IPA's Annual:

STABILITY PROGRAM CONFERENCE

For pharmaceutical, biopharmaceutical and allied industries

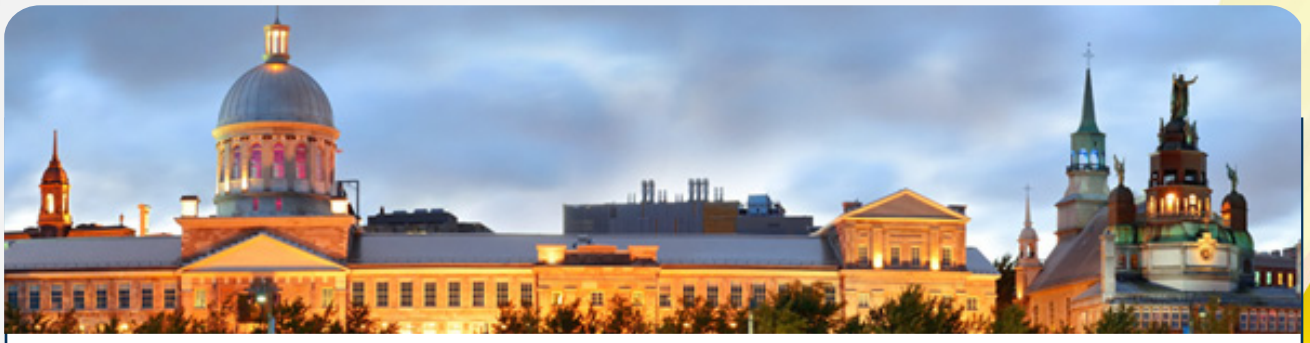
MAY 31 - JUNE 02, 2017
Montreal - Canada

Join us in Montreal this spring to learn and hear from industry experts on the lastest challenges, trends, updates and future developoment on Stability Program

Conference at a glance:

- Forced degradation studies: practical considerations for biopharmaceuticals development
- Quality by Design (QbD) for Combination Products – A Medical Device Perspective
- Accelerated Stability Modeling
- Protein formulations and their stability challenges
- Stability Programs for Leachable Impurities
- Antibody Drug Conjugates - A Peek into their Challenges to Successful Commercialization
- Development and Validation of a Stability Indicating Method
- Defining analytical testing & stability program for biologics
- Matrixing and Bracketing in Stability Sampling Plans
- Criteria for Establishing Shelf Life of Cosmetic Products
- ICH Q1E for estimating shelf life- shelf life statistics for non-statisticians
- Analytical Investigations on GMP Release / Stability Testing Out of Alert, Trend and Specification Results
- Interactive Exercise – Interpretation of Stability Data
- **And Much More...**

http://ipacanada.com/Events17/StabilityProgram2017/index.html



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Distinguished Presenters

Laure L. Larkin - MSc, CPP

Associate Director of Stability

Ethicon

Laure L. Larkin is currently the Associate Director of Stability at Ethicon Inc, a global leader in medical devices. Mrs. Larkin has acquired more than 20 years of experience in FDA regulated industries. She has previously worked for large Fortune 100 Companies such as Johnson & Johnson, medium sized companies which include Orthofix as well as small privately held companies such as Cosmaceutical Marketing Inc. This extensive professional experience has given Laure the ability to understand the perspective and needs of companies at different corporate growth stages.

Laure's diverse areas of product expertise include: infant formula & medical nutritional products, in vitro diagnostic reagents & instruments, OTC drugs & cosmetics, as well as orthopedic medical devices and instrumentation. Additionally, her areas of functional experience include validation activities related to stability, packaging, cleaning, equipment, software, test methods, as well as general compliance and risk management.

Mrs. Larkin has distinguished herself as a professional industry speaker and has authored several peer reviewed publications, articles and white papers concerning validation and the use of pharmaceutical stability techniques in the medical device arena. Laure's education includes a graduate degree in Food Microbiology (MS) and a professional certification in Package Technology (CPP).

Christine P. Chan, Ph.D.

Principal Scientist/Technical Lead,
Global Manufacturing Science & Technology,
Specialty Care Operations

Sanofi

Dr. Christine Chan is a protein biochemist with broad experience in the biopharmaceutical industry, including prior experience at Sandoz Pharmaceuticals and Merck & Co., Inc. She specializes in the analysis of recombinant products produced from mammalian cells for vaccines and biologics development. Her application experience includes expression cell line selection, drug substance & drug product process development, manufacturing tech transfers and lifecycle management of commercialized products.

Peter I. Tattersall, Ph.D.

Principal Scientist, Chemical & Synthetic Development

Bristol-Myers Squibb Company

Dr. Peter Tattersall received a BS in Chemistry and a PhD in Organic Synthesis from the University of Manchester in the UK. He is currently an R&D analytical scientist in the Chemical & Synthetic Development group within Pharmaceutical Development at the Bristol-Myers Squibb Company in New Brunswick, NJ. He is an analytical project lead providing support for early stage to NDA approval development projects for small molecules.

