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CONFERENCE OVERVIEW

Welcome to CHPA’s 2015 Regulatory, Scientific & Quality Conference in Washington, D.C.

Get ready to explore why collaboration, innovation, and quality are all equally powerful components in the “future of consumer healthcare” equation. Join hundreds of professionals from across the country to hear about the latest in regulatory, scientific, and product quality topics impacting the consumer healthcare products industry.

Enjoy joint sessions featuring keynote speakers, including experts from FDA and USP, plus breakout sessions to take a deeper dive into the regulatory, scientific, and quality disciplines. Expand your knowledge, take notes, and bring back actionable insights to the office!

CONNECT WITH US!

Join the conversation on Twitter using #RSQ15.
7:00 a.m. – 4:00 p.m.
Registration
Renaissance Ballroom Foyer

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

8:00 a.m. – 10:15 a.m.
Joint Opening Session
Renaissance Ballroom

Welcome

Speaker: Barb Kochanowski, Ph.D., Vice President, Regulatory & Scientific Affairs, CHPA

Overview of Regulatory, Scientific & Quality Conference (RSQ)

Speaker: Lisa Allgood, Director, North American Personal Health Care Regulatory, The Procter & Gamble Company [Chair, Regulatory, Scientific & Quality Conference Program Committee]

Regulatory & Scientific Affairs Committee (RSAC) Chair Report

Speaker: Greg Collier, Ph.D., Director, Global Regulatory, Safety & Analytical, Oral Care, Personal Health Care, and Fem Care, The Procter & Gamble Company [Chair, Regulatory & Scientific Affairs Committee]
Product Quality & Manufacturing Committee (PQMC) Chair Report

Speaker: Susan Beavis, Director, Regulatory Affairs – CMC, Johnson & Johnson Consumer Companies, Inc. [Co-Chair, Product Quality & Manufacturing Committee]

Collaborating for Greater Self-Care

Featuring leaders from the U.S. Food and Drug Administration (FDA), the U.S. Pharmacopeial Convention (USP), and the Consumer Healthcare Products Association (CHPA), this session will explore the collaborative roles these organizations play in the over-the-counter (OTC) medicine industry. Listen to a candid discussion on joint initiatives like USP and FDA monograph modernization to illustrate the importance of continued regulatory and industry partnership in advancing these efforts.

Speakers:

Scott Melville, President and CEO, CHPA

Ron Piervincenzi, Ph.D., Chief Executive Officer, USP

Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA
Moderator: Barb Kochanowski, Ph.D., Vice President, Regulatory & Scientific Affairs, CHPA

10:15 a.m. – 10:45 a.m.
Joint Refreshment Break
Renaissance Ballroom Foyer

Sponsored by Concentrics Research

10:45 a.m. – 11:45 a.m.
Joint Session
Renaissance Ballroom

Innovation and the Internet of Things

Some believe the future will look like more of the same—more smartphones, tablets, and screens embedded in every conceivable surface. David Rose has a different vision: technology that atomizes, combining itself with the objects that make up the very fabric of daily living. David Rose’s body of work focuses on making the physical environment an interface to digital information. Join this session to explore how advanced technology will be used to drastically alter the future of healthcare and medicine.

Speaker: David Rose, CEO, Ditto Labs; Instructor, MIT Media Lab; and Author, “Enchanted Objects”

Moderator: Jim DiBiasi, Partner, 3D Communications
11:45 a.m. – 1:00 p.m.
**Joint Luncheon**
*Congressional Hall A-B*

1:00 p.m. – 1:45 p.m.
**Joint Session**
*Renaissance Ballroom*

**FDA’s Ongoing Quality Initiatives – An Outside Perspective from a Former Insider**

Join this session to hear from John Taylor, a former FDA insider, as he shares his views on the impact of FDA’s globalization efforts and ongoing quality initiatives on the OTC industry. Taylor will also discuss areas for potential collaboration between the agency and industry to advance current and future key projects aimed at ensuring consumers have access to safe, effective products.

**Speaker:** John Taylor, J.D., Principal, Compliance and Regulatory Affairs, Greenleaf Health LLC

**Moderator:** Lisa Allgood, Director, North American Personal Health Care Regulatory, The Procter & Gamble Company [Chair, Regulatory, Scientific & Quality Conference Program Committee]
1:45 p.m. – 3:15 p.m.

Regulatory & Scientific Session 1
Renaissance Ballroom

Innovative Methods for Understanding Consumer Behavior

Join this session to learn about new research methodology available to gain an understanding of consumer behavior. Hear about a variety of research methods used to examine how consumers parse the Drug Facts label, new methods to test consumer responses to innovative labeling concepts (such as icons), and how changes in consumers’ lifestyles impact the design of consumer behavior studies. Also, understand how eye tracking studies can be used to further understand how consumers use the product package to locate key label information.

Speakers:

Laura Bix, Ph.D., Associate Professor, School of Packaging, Michigan State University

Lanqing Liu, Graduate Student, School of Packaging, Michigan State University

Clark Richardson, President, Pegus Research, Inc.

Speaker & Moderator: Saul Shiffman, Ph.D., Senior Scientific Advisor, Pinney Associates, Inc.
1:45 p.m. – 3:15 p.m.
**Product Quality Session 1**
*Meeting Room 4*

**GMP: Process Capability Metrics**
Explore a pair of case studies to better understand process capability metrics and studies to meet specifications.

**Speakers:**

Edward Isidor, Manager, Process & Packaging Technology, Bayer HealthCare LLC

John Levins, Ph.D., Senior Director, Technology Transfer & Process Innovation, Pfizer Consumer Healthcare

Moderator: **Bart Shrode**, Vice President Quality Operations, Perrigo Company
1:45 p.m. – 3:15 p.m.
Product Quality Session 2
Meeting Room 5

Integrity of Supply Chain Initiative: Pragmatic Supply Chain Practices
Creating the world’s best products and efficiently delivering them to consumers is not possible without a robust supply chain. Explore industry best practices for supply chain security and maintenance. Plus, get a first look at the Xavier Supply Chain initiative.

