PSDG/KENX Stability Track Session Descriptions in Progress:

(blue=PSDG primetime with polling, green=Exhibitor Thinktanks, brown= late day presentations with Q&A, red=breakout topic discussions, purple=alternate topics)

Day 1

12:00-1:00 PDT
Exhibitor Showroom and Virtual Platform Open House

1:00-1:15 PDT Conference Welcome

1:15-2:00 PDT
PSDG: Learn about PSDG and Stability News from Other Meetings 45 minutes
Presenter John O'Neill, PSDG Facilitator, Editor StabilityHub.com

A welcome back to PSDG veterans and orientation for those new to the concept. In this first Meeting within the framework of the PSDG/KENX Alliance, the old and the new will be discussed and the traditional "News from Other Stability Meetings" will be presented.

2:00-2:45 PDT
PSDG: Introduction Presentation with Discussion:
Stability 483s & Warning Letters 45 minutes
Here's the 411 on Stability Program 483s and Warning Letters!

Presenter 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

2:45-3:00 PDT Break

3:00-3:30 PDT
Exhibitor Think Tank Session: Monitoring Systems 30 minutes
Reduce stability study environment risks through effective monitoring systems

Presenter Pending

Following, documenting, and trending the moment by moment status of our stability chambers is a critical process to the Stability function. It can be done manually, but why tie up personnel and risk data

integrity liabilities when it can be performed through a validated system? This session explores the needed features and best practices of Stability Chamber Monitoring Systems.

3:30-3:45 PDT Break

3:45-4:30 PDT

Presentation with Q&A: Stability Windows 45 minutes

Explore Time Window Expectations for Stability Function Steps

Presenter Kim Huynh-Ba, Managing Director, Pharmalytik

This session will open a window on the length of time allotted for just about any segment of the Stability Process. In how many days must testing be completed following a Sample Pull? How many days can we pull a sample early or late? How long is allowed for a Laboratory Investigation? And where does it say that these are requirements? These and many other questions will be discussed.

4:30-5:15 PDT

Presentation with Q&A: Stability Budgeting 45 minutes

Account for "Shelf Life Expenses" Before Product Meets Patient

Presenter Pending

While cost is involved, we're talking about budgeting time rather than money. Bob Dylan said, "He not busy being born is surely busy dying". The clock on a product's shelf life starts ticking as it is being created. This presentation will address those areas of production, distribution and administration that are line items on a Product's Stability Budget and how to apportion them while trying to give the majority of shelf life to the pharmacies, doctors and patients on the receiving end of distribution

5:15-5:30 PDT Break

5:30 PDT

Game Night - Trivia / Welcome Reception

Day 2

7:00-7:15 PDT

Exhibitor Showroom Opens

7:15-8:00 PDT

PSDG: Introduction Presentation with Discussion

Handle OOS, OOT & OOE with Confidence and Expertise 45 minutes

When you're out of luck with stability results, handle the Out of's with aplomb and expertise

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

Surprises in the Stability world are generally unwelcome. This presentation will cover what to do when you experience results that are out of specification, trend or expectation and how to conduct effective investigations (including Laboratory Investigations).

8:00-8:15 PDT Break

8:15-9:45 PDT

PSDG Breakout Session Topics (2 sessions of 3 simultaneous topics. Pick 1 from each session)

Session 1 Topic A: Validating & Operating Stability Chambers 90 minutes

Introduction Presentation with Extensive Discussion

Mastering Chamber Validation & Operation is the basis of a sound stability program

Session Leader Pending

The Stability Chamber is to the Stability Program as what the Horse is to the Cowboy. No horse, no cowboy, No chamber, No stability Program. This Breakout session is for a discussion of all aspects of Stability Chambers, especially their validation, operation, and maintenance.

Session 1 Topic B: International Stability Regulations 90 minutes

Introduction Presentation with Extensive Discussion

Delve into the maze of International Stability Regulations to find your best path to compliance

Session Leader Pending

Stability is widely governed at a high level by world and regional guidances, but also by national regulations which can get more specific and prescriptive to suit their own scientific, medical, and political agendas. This Breakout Session will bring together the collective knowledge and experiences of Stabilitarians who navigate the wide seas and fast flowing rivers of stability regulations to highlight the hidden shoals as well as the helpful currents to be found in regulations and guidances large and small.

