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

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

Industries

Mike is 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.

Recently, Mike was awarded the 2022 Catholic University of America Columbus School of Law Distinguished Alumni award. The award recognizes outstanding alumni for their individual achievements, contributions to their industries or professions, service to their community, and demonstrated loyalty to Catholic Law.

Representative experience

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

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.

Assisted a large company to conduct an internal investigation and remediation plan following a whistleblower complaint.

Assisted a medical device manufacturer with a review of promotional materials and remediation strategy following FDA action.

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.

Assisted numerous device manufacturers and companies from other industry sectors in obtaining

Life Sciences and Health Care

Areas of focus

Postmarket Compliance and Enforcement Actions

Advertising and Promotion Compliance

In Vitro Diagnostics

Medical Devices

Cell, Tissue, and Gene Therapies

Whistleblowing

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

Emergency Use Authorizations during the COVID-19 pandemic.

Awards and rankings

- Healthcare: Pharmaceutical/Medical Products Regulatory (District of Columbia), Rank 3, *Chambers USA*, 2021-2023
- Leading Practitioner, FDA: Medical Device, *LMG Life Sciences*, 2016-2022
- Shortlisted for Regulatory Attorney of the Year, FDA Medical Device, *LMG Life Sciences*, 2020

Latest thinking and events

- Hogan Lovells Events
  - Tokyo: Life Sciences and Health Care Horizons 2024
- News
  - Podcast: Talking the cure
- News
  - FDA finalizes guidance on "Remanufacturing" vs "Servicing"
- News
  - U.S. device makers get 2 years to comply with FDA Quality Management System Regulations final rule
- Press releases
  - Hogan Lovells advises Palette Life Sciences on Acquisition by Teleflex
- Sponsorships and Speaking Engagements
  - Biomed Israel: 2023 Regulatory outlook: Medical technology trends shaping the future