KENX
KNOWLEDGE EXCHANGE NETWORK

Attend Virtually or In-Person

LABORATORY UNIVERSITY

ANALYTICAL PROCEDURES & METHODS VALIDATION

LAB DATA INTEGRITY GOVERNANCE

STABILITY TESTING & PROGRAM MANAGEMENT

POWERED BY Pharmaceutical Stability Discussion Group

June 22-24, 2021 | The Dana Mission Bay | San Diego, CA

PLATINUM SPONSOR

AZZUR GROUP

GOLD SPONSORS

CAI

PARAMETER GENERATION & CONTROL

NOVATEK INTERNATIONAL

SILVER SPONSORS

H&A Scientific
Better Software. Better Science.

VTI LIFE SCIENCES

VALGENESIS

ZIFO RnD SOLUTIONS

ACADEMIC SPONSORS

TEMPLE UNIVERSITY
School of Pharmacy

School of Pharmacy
TEMPLE UNIVERSITY
Regulatory Affairs and Quality Assurance Graduate Program of Temple University School of Pharmacy

Pharmaceutical Stability Discussion Group

STABILITYHUB

Register before Early Bird (Date) and SAVE $300
TEAM DISCOUNT: Register Three & Receive the Fourth FREE!
Register Online | www.kenx.org/conferences

DAY ONE	June 22, 2021
11:00 PDT	Exhibitor Showroom and Virtual Platform Open House
1:00 PDT	Chairman's Opening Remarks
	ANALYTICAL & DATA INTEGRITY SESSIONS
1:15 - 2:00 PDT	**Analytical Procedure Lifecycle Management / Validation, Verification, and Transfer of Analytical Procedures** Horacio N. Pappa, CQE, Ph.D., Director – General Chapters, Global Science and Standards Division, **U.S. Pharmacopeia**
2:00 - 2:45 PDT	**Prepare and Handle FDA Inspections – Ensure Your GMP Lab is Inspection Ready** Kim Huynh-Ba, Managing Director, **Pharmalytik LLC**; Adjunct Professor, Regulatory Compliance, **Illinois Institute of Technology (IIT)**
	STABILITY SESSIONS
1:15 - 1:45 PDT	**Learn about PSDG and Stability News from Other Meetings** John O'Neill, PSDG Facilitator, Editor, **StabilityHub.com**
1:45 - 2:15 PDT	**Here's the 411 on Stability Program 483s and Warning Letters!** Chris Latoz, Stability Manager, **Hollister Incorporated**
2:15 - 2:45 PDT	**Identify Data Integrity Gaps in Your Stability Workflow** Sheba Zaman, Head of Product Specialists &Training Services, **NOVATEK INTERNATIONAL**
3:00 - 3:30 PDT	Exhibitor Showroom and Think Tank Sessions Ensure Your GMP Lab is Inspection Ready Reduce Study Risk through Effective Monitoring Systems
	ANALYTICAL & DATA INTEGRITY SESSIONS
3:45 - 4:30 PDT	**Data Integrity in the GMP Lab - Overcome Top 5 Challenges** Robert J. Wherry, Principal, **White Birch Consulting Services**
4:30 - 5:15 PDT	**Creating a Quality Culture** Matthew LaPierre, Data Integrity Lead Consultant, **Jackson Scott Consulting**
	STABILITY SESSIONS
3:45 - 4:30 PDT	**Advanced Modeling from Accelerated Stability Testing (ASAP) to Determine Drug Product Shelf-life - Fundamentals and Case Studies** Kristina Flavier, Ph.D., Senior Scientist, Physical Sciences Group, **FreeThink Technologies**
4:30 - 5:15 PDT	**Explore Time Window Expectations for Stability Function Steps** Kim Huynh-Ba, Managing Director, **Pharmalytik LLC**; Adjunct Professor, Regulatory Compliance, **Illinois Institute of Technology (IIT)**
5:30 PDT	**Game Night - Trivia Welcome Reception**
DAY TWO	**June 23, 2021**
7:00 PDT	Exhibitor Showroom Opens
7:15 - 8:00 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Risk-based Development and Validation of Test Methods** John Long, Ph.D., Director, Bioanalytical Method Development and Validation, **Aldevron**
Data Integrity	**Learn How to Graph and Analyze Data for Decision Making** Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**
Stability	**Handle OOS, OOT & OOE with Confidence and Expertise** Emily Trubee, Quality Control Manger, Stability, **Glenmark Pharmaceuticals**
8:15–9:45 PDT	Select Between Knowledge Exchange Sessions