Speakers:

Al Kentrup, Director, Corporate Quality, The Procter & Gamble Company

Marla Phillips, Ph.D., Director, Xavier Health, Xavier University

Moderator: Gretel Benavides, Vice President, Corporate Quality Systems & Compliance, Perrigo Company

3:15 p.m. – 3:45 p.m.
Joint Refreshment Break

Sponsored by PEGUS RESEARCH
3:45 p.m. – 5.15 p.m.
**Regulatory & Scientific Session 2**
*Renaissance Ballroom*

**Dietary Supplements and Probiotics**

This session will provide an update on the science behind probiotics and the role of probiotics in health, wellness, and disease prevention. Speakers will explore the challenges, opportunities, and practicalities of manufacturing and marketing a probiotic.

**Speakers:**

-Ray Matulka, Ph.D., Director of Toxicology, Burdock Group

-Robert Osgood, Ph.D., Associate Professor of Microbiology, Rochester Institute of Technology

-Arthur Ouwehand, Ph.D., R&D Group Manager, DuPont Nutrition & Health

-Cara Welch, Ph.D., Acting Director, Division of Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA

**Moderator:** Maria Petrey, Senior Regulatory Manager, US Personal Health Care Regulatory Affairs, The Procter & Gamble Company
3:45 p.m. – 5:15 p.m.
Product Quality Session 3
Meeting Room 4

Elemental Impurities in Pharmaceutical Products: Risk Assessment Strategies and Analytical Challenges

Gain an understanding from industry representatives on the challenges of testing products for elemental impurities, including analytical challenges and risk assessment approaches. Exchange ideas and share with your colleagues about how to work toward the implementation of the new elemental impurities requirements.

Speakers:

Danae Christodoulou, Ph.D., Acting Branch Chief, Office of New Drug Products, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, FDA

Wally Hirth, Ph.D., Principal Scientist, P&G OneHealth, The Procter & Gamble Company

Donna Seibert, Ph.D., Senior Principal Scientist, Perrigo Company

Moderator: Saul Gylys, Senior Director of Analytical R&D of Consumer Healthcare, Perrigo Company
3:45 p.m. – 5:15 p.m.
**Product Quality session 4**
*Meeting Room 5*

**Stability Studies: How to Predict the Future II**

In response to the success of CHPA's 2014 Stability Training Workshop: How to Predict the Future, this session will serve as a “sequel” and take a deeper dive into the predictive and statistical methods for product stability studies. Attendees will also learn about microbiology testing in stability programs.

**Speakers:**

*Scott Sutton, Ph.D., Principal, Microbiology Network, Inc.*

*Ken Waterman, Ph.D., President, FreeThink Technologies, Inc.*

**Moderator: Mary Seibel, Section Head, The Procter & Gamble Company**

5:15 p.m. – 6:15 p.m.
**Joint Evening Reception**
*Congressional Hall A-B*
FRIDAY, MAY 15

7:00 a.m. – 10:30 a.m.

Registration
Renaissance Ballroom Foyer

7:00 a.m. – 8:00 a.m.

Continental Breakfast
Renaissance Ballroom Foyer

8:00 a.m. – 9:30 a.m.

Regulatory & Scientific Session 3
Renaissance Ballroom

Innovation & OTC Medicines: An Agency Perspective

Join this session to hear from the agency officials leading initiatives that will impact future OTC medicines. Gain an FDA perspective on consumer behavior studies, as well as updates on key agency initiatives such as FDA monograph modernization and the Safe Use Initiative.

Speakers:

Theresa Michele, M.D., Director, Division of Nonprescription Drug Products, Office of Drug Evaluation IV, Center for Drug Evaluation and Research, FDA

Jim Stansbury, Ph.D., Social Science Analyst, Division of Nonprescription Drug Products, Office of Drug Evaluation IV, Center for Drug Evaluation and Research, FDA

John Whyte, M.D., Director of Professional Affairs and Stakeholder Engagement, Center for Drug Evaluation and Research, FDA

Moderator: Ed Hemwall, Ph.D., Vice President, Rx-to-OTC Switch Science, Bayer HealthCare LLC
8:00 a.m. – 9:30 a.m.
Quality Session 5
Meeting Room 4

Quality Matters: Defining Metrics, Clinical Relevance, and Organizational Culture

Hear from FDA and industry on current thinking about quality metrics, including challenges and potential solutions for implementation within the OTC industry.

Speakers:

Lawrence Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, FDA

Louis Yu, Ph.D., Executive Vice President, Global Quality, Perrigo Company

Moderator: Anne LeMoigne, Senior Director, Clinical Excellence and Biometrics, and Global R&D, Pfizer Consumer Healthcare
8:00 a.m. – 9:30 a.m.
**Quality Session 6**
*Meeting Room 5*

**USP Monograph Modernization**

Listen to insightful perspectives from USP, FDA, and industry about USP-OTC monograph modernization efforts.

**Speakers:**

*Jon Clark*, *Vice President, Chemical Medicines, USP*

*David Fay*, *Ph.D., Product Compliance & Support, Mallinckrodt Pharmaceuticals*

*Larry Ouderkirk*, *Senior Policy Advisor, Office of Pharmaceutical Quality & Office of Policy for Pharmaceutical Quality, Center for Drug Evaluation and Research, FDA*

*Moderator: Kylen Whitaker, Ph.D., Principal Scientist, The Procter & Gamble Company*

9:30 a.m. – 10:00 a.m.
**Joint Refreshment Break**
*Renaissance Foyer*
10:00 a.m. – 12:00 p.m.

Joint Closing Session

Renaissance Ballroom

Just One More Thing: State and Alternate Regulations' Impact on OTC Products

Proposition 65 laws and green chemistry laws are two examples of regulations beyond FDA requirements that impact OTC products. Just when manufacturers think they are adhering to every regulation and requirement, they learn there is "just one more" to follow. Join this session to learn about the plethora of regulations coming from states that must be considered for an OTC product to be offered in the retail marketplace.

