May 17-18
Renaissance Hotel
Washington, DC

2018 RSQ
REGULATORY, SCIENTIFIC & QUALITY CONFERENCE

CONSUMER HEALTHCARE: INNOVATING FOR THE FUTURE

PROGRAM
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Nicholas Hall’s OTC New Directions
Nicholas Hall
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Welcome to CHPA’s 2018 Regulatory, Scientific & Quality Conference!

CHPA’s Regulatory, Scientific & Quality Conference (RSQ) brings together leaders from industry, regulatory authorities, and academia across the consumer healthcare landscape to focus on the self-care space. This year’s conference will focus on Consumer Healthcare: Innovating for the Future. Over the next two days, you’ll explore the key regulatory, scientific, quality, and legal issues impacting the consumer healthcare industry, including how to use new technologies, new ways of thinking, and new regulatory developments to advance consumer self-care.

Attendee Levels for Breakout Sessions

For our regulatory, product quality, and legal tracks, we have designated attendee levels to help you select the sessions most beneficial for you.

- **Beginner**—For the professional who is new to the industry and wants to learn basic or general information and best practices, or for those in the industry looking for a refresher on general topics.
- **Intermediate**—For the professional with 3-5 years of experience who has a general understanding of industry topics, but wants to learn more about specific topics.
- **Advanced**—For the seasoned professional with 10+ years of experience who wants to gain additional knowledge on a niche topic.

Connect with us on Twitter!

Join the conversation using #RSQ18.
PROGRAM
THURSDAY, MAY 17

DAY 1

7:30 a.m. – 5:00 p.m.
Registration
Grand Ballroom Foyer

7:30 – 8:30 a.m.
Continental Breakfast
Grand Ballroom Foyer

8:30 – 10:00 a.m.
Opening Session
Grand Ballroom

Welcome
Speaker:

Barbara A. Kochanowski, M.S., Ph.D.
Senior Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

Overview of Regulatory, Scientific & Quality Conference (RSQ)
Speaker:

Michael Bailey, M.B.A.
Head of Regulatory Affairs, North America and Rx-OTC Switch
Pfizer Consumer Healthcare and Chair, RSQ Program Committee

Regulatory & Scientific Affairs Committee (RSAC) Chair Report
Speaker:

Greg Collier, Ph.D.
Global Director, Healthcare Product Safety and Regulatory Affairs
The Procter & Gamble Company
Product Quality Manufacturing Committee (PQMC) Chair Report

Speaker:

Bart D. Shrode, M.B.A.
Vice President, Quality Operations
Perrigo Company

FDA Update

Speaker:

Douglas C. Throckmorton, M.D.
Deputy Director Regulatory Programs
Center for Drug Evaluation and Research
U.S. Food & Drug Administration

Dr. Throckmorton will provide an update on FDA’s efforts in the areas of environmental regulatory science and combatting the opioid crisis, as well as other key regulatory initiatives that are relevant to our industry.

10:00 – 10:30 a.m.
Refreshment Break
Grand Ballroom Foyer

Sponsored by Concentrics Research

10:30 – 11:30 a.m.
General Session: How Branding Impacts Consumer Decisions
Grand Ballroom

Moderator:

Greg Collier, Ph.D.
Global Director, Healthcare Product Safety and Regulatory Affairs
The Procter & Gamble Company
Speaker:

Kevin Keller, Ph.D.
E.B. Osborn Professor of Marketing
Tuck School of Business
Dartmouth College

Building on an understanding of OTC consumer choice and shopping experiences, Dr. Keller will offer some key principles for OTC branding.

