

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

## CSV/CSA

### Going Paperless Case Study: Understand the Value and ROI of Digitization Platforms

Geetanjali Abbi, Director, Digital Quality Assurance, **Alkermes**

### Superintelligence Governance: Advancements vs. Ethics – How to Safely Use Advanced Technologies and Avoid a Catastrophe

Steve Thompson, Senior Director Product Marketing, **ValGenesis**

### Cloud Computing, Cybersecurity and Data Integrity

Joanne Goldberg, Senior Principal Quality Systems Specialist, Global IT Quality & Compliance, **Medtronic**

### Software Fundamentals – Writing Test Scripts to Support CSA

Vignesh Srinivas, Service Delivery Manager, **Zifo RnD Solutions**

### (Panel) CSA – The Foundation for Digital Transformation

David DeLuca, Director, Engineering & Validation, **Compliance Group**  
Francisco (Cisco) Vicenty, Case for Quality Program Manager, **U.S. FDA**  
Bill Lee, Director of Information Services, **DAP Health**

### Computer Software Assurance (CSA) Implementation with Focus on Industry Case Study

Linda Lagrou, Senior Manager IT Quality, **Abbott Laboratories**  
Gaurav Walia, Senior Global Director and Sr. Associate Partner, **PQE Group**

### Lean Validation Case Study – Build a Modern, Risk-based CSV Program Aligning with CSA and Part 11

Calvin Kim, Head of Quality Systems and Validation, **Samsung Biologics**  
Suju Hwang, Senior Manager, Digital Quality & Compliance, **Samsung Biologics**

### Understanding the Implications and Opportunities of CSA Draft Guidance on 21 CFR Part 11

Stephen Cook, Sr. Director – Governance & Operational Excellence, **GSK**  
Louie Rayal, Vice President, Governance, Risk and Compliance, **GSK**  
Marc Koetter, Senior Manager Computer System Validation & IT Governance, **Fresenius Medical Care**  
Cisco Vicenty, Case for Quality Program Manager, **U.S. FDA**

# Conference Session Recordings

## CSV/CSA

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

Loganathan Kumarasamy

Head of US Compliance & Validation, **Zifo RnD Solutions**

### Software Fundamentals – Learn to Write Exemplary Test Scripts

Raul Soto, Senior Principal Quality Engineer, **Johnson&Johnson**

### Critical Thinking on Critical Thinking

Ken Shitamoto, MS, Sr. Director IT, **Gilead Sciences**

## GMP

### Establishing CAPA to Support Your Investigation And Promote Continuous Improvement

LeAnna Pearson, Associate Director Quality Compliance & Regulatory, **CAI**

### Data Integrity Program Management and Process Mapping

Kim Huynh-Ba, MS, PMP, FAAPS, Managing Director; Adjunct Faculty,

**Pharmalytik Consulting**; RAQA, **Temple University**

### Removing Bias from Quality Risk Management in Pharma and Biopharma Operations

Dr. Iris Ziegler, Director Pharmaceutical Sciences and QbD,

**Corden Pharma International**

### Moving to Objective, Data-Driven Decisions – The Who, What, When, Where, Why, and How of Statistics

Tara Scherder, Partner, **Synolo Stats, LLC**

# Conference Session Recordings

## **GMP (product complaints & Adverse Events)**

### Implement an Effective CAPA Management System to Ensure Accurate and Compliant Product Investigations

Sameer Kadam, Expert Solutions Engineer,  
**Sparta Systems, A Honeywell Company**

### Developing Robust Adverse Events Risk Management Processes and Execution

Taylor Dieringer, Risk Management Quality Engineer, **iRythmn**

### Design an Effective Product Recall and Withdrawal Strategy

Rucha Patel, Manager, Quality Assurance and Regulatory Affairs,  
**MIMOSA Diagnostics**

## **Cleaning**

### Digital Cleaning Validation Lifecycle

Rui Almedia, Director, Product Life Cycle Management Services, **ValGenesis. Inc.**