Speakers:

Roger Bernstein, President, Spur Wheel Advocacy, LLC

Christopher Guay, Regulatory Fellow, North American Regulatory and Technical Relations, The Procter & Gamble Company

Moderator: David Silberstein, Executive Director, Regulatory Affairs, Valeant Pharmaceuticals

Update on Office of Manufacturing Quality

Speaker: Thomas Cosgrove, J.D., Director, Office of Manufacturing Quality, Office of Compliance, Center for Drug Evaluation and Research, FDA
FDA Leadership Update

Get an insider’s view from FDA leaders on their achievements, future initiatives, and issues affecting the OTC medicine industry.

Speakers:

Thomas Cosgrove, J.D., Director, Office of Manufacturing Quality, Office of Compliance, Center for Drug Evaluation and Research, FDA

Theresa Michele, M.D., Director, Division of Nonprescription Drug Products, Office of Drug Evaluation IV, Center for Drug Evaluation and Research, FDA

Lawrence Yu, Ph.D., Deputy Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, FDA

Moderator: Lisa Allgood, Director, North American Personal Health Care Regulatory, The Procter & Gamble Company [Chair, Regulatory, Scientific & Quality Program Committee]

Closing Remarks and Adjournment

Speaker: Lisa Allgood, Director, North American Personal Health Care Regulatory, The Procter & Gamble Company [Chair, Regulatory, Scientific & Quality Program Committee]
2015 RSQ PROGRAM COMMITTEE

Lisa Allgood, The Procter & Gamble Company [Chair]
Vincent Argiro, Prestige Brands Holdings, Inc.
Sue Beavis, Johnson & Johnson Consumer Companies, Inc.
Debi Chinsky, Colgate-Palmolive Company
Sue Coleman, NCI Consulting
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Paula Markert, GSK Consumer Healthcare
Lucy Owen, Pinney Associates, Inc.
John Punzi, Consumer Healthcare Products Association
Alina Salvatore, U.S. Food and Drug Administration
Bart Shrode, Perrigo Company
Dave Silberstein, Valeant Pharmaceuticals
John Wesley, Colgate-Palmolive Company
Mary Williams, Bayer Healthcare LLC
SPEAKERS
Lisa Allgood

Lisa Allgood is director, North American Personal Health Care Regulatory at The Procter & Gamble Company (P&G). Trained as a neurochemist at Columbia University and an immunocytochemist at the University of Medicine and Dentistry in New Jersey, Allgood has filled research, clinical, and regulatory roles at Merck and P&G over the last 31 years. Allgood is the chair of CHPA’s RSQ Program Committee.

Susan Beavis

Susan Beavis began her industry career on the Rx side of the business working at Sandoz Pharmaceuticals (now Novartis) as a formulation scientist in product research and development with subsequent progression through a series of positions in regulatory compliance. Since 1995, she has worked in the OTC industry, spending 10 years at Whitehall-Robins Consumer Healthcare (formerly Wyeth) in regulatory affairs before accepting her current position as director of regulatory affairs-CMC (Chemistry, Manufacturing, and Controls) at Johnson & Johnson Consumer Companies, Inc. She is a licensed pharmacist and has been actively involved with compendial issues throughout her industry career. She is a co-chair of CHPA’s Product Quality and Manufacturing Committee.

Gretel Benavides

Gretel Benavides is the vice president for corporate quality systems & compliance at Perrigo where she is responsible for driving the overall quality strategy, creating the programs for global quality, and developing sustainable quality systems throughout the organization. She has 30 years of experience in the pharmaceutical industry and has held positions of increasing responsibility in quality control as well as quality assurance for both generic and research-based pharmaceutical companies. Prior to joining Perrigo, Benavides was global VP of process excellence at Solvay Pharmaceuticals where she had responsibility leading international teams for global company wide programs for quality systems, validation, auditing, and GXP training. She holds a bachelor’s degree in chemistry from Georgia Southern University.
Roger Bernstein

Prior to launching his state affairs consulting firm, Spur Wheel Advocacy, LLC, Roger Bernstein served as vice president of state affairs at the American Chemistry Council (ACC). He staffed, designed, and implemented winning strategies on thousands of contested state and local legislative proposals. His impressive win rate included issues ranging from environmental health, product attacks, and taxes. His track record has established him as a widely recognized expert in designing and implementing effective and efficient tailored responses to policy challenges across the country, including those at the local level. He also guided ACC’s Political Mobilization program, bringing together members of Congress with their industry constituents in their respective states. Before embarking on a 30-year career in government and public affairs, Bernstein was a newspaper reporter in the Washington, D.C., area and an instructor at the University of Maryland’s University College. He holds a bachelor’s degree from Washington and Jefferson College and a master’s degree from Northwestern University.

Laura Bix

Laura Bix, Ph.D., is an associate professor at the School of Packaging at Michigan State University (MSU) and an adjunct associate at Clemson University. She specializes in healthcare packaging at MSU, where she has taught an array of classes and has been recognized with an Excellence in Teaching Award (2007). Bix has served as the U.S. expert to ISO/TC 122 WG9, a guideline aimed at creating inclusionary packaging for several years, and as the vice-chair of ASTM Committee D10.32, the committee on consumer, pharmaceutical and medical packaging, from 2004-2008. In 2008 she was named one of the Medical Device Industry’s most notable people by Medical Device and Diagnostic Industry magazine. During the last three years, she has served on expert panels convened by the Centers for Disease Control and Prevention (CDC) with the goal of reducing the number of unintentional medicine poisonings in children, as well as a national panel formed by the Gerontological Society of America (GSA) and CHPA that examined behaviors related to medication use in older adults.
Jon Clark

Jon Clark joined USP in 2013. As vice president of chemical medicines, he leads the development of new monographs in the United States Pharmacopeia-National Formulary. Clark’s background includes extensive experience working in the global pharmaceutical industry and with the FDA. For 10 years prior to joining USP, Clark served as associate director for program policy, Office of Pharmaceutical Science, in FDA’s Center for Drug Evaluation and Research (CDER). Clark holds a master’s degree in chemistry from Rutgers University and a bachelor’s degree in chemistry from University of Michigan.