Session 1 Topic C: Best Practices using Contract Stability Organizations 90 minutes

Introduction Presentation with Extensive Discussion

Discuss Best Practices in using Contract Stability Organizations to maximum benefit

Session Leader Pending

Whether just starting, wildly succeeding, or looking for emergency back-up, contracting out some or all of the Stability Function is widely practiced. Depending on your degree of preparation and communication with your contracting partner, experiences can be mixed. This Breakout Session will bring Contractors and Clients together to discuss best practices in avoiding pitfalls and ensuring success of your shared endeavor.

9:45-10:00 PDT Break

10:00-10:30 PDT

Exhibitor Think Tank Session: Accelerated Stability 30 minutes

There's fast and then there's faster. Discover the latest in Accelerated Stability.

Presenter Pending

It's all relative to your product's point of failure. This session will explore the appropriate levels of stress in temperature, humidity, light, mechanical and fluctuation. Conventional and Isoconversion methods will be covered.

10:45-12:15 PDT

PSDG Breakout Session Topics (2 sessions of 3 simultaneous topics. Pick 1 from each session)

Session 2 Topic D: Laboratory Information Management Systems 90 minutes

Introduction Presentation with Extensive Discussion

Explore the best way to use LIMS for facilitating all aspects of your Stability program
Session Leader Pending

LIMS (Laboratory Information Management Systems) are great instruments for automating many aspects of the Stability Function. Experience and new applications grow annually, making it possible to capture and process more information with fewer errors and greater regulatory compliance. This Breakout Session will bring together the experience of many users to encourage others toward knowledgeable application of this tool.

Session 2 Topic E: Stability Statistics & Reports 90 minutes

Introduction Presentation with Extensive Discussion

Discuss Stability Statistics & Reports as means of quickly making the case for your product's shelf life
Session Leader Pending

Once Stability data is generated, how will it be organized, analyzed, trended, and reported. This is both a life cycle process as well as the final stage of a stability study required for a regulatory submission. There are many aspects such as guidance, tools, and practices to consider. This Breakout session will be an opportunity to discuss all angles.

Session 2 Topic F: Sample Handling 90 minutes

Introduction Presentation with Extensive Discussion

Discuss the best practices as well as pitfalls we all experience in the realm of Sample Handling
Session Leader Pending

This Breakout Session discussion will encompass all aspects of Stability Samples; how they are obtained, labelled, placed, inventoried, pulled for testing, transferred to the lab, tracked, and discarded. Included will be the qualifications and training of those who are part of the sample handling process, as well as associated windows of time for each stage of processing.

12:15-12:30 PDT Break

12:30-1:15 PDT

Presentation with Q&A: Shipping Studies 45 minutes

Explore the various options employed in conducting Shipping Studies to support product distribution
Presenter Emily Trubee, Quality Control Manger, Stability, Glenmark Pharmaceuticals

It is an expectation for manufacturers to prove that their products survive the journey through distribution channels and sustain their labelled shelf live. This presentation will examine what

companies are doing by way of shipping studies to meet that expectation, including accelerated testing, validating shipping containers and monitoring shipments.

1:15-1:30 PDT Break

1:30-2:00 PDT

Exhibitor Think Tank Session: Reference Standards Stability 30 minutes

Even Reference Standards have a shelf life, so how do you conduct Reference Standards Stability?
Presenter Pending

When all is said and done, a Stability sample is tested against a reference standard, but reference standards also have a shelf life. This presentation will explore stability programs specifically designed for reference standards. See how your program stacks up against others.