### Overcome Top Challenges in Cleanroom Management, Environmental Monitoring and Environmental Cleaning – Insight from the Front Line

David W. Vincent, MPH, Ph.D., Chief Scientific Officer, **VTI**

### Cleaning Validation Program Design – A Risk-based Lifecycle Approach

Matthew Jackson, Head of Quality, **Torbay Pharmaceuticals**

## **Lab**

### Stability Chambers Selection, Validation, and Calibration

John O'Neill, Stability Information Specialist, **StabilityHub**

### Understanding FDA's Revised OOS Investigation Guidance

Emily Purchase, Project Manager, Quality, Compliance & Regulatory, **CAI**

### 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**

# Conference Session Recordings

## VALIDATION

### Develop a Strategy to Transition to Paperless Validation C&Q

Philip Jarvis, Director, Integrated C&Q and Paperless Strategy, **Veqtor** & Mark Geldard, Director Sales EMEA, **Kneat**

### Navigate the Maze of Validation Regulatory Guidance – A Systematic Approach to Knowledge Management

Connie Hetzler, Global Head – Validation, **Alcon Laboratories**

### “Process Validation, What’s missing? – The Role of Knowledge in Talent Development Through the Use of Emerging Technologies and Digitalization

Donncadh Nagle, CQV Lead & Lecturer, **Jacobs Engineering & TU Dublin**

### Sustainability Case Study: Differentiate To Innovate! Innovation Through Supplier Diversity

Luiz Barberini, Operations Manager, External Manufacturing, **Bayer**

### Evaluate Your Validation Training Program Effectiveness

Ken Shitamoto, Executive Director, **Gilead Sciences**

### Combined Strategies for Process Control – Merging Risk and Data

Sofia Santos, Module Lead Engineer, **ValGenesis**

### Project Management Intelligence for Delivering Pharmaceutical CQV Capital Projects

David Egan, Managing Director, **WiiPlan**

### Integrate Risk Management into Change Control Procedures

Connie Hetzler, Global Head Of Validation, **Alcon Laboratories**

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

Kenneth Pierce, Colm O’Flynn and Fearghal Downey

# Conference Session Recordings

## VALIDATION (CLEANING)

Steps to a Successful Cleaning Cycle Development and Validation to Support Lifecycle Approach

David Vincent, Ph.D, Chief Scientific Officer, **VTI Life Sciences**

A Risk Based Approach to Developing and Maintaining an Environmental Monitoring Program

Anthony Grilli, CEO and Owner, **FOCUS Laboratories**

Establishing Critical Process Parameters, Acceptance Criteria and HealthLimits

Cindy Duhigg, Global Validation Steward, **Alcon**



# Journal Articles



ARTICLE	TOPIC
<u>Developing a Laboratory Disaster Plan</u> Christopher V. Latoz, Stability Manager, <a href="#">Hollister Incorporated</a>	Lab
<u>IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: ADDRESSING UNCERTAINTY</u> Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), <a href="#">Technological University Dublin</a> Professor Anne Greene, Director PRST, <a href="#">Technological University Dublin</a>	Validation
<u>IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: DETERMINING THE LEVEL OF FORMALITY</u> Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), <a href="#">Technological University Dublin</a> Professor Anne Greene, Director PRST, <a href="#">Technological University Dublin</a>	Validation
<u>IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: A CASE FOR RISK DECISION REVIEW POINTS (KDRPS) IN THE QUALITY RISK MANAGEMENT PROCESS</u> Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), <a href="#">Technological University Dublin</a> Professor Anne Greene, Director PRST, <a href="#">Technological University Dublin</a>	Validation
<u>IMPROVING RISK BASED DECISION MAKING EFFECTIVENESS: INSIGHTS FROM OTHER INDUSTRIES</u> Valerie Mulholland, Pharmaceutical Regulatory Science Team (PRST), <a href="#">Technological University Dublin</a> Professor Anne Greene, Director PRST, <a href="#">Technological University Dublin</a>	Validation
<u>Emerging Technologies in the Pharma and Life Sciences Industry — Mixed Reality</u> Donncadh Nagle, Jacobs Engineering & TU Dublin Researcher Michael Egan, Lead Validation Engineer, Alkermes Pharma Ireland	CSV/CSA
<u>High Stakes Change Management: Remediation Post FDA Warning Letter</u> Chris Gray, <a href="#">CAI</a>	GMP