Greg Collier

Greg Collier joined The Procter & Gamble Company (P&G) in 1986 as an analytical chemist in the Health and Personal Care Division and has spent his career at P&G within the Health Care and Oral Care Divisions. He has more than 20 years of experience in regulatory affairs. He is currently the global director of safety, regulatory and analytical for oral care and personal health care. During his career at P&G, Collier has participated on numerous CHPA task groups and conference planning teams. He was a steering team member on the FDA/CHPA seminar series since its inception and co-chaired the series for the past nine years. He recently assumed chairmanship of CHPA’s Regulatory and Scientific Affairs Committee succeeding Len Baum.
Thomas Cosgrove

Thomas Cosgrove is the director of the Office of Manufacturing Quality (OMQ) in the Office of Compliance within FDA’s Center for Drug Evaluation and Research (CDER). In this role, he directs CDER’s compliance activities with respect to CGMP and product quality. Before OMQ, he led CDER’s Office of Unapproved Drugs and Labeling Compliance (OUDLC), where he was responsible for FDA’s compliance divisions covering drug approval and labeling issues. Before joining CDER, Cosgrove was a litigator in FDA’s Office of Chief Counsel and prior to FDA, he was an attorney at Covington & Burling in Washington, D.C. He clerked for Judge Catherine Blake on the United States District Court for the District of Maryland and earned his law degree from The University of Michigan Law School.

Jim DiBiasi

Jim DiBiasi is a founding partner at 3D Communications, a strategic communications firm that prepares companies for high-stakes regulatory presentations, meetings, and media interviews. He is known for his ability to lead diverse teams and help them succeed at decisive communications opportunities. DiBiasi provides strategic and tactical communications counsel and coaching to top executives, scientists, and doctors at pharmaceutical, biotech, and device companies. He has guided scientists and executives through numerous regulatory communications, such as pre-NDA and IND meetings and challenging advisory committee meetings. He has been instrumental in developing 3D’s innovative, proprietary process and communications tools to help clients analyze their audiences and prepare for their communications in more effective ways. A gifted communicator, DiBiasi has practical experience in front of the camera and before live audiences. He has crafted and delivered hundreds of presentations and served as a legislative lobbyist and media spokesperson for Fortune 200 companies, leading them through numerous communications crises.
David Fay

David Fay, Ph.D., has worked in the pharmaceutical industry for 36 years. He is an analytical chemist trained at Iowa State University. His early involvement in an analytical laboratory serving all branches of the company led to a series of leadership roles in stability, R&D quality management, reference standards, and DEA compliance. Fay is currently a member of the USP Small Molecules 1 Expert Committee, a member of the recently formed Acetaminophen OTC Expert Panel, and past chairman of the Acetaminophen Expert Panel (2011 to 2014). He has been the USP Correspondent for Mallinckrodt Pharmaceuticals for 15 years. He also has served USP as a member of the Antivirals and Antimicrobials Expert Committee (2000 to 2010); the Reference Standards Project Team (2003); and the Reference Standards Expert Committee (2004 to 2010). He has been involved with CHPA working groups since 2011 on topics involving acetaminophen, OTC cough and cold medications, and monograph modernization.

Christopher Guay

Christopher Guay is a regulatory fellow in The Procter & Gamble Company’s (P&G) North American Regulatory and Technical Relations organization. His responsibilities span compliance with FDA food, drug, device, and cosmetic regulations; compliance with Drug Enforcement Agency requirements; North American product labeling; compliance with DHS plant and chemical security requirements, and California Proposition 65. Guay has been P&G’s Proposition 65 point person in both defending new listings and assuring compliance with listed chemicals since 1996. In this role, he has had to develop programs to help ensure products are compliant with Prop 65 requirements and create systems to educate and train employees and managers about Prop 65 and approaches for influencing proposed legislation, regulations, and chemical listings. Guay has degrees in chemical engineering, management, and finance.
Saul Gylys

Saul Gylys is senior director of analytical research and development of consumer healthcare at Perrigo. Gylys has more than 25 years of experience in the generic pharmaceutical industry. He is an active member of several committees within CHPA and was recently the chair of the CHPA Compendial Committee. Gylys has been an active member of various industry coalitions, including those dealing with guidelines for residual solvents, elemental impurities, and melamine. He has also been a member of select USP projects teams, including those for general chapters and compendial process improvements. He also was on the steering team for USP/FDA OTC Drug Substances and Drug Products Workshop, and is a nominated member of the USP Acetaminophen Expert Panel. He has been active in the USP Monograph Modernization initiative.

Ed Hemwall

Ed Hemwall, Ph.D., is a vice president at Bayer Consumer Care where he leads the RX-to-OTC Switch Science team. Prior to joining Bayer in 2014 he held a similar role at Merck Consumer Care. After completing an NIH fellowship in cardiology, he joined SmithKline & French Labs (now GSK) in 1983 as a basic researcher in cardio-renal pharmacology. This led to positions of increasing responsibility in clinical research, project management, and regulatory affairs. In 1993, he joined the regulatory affairs group at Merck, where he worked on a wide range of prescription and OTC programs. He was named in 1997 to lead the worldwide regulatory effort for the J&J-Merck Consumer joint venture. Hemwall has been a leader in several worldwide prescription and OTC drug development programs. He is currently the OTC industry representative on FDA’s Pharmaceutical Science and Clinical Pharmacology Advisory Committee. He is a former member of the board of directors of CHPA and served as chair of their Regulatory and Scientific Affairs Committee from 2003 to 2007. He received a B.S. from Penn State, and M.S. and Ph.D. degrees in pharmacology from Hahnemann Medical School (now part of Drexel University).
Wally Hirth

Wally Hirth, Ph.D., is a principal scientist at The Procter & Gamble Company (P&G) in the analytical global capability organization. He leads the P&G Compendial Compliance Forum and is responsible for corporate wide compendial compliance. Hirth has more than 25 years of pharmaceutical and medical device experience including as an analytical chemistry group leader, a QA group leader, and a regulatory affairs CMC manager. Hirth has authored and co-authored more than 30 journal publications and abstracts. Hirth received a bachelor’s degree in chemistry from Hanover College and a Ph.D. in analytical chemistry from the University of Cincinnati.

