

Erkang Ai, Ph.D.

Counsel

Philadelphia

Biography

A geneticist and biologist by training, Erkang Ai works closely with clients to navigate the complex FDA regulations. Speaking both languages of lawyers and scientists, he brings his technological know-how to assist medical device, diagnostics, and biologics companies in the most challenging legal and regulatory issues.

Erkang holds a doctorate degree in genetics. Prior to attending Harvard Law School, he also worked as a postdoctoral fellow at Stanford University. With 10 years of research experience, he has gained a deep understanding of genetics, genomics, oncology, biochemistry, and cell biology. He is passionate about leveraging his scientific and legal background to help companies bring their cutting-edge medical products to market.

Erkang's practice focuses primarily on premarket clearance or approval of medical devices. His experience includes evaluating the FDA's market requirements, designing analytical and clinical development plans, and formulating innovative regulatory strategies. He is also skilled in the regulation of in vitro diagnostic assays, including NGS-based genetic tests and laboratory developed tests.

Latest thinking and events

- News
 - Federal court vacates FDA Laboratory Developed Test rule



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Languages

English
Mandarin

Practices

Medical Device and Technology
Regulatory

Pharmaceuticals and
Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Medical Devices

Pharmaceuticals and

- News
 - Podcast: Talking the cure
- News
 - FDA under fire: Pared-down LDT Final Rule leaves unanswered questions
- Press releases
 - Hogan Lovells welcomes the New Year with 28 new partner and 59 new counsel promotions
- News
 - FDA pilots oncology companion diagnostic test/device program as LDT rulemaking nears
- Press releases
 - Hogan Lovells secures FDA emergency use authorization for Lucira Health for breakthrough OTC COVID-19 and flu test

Biotechnology

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., Harvard Law School, 2015

Ph.D., University of Wisconsin-Madison, 2010

B.S., Peking University, 2004

Bar admissions and qualifications

Pennsylvania