# Journal Articles



ARTICLE	TOPIC
<u>Cleaning Validation Equipment Grouping</u> Fred Ohsiek, <a href="#">Ecolab Life Sciences</a>	Validation (Cleaning)
<u>GxP Considerations for Compliance in the Cloud</u> Shanmugapriya Shanmugam, M.SC in Pharmaceutical Validation Technology, <a href="#">TU Dublin</a> Valerie Mulholland, PhD Researcher PRST, TU Dublin & Snr Consultant at <a href="#">GMP Services, Ireland</a>	GMP
<u>CPV Batch Record Digitization: Challenges and Role of AI</u> Akash Gajbhiye (Lead Data Scientist), Aventior, Inc. Abhijit Ray (CTO), <a href="#">Aventior, Inc.</a>	GMP
<u>Biosafety Cabinet Qualification</u> Wamika Vohra, <a href="#">CQV Engineer</a>	GMP
<u>Developing a Laboratory Disaster Plan</u> Christopher V. Latoz, Stability Manager, <a href="#">Hollister Incorporated</a>	Lab
<u>Drug Product Validation</u> Mark Moreno, Principal Consultant, <a href="#">CAI</a>	Validation
<u>Risk Management Tied Up With A Bow Tie</u> Valerie Mulholland, GMP Services & PhD Researcher, <a href="#">TUDublin</a> Shada Warreth NIBRT & PhD Researcher, <a href="#">TUDublin</a>	GMP
<u>The Big Reshuffle — Impact Assessments and System Criticality</u> _Laura Butchart, with Michael Egan, Donncadh Nagle, Philip Jarvis, Alma O'Reilly, Phillip W. Isom, and Siobhán Griffin	Validation
<u>Is Your Site Ready For Data Integrity?</u> Jonathon Thompson, Principal Consultant, <a href="#">CAI</a>	CSV/CSA
<u>Role-based Talent Planning for Operational Readiness</u> Harry Benson, <a href="#">CAI</a>	GMP

# Webinars

## TITLE

## TOPIC

### Cleaning Validation Demystified: A Comprehensive Guide and Case Studies

John Wrenn, Country Manager, Australia & New Zealand , **CAI**

Cleaning

### Navigating the Path of Annex 1 Compliance: A Journey towards Regulatory Adherence and Batch Release

Connie Leech, Global Director Quality, Compliance & Regulatory Affairs , **CAI**

GMP

### Digital Cleaning Validation Lifecycle

Rui Almeida, Director, Product Life Cycle Management Services, **ValGenesis. Inc.**

Validation  
(Cleaning)

### A Sustainable Model For Production System Excellence

Woon Lit Ong, Senior Director, APAC & AfME Operational Excellence, **Pfizer Global Supply** and Rajnish Narula, Director, Business Excellence, Tuas, **Pfizer Global Supply**

GMP

### CSV – Effective System Level Risk Assessment

Rohit Tyagi, President, **SAGAX Team**

CSV

### Shared Responsibility Model and Use Cases for Decentralized Technology in Life Sciences

Dori Gonzalez-Acevedo, Co-Founder and CEO, ProcellaRX & Tanya Sharma, Co-Founder, Assurea

