Medmarc Risk Management Webinar Series
Webinar Summary

Ripped from the Headlines: Hot Topics in Life Sciences
Presenters: Kate Klaus & Zuhal Reed | Medmarc Risk Management

In this on-demand webinar recorded live on November 15, 2023, presenters Kate Klaus and Zuhal Reed from Medmarc's Risk Management team tackled the hot topics in the life sciences industry from 2023.

Kate provided an update on the Drug Supply Chain Security Act. She also discussed the proposed ban by the FDA on formaldehyde in products due to potential harmful side effects. Kate touched on two significant issues related to the drug supply chain, focusing on eye drops. Finally, Kate discussed the breakthrough device designation at the FDA and a recent update to the breakthrough devices program guidance document.

Zuhal discussed the Modernization of Cosmetics Regulation Act (MoCRA) and its impact on the cosmetics industry. She also discussed the leading causes of drug shortages and the FDA's efforts to prevent or mitigate shortages and concluded by discussing the FDA's Draft guidance document that incorporates updated recommendations from the International Council for Harmonization's good clinical practice guidelines.

Full On-demand Recording

On-demand Chapters:

00:00 - Introduction of the Presenters
01:13 - Drug Supply Chain Security Act (DSCSA)
07:31 - Modernization of Cosmetics Regulation Act of 2022 (MoCRA)
15:00 - Proposed Ban: Formaldehyde
20:58 - Drug Shortages in 2023
28:49 - Eye Drops: Safety and Enforcement
41:00 - Artificial Intelligence in Medical Devices
45:58 - Breakthrough Devices: An Update
54:54 - Steps to Modernize Clinical Trials
01:01:31 - Closing

KATHRYN TARALLO KLAUS, ESQ.
Senior Attorney Risk Management / FDA Specialist

Kathryn (Kate) Tarallo Klaus, Esq., is a Risk Management Attorney with Medmarc. Her focus is on legal matters faced by participants in the life sciences industry, specifically FDA regulatory compliance. She began her career with FDA's Center for Biologics Evaluation and Research, where she worked on the Broad Spectrum Autism litigation under the National Childhood Vaccine Injury Act. After leaving FDA, she worked in private practice with two national law firms, counseling clients through all phases of the regulated product life cycle, including development and approval, manufacturing, labeling and advertising, and post-market concerns and enforcement.

Ms. Klaus advises clients regarding defense against regulatory enforcement actions, including FDA 483 Inspectional Observations, Warning Letters, U.S. Customs detentions, product recalls, and DHHS OIG exclusion proceedings. She has also counseled clients through all health law-related aspects of major transactions, from conducting facility and records compliance auditing during due diligence investigations to federal and state licensure requirements, and the development and implementation of improved compliance programs post-closing. She brings this experience in navigating the FDA landscape to Medmarc, where she works with colleagues in-house, as well as with policyholders, in developing regulatory compliance strategies to mitigate products liability losses.

Ms. Klaus is a graduate of The Catholic University of America, Columbus School of Law, and the College of the Holy Cross.

ZUHAL REED, ESQ.
Senior Staff Attorney, Life Sciences Risk Management

Zuhal Reed joined the Risk Management team in March 2021. Ms, Reed came to us from Shaub, Ahmuty, Citrin, and Spratt, LLP, a healthcare-centric law firm located in New York City, where she worked on healthcare professional liability litigation. Before that Zuhal interned with Intermountain Healthcare, where she advised the hospital system on compliance and risk management matters. Zuhal resides in Washington, DC.

Ms. Reed is a graduate of the University of Utah S.J. Quinney College of Law, Salt Lake City, and the University of Toronto, Ontario Canada with an Honors BS in Human Biology and Honors BA in English Literature.