AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS

Promoting Integrity • Quality • Trust Since 1923

Summit on Challenges & Solutions in Quality & Safety of Homeopathic Drug Products

9 a.m.–5 p.m., Friday, June 28, 2019
Hilton Baltimore

#SafetySummit

#Homeopathy

AMERICAN ASSOCIATION OF HOMEOPATHIC PHARMACISTS
Promoting Integrity · Quality · Trust Since 1923

Welcome to the AAHP Summit

Welcome to the AAHP Summit! The Summit was designed specifically for homeopathic manufacturers and our special challenges with high dilutions. Everyone in this room should be congratulated as a leader in the industry by coming together for an open exchange to solve our challenges.

We have a responsibility to produce products of the highest quality so that consumers and families across the U.S. and the world receive the full health benefits of homeopathy without safety risks or questionable reliability. To all the quality and regulatory staff here today with their top management, this should be your everyday mission: To minimize risk by manufacturing based on sound quality and safety principles.

AAHP has assembled the highest quality information on these topics in a format that is responsive to attendees needs and regulators expectations. Please make the most of this opportunity. Our discussions here will affect the future, providing retailers, practitioners and consumers better, safer, reliable products for their wellbeing.

Mark Land

AAHP President

8:00–9:00 a.m.	**Registration Open**		
9:00–10:00 a.m.	**Opening Session: Francis Godwin, Director, Office of Manufacturing Quality, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration**		
10:00–10:15 a.m.	**Morning Break (Networking Opportunity with JAHC Attendees)**		
10:15–11:45 a.m.	**Quality Track**	**Safety Track**	**Regulatory Track**
	Analytical Development Challenges in Homeopathy: Detect and Quantify Quality, and Toxicological Markers by Stéphanie Chanut, Boiron France	Best Practice Post Market Surveillance and the Ongoing Process of Monitoring, Assessing and Confirming Product Safety by Richard Kingston, PharmD, SafetyCall International, PLLC	Homeopathic Product Substantiation from Concept to Shelf by Amy Mozingo, MS, GRAS Associates LLC, A Nutrasource Company
11:45 a.m.–1:00 p.m.	**Networking Lunch**		
1:00–2:30 p.m.	Process Validation: What Is It for Homeopathic Products? by Eric Baier & Karl John Schottig, Hyland's, Inc., A division of Standard Homeopathic Co.	Industrial and Regulatory Toxicology Part I: Principles of Toxicology by Matthew D. Reed, PhD, DABT, Fellow ATS, Coelus LLC	Topics in Labels and Labeling by Eric L. Foxman, RPh AAHP
2:30–3:00 p.m.	**Afternoon Break (Networking Opportunity with JAHC Attendees)**		
3:00–4:30 p.m.	Moves Toward FDA Requirements: Establishing Homeopathic Finished Product Specifications and Shelf Life by Fanny Guillot, Boiron France	Industrial and Regulatory Toxicology Part II: Application of General Toxicology Studies to Support Regulatory Requirements by Matthew D. Reed, PhD, DABT, Fellow ATS, Coelus LLC	Enforcement Hot Topics: It's Not the 483, It's the Consumer by Mark Land, MS, RAC AAHP
4:30–5:00 p.m.	**Closing Session: Review by Track Leaders** George Bernstein, PhD, MAI Consulting, Inc. • Mark S. Phillips, Pharm.D., Standard Homeopathic Company Ann M. Begley, Morgan, Lewis & Bockius LLP		
5:00–6:30 p.m.	**Joint American Homeopathic Conference Opening Reception (cash bar)**		

Opening Keynote:

Francis Godwin, MBA, Director, Office of Manufacturing Quality, Office of Compliance, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

After receiving his undergraduate degree from MIT in Chemical Engineering in 2001, Francis Godwin worked as a process engineer designing, building, and optimizing chemical plants. In 2009 he received an MBA from Georgetown University and since then, has been working at FDA in CDER's Office of Compliance. Francis has served in various functions within compliance, and is currently the Director of the Office of Manufacturing Quality, overseeing regulatory and enforcement actions for both foreign and domestic drug CGMP cases.

