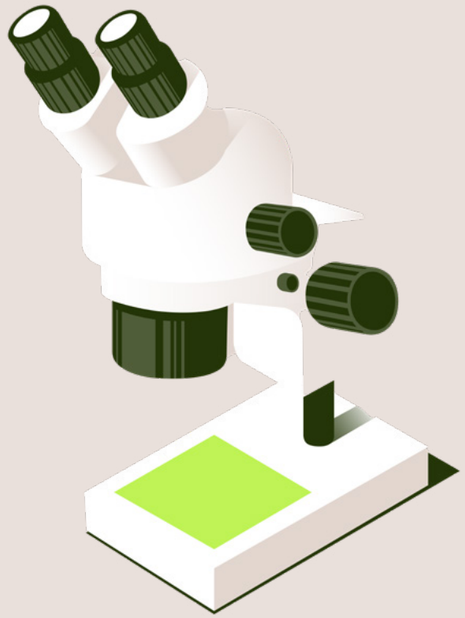
Hogan Lovells

Medical Device and Technology

Our regulatory, compliance & commercialization capabilities

2025

Medical device and technology



Bringing a medical device or a combination product regulated under the medical device pathways 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, iterating your products 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.

Collaborate relentlessly

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 United States, we've been helping companies get new products approved by the U.S. Food and Drug Administration (FDA) since the Medical Device Amendments of 1976 was signed into law.

Opportunities, not obstacles

We understand how to do things in a better way to expedite the FDA approval and EU CE marking processes, streamline how much data is needed for approval to be granted, and design programs to successfully launch products and ensure continuing compliance. We help you respond to the changing regulatory landscape so that your hard work becomes a business advantage. We can also help you develop reimbursement strategies and build the necessary infrastructure for a transaction or initial public offering.

> They are very responsive, they deliver the product as we request it, and they're very good about having a quick turnaround."
>
> *- Client, Life Sciences, Chambers*

Experience matters

Many of our lawyers have worked for regulatory agencies and in private industry, and have backgrounds in biostatistics, medicine, biomedical engineering, material science, pharmacy and genetics, among other disciplines. This means we understand the technology and the science 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.

Former leadership positions

- Michael "Moshe" Kasser, member of the MR Safety Working Group at the FDA Center for Devices and Radiological Health, specializing in orthopedic devices
- Gerry Prud'homme, member of the research faculty at the University of Maryland School of Medicine; biostatistician
- Jodi Scott, Principal FDA Counsel at Medtronic, Inc. (the largest medical device manufacturer)
- John Smith, associate professor, Massachusetts General Hospital/Harvard Medical School; Director of Regulatory Affairs at the Center for Integration of Medicine and Innovative Technology (CIMIT); Co-Director, Massachusetts General Hospital Center for Biomarkers in Imaging; consultant, Radiological Devices Panel, the Medical Devices Advisory Committee, the FDA's Center for Devices and Radiological Health
- Ryan Foringer, Consumer Safety Officer at the FDA Center for Food Safety and Applied Nutrition; Lead Reviewer and chemical engineer at the FDA Center for Devices and Radiological Health; engineer at the FDA Center for Tobacco Products
- Joshua Yao, Lead regulatory reviewer and biomedical engineer at the FDA Center for Devices and Radiological Health
- Eriko Yoshimaru, member of the MR Safety Working Group at the FDA Center for Devices and Radiological Health; biomedical engineer and medical device reviewer at the Center for Devices and Radiological Health at FDA

Areas of focus

- Premarket review
- Quality management systems and inspections
- Postmarket compliance and enforcement actions
- Recalls, corrections, and removals
- Advertising and promotion compliance
- Import and export
- Intellectual property
- Combination products
- Financing, distribution and other agreements
- Cell, tissue, and gene therapies
- In vitro diagnostics
- Good clinical practice compliance
- Digital health
- Artificial Intelligence
- State medical device distribution and manufacturer licensing
- Emergency Use Authorization and pandemic related products

In 2024, our practice assisted with more than 120 510(k) Notices and 40 de novo submissions. For 510(k) submissions we submitted, more than 88% were cleared, exceeding FDA's average clearance rate by more than 7%.

Pioneering FDA approval for first bioresorbable metal implant

Our team advised Bioretec LTD., a leader in bioresorbable orthopedic implants, in obtaining de novo pre-marketing authorization from the U.S. Food and Drug Administration (FDA) for its RemeOs™ trauma screw, the first and currently only FDA-approved bioresorbable metal implant. This approval represents a major advancement in orthopedic innovation by introducing a groundbreaking alternative to traditional metal implants. The successful FDA authorization marks a significant milestone for Bioretec, reinforcing its leadership in next-generation orthopedic solutions. The bioresorbable nature of the implant offers meaningful benefits for both providers and patients, including reduced risk of implant-related complications and improved long-term outcomes. The approval opens new opportunities for patient care and sets a precedent for future developments in bioresorable medical technology.

Premarket review

Our premarket review practice focuses on providing strategic advice from the earliest stages in the product development cycle in order to optimize the regulatory pathway. Leveraging the technical background of our lawyers and regulatory science professionals, we provide comprehensive regulatory assistance during all phases of the Food and Drug Administration (FDA) clearance or approval process.

We also assist clients in preparing all types of premarket submissions, including investigational device exemptions (IDEs), pre-submissions, 510(k) notices, de novo submissions, premarket approvals (PMAs), and related submissions. We are involved in a substantial portion of all PMA applications filed annually with FDA, as well as dozens of pre-submissions and IDE submissions and hundreds of 510(k) notices each year.

Representative experience

- Advised client on multi-year effort to obtain FDA clearance of a novel tissue expander for use with a next generation breast implant.
- Successfully advocated the FDA's reclassification of a novel imaging device, tissue culture media products for ex vivo growth of human cells, and a variety of in vitro diagnostic test systems, avoiding the need for a PMA approval.
- Although a client had received two non-approvable letters prior to our involvement, we assisted in the preparation of necessary PMA amendments and secured a unanimous Advisory Panel recommendation for approval.
- To assist a client in expediting a product to market, we obtained the FDA's designation of expedited review status for a novel orthopedic and women's health device and negotiated favorable review timetables.
- Though the FDA previously told our client that a device for diagnosing tubo-peritoneal infertility would require a PMA approval, we drafted a 510(k) notice that the agency cleared.
- When other FDA counsel had concluded a device would require PMA approval, we assisted a small start-up client in obtaining clearance of a 510(k) notice without clinical data for a cardiac bypass device.
- FDA determined that existing clinical data for a clinical laboratory device for identifying markers for myocardial infarction, which a client provided in a 510(k) notice, did not demonstrate substantial equivalence. We met with the agency to explain the data; addressed the FDA's issues in a subsequent response; and successfully assisted our client in obtaining 510(k) clearance.
- Managed the PMA and Advisory Panel process and helped secure approval for a novel, non-invasive screening test using advanced DNA technology to detect colorectal cancer.
- Managed the PMA and Advisory Panel Process and helped secure an approvable letter for a novel tissue glue product for use in abdominoplasty that can obviate the need for post-surgical drains.
- Assisted a client in preparing an abbreviated 510(k) notice for a surgical mesh that demonstrated the device's substantial equivalence based primarily on its conformance to a device-specific guidance document and the FDA's recognized consensus standards, which the agency cleared within 60 days of its submission.
- Assisted a foreign client in obtaining PMA approval for an extracorporeal device for removing cholesterol from the blood of certain types of patients with hypercholesterolemia.
- Assisted companies on numerous cardiovascular device approvals, including left ventricular assist devices and artificial heart devices.
- Managed the Advisory Panel process and helped secure a positive vote on the risk-benefit of the ResQCPR System, a CPR-assist device that increases likelihood of survival after cardiac arrest.
- Through a multi-year effort, assisted a client with securing FDA approval of a premarket approval application for a next generation breast implant, as well as a 510(k) for a novel tissue expander for use with the implant, which represent important advances for women's health in the area of breast reconstruction and augmentation.
- Advised a global oncology company in securing FDA approval for its non-invasive treatment for metastatic non-small cell lung cancer (mNSCLC), the first treatment of its kind for this disease.

Quality management systems and inspections:

U.S. Quality System Regulation and ISO 13485

Our medical device lawyers and regulatory science professionals have extensive experience in designing and implementing robust quality management systems for medical device manufacturers; auditing companies' quality management systems; and preparing companies for U.S. Food and Drug Administration (FDA), international regulatory inspections, other third party inspections, and EU notified body audits. This means that we can help you implement quality systems that are designed to improve your products and processes; recognize opportunities for improvement; and take remedial action as a result of audit and inspectional findings.

We also conduct training on a regular basis to help companies understand what to expect during an FDA inspection, an MDSAP audit, other third party inspections, international regulatory body inspections, and notified body audits and provide an opportunity to understand best industry practices and trends in the medical device enforcement space.

Our experience includes assessing gaps in a quality system in preparation for an inspection, developing plans to mitigate gaps that take into account a pending inspection, supporting international companies through U.S. FDA inspections, responding to 483 observations and Warning Letters; responding to non-conformities identified by notified bodies, negotiating civil settlements based on Quality System violations; assisting clients in addressing non-conformities raised by notified bodies; conducting investigations into whistleblower allegations of noncompliance with medical device requirements; and counseling clients who are under third party certification audit obligations. We also apply these skills in the context of conducting due diligence activities to the review target companies' compliance with medical device regulatory requirements.

Representative experience

- Conducted numerous Quality System Regulation (QSR and ISO 1345) audits both domestically and internationally to help companies make their processes more robust and to prepare them for inspections by regulators and audits by notified bodies.
- Assisted numerous companies in taking remedial actions related to FDA Warning Letters and 483 Notices of Observation.
- Evaluated quality systems and identified strategic opportunities to make improvements in advance of expected inspections.
- Assisted various medical device clients in addressing the quality management system non-conformities identified by their notified bodies.
- Prepared and built out a quality system tailored to the needs of a client entering the medical device space for the first time.
- Attended numerous foreign inspections in person when it was important to help facilitate communication between our client and FDA and assist the client in managing the inspection.
- Conducted a third party audit to certify to the FDA that our client had taken the necessary corrective actions to address the FDA's inspectional observations.
- Helped a company develop and monitor a corrective action plan designed to address systemic issues with the client's quality systems.

Navigating complex FDA pathways to preserve market access

Our team represented a medical device manufacturer in navigating a complex FDA regulatory process for a product that had already been on the market for several years. We advised on a de novo submission and successfully obtained enforcement discretion from the FDA, allowing the company to continue commercializing the product while it remained under review. The matter drew heightened regulatory scrutiny and required extensive data submission, strategic planning, and coordination across multiple FDA divisions. As part of our approach, we negotiated a field action that enabled product modifications in the field without triggering a recall, an outcome critical to preserving the client's business operations. Through our work, the company avoided disruption, maintained market presence, and is now positioned to obtain one of the first FDA marketing authorizations for a product of its kind.

Postmarket compliance and enforcement actions

Both domestic and foreign medical device companies that market their products in the United States must comply with the U.S. Food and Drug Administration's (FDA) complex postmarket regulations, as well as the equivalent requirements in the European Union (EU).

Our medical device lawyers help companies understand the regulators' requirements for developing and manufacturing their medical devices in accordance with applicable quality management system (QMS) standards; conducting product recalls (or determining whether one is needed); reporting adverse events; and disseminating labeling, advertisements, and other promotional materials.

We conduct in-house training so clients understand the government's enforcement priorities and complicated regulatory requirements; assist with the creation and review of quality systems; perform mock quality system audits to help companies prepare for FDA inspections; support companies as they defend their QMS during regulatory body inspections and assist in developing remediation plans, when needed following an inspection.

With the assistance of our white-collar criminal litigation colleagues, we conduct internal investigations of alleged code of business conduct and regulatory violations; especially in areas where liability can be significant with the potential civil and/or criminal liability.

We also work with companies to develop comprehensive corrective action plans to address issues raised during internal and third party investigations.

We have represented numerous companies in FDA criminal prosecutions, seizure and injunctive actions, civil money penalty actions, and import alerts.