GMP

### Customize Validation & GxP Knowledge on Demand – Using ChaptGPT in Enterprise Deployments

Nick Armstrong, Sr. Director, Digital Enablement, **CAI**

CSV/CSA

### Using and Qualifying ChatGPT – Compliantly Harness the Power of AI-Powered Platforms in Validation Processes

Steve Thompson, Sr. Director Product Marketing, **ValGenesis, Inc.**

CSV/CSA

### Best Practice Approach to Operational Readiness – Creating a Competitive Advantage through your Workforce

Harry Benson, Global Director, **Human Performance**

GMP

### Cleaning Contamination Control Program

David W. Vincent, MPH, Ph.D., CEO and Chief Scientific Officer, **VTI Life Sciences**

Cleaning

### Data-driven Risk Management: How to Minimize Subjectivity

Pedro Ferreira, Head of Validation and Quality and Risk Management Services, **ValGenesis®**

GMP

# Webinars

## TITLE

## TOPIC

Selection of Analytical and Sampling Methods for Cleaning Validation Based on Analyte Characteristics

Michael Lund, Program Manager, [Hyde Analytical Laboratories](#)

Cleaning

Select Fundamentals of Temperature Mapping for Controlled Environments

Fundamentals of Temperature Mapping for Controlled Environments

Hector Felix, Senior Validation Engineer at [VTI Life Sciences](#)

Lab

Automating CSA Risk Management: Perspectives from BD

Frank Meledandri Sr., Associate Director, Quality Strategy Quality Management, [BD](#)

Roy Devine, GPO Computer System Validation, [BD](#)

CSV/CSA

Stability Deviations & Out of Trend / Out of Specification (OOS/OOT)

Gary Ritchie, Consultant, [CAI](#)

Lab

Building Effective Stability Protocols and Beyond

John O'Neill, Stability information specialist, [StabilityHub](#)

Lab

An Overview of Good Laboratory Practice Regulations (GLPs)

Stacy Wilson, MS- QA/RA [Temple Adjunct Professor](#)

Lab

Avoiding Pitfalls When Acquiring Stability Rooms

Stefan Cazzonelli, Sales and Marketing Manager, [Parameter](#)

Lab

Conduct a Change Control Impact Assessment

Joscelyn Bowersock, Customer Success Manager, [L7 Informatics](#)

GMP

Quality System Effectiveness – Impact for the Future

Cheryl Bondurant, Principal Consultant, [CAI](#)

GMP

Quality's Role in Speed to Patient

David Shenberger, Vice President, Consulting Services, [CAI](#)

GMP

Reducing Risk in Early Cell and Gene Therapy Manufacturing in the Face of Capacity Crunch

Ravi Samavedam, Chief Innovation Officer (CINO), [Azzur Group](#)

GMP

# Webinars

## TITLE

## TOPIC

### Quality Risk Management in ATMP Production

Joseph Micsko, Global Director, Process Manufacturing Technology (PMT), **CAI**

Stephen Sanders, Senior Engineer/Project Manager, **CAI**

GMP

### Advances and Trends in Aseptic Fill / Finish for Targeted Therapy Products

Keith Dodson, Vice President of Business Development, **Automated Systems of Tacoma (AST)**

### Management in an Aseptic Environment

David Kendrick, Senior Training Specialist, **Azzur Training Center**

GMP

### State of Validation & Transformational Trends

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

Validation

### Women Leading Validation: Moving The Needle – Quality Panel

Dori Gonzalez-Acevedo – CEO, **ProcellaRX**;