AAHP Inaugural Industry Reception

5–7 p.m., Thursday, June 27

Hilton Baltimore Carroll Room overlooking Camden Yards

AAHP's special evening reception celebrates its inaugural Summit with senior executives from the homeopathic industry and other special guests. Remarks from thought leaders include:

- **Public Policy; What We Have Learned**
  Scott M. Melville is President and CEO of the Consumer Healthcare Products Association. He leads CHPA's efforts to preserve and expand choice and availability of consumer healthcare products. He was previously SVP of government affairs and general counsel for the Healthcare Distribution Alliance, has held public affairs and legal roles for Sterling-Winthrop, Hoffmann-LaRoche, and Cephalon, and has been a legislative assistant for a Member of Congress. He earned his bachelor's degree in economics and political science from Bucknell University, and his juris doctorate from George Mason University.

- **Business Report: State of the Homeopathic Retail Industry**
  Scott R. Emerson. Mr. Emerson is the founder and CEO of The Emerson Group and its subsidiaries, Emerson Healthcare and Emerson Marketing. The Emerson Group is a forward-thinking consumer products equity organization which manages CPG brands in excess of $4 billion, and holds equity positions with small and medium-size brands. (See sponsor section for company information.) Mr. Emerson has over 30 years' experience with companies including Johnson & Johnson, Unilever and Novartis Consumer Health. Prior to founding the Emerson Group, he has held senior management positions in Fortune 500 companies within brand management, new business development, sales operations and field sales. He received his B.A. in Accounting and Business Management from Texas State University.

- **Presentation of AAHP Interactive Medicine Award to Wegmans Food Markets, Inc.,** and remarks from recipient Karen Shadders, Vice President, Health, Wellness, Home & Entertaining. The award recognizes a retailer that promotes and sells products that encompass a broad range of therapeutic approaches to achieve optimal health and wellness for those consumers seeking to participate actively in their healthcare.

JACH Reception, Networking Breaks and Lunch

The AAHP Summit provides several opportunities to exchange ideas with fellow manufacturers, build relations with a retailer, or hear directly from practitioners and consumers attending the Joint Annual Homeopathic Conference.

Lunch (11:45 a.m.–1:00 p.m.): Self-served boxed lunches will be available. There are two choices:

- Chipotle grilled chicken on a Kaiser roll with cheddar, lettuce, tomato, chipotle aioli.
- Grilled vegetables and goat cheese with arugula on a gluten-free wrap.

Both boxed lunch choices include a penne primavera salad, sugar cookie, a whole fruit, and an individual bag of chips. An assortment of soft drinks and bottled water are also available.

Breaks and Reception with attendees from the JAHC: AAHP's two coffee breaks are coordinated with JAHC's breaks. Additionally, AAHP attendees are cordially invited to JAHC's cash bar reception, 5:00–6:30 p.m., Friday, June 28.

Workshop Choices
10:15–11:45 a.m.

Quality Track

Tubman A & B Meeting Rooms

Analytical Development Challenges in Homeopathy: Detect and Quantify Quality, and Toxicological Markers

Presented by Stéphanie Chanut, Pharmaceutical Development Laboratory Manager, Boiron (France)

The most frequently cited GMP deficiency during homeopathic facility inspections in 2018 was 21 CFR 211.160(b): "lack of scientifically sound laboratory controls." This workshop will review the presenter's research with various analytical methods applied to homeopathic active ingredients and dosage forms. Examples will be provided using case studies of the detection of alkaloids and other characteristic constituents in tinctures, dilutions and finished products.

What You Will Learn:

- Regulatory background of homeopathic drug products.
- Manufacturing techniques for finished products and the purpose of the analytical development.
- Detection, identification and quantification of analytical markers in tinctures.
- Analytical techniques from tincture to dilutions and finished products.

