Medical Devices and Diagnostics

COVINGTON

BEIJING BOSTON BRUSSELS DUBAI FRANKFURT JOHANNESBURG LONDON
LOS ANGELES NEW YORK PALO ALTO SAN FRANCISCO SEOUL SHANGHAI WASHINGTON

www.cov.com

Device & Diagnostics Capabilities

Covington's premier Medical Device Industry Group includes longstanding representation of clients in the medical device and diagnostics industries.

Covington's premier Food, Drug, and Device Practice Group includes longstanding representation of clients in the medical devices and diagnostics field. Covington lawyers act as regulatory counsel to device and diagnostics companies ranging from start-up ventures to large, multinational manufacturers and clinical laboratories, as well as industry trade associations. We also advise pharmaceutical and biotechnology companies regarding medical device requirements relevant to their pharmaceutical products and strategic partnerships.

Our experience includes a wide range of device types, including implants, surgical instruments, diagnostic imaging equipment, in vitro diagnostic products, mobile medical apps and computerized health information systems, companion diagnostics, and combination drug/device products. We have advised companies in connection with the gamut of device classification categories, including neurological, cardiovascular, ophthalmic, orthopedic, surgical, reproductive, abdominal, in vitro diagnostic, and radiological devices.

Our deep knowledge of the evolving FDA regulatory policy allows us to provide strategic insight to our clients. Covington lawyers not only are familiar with the governing laws and regulations, but also have broad-based practical experience with their application, including—

- Providing advice regarding FDA device regulation throughout the full lifecycle of products:
  - Research and development, including pre-submission documents and meetings with FDA to discuss data requirements;
  - Investigational device exemption (IDE) applications;
  - Development strategies, including with respect to clinical study issues, regulatory pathways, and co-development approaches;
  - Premarket notifications (510(k)s), premarket approval applications (PMAs), de novo applications, and humanitarian device exemptions (HDEs); and
  - Postmarket controls, including quality system regulation (QSR), postmarket reporting, and product recalls.
- Responding to notices of inspectional observations ("483") and warning letters.
- Advising on advertising and promotional claims.
- Developing compliance policies and systems.
- Defending against enforcement actions, and initiating or defending against litigation.
- Conducting regulatory due diligence in connection with mergers, acquisitions, and IPOs.

Covington is the only firm recognized by *Chambers* as a "Band 1" firm for Life Sciences across their U.S., UK, Europe, China and Global surveys

Chambers TOP RANKED USA 2023 Covington & Burling LLP

Chambers TOP RANKED UK 2023 Covington & Burling LLP

Chambers TOP RANKED Europe 2023 Covington & Burling LLP

Chambers TOP RANKED Global 2023 Covington & Burling LLP

Chambers RANKED IN Latin America 2023 Covington & Burling LLP

Chambers TOP RANKED Asia-Pacific 2023 Covington & Burling LLP

COVINGTON

Comprehensive and Integrated Advice

We bring the right skills to every matter with advice and representation across practices and multiple jurisdictions.

International Scope

In conjunction with our London, Brussels, Frankfurt, Beijing, Shanghai, and Seoul offices, we effectively advise companies on medical device regulatory requirements on a global basis. In the United Kingdom and European Union, we advise on regulatory pathways for devices and borderline products.

We review regulatory documents such as product licenses, certifications or registrations, and the underlying technical documentation, facility permits, and inspection reports, both from self- audits or those by third parties, such as notified bodies. We advise on compliance matters and represent companies in inquiries by notified bodies and European health authorities. In China, we advise companies on the regulatory requirements of the China FDA and provincial FDA authorities regarding clinical trials, premarket review and approval, manufacturing practices, import requirements, and post market compliance matters. Our lawyers in the United States, Europe, and Asia frequently work seamlessly together on device regulatory matters. In addition, we can address global regulatory questions through an existing network of trusted local counsel with expertise on device regulatory issues.

.

Cracking the Toughest Problems

"Covington are the only people we call for problems we can't fix ourselves. We can solve most of it–Covington are unique in that they are the only ones who can solve what we cannot."

Our Team

Scott Danzis
Partner, Washington
+1 202 662 5209
sdanzis@cov.com

Scott Danzis is a co-chair of Covington's Medical Device Industry Group and works with companies in developing strategies for interacting with the U.S. FDA, including strategies for clinical development and premarket review (including appeals and dispute resolution). He also advises on compliance with postmarket requirements, including advertising and promotion restrictions, quality system and manufacturing requirements, postmarket reporting, recalls, and enforcement actions.

Pamela Forrest
Partner, Boston
+1 617 603 8809
pforrest@cov.com

Pamela Forrest is a co-chair of Covington's Medical Device Industry Group and has over 25 years of experience advising medical device and digital health clients on a broad range of premarket and postmarket FDA regulatory issues. She regularly counsels firms on complex market entry strategies. In addition, Pam advises companies on responding to FDA inspectional observations and Warning Letters, developing and implementing corrective actions plans, and preparing for re-inspection. Pam also works closely with private equity firms, and leverages her regulatory expertise to help assess regulatory risk in life sciences-related transactions.

John Balzano
Partner, New York
+1 212 841 1094
jbalzano@cov.com

John Balzano represents companies on U.S. and China regulatory and policy matters related to medical devices, food, drug, cosmetics, and other regulated products. He has extensive experience with legal and regulatory matters for products regulated by China's State Administration for Market Regulation, National Medical Products Administration (NMPA), and other agriculture, animal and healthcare (including digital health) products and services.

Sarah Cowlishaw
Partner, London, Dublin
+44 20 7067 2403
scowlishaw@cov.com

Sarah Cowlishaw supports medical device, diagnostic, pharmaceutical, biotech, and technology companies in the EU and UK on regulatory, compliance, transactional, and legislative matters. Sarah has extensive experience on advising on the EU Medical Devices Regulation and In Vitro Diagnostics Medical Devices Regulation, along with associated transition issues, as well as UK-specific considerations caused by Brexit. She has particular expertise in advising on legal issues presented by digital health technologies, helping companies navigate regulatory frameworks while balancing challenges presented by the pace of technological change over legislative developments. Sarah is a co-chair of Covington's multidisciplinary Digital Health Initiative.

Kristin Davenport
Partner, Washington
+1 202 662 5286
kdavenport@cov.com

Kristin Davenport advises medical device companies regarding premarket strategies and pathways, the premarket submission process, advertising and promotion, compliance and enforcement matters, and import/export issues. She has extensive experience with 510(k) premarket notifications, de novo petitions, premarket approval applications, investigational device exemptions, device modifications, 513(g) Requests for Information, MDR reporting, device recalls, and Part 806 reports. Kristin regularly prepares 513(g) Requests for Information to obtain FDA's views regarding the classification and applicable regulatory requirements for novel devices, such as mobile medical applications.