Representative experience

- Helped a major device company draft a comprehensive set of Standard Operating Procedures (SOPs) governing the dissemination of labeling and advertising across all operating divisions of the company. We also assisted in developing a program to train regulatory personnel in these SOPs.
- Helped conduct a client's retrospective review of its files to assess its obligations in submitting Medical Device Reports to the FDA.
- Assisting a client in reviewing its complaint files and determining whether the complaint should be reported to the competent authorities in the EU Member States.
- We advised a pioneering bioresorbable orthopedic implant manufacturer in securing FDA De Novo premarket authorization for a bioresorbable metal implant trauma screw in the U.S. The screw is the first bioresorbable metal implant approved by FDA, and revolutionizes orthopedic treatment, offering a groundbreaking alternative to traditional implants that opens new avenues for patient care, with potential long-term benefits including reduced risk of implant-related complications and improved patient outcomes.
- Drug, and Cosmetic Act, and during the client's ensuing negotiations of a criminal plea and civil settlement agreement with the U.S. Department of Justice and the Department of Health and Human Services' Office of Inspector General.
- On behalf of a major corporation, we conducted multiple internal investigations of alleged regulatory violations raised by current and former employees and assisted the company in implementing comprehensive corrective action plans to address our findings.
- Assisted a multinational corporation with an internal investigation of alleged regulatory violations and an ensuing international product recall.
- Represented a company in negotiations with the Office of Inspector General (OIG) regarding alleged violations of the Homeland Security Act of 2002.

Recalls, corrections, and removals

A product recall is always an unplanned and unexpected event. The decision as to whether or not a field action is warranted is one of the most difficult decisions a medical device company can be faced with. Not only does it have the possibility to bring additional U.S. Food and Drug Administration's (FDA) scrutiny or other regulatory authority, but it can also be accompanied with significant legal liability and, if not managed well, damage to a company's reputation.

Our lawyers have a wealth of experience helping medical device companies work through those difficult decisions, and where a field action is needed, developing strategies that satisfy FDA and EU regulatory obligations, customer needs, and business objectives. Not every recall involves the removal of a product and our experience in developing field action plans and strategies allows companies to develop rational strategies to undertake their actions. We have helped clients manage global recalls, including many high risk recalls classified by FDA as Class I.

Our presence in the United States, Asia, South America, and Europe helps to provide full coverage for our clients when a global recall is undertaken, where coordination of the effort better manages the outcomes. Global regulators are coordinating where recalls are concerned, and our lawyers believe that the company should be similarly coordinating across geographies.

We can help guide companies through field action decision-making, recall compliance documentation, notification to FDA and international regulatory bodies, evaluation and planning for product liability issues, developing communication plans, addressing reimbursement, compensation requests, and warranty concerns. Where field actions necessitate modifications to FDA cleared or approved devices, or CE marked medical devices, we are able to assist the company in navigating the submission and approval process.

Representative experience

- Assisted a small international client in developing a recall strategy that involved all product produced by the company, which was classified as a Class I recall. Careful management mitigated the risk that the company would not be able to continue as a going concern.
- Assisted a client in managing a global recall in which the UK MHRA and German BfArM expressed serious concern about the products' continued presence on the market. International lawyers were able to interface with competent authorities to reach agreement on the approach for recall and the ongoing marketing of the product.
- Assisted a client in developing and executing a recall where FDA raised concerns regarding the approval status of the product after making modifications.

Advertising and promotion compliance

Our lawyers help companies balance legal compliance with their business objectives helping them to navigate the current environment, highlighted by evolving U.S. Food and Drug Administration (FDA) and EU Member States laws. From regulations and policies governing medical device labeling, advertising and promotion; to the ever-expanding types of media platforms available to companies to promote their devices, the Internet to social media; and ongoing, steady government enforcement.

Our pragmatic, tailored approach, founded on decades of experience, draws from a thorough understanding of the core framework and intricate nuances of relevant FDA and EU Member States laws, regulations and policies, and real-time monitoring and analysis of developments allowing us to expertly guide companies in all aspects of medical device promotion, from development of robust procedures, review of advertising and promotional materials, wholesale compliance audits, sales force training, and when needed, responding to enforcement actions and implementing corrective actions.

We advise clients on all aspects of product promotion, from what constitutes permissible discussion of investigational devices to the scope of allowable promotion of cleared, approved, and CE marked devices. We help clients craft promotional strategies that benefit their business while complying with the requirements of the Federal Food, Drug and Cosmetic Act (FDC Act) and FDA regulations, as well as intersection U.S. Federal Trade Commission (FTC) regulations and health care laws, such as anti-kickback statutes and the False Claims Act.

We also counsel on the nuanced and evolving aspects of this area, including First Amendment challenges of FDA and EU restrictions on off-label promotion; avenues for the dissemination of off-label information; the extent to which a manufacturer can be held responsible for third-party materials on traditional and newer media platforms; and the regulation of social media as a marketing tool.

Our services are wide ranging, and include reviewing product promotional materials and programs for compliance with FDA and, when appropriate, FTC, the U.S. Department of Justice (DOJ), and international regulations.

Representative experience

- Worked closely with our colleagues in the Health and Litigation groups to counsel numerous clients on the inter-relationships between FDA requirements and health care laws, as well as to assist these companies in developing and implementing corporate policies and procedures aimed at compliance in these important areas.
- Assisting a client in preparing a SOP on the promotion and marketing of its medical device in the EU Member States.
- Assisted a large, global client in conforming to government regulations, including abiding by the terms of a deferred prosecution agreement (DPA). As part of this work, we conducted a corporate investigation of sales and marketing practices, assessing internal procedures and advising senior managers and corporate boards on the risks and benefits of particular strategies and tactics.
- Conducted internal investigations and compliance audits arising out of concerns that current promotional activities may violate the FDC Act. In this role, we have reviewed and recommended revisions to marketing materials, practices, and SOPs so as to minimize regulatory risk.
- Conduct advertising and promotional trainings for every size of device firm, and for every level within these firms, from the C-suite to sales representatives, to lay the groundwork for effective and compliant marketing.
- Review client websites prior to launch and sit on Promotional Review Committees to assess regulatory risk from proposed promotional strategies and recommend how to revise claims to mitigate risk in delivering key marketing messages.
- Paralleling our extensive practice counseling clients on U.S. marketing and advertising, we assist clients in assuring compliance with European Union (EU) and member state requirements, and streamlining U.S. and OUS marketing procedures and practices to ensure global compliance.

Import and Export

Companies that import medical devices to and from the U.S. have faced increasing difficulty with the import process in recent years because of tightened requirements, due primarily to the increase in the number of products and subassemblies manufactured abroad, as well as terrorism concerns. For example, the U.S. Food and Drug Administration (FDA) now requires pre-clearance of imports and accountability of products at every point in the supply chain prior to entry. Additionally, FDA is inspecting more foreign facilities and is imposing limitations on a firms' ability to import as a negative consequence of unfavorable inspections.

We have a wealth of experience helping medical product importation go smoothly and solving problems with appropriate regulatory bodies and customs personnel, from the port of entry to agency headquarters. Our presence on both U.S. coasts, Asia, Europe, and the Middle East, helps to provide full coverage for our clients. Our practice includes the FDA's former top import official and we can draw on experienced colleagues in customs law from our International Trade practice.

Export of medical devices is made challenging by the complicated interplay of various export authorities that each impose their own requirements. Further, FDA has now woven its inspection and enforcement activity into the U.S. export certification process.

Our experience enables us to assist clients in determining whether and how their medical devices can be exported and what type of export certificate may be appropriate. We often advise clients in managing the consequences of unfavorable inspections that can affect the company's ability to export and obtain the necessary documentation to facilitate entry into other markets. Our International Trade lawyers and our global presence can assist companies in dealing with export issues efficiently and effectively.

Because the Import and Export of medical device products is so closely tied to a medical device manufacturer's supply chain and distribution model, our in-depth knowledge of the medical device industry and quality system requirements puts us in an ideal position to provide practical actionable guidance.

Representative experience

- Working closely with colleagues in our International Trade practice, we represented a client with the FDA and the U.S. Customs service regarding a notice of penalty for liquidated damages for failure to redeliver a product regulated under the Radiation Control for Health and Safety Act. The penalty was rescinded in its entirety.
- Work with several clients to file prior disclosure notices with U.S. Customs and Boarder Protection to mitigate the risk of enforcement and significant penalties associated with regulatory noncompliance with entries.
- Assist clients who receive Notices of Detention and Import Alerts and help them obtain release of products.
- To help ensure the import process will go smoothly, we frequently provide pre-import counseling and negotiate with the district Offices and Ports for the handling of unique situations before they are entered into the country.
- Assist a company in lifting an import ban from one of its OUS Contract Manufacturers.
- Assist clients with export planning to ensure the export meets the requirements of the U.S. and the receiving country.
- Work with clients in obtaining Certificates for Foreign Governments (CFGs) and Certificates of Exportability (COE) and negotiate the release of CFGs that have been held as a result of unfavorable inspections.

Intellectual property

Our patent lawyers believe that medical devices are often best protected through an interdisciplinary approach that takes into account not only patent law, but also regulatory requirements, health care-related revenue models, and health care policies, such as those involving privacy and reimbursement.

We also recognize that medical device patent protection often covers a wide range of technologies, from software to electronics, and from mechanics to biotechnology.

Companies seeking to obtain patent protection for medical devices confront unique considerations:

- Coordination of patent efforts and protection strategies with U.S. Food and Drug Administration (FDA) considerations, including those involving patent term extensions.
- Coordination of patent protection strategies with Medicare reimbursement issues and other revenue model considerations, such as those focusing on disposables, consumables, and provision of related services.
- Medical liability concerns, including safety issues, risk-reducing advantages of inventions, and prior art.
- U.S. Patent and Trademark Office requirements unique to medical products, such as the special considerations given to products asserting therapeutic or pharmacological utilities.
- Varying ability to protect life sciences inventions outside of the United States. Increased risks of early disclosures in the medical device industry, such as via clinical testing and medical publications.
- Application of current law to business methods, such as those related to software and computer applications, as business methods may include commercially valuable aspects of medical device technology.

Our intellectual property (IP) lawyers work in concert with our lawyers in other disciplines, including FDA regulation, to address these unique issues fully and facilitate the development and market entry of new medical device products. We have a team of seasoned IP lawyers with a blend of skills and experience that makes our practice particularly deep and well-rounded.

Many of our IP lawyers hold degrees in electrical, mechanical and chemical engineering, as well as biology, chemistry, physics, and computer science — several of them advanced degrees. Many of our IP lawyers also bring to bear substantive business experience in industries directly related to our areas of concentration, allowing them to understand fully the realities their clients face in running a business and achieving their objectives.

In addition to our internal resources, our IP group maintains close working relationships with foreign associates in virtually all industrialized countries. Members of the group represent both local and multinational clients including start-ups, Fortune 100 corporations, universities, hospitals, research organizations, and nonprofit entities.

Combination products

As medical technology continually advances, many products are being developed that are not simply new drugs, biological products, or devices, but rather are a combination of these products. Others are single entity products where regulatory responsibility is unclear because the product may have more than one mode of action.

Our medical device, pharmaceutical, and biotechnology lawyers provide advice on regulatory categorization. We also help clients obtain U.S. Food and Drug Administration's (FDA) determinations as to whether a product will be primarily reviewed by the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), or the Center for Devices and Radiological Health (CDRH).

We frequently help clients develop the complex scientific and regulatory arguments necessary to persuade the FDA for favorable jurisdictional assignments of combination products. In this process, we file Requests for Designation (RFDs) or seek informal discussion with, among others, the FDA's Office of Combination Products.

Once the lead office is identified and the product approved, we assist clients in navigating the applicable requirements for each component and the product as a whole, e.g., whether to file an adverse event report or a medical device report, whether drug good manufacturing practices or the quality system regulation applies, how to report a recall, etc.

Representative experience

- Filed numerous RFDs that have successfully persuaded the FDA to regulate our client's device-drug combination product in CDRH under the device authorities for products such as drug-eluting stents, drug-eluting leads, novel drug delivery devices, silver coated wound dressings, and biologically active wound care products.
- Assisted a client in determining the regulatory obligations applicable to its drug delivery system in the EU.
- One of our partners, who has published broadly on combination products, was invited by the FDA to speak at an agency workshop on the regulation of innovative drug delivery systems.
- Another of our partners, during his time as an FDA associate counsel, was an advisor to the chief ombudsman on combination product matters.

We are one of the very few firms to receive a **top-tier ranking** from **Chambers USA** in all areas of FDA regulation.

Financing, distribution, and other agreements

As in every industry, our medical device clients frequently seek private and public investment. They also engage in mergers and acquisitions and corporate restructurings. When they do, we frequently serve as special U.S. Food and Drug Administration's (FDA) and EU counsel to advise or provide an opinion. We are also retained by underwriters and investors for this purpose.

In this area, we conduct due diligence to determine a company's state of FDA/EU compliance or the likely regulatory pathway to market of its key pipeline products; draft disclosures describing, in plain English for investors, the FDA and EU regulatory framework and its application to a particular client; assist with the transfer of 510(k) notices and premarket approval applications (PMA); CE Certificates of Conformity; and review the FDA and EU provisions of merger-related contractual documents.

