

## Edward C. Wilson, Jr.

Partner

Washington, D.C.

### 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 28 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



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### Languages

English

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### Practices

Medical Device and Technology  
Regulatory

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### Industries

Life Sciences and Health Care

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### Areas of focus

Adverse Event Reporting  
Vigilance Reporting

Advertising and Promotion

untitled letters.

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

Compliance

Medical Devices

Cell, Tissue, and Gene Therapies

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## 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

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### Memberships

Editorial Board of the Journal of Medical Device Regulation

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### Bar admissions and qualifications

District of Columbia

Virginia

ISO 13485 Certified Auditor

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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

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

## Latest thinking and events

- 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
- News
  - FDA postpones foreign inspections amid growing concerns over coronavirus (COVID-19)
- News
  - Revised ISO 14971 Application of Risk Management to Medical Devices released
- News
  - FDA delays draft rule for QSR/ISO 13485 harmonization *Medical Device Alert*
- News
  - Appealing a denial of a drug/medical device export certificate: FDA final guidance