilience](#)

Cleaning Efficiency Reduce Cost and Environmental Impact for a Greener Future

Fred Ohsiek, [Cleaning Validation Expert](#)

Points to Consider When Considering a Rapid Microbiological Method (RMM)

Anthony Grilli, CEO, Laboratory Director, [Focus Laboratories](#)

STABILITY STATISTICS FOR NON-STATISTICIANS

Scripted vs. Unscripted Testing – Requirements Criticality Assessments

Emily Dickinson, MS, ASQ, CQA Quality Assurance Manager, [Criterium, Inc.](#)

COMPUTER SYSTEMS VALIDATION & SOFTWARE ASSURANCE UNIVERSITY

Critical Thinking on Critical Thinking

Ken Shitamoto, Executive Director, [Gilead Sciences](#)

Software Fundamentals - Learn How to Write Exemplary Test Scripts

Raul Soto, Senior Principal Engineer, [Johnson & Johnson Vision Care](#)

Scripted vs. Unscripted Testing – Requirements Criticality Assessments

Ivan Soto, Senior Director Quality Assurance Validation, [Sarepta Therapeutics](#)

Understand the Regulatory Landscape for Artificial Intelligence/Machine Learning (AI/ML) Solutions

Loganathan Kumarasamy, Head – Validation & Compliance Services, [Zifo Technologies Inc.](#)

Qualification/Validation Of Cloud Services & External Facing Applications

Pranita Barve, Validation Lead, ZS Princeton, [NJLaurent](#)
Saugrin, Associate Director Computer Software Assurance, [CAI](#)
Vinodh Rodrigues, VP, Customer Success, [Quartic.ai](#)

Conference Session Recordings

MEDICAL DEVICE UNIVERSITY

Supplier Quality Agreements

Ravi Nabar, Senior Vice President, Quality and Regulatory Compliance, Compliance Group; Steve Silverman, President, [The Silverman Group](#)

Know Your Enemy: Why Constant Evaluation of Your Process's Unique and Transient Microflora Is Necessary for Consistent Release of Sterile Devices

Anthony Grilli, CEO & Owner, [FOCUS Laboratories](#)

Vendor Audits: Best Practices for Compliance and Quality Assurance in Manufacturing

Kelly Menze, Senior Global Supplier Quality Engineer, Creation Technologies; Andrea Roether, Senior Director of Global Quality, [Creation Technologies](#)

Journal Articles



ARTICLE

TOPIC

High Stakes Change Management: Remediation Post FDA Warning Letter

Chris Gray, Principal Consultant, [CAI](#)

Change Control

Cleaning Validation Equipment Grouping

Fred Ohsiek, Senior Global Technical Manager, Life Science (Cleaning Validation), [Ecolab North America](#)

Cleaning

CIP Cleaning Cycle Development Pitfalls and Solutions

Fred Ohsiek, Senior Global Technical Manager, Life Science (Cleaning Validation), [Ecolab North America](#)

Cleaning

Cleaning Validation Program Design: Risk-Based Lifecycle Approach

Matthew Jackson, Validation Manager, [Torbay Pharmaceuticals](#)

Cleaning

How to Benefit from the Computer Software Assurance Guidance

Brian Stephens, Assistant Director, CSV, [CAI](#)

CSV/CSA

GxP Considerations for Compliance in the Cloud

Shanmugapriya Shanmugam, M.SC in Pharmaceutical Validation Technology, [TU Dublin](#)

CSV/CSA

Is Your Site Ready for Data Integrity

Jon Thompson, Principal Consultant, [CAI](#)

CSV/CSA

Biosafety Cabinet Qualification

Wamika Vohra, Commissioning & Qualification Engineer, [CAI](#)

GMP

CPV Batch Record Digitization: Challenges and Role of AI

Akash Gajbhiye, Lead Data Scientist, [Aventior Inc.](#)

GMP

Journal Articles



ARTICLE

TOPIC

Risk Management Tied Up With A Bow Tie

Valerie Mulholland, Principle Consultant, [GMP Services Ltd.](#)

GMP

Medical Product Excursions from Labeled Storage Conditions

John O'Neill, Editor, [StabilityHub.com](#)

Laboratory

QbD in Test Method Development & Validation

Ronald D. Snee, PhD, [Snee Associates, LLC](#)

Laboratory

Validation of Analytical Methods in Pharmaceutical Quality System: An Overview Focused on HPLC Methods

Breno M. Marsona, Victor Concentinoa, Allan M. Junkerta, Mariana M. Fachia, Raquel O. Vilhenaa and Roberto Pontarolo

