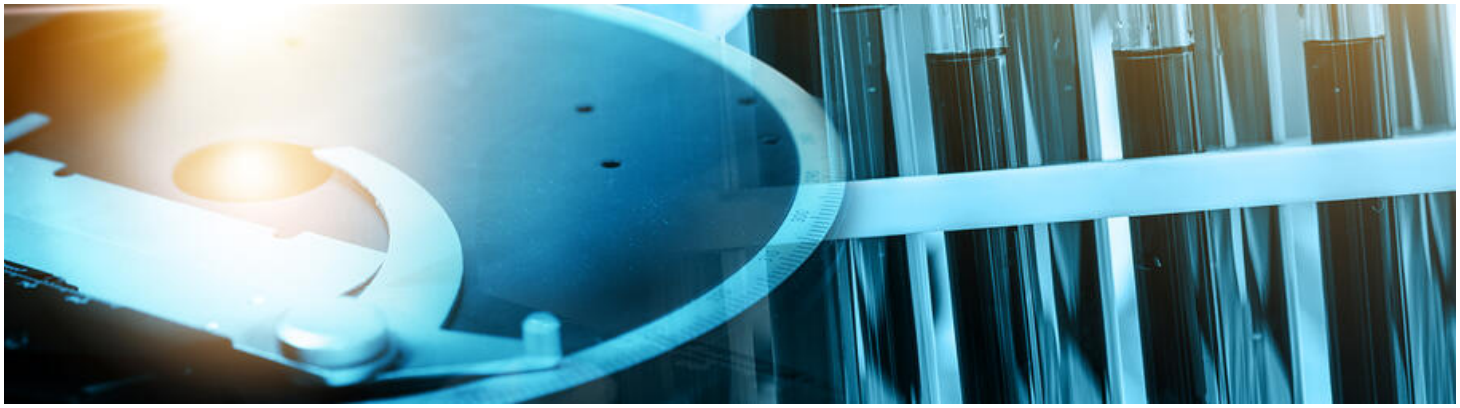
McElroy Deutsch

Pharmaceutical, Medical Devices & Life Sciences



Recognized as a national leader in this complex field.

Our attorneys from across the Firm represent pharmaceutical and medical device manufacturers, clinical research organizations (“CROs”) and other life sciences companies. These companies range in size from small start-ups to publicly traded multinational corporations, and include manufacturers of brand name and generic drugs, as well as those developing new chemical entities (“NCEs”).

McElroy Deutsch has assisted companies in all phases of their clinical studies, including discovery, preclinical, toxicology and Phases I, II, and III. Our pharmaceutical lawyers also have counseled clients on the regulatory and liability aspects of clinical pharmacology units (“CPUs”), including issues of state licensure, retention of physician investigators, procedures and requirements of sponsors governing the use of investigational new drugs, development and review of investigative review board (“IRB”) protocols, as well as issues of privacy, confidentiality and informed consent in connection with the use of human subjects.

Our law firm’s representation of CROs has been national in scope and includes litigation and consultation concerning actions arising from alleged breach of study agreement, breach of protocols, standard operating procedures and industry practices, as well as other study-related FDA issues. Our lawyers also have provided representation on issues arising from improper billing practices, antitrust allegations, wholesale pricing of drugs and workplace discrimination.

Our scope of expertise, with respect to agreements, includes:

- Consulting on and preparing Master Services Agreements
- Clinical and Analytical Study Agreements
- Clinical Site Agreements
- Project Agreements
- Intellectual Property Agreements
- Employment Agreements

Our pharmaceutical lawyers have conducted seminars for and offered counseling to pharmaceutical companies relating to drug liability trends in the United States, the prevention and detection of Medicare fraud and abuse issues, compliance with the federal anti-kickback statute and false claims act, sales and marketing guidelines promulgated by the Office of Inspector General, and internal safeguards for pharmaceutical billing/pricing practices. Our law firm also has assisted our pharmaceutical and life sciences clients with issues involving the Medicare Part D prescription drug coverage program, the Medicaid drug rebate program, and the 340B drug pricing program, as well as the review, development and implementation of corporate compliance programs, and environmental, health and safety policies and guidance for their manufacturing plants.

In addition, our pharmaceutical attorneys serve as both lead counsel and approved outside counsel for companies such as Abbott Laboratories, Bayer Corporation, Knoll Pharmaceutical Company, and Sanofi-Sythelabo in litigation involving claims of personal injury and wrongful death due to alleged defective pharmaceutical products. Our lawyers have also served as lead counsel in the Baycol and Phenylpropanolamine certified mass-tort litigations in New Jersey and have defended Aventis Pharmaceuticals in contaminated polio vaccine (SV40 virus) cases.

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