

## Blake E. Wilson

Counsel

Philadelphia

### Biography

When clients need help with premarket clearance and approval of new medical devices, Blake Wilson leverages his background in the life sciences industry to smooth regulatory hurdles.

Blake has advised on 510(k) premarket notifications, de novo submissions, premarket approval applications (PMAs), and investigational device exemption applications, among other regulatory filings. He also has experience in drafting clinical trial agreements and contracts for device development, manufacturing, and associated Quality System Regulation (QSR) responsibilities.

Prior to joining Hogan Lovells, Blake worked as an associate at another international law firm and was a lead research assistant at Brown University, where he managed phase 1 and 2 pharmaceutical clinical trials. Blake takes advantage of his clinical research background to help companies navigate the FDA's clinical data requirements.

While attending law school, Blake was executive editor for the University of Pennsylvania *Journal of International Law* and published a student comment regarding the use and regulation of foreign clinical trials in the FDA's drug marketing approval process. He also served as a judicial intern to the Honorable Leonard P.



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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

Postmarket Compliance and  
Enforcement Actions

Advertising and Promotion  
Compliance

Advisory Panel Preparation

Stark of the U.S. District Court for the District of Delaware.

## Awards and rankings

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

## Latest thinking and events

- News
  - After a long and winding road, FDA finalizes much-debated “intended use” rule
- News
  - First company receives FDA violation notice for ClinicalTrials.gov submission omission
- News
  - HHS withdraws proposal to exempt 84 medical device types from FDA 510(k) process
- News
  - FDA issues new policy for evaluating impact of viral mutations on COVID-19 tests
- Hogan Lovells Publications
  - Life sciences and health care horizons 2021
- Press Releases
  - Hogan Lovells welcomes the New Year and 25 new partner and 60 new counsel promotions

Combination Products

Medical Devices

Pharmaceuticals and Biotechnology

Clinical Trials

Cell, Tissue, and Gene Therapies

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## 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

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## Memberships

Pennsylvania Bar Association, 2011 - Present

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## Bar admissions and qualifications

Pennsylvania

New Jersey

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