STABILITY TESTING SUMMIT

Providing insight into industry-leading best practices to improve your supply chain, streamline operating costs, and reduce time to market

THE ONLY EDUCATIONAL EVENT IN THE U.S. SPECIFICALLY DEVOTED TO THE SCIENTIFIC AND BUSINESS ASPECTS OF STABILITY TESTING!

KEY TAKEAWAYS

1. **Explore strategies** to align stability testing and validation throughout the product life cycle
2. Determine best practices for stability **data evaluation** to support the distribution of medicinal products
3. Examine the application of **statistical tools** widely used in the manufacturing process
4. Learn how to implement a **risk-based approach** from development through commercialization
5. Understand stability-related regulatory queries and how to meet evolving expectations
6. Create a road map to **establish, manage, and improve** a stability program
7. Evaluate the **stability specifications** for biologics from both a regulatory and industry point of view

FEATURED SPEAKERS

Heather Egland
Stability Coordination Manager
FRESENIUS KABI USA

Peju Odunusi, Ph.D.
Group Leader, Stability
ABBOTT VASCULAR

Anthony Chikere, Ph.D.
MSAT-BT Process Management and Systems
BAYER PHARMACEUTICALS, BERKELEY CALIFORNIA

Emily Trubee, M.S.
Stability Manager, R&D
ADARE PHARMACEUTICALS

Chris Latoz
Manager Stability and Analytical Services
HOLLISTER INCORPORATED

Joseph Zelhof
Director, Global Stability
BRISTOL-MYERS SQUIBB

To Register, Call 201 871 0474 or Click Here

DEAR COLLEAGUE,

The time has never been more critical for companies to evaluate their stability testing programs and learn new, innovative approaches to product validation. As organizations look to streamline operating costs and reduce time to market, we invite executives in this field to gain insight into how real-life conditions can impact their supply chain, testing facilities, operating costs, formulations, manufacturing processes, packaging, and analytical methods.

Recognizing the demand for a one-stop shop for essentials, future-looking stability testing information, this is the only conference in North America to truly take a full-scope view of the business and scientific advancements essential to ensuring patient safety and the desired clinical outcomes. Participants will leave knowing how to save resources and improve the likelihood of regulatory approval of stability protocols.

You won't want to miss this one-of-a-kind Summit and networking event! I look forward to welcoming you to Boston in September!

Sincerely,

Alyssa Smail,
Associate Conference Producer

Scott Grossman
Division Head, Conference Production

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, medical device, and biotechnology companies with responsibilities in the following areas:

- Analytical Testing
- Stability Management
- Quality Control
- Quality Assurance
- Development and Manufacturing
- QA/QC
- Stability Laboratories
- Raw Materials
- Laboratory Management
- Regulatory Affairs
- Formulation
- Drug Discovery
- Manufacturing Technology
- Clinical Pharmacology
- Formulation/Preformulation
- Pharmaceutical Development
- Preclinical Development

This conference is also of interest to:

- Formulation Specialists
- Drug Delivery Specialists,
- Excipient Manufacturers/Suppliers
- CROs

VENUE INFORMATION

Hyatt Regency Boston Harbor
101 Harborside Drive
Boston, MA 02128

To make reservations, please call 1-888-421-1442 and request the negotiated rate for ExL's September Meetings. You may also make reservations online using the following weblink: **http://bit.ly/2WfCYHx**). The group rate is available until **September 3, 2019**. Please book your room early, as rooms available at this rate are limited.

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8:00 CONTINENTAL BREAKFAST

9:00 **INTRODUCTION FROM CHAIRPERSON**

Peju Odunusi, Ph.D., *Group Leader, Stability,* **ABBOTT VASCULAR**

9:15 **ALIGN STABILITY TESTING AND VALIDATION THROUGHOUT THE PRODUCT LIFE CYCLES**

Forward-thinking life sciences corporations are considering comprehensive, long-term product life cycle approaches to stability testing to validate the long-term stability and shelf-life of products through testing at routine intervals and utilizing data from early clinical phases in later product phases to reduce duplicative testing and operational expenditure. This type of life cycle approach to stability testing has many benefits for corporations and products, creating assurance of product stability through longer-term testing and data analysis, as well as statistical benefits of routine long-term testing. At the same time, life cycle approaches can be difficult to implement and carry out over long periods of time and requires thoughtful planning in order to execute correctly.

