2023

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

SESSION	TOPIC
Cleaning Validation Program Design – A Risk-based Lifecycle Approach Matthew Jackson, Head of Quality, Torbay Pharmaceuticals	Cleaning
Understand the Regulatory Landscape for Artificial Intelligence/Machine Learning (AI/ML) Solutions Loganathan Kumarasamy, Associate Director, Zifo Technologies Inc.	CSV/CSA
Software Fundamentals – Learn to Write Exemplary Test Scripts Raul Soto, MSc, CQE, Senior Principal Software Quality Engineer, Quality Assurance Operations, Johnson & Johnson Vision Care, Inc.	CSV/CSA
Critical Thinking on Critical Thinking Ken Shitamoto, Executive Director, Gilead Sciences	CSV/CSA
Develop a Compliant Test Method Validation (TMV) for Standard Operating Procedures (SOP) and Master Plan David W. Vincent MPH, Ph.D., CEO, VTI Life Sciences	Laboratory
Design an Effective Product Recall and Withdrawal Strategy Rucha Patel, Manager, Quality Assurance and Regulatory Affairs, MIMOSA Diagnostics	Product Complaints
Developing Robust Adverse Events Risk Management Processes and Execution Taylor Dieringer, Risk Management Quality Engineer, iRythmn	Product Complaints
Implement an Effective CAPA Management System to Ensure Accurate and Compliant Product Investigations Sameer Kadam, Expert Solutions Engineer, Sparta Systems, A Honeywell Company	Product Complaints
Project Management Intelligence for Delivering Pharmaceutical CQV Capital Projects David Egan, Managing Director, WiiPlan	Validation
Combined Strategies for Process Control – Merging Risk and Data Sofia Santos, Module Lead Engineer, ValGenesis	Validation
Integrate Risk Management into Change Control Procedures Connie Hetzler, Global Head Of Validation, Alcon Laboratories	Validation
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 Colm O'Flynn, Senior Design Engineer, Hyde Engineering + Consulting	Validation
Sustainability Case Study: Differentiate To Innovate! Innovation Through Supplier Diversity Luiz Barberini, Operations Manager, External Manufacturing, Bayer	Validation
Evaluate Your Validation Training Program Effectiveness Ken Shitamoto, Executive Director, Gilead Sciences	Validation
Qualification of the Pharmaceutical Supply Chain Emily Dickinson, MS, ASQ, CQA, Quality Assurance Manager, Criterium, Inc.	Validation

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
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
Emerging Technologies in the Pharma and Life Sciences Industry — Mixed Reality Donncadh J. Nagle, CQV Lead, Jacobs Engineering	CSV/CSA
GxP Considerations for Compliance in the Cloud Shanmugapriya Shanmugam, M.SC in Pharmaceutical Validation Technology, TU Dublin	CSV/CSA
CPV Batch Record Digitization: Challenges and Role of AI Akash Gajbhiye, Lead Data Scientist, Aventior, Inc. Abhijit Ray, CTO, Aventior, Inc.	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
Risk Management Tied Up With A Bow Tie Valerie Mulholland, Principle Consultant, GMP Services Ltd.	GMP
Developing a Laboratory Disaster Plan Christopher V. Latoz, Stability Manager, Hollister Incorporated	Laboratory
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

Journal Articles

ARTICLE	TOPIC
IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: INSIGHTS FROM OTHER INDUSTRIES Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), TU Dublin Professor Anne Greene, Director PRST, TU Dublin	Validation
IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: A CASE FOR RISK DECISION REVIEW POINTS (KDRPS) IN THE QUALITY RISK MANAGEMENT PROCESS Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), TU Dublin Professor Anne Greene, Director PRST, TU Dublin	Validation
IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: DETERMINING THE LEVEL OF FORMALITY Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), TU Dublin Professor Anne Greene, Director PRST, TU Dublin	Validation
IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: ADDRESSING UNCERTAINTY Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), TU Dublin Professor Anne Greene, Director PRST, TU Dublin	Validation
Role-based Talent Planning for Operational Readiness Harry Benson, Director, Human Performance, CAI	Operational Readiness

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
Cleaning Validation Program Design – A Risk-based Lifecycle Approach	Cleaning
Digitizing your Cleaning Validation Program and Strategy	Cleaning
Risk-Based Cleaning Validation	Cleaning
A Vision of your New and Improved 2022 Cleaning Validation Process	Cleaning
Risk Management and Environmental Monitoring	Cleaning
Current Regulatory Expectations Pertaining to Environmental Monitoring	Cleaning
Analytical Monitoring and Preventative Maintenance of Compendial Water Purification	Cleaning
Pharmaceutical Water Systems	Cleaning
Risk-Based EM Sampling Strategy — Using the Process Risk Control Strategy to Determine EM Sampling Strategy	Cleaning
Automating CSA Risk Management: Perspectives from BD	CSV/CSA
Automation in Process Validation: A Case Study	CSV/CSA
FDA Discusses the Implications and Opportunities of CSA Draft Guidance on 21 CFR Part 11	CSV/CSA
Benefits and Lessons Learned on the Journey to Electronic Validation	CSV/CSA
A Tactical Approach to Implementing CSA in Your Organization	CSV/CSA
Understand the Applicability of FDA's Computer Software Assurance Guidance to Data Integrity	CSV/CSA
Introduction to Modern Testing and FDA's CSA Proposed Draft Guidance	CSV/CSA
The Gartner Hype Cycle & CSA	CSV/CSA
Compliance Advantages of Moving Towards Paperless Integrated Risk-based CSV	CSV/CSA
Project Management - Understanding Your Sphere of Influence	CSV/CSA

