# Winston S. Kirton

Partner, Chair of the FDA Practice

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Winston S. Kirton chairs Frier Levitt's FDA Practice. He advises domestic and international companies on regulatory challenges involving products and services regulated by the FDA, including biopharmaceuticals, medical devices, foods, dietary supplements, cosmetics and enabling technologies. His practice centers on corporate transactions, research and development, manufacturing and supply chain, and commercial regulatory and compliance matters. He also counsels clients on business and legal strategies and disputes involving third-party manufacturing relationships, suppliers and strategic alliance partners.

Winston's depth in complex FDA requirements allows him to guide clients through every stage of FDA regulatory due diligence in their most significant transactions. His experience enables him to help clients navigate both the legal requirements and practical business considerations associated with bringing FDA-regulated products to market and maintaining compliance.

Before entering private practice, Winston built extensive in-house experience at several large multinational biopharmaceutical companies, working across quality and compliance, regulatory affairs, compliance and ethics, and legal affairs. He previously served as assistant general counsel and as the London-based head of compliance and ethics for a multinational U.S. pharmaceutical company, with responsibility for business units across multiple international markets. This in-house background gives Winston a practical understanding of the business realities facing FDA-regulated companies and informs his approach to developing regulatory and compliance strategies.

Winston serves on the Board of Directors of the Food and Drug Law Institute (FDLI), where he began a four-year term in 2026. He has also served on the *Food and Drug Law Journal* Editorial Review Board and on numerous FDLI conference planning committees.

## Education

- J.D., Seton Hall University School of Law
- Mini-MBA, Biopharma Innovation, Rutgers University
- B.S., Biology, Niagara University

## Admissions

- District of Columbia
- New Jersey

# Insights

## Alerts

- 06/24/2026 – Innovation and Commercialization Pathway in Gastrointestinal Endoscopy: A Practical Primer from American Society for Gastrointestinal Endoscopy (*Gastrointestinal Endoscopy*)
- 08/13/2025 – FDA's 'PreCheck' Program: New Pathway to Acceleration of US Drug Manufacturing
- 01/16/2024 – FDA Issues Final Guidance on Registration and Listing of Cosmetic Product Facilities and Products
- 10/23/2023 – FDA Forms Digital Health Advisory Committee to Navigate Emerging Technologies

## News

- 01/1/2026 – Winston Kirton Appointed to FDLI Board of Directors for a Four-Year Term
- 11/21/2025 – Winston Kirton Joins 2026 Healthcare Businesswomen's Association (HBA) Board Nominating Committee
- 05/28/2025 – Winston Kirton Joins Food and Drug Law Journal Editorial Review Board
- 11/26/2024 – Winston Kirton Comments on Racial Disparity in Clinical Trials in *The American Journal of Managed Care*
- 09/17/2024 – Winston Kirton Participates in Panel on Health Equity at 2024 HBA Annual Conference

## Podcasts

- 05/05/2026 – Regulatory Horizons: FDA's Current Inspection Focus: What Companies Are Really Getting Cited For
- 04/07/2026 – Regulatory Horizons: Supply Chain Sovereignty: How U.S. and EU Regulatory Priorities Are Reshaping Life Sciences Manufacturing
- 03/10/2026 – Regulatory Horizons: What Life Sciences Companies Should Know About the BIOSECURE Act
- 02/10/2026 – Regulatory Horizons: Cybersecurity and FDA Regulated Companies
- 01/07/2026 – Regulatory Horizons: AI & Digital Health – FDA Evolving Oversight

## Speaking Engagements

- 10/01/2025 – Winston Kirton Speaks on Panel at WOCIP® 9th Annual Conference
- 04/25/2025 – Winston Kirton Presents at 2025 Food & Drug Law Institute Annual Conference
- 01/22/2025 – Winston Kirton Presents at Legal, Regulatory and Compliance Forum on Cosmetics and Personal Care Products
- 10/21/2024 – Winston Kirton Speaks on Panel at TEDCO's 2024 Entrepreneur Expo
- 04/15/2024 – Winston Kirton Co-Chairs 2024 FDLI Annual Conference and

Moderates the Panel "Modernizing Clinical Trials: Improving Diversity and Efficiency While Maintaining High Standards."

## Experience

- Serves as outside general counsel for several emerging life sciences companies.
- Represents private equity clients on acquisitions and sale of FDA-regulated biopharmaceuticals, medical devices, foods and dietary supplement products.
- Advises pharmaceutical and medical device companies on responses to FDA enforcement actions and regulatory engagement.
- Represented pharmaceutical client on its acquisition of diabetes medical device asset.
- Represented Danish pharmaceutical client on collaboration negotiations with a U.S. medical device partner.
- Represented private equity client on its acquisition of large pharma consultancy.
- Conducted end-to-end compliance risk assessment of pharmaceutical company's corporate operations in connection with a derivative suit settlement agreement.
- Advised retail client on its strategy for introducing CBD products in stores nationally.
- Represented adhesive industry client on its acquisition of innovate adhesive medical device.
- Represented private equity client on its acquisition of wound care medical device.
- Helped client renegotiate its medical device supply agreement with key third-party alliance partner.
- Helped client develop Emergency Use Authorization (EUA) strategy for COVID-19 medical product introduction.
- Advised foreign company on FDA regulatory strategy for introducing foreign plant-based foods into U.S. market.
- Advised online marketing client on FDA compliance requirements for labeling and marketing dietary supplement products.
- Counseled client on FDA compliance requirements for labeling and launching a new line of liquid dietary supplements.
- Advised U.K. company on FDA Investigational New Drug Application (IND) submission strategy for switching a non-U.S. dietary supplement product to a U.S.-approved pharmaceutical
- Represented medical device executive client in response to DOJ civil investigative demand and deposition.

- Developed client's enterprise-wide corporate compliance risk survey.
- Helped client redesign its corporate compliance program including the development of sales force healthcare professionals (HCP) interactions policy.
- Assessed and redesigned client's Code of Ethics and delivered employee training.
- Assisted a client in successfully responding to an FDA Office of Criminal Investigations subpoena.

## Awards & Recognition

- Lexology Index (formerly Who's Who Legal): Healthcare & Life Sciences (2026)
- Law360: Life Sciences Editorial Advisory Board (2021, 2024)
- The Legal 500 United States
  - Recommended in: Healthcare: Life Sciences (2026)
  - Key Lawyer Intellectual Property: Patents: Prosecution (including re-examination and post-grant proceedings) (2024)
  - Key Lawyer in Dispute Resolution: Corporate Investigations and White-Collar Criminal Defense (2021 – 2022)
  - Key Lawyer in Healthcare: Life Sciences and Healthcare: Service Providers (2021)