Hogan Lovells

Michael S. Heyl

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Biography

Mike Heyl helps medical device companies navigate myriad regulatory and business matters. He guides clients through U.S. Food and Drug Administration (FDA) regulations, requirements, and compliance issues. These issues include FDA's Quality System Regulation (QSR); adverse event reporting; recall reporting requirements; FDA inspections and enforcement actions, such as Warning Letters; defense strategies; and corrective and remedial action plans.

He represents large multinational corporations facing FDA and criminal enforcement, and helps small startups develop and implement postmarket compliance programs. Because he understands FDA's requirements for importing and exporting medical devices, Mike is frequently called on to negotiate the release of detained goods being imported to the Unite States.

He has assisted in the defense of criminal investigations by the U.S. Department of Justice (DOJ), conducted internal investigations of whistleblower complaints, and prepared strategies for resolving such issues.

Mike also works with device companies in conducting regulatory due diligence and negotiating corporate mergers and acquisitions and initial public offerings (IPOs). He has been involved with numerous

Languages

English

Practices

Administrative and Public Law

Commercial

Government Relations and Public Affairs

Investigations, White Collar, and Fraud

Marketing and Advertising

Medical Device and Technology Regulatory

Private Equity

transactions ranging from multibillion-dollar acquisitions to the negotiation of supply and distribution agreements.

Mike recently became an ISO 9001:2008 certified internal auditor with focus on ISO 13485:2016 and Medical Device Single Audit Program (MDSAP).

Mike is a frequent speaker on regulatory compliance and enforcement issues in the device industry. He also serves as the device representative on our Life Sciences steering committee.

Representative experience

Assisted numerous clients to prepare for, defend and/or respond to domestic and international inspections.

Assisted a brand name device company with the acquisition of several medical device manufacturers.

Assisted a large multinational corporation with strategy and defense with an FDA enforcement action involving a highly publicized health risk.

Assisted a medium-sized medical device manufacturer in preparing corrective action strategy and drafting a response to an FDA inspection.

Successfully negotiated the release of devices being detained upon import to the United States.

Assisted a small-sized medical device manufacturer in responding to FDA inspections and grand jury subpoena.

Awards and rankings

- U.S. Regulatory Star, *LMG Life Sciences*, 2016-2018

Latest thinking and events

- Events
  - Legal Issues in Companion Diagnostics
- News

Industries

Life Sciences and Health Care

Areas of focus

Sales Promotions

Adverse Event Reporting Vigilance Reporting

Advertising and Promotion Compliance

In Vitro Diagnostics

Medical Devices

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., The Catholic University of America, Columbus School of Law, magna cum laude, 2002

B.A., University of Delaware, 1993

Bar admissions and qualifications

District of Columbia

Maryland

- 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

- Events
  - Sydney: Join leaders from Hogan Lovells Medical Device team for conversation and cocktails

- Sponsorships and Speaking Engagements
  - AusMedTech 2019