Edward Isidor

Edward Isidor is responsible for the process, packaging, and cleaning validation program at Bayer HealthCare’s primary solid dosage manufacturing site in the United States for consumer care products. Part of this responsibility is the incorporation of the most recent guidance regarding Continued Process Verification into this program for new and legacy products. Isidor has a bachelor’s degree in chemistry from the Richard Stockton College of N.J. and has held R&D, technical operations, and project management roles at various companies throughout his 19 years in the consumer care industry.
Anne LeMoigne has more than 20 years of experience in the pharmaceutical industry including consumer healthcare and switch programs across a wide variety of therapeutic areas. She joined Pfizer Consumer Healthcare in 2010. As the senior director of clinical excellence and biometrics, she is currently responsible for ensuring compliance to processes and quality standards, driving process improvements, and partnering with medical and regulatory to provide and review scientific content of regulatory submissions, and overseeing the design, execution, and reporting of clinical studies. She holds a Superior diploma in Biostatics from the Conservatoire Des Arts Et Métiers, Paris, France, and a Technical diploma from Vannes, France.

William A. (Al) Kentrup joined The Procter and Gamble Company (P&G) in December 2012 as director of corporate quality. He provides oversight and governance for all quality systems across all sectors of P&G businesses. Prior to joining P&G, he was vice president of quality for Sandoz (Novartis), North America where he provided quality leadership in remediation of the North America manufacturing sites. Additionally, while in this role, Kentrup was actively involved with the Rx360 industry consortium and completed a two-year term as vice chair. He has an extensive 31-year career in quality leadership positions having also worked at Pfizer (formerly Wyeth), Aventis, and predecessor companies. At Pfizer, he provided leadership in designing and implementing the Manufacturing and Supplier Quality Assessment organization. He began his career in 1982 at Merrell-Dow Pharmaceuticals as a quality control chemist. Kentrup holds a bachelor’s degree in chemistry from Northern Kentucky University.
Barb Kochanowski

Barb Kochanowski, Ph.D., is responsible for regulatory affairs activities, including cooperative programs with the FDA, ingredient safety, and dietary supplement programs at CHPA. Prior to joining CHPA in 2009, Kochanowski worked for more than 23 years in R&D at The Procter & Gamble Company, retiring in December 2008 as director, global personal health care, oral care, and feminine care product safety and regulatory affairs and corporate microbiology. She is experienced in pharmaceutical, medical device, and dietary supplement regulatory affairs, Rx-to-OTC switch, product safety, clinical research, and pharmacovigilance. Kochanowski is a member of the American Society of Nutrition. She also serves on the board of directors of the American Foundation for Pharmaceutical Education.

John Levins

John Levins, Ph.D., has worked for Pfizer since 2003 when he joined Wyeth’s Consumer Healthcare division as a member of the Global Technology Services team. Since then he has held a variety of leadership positions in the areas of technology innovation, new product tech transfers, co-development, and technical trouble-shooting. Levins has held previous positions in pharmaceutical development and API process development at other pharmaceutical companies. He also served for three years as an officer in the U.S. Army. He earned his bachelor and doctorate degrees in chemical engineering from Lehigh University and the University of Pennsylvania, respectively.
Lanqing Liu

Lanqing Liu received his master’s degree in packaging science at Michigan State University. He also obtained his bachelor’s degree in packaging in Beijing, China. He is a research assistant in the HUB (Healthcare, Universal Design, and Biomechanics) Laboratory working with Dr. Laura Bix on various projects. His research interests cover areas related to Human-Packaging Interaction (HPI), including packaging design, attentive behavior research, computer simulation, and virtual reality. His master’s thesis investigated older adults’ attentive behaviors and decision-making process during the over-the-counter drug selection.

Ray Matulka

Ray Matulka, Ph.D. is the director of toxicology at Burdock Group. Matulka has more than a decade of experience in the analysis of toxicity data and conducting safety and risk assessments. He earned a doctorate in toxicology from the Medical College of Virginia and has post-doctoral experience at both Boston University School of Medicine and the University of North Carolina. He has industry experience at the Nebraska Dept. of Environmental Control and as a senior genetic toxicologist at Genesys Research in North Carolina. He is co-author of two book chapters and has authored more than 30 publications since obtaining his doctoral degree. Matulka has experience presenting information to the FDA, USDA, and EPA. Among other responsibilities, Matulka is accountable for the development of consumption analysis and reporting, and offers guidance in strategic scientific business planning and critical decision making to Burdock Group clients in the food ingredient, health, and nutrition industries.
Scott Melville

Scott Melville is the president and chief executive officer of CHPA. With a diverse background in pharmaceuticals, association management, public policy, and law, Melville has advocated before Congress, FDA, state legislative and regulatory bodies, and the media. Prior to joining CHPA, Melville served as senior vice president for government affairs and general counsel for the Healthcare Distribution Management Association (HDMA). Before joining HDMA, Melville served as an attorney and head of government relations for Cephalon, Inc., and previously served in public policy and government affairs positions at Hoffmann-La Roche and Sterling Winthrop, Inc. Prior to joining the pharmaceutical industry, Melville served as legislative counsel and Appropriations Committee associate on the staff of former U.S. Congressman Jerry Lewis (R-Calif.). Melville earned his bachelor’s degree from Bucknell University, and his juris doctorate from George Mason University School of Law. He serves on the boards of the World Self-Medication Industry, the CHPA Educational Foundation, and the Food & Drug Law Institute.