He joined the pharmaceutical industry in 2001 as an organic chemist in Analytical Development at AstraZeneca, Wilmington before joining Bristol-Myers Squibb in 2003.

For the last 16 years his areas of focus include analytical method development in support of drug substance and drug product, project leadership and leading analytical investigations. He has interests in Quality by Design for method development and has experience with analytical method transfers around the world together with late stage filings.

Distinguished Presenters

Patrick Forenzo

Senior Fellow / Stability Expert

Novartis Pharmaceuticals Corporation

Pat Forenzo is a senior fellow at Novartis Pharmaceuticals and has been in the Pharmaceutical Industry for thirty years starting as a bench chemist and has been serving as Novartis Global Stability Expert for the last 16 years. He is a past co-chair and currently a member of the PQRI 'Stability Shelf Life Working Group'. Pat was a co-author of 'On the Shelf Life of Pharmaceutical Products', AAPS PharmSciTech, Vol 13, No. 3, September 2012 which was the initial offering from the PQRI 'Stability Shelf Life Working Group'.

Nila Das, Ph.D.

Senior Research Investigator

Bristol-Myers Squibb

Nila Das is a Senior Research Investigator at Bristol-Myers Squibb, based at New Brunswick NJ. Her research interests include product development, stability and CMC filings of therapeutic monoclonal antibodies, antibody-drug conjugates, and gene therapy. Most recently she had led the product development activities of parenteral products at Boehringer Ingelheim. She is a member of USP expert panels on biologics and analytical methods. She is also an assistant editor of mAbs journal, scientific advisor for Journal of Pharmaceutical Sciences and editorial board member of American Pharmaceutical Review Magazine. She has her Ph.D. in Industrial Pharmacy from St. John's University.

Geoff Carr, Ph.D.

Director, Analytical Development

Patheon Inc.

Geoff Carr was appointed as Manager, Analytical Development at Patheon Inc, Canada in 2000 and is now Director, Analytical Development, Ontario. Prior to that, he held positions of Manager, Analytical Sciences at Celltech-Chiroscience, UK, Head of Analytical Development at Medgenix, Belgium and before that at Wyeth Research, UK. He originally started his career in pharmaceutical analysis at The British Pharmacopoeia Laboratory where he held several posts and was finally appointed Head of the Laboratory. He has been a Member of various British Pharmacopoeia Committees, a UK representative to Committees of the European Pharmacopoeia and Member of USP Committees and is currently a Member of the 2015-2020 Cycle USP General Chapters – Physical Methods Expert Committee. He is the author of numerous papers and presentations at international conferences on various topics related to Pharmaceutical Analysis.

Evald Muraj

Stability Manager

Ironwood Pharmaceuticals

Biography will be available soon.

Distinguished Presenters

Wayland Rushing, Ph.D.
Director, Scientific Affairs
EAG Laboratories

Dr. Wayland Rushing is a technical expert in Chemistry Manufacturing and Controls (CMC) program design, analytical development and regulatory submissions. Over his career, he has led CMC development programs for a wide array of pharmaceutical products, including parenteral and inhalation drugs, drug/device combinations and other therapies with complex delivery systems. Dr. Rushing is a subject matter expert in HPLC and GC method development and validation, extractables and leachables program design and regulatory submission requirements; has drafted multiple IND and NDA submissions. Dr. Rushing currently serves on Parenteral Drug Association (PDA) advisory committees for Technology Transfer and Elastomeric Closures and Seals Defects.

Kenneth C. Waterman, Ph.D.
President
FreeThink Technologies, Inc.

Ken Waterman received his B.S. degree with honors in chemistry from UCLA, his Ph.D. in physical-organic chemistry from UC Berkeley and conducted post-doctoral studies in physical and photo-chemistry as an NIH research fellow at Columbia University. Dr. Waterman worked 12-years at Polaroid (as a distinguished scientist) developing imaging products, then 13 years at Pfizer (as a Research Fellow) working on drug stability, drug delivery, biopharmaceutics and prodrugs. He is the author of over 70 publications and was made an AAPS Fellow in 2011. In 2011, he started FreeThink Technologies which both produces and licenses

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Krista Coventry, M.Sc.
Director of Regulatory Services, East
Source Nutraceutical, Inc.

Ms. Krista Coventry is the Director of Regulatory Affairs (Eastern Canada) for Source Nutraceutical, Inc., a Canadian contract research organization. She is a regulatory affairs specialist in the North American health products sector with 15 years of experience providing project management, regulatory strategies and market compliance solutions to industry clients, globally. Krista has expert knowledge of acts, regulations, policies and guidelines relating to natural health products (NHPs) and foods. She has worked extensively within the Canadian regulations to communicate the health benefits of various health products through regulatory efforts, and has vast experience critically evaluating evidence in support of health claims. Krista has also advised numerous clients with products at the interface of the NHP, food, cosmetic and drug regulations navigate the Canadian requirements for pre-market approval.

