AND KENX HAVE JOINED FORCES TO DELIVER AN INCREDIBLE LEARNING EXPERIENCE

Attend Virtually or In-Person

STABILITY TESTING & PROGRAM MANAGEMENT

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

HEAR FROM LEADING STABILITY EXPERTS COVERING TODAY'S MOST PRESSING CHALLENGES, INCLUDING:

Explore Time Window Expectations for Stability Function Steps
Kim Huynh-Ba, Managing Director, **Pharmalytik**; Adjunct Professor, Regulatory Compliance, **Illinois Institute of Technology (IIT)**

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**

Handle OOS, OOT & OOE with Confidence and Expertise
Emily Trubee, Quality Control Manger, Stability, **Glenmark Pharmaceuticals**

Conduct Drug Excipient Compatibility Studies – A Case Study
Geoff Carr, Ph.D., Director, Analytical Development, **Patheon, part of Thermo Fisher Scientific**

Understand the Stability Needs of Vaccines/Biologics/ Gene Therapies
Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**

Stability Requirements for Devices and Combination Products
Chris Latoz, Stability Manager, **Hollister Incorporated**

Conducting Shipping Studies to Support Product Distribution
Emily S. D. Trubee, Quality Control Manger, Stability, **Glenmark Pharmaceuticals**

Shelf-Life Determination of Drug Products using ANCOVA and Regression Analysis
Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

Explore the Power of Leveraging and Equivalence Studies
John O'Neill, PSDG Facilitator, Editor, **StabilityHub.com**

AND MUCH MORE – SEE INSIDE FOR DETAILS!

PLATINUM SPONSOR

AZZUR GROUP

GOLD SPONSORS

CAI

PARAMETER GENERATION & CONTROL

NOVATEK INTERNATIONAL

SILVER SPONSORS

H&A Scientific
Better Software. Better Science.

VTI LIFE SCIENCES

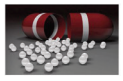
VALGENESIS

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



STABILITYHUB

Pharmaceutical Stability Discussion Group

SEND YOUR TEAM! THIS EVENT IS CO-LOCATED WITH:

ANALYTICAL PROCEDURES & METHODS VALIDATION

LABORATORY DATA INTEGRITY COMPLIANCE CONGRESS

Register Online | www.kenx.org/conferences/laboratory-university-2/

Day One – June 22, 2021

12:00 PT Exhibitor Showroom & Virtual Platform Open House

1:00 PT Chairman's Opening Remarks

1:15-1:45 PT Learn about PSDG and Stability News from Other Meetings

John O'Neill, PSDG Facilitator, Editor, **StabilityHub.com**

- Welcome and introduction of the KENX/PSDG alliance
- A Pharmaceutical Stability Discussion Group meeting process primer
- Introduction of participants and meeting demographics
- News from other stability meetings

1:45-2:15 PT Here's the 411 on Stability Program 483s and Warning Letters!

Chris Latoz, Stability Manager, **Hollister Incorporated**

- Learn the difference between an FDA 483 and a Warning Letter
- Learn one surefire way for improving compliance of your stability program
- Review examples of Warning Letters related to elements of stability programs including: OOS results, chamber excursions, sample Inventory, data Integrity, and training
- Learn three critically important SOPs that every stability program should have
- Learn the do's and don'ts of an FDA inspection

Takeaway Tools

- "Stability Contingency and Disaster Recovery" White Paper from Intertek.

2:15-2:45 PT Identify Data Integrity Gaps in Your Stability Workflow

Sheba Zaman, Head of Product Specialists &Training Services, **NOVATEK INTERNATIONAL**

- Map out a stability process in terms of data flow
- Learn the main Data Integrity (DI) requirements (FDA, MHRA, EMA and PICS)
- Define metadata, audit trails, static vs dynamic forms, cGMP records, access rights, generation of data, retention of data, data use for decision making, data archival, electronic signatures
- Perform a DI risk assessment on the mapped stability workflow
- Learn to apply the DI requirements to improve the Stability workflow

Takeaway Tools

- Example of process flow chart
- List common/inherent stability process risks
- List of guidance documents

3:00 - 3:30 PT Exhibitor Showroom & Think Tank Session
Reduce Study Risk Through Effective Monitoring Systems

3:45-4:30 PT 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**

- Understand the advantages of using ASAP to aid in product development and decision-making
- Learn about using the isoconversion approach to predict time to reach the specification limit
- Apply a humidity-modified Arrhenius equation to determine the temperature and moisture dependence of degradation
- Learn about the experimental setup and design of ASAP studies
- See case studies of accelerated studies to predict chemical stability and appearance changes
- Mean kinetic temperature

Takeaway Tools

- White Papers on Accelerated Stability
  - » "Science of Temperature Dependence: Science of Temperature Impact on Degradation Rates"
  - » "Science of Humidity Dependence: Science of Humidity Impact on Degradation Rates in Solids"

