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*, 2020
- Band 1 for Life Sciences, *Chambers Global*, 2020
- Band 1 for Life Sciences, *Chambers Europe*, 2020
- Tier 1: EU Regulatory: Pharmaceuticals, Medical Devices, and Biotech, *Legal 500 Belgium*, 2020
- Regulatory Firm of the Year, *LMG Life Sciences Awards*, 2019
- Highly Recommended for FDA Medical Devices, *LMG Life Sciences*, 2019

Latest thinking and events

News

New FDA inspection program released for "streamlined approach" for combination product cGMP

News

Five key takeaways from the Senate hearing on FDA oversight of foreign drug manufacturing

Webinar

Virtual health: What's on the horizon for telehealth and remote monitoring?

Announcements

Hogan Lovells advises Joe and Clara Tsai Foundation in shipping thousands of ventilators and millions of units of PPE to the US from China

News

European Commission issues guidance on lawful placing on the market of PPE and medical devices

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 & Manufacturer Licensing

News

COVID-19: Daily Report for Life Sciences and Health Care Companies