Denise Dajles – Senior VP of R&D, Regulatory and Quality

at **Sientra**; Catherine Hall – VP of Clinical Innovation and Quality at

**EndPoint Clinical**; Elena Mack – VP, Global Manufacturing Quality,

**Olympus Corporation**; Dinamarie Stefani – Head of Quality at

**Verily**; Katie Terry – President & Founder of **KT Consulting**;

Ann Vu – Senior VP of Quality, Regulatory and Clinical at **ZimVie**

Validation

### Select Automation in Process Validation: A Case Study

### Automation in Process Validation: A Case Study

Mr. Vipul Doshi, Chief Quality & Compliance Officer at

**Zydus Lifesciences Limited**

CSV/CSA

### FDA Discusses the Implications and Opportunities of CSA Draft

### Guidance on 21 CFR Part 11

Joanne Goldberg, Senior Principal Quality Systems Specialist,

Global IT Quality & Compliance, **Medtronic**; Khaled Moussally, EVP

Clients & Regulatory Relations, **Compliance Group**

Francisco Vicenty, Program Manager, Case for Quality, **U.S. FDA**

Daniel Walter, Policy Analyst, **U.S. FDA**

CSV/CSA

### Product Complaints – Is It Really That Bad?

### Finding The Right Approach

Yarismar Fernández-Alicea, Quality Assurance Specialist,

**Amgen PR**

GMP  
(product  
complaints  
& Adverse  
Events)

### Creating an Effective Complaint Handling System

Kimberly Wallbank, Principal Consultant, **Quality Systems Services, LLC**

GMP  
(product  
complaints  
& Adverse  
Events)

# Tools, Templates & SOPs

TITLE	TOPIC
<u>GAMP5 Checklist</u> Mehron Mirian, Director of Automation Services, <b>VTI Life Sciences</b>	CSV/CSA
<u>Data Integrity Assessment</u> Jacob Hodovsky Computer Systems Validation and Project Manager, <b>CAI</b>	CSV/CSA
<u>Data Integrity Maturity Factor Assessment</u> Jacob Hodovsky Computer Systems Validation and Project Manager, <b>CAI</b>	CSV/CSA
<u>Validation SOP Writing</u> Nathan Pofahl, Associate Director of GxP Learning, <b>Ultragenyx</b>	Validation
<u>Effective Training In CSV and CSA</u> Danielle Duran, Senior Manager, Training And Development, Site Bus, <b>BioMarin Pharmaceutical</b> ; Kosal Keo, Founder and Chief Product Officer, <b>Sware, Inc.</b>	CSV/CSA
<u>Applying and Mastering Stability Statistics</u>	Lab
<u>Data Integrity Process Mapping</u> Nanda Subbarao, Ph.D., Senior Consultant, <b>Biologics Consulting</b>	Lab
<u>QC Lab Data Integrity Programs</u> Nanda Subbarao, Ph.D., Senior Consultant, <b>Biologics Consulting</b>	Lab
<u>Evaluation of Stability Data</u> Laura Pack, Senior Director, QC & Statistics, <b>Rezolute</b>	Lab
<u>Initiating, Performing and Documenting a Complaint Investigation</u> Yarismar Fernández-Alicea, EIT, MS Quality Assurance Specialist, <b>Amgen PR</b>	GMP (product complaints & Adverse Events)

# Tools, Templates & SOPs

TITLE	TOPIC
<u>Post-Market Surveillance SOP Template</u> Rucha Patel, Manager, Quality Assurance and Regulatory Affairs, <b>MIMOSA Diagnostics</b>	GMP (product complaints & Adverse Events)
<u>Evaluation of stability data per ich q1e</u> Laura Pack, Senior Director, QC & Statistics, <b>Rezolute</b>	Lab
<u>Digital Validation Handbook</u> <b>Kneat</b>	GMP
<u>FDA Multi User Spreadsheet internal guidelines</u> Dennis Cantellops, Evelyn Bonnin and Anne Reid, <b>Southeastern Regional Laboratory</b>	CSV/CSA
<u>FDA Single user Spreadsheet Internal guidelines</u> Dennis Cantellops, <b>Southeastern Regional Laboratory</b>	CSV/CSA
<u>Spreadsheet Validation 101</u> Raul Soto, MSC , <b>CQE</b>	CSV/CSA
<u>Decommissioning List of Considerations</u> Curt Gendler, Senior Quality Engineer, <b>AstraZeneca Biologics</b>	CSV/CSA
<u>CSV/CSA Checklist</u>	CSV/CSA
<u>ISPE GAMP® Data Integrity Maturity Model</u> <b>Azzur Group</b>	CSV/CSA
<u>CMMI Institute Data Management Maturity Model</u> <b>Azzur Group</b>	CSV/CSA
<u>Data Integrity &amp; CSA Aligned Framework Model</u> <b>Azzur Group</b>	CSV/CSA
<u>Incorporating Effective SOP's In Training Programs - it's not just for the what</u> Nathan Pofahl, Associate Director of GxP Learning, <b>Ultragenyx</b>	CSV/CSA