About the Presenter

Now in her 13th year at Boiron, Stéphanie Chanut manages a team responsible for analytical development, stability studies, and liquid and gas chromatography set-up. She previously worked as a Regulatory Affairs Manager Engineer at Boiron. Stéphanie started her career at Sanofi Pasteur and then Merck Generics in technical regulatory affairs.

Safety Track

Stone Meeting Room (Live Video)

Best Practice Post Market Surveillance and the Ongoing Process of Monitoring, Assessing and Confirming Product Safety

Presented by Richard Kingston, PharmD, President, Regulatory and Scientific Affairs, SafetyCall International, PLLC, & Clinical Professor of Pharmacy, University of Minnesota

Simply meeting regulatory requirements may not aid the manufacturer in the detection and mitigation of the most serious threats affecting a company's product and brand. This presentation reviews best practice post-market surveillance at a corporate level, and how implementation can aid in the detection, management, and mitigation of the most serious product safety threats a company may face.

What You Will Learn:

- Key principles behind Best Practice Post-Market Surveillance.
- Thinking outside the box in the application of safety signal detection.
- How to identify and separate "background noise" from emerging threats when analyzing spontaneously reported adverse events.
- How to package and communicate the adverse event experience into a positive product safety message.

About the Presenter

Dr. Kingston has 40 years' experience in clinical toxicology and pharmacology, poison control, product post-market surveillance, and drug and dietary supplement safety. He has helped shape national policy on a variety of critical issues related to product safety. Richard also co-founded SafetyCall after holding top leadership roles in academia and the Minnesota regional Poison Center where he gained critical care toxicology experience while practicing in a University-affiliated Level One Trauma Center.

Regulatory Track

Chase Meeting Room

Homeopathic Product Substantiation from Concept to Shelf

Presented by Amy Mozingo, MS, Director of Operations, GRAS Associates LLC, a Nutrasource Company

In light of FTC's disclaimer request, what can the homeopathic industry learn from the supplement industry? When bringing products to market, it is essential to build a platform that allows all information generated to be available for future use. Manufacturers and labelers will learn about factors in substantiating claims and which business partners are held responsible in the eyes of the law. FTC history and "no-nos" are reviewed before closing with a comparison of regulations for homeopathy in the U.S., Canada and the U.K.

What You Will Learn:

- Substantiation per FTC and FDA guidance.
- How to develop a substantiation file.
- What types of claims you can make.
- How to navigate the regulatory environment while still providing true homeopathic products.

About the Presenter

Amy Mozingo, MS, Director of Operations, GRAS Associates LLC, a Nutrasource Company, has more than 15 years of experience in industry and consulting related to FDA regulated products (food, supplements, cosmetics, homeopathic/OTC). She holds a certificate as a Preventive Control Qualified Individual and is trained and experienced in safety evaluations, ingredient approvals (GRAS, NDIN, FAP, CAP), product labelling, formulation reviews, claims substantiation and current good manufacturing requirements for dietary supplements.

Workshop Choices
1:00–2:30 p.m.

Quality Track

Tubman A & B Meeting Rooms

Process Validation: What Is It for Homeopathic Products?

Co-presented by Eric Baier, Senior Vice President, Regulatory and Technical Affairs, and Karl John Schlottig, Director, Process Validation, both at Hyland's Inc., a division of Standard Homeopathic Co.

Validation approaches changed with FDA's 2011 Guidance. Learn key differences between this guidance and previous practices. After a survey of the requirements, many of the unique challenges and considerations for homeopathic manufacturers will be discussed, including what you must know before you begin to develop a successful process validation program. This will include the pros and cons of different approaches to demonstrating the effectiveness and consistency of your processes to auditors.

What You Will Learn:

- Process validation defined (old vs. 2011).
- Process knowledge needed.
- How do I get what I need and trade-offs.