Krista has extensive experience lecturing on regulatory topics impacting the NHP and food sectors at various industry conferences, workshops and seminars, and also regularly authors articles for several health product industry publications. She has numerous distinguished volunteer affiliations with regulatory-based professional and scientific societies. Krista is the Vice-President of the Natural Health Product Research Society (NHPRS) of Canada; an active member of Health Canada's Food Expert Advisory Committee (FEAC); an active member of the Board of Directors for CAPRA (Canadian Association for Professionals in Regulatory Affairs); Chair of the Canadian Health Food Association's Food Regulatory Advisory Committee (CHFA-FRAC); and an active member of Seneca College's Ad Hoc Program Advisory Committee for the Fundamentals of NHPs program. Krista is also a past member of the International Regulatory Affairs Committees for the Council for Responsible Nutrition (CRN) and GOED (Global Organization for EPA+DHA).

Krista is also completing a Ph.D. at the University of Guelph, with a research focus on clinical research involving natural health products and functional foods.

Distinguished Presenters

Zahra Shahrokh, Ph.D.

CMC Consultant, **ZDev Consulting**
Chief Development Officer, **STC Biologics, Inc.**

With 30 years experience in biotechnology product development, Dr. Shahrokh has a track record in global regulatory approvals of several biological products, authoring 8 BLAs and dozens of INDs. As a CMC Consultant, she provides technical and strategic guidance to advance biotech products through development life cycle. As Chief Development Officer for STC Biologics, Dr. Shahrokh provides Development, Quality, and Regulatory strategy to advance STC's products and Bioservices programs. She was Senior VP of Development at Aurabiosciences, responsible for regulatory, nonclinical and CMC development of protein nanoparticle delivery systems. She led Pharmaceutical and Analytical Development at Shire for ten years, and was Head of CMC & PD Operations. She had technical and leadership roles at Genentech's Pharmaceutical R&D department for ten years, where she drove pharmaceutical development of several classes of biologics and small molecules.

Dr. Shahrokh has a PhD in Biophysics from UC Berkeley, BA in Chemistry and in Physics from University of Pennsylvania, and post-doctoral fellowship at UCSF. She holds several pharmaceutical patents and over 60 papers & invited presentations.

Craig Voellmicke

Vice President, Business Development
Advisory board of the Active & Intelligent Packaging Industry Association (AIPIA
CSP Technologies

Mr. Voellmicke is the VP of Business Development at CSP Technologies, a leader in delivering, innovative, high-quality product and packaging solutions that give customers a competitive edge and consumers a better product experience.

Voellmicke has 19 years of experience in the medical device and pharma packaging industries and serves on the advisory board of the Active & Intelligent Packaging Industry Association (AIPIA).

His current work focuses on enhancing stability and extending the shelf life of transdermal drug delivery and oral solid dose products with engineered polymers for headspace management.

Glen McCarthy, P.Eng.

Founder and President
Labworks International Inc.

Glen McCarthy, P.Eng., is the founder and President of Labworks International Inc. Graduating from Ryerson Polytechnical University, Glen has over 25 years of experience designing and building temperature and humidity controlled environments for critical applications. Glen is a member of Professional Engineers Ontario; ASHRAE and ISPE. Glenn started Labworks International Inc. in 1996 and it has now grown to a team of 6 professional engineers.

Distinguished Presenters

Karl F. Popp, R. Ph.

Founder

KPopp Consulting, LLC.

Karl Popp founded KPopp Consulting, LLC in 2010 as a consulting firm providing services to pharmaceutical, cosmetic and allied industries. He also is a practicing retail pharmacist.

From 1989 to 2008 he was associated with Stiefel Laboratories as Director of Product Development, and later as Senior Director of Special Projects coordinating external manufacturing, global research activities, and managing the corporation's intellectual property estate. Prior to joining Stiefel in 1989, he was a Scientist and Project Manager for the Sterling-Winthrop Research Group. During his career he has been responsible for the development of products that have generated over $2 billion in sales.

He earned his B. S. in Pharmacy from the Albany College of Pharmacy, an M.B.A. from Rensselaer Polytechnic Institute and is licensed to practice pharmacy in NY.

He has been active in the SCC in coordinating local educational seminars, served on the National Committee on Scientific Affairs and as the Society's President in 1999. Karl was elected a Fellow of the Society in 2002. Served as a Past Chair of the New England Chapter, and more recently elected an Emeritus Member.

He is an inventor, an author and a scientist. His interests encompass topical, oral, inhalation, and parenteral dosage forms in addition to various therapeutic categories. During his over 40 years in the industry, Karl Popp has lectured around the globe on new product development activities including GMPs, regulatory strategies, product pipeline efforts, process validation, product life cycle management, and management of intellectual property. He has also served as an expert witness in matters before the U.S. federal courts.

Jacques-Marcoux

Viking Technical Services inc.

With 29+ years experience working for the Canadian Pharmaceutical manufacturing industry, Jacques has extensive knowledge with respect to maintenance, calibration and validation activities with processing equipment and clean utilities both from an operational and a regulatory perspective.

