Hogan Lovells

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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

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Hogan Lovells China Desk

Regulatory Inspections and cGMP

Cell, Tissue, and Gene Therapies

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
  - Appealing a denial of a drug/medical device export

admissions

Education

J.D., Marquette University Law School, 2005

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

Bar admissions and qualifications

District of Columbia

Wisconsin

certificate: FDA final guidance

- News
  - China adds 30 drugs to its "urgently needed" list
- News
  - FDA, EMA Address Quality & Manufacturing Issues for Breakthrough Therapies with Expedited Approval
- Blog Post
  - FDA and EMA Address Quality and Manufacturing Challenges for Breakthrough Therapies Undergoing Expedited Approval
- News
  - New FDA draft guidance on voluntary recalls highlights importance of recall initiation plans *Focus on Regulation*
- Hogan Lovells Publications
  - Good Manufacturing Practice and the global supply chain