2:00-2:15 PDT Break

2:15-3:00 PDT

Presentation with Q&A: Stability Data Integrity 45 minutes

Consider Stability Data Integrity when touting the fuzzy numbers unique to the Stability process
Presenter John O'Neill, Editor, StabilityHub.com

Data Integrity has been a hot topic for well over a decade and we are beginning to incorporate DI principles at all levels and throughout our industry, but who has looked carefully at the softer numbers that see frequent employment in the Stability Function? How precise are the terms "6 months", 40 degrees Centigrade", and "Date of Manufacture"? There is a lot of "acceptable" variability in these numbers and that can make a significant difference (for example, in Stability speak, 6 months at 40C could be 5.5 months at 38C). Our reports can be a sorry reflection of Data Integrity. This session will help us to think in new ways about making sure DI isn't lost in the stability shuffle.

3:00-3:45 PDT

Presentation with Q&A: Photostability 45 minutes

Join those who are LED to learn the latest (or lack thereof) in the world of Photostability
Presenter pending

Exposure to light can bring product degradation anywhere in our process from manufacture to patient consumption. This presentation will do a quick review of the requirements and then camp out on common and best practices, typical pitfalls, and challenges of the contemporary movement to LED lighting.

3:45-4:00 PDT Break

4:00-4:30 PDT

Exhibitor Think Tank Session: Extractables & Leachables 30 minutes

Discover the ins and outs of Extractables & Leachables

Presenter Pending

While determination of E&L liabilities typically occurs well in advance of Commercial Product Stability studies, it is during Stability testing that leachables can rear their ugly head in testing outcomes. Worse yet, something that didn't make the experimental phase Leachable list, may appear and the Extractables come back into the spotlight. This session will review the definitions of E&L and how E&L data should be at the fingertips of the Stabilitarian when surprises arise during the course of a stability study.

4:30-4:45 PDT Break

4:45-6:15 PDT

Presentation with Q&A: Shelf Life Determination 90 minutes

Shelf Life Determination of drug products using ANCOVA and Regression Analysis

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

Day 3

7:00-7:15 PDT

Exhibitor Showroom Opens

7:15-8:00 PDT

PSDG: Stability Stew 45 minutes

Opening of Day 3 Knowledge Quiz, Virtual Tour, Stability Landscape

Presenter John O'Neill & Volunteer Tour Narrators

Day 3 kicks off with a light-hearted test of recall for items covered on the previous days, a virtual tour of a Stability facility and an overview of the Stability landscape; where to pick up stability knowledge, news of events and latest trends.

8:00-8:15 PDT Break

8:15-9:45 PDT

PSDG: Breakout Topics Wider View Session 1 of 2 90 Minutes

A wider view of Day 2 Breakout Topics for the entire Stability Track assemblage

Led by Day 2 Moderators

Chambers	30 Minutes 8:15-8:45
Regulations	30 Minutes 8:45-9:15
CRO's	30 Minutes 9:15-9:45

9:45-10:00 PDT Break

10:00-10:30 PDT

Exhibitor Think Tank Session: Inventory Systems 30 minutes

Challenge your Stability Inventory System for maximum benefit and minimal issues

Presenter Pending

On an elementary level, inventories provide assurance that "we have enough of something to do what we want". In the regulated world of medical products, accurate inventories are a proof of control and evidence of an effective quality system. However, thanks to complex and sometimes poorly administered systems, an accurate inventory can be difficult to achieve. This presentation will explore the challenges and how to overcome them.

10:30-10:45 PDT Break

10:45-12:15 PDT

PSDG Breakout Topics Wider View Session 2 of 2 90 Minutes **Led by Day 2 Moderators**

A wider view of Day 2 Breakout Topics for the entire Stability Track assemblage

Led by Day 2 Moderators

LIMS	30 Minutes 10:45-11:15
Stats & Reports	30 Minutes 11:15-11:45
Sample Handling	30 Minutes 11:45-12:15

12:15-12:30 PDT Break

12:30-1:15 PDT

Presentation with Q&A: Drug Excipient Compatibility Studies 45 minutes

Conducting Drug Excipient Compatibility Studies (ECS) – A Case Study

Presenter 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

1:15-1:30 PDT Break

1:30-2:00 PDT

Exhibitor Think Tank Session: Innovative Labeling 30 minutes

Solve the challenge of putting a lot of information on minimal surface area through Innovative Labeling

Presenter Pending

Teeny-Weeny Package, Great Big Clumsy Label. This presentation will explore creative ways to associate a lot of information to packages without much surface area. Conventional labels in new shapes, direct printing and scannable codes are among the approaches to be discussed in this session.