Sean D. Benedik

Principal and Subject Matter Expert

Aliquo Pharma Consulting

SINCE 1998, Sean has been a leader in numerous areas of GMP pharmaceutical and medical device product manufacturing, testing, distribution, and validation for a wide range of companies across Canada, the United States, Mexico, and Europe. Leveraging his expertise as an analytical chemistry & quality systems professional, he has a proven track record as a solutions-based innovator that specializes in validation, quality assurance, quality control, design controls, and product development. Sean is a native speaker of the English and French languages with highly developed oratory skills. He is also well versed in adult learning techniques.

Preliminary Conference Agenda

Day 1 - Wednesday May 31, 2017

7:45 AM – 8:30 AM
Registration, Networking and Continental Breakfast

8:30 AM – 8:45 AM
Chair's Welcome Note – Day 1

8:45 AM – 9:45 AM
Designing Stability Studies in Support of Early Development

Geoff Carr, Ph.D., *Director, Analytical Development, Patheon Inc.*

Forced degradation studies are very important to demonstrate that analytical procedures are suitable for monitoring stability studies. It is strongly recommended that rational approaches are applied to the design of these studies and this presentation will discuss:

- Stability Studies for Phase 1
  - Dealing with powder in bottle presentations
  - Importance of appropriate reconstitution media
  - Designing in-use stability studies
- Studies to Support Blinded Clinical Programs
  - The CMC significance of clinical double blinded studies
  - Dealing with placebo stability
  - Challenges of working with clinical comparators
- Blinded Clinical Comparator Example
  - An example will be provided of a situation where we need to establish analytical procedures to support a stability study to support a blinded comparator

9:45 AM – 10:30 AM
Forced degradation studies: practical considerations for biopharmaceuticals development

Christine P. Chan, Ph.D., *Principal Scientist, Global Manufacturing Science and Technology, Specialty Care Operations, SANOFI, MA, USA*

Forced degradation studies are now an integral part of biopharmaceutical product development. The purpose of these studies varies depending on the stage of development and application areas, which include characterization of degradation pathways, formulation development, assay development and comparability studies. This talk discusses some key design considerations of forced degradation studies for proteins.

- Overview of forced degradation studies applications
- Mechanisms of protein degradation and typical stress conditions
- Forced degradation studies data summary: product stability profile, comparability evaluation

10:30 AM – 10:45 AM
Mid-morning Refreshment Break

10:45 AM – 11:30 AM
Quality by Design (QbD) for Combination Products – A Medical Device Perspective

Laure L. Larkin - MSc, CPP., *Associate Director of Stability, Ethicon*

11:30 PM – 12:15 PM
Stability Testing for Natural Health Products (NHP)

Speaker information will be post shortly

Note: Agenda is subject to change without notice. Please check back regularly for updates.

Preliminary Conference Agenda

Day 1 - Continued

12:15 PM – 12:30 PM

Panel Q & A

Geoff Carr, Ph.D., *Director, Analytical Development, Patheon Inc.*

Christine P. Chan, Ph.D., *Principal Scientist, Global Manufacturing Science and Technology, Specialty Care Operations, SANOFI*

Laure L. Larkin, MSc, CPP., *Associate Director of Stability, Ethicon*

12:30 PM – 1:30 PM

Networking Lunch

1:30 PM – 2:15 PM

Accelerated Stability Modeling

Kenneth C. Waterman, Ph.D., *President, FreeThink Technologies, Inc.*

- Using science to set shelf-life rapidly
- How to assign shelf-life when nothing happens
- Regulatory response to using accelerated stability modeling approaches: latest update

2:15 PM – 3:00 PM

Protein formulations and their stability challenges

Nila Das, Ph.D., *Senior Research Investigator, Bristol-Myers Squibb*

This presentation will focus on the unique structural features of proteins, their degradation pathways, and the presently employed approaches to mitigate the stability challenges at the formulation level, distribution channels and with the end user. All these challenges will be discussed in context to case studies derived from drug product development phase and commercial arena.

3:00 PM – 3:15 PM

Mid-Afternoon Refreshment Break

3:15 PM - 4:00 PM

Stability Programs for Leachable Impurities

Wayland Rushing, Ph.D., *Director, Scientific Affairs, EAG Laboratories*

Leachables are impurities which originate from contact surfaces (typically the final container/closure system). Performing leachable stability studies can be challenging and is generally less understood than for typical drug product related impurities. ICH stability requirements are not directly applicable to leachables. This presentation will cover: what are leachables and where do they come from, what are the similarities and difference to drug product related impurities, what are the method and stability requirements.

4:00 PM – 4:45 PM

User Requirements & Implementation of a Risk Based, Compliant Stability Management System based on Health Canada Data Integrity Guidelines

Parsa Famili, *President and CEO, Novatek International*

- Benefits of Compliant Stability System
- Stability System Components
- Stability User Requirements Based on Inherent Risks

Note: Agenda is subject to change without notice. Please check back regularly for updates.