About the Presenters

Eric Baier has 25 years of experience in pharmaceutical manufacturing, validation, quality and technical roles. After working in injectables and biotech, Eric joined Hyland's in 1997 as Production Manager and has served as Plant Manager as well as Technical Director. He became the head of Quality at Hyland's in 2012.

Karl John Schlottig has held senior management positions for more than 20 years in manufacturing, validation, and quality at pharmaceutical and biotech companies such as Alpha Therapeutics and Genentech. Karl is skilled in global regulatory compliance; new manufacturing facility design, construction, commissioning and validation; and sterile product processing.

Safety Track

Stone Meeting Room

Part I: Principles of Toxicology

Presented by Matthew D. Reed, PhD, DABT, Fellow ATS, Principal, Coelus LLC

How do precedents for methods of determining safe human exposure and dose levels pertain to FDA's emphasis on certain botanicals with potentially toxic alkaloids? Matt's presentation will prepare you and your staff with the background and information necessary to understand and perform in-house confirmation of the HPUS first OTC attenuations in line with international assessment standards, so you can be certain your products are safe for sale to consumers.

What You Will Learn:

- Overview of risk assessment principles.
- Basic tenets of toxicology T=testing.
- Program design considerations.
  - o General regulations and guidelines (pharmaceutical examples).
  - o Species selection.
  - o Specific chemical/product class/use.
- Study design considerations.
  - o Specific design parameters.

About the Presenter

Matt Reed is the Principal and CEO of Coelus LLC where he facilitates full phase development of pharmaceutical IP and provides consulting services in toxicology, pharmacology, and hazard assessment. Dr. Reed is a pharmacologist, board certified toxicologist, ABT Board Member, and Fellow-Academy of Toxicology Sciences. He has more than 25 years' experience in transitioning multiple R&D programs through regulatory registration milestones.

Regulatory Track

Chase Meeting Room

Topics in Labels and Labeling

Presented by Eric L. Foxman, RPh, Regulatory Consultant, Secretary for American Association of Homeopathic Pharmacists, and Senior Scientist for Homeopathic Pharmacopeia Convention of the United States

FDA's draft guidance states the agency's enforcement actions will focus on various types of products, including those associated with otentially significant safety concerns; those intended for the prevention or treatment of serious and/or life-threatening diseases and conditions; and those intended for vulnerable populations. Learn how to minimize risk in these categroies.

What You Will Learn:

- OTC label format and content requirements.
- Self-medication vs. prescription indications disease claims:
  - o Limits of self-medication.
  - o Range of self-medication indications.
  - o Implications on non-self-limiting indications on a consumer product.
- See wording and promtional presentation that FDA has flagged recently to help you set label guideposts.
- Review of standard regulatory labeling requirements.

About the Presenter

Eric L. Foxman, RPh, has been actively engaged in the homeopathic industry for more than four decades, both on the manufacturing/laboratory side and on the regulatory/consulting side. He brings his years of experience working with both domestic and overseas manufacturers and clients to address labeling issues of critical importance.

Workshop Choices
3:00–4:30 p.m.

Quality Track

Tubman A & B Meeting Rooms

Moves Toward FDA Requirements: Establishing Homeopathic Finished Product Specifications and Shelf Life

Presented by Fanny Guillot, Regulatory Affairs Officer, AMM (marketing authorization) Development Unit, Boiron (France)

Homeopathy is a singular drug product with singular challenges. Globally, regulatory officials are drawing upon successful marketing authorization requirements from different parts of the world. Fortunately, this convergence of different interpretations and viewpoints is creating a consistent manner helpful to all involved. Manufacturers and private labelers can also use global synergies to demonstrate quality and safety to U.S. health authorities.

What You Will Learn:

- Regulatory framework for specifications and shelf life.
- Proposed approach through Europe for homeopathic dilutions and finished products.
- Establishing specifications for a homeopathic finished product; pharmacotechnical parameters.
- Transposition for stability evaluation of dilutions and finished products.
- A regulatory approach in the context of FDA's new dynamic to provide guarantees as regarding the quality of homeopathic finished products.