Theresa Michele

Theresa “Terri” Michele, is the director of the Division of Nonprescription Drug Products (DNDP) within the Office of Drug Evaluation (ODE) IV. ODE IV, a division of FDA’s Center for Drug Evaluation and Research (CDER), is charged with reviewing imaging products and over-the-counter drug products. Michele, an FDA employee since 2007, was previously medical team leader in the Division of Pulmonary, Allergy and Rheumatology Products and has also served on the Chronic Fatigue Syndrome Advisory Committee at the Department of Health and Human Services.
Robert Osgood

Dr. Robert C. Osgood is an associate professor of microbiology at Rochester Institute of Technology and holds a Ph.D. in microbiology from the University of Southern Mississippi. After completion of the doctorate, Osgood was awarded and completed a three-and-a-half year postdoctoral fellowship in oral microbiology at the University of Alabama Birmingham, School of Dentistry. Presently at the Rochester Institute of Technology, Osgood conducts research in the area of oral microbiology where his focus is the development of rapid and precise quantitative methodologies designed to accurately count cariogenic organisms in oral samples. The other active area of his research is the study of biofilm formation of organisms of interest as well as those organisms that commonly cause middle ear infections in children. His research has yielded publications that appear in The Journal of Clinical Microbiology, The Journal of Dental Research, The Journal of Pediatric Dentistry, The European Journal of Oral Science, Caries Research, and Ultrasound in Medicine and Biology.

Larry Ouderkirk

Larry Ouderkirk is currently a senior policy advisor in the Center for Drug Evaluation and Research (CDER) Office of Pharmaceutical Quality (OPQ)/Office of Policy for Pharmaceutical Quality (OPPQ). In that capacity he helps to identify, create, and revise internal CDER policies and procedures dealing with all aspects of drug quality. Before coming to the new OPQ/OPPQ when it launched this past January, he worked for six years as a senior policy advisor in the CDER Office of Compliance/Office of Manufacturing and Product Quality (OMPQ). In that position, he helped to develop policy and guidance to support OMPQ programs, including its inspection and surveillance activities. Ouderkirk’s compendial experience comes primarily from his 11 years in CDER’s compendial operations staff working as a principal liaison to the US Pharmacopeia. Since 2010, he has co-chaired the agency’s Monograph Modernization Task Group and, more recently, the CDER OTC Modernization Working Group. These groups are tasked with assisting USP to prioritize and modernize compendial requirements for pharmaceuticals.
Arthur Ouwehand

Dr. Arthur Ouwehand is R&D group manager at Active Nutrition in Kantvik, DuPont Nutrition & Health, Finland. He has a research background in both academia and industry. His main interest is on functional foods; in particular, probiotics and prebiotics and their influence on the intestinal microbiota composition and activity. He is active in the International Life Sciences Institute Europe, the International Dairy Federation, the International Scientific Association for Probiotics and Prebiotics, the Global Alliance for Probiotics, and the International Probiotic Association. Ouwehand received his master’s degree (1992) in cell biology from Wageningen University (the Netherlands) and his Ph.D. degree (1996) in microbiology from Göteborg University (Sweden). In 1999 he was appointed to adjunct professor in applied microbiology at the University of Turku (Finland). Ouwehand is the author of more than 200 journal articles and book chapters. He is the editor of three books on lactic acid bacteria and the intestinal microbiota and co-inventor on 13 approved patents.

Maria Petrey

Maria Petrey is a senior regulatory affairs manager at The Procter & Gamble Company (P&G) Personal Health Care Division with more than 18 years of experience in the pharmaceutical and health care industry. Prior to joining P&G, Petrey worked at Eli Lilly and Company and Dow AgroSciences (previously Dow Elanco). She received her bachelor’s and master’s degrees in molecular and cellular biology at Indiana University and University of Cincinnati, respectively. She also received her Regulatory Affairs Certification from the Regulatory Affairs Professional Society. Petrey has broad regulatory expertise in prescription and OTC drugs, dietary supplements, conventional foods, and functional foods. In her current position, she provides regulatory guidance and training for various aspects of OTC drug and dietary supplement product development and lifecycle management such as labeling, claims, advertising and promotion, manufacturing, clinical/consumer trials, new drug development strategy, and regulatory submissions to FDA.
Ron Piervincenzi, Ph.D., is the chief executive officer of USP. He also serves as chair of the Council of Experts, USP’s scientific standards-setting body. For 12 years, Dr. Piervincenzi was a partner and leader in McKinsey & Company’s Global Pharmaceutical and Medical Products Practice where, among other responsibilities, he launched McKinsey’s global drug safety, medical, and regulatory service line. Most recently, as a VP in Development Sciences with Biogen Idec, he launched a new group (Value-Based Medicine) focused on applying tools and technologies of personalized medicine to the multiple sclerosis disease area. Piervincenzi earned his M.S. and Ph.D. from Duke University in biomedical engineering, with research focused on protein engineering. He is the founder of multiple non-profits in the community service and scientific spaces including serving currently as board chair for the Newark Mentoring Movement and the NextStep Translational Research Foundation.

Marla Phillips, Ph.D., is the director, Xavier Health at Xavier University. She began working in the pharmaceutical industry for Merck in 1996 as a senior project chemist in the Analytical Methods Development group. She quickly took on positions of increasing responsibility, culminating in the position of head of quality operations at the Merck North Carolina facility in 2000. In 2008, Phillips joined Xavier University as the founding director of Xavier Health, where she leads initiatives for the Pharmaceutical and Medical Device Industries. She works in conjunction with FDA and aligns the mission of Xavier Health with the strategic priorities of FDA. She holds a bachelor’s degree in chemistry from Xavier University, and a Ph.D. in organic chemistry from the University of North Carolina – Chapel Hill.
Clark Richardson began work in OTC consumer research in 1997, immediately after completing graduate studies in public health. Since those early days, his responsibilities have ranged from assistant project manager to SAS programmer, project manager, director of operations, vice president, and most recently president at PEGUS Research. After completing scores of OTC consumer studies (including numerous label comprehension, self-selection and actual use projects) for sponsors over the last 18 years, he brings a strong orientation toward process improvement, program strategy, FDA interaction, study design, analytic issues and solid, practical, high-quality research.