Preliminary Conference Agenda

Day 1 - Continued

- Benefits of Compliant Stability System
- Stability System Components
- Stability User Requirements Based on Inherent Risks

4:45 PM - 5:30 PM

Panel Q & A

Kenneth C. Waterman, Ph.D., *President, FreeThink Technologies, Inc.*
Nila Das, Ph.D., *Senior Research Investigator, Bristol-Myers Squibb*
Wayland Rushing, Ph.D., *Senior Scientific Advisor, EAG Laboratories*
Parsa Famili, *President and CEO, Novatek International*

Interactive Round Table Discussions with all avaiable presenters.

5:30 PM

Conclusion of Day 1 Conference

Note: Agenda is subject to change without notice. Please check back regularly for updates.

IPA Speaking Opportunities

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We are continually looking for industry experts to present at our international conferences throughout the world and to share their in-depth knowledge of their speciality with our attendees. If you have an interest in becoming one or our select cadre of experts, please contact us at:

Tel: 416-410-7402 or enquiry@ipacanada.com

Preliminary Conference Agenda

Day 2 - Thursday June 1, 2017

7:45 AM – 8:25 AM
Networking and Continental Breakfast - Exhibition Opens

8:25 AM – 8:30 AM
Chair's Welcome Note

8:30 AM – 9:15 AM
Antibody Drug Conjugates - A Peek into their Challenges to Successful Commercialization

Nila Das, Ph.D., *Senior Research Investigator, Bristol-Myers Squibb*

Antibody-drug conjugates (ADCs) have witnessed a lot of interest as a drug targeting technology in recent years for the treatment of cancer. This presentation will focus on the unique structural characteristics of ADCs and their degradation pathways. The successful commercialization of ADCs will be discussed in context to associated challenges at the levels of conjugation, formulation and manufacturing, and stability and analytical, citing case studies.

9:15 AM – 10:00 AM
Development and Validation of a Stability Indicating Method

Peter I. Tattersall, Ph.D., *Principal Scientist, Chemical & Synthetic Development, Pharmaceutical Development, Bristol-Myers Squibb Company*

The small molecule stability indicating HPLC method is the cornerstone of a registrational stability study and release testing of API and Drug Products. Thorough method development requires a number of areas of study including stability indicating selectivity based on potential degradation profiles obtained from previous knowledge and a detailed forced degradation study. A quality by design approach to development is recommended to ensure the method is fit for purpose (FFP), robust and simple to transfer around the world. Validation should be performed according to ICH Q2 and formally documented with both a protocol and a report.

The outline of the presentation is:

- Industry guidance and recent trends
- Internal practices
- Method development / validation workflow
  - Forced Degradation Studies
  - ATP / QBD
  - Validation / procedure documentation
- Illustrative examples including:
  - QBD development through to registrational stability
  - TT approaches/experiences

10:00 AM – 10:15 AM
Mid-morning Refreshment Break & Exhibition viewing

10:15 AM – 11:00 AM
Defining analytical testing & stability program for biologics

Christine P. Chan, Ph.D., *Principal Scientist, Global Manufacturing Science and Technology, Specialty Care Operations, SANOFI, MA, USA*

Protein therapeutics are challenging to develop due to complexity of the molecular structure as well as the manufacturing process. The Quality-by-Design approach provides a framework for integrated development of analytical testing and stability monitoring programs.

This talk discusses some key elements of analytical control strategy including considerations for defining stability programs:

- Critical quality attributes (CQAs) assessment & product quality profile
- Analytical control strategy and test methods selection
- Managing stability testing program: challenges & some examples

Preliminary Conference Agenda

Day 2 - Continued

11:00 AM – 11:45 AM

Analytical method transfers: Practice and pitfalls

Wayland Rushing, Ph.D., *Director, Scientific Affairs, EAG Laboratories*

Analytical method transfers are a very common occurrence in our industry. They can range from simple to complex in nature and unfortunately can be a source of regulatory headaches. All too often the task is approached as a check-box exercise without proper planning resulting in failures that are preventable. This presentation will cover common pitfalls that cause method transfer failures, how to decide what type of method transfer makes sense for your study, and how to implement a fail-safe communication and transfer plan that will help keep your program moving. Example case studies will be presented as well.

