

# FDA and Life Sciences

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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

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

LAW360, 2016-2019

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

U.S. NEWS AND WORLD REPORT

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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

[VIEW ALL](#)

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#### Insights

##### NEWSLETTER

*May 13, 2024*

Health Headlines – May 13, 2024

##### CLIENT ALERT

*April 30, 2024*

LDT Final Rule: Shifting the LDT Battlefield

##### NEWSLETTER

*April 29, 2024*

Health Headlines – April 29, 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

*May 8, 2024*

Lisa Dwyer discusses the FDA's struggle to review Moderna and Merck's mRNA-4157 melanoma cancer vaccine candidate as the companies used artificial

Sciences Stars" in the 2019 edition

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

[JUVE HANDBOOK](#)

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

[CHAMBERS USA](#)

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

[CHAMBERS USA](#)

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Named Medical Device "Firm of the Year"

[LMG LIFE SCIENCES](#)

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

[LEGAL 500](#)

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

[LEGAL 500, 2020-2021, 2023](#)

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intelligence to determine the formulation of the individualized vaccine

## IN THE NEWS

*May 7, 2024*

Eric Henry comments on the atrial fibrillation history feature on Apple Watches and how they can be used to track AFib during cardiac device clinical trials

## IN THE NEWS

*May 2, 2024*

Keri Borders, Dale Giali and Rebecca Johns represent Kind before the Second Circuit, which affirmed a summary judgment in favor of the company in a multidistrict class action labeling dispute. Keri and Dale are recognized by Law.com as a Litigators of the Week for their win on behalf of Kind, which secured a summary judgment in a multidistrict class action labeling dispute.

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