Hogan Lovells

In Vitro Diagnostics

Hogan Lovells' 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.

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

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Practices

Medical Device and Technology Regulatory

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.

Representative experience

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.

Assist IVD and reagent manufacturers, as well as clinical laboratory service providers, in navigating the parallel universes of IVD and analyte-specific reagent regulation and laboratory-developed tests.

We have established regulatory training programs to educate the internal units of major companies on the development, testing requirements, premarket submissions, and manufacturing requirements regarding QSRs.

We assisted a company in obtaining the first waiver from the FDA under the Clinical Laboratory Improvement Amendments (CLIA) for a syphilis screening test.

Assisted T2 Biosystems, Inc. in preparing a direct de novo product authorization petition for the company's T2 Candida diagnostic test system.

Assisted with preparing and obtaining FDA approval for the first non-invasive screening test for colorectal cancer that analyzes both stool DNA and blood biomarkers.

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