Hogan Lovells

Blake E. Wilson

Partner
Philadelphia

Phone
+1 267 675 4633

Fax
+1 267 675 4601

Email
blake.wilson@hoganlovells.com

Biography

Blake Wilson helps medical device, drug, and biologic companies successfully navigate FDA's evolving regulatory landscape. With a focus on premarket submissions and clinical trial design and conduct, Blake helps sponsors plan their product development strategy and minimize regulatory risks.

When advising companies, Blake draws on years of experience practicing in front of the FDA. He has assisted clients across a wide range of submissions (e.g., presubmissions, investigational products, combination products, humanitarian/orphan products, marketing applications, breakthrough requests) with a focus on novel treatments . When feedback from the agency is needed, Blake helps sponsors craft a well-tailored regulatory strategy and is effective at presenting the plan to FDA. He also prepares sponsors for advisory panel hearings.

Leveraging his prior experience in clinical research and biostatistics, Blake advises sponsors on study design considerations and reporting study outcomes. By stress testing clinical evidence through the lens of an FDA reviewer, Blake helps sponsors avoid pitfalls that can delay or derail a project. He also prepares sponsors for FDA Bioresearch Monitoring (BIMO) audits, and can host the inspection. Whether crafting a regulatory strategy, preparing a submission, or negotiation a solution with the agency, Blake provides technical acumen and creativity to help companies achieve their goals.

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Postmarket Compliance and Enforcement Actions

Advertising and Promotion Compliance

Advisory Panel Preparation

Combination Products

Blake also advises on due diligence and other corporate matters related to medical products (e.g., mergers and acquisitions). He also assists companies with compliance challenges, including government and internal investigations, and 483 and Warning Letter responses.

While at Penn Law, Blake was an executive editor for the Journal of International Law and published a comment regarding the use of foreign clinical trials in the FDA's drug marketing approval process. He also served as a judicial intern to the Honorable Leonard P. Stark of the U.S. District Court for the District of Delaware. Prior to becoming a lawyer, Blake was a lead research assistant at Brown University, where he managed phase I and II pharmaceutical clinical trials; he later went on to obtain a master's degree in biostatistics from Columbia University.

Awards and rankings

- Healthcare: Life Sciences, Rising Star, *Legal 500 US*, 2020-2021

Latest thinking and events

- News
  - New FDA clinical trials guidances promote efficient drug development, innovative designs, diversity
- News
  - FDA publishes long-awaited clinical trial diversity guidance
- News
  - FDA publishes long-awaited clinical trial diversity guidance
- News
  - FDA summarizes LDT rule requirements in new compliance guide
- News
  - First salvo fired against FDA's laboratory developed test rule
- News

Medical Devices

Pharmaceuticals and Biotechnology

Clinical Trials

Cell, Tissue, and Gene Therapies

Artificial Intelligence

Education and admissions

Education

M.S. Biostatistics, Columbia University, Mailman School of Public Health, 2021

J.D., University of Pennsylvania Law School, 2012

Certificate in Business Economics and Public Policy, University of Pennsylvania, Wharton School of Business, 2012

B.S., Northeastern University, summa cum laude, 2007

Memberships

Pennsylvania Bar Association, 2011 - Present

Bar admissions and qualifications

Pennsylvania

New Jersey

- FDA under fire: Pared-down LDT Final Rule leaves unanswered questions