Hogan Lovells

Medical Device and Technology Regulatory

Bringing a medical device to market involves addressing a host of issues: regulatory approval, patents, financing, manufacturing, distribution, and more.

After your product debuts, the challenges continue throughout its life cycle, from running compliance programs to responding to enforcement actions. And if you're operating globally, the last thing you want to do is to oversee a patchwork of different firms in different locations.

That's where Hogan Lovells comes in. We operate on a global scale, coordinating among lawyers in offices in all of the world's major medical markets to sequence and streamline regulatory approvals. In the U.S., we've been helping companies get new products approved by the Food and Drug Administration (FDA) since the Medical Device Amendments of 1976 was signed into law.

We understand how to do things in a better way to expedite the FDA approval process, streamline how much data is needed for approval to be granted, and design programs to successfully launch products and ensure continuing compliance. We can also help you develop reimbursement strategies and build the necessary infrastructure for a transaction or initial public offering.

We are unique in achieving all this because of our interdisciplinary team. Many of our lawyers have worked for regulatory agencies and in private industry, and have

Key contacts

Janice M. Hogan,
Philadelphia

Jonathan S. Kahan,
Washington, D.C.

Randy J. Prebula,
Washington, D.C.

Trending Topics

Total Product Life Cycle

Hogan Lovells has you covered during the total life cycle of a Medical Device. We have been there before. We know the rules. We know the regulators.

Individualized therapies and the future of drug regulation

The emergence of intelligent systems in health care

Areas of focus

backgrounds in biostatistics, medicine, biomedical engineering, material science, and genetics, among other disciplines. This means we understand the technology and can make better arguments on your behalf. From inception and approval to debut and product maturity, we provide guidance that takes into account the complex considerations where business and compliance meet.

Awards and rankings

- Band 1 for Healthcare: Pharmaceutical/Medical Products Regulatory in the District of Columbia, *Chambers USA*, 2019
- Highly Recommended for FDA Medical Devices, *LMG Life Sciences*, 2018
- Regulatory Firm of the Year, *LMG Life Sciences Awards*, 2018
- Ranked second tier for health care and life sciences in the U.S., *The Legal 500*, 2018
- Band 1 for Life Sciences, *Chambers Global*, 2018
- Band 1 for Life Sciences, *Chambers Europe*, 2018

Latest thinking and events

Hogan Lovells Publications

Podcast series: False Claims Act 2019 and the road ahead
Hogan Lovells

Insights

Germany is going to specify safety expectations for reimbursable digital health applications

Hogan Lovells Publications

Podcast: Talking the cure

Insights

Federal Circuit Acetris decision changes procurement country of origin landscape

Insights

OIG clears manufacturer-sponsored travel and lodging support in limited circumstances

Insights

Adverse Event Reporting
Vigilance Reporting

Advertising and Promotion Compliance

Advisory Panel Preparation

Clinical Trials

Combination Products, FDA Jurisdictional Issues, FDA Postmarket Compliance Issues

In Vitro Diagnostics

Medical Device Artificial Intelligence

Premarket Review

Unique Device Identifiers

State Medical Device Distribution and Manufacturer Licensing

“Misleading” to suggest a biosimilar is inferior, FDA draft guidance warns