About the Presenter

As Boiron's regulatory affairs officer, Fanny Guillot has a global perspective of evaluating if products in a wide variety of therapeutic categories meet regulatory requirements for distribution in more than 50 countries. Specializing in regulatory requirements throughout the life cycle of health products, Fanny joined the global headquarters of Boiron two years ago.

Safety Track

Stone Meeting Room

Part II: Application of General Toxicology Studies to Support Regulatory Requirements

Presented by Matthew D. Reed, PhD, DABT, Fellow ATS, Principal, Coelus LLC

Public safety is FDA's top priority, as it should be for manufacturers too. Building upon the previous Safety Workshop, Dr. Reed will detail how toxicology is utilized to determine safe starting doses for human use comparing and contrasting pharmaceutical and homeopathic approaches. Is your company worried about potential litigation regarding the safety of your products? Matt's presentation will equip your company with the tools and background to make a rational and science-based justification that your products are safely formulated for sale to consumers.

What You Will Learn:

- Principles of toxicology testing applied to product development.
- How these methods are used to support safe human starting doses.
- Comparing and contrasting pharmaceutical and homeopathic approaches

About the Presenter

Matt Reed is the Principal and CEO of Coelus LLC where he facilitates full phase development of pharmaceutical IP and provides consulting services in toxicology, pharmacology, and hazard assessment. Dr. Reed is a pharmacologist, board certified toxicologist, ABT Board Member, and Fellow-Academy of Toxicology Sciences (ATS). He has more than 25 years' experience having successfully transitioned multiple R&D programs through regulatory registration milestones.

Regulatory Track

Chase Meeting Room

Enforcement Hot Topics: It's Not the 483, It's the Consumer

Presented by Mark Land, MS, RAC, President of American Association of Homeopathic Pharmacists and Vice President of Government & Regulatory Affairs, Boiron USA

FDA's draft guidance is a shift from a compliance policy guide to risk-based enforcement. This workshop will identify areas in which you can properly understand the aims of a pharmaceutical quality system and reduce their risk through an analysis of warning letters, import alerts, inspection citations and recalls. The statistics will provide insight on the agency's enforcement approach and priorities. FTC activities will also be examined.

What You Will Learn:

- Quality systems best practices, checklists, and profiling to prepare for your next inspection.
- Post-inspection programs to reduce risk.
- FDA inspection trends (e.g., inspection frequency, observations vs. enforcement, domestic vs. international action).
- Where lie the hot topics: data integrity, analytical methods, process validation, adverse event reporting, non-self-limiting indications or supplier management.
- Cost of non-compliance.

About the Presenter

AAHP President Mark Land is also V.P. of Government & Regulatory Affairs for Boiron USA, where he has worked in the homeopathic pharmaceutical industry for 39 years. He volunteers as the Chairman of the Monograph Review Committee for HPUS. His expertise is in legal and regulatory issues, manufacturing, quality control and distribution of homeopathic products.

Closing Keynote Speakers

A review of the day's key learnings will be summarized by the Summit's Track Leaders. This briefing of all issues is especially educational for companies with only one representative at the Summit who cannot attend all tracks. For others, the overview is a last chance to clarify concepts or interact with the following industry experts.

Track Leaders

AAHP Summit attendees will gain valuable insight on quality, safety and regulatory issues in workshops developed under the guidance of three experts. The limited-seating workshops also provide easy access to these notable professionals for specific questions.

Quality Track Leader

George Bernstein, PhD

President, MAI Consulting, Inc.

www.ConsultMAI.com

Dr. Bernstein's expertise ranges from GMP compliance, facility design, construction, and commissioning to business process re-engineering and process optimization. He has developed global quality standards (GLP, GCP, GPP) for a major international pharmaceutical company, and has assisted many clients with audit preparation, remediation activities, and communications with FDA. And for 30 years, his family (including pets) have used homeopathic medicines.

Safety Track Leader

Mark S. Phillips, Pharm.D.