11:30 a.m. – 1:00 p.m.
Luncheon
Congressional A&B

1:00 – 2:15 p.m.
Quality Session #1
Drug Dosage Form and Stability Modeling Innovations in the OTC Market
Mount Vernon Square A

Attendee Level: Intermediate/Advanced

Moderators:

Bart D. Shrode, M.B.A.
Vice President, Quality Operations
Perrigo Company

Aditya Dinge, Ph.D.
Process Development Scientist
Bayer HealthCare LLC
This session explores innovative and alternative dosage forms for the OTC market. Attendees will learn about overcoming technical challenges to make confectionary forms into OTC drug products (gums, gels, lozenges). These developments are directed to meet consumer needs like fast acting or easy to swallow dosage forms. Advanced stability modeling using ASAPprime software approaches that could be applied to these novel dosage forms to improve timing to bring to market, as well as experiences with traditional dosage forms will also be demonstrated.

1:00 – 2:15 p.m.
Regulatory/Science Session #1
The Evolution of Self-Care
Grand Ballroom

Moderator:

Cmdr. Daniel Brum, Pharm.D.
Chief, Project Management Staff
Office of Drug Evaluation IV/Division of Nonprescription Drug Products
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Speakers:

Bakul Patel, M.S., M.B.A.
Associate Director for Digital Health
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Tine Hansen-Turton, MGA, J.D., FCPP, FAAN
Executive Director
Convenient Care Association

Jenelle Sobotka, Pharm.D., FAPhA
Professor and Director, Online Certificate and Masters Programs in Pharmacy Leadership
James L. Winkle College of Pharmacy
University of Cincinnati

The self-care environment is rapidly evolving. What is the pharmacist’s role in counseling patients and delivering care? How is technology, including mobile apps, impacting consumer decisions? How does all of this impact the regulatory environment? This session will feature presentations and an interactive panel discussion with three experts on these topics.

1:00 – 2:15 p.m.
Legal Session
OTC Legal 101/201: Evolving Legislation—Changing Laws and Regulations Impacting OTC Products
Mount Vernon Square B

Moderator:

Carolyn Herrmann, Esq.
Deputy General Counsel
Consumer Healthcare Products Association
Speakers:

Todd Halpern, Esq.
Partner
Venable LLP

David J. Horowitz, Esq.
Partner
Hogan Lovells U.S. LLP

Raqiyyah R. Pippins, Esq.
Counsel
Arnold & Porter Kaye Scholer LLP

As regulatory and legal experts for OTC products, it is key to understand the laws and regulations impacting nonprescription medicines marketed in the U.S. While industry experts are familiar with the Federal Food, Drug & Cosmetic Act (FD&C Act), new statutes and policies have been enacted to ensure governmental oversight is up-to-date. At the end of this session, attendees will have a clear understanding of:

- The changing FDA regulatory requirements beyond the FD&C Act for OTC drug products (such as 21st Century Cures and PREA),
- The potential challenges and opportunities for nonprescription drugs should OTC monograph reform legislation become law, and
- Best practices and avoidable missteps key to maintaining regulatory compliance.
2:15 – 2:45 p.m.
Refreshment Break
Grand Ballroom Foyer

Sponsored by

2:45 – 4:00 p.m.
Quality Session #2
From Icebox to Oven: OTC Products and Temperature Fluctuations Throughout the Supply Chain
Mount Vernon Square A
 Attendee Level: Intermediate/Advanced

Moderator:

Lillian M. Tan
Manager, North America Analytical Outsourcing & Offshoring Governance/Compliance/Central Testing Team
Johnson & Johnson Consumer, Inc.

Speakers:

Jing Capucao, Ph.D.
R&D Stability Manager
Johnson & Johnson Consumer, Inc.

Steven A. Greer
Corporate Quality Assurance External Engagement Leader
The Procter & Gamble Company
Attendees will obtain a perspective on good distribution practices and requirements per USP <659> and USP <1079>, and learn how OTC companies are developing quality systems around temperature control during distribution. Highlighting the session will be an industry survey on processes, experiences, and practices on product handling from distribution center to store shelf, focusing on temperature control issues and how they are resolved.