David Rose is an award-winning entrepreneur, author, and instructor at the MIT Media Lab. His research focuses on making the physical environment an interface to digital information. He is the CEO at Ditto Labs, an image-recognition software platform which scours social media photos to find brands and products. His new book, Enchanted Objects, focuses on the future of the Internet of things and how these technologies will impact the ways we live and work. Prior to Ditto, Rose founded and was CEO at Vitality, a company that reinvented medication packaging now distributed by CVS, Walgreens, and Express Scripts. He founded Ambient Devices, which pioneered glanceable technology: embedding internet information in everyday objects like lamps, mirrors, and umbrellas. He holds patents for photo sharing, interactive TV, ambient information displays, and medical devices. His work has been featured at the MoMA, covered in “The New York Times”, “WIRED”, “The Economist”, and parodied on the Colbert Report.
Mary Seibel

Mary Seibel is a section head in the One Health Sector at The Procter & Gamble Company (P&G). She leads the personal health care analytical department which includes the One Health Stability and Raw Materials capabilities. Seibel has more than 35 years of experience in clinical and R&D healthcare and more than 10 years in stability. She is a member of the USP Expert Panel on Organic Impurities in Drug Substances and Drug Products, CHPA Stability Workgroup, and Pharmaceutical Stability Discussion Group (PSDG). She presented at the first stability workshop organized by the American Association of Pharmaceutical Scientists (AAPS) held September 2007. In addition, she co-authored a chapter in Stability Design for Consumer Healthcare Products, Pharmaceutical Stability Testing to Support Global Markets published in 2010.

Donna Seibert

Donna Seibert, Ph.D., is senior principal scientist in analytical research and development in consumer healthcare at Perrigo Company, a leading global healthcare supplier that develops, manufactures and distributes OTC and generic prescription pharmaceuticals, infant formulas, nutritional products, and active pharmaceutical ingredients. Seibert has more than 13 years of pharmaceutical R&D experience, spanning branded, generic prescription, and generic OTC product lines. In her current role, Seibert’s responsibilities include new product development, cleaning method development, and validation, as well as both organic and elemental impurity aspects of the USP monograph modernization initiative.
Saul Shiffman

Saul Shiffman is senior scientific advisor to Pinney Associates, a science and policy consultancy with particular focus on Rx-to-OTC switches and pharmaceutical risk management. He is also a research professor of psychology (clinical and health psychology), psychiatry, pharmaceutical sciences (pharmacy), and translational clinical research at the University of Pittsburgh. Shiffman, a behavioral scientist, has been involved in many of the major or controversial OTC switches and switch attempts since 1993, including nicotine replacement, omeprazole, and statins, among others. Shiffman has most recently been involved in behavioral surveillance, consumer research, and design of interventions for overuse of acetaminophen in both OTC and Rx products. Shiffman has published more than 375 scientific papers. He is the inaugural recipient of the Lifetime Achievement Award for clinical research awarded by the Good Clinical Practices Journal and the Research-to-Practice award from the Society for Behavioral Medicine.

Bart Shrode

Bart Shrode has worked for Perrigo Company since 1996. Currently, as vice president quality operations, he has responsibility for all quality control and quality assurance functions for the Michigan operational sites. Shrode’s background includes various management roles in quality control, quality assurance, operations, and technical operations across multiple Perrigo sites. Shrode holds a B.S. in biology from Hope College and an M.B.A. from Grand Valley State University, both in Michigan.
David Silberstein

David Silberstein joined Valeant Pharmaceuticals in 2012. As executive director, regulatory affairs, he leads a team that deals with both new and marketed OTC drugs (both NDA and monograph), nutritional supplements, cosmetics, and ANDA products. The broad portfolio includes products in skin care, ophthalmology, podiatry, and dental care. Silberstein's background includes extensive experience working in the global pharmaceutical industry. For three years prior to joining Valeant, Silberstein served as associate director for global regulatory affairs at Bayer Pharma, and prior to that for 25 years at Bristol-Myers Squibb.

Jim Stansbury

Jim Stansbury, Ph.D., M.P.H. is a social science analyst with FDA's Center for Drug Evaluation and Research (CDER) in the Division of Nonprescription Drug Products (DNDP) within the Office of Drug Evaluation (ODE) IV. Stansbury was educated as a social and behavioral scientist with a specialization in medical and nutritional anthropology. He has extensive experience in field and clinical studies, rural development work, surveys and formative ethnographic research, monitoring and evaluation, and capacity building. He has conducted research and program evaluations in Latin America and Africa, as well as domestic health services research and clinical trial coordination. Since joining FDA in 2010, Stansbury has focused on the evaluation of drug development tools used in clinical studies, consumer studies to inform safe use, and methods issues in regulatory science. He holds degrees from the University of New Mexico, University of Kentucky, and the Johns Hopkins, Bloomberg School of Public Health.
Scott Sutton

Scott Sutton, Ph.D., is the principal of Microbiology Network, Inc., a company he started in 1996 as a means to encourage training and communications within the microbiological community. The Microbiology Network operates two email discussion groups – the PMFList (for pharmaceutical microbiology) and the PSGDList (for stability issues). With more than 90 publications and hundreds of presentations, Sutton is a recognized consultant and trainer with emphasis in CGMP, investigations, environmental monitoring, and contamination as well as microbiology laboratory audits and quality operations. He has helped companies in pharma, compounding pharmacies, and personal care products with questions and product development issues in both sterile and non-sterile production. Sutton is an adjunct faculty member of the Wegman’s School of Pharmacy at St. John Fisher University (Rochester, N.Y.) and is a long-time USP volunteer, having served as an elected member of the USP Microbiology Committee of Experts since 1995.