2:00-2:15 PDT Break

2:15-3:00 PDT

Presentation with Q&A: Equivalence Studies 45 minutes

Use Equivalence Studies to speed product submissions for similar or slightly changed products

Presenter Pending

If A = B and B = C, then can you skip extensive studies on C? This presentation will explore the possibilities of leveraging and equivalence in making a case to regulatory authorities that fewer studies (and less expense as well as time) are needed to prove stability of a product made with different suppliers, packaging, fills, or manufacturing steps than the approved original product. Attend to see where the lines for change are drawn and what has worked or not worked for industry

3:00-3:45 PDT

Presentation with Q&A: Vaccines/Biologics/Gene Therapies Stability 45 minutes

Chill out with the stability concerns of Vaccines, Biologics & Gene Therapies Products

Presenter Pending

Technology has evolved from small molecules to large, “controlled poisons” to attenuated viruses, Messenger RNA and Gene Therapies. Stabilitarians have needed to evolve as well with colder storage conditions, sophisticated sample handling, appropriate Stability-indicating tests, and tighter testing windows. This session will explore these developments and how the associated challenges are being met.

3:45-4:00 PDT Break

4:00-4:45 PDT

Presentation with Q&A: Stability Requirements for Devices & Combination Products 45 minutes

Tongue Depressors, Catheters, and Drug-eluting Stents: Are they Stable?

Presenter Chris Latoz, Stability Manager, Hollister Incorporated

- 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 PDT

Presentation with Q&A: Clinical Supplies Stability 45 minutes

Explore the fast and furious world of Clinical Supplies Stability

Presenter Pending

With limited experience in manufacturing and stability, medicine needs to meet patient in order to demonstrate safety and effectiveness before further commitment is made toward commercialization. Stability requirements are lighter at this stage, but there must be proof that the product is stable for the period required to ship, store, and administer it. This presentation will address the guidances and practices governing the stability of Clinical Trials Material.

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Alternative Topic: Stability Review Boards 45 minutes

Discover how to use a Stability Review Board to cut bureaucratic red tape and prevent delays

Stability Review Boards can be a pathway for efficient review and speedy decisions regarding stability protocols and issues, or a bureaucratic boondoggle of delay. This session will explore the ingredients for success in composition and function as well as what stability processes are best served by a Stability Review Board.

Alternative Topic: Stability Automation 30 minutes Exhibitor/45 minutes Presenter

Learn what's coming down the pike to save Stability Function time and costs

They're coming (and some are here)! Robots, cameras, meters, labelers, scanners, and samplers are replacing human hands, reducing staff needs and preventing common errors. This session will cover the latest applications of technology to the Stability Function.

Alternative Topic: Stability Training 45 minutes

There is no Bachelor of Science in Stability, so where do we turn for Stability Training?

You may be participating in Laboratory University, but won't walk away with a Bachelor's degree in Stability. This session will address the many avenues of training that are available for budding Stabilitarians. Some are organized curricula, some are gregarious exchanges, while others are independently researched. See what fits best to the needs of your organization.

Alternative Topic:
Presentation with Q&A: Stability Protocols 45 minutes

Determine whether your Stability Protocols serve you best as a recipe or a cookbook

Presenter Pending

Stability Protocols are basic plans for conducting a stability study, but can also be instruments to convey purpose, component information, developmental history, project information and associated studies, among others. Some have even been the means of avoiding an FDA 483. This session will explore the opportunities and pitfalls of stability protocols

Alternative Topic:
Presentation with Q&A: Stability Stakeholders 45 minutes

Identify Stability Stakeholders and gain maximum benefit through strategic relationships

Presenter Pending

The Stability Function requires a universe of stakeholders ranging far beyond the expertise of the Stabilitarian. This presentation explores who those stakeholders are and how best to engage them in the Stability Function as well as having them as effective partners in regulatory inspections.