

LIFE SCIENCES SECTOR

The life sciences sector is experiencing significant growth and expansion in California, nationally and globally. The sector is comprised of a broad range of organizations that work to develop and advance life science technologies, from pharmaceuticals, biopharmaceuticals, and biotechnology to medical devices, diagnostics and health care.

Even though organizations throughout the life sciences sector are making tremendous strides and advances, they operate in an increasingly competitive global environment. Strict government oversight and regulations at the state, national and international levels present many challenges for life science organizations. Additionally, these organizations must carefully navigate health care reform initiatives in the United States and in countries across the globe, adapting to changes and taking advantage of new and expanding opportunities.

Laws and Regulations Governing the Life Sciences Sector

The multiple industries that make up the life sciences sector are subject to significant regulatory oversight. In the United States, the U.S. Food and Drug Administration (FDA) is responsible for protecting public health through the regulation of food products for human and animal consumption; prescriptions and over-the-counter (OTC) pharmaceutical drugs; medical devices; biological products including blood, vaccines, and biological therapeutics; radiation emitting devices such as microwaves; cosmetics; and veterinary products. In addition to FDA regulations, many life science companies, including those operating in the pharmaceutical industry, may be subject to the federal Toxic Substances Control Act (TSCA) requirements and various state environmental law mandates requiring these companies to develop and implement take-back programs and other recycling initiatives.

Navigating Organizations through Complex Regulatory Schemes

Each California environmental regulatory lawyer in our practice is familiar with the many different types of organizations operating across the life sciences sector. We draw upon our backgrounds in business, science and law to help these organizations develop innovative and practical solutions for complex environmental problems.

The lawyers at our firm are well known throughout the U.S. and beyond for their ability to deliver comprehensive environmental counsel to life sciences clients. We offer individualized support and assistance to pharmaceutical, medical devices, biotechnology and other companies facing a wide range of legal and regulatory compliance matters. Our lawyers are well-versed in all aspects of environmental law and continually monitor and evaluate changes and new developments to ensure that our clients' operations and activities are in line with regulatory requirements both domestically and abroad. We also counsel clients in government agency enforcement actions, citizen suits and litigation arising under federal, state and local laws. Additionally, our environmental transaction practice works with clients to ensure that their business deals and real estate transactions are structured to support and advance their company's objectives while avoiding potential high-stakes environmental risks and litigation.