# LIFE SCIENCES

## FDA and REGULATORY PRACTICE

***FUELING YOUR MISSION***

We'll clear your path to success at every stage of your product's lifecycle. Whether you're a global biopharma leader in medical devices and drugs, a cutting-edge digital health innovator or something completely new, we help you navigate the regulatory and compliance landscape so you can keep moving forward.

**FDA practice chair awarded FDA/Regulatory Attorney of the Year – Medical Devices and Life Science Star**

***LMG 2018***

**Nationally Ranked Life Sciences Practice**

***Chambers USA***

**Recognized for FDA: Medical Device**

***LMG 2019***

## ENABLING PASSIONATE PURSUIT OF PROGRESS

As the top-ranked law firm for health and a leader in life sciences, we are dedicated to our clients and passionate about the work we do together. Led by a former US Food and Drug Administration (FDA) Associate Chief Counsel and including former senior in-house counsel to leading life sciences companies, our FDA regulatory team offers deep industry experience, strategic legal advice, diverse perspectives and practical solutions that address the full scope of regulatory and compliance issues life sciences companies face. Our team will work collaboratively to help you clear your path to success.

McDermott Will & Emery

mwe.com

## OUR SERVICES

- **PRODUCT LAUNCH, MARKETING AND DISTRIBUTION**
  Develop comprehensive compliance, marketing and distribution programs to address FDA and healthcare requirements, marketing, sales, labeling, licensing, pharmacovigilance, good manufacturing practice (GMP), good clinical practice (GCP), FDA clinical holds licensing and clinical research agreements, manufacturing, supply and quality issues, and health care provider and patient engagement
- **PREMARKET STRATEGY AND FDA ENGAGEMENT**
  Develop market pathway and FDA engagement strategies for drugs, medical devices, novel digital health products, Laboratory Developed Tests, Companion Diagnostics, and other products under personalized medicine
- **DATA PRIVACY AND SECURITY**
  Counsel clients on global data-use issues, data transfers and privacy compliance under US and foreign laws.
- **POST-MARKET COMPLIANCE**
  Program development and implementation, auditing and monitoring in accordance with FDA and FTC regulations, OIG Guidance, PhRMA Code/ADVAMED and related industry standards, laws and regulations
- **PRICING AND REIMBURSEMENT**
  Analysis and evaluation of commercial arrangements and strategies for drugs, devices, diagnostics, and digital health solutions
- **CROSS-BORDER REGULATION**
  Assist with cross-border regulatory issues for medical products by leveraging our global teams in Europe and China. Provide US market entry guidance for clinical studies, approval, prelaunch, postmarket compliance program and other matters
- **REGULATORY DUE DILIGENCE FOR M&A TRANSACTIONS**
  Conduct due diligence for investors and acquiring companies prior to M&A transactions
- **COMPLIANCE AND ENFORCEMENT**
  FDA inspection preparedness and response to Inspectional Observations (483s), Warning Letters and defense of companies and executives in Injunction, Consent Decree actions and related US Department of Justice (DOJ) actions arising from alleged cGMP and post-market compliance violations; development of compliance programs

## UNPARALLELED EXPERIENCE

+ Biologics
+ Clinical Laboratories
+ Drugs
+ Digital Health Technology
+ Medical Devices
+ Investors & Due Diligence
+ Pharmaceuticals
+ Pricing & Reimbursement
+ FDA & Health Care Enforcement Defense
+ Compliance
+ Product Approvals

## FDA PRACTICE LEAD

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