FDA Policies:
Reflecting on the Past, Understanding the Present, and Preparing for the Future

Presenters: Jennifer (Jen) Diaz, and Rick D. Quinn | Diaz Trade Law

In this on-demand webinar recorded live on August 20, 2025, Jennifer (Jen) Diaz and Rick D. Quinn explored FDA policies and their implications for medical devices, with presentations covering past milestones, the Make America Healthy Again agenda, and the impact of AI and machine learning on compliance. Speakers discussed the evolving regulatory landscape, including FDA's enforcement actions, supply chain resilience, and the integration of technology in compliance, while highlighting key developments such as new guidance and cybersecurity requirements. The session concluded with a discussion of challenges in the centralized review system, the increasing importance of AI-enabled devices, and upcoming regulations requiring firms to invest in digital quality systems to meet new requirements.

Full On-Demand Recording

On-demand Chapters

00:00 – Introduction of the Presenters, Jennifer Diaz and Rick Quinn | Diaz Trade Law
03:04 – Agenda
04:40 – Policy Context & Device Impact
10:18 – The Enforcement Evolution
16:05 – Import Refusals
17:27 – Observable Trends
20:42 – Current Enforcement Landscape
29:14 – Three Priority Areas: Quality Systems, Cybersecurity/Safety, Supply Chain
34:14 – Enforcement Patterns
44:02 – AI/ML Device Regulation
53:13 – Upcoming Guidance
59:15 – Resources and Support

Jennifer (Jen) Diaz is the President and Founder of Diaz Trade Law. Jen is a Chambers ranked, Board Certified International Attorney specializing in customs and international trade. For more than 17 years, Jen has provided legal advice and customized training on import and export compliance to industry, with a strong record of success in mitigating federal administrative enforcement actions. Jen has received many accolades from the legal community, including being recognized by "Super Lawyers" as a Top International Attorney, having an AV rating of "Superb," and serving as President of the Organization of Women in International Trade (OWIT International) as well as OWIT South Florida. A frequent media commentator, Jen has authored book chapters for The Florida Bar and the American Bar Association, numerous Bloomberg Law articles, and other leading publications. Jen is Editor of the Customs & International Trade Law blog recognized by the U.S. Library of Congress as being an important part of the legal historical record.

Rick D. Quinn Esq. is an Of Counsel attorney with Diaz Trade Law and an active member of the California Bar. He is admitted to practice before the United States District Court, Central District of California. Mr. Quinn attended Loyola Law School of Los Angeles and received his Juris Doctor degree in 2005. His practice focuses primarily on U.S. Food & Drug Administration matters, including all premarket qualification requirements, post-market compliance matters, and import-related enforcement actions for start-ups, small-to-medium size privately held firms, and public companies. Mr. Quinn provides agreement drafting and review for regulated businesses, insurance coverage analysis, M&A transaction-related regulatory due diligence, litigation-related expert services regarding FDA compliance matters. Having worked with firms in more than 100 countries, his clients include manufacturers, distributors, and retailers in the food and beverage, medical device, cosmetics, dietary supplements, and drug companies.