



## James (Jim) R. Johnson

Partner

Washington, D.C.

### Biography

Positioned at the forefront of FDA compliance and regulatory issues critical to the business of life science companies, Jim Johnson excels at knowing what's ahead.

He works with life science clients on U.S. Food and Drug Administration (FDA) compliance and enforcement matters, focusing on FDA inspections, current good manufacturing practice (GMP) requirements, data integrity responsibilities, import and export issues, and pharmacovigilance obligations. He helps clients around the world identify compliance risks early, prevent problems from happening, efficiently resolve issues with minimal corporate pain, and improve agency relationships.

Jim knows the FDA well. Prior to joining Hogan Lovells, he served as Associate Chief Counsel for Enforcement in the FDA's Office of the Chief Counsel. He handled GMP enforcement and provided legal counsel on a range of inspectional and compliance issues to agency components, particularly the FDA's Office of Regulatory Affairs (ORA) and Center for Drug Evaluation and Research's (CDER) Office of Compliance.

Whether preparing an international manufacturing site for an FDA inspection, or working with a U.S.-based facility in response to FDA inspectional observations (a



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### Practices

Pharmaceuticals and Biotechnology  
Regulatory

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### Industries

Life Sciences and Health Care

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### Areas of focus

Pharmaceuticals and Biotechnology  
Hogan Lovells China Desk  
Regulatory Inspections and cGMP  
Cell, Tissue, and Gene Therapies

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### Education and

Form FDA 483), Jim uses his extensive agency and private practice experience to assist pharmaceutical, biotechnology, and cosmetic companies worldwide. He regularly conducts GMP assessments and investigations, resolves warning letters and import alerts, and appears in front of the FDA on behalf of companies to resolve enforcement actions.

Jim also advises life science companies on drug approval and life-cycle management strategies, and represents clients in related litigation against the FDA and U.S. Patent and Trademark Office. Jim honed these skills at the FDA, where he defended the agency in Hatch-Waxman cases involving agency exclusivity and patent-term extension determinations.

## Representative experience

Assist numerous global pharmaceutical companies in responding to FDA enforcement involving a range of GMP and data-integrity issues.

Routinely draft responses to FDA warning letters and Form FDA 483 inspectional observations.

Resolve import alert for global pharmaceutical company.

Represent pharmaceutical companies in Hatch-Waxman litigation against FDA over drug exclusivity and patent-term extension disputes.

Conducting GMP assessments and investigations for an array of pharmaceutical, biotech, and cosmetic companies.

## Awards and rankings

- Healthcare: Life Sciences, *Legal 500 US*, 2018

## Latest thinking and events

- News
  - COVID-19 Report for Life Sciences and Health Care

## admissions

### Education

J.D., Marquette University Law School, 2005

B.S., Molecular Biology and Genetics, University of Wisconsin-Madison, 2002

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### Bar admissions and qualifications

District of Columbia

Wisconsin

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## Companies

- News
  - COVID-19 Report for Life Sciences and Health Care Companies (16 - 19 November 2020)
- Hogan Lovells Publications
  - Podcast: Talking the cure
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (9 - 12 November 2020)
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (2 - 5 November 2020)
- News
  - COVID-19 Report for Life Sciences and Health Care Companies (26 - 29 October 2020)