Vice Chairman, Standard Homeopathic Company

www.Hylands.com

Beyond his technical, strategic and advisory contributions at SHC, Mark Phillips is an active leader in AAHP and the Homeopathic Pharmacopoeia Convention of the United States. A third-generation homeopathic pharmacist, he has guest lecturered on Homeopathic Pharmacy at his alma matter, the University of Southern California School of Pharmacy, and has authored and presented accredited CE programs to numerous state and professional pharmacy organizations.

Regulatory Track Leader

Ann M. Begley

Partner, Morgan, Lewis & Bockius LLP

www.MorganLewis.com

Based in Washington D.C., Ann Begley advises clients on FDA and FTC legal and regulatory issues relating to drug, cosmetic, dietary supplement, food, and medical device products — specializing in OTC drugs and clinical research matters. She has represented many clients in connection with FDA and FTC enforcement actions/inquiries, as well as competitor challenges before the Better Business Bureau's National Advertising Division.

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The Emerson Group

www.EmersonGroup.com

The Emerson Group is a consumer products equity organization focused on accelerating mid-market brand growth. It also operates internationally, providing partners in the European, South American and Asian Pacific regions with the expertise and infrastructure necessary to successfully operate in the U.S. market. An Emerson Group division, Emerson Logistics is a consumer products logistics solutions provider. A third division, Emerson Marketing, is an analytics and insights-based consumer products communications organization.

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Boiron

www.BoironUSA.com

In 1932 in Lyon, France, twin brothers and pharmacists Jean and Henri Boiron set out to develop a way to prepare reliable homeopathic medicines for their patients. Today Boiron continues as an independent pharmaceutical laboratory that prides itself on quality manufacturing and responsible environmental practices. We are passionate about integrating the benefits of homeopathic medicine into daily life.

Hyland's Inc.

www.Hylands.com

Founded in 1903 and dedicated to supporting the health and wellness of families, Hyland's is a leading homeopathic company in North America and a top natural OTC brand. Hyland's products have been shared by families for generations. Hyland's medicines are prepared with the highest quality active ingredients and follow strict standards of preparation.

MAI Consulting, Inc.

www.ConsultMAI.com

MAI Consulting Inc. in Chapel Hill, N.C., helps homeopathic manufacturers prevent inspection problems before they arise and address existing compliance issues. As a pharmaceutical consultant, Dr. George Bernstein, PhD, works to improve the efficiency, compliance, and quality of small, medium, and large domestic and global allopathic and homeopathic companies.

Matrixx Initiatives, Inc.

www.Zicam.com

Matrixx Initiatives has been engaged in the development and marketing of better ways to feel better through over-the-counter health care products for over 20 years. Matrixx Initiatives manufactures and markets Zicam® brand homeopathic OTC products, including its clinically proven homeopathic ZICAM Cold Remedy Nasal Spray and Swabs and Cold Remedy RapidMelts®.

Nelsons

www.Nelsons.net

Nelsons is the U.K.'s leading manufacturer of natural health care products, with a long-standing commitment to supplying the highest quality natural health care products that meet all regulatory and quality standards. Since 1995, Nelson Bach USA Ltd has been the sole North American distributor of RESCUE REMEDY®, BACH® Original Flower Remedies and SPATONE®.

Similasan Corp.

www.SimilasanUSA.com

Similasan is dedicated to helping families feel good about feeling better. Our natural remedies provide temporary symptomatic relief from ailments of the eyes, ears, nose, head, and chest. Originating in Switzerland in 1980, the Similasan brand became popular across Europe. Today, Similasan remedies are widely used and well-respected in North America.

Event Supporters

Eric L. Foxman Consulting

https://sites.google.com/site/ericlfoxman/home

Using in-depth expertise from decades of positions within HPCUS and AAAP, Eric Foxman, RPh, offers private consultations to find solutions to our industry's special compliance challenges. Eric helps companies comply in the areas of labeling design/text, with the HPUS, and cGMP through reviews of literature, protocols, and manufacturing technologies. He is also available to serve as a spokesperson in these areas.

