2025

MEMBERSHIP PRODUCT CATALOG

KENX
KNOWLEDGE EXCHANGE NETWORK

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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

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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

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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
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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

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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 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.	Validation
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
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A Tactical Approach to Implementing CSA in Your Organization	CSV/CSA
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Achieving Readiness Under Uncertainty- Improving Your Speed to Market	Operational Readiness
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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
ASQ Control Chart	Validation
Visio-Requal Program Flowchart	Validation
Crucial Considerations in Monitoring Process Performance and Product Quality	Validation

Membership

KENX MEMBERSHIP

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