(as of 2/23/25 subject to change)

2025 WORKING PROGRAM

1625 I (eye) Street NW (7th floor) - Washington, DC 20006

TUESDAY, APRIL 22

7:30 am-4:30 pm — **Registration –**

7:30-8:00 am — **Networking Breakfast –**

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

8:15-9:15 am — **Session #1 - The State of The Industry: Commercial Update 2025 –**
Circana will outline the sales size, key brands, manufacturers & marketers, retailers, consumer behavior and key trends for the industry in 2025. OTCs, medical devices, as well as supplements will be covered.
Speaker:
Dave Hyland*, VP, CPG Analytics and Business Development, Circana*

9:15 - 10:15 am — **Session #2 - FDA Oversight of Nonprescription Drug Products - Part I –**
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*

10:15-10:30 am — **Break**

10:30-11:30 am — **Session #2 - FDA Oversight of Nonprescription Drug Products - Part II –**
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*

11:30 am-12:15 pm — **Session #3 - 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.
Speakers:
Caitlin Ondracek*, Ph.D., Senior Director, Regulatory & Scientific Affairs, CHPA*
Jay Sirois*, Vice President, Regulatory & Scientific Affairs, CHPA*

12:15-1:00 pm — **Networking Lunch**

1:00-2:00 pm — **Session #3 - 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 (Dan) Keravich, *Principal, Chesapeake OTC Regulatory Strategies, LLC*

2:00-3:15 pm — **Session #5 - 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*, Ph.D., Principal, Edwin Hemwall LLC*
Marcia D. Howard*, Ph.D., CAE, Vice President, Regulatory & Scientific Affairs, CHPA*

3:00-3:45 pm — **CHPA at Work to Advance Selfcare**
This session is a chance for attendees to hear about key projects that are ongoing under CHPA committee umbrellas and through the work of the Foundation. Hear from staff leads who work to promote selfcare as a critical component of public health via CHPA's Health in Hand Foundation and the Public Affairs Committee. Attendees will also learn about insights on the regulatory, legislative, and legal fronts with the recent changes in administration.
Speakers:
Brandon Ciampaglia*, Director, Health in Hand Foundation*
Mike Tringale*, SVP Communications, CHPA (Public Affairs Committee Activities & Highlights)*
Carolyn Herrmann*, Deputy General Counsel, CHPA (State and Federal Affairs Activities & Highlights)*

4:00-5:00 pm — **Networking Reception** – *Welcome remarks*
Scott Melville, *President & CEO, CHPA*

WEDNESDAY, APRIL 23

8:00-2:00 pm **Registration –**

8:00-8:30 am **Networking Breakfast –**

8:30-9:45 am **Session #1 - Medical Devices –**
An overview of FDA regulations and guidance related to safety, effectiveness, manufacturing, and claims applicable to medical devices.
Speakers:
Marcia D. Howard*, Ph.D., CAE, Vice President, Regulatory & Scientific Affairs, CHPA*
Christina Kuhn*, Senior Associate, Covington & Burling LLP. No*

9:45-10:45 am **Session #2 - FDA Oversight in Cosmetics & Update on MOCRA –**
An overview of the FDA regulations related to safety, labeling, manufacturing and claims for cosmetics.
Speaker:
Emily Manoso, *Executive VP of Legal & Regulatory Affairs & General Counsel, PCPC*

10:45-11:00 am **Break –**

11:00 am-12:00 pm **Session #3 - 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, Office of Dietary Supplements Programs, FDA*
Duffy MacKay, ND, *Senior Vice President, Dietary Supplements, CHPA*

12:00-12:45 pm **Networking Lunch –**

12:45-2:00 pm **Session #4 - 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*

2:00 - 3:00 pm **Session #5 - Quality Grand Slam: Exceeding the First Base of GMP Compliance**
An analysis of frequent observations during regulatory inspections in OTC medicines and dietary supplements manufacturing facilities, along with effective strategies to prevent recurrence and ensure consistent quality.
Speaker:
Fred Meadows*, Ph.D., Senior Director, Regulatory & Scientific Affairs, CHPA*

3:00 pm **ADJOURN**