

## Biotechnology and Life Science

### Related Practices

Corporate Finance  
 Government Policy & Practice  
 Health Care  
 Intellectual Property  
 Labor & Employment  
 Litigation  
 Real Estate

## Overview

As companies in the biotechnology and life sciences sector strive to turn their scientific breakthroughs into commercial successes, they face a growing number of challenges. Whether these challenges come in the form of regulatory compliance, protecting important intellectual property, or unexpected litigation—through foresight, efficiency and imagination—our biotechnology and life science legal team can help. Drawing from our major practice groups, Dykema's biotechnology and life science lawyers provide comprehensive legal counsel to biotechnology manufacturers, pharmaceutical companies, health care providers that conduct clinical trials, contract research organizations and IT companies involved in life sciences—from start-ups and public and private companies to universities and nonprofits.

Boasting a deep technical, scientific and legal understanding of the complexities of the field, we are uniquely positioned to provide strategic guidance and representation in the following areas:

### Corporate and Finance

We represent clients on the full spectrum of transactional matters, from initial entity formation, mergers, acquisitions and IPOs to venture capital, angel and other debt and equity financings. We try to be as creative as the biotechnology industry itself to help our clients explore innovative strategic alliances, joint ventures, partnering arrangements and research and development collaborations.

### Employment and Operational Matters

We provide complete employment and benefits counsel to our clients—from executive contracts and compensation to employee stock option plans, and from confidentiality and non-competition agreements to compliance with federal and state employment and labor laws. For clients facing immigration issues, we can help with the issuance of H1-B visas to foreign professionals.

We can also help our biotechnology and life science clients with their general operational legal needs, such as corporate governance, tax, insurance and contract issues.

### Government Policy and Regulatory

Our government policy lawyers and regulatory advisors offer guidance on state and federal legislative matters that impact the biotechnology and life science industry, as well as on such issues as government contracts, grants and research agreements, export control and technology transfers.

### Health Care and Compliance

Experienced in the wide range of health care issues that impact the biotechnology and life science industry, we help our clients file applications for FDA approval and address complex FDA compliance issues; clinical research issues, including clinical trial agreements and

informed consents; and HIPAA issues. If the need arises, we also advise clients with adverse event reporting issues.

## Intellectual Property, Technology and Licensing

Our comprehensive services include preparing and prosecuting U.S. and foreign patent applications, copyrights and trademarks, and drafting and negotiating confidentiality, proprietary rights, distribution, manufacturing, sales, licensing, collaboration and technology transfer agreements.

## Litigation

We have an exemplary track record in product liability and general commercial litigation, and in defending clients against allegations of white-collar crime. We are masters of dispute resolution in and out of the courtroom, helping clients to expeditiously resolve their disputes so they can focus on business.

## Real Estate and Facilities

Our health care lawyers team with Dykema's nationally recognized real estate practice attorneys (*Chambers USA* and *Midwest Real Estate News*) to help our biotechnology and life science clients with their facility projects, providing both legal and strategic guidance to ensure that each phase of their project is timely completed in a cost-effective manner. Clients wishing to expand and grow their companies benefit from solutions that address their building, construction and leasing and/or equipment purchase and leasing needs.

## Experience Matters

We have:

- Assisted an equipment manufacturer to obtain 513(g) guidance to determine whether product is subject to FDA regulation.
- Assisted medical device manufacturer in analysis of state laws relating to the regulation of the sale, distribution and use of the device.
- Successfully represented biotechnology manufacturer in an FDA audit and investigation.
- Represented a leading provider of human tissue and human tissue-based services to pharmaceutical and biotechnology companies in its acquisition of a company that was pioneer in the application of predictive human biology.
- Represented human tissue business in its sale to company engaged in innovative research products and services relating to advance cellular reprogramming and stem cell research.
- Counseled biotechnology industry participants regarding compliance with FDA requirements, including obtaining required clearances and approvals, labeling, informed consent and IRB.
- Reviewed and negotiated clinical research, collaboration, license and technology transfer contracts and policies and procedures.
- Advised biotechnology manufacturers and distributors regarding reimbursement, HIPAA and tax issues related to clinical research.

## Publications

"The Curious Case of Wuhan's Institute of Virology and Remdesivir"

April 20, 2021

*Life Sciences Intellectual Property Review*

## Speaking Engagements

The Intersection of Regulatory and Intellectual Property Issues in the Medical Device World

May 25, 2021

Biotechnology and Life Science (Cont.)

*Business Structure, and Development of Management Teams and Scientific Advisory Boards*, MichBio Entrepreneurial Bootcamp, Bio Pharma Drug Development  
June 2013

Crowdfunding and the IPO On-Ramp  
June 5, 2012 (Los Angeles-area)

Crowdfunding and the IPO On-Ramp  
May 23, 2012 (Detroit) and May 24, 2012 (Chicago)