



Medmarc Risk Management Webinar Series

Webinar Summary

Ripped from the Headlines: Hot Topics in Life Sciences 2025

Presenters: Kate Klaus & Zuhal Reed | Medmarc Risk Management

In this on-demand webinar recorded live on November 12, 2025, 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 webinar focused on key developments in life sciences risk management, with discussions covering changes in healthcare leadership, FDA regulations, and staff reductions that have impacted agency operations and approval processes. Kate and Zuhal explored evolving guidelines for artificial intelligence-enabled devices and their implications for manufacturers, while also addressing significant changes in vaccine regulation and policy that have affected public health operations. The session concluded with discussions on trade policy impacts and the FDA's Quality Management System Regulation (QMSR) changes, and how to prepare.

Full On-demand Recording

On-demand Chapters:

- 00:00** - Intro of Speakers; Medmarc's Kate Klaus, Esq. & Zuhal Reed, Esq.
- 01:49** - New Leadership and Direction at HHS and FDA
- 12:01** - FDA Guidance on AI-Enabled Devices
- 19:17** - Dismantling the Vaccine Infrastructure
- 34:17** - FDA's Vacated Rule on Lab-Developed Tests
- 40:12** - Tariffs and Supply Chain Localization
- 47:20** - FDA's Final Rule on QMSR: What Changed and Why it Matters
- 51:36** - FDA's Final Rule on QMSR: How to Prepare
- 52:39** - 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.

Risk Management Attorney, Biotechnology Specialist

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. She most recently earned her Master of Science in Applied Biotechnology from the University of Wisconsin at Green Bay.