- Early stability testing pre-clinical through Phase 2
- Testing stability ahead of pivotal Phase 3 trials
- Postmarket stability testing and annual review

Peju Odunusi, Ph.D., *Group Leader, Stability,* **ABBOTT VASCULAR**

10:00 **STABILITY DATA EVALUATION TO SUPPORT THE DISTRIBUTION OF MEDICINAL PRODUCTS**

The objective of this session is to describe and justify studies using scientific data and rationale in support of the distribution of product through the supply chain to the end user. The conditions of transport for medicinal products must be appropriate to maintain the quality of the product. Consideration must be given to assuring protection against exposure to unacceptable environmental conditions that may impact the stability attributes of the product. Balancing prescriptive guidance afforded by the product label with the risks associated with the excursions that may result through the distribution of the product to the end user may require a comprehensive review of risk resulting in the budgeting stability data.

- Navigate regulatory expectations regarding product label and support for distribution excursions
- Design of stability studies, excursion studies, and temperature cycling studies to support product distribution through the supply chain to the end user
- Stability budgeting
- Supply chain risk and mapping
- Label storage interpretation

Joseph Zelhof, *Director, Global Stability,* **BRISTOL-MYERS SQUIBB**

10:45 NETWORKING BREAK

11:15 **MONITOR OF STABILITY DATA THROUGH PRODUCT LIFE CYCLE**

Stability studies ensuring the maintenance of product quality, safety, and efficacy throughout the shelf life are considered a pre-requisite for the commercialization of a pharmaceutical product. These studies are performed under ICH, WHO, and or other health agency guidelines. Estimates of the shelf life of drug substances and drug products derived from accelerated predictive stability (APS) testing under less stressful conditions are subsequently confirmed by real-time testing under normal storage conditions. Results of stability testing can often be impacted by other non-product specific factors such as the analytical method and instrument performance, often not considered when evaluating stability testing data. Therefore, the trending of the analytical method performance using control charts with defined trigger rules can be diagnostic of aberrant stability testing outcomes such as drifts and out of trend (OOT) results. In addition, it provides ongoing assurance that the method performance remains in a state of control, and increases confidence in decisions made based on the resulting analytical data.

- Application of statistical tools widely used in manufacturing process
- Monitoring for ongoing verification of stability data through the life cycle of licensed drug substance drug products, with a focus on biologics

Anthony Chikere, Ph.D., *MSAT-BT Process Management and Systems,* **BAYER PHARMACEUTICALS, BERKELEY CALIFORNIA**

12:00 **KEY THEMES OF RECENT STABILITY-RELATED REGULATORY QUERIES: PFIZER'S STRATEGY TO MEET EVOLVING EXPECTATIONS**

Amy St. Charles, *Senior Principal Scientist/Group Leader of Biotherapeutics Stability, Reference Materials and Raw Materials,* **PFIZER**

12:45 NETWORKING LUNCH

1:45 **IMPLEMENT A RISK-BASED APPROACH FROM DEVELOPMENT THROUGH COMMERCIALIZATION**

Stability testing is an activity which is crucial in supporting both the development and the commercialization of pharmaceutical products. Depending on the phase, there are different study objectives as well as stability study requirements which need to be addressed. Product development is accelerating, the pharmaceutical industry is becoming more global, and many companies are being asked to do more with fewer resources. Introducing a risk-based approach to the design and execution of product stability studies has become key, and understanding the risks and rewards of such designs is crucial.

By participating in this presentation, you will learn:

- The minimum requirements are for each type of study
- What region-specific requirements need to be considered?
- How can Quality Risk Management be used for stability studies?
- What are some examples of acceptable risk-based approaches to stability?
- How can stability data be used to leveraged to satisfy multiple requirements?
- Examples of risk-based stability study designs
- Current industry trends for the acceptance of risked-based stability studies

Emily S. D. Trubee, M.S., *Stability Manager, R&D,* **ADARE PHARMACEUTICALS**

2:30 **A ROAD MAP TO ESTABLISHING, MANAGING, AND IMPROVING A STABILITY PROGRAM**

- Assess existing resources (personnel and equipment)
- Purchase and qualify chambers-IQ, OQ, PQ (including temperature and humidity mapping)
- Write a comprehensive set of SOPs for Stability Program and Disaster Recovery Plan (power, chamber or monitoring system failure)
- The importance of proper stability sample handling, management, and inventory control
- Opportunities for improvements to overall stability program

Chris Latoz, *Manager Stability and Analytical Services,* **HOLLISTER INCORPORATED**

3:15 NETWORKING BREAK

3:45 **STABILITY STRATEGIES AND CONSIDERATIONS FOR ACCELERATED PRODUCTS**

- Utilize pooled knowledge to model stability behavior and evaluate the potential to extrapolate expiry
- Phase appropriate specification setting for late-stage products and life cycle management
- Method Bridging in support of specification setting and stability expiration