We are also often asked to advise on post-transaction integration planning and execution to preserve regulatory compliance following the transaction.

We assist clients in the FDA and EU regulatory compliance aspects of drafting or reviewing supply or distribution agreements, including the preparation of Quality Agreements or Own Brand Labeling Agreements.

Representative experience

- Helped draft a complex supply agreement in which Company A, the manufacturer and PMA owner, would transfer its PMA to Company B, the distributor, while remaining the exclusive supplier. This arrangement raised uncertainties about regulatory compliance that were carefully negotiated and spelled out in the supply agreement.
- On behalf of an investment bank, we conducted due diligence on a small medical device start–up, uncovering several important FDA issues that substantially altered the target's valuation.
- Assisting several medical devices clients in preparing distribution, importer, and authorized representative agreements reflecting the obligations of the EU MDR.
- Just as our medical device client was about to launch an initial public offering (IPO), it received an FDA Warning Letter. We evaluated the significance and helped draft disclosures that ensured compliance with Securities Exchange Commission (SEC) requirements, while keeping the offering on track to a successful conclusion.

Cell, tissue, and gene therapies

Medical therapies at the frontiers of science and medicine, such as those using stem cells, placental tissue, and viral vectors to correct defective genes, pose unique challenges. One critical issue is how they will be regulated, both within and outside the U.S. We have a cross-disciplinary, international working group with extensive experience advising clients on regulatory pathways for a wide range of cell, tissue and gene therapies. Many human cell or tissue products (HCT/Ps) can be marketed without prior FDA approval, while some are much more highly regulated in the United States.

We frequently counsel clients on how FDA and competent authorities in the EU may seek to regulate their HCT/Ps, and (where they do not require premarket review) how to market them without putting their regulatory status at risk. For all kinds of HCT/Ps, we advise clients on how to comply with FDA's Good Tissue Practice regulations and the applicable EU requirements, as well as on a wide range of approval and post-market issues. Those issues include expedited development programs such as breakthrough therapy, regulatory exclusivities such as orphan drug status, and commercialization issues such as tech transfer, reimbursement, and licensing.

Our regulatory experience in regenerative medicine, stem cell technology, and other emerging product types and issues enables us to advise clients interested in purchasing companies that are expanding the frontiers in these technologies.

Our team includes members with expertise in providing legal guidance to researchers and entities, including issues such as proper institutional oversight for research, formulation of informed consent standards, drafting informed consent forms, compensation for participants in research, and the Health Insurance Portability and Accountability Act and other privacy/confidentiality issues.

As other countries develop new regulatory practices in response to these product types, we are carefully monitoring these developments and have assisted our clients in understanding the scope of consequences of laws such as the EU tissue collection directives and the EU Regulation on Advanced Therapies.

Representative experience

- Assisted multiple clients with Tissue Reference Group advisory opinion requests and Office of Combination Product Requests for Designation (RFD) for allogeneic and autologous cord blood products, cell sorter and isolation systems, mesenchymal cells of multiple tissue origins for both structural and supportive uses, and products intended for reproductive and assisted reproductive technology applications.
- Advised a company on obtaining a Patent Term Extension for a product containing mesenchymal stem cells.
- Advised a medical device company on the regulation of tissue and cell products in the EU and in France.
- Advised a biotech company on the regulatory feasibility and risks of selling a form of stem cells without any FDA pre-market approval when intended solely as a reagent in manufacturing other biological products.
- Advised human tissue companies on how to transition a product from 361 HCT/P status to licensure as a biologic under section 351 of the Public Health Service Act.
- Assisted a human tissue company on responding to an FDA Untitled Letter and in maintaining its FSS contracts.
- Advised a foreign company on various FDA clinical hold issues.
- Assisted leading pharmaceutical companies in determining the appropriate classification of their tissue products in the EU.
- Assisted a client in understanding the impact of the EU MDR on the regulation of its tissue products.
- Assisted a major pharmaceutical company with due diligence on the purchase of a company developing a mesenchymal stem cell product.
- Advised biotechnology companies, hospitals, and researchers on interpreting critical terms and provisions in the HCT/P regulations, such as "same surgical procedure," "minimally manipulated," and "homologous use."
- Advised gene therapy companies on genotyping programs.
- Performed due diligence supporting a client's purchase of an umbilical cord blood bank.
- Worked with skin substitute manufacturers to navigate Medicare's new payment rules that package skin substitute payment with underlying procedures in hospital outpatient departments.
- Obtained Healthcare Common Procedure Coding System (HCPCS) codes for cellular therapies.
- Analyzed potential alternatives for coverage reimbursement of gene therapies.
- Represented the University of Pennsylvania in connection with its exclusive license and collaboration of CAR-T technologies with Novartis.
- Advised a leading global pharmaceutical company on a global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology.
- Advised several clients developing novel cell-based therapies to treat oncology indications and their regulatory strategies for seeking approval of these innovative therapeutics.
- Provided Dendreon Corporation with reimbursement support for the immunotherapy cell-based product Provenge, including obtaining a positive Medicare National Coverage Determination for the product.

Supporting clients in the fight against cancer

We advised P-Cure in securing FDA market clearance for a proton therapy system for targeted cancer treatment where the patient is treated in a seated position rather than the conventional proton therapy systems which rely upon supine positioning. The gantry-less system allows for imaging and treatment in the same position, ensuring that the noninvasive therapy is delivered to the targeted tumors. The P-Cure proton therapy system is a single room treatment system with a smaller footprint that the conventional proton therapy systems which require 200 tons of proton equipment and most often exceed US$50 million per single room. The space and cost requirements of these other systems prevent access to the technology, with only 1% of hospitals providing proton therapy treatment. By securing FDA clearance, the company can deliver this long-awaited treatment modality to many more radiotherapy departments.

In vitro diagnostics

Our lawyers, including technically trained consultants and scientists, have a broad range of experience in the field of in vitro diagnostic (IVD) products at all stages of development and for a variety potential uses. Due to the mix of our professional staff, we are able to offer both legal and regulatory services to pharmaceutical, life sciences, biological, and medical device/ diagnostic manufacturers and health care service providers.

Of the approximately 700 medical device companies represented by Hogan Lovells before the U.S. Food and Drug Administration (FDA), approximately 60 to 70 are IVD companies ranging from start-ups to well-established companies both in the United States and internationally. We also support clinical laboratories, diagnostic equipment and instrument manufacturers, and trade associations focused on diagnostics, personalized medicine, and clinical laboratory technologies.

Our FDA legal experience in the drug, biologic, and medical device areas positions us uniquely to assist companies with developing clinical and regulatory strategies for IVD assays, whether as a companion diagnostic for drugs or for other disease/medical condition detection.

Our team includes numerous lawyers and technical specialists with many years of experience in the IVD area, in both industry and advisory positions. This includes partners with expertise in blood screening and companion diagnostics, a partner and biostatistician who was formerly responsible for clinical trial development at universities and nonprofit organizations for both drugs and devices; a partner who has served as legal counsel for over 15 years for the Association of Medical Diagnostic Manufacturers, one of the largest U.S. trade organizations that specifically targets IVDs; and a team of lawyers with extensive knowledge of the diagnostic quality system regulations.

Our team regularly assists clients in obtaining market approvals and clearances for diagnostic tests, as well as related instruments, accessories, and software, which are regulated by CDRH or CBER. We have similar capabilities in the European Union through lawyers in our Brussels and other EU offices.

We work on regulatory issues from some of the most basic IVD products, such as sample preparation and culture media devices, to those with the most cutting-edge diagnostic technology under development, including genetic microarray assays in the cancer diagnostics area, molecular assays for infectious diseases, and test systems predictive of drug responses.

Representative experience

- Support multiple IVD manufacturers in responding to and addressing postmarket compliance concerns, including responding to inspectional observations, addressing complaints and recalls, reviewing Medical Device Reporting analyses; and addressing disputes arising from product use and marketing.
- Help develop clinical and regulatory strategies for a number of clients that are developing biomarkers and molecular diagnostics that would be companion assays to drugs.
- Worked on numerous pre-market submissions for IVDs in the medical device and biologics areas and on Investigational New Drug (IND) applications for various imaging agents, and we have extensive experience in negotiating clinical study design and regulatory pathways with the FDA on behalf of our client companies.
- We have established regulatory training programs to educate the internal units of major pharmaceutical, biotechnology, and medical device companies on the development, testing requirements, premarket submissions, and manufacturing requirements regarding QSRs.
- Our regulatory and legal experience in the IVD area provides a unique ability to assist IVD and reagent manufacturers, as well as clinical laboratory service providers, in navigating the parallel universes of IVD and analyte-specific reagent (ASR) regulation on one hand, and laboratory-developed tests (LDTs) on the other.
- Assisted a company in obtaining the first waiver from the FDA under the Clinical Laboratory Improvement Amendments (CLIA) for a syphilis screening test.

Bringing to market the first bioresorbable metal implant in the U.S.

We advised Bioretec in securing FDA De Novo premarket authorization for Bioretec's RemeOs™ trauma screw in the U.S. The screw is the first and currently only bioresorbable metal implant approved by the FDA. Bioretec will launch the RemeOs™ trauma screws in the U.S. in collaboration with clinical professionals specialized in ankle fractures, which are one of the most frequently occurring fracture types among the adult patient population. The RemeOs™ trauma screw had previously been granted the FDA's Breakthrough Device Designation for use in skeletally mature adults, as bioresorbable metals combine the surgical techniques of traditional metal implants and the patient-friendly care and benefits of last-generation bioresorbable polymer implants.

Good clinical practice compliance

We have established industry-leading strength in advising companies on good clinical practice (GCP) compliance in the medical device and pharmaceutical and biotechnology sectors.

Our medical device and pharmaceutical and biotechnology groups also have well-established relationships with a large network of outside GCP consultants and auditors, many of whom have substantial U.S. Food and Drug Administration (FDA) and industry experience. One of our partners regularly works with medical device companies to develop clinical trial quality systems, responses to Warning Letters and Form 483s, corrective action plans, and clinical standard operating procedures (SOPs). Our GCP auditors also often assist with pre-approval inspections.

In addition to our U.S.-based partners and associates, we have complementary skills throughout our offices in the EU, Eastern Europe, Russia, and Asia. Our Brussels office includes a team of lawyers with significant experience, developed in both private practice and in international institutions, in EU regulatory law governing medical devices and pharmaceuticals and biotechnology products.

We have developed a global network of local regulatory counsel who are available to advise on local clinical trial issues in many regions, including Europe, Latin America, India, East Asia, and Southeast Asia.

Representative experience

- Assisting companies who have come under the FDA's Application Integrity Policy or are on integrity hold.
- Counseling numerous companies on compliance with the clinical trial provisions in the Food and Drug Administration Amendments Act of 2007 and in EU clinical trials legislation.
- Working with companies to develop policies and procedures to help them come into compliance with federal and state clinical trial disclosure requirements.
- Working with companies to develop clinical trial SOPs and corrective action plans.
- Defending clinical investigators in FDA disqualification proceedings.
- Assisting companies to build compliance structures (including written policies) and to conduct compliance audits and establish training programs.
- Counseling companies on compliance with the Foreign Corrupt Practices Act (FCPA) when conducting international clinical trials.

Digital health

The intersection between tech and health care brings enormous business potential, as well as unique legal and regulatory issues. From mobile medical apps and standalone software as a medical device to wearable sensors and digital therapeutics, our digital health team has extensive experience counseling clients on the U.S. Food and Drug Administration (FDA) and EU implications for new technology.

We assist clients in determining whether their digital health products are regulated by FDA and other regulators as medical devices and help them navigate the unique regulatory issues involved in seeking clearance/approval/CE marking and staying compliant in the postmarket phase. From inception and approval/CE marking to debut and product maturity, our clients benefit from guidance that reflects their business strategies and legal needs.

Our team regularly advises clients on a wide range of digital health product issues, such as cybersecurity, use of wireless communication technology, and software validation.

We counsel companies on all aspects of regulation involving the FDA, the EU authorities, and other local, national, and international regulatory entities. We regularly advise clients regarding strategic plans that not only comply with government regulations, but also achieve their business objectives.

Representative experience

- Advising companies developing digital therapeutic tools on the regulatory pathway and associated clinical data needs.
- Assisting a medical device manufacturer in the classification and CE marking of its new medical app and identifying a notified body for the conformity assessment procedure.
- Obtaining clearance for a number of wearable sensors measuring various physiological signals.
- Assisting a major Health IT company in conducting a complete regulatory assessment of all portfolio and pipeline products to determine which products may be subject to regulation and assisting with bringing products into compliance where needed.
- Successfully obtaining clearance for standalone software products in the imaging, anesthesia, and remote patient monitoring spaces.
- Counseling a major pharmaceutical company on the development and regulatory requirements for mobile applications and smart drug delivery tools to be used by patients.

