FDA Regulation of Artificial Intelligence

Presenter: Nathan Downing | Senior Attorney at Gardner Law, PLLC

In this on-demand webinar, Nathan Downing, Senior Attorney at Gardner Law, PLLC, discussed the potential benefits and challenges of AI and machine learning in healthcare. He covered the FDA's review process for medical devices, emphasizing the complexities of AI-enabled devices and their regulatory challenges. Nathan outlined the importance of understanding device classification, identifying required testing, and incorporating real-world device post-market studies into the submission process. He also highlighted the need for a quality system that can account for both software and AI development. The presentation aimed to help participants understand the concept of artificial intelligence, its FDA regulation, and associated challenges. The objective was also to learn how to effectively partner with the FDA to navigate the regulatory process. The meeting addressed the rapid growth of AI-enabled devices and the potential challenges the FDA might face in understanding and regulating them.

Full On-demand Recording

On-demand Chapters:

00:00 – Introduction - About the Speaker Nathan Downing
02:49 – Objectives
09:35 – Artificial Intelligence (AI)/Machine Learning (ML) in Healthcare
14:58 – FDA Regulation of AI in Medical Devices
40:23 – FDA April 3, 2023 Draft Guidance
52:48 – AI is Complex
54:58 – How to Mitigate Device Risks
56:50 – FDA Communication Strategy and Considerations
59:57 – In Closing Summary
01:00:23 – Questions

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Nathan focuses his practice on FDA-regulated clients. His industry experience allows him to provide actionable legal advice on a variety of health law matters.

Nathan regularly advises FDA-regulated clients on regulatory and compliance matters. He advises clients on their advertising and promotion programs, represents clients in front of the FDA on a variety of matters, and assesses industry initiatives for compliance concerns. Nathan's extensive regulatory experience allows him to advise clients regarding a variety of medical products, including pharmaceuticals, medical devices, medical foods, and nutritional supplements.