2:45 – 4:00 p.m.
Regulatory Session #2
Finding Your Way with MAPPs and Compliance Policies
Mount Vernon Square B

Attendee Level: Beginner

Moderator/Speaker:

Judy Doyle, M.S.
Director - Regulatory Affairs
Sanofi

Speakers:

Capt. Melissa Burns
Senior Program Manager
Office of Medical Product and Tobacco, Combination Products
U.S. Food and Drug Administration
Lost in a regulatory maze? Find your way with CDER MAPPs, agency compliance policies, and the FDA’s website! This session will provide an overview of how FDA uses MAPPs and compliance policies in their day-to-day work, and how industry can benefit from using them. Hear from agency experts as they discuss how regulators use the IND Development and Review, and Refuse to File MAPPs, and key points from the recently released compliance policy on post-marketing safety reporting requirements for combination products. Industry representatives will give suggestions for how to incorporate concepts from these documents into company procedures. The session will conclude with a demonstration of the FDA website to help you improve your navigational skills.
2:45 – 4:00 p.m.
Regulatory Session #3
The Consumer Study Experience: “Choose Your Own Adventure”
Grand Ballroom

Attendee Level: Beginner/Intermediate/Advanced

Speakers:

Kimberly Anderson, M.P.H.
Vice President, Clinical Operations
PEGUS Research, Inc.

Russell D. Bradford, M.D., MSPH
Vice President, Medical Affairs
PEGUS Research, Inc.

Sarah Farnsworth, Ph.D.
Vice President, Scientific Affairs
PEGUS Research, Inc.

Amanda H. Pike-McCrudden
Social Science Analyst
Office of Drug Evaluation IV/Division of Nonprescription Drug Products
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
This highly interactive session will provide attendees with practical experience and understanding about consumer behavior research for OTC switch by following one or more key communication messages (for a single fictitious OTC candidate product) throughout the consumer research life-cycle. During this session, participants will:

- Learn how key indication, safety, and dosing messages from Rx labeling get translated to “consumer-friendly” Drug Facts label (DFL) language,
- Design intuitive, effective comprehension questions to assess consumer understanding of the DFL key communication messages, and
- See how the key communication messages tested in label comprehension help drive later consumer research (in studies like human factors, self-selection or actual use).

4:00 – 4:15 p.m.

Break

Grand Ballroom Foyer
4:15 – 5:15 p.m.
Keynote Session
The Great Rewrite
Grand Ballroom

Speaker:
Leonard Brody
Entrepreneur, Best-Selling Author and Emmy-Nominated Media Visionary

We are living in a unique moment in history, when revolutionary change in all sectors is occurring at a frenzied pace. This massive scale of disruption has understandably left organizations on shaky footing, struggling to engage consumers and employees alike and stay relevant. Those that learn to adapt, those that allow themselves to be “rewritten” for the modern day, will survive and prosper. Those that do not will collapse. Leonard Brody explains how to deal with the questions the future holds, and how organizations can harness the uncertainty they’re faced with and turn it into excitement, innovation, and success.

5:15 – 6:15 p.m.
Reception
Congressional A & B

Evening entertainment provided by

Band sponsored by

Band Members:
CHPA Member: Saul Gylys
FDA: Scott Abernethy, Dan Brum, Francis (Frank) Becker
USP: Tim (Mit) Greiner
7:00 – 10:00 a.m.
Registration
Grand Ballroom Foyer

7:00 – 8:00 a.m.
Continental Breakfast
Grand Ballroom Foyer

8:00 – 9:15 a.m.
Quality Session #3
Data Integrity in the OTC World
Mount Vernon Square A

Attendee Level: Intermediate

Moderator:

Catherine Vicente, M.S.
ERO Manager
Johnson & Johnson Consumer, Inc.

Speakers:

Jennifer D. Ahearn
Director of Regulatory & Compliance
Engineering Systems Inc.

Tom Himmelsbach, M.S.
North America Regional Quality Director
Johnson & Johnson Consumer, Inc.
This session will focus on recent inspection findings from firms regarding Data Integrity. Speakers from FDA, Industry, and GMP consulting practices will discuss best practices on data integrity (GMP, lab practices, data collection, electronic signatures, etc). Participants will hear a discussion of inspection findings and the expectations and impact of the new data integrity guidance.