# Tools, Templates & SOPs

TITLE	TOPIC
<u>Medical Product Excursions from Labeled Storage Conditions</u> John O'Neill, Editor, <a href="#">StabilityHub.com</a>	Cleaning
<u>Cleaning Validation Program Design: Risk-Based Lifecycle Approach</u> Matthew Jackson, Validation Manager, <a href="#">Torbay Pharmaceuticals</a>	Cleaning
<u>CIP Cleaning Cycle Development Pitfalls and Solutions</u> Fred Ohsiek, Senior Global Technical Manager, Life Science (Cleaning Validation) for <a href="#">Ecolab in North America</a>	Cleaning
<u>Adult Learning Theory Overview</u> Shelley Preslar, President and COO, <a href="#">Azzur Training Center</a>	Cleaning
<u>Cleaning Validation Risk Assessment Template</u> Chip Bennett, Associate Director, Global C&Q, SME, CQV Program Development, QRM, <a href="#">CAI</a>	Cleaning
<u>Air Velocity Measurements and Correlation to Smoke Studies for Aseptic Operations</u> Morgen Polen, Cleanroom, Particulate and Airflow Expert, <a href="#">Microrite, Inc.</a>	Cleaning
<u>Example Cleaning Validation and Cross Contamination Assessment</u> Matthew Jackson, Head of Quality, <a href="#">Torbay Pharmaceuticals</a>	Cleaning
<u>Interrelationship Between Data Integrity and Computer Software Assurance</u> Scott Cady, Senior IT Quality & Compliance Consultant, <a href="#">Azzur Group</a>	CSV
<u>Sample Mock Audit Workflow</u> Leslie Lighton-Humphreys, ISO IT CSV & QA Manager, <a href="#">AmerisourceBergen</a>	CSV
<u>Sample CSV Mock Audit Checklist</u> Leslie Lighton-Humphreys, ISO IT CSV & QA Manager, <a href="#">AmerisourceBergen</a>	CSV



# Tools, Templates & SOPs

TITLE	TOPIC
<u>ISPE GAMP (C) Data Integrity Maturity Model Combined Maturity Factors &amp; Maturity Level Characterizations</u> Azzur Group	GMP
<u>Risk Management Plans to Mitigate the Potential for Drug Shortages Guidance for Industry</u> Karen Ginsbury, MSc, BPharma, CEO, PCI Pharmaceutical Consulting Israel	GMP
<u>Quality Risk Management, ICH Q9(R1) Powerpoint</u> Karen Ginsbury, MSc, BPharma, CEO, PCI Pharmaceutical Consulting Israel	GMP
<u>Quality Risk Management, ICH Q9(R1) Guideline</u> Karen Ginsbury, MSc, BPharma, CEO, PCI Pharmaceutical Consulting Israel	GMP
<u>Reserved Word Dictionary</u> Laura Pack, Senior Director, QC & Statistics, Rezolute	Lab
<u>Risk-Based Test Method Development, Validation and Life Cycle</u> Ronald Snee, Founder and President, Snee Associates, LLC	Lab
<u>Going on Feel: Monitor and Improve Process Stability to Make Customers Happy</u> Ronald Snee, Founder and President, Snee Associates, LLC	Lab
<u>Show Me the Pedigree</u> Ronald Snee, Founder and President, Snee Associates, LLC	Lab
<u>Process Variation - Enemy and Opportunity</u> Ronald Snee, Founder and President, Snee Associates, LLC	Lab
<u>Science of Humidity Impact on Degradation Rates in Solids</u> Ronald Snee, Founder and President, Snee Associates, LLC	Lab
<u>Science of Temperature Impact on Degradation Rates in Solids</u> Kristina Flavier, Senior Scientist, FreeThink Technologies	Lab