Artificial Intelligence

From smartphones to self-driving cars, artificial intelligence (AI) influences nearly every aspect of modern life. Health care is no exception. Use of artificial intelligence systems promises better health care management for patients and faster, more accurate diagnoses for doctors. Companies pursuing AI technologies must realize that while the health care industry is embracing this technology, the regulatory landscape is still finding its footing.

Hogan Lovells has been at the forefront of medical device AI regulation. We have advised our clients on the clearance or approval of numerous medical devices that incorporate artificial intelligence algorithms. From analysis of medical imaging such as echocardiograms, computed tomography (CT), endoscopy, and skin photographs, to tissue histology and physiological data, such as electrocardiograms (ECG), these technologies have demonstrated enormous potential for health care. They are designed to screen for diseases, classify malignancies, and provide personalized treatment recommendations, among other things, often sooner than has been possible using traditional technologies.

At the same time, these products raise unique regulatory questions due to their iterative and potentially self-updating nature, which is incongruent with historical regulatory approaches. The use of machine or deep learning offers the opportunity for continual optimization of an algorithm as new training data becomes available; whereas traditional regulatory approaches have focused on frozen algorithms that require new clearance or approval if changes are made postmarket.

Our medical device and technology lawyers have extensive experience counseling clients on the FDA and EU implications for new medical technologies, including AI technologies. We assist clients in determining whether these products are regulated as medical devices by FDA and other regulators.

We understand the regulatory frameworks at issue, including FDA's new proposed framework for regulating AI devices. We have successfully advised our clients in navigating the unique regulatory issues involved in seeking FDA clearance, approval or CE marking for AI-based devices and staying compliant in the postmarket phase.

Representative experience

- Developed an innovative strategy for interacting with FDA to allow our client **Viz. ai** to gain a quick De Novo clearance for a novel Computer-Aided Triage and Notification Platform to identify Large Vessel Occlusion (LVO) strokes in CTA imaging, meeting the company's tight deadlines.
- Successfully assisted **Digital Diagnostics** to achieve De Novo reclassification from the FDA for the groundbreaking AI-based device IDx-DR, which autonomously analyzes images of the retina for signs of diabetic retinopathy.
- Assisted **CSD Labs** in obtaining 510(k) clearance of eMurmur, an innovative, AI-based murmur detection software.
- Helped **Aidoc Medical, Ltd.** to obtain 510(k) clearance for Briefcase—an AI based computer aided triage and notification software for analysis of non-enhanced head CTimages.
- Successfully advised **Bay Labs** in seeking 510(k) clearance for its EchoMD Automated Ejection Fraction (AutoEF) software, which applies machine learning algorithms to process echocardiography images in order to calculate left ventricular ejection fraction.
- Assisted numerous clients with novel medical devices featuring AI and machine learning algorithms in developing and gaining FDA alignment on creative regulatory strategies to bring these innovative products to market in the United States quickly and efficiently.

State medical device distribution and manufacturer licensing

Medical Device manufacturers who distribute prescription and over-the-counter (OTC) devices are subject to a complex web of state licensing requirements that can attach to their manufacturing and/or distribution activity. Further, many medical device manufacturers take advantage of the services of third party logistics (3PL) providers who are also subject to separate state licensing requirements; all of which are separate from the business licenses that companies need to obtain conduct business in the state.

Licensing rules vary between prescription and OTC devices, recipient (health care professional versus patients) and in-state and nonresident operations. There are even a fair number of states that have no licensure requirements for medical devices of any sort. Adding further complexity is the fact that most state licensing regimes are developed to handle prescription drugs and controlled substances and are not always suitable for the distribution models used for medical devices and in fact are not always applied to medical devices.

Where state licensure obligations exist, medical device manufacturers must satisfy them in order to distribute into and within the state. Having the necessary licenses become particularly critical as there are times where companies must certify compliance with all necessary state and federal law such as when contracting with the federal government or submitting for reimbursement. Failure to have the necessary licenses in place when signing such a certification can raise the possibility of penalties for making false statements to the government under 18 USC § 1001.

Where medical device companies are required to hold state licenses to cover their manufacturing and / or distribution activities, companies must complete complex initial licensing and renewal forms with variable requirements and guidelines. Additionally, many licenses come with associated process requirements that must be woven throughout the distribution processes that are often part of the company's Quality Management System (QMS).

Because Hogan Lovells' lawyers have expertise in Quality System compliance, the medical device industry and the various distribution models, our Lawyers are able to leverage that knowledge in determining whether licensure is required in a given state, assisting the company in obtaining those licenses and building the necessary compliance infrastructure that is required for a licensed entity.

With experience in licensing projects with diverse scopes, business models and timelines, our lawyers can identify federal requirements related to a medical device company's business model; identify necessary state licenses, prerequisites and the proper order for filing applications; prepare, review and file applications through all licensing bodies; tailor applications to distribution models; and identify necessary compliance measures with requisites and prerequisites, including bonding, fingerprinting, and licenses to do business, and testing of designated personnel.

Our lawyers have assisted clients in addressing state licenses for new product launches by identifying those states that require licensure and assisting the company is preparing those applications. In addition, our lawyers have negotiated enforcement discretion with states for unique medical devices where licenses may have been required under the letter of the law, but the states elected not to require licensure due to the low risk of the product and low benefit of licensure. Additionally, our lawyers have assisted companies with developing remediation strategies and also handling notices of violations from state regulatory bodies. We have also assisted with the negotiation of distribution agreements with distribution partners and 3PLs to ensure that state licensing obligations are handled.

Representative experience

- Assisted client in addressing state licenses for new product launches for an AI based digital therapeutic by identifying those states that require licensure, assisting the company in preparing those applications, and advising the company on the infrastructure needed to manage compliance with the license obligations for a Software only product.
- Negotiated enforcement discretion with states for unique medical devices where licenses may have been required under the letter of the law, but the states elected not to require licensure due to the low risk of the product and low benefit of licensure.
- Assisted companies with developing remediation strategies and also handling notices of violations from state regulatory bodies.
- Assisted with the negotiation of distribution agreements with distribution partners and 3PLs to ensure that state licensing obligations are handled.
- Assisted a major medical device manufacturer in negotiating state board enforcement action settlement for manufacturer/ distributor licensure lapses.

Emergency Use Authorization and pandemic related products

Ranked Band 1 for Healthcare: Pharmaceutical/ Medical Products Regulatory in the District of Columbia, Chambers USA, 2023

Ranked Band 1 for Life Sciences: Chambers Global, 2023

Ranked Band 1 for Life Sciences: Chambers Europe, 2023

Ranked Band 1 for EU Regulatory: Medical Devices, Pharma and Biotech, Legal 500, 2023

Regulatory Firm of the Year by LMG Life Sciences, 2018-2021, 2022

Our Medical Device and Technology team has been at the forefront of the COVID-19 legal response since the pandemic swept across the globe. Our team has taken on over 200 matters, ranging from attaining U.S. Food and Drug Administration (FDA) Emergency Use Authorizations (EUAs) for critical medical devices and testing kits, to advising on legal risks of producing various types of personal protective equipment (PPE) and importing devices – such as ventilators from China – for use in the U.S. and around the world.

The COVID-19 pandemic requires quick-turn, out-of-the-box approaches to mitigating a global health crisis that evolves daily. We are helping our clients navigate the minefield of regulations and work with the relevant government agencies to develop creative approaches that respond to immediate needs, and potentially alter the long-term implications of this disease.

Below are examples of a few key areas in which our team has assisted clients.

Telehealth and remote patient monitoring are here to stay now that COVID-19 has forced us to prove that virtual health technology works, and that patients can make the technology work for them. We have assisted clients in implementing these solutions, whether it be through expedited 510(k) notices or enforcement discretion for products that do not fall under traditional EUAs.

Emergency Use Authorization authority has been granted to FDA to permit the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent SARS-CoV-2 infection and COVID-19 disease. We have helped many clients submit COVID-19 related EUA requests for: molecular and serology diagnostic tests; ventilators, respirators, and their associated parts; remote monitoring devices; surgical masks and other PPE and PPE reprocessing methods; and other treatment devices. We are closely tracking FDA's evolving guidance on EUA's and additional enforcement discretion approaches during the pandemic, and helping manufacturers and laboratories offering COVID-19 tests and test validation – who rely on EUA authority – to remain in compliance with FDA standards.

Disruptions to operations caused by the COVID-19 pandemic are unprecedented, creating the ultimate stress test for global businesses. For manufacturing operations, ability to source components and supplies for medical devices, especially from foreign countries, has been adversely affected by travel and other restrictions. We have assisted companies in dealing with supply chain issues, as well as responding to supply chain issues (e.g., using manufacturing capabilities for different purposes than intended). For clinical studies, insufficient supply of the study product and missed study visits could cause protocol deviations resulting in problems with obtaining data to assess outcomes, measurements, or statistical analyses. Sponsors with ongoing clinical studies, or those deciding whether to proceed with a clinical study, must carefully consider how to handle these challenges, including changes to study protocols and analysis plans, and the associated regulatory implications. Our team has helped clients navigate this crisis, assess risk, and consider pragmatic and tailored solutions. We are closely monitoring FDA and European Union guidance on the issue, which provide significant regulatory flexibility.

Importing medical devices has always presented sizable regulatory challenges. But through our work with clients during the COVID-19 crisis, we have helped speed up that process while ensuring safety standards are retained. We have helped many clients to understand the European marking requirements applicable to face masks, including FFP2 masks and surgical masks. In the U.S., we have helped clients navigate strict FDA requirements and the sheer logistical complexity involved to move the products across borders. We are also facilitating long-term opportunities, such as seeking marketing authorizations and analyzing supply chain vulnerabilities that will benefit the post-pandemic marketplace.

Requiring reporting of test results has been a key feature of governments' COVID-19 responses. As clients have sought to expand testing beyond "traditional" health care and laboratory settings, and into point-of-care use (e.g., the workplace, public gatherings), compliance with these reporting requirements has become more challenging. Our compliance team helps clients to assess and understand the ever-expanding patchwork of reporting obligations – at the local, state/regional, and national levels – and to comply with emerging regulations.

Remote audits and inspections have become necessary as travel restrictions affect the ability of the FDA, notified bodies, and MDSAP Auditing Organization to perform on-site audits. Further, limitations on personnel and staffing are creating challenges to completing scheduled internal audits or preparing for preapproval or postmarket surveillance inspections. Our team has received ISO 13485 auditor certification, and has developed a plan for conducting remote Quality System Audits of most elements of your Quality Management System. We are able to use numerous platforms, including Web-Ex, Zoom, Skype, Google Meet and others. We also can utilize secure file transfers to ensure confidentiality and data protection.

Representative experience

- Assisting multiple clients regarding EUA submissions for COVID-19 diagnostic tests, treatments, and surgical masks.
- Advising numerous non-traditional life sciences and device companies on the requirements and logistics of producing critical need supplies.
- Advised **Vayu Global Health Innovations** in obtaining an EUA from FDA that allowed its bubble CPAP (bCPAP) device to be immediately distributed to hospitals to help alleviate the ventilator shortage associated with COVID-19.
- Teamed up with regulatory consultant Wanda Henry Co. to advise **Sansure Biotech, Inc.** in its FDA EUA for a molecular diagnostic test kit for COVID-19.
- Advising **Ford Motor Company** in its collaboration with GE Healthcare to help reinforce the Strategic National Stockpile and to support the treatment of coronavirus patients.
- Advised the **Kraft Group/New England Patriots** to obtain the necessary government approvals to pick up 1.3 million N95 masks from Shenzhen, China, and deliver them to the Commonwealth of Massachusetts.

Our Team

Practices

Medical Device and Technology Regulatory

Areas of focus

Advisory Panel Preparation

Digital Health

Medical Devices

Education

J.D., Georgetown University Law Center, 2015

B.A., University of Virginia, 1998

Kristin Zielinski Duggan

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With a background in biology and economics, Kristin Zielinski Duggan provides strategic advice to companies on scientific and U.S. Food and Drug Administration (FDA) regulatory challenges, while always keeping business needs in mind. For over 20 years, she has been counseling cutting-edge companies regarding the development and regulation of medical devices, pharmaceuticals, and combination products.