Coelus LLC

www.CoelusBio.com

Our staff conceptualizes and facilitates early to late phase development of pharmaceutical intellectual property and provides consulting services in integrated drug development strategies, toxicology, and pharmacology. We specialize in applying our expertise to pharmaceutics, due diligence, pharmaceutical-related government grants and contracts, inhaled drug development, inhalation and general toxicology, and human health hazard assessment.

CPG Linkages, LLC

www.CPGlinkages.com

Connecting senior-level association, manufacturer and retailer executives through targeted 1:1 meetings, annual industry overviews, conferences and other opportunities to drive mutual business growth.

Morgan, Lewis & Bockius LLP

www.MorganLewis.com

The Washington, D.C. office of our global law firm specializes in the law involving the intersection of business and government. Many of our lawyers are former senior government officials and our nationally recognized talent includes a former FTC chairman. Our lawyers interact daily with agencies of the government on FDA, healthcare, and life sciences issues, and much more.

Nutrasource

www.Nutrasource.ca

Nutrasource is your one-stop shop for health product development and market entry services — from concept to claim. Through our vertically-integrated service platform, we offer full regulatory, clinical, and testing solutions for products ranging from dietary supplements to pharmaceuticals in Canada, the U.S., and Europe.

SafetyCall International, PLLC

www.SafetyCall.com

Founded in 2004, SafetyCall is the world's largest 24/7 Adverse Event call center, and a leader in Adverse Event Management and Post-Market Surveillance services. We provide immediate access to clear and trusted health, safety, and medical information to clients and their customers. Our clients range from dietary supplements to industrial products to animal health products.

Van Scoyoc Associates

www.VSAdc.com

VSA is a bipartisan, bicameral government relations firm with talented and experienced policy experts, who provide comprehensive and strategic services encompassing all aspects of the federal process. VSA's experts have hundreds of years of combined experience and bring an insider's knowledge of Capitol Hill and the Executive Branch.

Attendees of the AAHP Reception and Summit

AmerisourceBergen
- Doug Trueman, V.P., Consumer Products
- Jim Beck, Director

Boiron
- Alissa Gould, Dir., Corp. Comm. & Public Affairs
- Fanny Guillot, Manager, Regulatory Affairs
- Gary Wittenberg, V.P., National Accounts
- Janick Boudazin, President & CEO
- Kristina Skowronek, Dir., Quality & Regulatory Compliance
- Mark Land, V.P., Government & Regulatory Affairs
- MaryEllen Tefft, Director of Sales-FDM
- Melissa Boyle, Regulatory Administrative Specialist
- Ray Petrick, Vice President of Sales
- Scott Bradley, Regional Account Manager, Mid-Atlantic
- Scott Osborne, Dir., Strategic Account Development
- Stacey Kelly, Quality Assurance Manager
- Stephanie Chanut, Analytical Methods Dev. Lab. Mgr.

Brandperx
- Mark Collins, National Account Director

Coelus, LLC
- Matthew Reed, Principal

Consumer Healthcare Products Association
- Barbara Kochanowski, Sr., V.P., Regulatory & Scientific Affairs
- Jay Sirois, Sr. Dir., Regulatory & Scientific Affairs
- Scott Melville, President & CEO

CPG Linkages, LLC
- Ted Peterson, President

Customer Marketing Group
- Bruce Montgomery, General Manager

ECRM
- Wayne Bennet, Sr., V.P., Retail

Eric L. Foxman Consulting
- Eric Foxman, AAHP Secretary

FDA Connect
- Leonard Krause, President

GRAS Associates LLC, a Nutrasource Co.
- Amy Mozingo, Director of Operations

Guna Spa
- Alan Lucero, U.S. Agent
- Sofia Pizzoccaro, Regulatory Affairs Director
- Stella Pizzoccaro, International Sales Manager