Webinars

TITLE	TOPIC
Cybersecurity, Data Integrity & Validation – Addressing Malicious Threats to the Life Science Industry	Data Integrity
Data Integrity by Design – A PROACTIVE Approach	Data Integrity
Implement a Holistic Data Integrity Assurance Plan – From Data Creation to Retirement	Data Integrity
Quality's Role in Speed to Patient	GMP
Quality System Effectiveness – Impact for the Future	GMP
Conduct a Change Control Impact Assessment	GMP
How – and Why – to Integrate Quality Risk Management (QRM) into Commissioning & Qualification (C&Q)	GMP
CGMP's – Why Are We Still Getting It Wrong?	GMP
Fundamentals of Temperature Mapping for Controlled Environments	Laboratory
Stability Deviations & Out of Trend / Out of Specification (OOS/OOT)	Laboratory
Avoiding Pitfalls When Acquiring Stability Rooms	Laboratory
An Overview of Good Laboratory Practice Regulations (GLPs)	Laboratory
Building Effective Stability Protocols and Beyond	Laboratory
Stability Statistics in Practice – An Implementation Example	Laboratory
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
A Staged Approach to Achieving Operational Readiness	Operational Readiness
Drug Shortages & Potential Solutions	Supply Chain
State of Validation & Transformational Trends	Validation
Women Leading Validation: Moving The Needle – Quality Panel	Validation
Project Management Intelligence for Delivering Pharmaceutical CQV Capital Projects	Validation
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
Building Workstreams, Process Flows & Defining Critical Roles - Value Stream Emphasis	Validation
Digitizing Validation: Transforming Commissioning & Qualification	Validation
Data-Based Process Monitoring, Control and Improvement: A Systematic Approach	Validation

Tools, Templates & SOPs

TITLE	TOPIC
Medical Product Excursions from Labeled Storage Conditions	Cleaning
Cleaning Validation Program Design: Risk-Based Lifecycle Approach	Cleaning
CIP Cleaning Cycle Development Pitfalls and Solutions	Cleaning
Adult Learning Theory Overview	Cleaning
Cleaning Validation Risk Assessment Template	Cleaning
Air Velocity Measurements and Correlation to Smoke Studies for Aseptic Operations	Cleaning
Example Cleaning Validation and Cross Contamination Assessment	Cleaning
Example of a Requirement Traceability Matrix	Cleaning
Interrelationship Between Data Integrity and Computer Software Assurance	CSV
Sample Mock Audit Workflow	CSV
Sample CSV Mock Audit Checklist	CSV
ISPE GAMP (C) Data Integrity Maturity Model Combined Maturity Factors & Maturity Level Characterizations	Data Integrity
Risk Management Plans to Mitigate the Potential for Drug Shortages Guidance for Industry	GMP
Quality Risk Management, ICH Q9(R1) Powerpoint	GMP
Quality Risk Management, ICH Q9(R1) Guideline	GMP
Reserved Word Dictionary	Laboratory
Risk-Based Test Method Development, Validation and Life Cycle	Laboratory
Going on Feel: Monitor and Improve Process Stability to Make Customers Happy	Laboratory
Show Me the Pedigree	Laboratory
Process Variation - Enemy and Opportunity	Laboratory
Science of Humidity Impact on Degradation Rates in Solids	Laboratory
Science of Temperature Impact on Degradation Rates in Solids	Laboratory
Statistics Tables	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
Modeling of In-Use Stability for Tablets and Powders in Bottles	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
Guideline for Industry Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products	Laboratory
ASQ Control Chart	Statistics

Tools, Templates & SOPs

TITLE	TOPIC
Shifting Behaviors Evaluation and Planning Tools	Validation
Cleaning Gap Analysis Summary Example	Validation
Single Use Technology Master Plan Example	Validation
Single Use Technology Example Protocol	Validation
Single Use Technology Example URS Requirements	Validation
Understanding Human Behavior and Quality Culture In Validation and GMP Operations	Validation
Visio-Requal Program Flowchart	Validation
Adjust, Adapt: An Enhanced Version of Quality by Design	Validation
Crucial Considerations in Monitoring Process Performance and Product Quality	Validation
EM Trend Evaluation Tool (Trend Reporting Procedure Tips)	Validation
QRM Based Validation Program Assessment	Validation

Membership

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- **1 Free Full Day Virtual Training – $995 Value**
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