Analytical	**Establish Test Parameters, Conditions and Acceptance Criteria for Analytical Measurements** Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**
Data Integrity	**Rethinking Your Approach to Technology** Matthew LaPierre, Data Integrity Lead Consultant, **Jackson Scott Consulting**
Stability	**Breakout Sessions - Stability Chambers, Intenational Regs, CRO's** Stefan Cazzonelli, Sales and Marketing Manager, **Parameter** Loren "Lonnie" Stuckert, Associate Researcher, **Procter & Gamble** Bette Monnot-Chase, Director, Analytical Sciences, **Marinus Pharma**
10:00 -10:30 PDT	Exhibitor Showroom and Think Tank Sessions Method Variation – Handling Measurement Uncertainty Stability Budgeting – Account for Shelf Life Expenses
10:45 – 12:15 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Implementation of Lifecycle Management of Analytical Procedures** Bette Monnot-Chase, Director, Analytical Sciences, **Marinus Pharma**
Data Integrity	**Identify Root Cause and Implement Corrective Action** Robert J. Wherry, Principal, **White Birch Consulting Services**
Stability	**Breakout Sessions: LIMS, Stats & Reports, Sample Handling** Tina Dean, Technical Manager, **Eli Lilly and Company** Lina Patel, Director, Quality Control, **Catalent Cell and Gene Therapy**
12:30 - 1:15 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Establish System Suitability and Monitor Method Performance** Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**
Data Integrity	**Data Quality Considerations that Survive the Method Lifecycle** Kevin Walsh, Senior Director, **Azzur Labs**
Stability	**Conducting Shipping Studies to Support Product Distribution** Emily Trubee, Quality Control Manger, Stability, **Glenmark Pharmaceuticals**
1:30 – 2:00 PDT	Exhibitor Showroom and Think Tank Sessions Data Integrity Process Mapping Learn the Latest in the World of Photostability
2:15 - 3:45 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Validation, Verification, and Transfer of Analytical Methods** John Wass, Director, MSAT and Validation, **Xellia** *(Invited)*
Data Integrity	**Conquer Data Integrity by Minimizing Human Error** Steve Thompson, Director Industry Solutions, **ValGenesis**
Stability	**Establish Stability Protocols and Review Boards** John O'Neill, Editor, **StabilityHub.com**
Stability	**Reference Standard Qualification – Ensure Integrity in Stability Studies** John O'Neill, Editor, **StabilityHub.com**
4:00 - 4:30 PDT	Exhibitor Showroom and Think Tank Sessions Apply QbD Principles to Analytical Procedures Common Challenges in Extractables and Leachables Studies
4:45 - 6:15 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Control *N*-Nitrosamine Impurities in Pharmaceutical Products** Geoff Carr, Ph.D., Director, Analytical Development, **Patheon, part of Thermo Fisher Scientific**
Data Integrity	**Use Process Mapping to Identify Gaps** Steve Thompson, Director Industry Solutions, **ValGenesis**