Hahnemann Labs, Inc.
- John Feiseel

HBC Naturals
- Guillaume Lois, CEO

Homeopet
- Aindriu Farrington
- Ingrid Semino, Supply Chain Manager

Informa (*Pink Sheet* and *HBW Insight*)
- Eileen Francis, Reporter
- Malcolm Spicer, Consumer Health Writer

Little Big Brands
- Katie Littlefield, Business Development Acc. Dir.
- Katie Lopez, Account Director

Lorman Law DC
- Al Lorman

MAI Consulting, Inc.
- George Bernstein, President
- Jan Owens

Matrixx Initiatives
- Arlene Ascarate, Director of R&D
- John Clayton, Regulatory Consultant
- Lou Fraser, Director of Quality Assurance
- Tim Clarot, Sr., V.P., R&D and Product Quality

Medinatura Inc.
- Cathy Raish, V.P., Regulatory/Quality
- Elena Elliott-Hind, QC Lab Manager

Miers Laboratories
- Andrew Criglington
- Michael Dong

Morgan Lewis & Bockuis
- Ann Begley, Partner

Nartexlabs
- Eduardo Acosta, CEO

National Association of Chain Drug Stores
- Jim Whitman, Sr., V.P., Member Programs & Services

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- Sara Miyasaki, Regulatory Affairs Supervisor

Nelson Bach USA Ltd.
- Carol Wasteneys, Regulatory and Quality Mgr.
- Denise Eaton, Bach Brand/Education Mgr.
- John Ende, General Manager

OHM Pharma, Inc.
- Justyna Mazur, Dir., Regulatory Compliance
- Robert Melo, President

Procter & Gamble
- Adrian Land

Propulsora de Homeopatia
- Javier Lopez
- Jesus Navarro, CEO

RB Health
- Donna Alvarez, Senior Regulatory Associate

Racher Press *(Chain Drug Review)*
- Andrea Fallin, Director
- Mark Baumgartner, Senior Editor

Similasan Corp
- Dan Quail, President
- Kimberly Stark, Dir., Quality & Regulatory Affairs
- Yann Pigeaire, Vice President, Marketing

Standard Homeopathic/Hyland's
- Alison McPeak, Manager, Pharmacy
- Jay Borneman, CEO
- Les Hamilton, President
- Mary Borneman, Sr. Dir., Comm. & Public Affairs
- Eric Baier, Sr. V.P., Regulatory & Technical Affairs
- John Karl Schlottig, Director of Process Validation
- Mark Phillips, Vice Chairman
- Stephen Reta, Regulatory Affairs Manager

Tec Labs
- Mary Cha, Regulatory Affairs
- Nikki Frum

Terravitals R
- Navid Pezeshkzad, Homeopathic Consultant

The Emerson Group
- Scott Emerson

The Markens Group
- Brian Westerlind, Communications Manager
- Emily Leonczyk, Director of Marketing

TRP Company
- Stephen Pike, Supply Chain Strategist

U.S. Food and Drug Administration
- Francis Godwin, Director, OMQ
- Elizabeth Kelley, Regulatory Counsel
- Tamara Ely, Consumer Safety Officer

Van Scoyoc Associates
- Pete Evich, Vice President

Washington Homeopathic Products
- Belle Noorzai, Dir., Sales & Marketing
- Linda Lillard, President
- Wais Noorzai, Quality Assurance Manager

Wegmans Food Market, Inc.
- Katie Niles, Healthcare Category Merchant
- Karen Shadders, V.P., Health, Wellness, Home & Entertaining

Weleda, Inc.
- Petra Augenstein

Whole Foods Market
- Lee Mayberry, Global Legal Regulatory Coordinator

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- Strategic Sales Planning
- Brand & Shopper Marketing
- Sales Operations Infrastructure
- Category Management
- Shopper Insights & Analytics
- E-Commerce Strategy & Management
- Comprehensive Syndicated Data

For additional information about the advantages of the Emerson Group call Roger Gravitte at 610.971.9600

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