# Tools, Templates & SOPs

TITLE	TOPIC
<u>Statistics Tables</u> Steve Kuwahara	Lab
<u>A Strategy for the Analysis of Dissolution Profiles</u> Ronald Snee, Founder and President, <b>Snee Associates, LLC</b>	Lab
<u>Case Study: ActivBlister TM Solutions Provide Superior Protection of a Model Drug Product Over Coldform Foil</u> Patrick Kelleher	Lab
<u>Modeling of In-Use Stability for Tablets and Powders in Bottles</u> Patrick Kelleher	Lab
<u>Why Bottles with Desiccant Outperform Foil-Foil Blister-Packaging</u> Patrick Kelleher	Lab
<u>Guidance for Industry Q1A(R2) Stability Testing of New Drug Substances and Products</u> Steve Kuwahara	Lab
<u>Guideline for Industry Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products</u> Steve Kuwahara	Lab
<u>ASQ Control Chart</u> <b>ASQ</b>	Statistics
<u>Shifting Behaviors Evaluation and Planning Tools</u> Danielle Duran, Senior Manager, Training And Development, Site Bus, <b>BioMarin Pharmaceutical</b>	Validation
<u>Cleaning Gap Analysis Summary Example</u>	Validation
<u>Single Use Technology Master Plan Example</u> David W. Vincent, MPH, Ph.D., Chief Scientific Officer, <b>VTI</b>	Validation

# Tools, Templates & SOPs

TITLE	TOPIC
<u>Single Use Technology Example Protocol</u> David W. Vincent, MPH, Ph.D., Chief Scientific Officer, <b>VTI</b>	Validation
<u>Single Use Technology Example URS Requirements</u> David W. Vincent, MPH, Ph.D., Chief Scientific Officer, <b>VTI</b>	Validation
<u>Understanding Human Behavior and Quality Culture In Validation and GMP Operations</u> Danielle Duran, Senior Manager, Training And Development, Site Bus, <b>BioMarin Pharmaceutical</b>	Validation
<u>Visio-Requal Program Flowchart</u> Aaron Roth	Validation
<u>Adjust, Adapt: An Enhanced Version of Quality by Design</u> Ronald Snee, Founder and President, <b>Snee Associates, LLC</b>	Validation
<u>Crucial Considerations in Monitoring Process Performance and Product Quality</u> Ronald Snee, Founder and President, <b>Snee Associates, LLC</b>	Validation
<u>EM Trend Evaluation Tool (Trend Reporting Procedure Tips)</u> Elizabeth Brockson, Associate Director, Global Quality Control, <b>CAI</b>	Validation
<u>QRM Based Validation Program Assessment</u>	Validation

# One-Day Virtual Trainings

Attend One Free with your Member Plus Membership

**TITLE**

**TOPIC**

Stability Statistics in Practice – An Implementation Example  
Emily Dickinson, MS, ASQ, CQA, Quality Assurance Manager,  
Criterium, Inc.

Lab

# Membership



## MEMBER PLUS (\$195)

- **1 Free Full Day Virtual Training - \$995 Value**
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- **SOPs, Tools, and Templates - \$795+ Value**
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- **Your Choice of 5 Complimentary Webinars - \$225 Value**
- **Your Choice of 5 KENX Insight Articles - \$225 Value**
- **5% Discount to Conferences - \$125+ Value**

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[info@kenx.org](mailto:info@kenx.org)**