Medmarc Risk Management Webinar Series
Webinar Summary

Ripped from the Headlines: Hot Topics in Life Sciences 2024
Presenters: Kate Klaus & Zuhal Reed | Medmarc Risk Management

In this on-demand webinar recorded live on November 20, 2024, presenters Kate Klaus and Zuhal Reed from Medmarc's Risk Management team addressed the key topics in the life sciences industry for the year. The discussion included various updates and changes within the pharmaceutical sector, such as upcoming modifications to over-the-counter cold medications, the FDA's adoption of ISO 13485 standards, and new regulations for drug advertising.

Additionally, the team covered the FDA's final rule regarding laboratory-developed tests (LDTs), the potential challenges associated with its implementation, and the proposed regulations for biosimilars. Finally, they highlighted the difficulties of regulating artificial intelligence (AI) and machine learning technologies.

Full On-demand Recording

On-demand Chapters:

00:00 - Intro of Speakers; Medmarc's Kate Klaus, Esq. & Zuhal Reed, Esq.
01:07 - OTC Changes Ahead for Cold Meds
06:28 - FDA's QS Final Rule for Medical Devices
14:06 - Direct-to-Consumer Advertising
24:40 - FDA's Final Rule for Laboratory Developed Tests (LDTs)
30:52 - Laboratory Developed Tests (LDTs): Is that the end of the story?
36:50 - FDA's Proposed Rule for Biosimilars
42:21 - AI and the Impossible Task of Regulating the Hottest Tech
51:00 - 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.