Kayla Woodlief, *Senior Manager, Biologics Stability and Analytics,* **BIOGEN**

4:45 DAY ONE CONCLUDES

8:00 CONTINENTAL BREAKFAST

9:00 DAY TWO CHAIRPERSON INTRODUCTION

Joseph Zelhof, *Director, Global Stability,* **BRISTOL-MYERS SQUIBB**

9:15 DRUG PRODUCT INTERMEDIATE STABILITY: ESTABLISHING PHYSICAL AND CHEMICAL STABILITY OF SPRAY-DRIED DISPERSIONS AND NAVIGATING COMPLEX GLOBAL REGULATORY EXPECTATIONS AND REQUIREMENTS FOR ESTABLISHING SHELF LIFE

With a majority of drug candidates in development identified as BCS Class III or IV compounds, novel formulation strategies must be used to achieve the desired exposure. Spray-dried dispersion intermediates are being utilized more frequently in pharmaceutical development to enhance solubility and exposure. A key challenge for utilizing a drug product intermediate in pharmaceutical drug product manufacturing is gaining regulatory agency acceptance of the shelf life strategy for these materials. Country-specific expectations and requirements can vary significantly resulting in expiry/shelf life periods. This can lead to numerous, complex, and resource-intensive stability studies to support the regulatory expectations for all regions with the potential of needing to manage shelf life and supply chain.

This presentation will include:

- Stability testing considerations, including establishing and demonstrating physical and chemical stability of sprayed-dried dispersions
- Unique and risk-based stability strategies to mitigate the need of region-specific supply chains
- Experience and expectations of specific countries (e.g., site-specific manufacturing, scale, representative stability, etc.)
- Differences in clinical versus commercial regulatory expectations/strategies

Tyson Chasse, Ph.D., *Senior Director Analytical Sciences, CMC,* **AGIOS PHARMACEUTICALS**

10:00 ACCELERATED VS. REAL-TIME STABILITY TESTING: CLOSING THE GAP

Stability testing provides guidance for expiry dating/shelf life, together with an evaluation of environmental conditions affecting the quality of drug products. Accelerated stability studies provide useful information on the stability of a drug earlier in development. These studies are an important strategy for reducing regulatory approval timelines. Accelerated studies for Biologics carries a high risk, and often gaps exist between the accelerated study and real-time stability.

The presentation will discuss:

- Stability specifications for biologics from both a regulatory and industry point of view
- How accelerated stability studies act as their surrogates
- The factors to consider with accelerated studies and what their limitations are will be presented
- Approaches to improve the predictive ability of accelerated studies will be discussed, as well as their limitations

Timothy Forsyth, Ph.D., *MSAT-BT Process Management and Systems,* **BAYER PHARMACEUTICALS, BERKELEY CALIFORNIA**

10:45 NETWORKING BREAK

11:15 REGULATORY FILING AND REPORTING REQUIREMENTS FOR STABILITY TESTING

- Putting together the initial filing — Phased approach for clinical through commercial filing
- Testing and method validation at the various stages, including early submission
- Storage condition selection — use of intermediate or multiple long-term conditions
- Inspection readiness
- Stability updates to regulatory filings

Joshua T. Ayers, Ph.D., *Stability Manager,* **ASTRAZENECA**

12:00 LUNCHEON

1:00 STABILITY TESTING PROGRAM DESIGN

Presenting an overview of best practices for creating and maintaining a team devoted to stability testing for regulatory applications and commitments. Balancing the need for outsourcing vs. internal resources, encouraging ownership and accountability, and considering the effect of company culture on the success of the organization.

Key Points:

- Resource Acquisition and Management
- Storage and Testing Logistics
- Procedures and Quality Systems
- Reporting

Heather Egland, *Stability Coordination Manager,* **FRESENIUS KABI USA**

1:45 STABILITY IN THE INTERNATIONAL OTC AND NUTRITIONAL SUPPLEMENT INDUSTRY

- The difficulties of building a small company stability program to appeal to U.S. and foreign regulatory bodies
- The differences between U.S. and China markets in terms of sales, regulations, and market entry
- What can regulatory bodies do across the board to make products safer and have higher standards?
- Major differences in product and stability testing between U.S. and China
- Stability in emerging markets (CBD, fitness supplements, etc.)

Chris Vitkun, *Analytical Chemist/Stability Systems,* **A&Z PHARMACEUTICALS, INC.**

2:30 CONFERENCE CONCLUDES

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