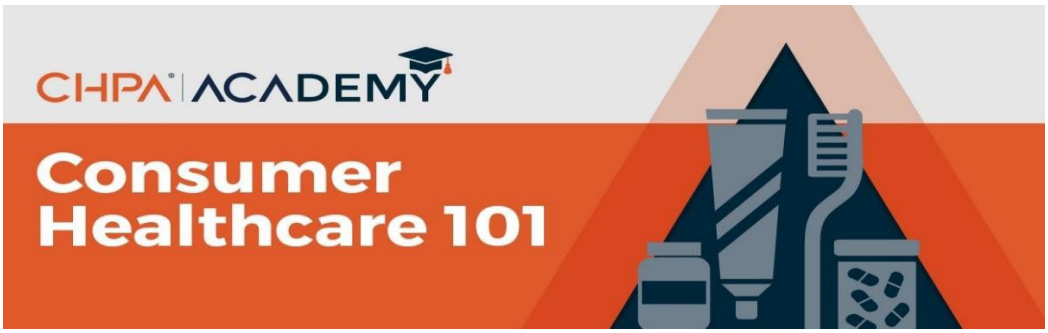


2024 WORKING PROGRAM

As of 2/15/24 (subject to change)

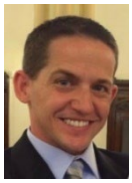
TUESDAY, APRIL 9

7:00 am-5:00 pm — **Registration –**

7:00-8:00 am — **Networking Breakfast –**

8:00-8:15 am — **Welcome and Introductions –**
Beth Allgaier, *SVP of Business Development, CHPA,*

8:15-9:15 am — **The State of The Industry: Commercial Update 2023 –**
Circana will outline the sales size, key brands, manufacturers & marketers, retailers, consumer behavior and key trends for the industry in 2023. OTCs, medical devices, as well as supplements will be covered.
Speaker:
Dennis Permar, *Client Insights Consultant, Circana*



9:15-9:45 am — **Health in Hand Foundation –**
Learn about the Foundation's mission to empower consumers to make safe, informed decisions when choosing and using self-care products.
Speaker:
Mary Leonard*, Executive Director, Health in Hand Foundation*

9:45-10:00 am — **Break –**

10:00 am -12:00 pm — **FDA Oversight of Nonprescription Drug Products –**
A discussion of FDA as the industry's leading regulator will include an overview of FDA's structure and the regulatory framework for OTC drug products.
Speaker:
Doug Bierer, *President, Douglas Bierer Consulting, LLC*

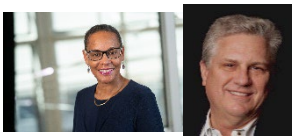
12:00 -1:00 pm — **Networking Lunch –**

1:00 -2:00 pm — **OTC Drug Labeling Regulations –**
The presentation will cover OTC Drug labeling requirements per 21 CFR 201.66. The importance of drug monographs will also be covered as well as some things that may change under the new OTC Drug Safety, Innovation & Reform Act.
Speaker:
Daniel Keravich, *Principal, Chesapeake OTC Regulatory Strategies, LLC*

2:00 -3:00 pm — **OTC Monograph Reform –**
On March 27, 2020, the CARES Act reformed and modernized the regulation of OTC monograph drugs and authorized FDA to assess and collect user fees. Session attendees will learn why reform was necessary, the key elements of policy reform covered by the legislation and FDA goals letter, how user fees will be assessed and used to fund reform activities at FDA and hear updates on OMUFA reauthorization activities, including FDA public meetings and negotiations with industry.
Speaker:
Jay Sirois*, Vice President, Regulatory & Scientific Affairs, CHPA*

3:00-3:15 pm — **Break –**

3:15-4:45 pm — **RX- TO- OTC Switch –**
An introduction to the commercial, scientific, and regulatory considerations and challenges when converting a prescription drug to a consumer product for self- care.
Speakers:
Edwin (Ed) Hemwall, *Principal, Edwin Hemwall LLC*
Marcia D. Howard*, Vice President, Regulatory & Scientific Affairs, CHPA*



5:00-6:00 pm — **Networking Reception –**

WEDNESDAY, APRIL 10

7:00-4:00 pm — **Registration –**

7:00-8:00 am — **Networking Breakfast –**

8:00 – 9:00 am — **Medical Devices –**
An overview of FDA regulations and guidance related to safety, effectiveness, manufacturing, and claims applicable to medical devices.
Speakers:
Marcia D. Howard*, Vice President, Regulatory & Scientific Affairs, CHPA*
Christina Kuhn*, Senior Associate, Covington & Burling LLP*

9:00-10:00 am — **FDA Oversight in Cosmetics & Update on MOCRA –**
An overview of the FDA regulations related to safety, labeling, manufacturing and claims for cosmetics.
Speakers:
Kelly Bonner, *Associate, Duane Morris LLP*
Mary Schilling*, Assistant General Counsel at PCPC*

10:00 -10:15 am — **Break –**

10:15 – 11:15 am — **Dietary Supplements –**
An overview of regulations related to safety, labeling, manufacturing and claims dietary supplements. Dr. Hu will address FDA Regulation of Dietary Supplements and Duffy MacKay will cover the industry's role in product integrity, safety, and informed consumer decision making.
Speakers:
Haijing Hu, *Ph.D., Chief, Regulatory Implementation Branch, FDA Office of Dietary Supplements Programs (ODSP)*
Duffy MacKay, N. D., *Senior Vice President, Dietary Supplements, CHPA*

11:15 – 11:45 — **CHPA Public Affairs and Communications –**
A look at how OTCs, dietary supplements, and consumer medical devices are covered in the trade, consumer, and scientific media, and examples of how CHPA defends and promotes consumer healthcare issues, ingredients, and products."
Speaker:
Mike Tringale, *Senior Vice President, Communications, CHPA*

11:45 -12:30 pm — **Networking Lunch –**

12:30 - 1:45 pm — **Advertising 101 for Consumer Healthcare Products –**
Overview or regulatory standards governing consumer health product advertising for OTC drugs, dietary supplements, and medical devices, including new guidance issued by the Federal Trade Commission regarding claim substantiation, social media, and use of influencers and lessons from the Food & Drug Administration and National Advertising Division of BBB National Programs.
Speaker:
Raqiyyah Pippins*, Partner, Arnold & Porter*

1:45 -2:45 pm — **Manufacturing & Product Quality –**
A review of the top five deficiencies related to OTC medicines and dietary supplements identified during regulatory inspections plus learnings from recent FDA regulatory action. Our goal is to share some insight, potential solutions, and to inspire continuous improvement for your quality systems.
Speakers:
Jen Ahearn*, CEO, GMPACT, LLC*

2:45 – 3:15 pm — **CHPA State and Federal Affairs Overview –**
Learn from CHPA's State & Local Government Affairs team who actively advocates on state and local legislation impacting the consumer healthcare industry. Our portfolio of policy work includes sustainability, chemical restrictions, accessibility to over-the-counter (OTC) healthcare products, affordability of OTC healthcare, and more.
Speaker:
Carolyn Herrmann, *Deputy General Counsel, Legal, Government Affairs & Policy, CHPA*

3:15 pm — **ADJOURN**