Kristin has a wealth of experience with the entire FDA regulatory process and agency interactions, from devising regulatory strategy for innovative products to pre-submission meetings; to assisting with preclinical and clinical programs and IDEs; to preparing regulatory submissions (510(k)s), de novo petitions and premarket approvals (PMAs); to appeals of agency decisions. Having prepared companies for dozens of advisory panel meetings over the years – including panel meetings to review 510(k) notices and PMAs, general issues panels, and classification panels – Kristin is a top thought leader in this area. She has been involved with all of the meetings of the Medical Devices Dispute Resolution Panel (MDDRP) to date.

Kristin also assists companies with compliance challenges, including 483 and Warning Letter responses, adverse events reporting, recalls, Department of Justice (DOJ) investigations, and product liability litigation, as well as with due diligence for investments and acquisitions.

Kristin's practice covers products in many therapeutic areas, including software products, cardiovascular products, orthopedic and gynecologic implants, plastic and reconstructive surgery devices, radiology devices, gastroenterology devices, wound care products, dental implants, endoscopes and minimally-invasive surgical solutions, and in vitro diagnostics.

Kristin previously served as Vice President for Strategic Consulting at a Washington, D.C.-based scientific consulting firm. Throughout her career, she has published and presented on various FDA regulatory issues. She is also an adjunct professor teaching an experiential seminar on FDA Regulation of Medical Products (Medical Devices, Drugs, and Biologics), which is part of the Executive Master of Science in Health Systems Administration (EMHSA) program at Georgetown University's School of Nursing and Health Studies.

Practices

Administrative and Public Law

Commercial

Government Relations and Public Affairs

Investigations

Marketing and Advertising

Medical Device and Technology Regulatory

Private Equity

Areas of focus

Sales Promotions

Adverse Event Reporting

Vigilance Reporting

Advertising and Promotion Compliance

In Vitro Diagnostics

Medical Devices

Quality System regulation and ISO 13485 Compliance

Education

J.D., The Catholic University of America, Columbus School of Law, magna cum laude, 2002

B.A., University of Delaware, 1993

Michael S. Heyl

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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.

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, and is ranked in *Chambers* and *LMG Life Sciences*.

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.

Practices

Medical Device and Technology Regulatory

Areas of focus

Advisory Panel Preparation

Combination Products, FDA

Jurisdictional Issues, FDA

Postmarket Compliance Issues

In Vitro Diagnostics

Medical Devices

Premarket Review

Cell, Tissue, and Gene Therapies

Education

J.D., Georgetown University Law Center, magna cum laude, Order of the Coif, 1995

B.S. Mechanical Engineering and Literature, Massachusetts Institute of Technology, 1988

Janice M. Hogan

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Janice Hogan has been involved in medical technology for over 25 years. From her engineering training at M.I.T. to work in the pharmaceutical industry, to her current practice representing medical device companies before the FDA, Janice has focused her career on the intersection of technology, regulation, and health care.

Widely recognized as a leader in FDA regulation of devices, Janice is co-director of the FDA Medical Device practice. She leverages her technical background to help companies with cutting-edge technologies navigate and optimize the FDA approval process.

Janice focuses on FDA regulation of high-tech products in women's health, diagnostics, neurology, cardiovascular, and orthopedics. She has assisted companies to obtain "first of a kind" FDA approvals, providing guidance on regulatory strategy, clinical study design, advisory panel proceedings, and tools to expedite product approval.

Janice brings her lifelong passion for science and innovation to bear in her client advocacy. Through her extensive experience representing companies in a wide range of FDA interactions, Janice has been at the forefront of several of the most innovative medical device approvals, including the first successful FDA/CMS parallel review project, as well as first-in-class approvals for devices used in treatment of breast cancer, diabetes management, obesity, spinal surgery, and neurology, as well as a variety of drug/device combination products. Janice also has substantial experience using newer FDA approval mechanisms such as the de novo process to reduce review time and bring products to market earlier, accelerating patient access.

Practices

Medical Device and Technology Regulatory

Areas of focus

Adverse Event Reporting
Vigilance Reporting
Advisory Panel Preparation
Combination Products, FDA
Jurisdictional Issues, FDA
Postmarket Compliance Issues
Medical Devices
Advertising and Promotion Compliance
Premarket Review

Education

J.D., The George Washington University Law School, with honors, Order of the Coif, 1973

B.A., The George Washington University, with honors, 1970

Jonathan S. Kahan

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With more than 40 years of legal experience, Jonathan Kahan is an industry leader in obtaining FDA market clearance of novel medical devices for medical technology and diagnostics companies. He also advises on post-market compliance matters.

Jonathan helps clients navigate complicated regulatory processes, including those related to combination products such as combinations of devices, drugs, biologics, and human tissues. He authored the leading text on medical device law, *Medical Device Development: Regulation and Law* (Parexel 2020).

Jonathan is the former director of the firm's Medical Device and Technology practice group and an adjunct professor at the George Washington University Law School teaching medical device law. He presently serves as a member of the George Washington University President's Leadership Advisory Council and he is also the general counsel of the Association of Medical Diagnostics Manufacturers.

Jonathan is highly ranked by Chambers as well as other legal directories. He has been consistently included in Washington, D.C. *Super Lawyers* and Washingtonian magazine's Top Lawyers in D.C. Jonathan has been named Regulatory Lawyer of the Year by *LMG Life Sciences* in the FDA Medical Devices category. He also received the Food and Drug Law Institute (FDLI) Distinguished Service and Leadership Award, recognizing his contribution in promoting public health, advancing the medical device and technology law field, and ensuring a robust and innovative regulatory environment.

Practices

Medical Device and Technology Regulatory

Areas of focus

Advertising and Promotion Compliance
Advisory Panel Preparation
Combination Products, FDA
Jurisdictional Issues, FDA
Postmarket Compliance Issues
Premarket Review
Unique Device Identifiers
Medical Devices
Digital Health

Education

J.D., Georgetown University Law Center, 2006

B.S., Carnegie Mellon University, 2002

Lina R. Kontos

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Lina Kontos' technical engineering background lets her craft strategic and creative solutions for companies facing regulatory matters before the U.S. Food and Drug Administration (FDA). She works exclusively with medical device companies with a deep focus on the premarket clearance and approval of new medical devices.

Lina leverages her professional experience to view medical devices both from the company's perspective in designing and marketing a new product and from the perspective of an FDA reviewer. She has wide-ranging experience in assisting companies in matters pertaining to product development, regulatory strategy and product submissions (pre-submissions, 510(k)s, IDEs, de novo petitions, and premarket approval applications (PMAs). She works with companies through the entire medical device life cycle, providing advice from the product development phase in order to optimize the regulatory pathway, helping to navigate the FDA process in determining the testing and information necessary to get to market, presenting the strategy to FDA, and advising on issues once a product is being distributed, including advertising and promotion and diligence for mergers and acquisitions.

Her interest in technology and development carries over into her law practice helping tech companies with determining when and how medical device regulation applies and navigating FDA's evolving regulations in digital health. Lina has special experience with devices intended to be sold over-the-counter (OTC) and the accompanying usability and human factors evaluations to support those applications, radiation emitting products in both medical and nonmedical applications, and FDA's requirements for Unique Device Identifiers (UDI).

Prior to joining Hogan Lovells, Lina worked as a biomedical engineer and reviewer in the Office of Device Evaluation/ Center for Devices and Radiological Health at the FDA. While at the FDA, she evaluated 510(k) notices, investigational device exemption applications (IDEs), and PMAs for peripheral vascular medical devices. Now Lina utilizes both her engineering background and FDA experience in advising clients on getting new and novel products to market.

Practices

Medical Device and Technology Regulatory

Areas of focus

Digital Health

Medical Device Artificial Intelligence

Advertising and Promotion Compliance

Medical Devices

Premarket Review

Clinical Trials

Education

J.D., The Catholic University of America, Columbus School of Law, 2005

B.S., The Catholic University of America, 1998

Kelliann H. Payne

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Kelliann Payne's science education and background in the medical device industry allow her to quickly understand emerging medical device technology, including digital health products, and informs her current focus on related legal and business issues. Her experience includes the development, regulation, advertising, and litigation of medical devices and digital health products, including machine learning-based clinical decision support software.

Kelliann drafts premarket submissions for diagnostic and therapeutic medical devices, evaluates and formulates applicable regulatory strategies, and reviews the accuracy of marketing claims. She helps companies in their preclinical and clinical programs and leads due diligence reviews for investments and acquisitions.

In her role as Assistant General Counsel at QVC, Inc. from 2013 to 2014, Kelliann counseled internal clients on Food and Drug Administration (FDA) and Federal Trade Commission (FTC) regulations applicable to health, wellness, beauty, and cosmetic products.

As a consultant for the medical device industry, she assisted companies with complex regulatory challenges and strategies for marketing innovative products. Kelliann majored in biology prior to pursuing a career in law.

Practices

Medical Device and Technology Regulatory

Pharmaceutical and Biotechnology Regulatory

Areas of focus

Adverse Event Reporting

Vigilance Reporting

Advisory Panel Preparation

Cell, Tissue, and Gene Therapies

Combination Products, FDA

Jurisdictional Issues, FDA

Postmarket Compliance Issues

In Vitro Diagnostics

Premarket Review

Product Development and Approval

Quality System regulation and ISO 13485 Compliance

Education

J.D., Catholic University of America, cum laude, 2010

B.S., University of South Carolina, 1984

Randy J. Prebula

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Whether describing complex science in straightforward terms to lawyers or translating premarket and compliance regulatory requirements to scientists, Randy Prebula focuses on practical industry experience and a deep understanding of Food and Drug Administration (FDA) regulations to help clients navigate the intersections of science, policy, and law. By helping companies focus on both what they have done and why their approaches address patient and public health needs within their relevant regulatory processes, Randy seeks to promote public health by helping ensure that medical products are safe and effective.

Randy is a key resource for companies designing, developing, and producing health care products and treatments, including medical devices, drugs, biologics, human tissues, and combination products. Randy works seamlessly across borders with clients and internal teams to help bring innovative medical products to market, monitor their performance throughout their unique life cycles, and ensure their availability to help meet individual patient and public health needs.

As director of the firm's FDA Medical Device & Technology practice area, Randy helps develop and integrate legal and non-legal professionals to leverage their technical and legal knowledge to provide clients with practical, implementable solutions to meet their regulatory goals. He also helps companies with cutting-edge technologies navigate and optimize the FDA approval process.

He brings a wealth of experience in immunology, biochemistry, and new product development and provides real-world experience in developing, implementing, and maintaining compliant regulatory systems and procedures.

Practices

Medical Device and Technology Regulatory

Areas of focus

Digital Health

Medical Devices

Cell, Tissue, and Gene Therapies

ISO 13485 Compliance

Education

D.E.S.S. European Law, Université de Rennes 1, with merit, 2007

Fabien Roy

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As partner of our Life Sciences practice, Fabien Roy focuses his practice at Hogan Lovells on advising clients on European Union (EU) and national regulatory matters involving medical devices and pharmaceutical laws and guidelines. Fabien follows the new regulations on medical devices (MDR and IVDR) and the GDPR very closely and regularly advises clients on the requirements applicable to their digital health technologies. With a practice entirely focusing on complex regulatory issues faced by Life Sciences clients, he can quickly address and anticipate complex challenges and propose innovative solutions enabling clients to focus on their business.

Fabien focuses particularly on guiding clients through the regulatory and technical regulatory requirements applicable to the CE marking of medical devices. He assists clients in addressing a range of complex issues during clinical investigation procedures (e.g. authorisation from the EU Member States competent authorities, opinion from Ethics Committee, amendment to the Protocol, informed consent, serious adverse event qualification and notification, handling of personal data), conformity assessment and registration procedures (e.g. preparation and review of Technical Files, preparation and review of responses to the competent authorities' and Notified Bodies' requests) and post-market activities (e.g. adverse event reporting, Field Safety Corrective Actions and promotional and advertising of medical devices).

Fabien is also a qualified lead auditor for ISO 13485 quality management systems. He consequently has a deep understanding of the range of quality issues encountered by medical device Clients. Fabien also assists Life Sciences Clients in the preparation, drafting and review of numerous agreements including clinical study agreements, sponsor's representative agreements, registry agreements, CRO agreements, European Authorised Representative Agreements and distribution agreements.

Practices

Medical Device and Technology Regulatory

Investigations, White Collar, and Fraud

Administrative and Public Law

Areas of focus

Medical Devices

Digital Health

Adverse Event Reporting

Vigilance Reporting

Advertising and Promotion Compliance

Combination Products, FDA

Jurisdictional Issues, FDA

Postmarket Compliance Issues

Unique Device Identifiers

State Medical Device Distribution & Manufacturer Licensing

Quality System regulation and ISO 13485 Compliance

Education

J.D., The Catholic University of America, Columbus School of Law, cum laude, 1998

B.S., Drake University, College of Pharmacy, 1995

Jodi Scott

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Jodi Scott developed and honed her practical, real-world sensibility and business acumen during the time she spent as an in-house FDA counsel with Medtronic PLC, the world's largest medical device manufacturer.

