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‘Inside Regulatory Affairs’ With CHPA’s Mike Bailey, Marcia Howard And Jay Sirois

by

This HBW Insight series profiles regulatory affairs specialists working in or supporting the consumer health and beauty product industries. In this installment, we speak to CHPA’s Mike Bailey, senior vice president of regulatory and scientific affairs; and regulatory and scientific affairs VPs Marcia Howard and Jay Sirois.

HBW Insight is shining a spotlight on the work of regulatory affairs specialists operating in and supporting the consumer health and cosmetics industries. We are profiling this important role, hearing what a typical day involves and finding out what is top of mind for these individuals today. Look out for further installments in this series in HBW Insight over the coming weeks.

Regulatory affairs specialists in the OTC drug and dietary supplement industries, says the Consumer Healthcare Product Association’s Mike Bailey, likely end most workdays without deeming a project complete.

One reason for that is that more information constantly is being generated about manufacturing and marketing consumer health products, creating the potential for changes in maintaining regulatory compliance as well as in continuing production and distribution.

And managing those issues only begins with identifying them. Regulatory affairs specialists also are determining how to meet those challenges.

This article in HBW Insight’s series profiling regulatory affairs specialists working in or supporting the consumer health and cosmetics industries features Bailey, the CHPA’s senior vice president for regulatory and scientific affairs, and the trade groups VPs for the areas, Marcia

Howard and Jay Sirois.

Q **Q: What is a typical day in the life of a regulatory affairs specialist?**

A (Bailey) Considering the responsibility the consumer healthcare industry holds when it comes to serving the health and wellness needs of patients and consumers, our industry operates under stringent regulations. Regulatory Affairs professionals are tasked with ensuring both compliance and growth, in other words – keeping existing products on the market while also registering new innovations. These responsibilities compete intensely with each other daily for regulatory attention, requiring a careful balance between strategic and operational measures. Because regulatory affairs professionals occupy a unique space between companies and regulators such as FDA, the role demands collaboration and the representation of multiple cross functional disciplines, which means we dedicate an enormous amount of time and effort to continuous learning and stakeholder engagement. It's undoubtedly a profession of continuous learning."

Q **How has this role/department changed over time?**

A (Howard) CHPA has been the face of the OTC or nonprescription drug industry since 1881. However, my first job at CHPA was as the staff liaison to the dietary supplements committee, which was the second FDA-regulated product category officially under CHPA purview. Fast forward to 2020, and CHPA now represents members' interest across three categories: OTC medical devices, OTC drugs, and dietary supplements. The expanded scope of CHPA means there are continually new opportunities to learn and ways to help shape the self-care industry in a way that is positive and meaningful to consumers. And as our regulatory department continues to grow, I look forward to the opportunity to gain an even deeper understanding of the technical and manufacturing aspects of nonprescription medicines, while also continuing to develop my leadership and mentoring skills.

(Sirois) Since I started in CHPA's Regulatory and Scientific Affairs Department in 2011, the responsibilities and the workload have certainly evolved. I am working on

significantly more projects related to ingredient defense and advocacy on behalf of CHPA members. My role necessitates that I have a deep understanding of the science and regulations impacting the issues. However, I've also developed a greater understanding of how the work undertaken by our department cuts across several disciplines – communications, legal, and both state and federal government affairs – and the importance of cross-functional collaboration at CHPA. I've really been fortunate to work with and learn from several intelligent, dedicated people over the years who excel at their jobs and have helped me develop a greater understanding of the value the self-care industry brings to consumers.

Q **What is currently keeping you up at night?**

A (Bailey) I'd venture to say that nearly all regulatory affairs specialists, myself included, rarely ever have a sense of true completeness in any day. Regulation begins and ends with data, and the stream of new information is constant. Data comes to us from internal and external sources, which is also being captured by our regulators. This information drives strategic planning and operational measures across compliance and innovation activities. I'm kept up at night over the constant flow of information from all directions and the challenge of how to most efficiently and effectively act on this data while balancing compliance, innovation, and regulatory demands.

Q **What is your company doing to deal with these challenges?**

A (Bailey) Whether working as a regulatory affairs specialist in industry or at a trade association, our overall mission and strategic operating plan dictates both what must be done and how – responsibilities which are equally important. Ensuring we have the correct regulatory, scientific and quality competencies, capabilities, and resources in place to execute against the plan, while also making prioritization paramount against shifting demands, is key to setting up any department for success. Since our output relies heavily on internal and external data and cross-functional collaboration between internal and external colleagues, we emphasize the importance of teamwork and building meaningful relationships with key

> stakeholders.

CHPA Bios

- Bailey joined CHPA in April after previously leading Sanofi's consumer health care's scientific affairs for North America. His nearly four decades of scientific and regulatory affairs experience also has included work for other health care businesses, including Scios Inc., Bausch + Lomb, Corporation, Mylan Specialty, Boehringer Mannheim, Roche, Johnson & Johnson and Pfizer Inc. He's led the worldwide regulatory development, submission and approval of multiple new clinical trial applications and marketing applications, new drug applications, abbreviated and supplemental NDAs as well as investigational new drug applications and 510(K) device clearances.

- Howard joined CHPA in 2004 from the Department of Physiological Sciences at Oklahoma State University College of Veterinary Medicine. She has been scientific liaison for the CHPA Pediatric Cough Cold Task Group since 2009 and also assists with OTC medicine issues while coordinating its annual Regulatory, Scientific & Quality Conference. She is a member of the Drug Information Association, Regulatory Affairs Professional Society, Society of Toxicology and the American Society of Association Executives, where she was named to the ASAE Diversity Executive Leadership Program scholar class of 2016-2018 and received her designation as a certified association executive in 2018.
- Sirois has regulatory and scientific affairs activities responsibilities for cooperative programs with the FDA, ingredient safety and dietary supplement programs at CHPA. Prior to joining CHPA in October 2011, he was director of Pharmaceutical Development Group's Scientific Research and Clinical Studies. He is experienced in pharmaceutical, medical device and dietary supplement regulatory affairs, pharmacovigilance, Rx-to-OTC switch, product safety, and clinical research and is a member of the Regulatory Affairs Professionals Society and an ad hoc reviewer for the journal Neurotoxicology .

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