John Taylor

John Taylor joins Greenleaf following a distinguished career of more than 20 years at FDA. At Greenleaf, Taylor continues his commitment to healthcare innovation as the firm’s principal of compliance & regulatory affairs, providing strategic consultation to FDA-regulated clients on enforcement and compliance matters. From 2009 – 2014, Taylor held three high-profile positions at FDA: counselor to the commissioner; acting deputy principal commissioner; and acting deputy commissioner for global regulatory operations and policy. In 2005, Taylor left FDA to spend four years working in industry, first as divisional vice president for federal government affairs at Abbot, then, in 2007, as executive vice president for health at the Biotechnology Industry Organization (BIO). He has received multiple honors, including the Health and Human Services Secretary’s Award for Distinguished Service and the FDA Award of Merit. He received his law degree from the College of William and Mary and is a graduate of Pennsylvania State University with a bachelor’s degree in history.
Ken Waterman

Ken Waterman, Ph.D., studied physical-organic chemistry, completing his undergraduate at UCLA, his graduate at UC Berkeley, and his post-doctorate at Columbia University. Waterman worked 12 years at Polaroid, then 13 years at Pfizer working on drug stability, drug delivery, biopharmaceutics, and prodrugs, before starting FreeThink Technologies in 2011. FreeThink launched its software ASAPprime and opened its R&D laboratories in 2012. He is the author of more than 75 publications and was made an AAPS Fellow in 2011.

Cara Welch

Cara Welch, Ph.D., serves as acting director of the Division of Dietary Supplement Programs at FDA. Prior to joining FDA, she worked as senior vice president of scientific and regulatory affairs at the Natural Products Association (NPA). In her role at NPA, Welch oversaw NPA’s quality assurance programs, including the NPA Natural Seal and Good Manufacturing Practices (GMP) Certification for dietary supplements. Welch earned her Ph.D. from the Department of Medicinal Chemistry at Rutgers University under renowned plant biologist, Dr. James E. Simon.

Kylen Whitaker

Kylen Whitaker, Ph.D., has worked as an analytical chemist in pharmaceutical and OTC drugs at The Procter and Gamble Company (P&G) for the past 15 years. His experience includes methods development and validation for well characterized biotechnology pharmaceuticals, synthetic peptides, chiral drugs and OTC products. Whitaker is co-chair of CHPA’s Impurities Monograph Modernization Group and also a member of the USP Acetaminophen Expert Panel.
John Whyte

John J. Whyte, M.D., M.P.H., oversees the Center for Drug Evaluation and Research’s (CDER) public outreach. Whyte is the director of professional affairs and stakeholder engagement (PASE). Previously, Whyte served as the chief medical expert and vice president, health and medical education at Discovery Channel. Before joining Discovery, Whyte was in the immediate office of the director at the Agency for Healthcare Research Quality. He served as medical advisor/director of the Council on Private Sector Initiatives to Improve the Safety, Security, and Quality of Healthcare. Prior to this assignment, Whyte was the acting director, Division of Medical Items and Devices in the Coverage and Analysis Group in the Centers for Medicare & Medicaid Services (CMS). Whyte is a board-certified internist. He completed an internal medicine residency at Duke University Medical Center and earned a master’s of public health in health policy and management at Harvard University School of Public Health. He was a health services research fellow at Stanford and an attending physician in the Department of Medicine. Whyte has written extensively in the medical and lay press on health policy issues.

Janet Woodcock

Janet Woodcock, M.D., is the director of the Center for Drug Evaluation and Research (CDER) at FDA. The center makes sure that safe and effective drugs are available to improve the health of people in the United States. Since 2002, she has led the “Pharmaceutical Quality for the 21st Century Initiative,” FDA’s highly successful effort to modernize drug manufacturing and its regulation. In 2004, she introduced FDA’s “Critical Path” Initiative, which is designed to move medical discoveries from the laboratory to consumers more efficiently. Most recently, Woodcock launched the “Safety First” and “Safe Use” initiatives designed to improve drug safety management within and outside FDA, respectively. Woodcock previously served as FDA’s deputy commissioner and chief medical officer. She also led CDER as director from 1994–2005. Woodcock received her medical degree from Northwestern University Medical School and her undergraduate degree from Bucknell University. She has held teaching appointments at Pennsylvania State University and the University of California at San Francisco. She joined FDA in 1986.
Dr. Lawrence X. Yu is the acting director for the Office of Pharmaceutical Science at FDA, overseeing Office of New Drug Quality Assessment, Office of Generic Drug Quality Assessment, Office of Biotechnology Products, and Office of Testing and Research. He is also adjunct professor of pharmaceutical engineering at the University of Michigan. Prior to joining FDA, Yu had worked at Pfizer and GlaxoWellcome for eight years. Yu joined FDA in 1999 and has served as team leader, deputy division director, division director, and deputy office director. Yu is a fellow and the past section chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the “AAPS Journal.” Yu has authored/co-authored more than 120 papers, presented more than 100 abstracts, and given more than 180 invited presentations. He is a co-editor of the book entitled Biopharmaceutics Applications in Drug Development.

Louis W. Yu, Ph.D., is executive vice president, global quality at Perrigo Company. Yu is a member of the Perrigo Executive Committee. Yu’s pharmaceutical industry career spans 40 years in research/development, scientific affairs, and quality. He previously served as the highest quality officer in life cycle and innovative drug development and manufacturing companies, including CV Therapeutics, Forest Laboratories, Par Pharmaceutical, and Solvay Pharmaceutical USA. He also served for more than 16 years in R&D and quality roles with the pharmaceutical and consumer healthcare product divisions of Johnson and Johnson. Yu earned a B.S. in chemistry from the University of Wisconsin, and a M.S. and Ph.D. in analytical chemistry from Rutgers University. He has served as an Adjunct Professor of the School of Pharmacy, Extension Services in Pharmacy at the University of Wisconsin in Madison. He currently serves as a member of the USP Committee of Experts for small molecules, and as a director and treasurer on the board of directors of the Product Quality Research Institute.
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CHPA UPCOMING MEETINGS

Market Exchange (MX)
September 16-17, 2015
Sheraton Parsippany Hotel | Parsippany, NJ
chpa.org/MX

Retail Immersion (RI)
October, 2015
TBD
chpa.org/RI

Annual Executive Conference (AEC)
March 14-16, 2016
Turnberry Isle Miami | Aventura, FL
chpa.org/AEC