11:45 AM - 12:00 PM

Panel Q & A

Nila Das, Ph.D., *Senior Research Investigator, Bristol-Myers Squibb*

Peter I. Tattersall, Ph.D., *Principal Scientist, Chemical & Synthetic Development, Pharmaceutical Development, Bristol-Myers Squibb Company*

Christine P. Chan, Ph.D., *Principal Scientist, Global Manufacturing Science and Technology, Specialty Care Operations, SANOFI, MA, USA*

Wayland Rushing, Ph.D., *Director, Scientific Affairs, EAG Laboratories*

12:00 PM – 1:00 PM

Networking Lunch & Exhibition viewing

1:00 PM – 1:45 PM

Accelerated Tablet Dissolution Stability

Kenneth C. Waterman, Ph.D., *President, FreeThink Technologies, Inc.*

The Accelerated Stability Assessment Program (ASAP) approach of assigning storage times to hit the dissolution failure point at a range of temperatures and relative humidities (RHs) below the critical relative humidity (CRH) at each storage condition can be used to model the dissolution and disintegration stability of immediate-release tablet products. Ambient condition stability could be determined based on a modified Arrhenius equation using the inverse of the failure times in place of rate constants. This use of failure times, rather than a rate of change, was critical for modeling dissolution and disintegration stability because the onset of the failures was sudden. In both cases, dissolution and disintegration failures were correlated with each other, but with greater storage times needed to effect destabilization for dissolution than disintegration.

1:45 PM – 2:30 PM

Matrixing and Bracketing in Stability Sampling Plans

Sean D. Benedik, *Principal and Subject Matter Expert, Aliquo Pharma Consulting Inc.*

Sampling plan decisions made during stability protocol design have a big impact on laboratory operations, data analysis, and sample storage requirements. In this segment we will discuss the matrixing and bracketing approach to rationalizing sampling plans that maximize logistical and data efficiency.

Les plans d'échantillonnage élaborés pendant le design des protocoles de stabilité ont un grand impact sur les opérations du laboratoire, l'analyse des données et l'entreposage des échantillons. Nous discuteront dans ce segment des justifications de plans d'échantillonnage utilisant les approches matricielles ainsi que le 'bracketing'.

2:30 PM – 2:45 PM

Mid-Afternoon Refreshment Break & Exhibition viewing

Preliminary Conference Agenda

Day 2 - Continued

2:45 PM – 3:30 PM

Considerations in the determination of shelf life: a PQRI perspective

Patrick Forenzo, *Senior Fellow / Stability Expert, Novartis Pharmaceuticals Corporation*

- About the Working Group
- Defining Shelf Life
  - Harmonized Guidance
  - Disharmonized Interpretation
- Terminology and Distributions
- It's All about Risk
  - Shelf Life and Risk
  - Characteristics of a "Good" Shelf Life Estimation Procedure
  - ICH and Beyond

3:30 PM – 4:15 PM

Criteria for Establishing Shelf Life of Cosmetic Products

Karl F. Popp, R. Ph., *Founder, KPopp Consulting, LLC.*

Last year's presentation encompassed the world of unclear regulations and many, many opinions on the stability testing of cosmetics. The question left unanswered was "What are the criteria for setting a use before date, expiry date, and /or period after opening for a cosmetic product?"

This presentation will discuss the salient aspects of establishing a point in time where a cosmetic product is no longer "suitable" to be in the marketplace. What tests are critical? What is an acceptable result? How long should a cosmetic product be stability tested? Do you need to prove your product works as claimed when first produced? at the end of its labelled life? when the package is full, half full, or almost empty? Is there a correlation between months of acceptable accelerated stability of a cosmetic product and setting of an expiry date?

Shelf life of a product is also impacted by many factors such as distribution and shipping, store presence, and, of course, how the consumer stores and uses the product.

Key regulatory criteria for a cosmetic product are that (a) they must be safe to use, (b) they must not be adulterated and (c) they must not misbranded. But, where does shelf life come into view? Industry practices will be shared along with examples for discussions purposes.

4:15 PM – 5:00 PM

ICH Q1E for estimating shelf life- shelf life statistics for non-statisticians

Patrick Forenzo, *Senior Fellow / Stability Expert, Novartis Pharmaceuticals Corporation*

- Demystify the statistical terms and concepts related to Shelf Life statistics
- Discuss poolability tests and resulting models using examples to demonstrate the concepts
- Cover examples of the effects of length of available study data and variability on the estimated shelf life
- Explore the ICH Q1E decision tree and its use in establishing the proposed shelf life vs the statistically estimated shelf life

5:00 PM – 5:30 PM

Panel Q & A

Kenneth C. Waterman, Ph.D., *President, FreeThink Technologies, Inc.*

Sean D. Benedik, *Principal and Subject Matter Expert, Aliquo Pharma Consulting Inc.*

Karl F. Popp, R. Ph., *Founder, KPopp Consulting, LLC.*

Patrick Forenzo, *Senior Fellow / Stability Expert, Novartis Pharmaceuticals Corporation*

Interactive Round Table Discussions

5:30 PM - Conclusion of Day 2

Preliminary Conference Agenda

Day 3 - Friday June 2, 2017

7:45 AM – 8:25 AM

Continental Breakfast and Exhibition Viewing

8:25 AM – 8:30 AM

Chair's Welcome Note

8:30 AM – 9:15 AM

Integrating Pharmaceutics, Analytics, and Biology to Develop Stable Biologics and Biosimilars

Zahra Shahrokh, Ph.D., *CMC Consultant, ZDev Consulting Chief Development Officer, STC Biologics, Inc.*

Development of a stable product begins with the molecule's design. Forgotten stability profiling often leads to the selection of a drug candidate that faces development hurdles and possibly barriers to commercialization. For Biosimilars, where the molecule's design is fixed and little is known of the originator's drug substance stability characteristics, unique challenges arise, requiring creative process engineering solutions.