Today, she uses that background to solve the challenges that confront her clients in areas that include MDRs, regulatory due diligence, importing and exporting medical devices, advertising and promotion, preparing for and managing FDA inspections, developing systems to mitigate the risks associated with the unapproved use of approved products (AKA off-label uses), developing digital health technology, and securing the necessary state medical device manufacturer and distributor licenses.

Jodi assists the medical device industry in navigating the complex requirements so as to maintain compliance with the U.S. Food and Drug Administration's (FDA) quality system (QSR) and other post-market regulatory rules. She spends much of her time developing and implementing strategies to manage FDA-initiated enforcement actions, such as FDA inspections that result in FDA Form 483s, untitled letters, Warning Letters, investigations, and consent degrees of permanent injunction. She has received ISO 13485 auditor certification and assists companies in preparing for managing and responding to ISO and MDSAP audits.

She also guides her clients through complex medical device recalls by helping them work through the difficult decisions of whether a recall is warranted and, if so, how to execute it in a way that best achieves a balance between patient and customer risk and the agency's interests, while also demonstrating the company's commitment to safety and its regulatory obligations.

She also applies her regulatory knowledge in assisting clients with regulatory due diligence related to mergers and acquisitions and funding, such as private equity deals, initial public offerings, and other financial transactions.

Jodi co-leads the firm's cross-functional Digital Health Working Group and regularly assists clients in navigating the complexities of FDA regulation of digital health technologies with an eye to helping them meet their business objectives while being mindful of the potential for regulatory obligations.

Practices

Medical Device and Technology Regulatory

Areas of focus

Advertising and Promotion Compliance
Combination Products, FDA
Jurisdictional Issues, FDA
Postmarket Compliance Issues
Medical Devices
Premarket Review
Digital Health
Advisory Panel Preparation
Medical Device Artificial Intelligence

Education

J.D., University of Virginia School of Law, Order of the Coif, 1993

M.D., University of Virginia, 1992

B.A., Brown University, magna cum laude, 1986

John J. Smith, M.D., J.D.

Partner, Washington, D.C.

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As both a physician and a lawyer, John Smith combines clinical and regulatory experience relating to the Food and Drug Administration (FDA) with a practical approach to addressing the FDA regulatory issues facing his clients. He places a particular focus on bringing device-based technologies to market.

A board-certified diagnostic radiologist and former associate professor of radiology at Harvard Medical School, John joined the Hogan Lovells Medical Device Group in 2005. Since then, he has assisted clients in a range of FDA premarket submissions, including 510(k) notices, de novo reclassification petitions, humanitarian device exemption applications, and premarket approval applications, including the advisory panel process.

John identifies successful regulatory strategies and presents them to the FDA via the pre-submission process; he assists with problem submissions through submission-issue meetings and administrative appeals. He also navigates the increasingly challenging FDA compliance landscape, addressing 483 and Warning Letter issues.

Bringing new products to the U.S. market is continually complex and demanding. Having worked in the medical device area in academia, industry, and at Hogan Lovells, John understands how to address both pre- and postmarket FDA regulatory issues. His practical approach has guided clients through successful marketing applications, addressed significant differences of opinion with the FDA through submission-issue meetings and regulatory appeals, and provided crucial support through challenging FDA enforcement actions. To serve his clients, John draws on the broad experience and skills of his colleagues in the Medical Device Group and effectively communicates with reviewers and decision makers at the FDA. A *Super Lawyers* designee for multiple years, John is a leader in the medical device bar and well known to the FDA.

Practices

Medical Device and Technology Regulatory

Pharmaceutical and Biotechnology Regulatory

Areas of focus

Adverse Event Reporting
Vigilance Reporting
Advertising and Promotion Compliance
Advisory Panel Preparation
Combination Products, FDA
Jurisdictional Issues, FDA
Postmarket Compliance Issues
Medical Devices
Pharmaceutical and Biotechnology
Clinical Trials
Cell, Tissue, and Gene Therapies

Education

M.S. Biostatistics, Columbia University, Mailman School of Public Health, 2021

J.D., University of Pennsylvania Law School, 2012

Certificate in Business Economics and Public Policy, University of Pennsylvania, Wharton School of Business, 2012

B.S., Northeastern University, summa cum laude, 2007

Blake E. Wilson

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Blake Wilson helps medical device, drug, and biologic companies successfully navigate FDA's evolving regulatory landscape. With a focus on premarket submissions and clinical trial design and conduct, Blake helps sponsors plan their product development strategy and minimize regulatory risks.

When advising companies, Blake draws on years of experience practicing in front of the FDA. He has assisted clients across a wide range of submissions (e.g., presubmissions, investigational products, combination products, humanitarian/orphan products, marketing applications, breakthrough requests) with a focus on novel treatments . When feedback from the agency is needed, Blake helps sponsors craft a well-tailored regulatory strategy and is effective at presenting the plan to FDA. He also prepares sponsors for advisory panel hearings.

Leveraging his prior experience in clinical research and biostatistics, Blake advises sponsors on study design considerations and reporting study outcomes. By stress testing clinical evidence through the lens of an FDA reviewer, Blake helps sponsors avoid pitfalls that can delay or derail a project. He also prepares sponsors for FDA Bioresearch Monitoring (BIMO) audits, and can host the inspection. Whether crafting a regulatory strategy, preparing a submission, or negotiation a solution with the agency, Blake provides technical acumen and creativity to help companies achieve their goals.

Blake also advises on due diligence and other corporate matters related to medical products (e.g., mergers and acquisitions). He also assists companies with compliance challenges, including government and internal investigations, and 483 and Warning Letter responses.

While at Penn Law, Blake was an executive editor for the Journal of International Law and published a comment regarding the use of foreign clinical trials in the FDA's drug marketing approval process. He also served as a judicial intern to the Honorable Leonard P. Stark of the U.S. District Court for the District of Delaware. Prior to becoming a lawyer, Blake was a lead research assistant at Brown University, where he managed phase I and II pharmaceutical clinical trials; he later went on to obtain a master's degree in biostatistics from Columbia University.

Practices

Medical Device and Technology Regulatory

Areas of focus

Medical Devices

Advisory Panel Preparation

Clinical Trials

Education

J.D., University of Maryland School of Law, 1986

M.A., Johns Hopkins University, 1973

B.A., Johns Hopkins University, 1971

Gerard J. Prud'homme

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Gerry Prud'homme works closely with medical device companies to get their products approved by the FDA. He has more than 20 years of experience helping companies with FDA regulatory strategy and medical device submissions, including investigational device exemptions (IDEs), premarket approvals (PMAs), 510(k)s, and de novo applications. He is one of the few FDA lawyers in the country who is also a biostatistician with expansive experience in clinical studies.

With a technical background, Gerry also advises medical device clients on scientific requirements to get their products approved by the FDA. Having 30 years of experience in clinical trials, he routinely helps clients design and analyze all types of medical device clinical studies — from first-in-human to feasibility, pilot, pivotal, and post-approval studies. He is widely recognized for his experience in this area. Gerry often lectures new FDA employees on IDEs and PMAs.

Understanding the critical nature of FDA panel meetings to clients, Gerry works hand-in-glove with medical device and pharmaceutical companies, together with their expert clinicians and statisticians in preparing for advisory committee meetings. Often coordinating the entire process, he brings a wealth of knowledge and experience to clients preparing for panel meetings and is nationally well-regarded for his capabilities and depth of experience.

Gerry also regularly works closely with companies on issues relating to bioresearch monitoring, institutional review boards (IRBs), informed consent, advertising and promotion of medical devices, and regulatory due diligence reviews, as well as a variety of other FDA matters.

Gerry has authored a number of articles and book chapters on topics relating to regulation of medical devices, as well as scientific articles relating to medical devices, drugs, and clinical studies.

Practices

Medical Device and Technology Regulatory

Areas of focus

Adverse Event Reporting

Vigilance Reporting

Advertising and Promotion Compliance

Medical Devices

Cell, Tissue, and Gene Therapies

Quality System regulation and ISO 13485 Compliance

Education

J.D., University of Virginia School of Law, Recipient of Charles J. Frankel Award in Health Law, 1990

A.B., Davidson College, cum laude, Phi Beta Kappa, 1987

Edward C. Wilson, Jr.

Senior Counsel Emeritus, Washington, D.C.

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Whether it's a multinational corporation or a growing business looking to expand in the U.S. market, complying with the U.S. Food and Drug Administration's (FDA) web of medical device regulations can be challenging and resource intensive.

Ted Wilson has over 28 years of experience advising clients on complex regulatory, enforcement, and product submission matters throughout the total product life cycle of medical devices. He represents clients before FDA to help attain workable solutions to public health and safety emergencies, regulatory and business challenges, and compliance matters.

Ted has assisted hundreds of clients prepare for, defend, and respond to domestic and international inspections and audits. He has conducted numerous quality system audits and completed the ISO 9001:2008 3-Day Certified Internal Auditor with Medical Device Focus (ISO 13485:2016) training and the Medical Device Single Audit Program (MDSAP) 1-Day Overview Training through AQS Solutions (a DEKRA company).

In addition to extensive auditing, his work has included designing and implementing robust quality systems for medical device manufacturers, and responding to Form 483 inspectional observations, warning letters, and untitled letters.

Ted has defended companies in government investigations involving quality system and other medical device regulations, negotiated consent decrees of permanent injunction, and counseled clients under third-party certification audit obligations.

His experience in assisting medical device companies with public health and safety matters includes emergency preparedness operations, health hazard evaluation assessments, risk mitigation strategies, recall decision-making and execution, adverse event reporting, root cause investigations, and corrective action plans to address quality and safety issues.

Ted has assisted medical device companies in making product submission determinations for proposed device labeling, design, and manufacturing changes. He also has assisted in drafting numerous 510(k) notices, premarket approval (PMA) applications, and investigational device exemption (IDE) applications for a wide range of device technologies.

Practices

Medical Device and Technology Regulatory

Pharmaceutical and Biotechnology Regulatory

Areas of focus

Medical Devices

Pharmaceutical and Biotechnology

Cell, Tissue, and Gene Therapies

Education

J.D., Harvard Law School, 2015

Ph.D., University of Wisconsin–Madison, 2010

B.S., Peking University, 2004

Erkang Ai, Ph.D.

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A geneticist and biologist by training, Erkang Ai works closely with clients to navigate the complex FDA regulations. Speaking both languages of lawyers and scientists, he brings his technological know-how to assist medical device, diagnostics, and biologics companies in the most challenging legal and regulatory issues.

Erkang holds a doctorate degree in genetics. Prior to attending Harvard Law School, he also worked as a postdoctoral fellow at Stanford University. With 10 years of research experience, he has gained a deep understanding of genetics, genomics, oncology, biochemistry, and cell biology. He is passionate about leveraging his scientific and legal background to help companies bring their cutting-edge medical products to market.

Erkang's practice focuses primarily on premarket clearance or approval of medical devices. His experience includes evaluating the FDA's market requirements, designing analytical and clinical development plans, and formulating innovative regulatory strategies. He is also skilled in the regulation of in vitro diagnostic assays, including NGS-based genetic tests and laboratory developed tests.

Practices

Medical Device and Technology Regulatory

Areas of focus

Advertising and Promotion Compliance

Premarket Review

Cell, Tissue, and Gene Therapies

In Vitro Diagnostics

Quality System regulation and ISO 13485 Compliance

Education

J.D., University of Pennsylvania Law School, 2014

M. Bioethics, University of Pennsylvania School of Medicine, 2014

B.A., Princeton University, cum laude, 2008

Suzanne Levy Friedman

Counsel, Washington, D.C.

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Global clients in the medical device sector call on Suzanne Levy Friedman to help them navigate key legal and business issues. Suzanne's practice focuses primarily on matters related to the U.S. Food and Drug Administration's (FDA) regulation of medical devices.

Suzanne assists device companies in a wide range of activities across the life cycle of their products, including preparing regulatory submissions for clearance or approval of new devices, advising manufacturers on the lawful promotion and advertising of their devices, and addressing postmarket enforcement issues. Suzanne is well-versed regarding FDA's evolving paradigm for software and digital health products, and she has helped clients determine the appropriate regulatory pathway for various products in this space and bring them to market. She also conducts regulatory due diligence in preparation for mergers and acquisitions.

Suzanne frequently works on human tissue and combination products that combine a medical device element with a drug or a biologic. In conjunction, she helps advise clients on regenerative medicine and cell/gene therapies, which often raise questions that touch on multiple areas of FDA regulation.