Stability	**Shelf Life Determination of Drug Products using ANCOVA and Regression Analysis** Raul Soto, Senior Principal Engineer, **Johnson & Johnson Vision Care**
6:15 PDT	Close of Day Two
DAY THREE	**June 24, 2021**
7:00 PDT	Exhibitor Showroom Opens
7:15 - 8:00 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Regression Analysis for Instrument Calibration Curves** Raul Soto, Senior Principal Engineer, **Johnson & Johnson Vision Care**
Data Integrity	**Audit Trail Review – Implement Routine Monitoring** Loganathan Kumarasamy, Head – US Validation & Compliance Services, **Zifo RnD Solutions**
Stability	**Tour a Facility, Explore Stability Landscape & Test Your Knowledge** John O'Neill, PSDG Facilitator, Editor, **StabilityHub.com**
8:15 - 9:45 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Continued Method Performance Verification - An Effective Approach** Ronald D. Snee, Ph.D., Founder and President, **Snee Associates, LLC**
Data Integrity	**Manage Data Integrity Inspections and Respond to Findings** Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**
Stability	**Breakout Topics: Wider View of Chambers, International Regs, CRO's** Stefan Cazzonelli, Sales and Marketing Manager, **Parameter** Loren "Lonnie" Stuckert, Associate Researcher, **Procter & Gamble** Bette Monnot-Chase, Director, Analytical Sciences, **Marinus Pharma**
10:00 - 10:30 PDT	Exhibitor Showroom and Think Tank Sessions Understand the Human Impact in the QC Laboratory Challenge Your Inventory Systems for Maximum Benefit and Minimal Issues
10:45 - 12:15 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Investigate OOS/OOT in Analytical Testing** Erin Thane, Vice President, **Azzur Labs**
Data Integrity	**Selection and Qualification Laboratory Instrumentation – Implement a Risk Assessment and Data Integrity Strategy** David W. Vincent, MPH, Ph.D, CEO, **VTI Life Sciences**
Stability	**Breakout Topics Wider View LIMS, Stats & Reports, Sample Handling** Tina Dean, Technical Manager, **Eli Lilly and Company** Lina Patel, Director, Quality Control, **Catalent Cell and Gene Therapy**
12:30 - 1:15 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Documentation and Revalidation Strategies after Method Changes** John Long, Ph.D., Director, Bioanalytical Method Development and Validation, **Aldevron**
Data Integrity	**Develop a Training Program for the QC Scientist** Lina Patel, Director, Quality Control, **Catalent Cell and Gene Therapy**
Stability	**Conduct Drug Excipient Compatibility Studies – A Case Study** Geoff Carr, Ph.D., Director, Analytical Development, **Patheon, part of Thermo Fisher Scientific**
1:30 - 2:00 PDT	Exhibitor Showroom and Think Tank Sessions Evaluate Method Validation Factors with Simple Statistical Methods Stability Chamber User Design

2:15 - 3:45 PDT	Select Between Knowledge Exchange Sessions
Analytical	**A Useful Strategy for the Analysis of Dissolution Profiles** Ronald D. Snee, Ph.D., Founder and President, **Snee Associates, LLC**
Data Integrity	**Cultivate the Culture of Integrity in Data Management** Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**
Stability	**Determine Which Packaging Factors Are Sufficient for Protecting Your Product Without Over-Spending to Over-Protect** Patrick Kelleher, Senior Scientist, Physical Sciences Group, **FreeThink Technologies**
Stability	**Chill with Stability Needs of Vaccines/Biologics/Gene Therapies** Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**
4:00 - 5:30 PDT	Select Between Knowledge Exchange Sessions
Analytical	**Validation and Development of Stability-Indicating Methods** Peju Odunusi, Ph.D., Owner, **PJ Pharmaceutical Consulting LLC**
Data Integrity	**Learn Statistical Methods to Analyze Data of Validation Test Results** Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**
Stability	**Stability Requirements for Devices and Combination Products** Chris Latoz, Stability Manager, **Hollister Incorporated**
Stability	**Explore the Power of Leveraging and Equivalence Studies** Lori McCaig, Director, Stability Program Strategy, **Seagan** *(Invited)*
5:30 PDT	Close of Conference

SELECT YOUR REGISTRATION:

- ❑ **EARLY BIRD:** $2295 (by May 14, 2021)
- ❑ **STANDARD:** $2595 (after May 14, 2021)

TEAM DISCOUNT:
Register three and receive the fourth free!

Send cancellation requests in writing 7 days before the event in order to receive a refund (minus a $200 processing fee). Cancellation requests within 7 business days before the event, your registration will be transferred an equivalent KENX event.