4:30-5:15 PT Explore Time Window Expectations for Stability Function Steps

Kim Huynh-Ba, Managing Director, **Pharmalytik LLC**; Adjunct Professor, Regulatory Compliance, **Illinois Institute of Technology (IIT)**

- Define the purpose of a stability program
- Establish critical attributes of stability function.
- Determine the importance of different timetables and how they impact the decisions
- Develop tolerances for managing time windows of different stability functions and establish quality metrics

Takeaway Tools

- Flowchart of stability timetables
- Understand tolerance of different stability functions.
- The deficiencies of current stability guidelines

5:30 PT Game Night - Trivia Welcome Reception

Day Two - June 23, 2021

7:00 PT Exhibitor Showroom Opens

7:15 - 8:00 PT | Handle OOS, OOT & OOE with Confidence and Expertise

Emily Trubee, Quality Control Manger, Stability, **Glenmark Pharmaceuticals**

- Develop a plan to deal with unwelcome stability surprises
- Learn two ways to define your trend limits
- Discover why great expectations are on the outs
- Conduct effective investigations (including laboratory investigations)
- Harness software tools to keep from going out of control

8:15 - 9:45 PT | 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**

Bring your knowledge, experience, questions and explore with your peers:

- Mastering Chamber Validation & Operation is the basis of a sound stability program
  - » explore chamber topics with the aid of a chamber innovator and a career-long big pharma chamber specialist
- Delve into the maze of International Stability Regulations to find your best path to compliance
  - » probe the world of popular, obscure, notorious, and even mysterious guidances
- Discuss Best Practices in using Contract Stability Organizations to maximum benefit
  - » begin your quest toward optimizing bi-lateral satisfaction and minimizing frustrating pain points

10:00 - 10:30 PT Exhibitor Showroom & Think Tank Sessions
Stability Budgeting - Account for Shelf Life Expenses

10:45 - 12:15 PT | 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**

Bring your knowledge, experience, questions and explore with your peers:

- Discover the best way to use LIMS for facilitating all aspects of your stability program
  - » learn from others who have played the LIMs edition of Chutes and Ladders
- Discuss Stability Statistics & Reports as means of quickly making the case for your product's shelf life
  - » explore the functions and features of the tools we can use to keep you and your stakeholders satisfied
- Delve into best practices as well as pitfalls we all experience in the realm of Sample Handling
  - » keep all things samples off the Regulatory Inspector's citation list

12:30 - 1:15 PT | Conducting Shipping Studies to Support Product Distribution

Emily Trubee, Quality Control Manger, **Stability, Glenmark Pharmaceuticals**

- Explore the ups and downs of your shipping routes
- Know where to look for unexpected challenges
- Evaluate your need for cycling studies
- Develop an awareness of controlled environment container options
- Learn why shipping specs should not differ from labeled specs"

1:30 - 2:00 PT Exhibitor Showroom & Think Tank Sessions
Learn the Latest in the World of Photostability

2:15 - 3:00 PT | Establish Stability Protocols and Review Boards

John O'Neill, Editor, **StabilityHub.com**

- Establish and maintain reference standards
- Discover when primary vs. secondary standards come into play
- Learn if standards are stored, dispensed, labeled and shipped like stability
- Learn resources that can be shared with a stability program
- Evaluate and trend reference standard test results

4:00 - 4:30 PT Exhibitor Showroom & Think Tank Sessions
Common Challenges in Extractables and Leachables Studies

4:45 - 6:15 PT | Shelf Life Determination of Drug Products using ANCOVA and Regression Analysis

Raul Soto, Senior Principal Software Quality Engineer, **Johnson & Johnson Vision Care**

- Use regression analysis to construct a mathematical model of drug potency (as a % of label claim) as a function of time (months)
- Use Analysis of Covariance (ANCOVA) to determine when you can pool multiple stability lots into a single model, and when you need separate models for each lot; following EU ICH Q1E and US FDA guidance.

- Estimate the potency of a given lot after a specific amount of time, and compare it to the label claim
- What is the meaning of prediction intervals and confidence intervals in these potency predictions?
- Estimate the shelf life for a drug lot, as the time period in which you can be 95% confident that at least 50% of the regression response is above the lower specification limit (90% potency)
- Estimate the potency of your drug at the end of its shelf life
- How to use Minitab's Stability Study module to perform stability studies and reports

6:15 PT **Close of Day Two**

Day Three – June 24, 2021

7:00 PT Exhibitor Showroom Opens

7:15 - 8:00 PT | **Tour a facility, Explore Stability Landscape & Test Your Knowledge**

John O'Neill, Editor, **StabilityHub.com**

- See what a full stability program looks like in a commercial CRO setting
- Keep your eyes open for best practices and equipment you might like
- Learn what CROs do to optimize their customer service and minimize liability
- Bring your facility questions for our tour guides to answer"

8:15 - 9:45 PT | **Breakout Topics: Wider View of Chambers, International Regs, CRO's**

Stefan Cassonelli, Sales and Marketing Manager, **Parameter**; Loren "Lonnie" Stuckert, Associate Researcher, **Procter & Gamble**; Bette Monnot-Chase, Director, Analytical Sciences, **Marinus Pharma**

Since you were only able to attend one of these three on Wednesday, come and find out what happened in the other two. Bring your questions and benchmarking poll topics for these "30-minute Wider Views" excerpts.

