

## LIFE SCIENCES SECTOR

The life sciences sector is experiencing significant growth and expansion in California, nationally and globally. The sector includes organizations developing 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, 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. These organizations must navigate health care reform initiatives in the United States and in countries across the globe. Additionally, they must learn to adapt to changes and take 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. The Food and Drug Administration (FDA) is responsible for protecting public health by regulating food products for human and animal consumption. The FDA also monitors prescription and over-the-counter (OTC) pharmaceutical drugs, medical devices, and biological products (blood, vaccines, and biological therapeutics). However, the FDA's responsibilities extend much further than even these well-known parameters. The FDA is also in charge of 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.

Our lawyers are well known for their ability to deliver comprehensive environmental counsel to life sciences clients. We offer individualized assistance to pharmaceutical, medical devices, biotechnology and other companies facing a range of compliance matters. Our attorneys are well-versed in all aspects of environmental law and regularly monitor changes and new developments. This ensures 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 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.