

## Michael S. Heyl

Partner

Washington, D.C.

### 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



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### Languages

English

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### 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

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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

- News
  - COVID-19 Report for Life Sciences and Health Care Companies

## Industries

Life Sciences and Health Care

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## Areas of focus

Sales Promotions

Postmarket Compliance and Enforcement Actions

Advertising and Promotion Compliance

In Vitro Diagnostics

Medical Devices

Cell, Tissue, and Gene Therapies

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## 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

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## Bar admissions and qualifications

District of Columbia

Maryland

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- Hogan Lovells Publications
  - Podcast: Talking the cure
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (19 - 22 October 2020)
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (12 - 15 October 2020)
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (5 - 9 October 2020)
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (28 September - 1 October 2020)