Laboratory

An overview of experimental designs in HPLC method development and validation

Prafulla Kumar Saha, Nageswara Rao Ramiseti b, *, Teresa Cecchi c, *, Suryakanta Swaind, Chandra Sekhar Patroa, Jagadeesh Panda

Laboratory

Flowchart - Analytical Lifecycle approach

Jennifer Lewis, Ph.D., Director, [University of Rhode Island](#)

Laboratory

Validation Of Analytical Methods In A Pharmaceutical Quality System: An Overview Focused on HPLC Methods

Breno M. Marsona, Victor Concentinoa, Allan M. Junkerta, Mariana M. Fachia, Raquel O. Vilhenaa and Roberto Pontarolo

Laboratory

QbD in Test Method Development & Validation

Ronald D. Snee, PhD, Snee Associates, [LLC Snee](#)

Laboratory/
Validation

Stability Considerations for Drug-Device Combination Products-21 CFR Part 4 Update

Chris Latoz & Kim Huynh-ba

Laboratory

Journal Articles



ARTICLE

TOPIC

Drug Product Validation

Mark Moreno, Principal Consultant, **CAI**

Validation

The Big Reshuffle — Impact Assessments and System Criticality

Laura Butchart, Validation Engineer, **Alkermes Pharma Ireland**

Michael S. Egan, Lead Validation Engineer I, **Alkermes Pharma Ireland**

Donnacha J. Nagle, CQV Lead, **Jacobs Engineering** & Lecturer **TU Dublin**

Philip Jarvis, Director Integrated C&Q and Paperless Strategy, **Veqtor Solutions**

Validation

Alma O'Reilly, Validation Manager, **LEO Pharma Dublin**

Phillip W. Isom, Small Molecule Engineering Strategy and Integration Consultant

Siobhán Griffin, Project Engineer, **Astellas Ireland Co. Ltd.**

Emerging Technologies in the Pharma and Life Sciences Industry — Mixed Reality

Donnacha J. Nagle, CQV Lead, **Jacobs Engineering** & Lecturer **TU Dublin**

Validation

Role-based Talent Planning for Operational Readiness

Harry Benson, Director, Human Performance, **CAI**

Operational Readiness

Innovative considerations for efficient multi-(product) use of Protein-A columns

Jennifer Spiegler, Staff Validation Engineer at **Janssen Biologics** Leiden, the Netherlands

Biopharma

Flowchart – Analytical Lifecycle Approach

Jennifer Lewis, Ph.D., Director, **University of Rhode Island**

ICH-Q14_Takeaway-Tool-(Laboratory University)

Webinars

TITLE	TOPIC
Management in an Aseptic Environment	Biopharma
Advances and Trends in Aseptic Fill / Finish for Targeted Therapy Products	Biopharma
Quality Risk Management in ATMP Production	Biopharma
Reducing Risk in Early Cell and Gene Therapy Manufacturing in the Face of Capacity Crunch	Biopharma
<u>Digitizing your Cleaning Validation Program and Strategy</u>	Cleaning
<u>Risk-Based Cleaning Validation</u>	Cleaning
<u>A Vision of your New and Improved 2022 Cleaning Validation Process</u>	Cleaning
<u>Risk Management and Environmental Monitoring</u>	Cleaning
<u>Current Regulatory Expectations Pertaining to Environmental Monitoring</u>	Cleaning
<u>Analytical Monitoring and Preventative Maintenance of Compendial Water Purification</u>	Cleaning
<u>Pharmaceutical Water Systems</u>	Cleaning
<u>Risk-Based EM Sampling Strategy — Using the Process Risk Control Strategy to Determine EM Sampling Strategy</u>	Cleaning
<u>Annex 1 & Contamination Control Strategy</u>	Cleaning
<u>Managing Cleaning Validation at an Operational Facility</u>	Cleaning