10:00 -10:30 PT Exhibitor Showroom & Think Tank Sessions
Challenge Your Inventory Systems for Maximum Benefit and Minimal Issues

10:45 - 12:15 PT | **Breakout Topics Wider View LIMS, Stats & Reports, Sample Handling**

Geoff Carr, Ph.D., Director, Analytical Development, **Patheon, part of Thermo Fisher Scientific**

- Understand some problems caused by excipients
- Review the design of an ECS
- Learn the benefits that can be achieved when good science is used to interpret study results
- Understand how well designed ECS studies with thorough data interpretation can make formulation development far more efficient with overall time savings
- See how the application of thorough interpretation of ECS data enabled us to recommend design options to our client for a delayed release (DR) tablet

1:30 - 2:00 PT Exhibitor Showroom & Think Tank Sessions
Stability Chamber User Design

2:15 - 3:00 PT | **T Determine Which Packaging Factors Are Sufficient for Protecting Your Product Without Over-Spending to Over-Protect**

Patrick Kelleher, Ph.D., Senior Scientist, Physical Sciences Group, **FreeThink Technologies**

- Review the basis of modeling stability with the humidity-corrected Arrhenius equation
- Understand the different mechanisms by which moisture impacts product stability
- Examine how the impact of oxygen on product stability can be quantified and modeled predictively
- Learn how to select appropriate packaging based on highly accelerated stability studies
- Demonstrate how to quantify the impact of excursions on product shelf life

Takeaway Tools

- White Papers on Accelerated Stability
  - » Science of Temperature Impact on Degradation
  - » Science of Humidity Impact on Degradation Rates in Solids
- Packaging Case Study Publications
  - » Case Study: Activ-Blister™ Solutions Provide Superior Protection of a Model Drug Product Over Cold-Form Foil
  - » Modeling of In-Use Stability for Tablets and Powders in Bottles
  - » Why Bottles with Desiccant Outperform Foil-Foil Blister Packaging

3:00 - 3:45 PT | **T Chill with Stability Needs of Vaccines/Biologics/Gene Therapies**

Steven S. Kuwahara, Ph.D., Principal Consultant, **GXP BioTechnology**

- Yes, there are all sorts of stability issues – Overcome the challenges

- Learn how to deal with the problems of biologics
  - » understand the regulations and guidelines
    - ◊ know the different challenges from small molecules
    - ◊ discuss the point of view of physical chemistry
    - ◊ just because the molecule is intact the product may not be stable
- Understand and consider the different circumstances
  - » combination products
  - » reconstitution of products
  - » storage and transportation
- How to set your own specifications
  - » Understand the regulatory approval process

Takeaway Tools

- Copies of Guidance Documents for small molecules and biologics

3:45 - 4:00 PT Exhibitor Showroom and Refreshment Break

4:00 - 4:45 PT | Stability Requirements for Devices and Combination Products

Chris Latoz, Stability Manager, **Hollister Incorporated**

- Tongue Depressors, Catheters, and Drug-eluting Stents – Are they Stabile?
- Review of Guidance Documents for medical devices, including FDA Shelf Life of Medical Devices, ASTM F1980-16, ISO 11607-1:2019
- Review of polymer fundamentals, polymer degradation kinetics, and sterilization methods
- Learn commonly used stability tests in the medical device industry
- See an example of "bracketing" for medical device stability
- Brief review of stability requirements for combination devices

Takeaway Tools

- 1991 FDA Shelf Life of Medical Devices by Geoffrey S. Clark

4:45 - 5:30 PT | Explore the Power of Leveraging and Equivalence Studies

John O'Neill, PSDG Facilitator, Editor, **StabilityHub.com**

- Develop a strategy early in your project to leverage stability information
- Test your theory that you have the necessary ingredients for Comparability studies
- Explore the possibilities of leveraging and equivalence in making a case to regulatory authorities
- Identify your internal and external allies in establishing your plan

5:30 PT Close of Conference

SELECT YOUR REGISTRATION:

❑ **EARLY BIRD:** $2,295.00 (by May 14, 2021)

❑ **STANDARD:** $2,595.00 (after May 14, 2021)

TEAM DISCOUNT:
Register three and receive the fourth free!

COMPLETE THE FOLLOWING:

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

_____

CITY: _____ **STATE:** _____

ZIP: _____ **COUNTRY CODE:** _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

EMAIL: _____

PAYMENT METHOD:

❑ VISA ❑ MASTERCARD ❑ AMEX

CARD NUMBER: _____

EXPIRATION DATE: _____ **CVS:** _____

NAME ON CARD: _____

SIGNATURE: _____

BILLING ADDRESS: _____

_____

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.