Hogan Lovells

Edward (Ted) C. Wilson, Jr.

Senior Counsel
Washington, D.C.

Phone
+1 202 637 5839

Fax
+1 202 637 5910

Email
ted.wilson@hoganlovells.com

Biography

Whether it's a multinational corporation or a growing business looking to expand in the U.S. market, complying with the U.S. Food and Drug Administration's (FDA) web of medical device regulations can be challenging and resource intensive.

Ted Wilson has over 30 years of experience advising clients on complex regulatory, enforcement, and product submission matters throughout the total product life cycle of medical devices. He represents clients before FDA to help attain workable solutions to public health and safety emergencies, regulatory and business challenges, and compliance matters.

Ted has assisted hundreds of clients prepare for, defend, and respond to domestic and international inspections and audits. He has conducted numerous quality system audits and completed the ISO 9001:2008 3-Day Certified Internal Auditor with Medical Device Focus (ISO 13485:2016) training and the Medical Device Single Audit Program (MDSAP) 1-Day Overview Training through AQS Solutions (a DEKRA company).

In addition to extensive auditing, his work has included designing and implementing robust quality systems for medical device manufacturers, and responding to Form 483 inspectional observations, warning letters, and untitled letters.

Ted has defended companies in government investigations involving quality system and other

Languages

English

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Postmarket Compliance and Enforcement Actions

Advertising and Promotion Compliance

Medical Devices

medical device regulations, negotiated consent decrees of permanent injunction, and counseled clients under third-party certification audit obligations.

His experience in assisting medical device companies with public health and safety matters includes emergency preparedness operations, health hazard evaluation assessments, risk mitigation strategies, recall decision-making and execution, adverse event reporting, root cause investigations, and corrective action plans to address quality and safety issues.

Ted has assisted medical device companies in making product submission determinations for proposed device labeling, design, and manufacturing changes. He also has assisted in drafting numerous 510(k) notices, premarket approval (PMA) applications, and investigational device exemption (IDE) applications for a wide range of device technologies.

Representative experience

Represented a major medical device company in an internal investigation of claims brought by employees regarding alleged FDA violations.

Assisted in the response to a warning letter issued to a global company regarding alleged quality system and medical device reporting violations.

Assisted in the creation and execution of advertising and promotion guidelines to comply with government settlement agreements.

Assisted in the preparation for, and defense of, international inspection in follow up to an import ban.

Assisted in the settlement of civil monetary penalties imposed on a global medical device company.

Assisted in the settlement of a consent decree of permanent injunction and ensuing compliance plan.

Defended a major medical device corporation in a criminal investigation regarding the shipment of alleged adulterated and misbranded devices.

Awards and rankings

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., University of Virginia School of Law, Recipient of Charles J. Frankel Award in Health Law, 1990

A.B., Davidson College, cum laude, Phi Beta Kappa, 1987

Memberships

Editorial Board of the Journal of Medical Device Regulation

Bar admissions and qualifications

District of Columbia

Virginia

ISO 13485 Certified Auditor

Vermont

- Healthcare: Life Sciences, *Legal 500 U.S.*, 2014

Latest thinking and events

- Insights and Analysis
  - FDA proposes to conform the Quality System Regulation to the ISO 13485 standard
- News
  - "Remanufacturing" or "Servicing"? New FDA guidance clarifies distinction for medical devices
- News
  - FDA updates VMSRP instructions for summary MDR reporting – including reasons for possible program exclusion
- Hogan Lovells Publications
  - Helping companies navigate the COVID-19 pandemic
- Hogan Lovells Publications
  - We can help you prepare remotely for your next Quality Management System inspection or audit
- News
  - FDA temporarily postpones all domestic routine facility inspections in response to COVID-19 pandemic