FDA and Life Sciences

Regulation has posed increased challenges for the life sciences industry. Companies now face a changing political landscape. Our FDA and Life Sciences team guides companies regulated by the FDA, including in pharmaceuticals, biotech, devices, food, supplements, cosmetics. and tobacco, through all aspects of U.S. and EU regulatory compliance challenges. We draw on years of industry experience to work through every issue at every stage of a product's life cycle. Manufacturers, investors, and other regulated entities value our practical advice and relationships with U.S. state, federal and EU regulatory bodies. The team's 40+ lawyers and consultants have held senior positions in government, industry, academia and the medical profession. Through benchmarking from over 300 industry clients, our annual marquee conferences, and cutting-edge webinars and client alerts, our attorneys share and analyze key developments and practical insights on the most relevant issues in the life sciences space.

We are distinguished not only by our outstanding attorneys, but also by our industry consultants, including physicians and former senior FDA officials focused on quality and safety, good manufacturing practices, inspections and product approvals. Our consultants work under privileged legal supervision to provide companies with integrated medical and technical assessments and recommendations, including for FDA interfaces, meetings and submissions; system audits and mock inspections; and crisis management.

Our team in the EU focuses on EU and national (French, Belgian and German) issues associated with the legal requirements of the pharmaceutical, biologic, medical device, cosmetic and food industries. They advise life sciences clients on successful strategies for addressing significant EU policy developments and the EU regulatory regimes. The EU team represents our clients in litigation

Capability Lawyers

Mark S. Brown
Washington, D.C.

Seth H. Lundy
Washington, D.C.

Ulf H. Grundmann
Frankfurt

Elaine H. Tseng
San Francisco

Recognition

Named "Law Firm of the Year" for FDA Law

U.S. NEWS & WORLD REPORT

Named 'Practice Group of the Year' for the Life Sciences Practice

LAW360, 2016-2019

Ranked Tier 1 (National and in DC) for FDA Law

U.S. NEWS AND WORLD REPORT

LMG Life Sciences named 20 K&S lawyers as "Life

cases before German and European courts, including the General Court and the Court of Justice of the European Union, and in investigations.

Cases & Deals

November 17, 2022
King & Spalding represents Novartis on landmark ECJ pharma packaging victory

June 22, 2022
Cathay Capital Private Equity and 3i Enter into an Agreement to Sell Havea Group to BC Partners

King & Spalding Advises Insulin-Related Digital Health Apps/Software Company

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Insights

NEWSLETTER
April 15, 2024
Health Headlines – April 15, 2024

NEWSLETTER
April 8, 2024
Health Headlines – April 8, 2024

NEWSLETTER
April 1, 2024
Health Headlines – April 1, 2024

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Events

CONFERENCE
May 15, 2024
Annual King & Spalding California Life Sciences Summit

WEBINAR
March 29, 2024
The Machines Are Coming (And Lawsuits Too): Mitigating Risks of Product Design, Manufacture, and Sale Amidst the AI Revolution

SPEAKING ENGAGEMENT
March 15, 2024
Ulf Grundmann to Speak at 27th Marburg Discussions

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News

IN THE NEWS
April 8, 2024
Lisa Dwyer comments on the FDA's drug center gearing up to issue guidance on use of artificial intelligence to enhance its regulatory decision-making

Sciences Stars" in the 2019 edition

K&S Frankfurt team recognized in pharmaceuticals, medical products & food law

JUVE HANDBOOK

Food practice ranked as one of the leading practices in the nation

CHAMBERS USA

Ranked as one of the leading firms in Pharmaceutical and Medical Products Regulatory

CHAMBERS USA

Named Medical Device "Firm of the Year"

LMG LIFE SCIENCES

Selected as a leading firm in the nation in the Life Sciences industry

LEGAL 500

Tier 1 for Product Liability, Mass Tort and Class Actions: Defense – Pharmaceuticals and Medical Devices

LEGAL 500, 2020-2021, 2023

IN THE NEWS

April 8, 2024

Ashley Parrish, John Shakow and Nicole Bronnimann counsel AbbVie before a Louisiana federal court in a dispute involving the federal 340B drug discount program

IN THE NEWS

March 26, 2024

John Shakow comments on a federal district judge's decision to dismiss a suit against four pharmaceutical companies related to alleged fraudulent 340B overcharges

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