

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

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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, COE, 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		
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 FDA, USP, ICH and Other Global Guidance - Navigate the Maze 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		
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, Aldebron		
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 Cazonelli, 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 in the Method Life Cycle 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 Measurements 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	Qualification Strategy and Data Integrity Compliance of Lab Instruments 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	Drug Excipient Compatibility Studies /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	Make Informed Packaging Decisions Based on Highly Accelerated Stability Testing Patrick Kelleher, Senior Scientist, Physical Sciences Group, FreeThink Technologies
Stability	Chill with Stability Needs of Vaccines/Biologics/Gene Therapies Lori McCaig, Director, Stability Program Strategy, Seagan (Invited)
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)

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