In this talk case examples of stability challenges of biologics and biosimilars will be presented, with solutions that did or could have prevented slowed progress. An outline of best practices will be presented which integrates analytics, biology, and pharmaceutics.

9:15 AM – 10:00 AM

Analytical Investigations on GMP Release / Stability Testing Out of Alert, Trend and Specification Results

Peter I. Tattersall, Ph.D., *Principal Scientist, Chemical & Synthetic Development, Pharmaceutical Development, Bristol-Myers Squibb Company*

Analytical investigations are performed on out of alert, trend and specification (OOA, OOT and OOS) results as part of due diligence and policy for release of clinical/manufacturing material and formal stability studies. These investigations are part of a systematic framework of quality assurance that is fundamental to the quality and integrity of pharmaceutical products.

The outline of the presentation is:

- Industry guidance on OOA / OOT / OOS investigations
- Investigation workflow
- Steps for analytical investigations
- Root Cause, CAPAs, next steps and trending
- Setting alert limit criteria for registrational studies
- Case Studies from stability / reapproval testing
- Situation appraisals
- Investigation path and conclusions
- Learnings and corrective actions

10:00 AM – 10:15 AM

Mid-morning Refreshment Break & Exhibition viewing

10:15 AM – 11:00 AM

Design, Implementation and Calibration of GMP Controls for ICH Rooms

Glen McCarthy, P.Eng., *Founder and President , Labworks International Inc.*

Jacques-Marcoux, *Viking Technical Services inc.*

Critical to the successful operation of ICH rooms are controls which meet the requirements of GMP / ISO guidelines while being resilient and easy for operators to use correctly. This presentation will cover the design and operational requirements of control system for ICH Chambers with a focus on regulatory compliance, design for certification, redundancy, and maintenance. There will be discussion on the calibration of systems to meet ISO 17025 and GAMP Best Practice Guidelines.

Preliminary Conference Agenda

Day 3 - Continued

11:00 AM – 11:45 AM

Statistical Analysis (Stability Data)

Speaker information will be post shortly

11:45 AM – 12:00 PM

Panel Q & A

Zahra Shahrokh, Ph.D., *CMC Consultant, ZDev Consulting Chief Development Officer, STC Biologics, Inc.*

Peter I. Tattersall, Ph.D., *Principal Scientist, Chemical & Synthetic Development, Pharmaceutical Development, Bristol-Myers Squibb Company*

Glen McCarthy, P.Eng., *Founder and President , Labworks International Inc.*

Jacques-Marcoux, *Viking Technical Services inc.*

12:00 PM – 1:00 PM

Networking Lunch & Exhibition viewing

1:00 PM – 2:00 PM

Interactive Exercise – Interpretation of Stability Data

Geoff Carr, Ph.D., *Director, Analytical Development, Patheon Inc.*

In accordance with ICH Guidelines on Stability Studies, we need to present data in an orderly manner which is generally achieved in the form of trend tables. Statistical analysis is then applied to generate a proposal for product shelf life. However, as well as all this, a report should be generated that provides interpretations of the analytical results obtained. This session will provide an exercise in data interpretation

- Trend tables will be provided for up to 12 months real time data and 6 months accelerated data for a tablet product in 2 different packs
- Working in Groups the challenge will be to identify various results that require further attention or investigation
- Groups will be invited to suggest explanations for these observations
- Recommendations should then be proposed for ways to continue development to achieve a product that is suitable for marketing

2:00 PM – 2:45 PM

Testing for Packaging Failures during Stability Testing of Consumer Products

Karl F. Popp, R. Ph., *Founder, KPopp Consulting, LLC.*

Consumers of non-prescription and cosmetic products expect the product- package combination they purchase not to fail, especially when stored and used under the labelled conditions. We, as consumers, expect no less. The challenge to the product development scientist is selecting which tests to complete during the developmental product stability study to ensure data generated supports package will remain intact and function properly during its life cycle.

The types and number of tests one needs to perform on a package during stability testing depends on the package construction, design, directions for use, labelling, and storage conditions, both at retail and in the home. Packaging from glass and plastic bottles, foil and laminated pouches, to aerosols in glass, steel and plastic tubes, to individual use packs in a variety of materials have led to numerous challenges, and opinions, as to what confirms a product is acceptable to place on the market. No regulatory statute currently exists that speaks directly to package defects or what testing should be performed on a specific product-package configuration.

This presentation will discuss common tests used to verify the integrity and functionality of package formats common to both non-prescription and cosmetic products, and to some that are unique to their unique product category.

