Podcasts | December 12, 2025

Navigating FDA’s 2025 AI Guidance: Risk-Based Framework, Public Comments, and Generative Models

SPEAKERS

Brett Mason | Kyle A. Dolinsky

In this episode of *The Good Bot*, recorded in August of this year, Brett Mason welcomes FDA regulatory attorney Kyle Dolinsky to unpack the FDA’s January 2025 draft guidance on artificial intelligence in drug and biologic development. They explain the agency’s seven-step, risk-based framework for model planning, development, validation, and monitoring, and highlight practical takeaways such as early FDA engagement and documentation expectations. The conversation explores themes from public comments — including requests for more examples, clarity on generative and foundation models, and risks with third?party AI — along with how administrative changes could shape the final document. The discussion analyzes comments and assesses their influence on the guidance and underscores that the FDA’s approach is designed to enable responsible innovation, not restrict it.

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