Hogan Lovells

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Biography

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

Practices

Medical Device and Technology Regulatory

Industries

Life Sciences and Health Care

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.

Representative experience

Worked with more than 50 companies and their consultants to effectively prepare for FDA panel meetings.

Represented more than 100 companies in preparation and submission of their PMAs.

Developed clinical study designs and strategy for scores of companies for more than 20 years.

Assisted clients in the preparation of dozens of IDEs for more than 20 years.

Developed successful post-approval study strategy for numerous companies.

Represented companies in the development of postmarket surveillance studies and strategy.

Latest thinking and events

- PMA Submissions Workshop - Spring 2019
- Sponsorships and Speaking Engagements
  - IDE Submissions Workshop - Spring 2019
- Analysis
  - What device companies need to know ahead of an advisory panel meeting

Areas of focus

Medical Devices

Advisory Panel Preparation

Clinical Trials

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., University of Maryland, Francis King Carey School of Law, 1986

M.A., Johns Hopkins University, 1973

B.A., Johns Hopkins University, 1971

Bar admissions and qualifications

District of Columbia

Maryland

Court admissions

U.S. District Court, District of Maryland

- Hogan Lovells Publications
  - New FDA final guidance on medical device panel meetings provides certain changes to timelines and procedures *Medical Device Alert*
- Webinar
  - The FDA Advisory Panel Meeting: Ensuring Success in an Unpredictable Process
- Hogan Lovells Publications
  - FDA Updates Supporting Materials for Expedited Access Program *Medical Device Alert*