Suzanne brings significant experience in FDA space to her work at the firm. During law school, she interned for FDA's Office of Chief Counsel, where she learned firsthand about the range of legal and regulatory issues addressed by the agency's Food, Drug, Device, Veterinary, and Tobacco centers. Prior to law school, Suzanne spent two years with a health policy consulting firm in Washington, D.C., advising clients on the business impacts of FDA actions and related legislation. Suzanne also has a master's degree in bioethics.

In law school, Suzanne co-led Penn Law's health law and policy pro bono group, and she remains actively involved in pro bono service at Hogan Lovells.

Practices

Health Law

Medical Device and Technology Regulatory

Pharmaceutical and Biotechnology Regulatory

Investigations, White Collar, and Fraud

Areas of focus

Administrative Procedure Act

Adverse Event Reporting

Vigilance Reporting

Advertising and Copy Clearance

Advertising and Promotion Compliance

Combination Products, FDA

Jurisdictional Issues, FDA

Postmarket Compliance Issues

Medical Devices

Pharmaceutical and Biotechnology

Unique Device Identifiers

Cell, Tissue, and Gene Therapies

Quality System regulation and ISO 13485 Compliance

Education

J.D., University of Denver Sturm College of Law, Order of the Coif, Order of St. Ives, 2015

M.B.A., Kellogg School of Management at Northwestern University, 1997

B.S., University of Illinois, 1993

Wil Henderson

Counsel, Denver

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Wil Henderson's nuanced insight into the multiple facets of the complex and highly regulated health care industry helps him to work alongside his clients to assist them in achieving their business goals, while anticipating and side-stepping potential risk.

Wil draws on his deep experience and broad background in this industry to inform his practice, which focuses on the Food and Drug Administration (FDA) and medical device regulatory and compliance issues. Wil advises medical device and technology companies in the life sciences space on matters related to regulatory approvals, total product life cycle management, promotional issues, quality system, and other regulatory compliance matters. He also provides general advice on navigating the FDA's regulatory framework.

Wil brings a unique perspective to his clients' issues because he's been in their shoes. Prior to becoming a lawyer, Wil worked in various roles for health companies, including brand management and mergers and acquisitions for Searle Pharmaceuticals (now part of Pfizer), where he launched Celebrex, a blockbuster nonsteroidal anti-inflammatory; as a strategic planner for a health care planning and facility development company; and as the chief financial officer of a health care consulting firm focused on nonprofit hospitals and health systems.

Before joining the firm, Wil worked at two Denver law firms where he honed his skills in handling health care regulatory matters, including regulatory compliance, licensing, and government enforcement actions.

In addition to graduating fourth in his class from the University of Denver Sturm College of Law, he holds an MBA from the Northwestern University Kellogg School of Business. Wil is currently an ISO 13485 certified internal auditor and was formerly a Certified Healthcare Financial Professional with the Healthcare Financial Management Association (HFMA).

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Health

Complex Contracting

Strategic Operations, Agreement and Regulation

Areas of focus

Medical Devices

Pharmaceutical and Biotechnology

Education

Bachelor of Laws (First Class Honours), University of Porto, 2012

Cláudia Mendes Pinto

Senior Associate, Brussels

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As a member of the Global Regulatory Life Sciences team, Cláudia Mendes Pinto advises on a wide range of regulatory and commercial matters for clients in the medical devices, pharmaceutical and biotechnology sectors.

Cláudia assists clients throughout the full products' life cycle, from early pre-market stages (pre-clinical, regulatory pathways, clinical trials/investigations design and authorisation, clinical data requirements), to certification/authorization (CE marking of medical devices and marketing authorizations for medicinal products) and post-market matters (promotional activities, interactions with health care professionals, pharmacovigilance and device vigilance, etc.). Cláudia also frequently works in EU and global multijurisdictional projects for clients in the life sciences sector. A particular area of focus is on advanced therapy medicinal products and the regulation of human blood, tissues and cells.

Cláudia also frequently assists clients with the drafting, reviewing and negotiation of a variety of agreements, such as clinical trials, supply, manufacturing and distribution agreements. She has also assisted life sciences clients in M&A transactions with regulatory due diligence and contract drafting.

Practices

Medical Device and Technology Regulatory

Education

J.D., Catholic University of America, 2023

M.P.H., The George Washington University, 2014

B.A., Reed College, 2012

Megana V. Sankaran

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Megana Sankaran advises clients on medical device matters, with a particular focus on the pre-market clearance and approval of new devices and statistical considerations.

Megana has experience in the design and statistical aspects of clinical trials. She has also advised clients about the presentation of clinical data for FDA submissions and the design of clinical studies, and on pre-market submissions.

Prior to joining Hogan Lovells, Megana was a clinical research coordinator at Millennium Clinical Trials and oversaw the daily operations of several pharmaceutical clinical trials. At the George Washington University, she completed her Master of Public Health in epidemiology, which she now adapts to her work in the forms of the creative design of clinical studies and problem solving for her clients.

Practices

Medical Device and Technology Regulatory

Areas of focus

Medical Devices

Education

Master en Droit, Université Libre de Bruxelles, 2017

LL.M in International Investment and Trade Law, Maastricht University, 2015

Bachelor in European Law, Maastricht University, 2014

Hélène Boland

Senior Associate, Brussels

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Hélène Boland advises clients on EU and Belgian regulation of medical devices and medicinal products, as well as cosmetics, food and feed, and other consumer goods. She has assisted clients through the marketing authorization of medicinal products and related post-marketing activities. Hélène has gained a wealth of experience in relation to medical devices including the conformity assessment process for medical devices, and advising clients on the requirements introduced by the new medical devices regulations and various aspects of digital health technologies.

Hélène counsels clients on compliance with rules governing the promotion and advertising of health care products, interactions with health care professionals, as well as transparency and anti-benefits requirements. She also has experience in conducting due diligence and related counseling in connection with life sciences transactions.

Hélène advises clients on different aspects of the General Data Protection Regulation that are of particular importance in the life sciences sector, including the collection and processing of patients' personal health data and the transfer of personal health data outside the EU.

As a Belgian-qualified lawyer, Hélène regularly advises international companies with complex queries in relation to Belgian law.

Prior to joining Hogan Lovells, Hélène worked as a trainee at the Food Task Force of the European Commission's Directorate General for Competition and was an associate in the life sciences practice of another international law firm in Brussels.

Practices

Medical Device and Technology Regulatory

Pharmaceutical and Biotechnology Regulatory

Areas of focus

Medical Devices

Pharmaceutical and Biotechnology

Education

J.D., Georgetown University Law Center, magna cum laude, 2020

B.S., Muhlenberg College, magna cum laude, 2014

Gabrielle Field

Associate, Philadelphia

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When clients are facing regulatory hurdles, Gabrielle Field is ready to help guide their cutting-edge medical technologies through the often labyrinthine approval process.

Gabrielle leverages her background in neuroscience to provide grounded advice on a wide variety of Food and Drug Administration (FDA) programs. She has experience working with startups and established companies alike on 510(k) premarket notifications, De Novo classifications, Premarket Approval (PMA) applications, Investigational Device Exemption (IDE) submissions, Humanitarian Use Device designations, and Breakthrough Device designations.

During law school, Gabrielle practiced housing law as a student attorney in the Health Justice Alliance Law Clinic. She was also elected president of the Health Law Society, taught legal research and writing as a law fellow, and served as an editor of the Georgetown Journal of Gender and the Law. Following her undergraduate studies, Gabrielle worked in public health communications in Dhaka, Bangladesh and helped administer direct services for pregnant women and families in Philadelphia.

Practices

Medical Device and Technology Regulatory

Areas of focus

Medical Devices

Quality System regulation and ISO 13485 Compliance

Compliance Readiness

Postmarket Compliance and Enforcement Actions

Customs and Import Compliance

Advertising and Promotion Compliance

Combination Products

Education

J.D., Vanderbilt University Law School, 2020

B.S., University of Vermont, 2011

Gregory A. Kass

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Greg finds actionable solutions to complex regulatory problems, and helps clients navigate critical challenges to maximize profitability and succeed in a dynamic landscape.

With a deep familiarity of ISO 13485 and FDA's Quality System Regulation, Greg frequently works with firms to address regulatory violations such as FDA Warning Letters; It Has Come To Our Attention Letters; product recalls, corrections, and removals; and quality system deficiencies. This includes drafting regulatory communications, interfacing with FDA, and leveraging prior experience to achieve desired results.

Medical device firms rely on Greg's high-quality regulatory advice when buying, selling, investing in, or restructuring medical device firms or assets. His collaborative approach, thoughtfulness, and working knowledge of FDA medical device regulation and enforcement trends preserves value, significantly minimizes the probability of post-close surprises, and reduces overall risk.

Greg leverages over a decade of clinical healthcare experience to ensure that when presented with fast-paced and high-stakes regulatory challenges, good judgment and sound advice prevail.

Practices

Medical Device and Technology Regulatory

Education

J.D., University of Denver Sturm College of Law, 2024

B.A., University of Colorado Boulder, 2018

Lauren Massie

Associate, Global Regulatory

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Lauren assists clients on complex medical device matters throughout the product life cycle.

Lauren graduated from the University of Denver Sturm College of Law, where she received a certificate in Intellectual Property and Technology Law. She served as a Production Editor of the Denver Law Review. Prior to attending law school, Lauren graduated from the University of Colorado Boulder with a degree in Molecular, Cellular, and Developmental Biology and a degree in English Literature.

Practices

Medical Device and Technology Regulatory

Education

J.D., University of Pennsylvania Carey Law School, 2024

Master Degree, University of Pennsylvania Perelman School of Medicine, 2024

B.S., Yale University, 2018

Evelyn Tsisin

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By combining her background in bioethics with practical regulatory experience, Evelyn Tsisin empowers clients to advance their medical technologies responsibly while navigating the commercialization process efficiently.

Whether emerging start-ups or key industry players, Evelyn effectively collaborates with clients to develop regulatory strategies that get their cutting-edge medical technologies on the market and help them stay on the market.

Evelyn focuses on advising on a broad range of Food and Drug Administration (FDA) programs and regulations. Evelyn has experience drafting and filing 510(k) premarket notifications, De Novo requests, premarket approval applications (PMAs), investigational device exemptions (IDE), as well as attending pre-submission discussion meetings among clients and representatives of FDA.

Evelyn's experience extends to addressing advertising and promotion issues related to medical devices, ensuring compliance with relevant regulations while also fostering innovative marketing strategies.

Evelyn has been with Hogan Lovells since 2018, first as a paralegal then summer associate and LCLD Scholar all the while building practical insights as a member of the FDA Medical Device and Technology practice group.

Prior to rejoining the firm as an associate in 2024, Evelyn earned a dual J.D./Masters in Bioethics from University of Pennsylvania Carey Law School and University of Pennsylvania Perelman School of Medicine. At Penn, Evelyn was both on the Journal of Law and Social Change and a Board Member and Contributor to The Regulatory Review, where she published on healthcare regulation, policy, and equity issues.

Evelyn focused her pro bono efforts on research and advocacy as a member of the Health Law and Policy Project and as an instructor for the Youth Education Program, teaching local Philadelphia high school students about Constitutional law and legal writing in preparation for a yearly moot court competition.

Practices

Medical Device and Technology Regulatory

Areas of focus

Medical Devices

Digital health

Education

LL.M. in IP and ICT Law, Catholic University of Leuven, Cum Laude, 2022

LL.M. in Global Health Law, Georgetown University Law Center, Distinction, 2020

Bachelor of Laws, National and Kapodistrian University of Athens, 2018

Anastasia Vernikou

Associate, Brussels

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Anastasia Vernikou advises international life sciences companies on EU law and regulation of medical devices, digital health solutions, biotechnology, medicinal products and food. Anastasia is a member of the Global Regulatory Life Sciences team and is qualified to practice law in Greece.

Anastasia assists life sciences clients throughout the various stages of the regulatory lifecycle of their products, from clinical development to regulatory approval/CE marking and post-marketing activities, including interactions with regulatory authorities and notified bodies. Anastasia also counsels clients on issues related to anti-benefits and transparency obligations in the context of interactions with healthcare professionals and healthcare organizations.

Anastasia also closely follows legislative and regulatory developments concerning the interaction between the regulation of medicines and medical devices and forthcoming rules governing digital health and artificial intelligence ("AI").

Prior to joining Hogan Lovells, Anastasia was a trainee in the life sciences regulatory practice of another international law firm in Brussels. She also worked as a legal consultant at the World Health Organization and as a legal researcher on health law matters at a US-based research institute.