2:45 PM – 3:00 PM

Mid-Afternoon Refreshment Break & Exhibition viewing

Preliminary Conference Agenda

Day 3 - Continued

3:00 PM – 3:45 PM

Enhancing Shelf Life and Simplifying Package Design and Production for Transdermal and Oral Solid Dose Drug Delivery with Engineered Polymers for Head-Space Management

Craig Voellmicke, *Vice President, Business Development, Advisory board of the Active & Intelligent Packaging Industry Association (AIPIA) CSP Technologies*

Transdermal patches and oral solid doses are two very different drug delivery technologies that can face very similar packaging head-space challenges that impact shelf life; moisture, oxygen, VOC's and other gases can interact with drug product of either technology and impact stability.

Engineered polymers utilized within a pouch, blister packaging and standard bottles can be an effective and efficient head-space management solution, addressing a wide range of desiccant and scavenging needs, without the use of adhesives, purging, or drop-in sachets and canisters, among other benefits.

3:45 PM – 4:30 PM

Leveraging Stability Data for Cold Supply Chain Quality

Sean D. Benedik, *Principal and Subject Matter Expert, Aliquo Pharma Consulting Inc.*

Product knowledge and cycling stability data can save batches from unfavorable outcomes when excursions happen. This talk will discuss acquiring and interpreting the information you need to make science-based decisions.

Une bonne compréhension de votre produit et des données de stabilité aux extrêmes de température peuvent prévenir des dispositions de lot défavorables. Nous discuteront l'acquisition et l'interprétation de l'information nécessaire pour prendre des décisions scientifiques.

4:30 PM – 4:45 PM

Panel Q & A and Wrap Up

Geoff Carr, Ph.D., *Director, Analytical Development, Patheon Inc.*

Karl F. Popp, R. Ph., *Founder, KPopp Consulting, LLC.*

Craig Voellmicke, *Vice President, Business Development, Advisory board of the Active & Intelligent Packaging Industry Association (AIPIA) CSP Technologies*

Sean D. Benedik, *Principal and Subject Matter Expert, Aliquo Pharma Consulting Inc.*

4:45 PM

Conclusion of Conference

Note: Agenda is subject to change without notice. Please check back regularly for updates.

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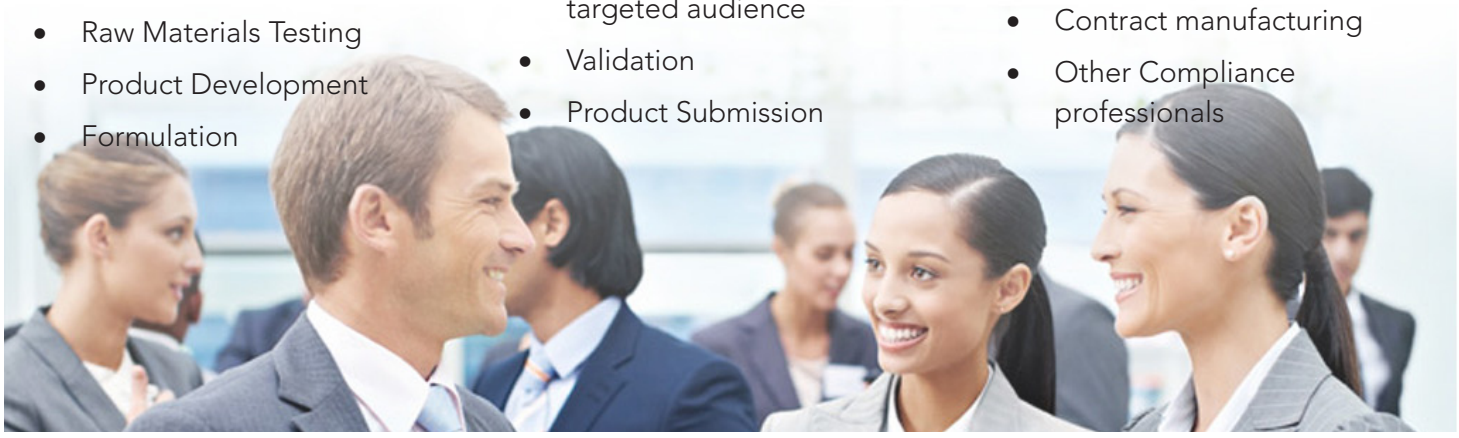
Interested in Exhibiting or Sponsoring at this event? Contact us at 416-410-7402 or enquiry@ipacanada.com

Who Should Attend

This 3 day conference is directed toward Directors, Managers, Supervisors, Analysts and Associates in the Pharmaceutical, Biotechnology, and allied industries with responsibilities in the following areas:

- Stability
- Analytical R&D
- Quality Control
- Quality Assurance
- Raw Materials Testing
- Product Development
- Formulation
- Chemistry, Manufacturing and Controls (CMC)
- Pre-Clinical Research
- Regulatory Affairs but targeted audience
- Validation
- Product Submission
- Documentation and Technical Writing
- Contract Laboratories
- Consultants
- Contract manufacturing
- Other Compliance professionals



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Call the hotel directly at the above number and mention you are attending
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Substitution of delegate/s with the member/s of the same organization is permitted at any time with no penalty.

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