

## Erkang Ai, Ph.D.

Associate

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



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### Languages

English  
Mandarin

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### Practices

Medical Device and Technology  
Regulatory

Pharmaceuticals and Biotechnology  
Regulatory

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### Industries

Life Sciences and Health Care

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### Areas of focus

- Hogan Lovells Publications
  - FDA resumes enforcement relating to laboratory developed tests *Medical Device & Technology Alert*
- Hogan Lovells Publications
  - Paving the way for product authorization: FDA proposes rule to reclassify medical image analyzers *Medical Device Alert*
- Hogan Lovells Publications
  - FDA finalizes guidances for NGS-based tests *Medical Device Alert*
- Hogan Lovells Publications
  - FDA finalizes guidance on evaluation and reporting of age-, race-, and ethnicity-specific data in medical device clinical studies *Medical Device Alert*
- Hogan Lovells Publications
  - FDA's software Pre-Cert program: More details revealed *Medical Device Alert*
- Hogan Lovells Publications
  - FDA unveils software pre-certification pilot program to foster digital health innovation *Medical Device Alert*

Medical Devices

Pharmaceuticals and Biotechnology

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## Education and admissions

### Education

J.D., Harvard Law School, 2015

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

B.S., Peking University, 2004

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## Bar admissions and qualifications

Pennsylvania

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