Practices

Medical Device and Technology Regulatory

Education

Ph.D. Materials Science and Engineering, University of Maryland, College Park, summa cum laude, 2009

B.S. Materials Science and Engineering, University of Maryland, College Park, magna cum laude, 2006

Michael Kasser, Ph.D.

Senior Director of Regulatory Strategy, Rehovot, Israel

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Michael (Moshe) Kasser has been involved in the regulation of medical devices since he obtained his Ph.D. in materials science and engineering. His thesis focused on novel materials used in joint replacement, and upon graduation, he immediately put this knowledge to use at the FDA as a scientific reviewer of orthopaedic devices. Michael brought a powerful and unique blend of the regulatory know-how and technical understanding required to comprehend and address the FDA's scientific concerns with novel technologies.

Today, Michael has combined that understanding with a knack for explaining technical concepts in a way that both the industry and FDA can easily understand. He uses his knowledge and communications skills to assist medical device companies to clear FDA hurdles and bring novel technologies to the U.S. market. This includes cutting edge technologies such as brain/computer interfaces, robotic surgical systems, cartilage replacement devices, wearable sensors, digital health, and many others.

Michael provides deep technical knowledge in the areas of mechanical testing, MRI safety testing of implants, biocompatibility testing, chemical characterization, and electrical testing. He published articles in both scientific and regulatory journals on a variety of topics. His favorite hobby is boardgaming with friends.

Practices

Medical Device and Technology Regulatory

Education

Ph.D., University of Arizona, 2013

B.S., Western New England University, 2008

Eriko S. Yoshimaru, Ph.D.

Senior Director of Regulatory Sciences, Washington, D.C.

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Eriko Yoshimaru leverages her technical background as an engineer, her experience as a former U.S. Food and Drug Administration (FDA) reviewer and a regulatory affairs professional within the medical device industry to assist and advise clients on medical device matters. Eriko focuses her practice on digital health products and helps clients develop regulatory strategies and regulatory submissions to bring novel technologies to the market.

Eriko obtained her doctorate in biomedical engineering from the University of Arizona with a focus in medical imaging and radiology. In her post-doctoral positions, she combined her technical and project management skills to help transition preclinical research into clinical studies. Upon completing her academic positions, Eriko continued on to a position as a biomedical engineer and medical device reviewer at the Center for Devices and Radiological Health (CDRH) at FDA.

She leveraged her background in medical imaging at her position in the CDRH and contributed to the agency not only as lead and consulting reviewer, but also by her involvement in FDA internal working groups and as a representative to technical standard organizations. Her involvement with FDA submissions across multiple centers, offices, and divisions, as well as her experience with a wide range of FDA submission types within CDRH, brings valuable insight into how to address and navigate regulatory challenges.

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Education

M.B.A., University of Maryland, 2013

B.S. Computer Science, University of Maryland, 1999

B.A. History, University of Maryland, 1999

Regulatory Affairs Certification (RAPS)

Microsoft Certified System Engineer

W. Alex Smith

Director of Regulatory Sciences, Washington, D.C.

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Alex Smith understands the pressure medical device and pharmaceutical companies around the world face when working with the U.S. Food and Drug Administration (FDA) to resolve premarket and postmarket technical compliance concerns within the ISO/USP/QSR and cGMP frameworks. Alex is RAC certified for FDA Drugs and Devices by the RAPS organization.

As a former process and software engineer at GlaxoSmithKline and Human Genome Sciences, Alex's primary practice involves assisting companies with medical device and pharmaceutical submissions that involve software such as AI/ML submissions and 21 CFR Part 11 concerns. During his time at Hogan Lovells, Alex has provided software architecture and lifecycle advice on substantial variety of devices such as AI radiological imaging, 3D adaptive manufacturing, infusion pumps, and individualized vaccines involving AI.

In addition to providing software services, Alex frequently works with companies around the world to avoid and respond to QSR and cGMP enforcement from FDA and Health Canada. Alex has assisted companies with not only substantial quality and regulatory re-organization following Warning letters and import alerts, but has also provided direct technical advice such as developing master validation plans and validation execution for lab and manufacturing equipment such as HPLC, endotoxin, cell culture, sterilizers and plant automation.

Practices

Medical Device and Technology Regulatory

Education

B.S. Chemical Engineering, Rochester Institute of Technology, High Honors, 2013

Ryan Foringer

Director of Regulatory Affairs, Washington, D.C.

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Ryan Foringer assists clients with U.S. Food and Drug Administration (FDA) regulations and policies focused on medical device technology. He leverages his training as an engineer and his combination of FDA and private sector experience to develop regulatory strategies and advise clients on medical device matters.

Ryan spent nearly four years at the FDA serving as a consumer safety officer, chemical engineer, and lead reviewer evaluating the safety of regulated products. He took his FDA experience to the private sector where he served as senior director of regulatory operations focusing on regulatory and clinical development of neurological, cardiovascular, and diabetes medical devices in a start-up environment. In this role, he led an international, interdisciplinary team in the preparation of FDA regulatory submissions while also advising affiliates on regulatory matters and compliance.

Ryan's technical background, private sector experience, and training as a medical device reviewer at the FDA, give him a well-rounded perspective that he brings to clients as they navigate the FDA regulatory process.

Practices

Medical Device and Technology Regulatory

Education

M.S. Biomedical Engineering, Tulane University, 2019

B.S. Biomedical Engineering, Tulane University, Cum Laude, 2018

Joshua Yao

Director of Regulatory Affairs, Washington, D.C.

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Joshua Yao focuses his practice on medical device regulation, leveraging his background in biomedical engineering to solve complex regulatory issues concerning a broad range of clinical applications. Joshua advises clients on both pre-market strategy and post-market compliance.

Prior to joining Hogan Lovells, Joshua served as a biomedical engineer and lead regulatory reviewer at the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA), where he evaluated various pre-market submissions in the respiratory technologies landscape, including Premarket Approval (PMA) applications, Investigational Device Exemption (IDE) applications, 510(k) Notifications, 513(g) Requests for Information, Breakthrough Designation Requests, and more. Joshua capitalizes off his valuable insights on FDA's internal review policies and nuances to help clients optimize entry-to-market timelines.

Joshua was also a duly accredited FDA investigator working closely with the CDRH Office of Regulatory Affairs (ORA) as a Ventilator Subject Matter Expert. He performed on-site manufacturer inspections of Quality Systems Regulations (QSR) compliance, classified high-profile Class 1 medical device recalls, and provided technical review of the adequacy and feasibility of risk mitigation strategies. Joshua offers a first-hand understanding of FDA's perspectives on post-market regulation when assisting clients with compliance strategy.

Joshua completed his Bachelor of Science and his Master of Science, both in biomedical engineering, at Tulane University, where he published cross-cutting research in pulmonary health and computational quantification ventilator-induced lung injury.

Practices

Medical Device and Technology Regulatory

Areas of focus

Medical Devices

Education

M.Sc. in Life Sciences, The Weizmann Institute of Science, 2016

B.Sc. in Chemistry and Life Sciences, The Open University of Israel, w. Honors, 2014

David Schreiber

Senior Specialist, Rehovot, Israel

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David Schreiber assists medical device clients with regulatory matters. Prior to joining Hogan Lovells, David was a Senior Life-Science Grant Consultant at FreeMind. The FreeMind Group specializes in non-dilutive life science consulting, and is the largest consulting group of its kind, working with academics and industry alike. As a grant consultant, David specialized in obtaining non-dilutive funding for clients through U.S. federal agencies (National Institutes of Health, United States Department of Defense, and others). Taking a strategic, funding agency-oriented approach, David managed over 50 major multi-team international grant projects across all areas of medical device and drug development, and secured millions of dollars in project funding for his clients.

At FreeMind, David was also a Professional Leader for all clinical proposals. David is CRA-qualified and familiar with regulatory and practical aspects of clinical study design and management. He was the authority at departmental level when it came to clinical projects and related regulation.

A critical reviewer, David loves to dive into a project, familiarize himself with new concepts and provide valued, content-related feedback, while paying great attention to details.

David is fluent in multiple languages including English, French, Hebrew and Dutch, and proficient in German. This often helps him in better connecting with European and Israeli clients.

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Education

Ph.D., Genetics and Molecular Biology, Emory University, 2023

MPH Epidemiology, Emory University, 2019

B.S. Biology, Virginia Tech, 2015

Mike Mortillo, Ph.D.

Senior Regulatory Specialist, Washington, D.C.

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Mike Mortillo leverages his background as a genetic epidemiologist and statistician to advise on complex medical device and pharmaceutical matters. He places a particular focus on scientific understanding and statistical considerations related to clinical trial design to assist clients in bringing their products to market.

Prior to joining the firm, Mike obtained his Ph.D. in Genetics and Molecular Biology and Masters in Public Health (MPH) in Epidemiology from Emory University. His doctoral thesis focused on epigenetic regulation in placenta. In this role, he utilized his programming skills to design and implement large-scale statistical techniques related to transcriptomics and methylomics.

Mike also served as a consultant for an epidemiological methods firm, where he summarized occurrence estimates of various rare diseases to assist clients in preparing orphan drug applications. His involvement with FDA submissions in this role allows him to provide valuable insight on how to address these complex regulatory challenges.

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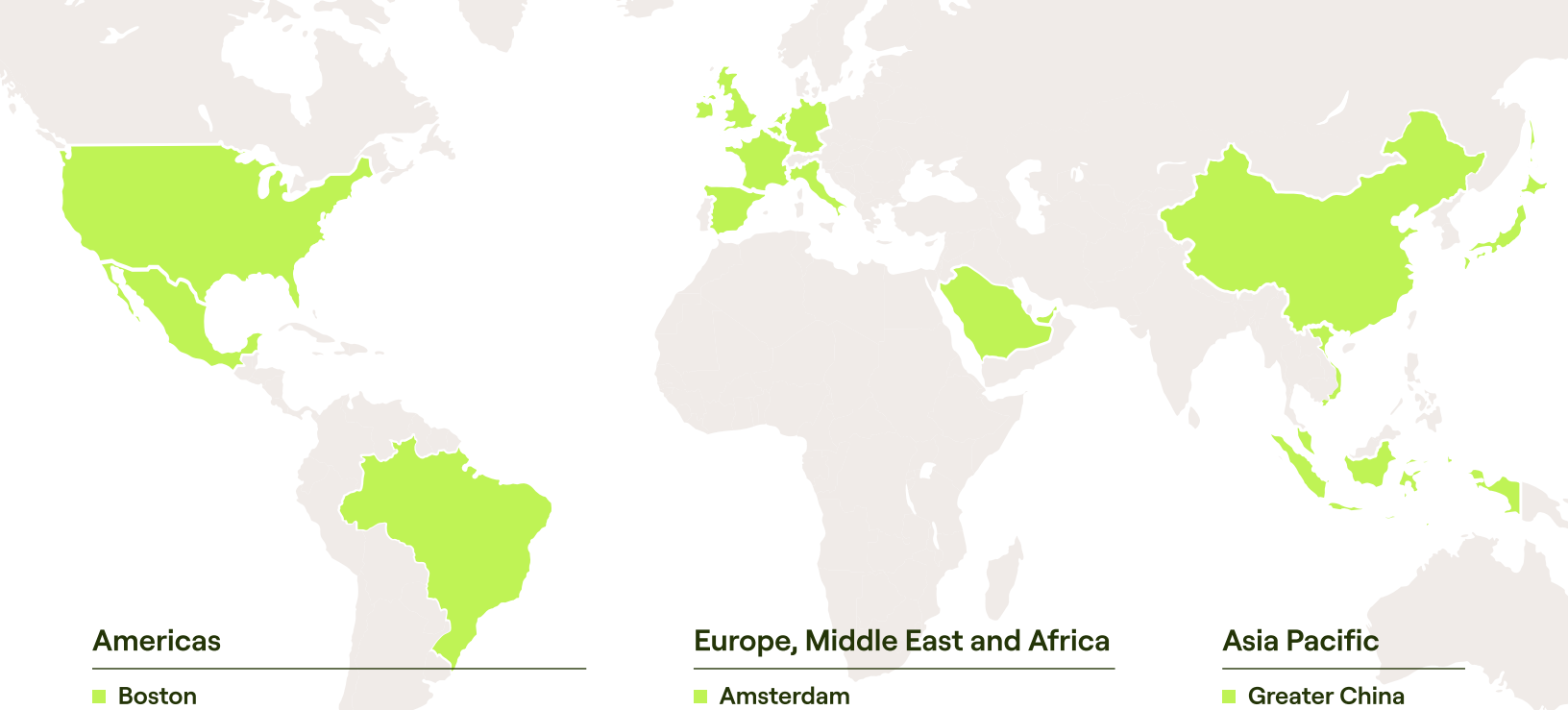

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