Webinars

TITLE	TOPIC
<u>Unleashing the Power of AI: Practical Applications in Computer System Compliance</u>	CSV/CSA
<u>Preparing for FDA Inspections in a Digitalized Landscape: A CSA Perspective</u>	CSV/CSA
<u>A Tactical Approach to Implementing CSA in Your Organization</u>	CSV/CSA
<u>Benefits and Lessons Learned on the Journey to Electronic Validation</u>	CSV/CSA
<u>Understand the Applicability of FDA's Computer Software Assurance Guidance to Data Integrity</u>	CSV/CSA
<u>Introduction to Modern Testing and FDA's CSA Proposed Draft Guidance</u>	CSV/CSA
<u>The Gartner Hype Cycle & CSA</u>	CSV/CSA
<u>Compliance Advantages of Moving Towards Paperless Integrated Risk-based CSV</u>	CSV/CSA
<u>Automation in Process Validation: A Case Study</u>	CSV/CSA
<u>Project Management - Understanding Your Sphere of Influence</u>	CSV/CSA
<u>The Impact of AI on the GxP Landscape</u>	CSV/CSA
<u>What's Stopping You? Overcoming CSA Adoption Concerns</u>	CSV/CSA
<u>How to Enable Validation/Pharma 4.0 Through Digital Validation and Emerging Technologies</u>	CSV/CSA
Quality's Role in Speed to Patient	GMP
Quality System Effectiveness – Impact for the Future	GMP
Conduct a Change Control Impact Assessment	GMP
<u>Creating & Executing a Talent Plan with Job Role Clarity</u>	GMP
<u>How – and Why – to Integrate Quality Risk Management (QRM) into Commissioning & Qualification (C&Q)</u>	GMP
<u>CGMP's – Why Are We Still Getting It Wrong?</u>	GMP
Avoiding Pitfalls When Acquiring Stability Rooms	Laboratory
An Overview of Good Laboratory Practice Regulations (GLPs)	Laboratory
Building Effective Stability Protocols and Beyond	Laboratory

Webinars

TITLE

TOPIC

Operational Excellence: Does Your Site Truly Take Continuous Improvement Seriously?

Operational Readiness

Management Training and Staff Qualifications

Operational Readiness

Achieving Readiness Under Uncertainty- Improving Your Speed to Market

Operational Readiness

Post-Market Surveillance in a Digital World

Product Complaints

Creating an Effective Complaint Handling System

Product Complaints

Product Complaints – Is It Really That Bad? Finding the Right Approach

Product Complaints

Drug Shortages & Potential Solutions

Supply Chain

Creating Efficiencies in Validation by Use of Standardization Tools with Digital and Non-Digital Processes

Validation

Managing Effective Investigations During Process Validation

Validation

Facility Inspection Organization – The FIO you REALLY need!

Validation

Process Capability Analysis and Tolerance Intervals

Validation

Developing Effective Procedures

Validation

Digitizing Validation: Transforming Commissioning & Qualification

Validation

Building Workstreams, Process Flows & Defining Critical Roles - Value Stream Emphasis

Validation

Automating Digital Validation

Validation

Digital CQV and Pharma 4.0: Paving the Way for Future Success

Validation

Webinars

TITLE

TOPIC

Data-Based Process Monitoring, Control and Improvement: A Systematic Approach

Validation

Risk Management of Biopharma Operations Over Lifecycle – An ICH Q12 Overview

Validation

How to Enable Validation 4.0 through Digital Validation and Emerging Technologies

Validation

Integrated Compliance: Synergy Between GxP and Other Regulatory Requirements

Validation

Regulatory Requirements and Standards for Medical Device Validation & Verification

Validation

Annex 1 & Contamination Control Strategy

Validation

Managing Cleaning Validation at an Operational Facility

Validation

Tools, Templates & SOPs

TITLE	TOPIC
Example of a Requirement Traceability Matrix	Cleaning
<u>Cleaning Validation Risk Assessment Template</u>	Cleaning
ISPE GAMP (C) Data Integrity Maturity Model Combined Maturity Factors & Maturity Level Characterizations	CSV
<u>Sample CSV Mock Audit Checklist</u>	CSV
Risk Management Plans to Mitigate the Potential for Drug Shortages Guidance for Industry	GMP
Quality Risk Management, ICH Q9(R1)	GMP
Risk-Based Test Method Development, Validation and Life Cycle	Laboratory
Science of Temperature Impact on Degradation Rates	Laboratory
A Strategy for the Analysis of Dissolution Profiles	Laboratory
Case Study: ActivBlister™ Solutions Provide Superior Protection of a Model Drug Product Over Coldform Foil	Laboratory
Why Bottles with Desiccant Outperform Foil-Foil Blister-Packaging	Laboratory
Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products	Laboratory
Cleaning Gap Analysis Summary Example	Validation
Single Use Technology Master Plan Example	Validation
Single Use Technology Example URS Requirements	Validation
<u>ASQ Control Chart</u>	Validation
Visio-Requal Program Flowchart	Validation
Crucial Considerations in Monitoring Process Performance and Product Quality	Validation

Membership



MEMBER PLUS (\$195)

- **1 Free Full Day Virtual Training - \$995 Value**
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- **Your Choice of 5 KENX Insight Articles - \$225 Value**
- **5% Discount to Conferences - \$125+ Value**

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Membership & Training
Opportunities Contact
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