8:00 – 9:15 a.m.

Regulatory Session #4

Considerations for Developing OTCs Using Drug Facts Labeling and Technology

Grand Ballroom

Attendee Level: Intermediate/Advanced

Moderators:

Doug Bierer, Ph.D.
President
Douglas Bierer Consulting, LLC

LaMont Bryant, Ph.D.
Worldwide Vice President, Regulatory Affairs
Ethicon, Inc., a Johnson & Johnson Company
OTC products must demonstrate that a consumer can correctly self-diagnose, self-treat, and self-manage the condition without the intervention of a health care professional. With innovative inputs to current prescription to OTC switch pathways, the goal of improving patient access to a wider range of nonprescription medications will be reached. In this session, attendees will hear from leading industry experts as they highlight key questions for consideration as sponsors develop R&D programs which use technology in conjunction with the Drug Facts label.
8:00 – 9:15 a.m.
Regulatory Session #5
Consumer Healthcare Advertising in the Age of Social Media
Mount Vernon Square B

Attendee Level: Beginner/Intermediate

Moderator:

Raqiyyah Pippins, Esq.
Counsel
Arnold & Porter Kaye Scholer LLP

Speakers:

Laura Brett, Esq.
Director, National Advertising Division
Council of Better Business Bureaus, Inc.

Mary K. Engle, Esq.
Associate Director of Advertising Practices
U.S. Federal Trade Commission

In order to compete in today’s marketplace, consumer healthcare product companies are increasingly using social media and influencers to reach their consumers. Understanding the laws and regulations concerning social media marketing is a necessity in order to successfully navigate the digital landscape. Hear directly from the regulators about their expectations, so you can avoid the pitfalls of litigation and enforcement actions.
At the end of this session, attendees will have a clear understanding of:

- Who or what an influencer is,
- The laws and regulations surrounding social media marketing, and
- What to expect when you are not compliant.

9:15 – 9:45 a.m.
**Refreshment Break**
Grand Ballroom Foyer

**Sponsored by**
Nicholas Hall’s
OTC>NewDirections
Where Innovation Meets Regulation

9:45 – 11:45 a.m.
**Closing Session**
Grand Ballroom

**Sponsored by**
The Emerson Group

**Online Retail and the Consumer Healthcare Industry: An Inside Perspective**

**Moderator:**
Scott Melville  
President and CEO  
Consumer Healthcare Products Association

**Speaker:**
Tom Furphy  
CEO and Managing Director  
Consumer Equity Partners
Everyone is talking about online retailers. How are they impacting the consumer healthcare marketplace now and what can we expect in the future? Tom Furphy, a former Amazon executive, will provide an insider’s view of the Amazon model and its potential. He’ll share his unique perspective on how the company innovates, how they approach new markets and businesses, and how they grow new categories once established. During this interactive session, Furphy will challenge attendees to raise questions and concerns specific to the regulatory, scientific, and quality community, and help frame how these issues might be addressed by Amazon as online retail evolves.

**Closing Panel**

**Moderator:**

**Michael Bailey, M.B.A.**  
*Head of Regulatory Affairs, North America and Rx-OTC Switch*  
*Pfizer Consumer Healthcare*

**Speakers:**

**Donald D. Ashley, J.D.**  
*Director, Office of Compliance*  
*Center for Drug Evaluation and Research*  
*U.S. Food and Drug Administration*

**Richard Cleland, Esq.**  
*Assistant Director, Advertising Practices*  
*U.S. Federal Trade Commission*
Theresa M. Michele, M.D.
Director, Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
U.S. Food & Drug Administration

Elizabeth Miller, Pharm.D.
Vice President, U.S. Regulatory Affairs
U.S. Pharmacopeial Convention

A distinguished panel of leaders from FDA, FTC, and USP will close out RSQ with an overview of their priorities and an interactive dialogue exploring existing and potential opportunities for collaboration.