Hogan Lovells

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Biography

Christopher (Chris) Fanelli works closely with life sciences clients globally to develop and implement practical, forward-thinking strategies to address 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.

Prior to joining Hogan Lovells, Chris served as Associate Chief Counsel for Enforcement in the FDA's Office of the Chief Counsel, where he handled GMP enforcement and provided legal counsel on a range of inspectional, compliance, and policy issues to agency components.

His agency and private practice experience equips him with the tools needed to assist manufacturers with preparing for FDA inspections; responding to FDA inspectional observations (a Form FDA 483), Warning Letters, and Complete Response Letters; resolving import alerts; and preparing for meetings with the FDA. Chris enjoys working alongside clients to identify risks early through on-site GMP assessments and investigations, including data integrity investigations and Part 11 assessments, and mock inspections.

Chris also guides life sciences and private equity clients

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Product Compliance

Manufacturing

Hogan Lovells China Desk

Regulatory Inspections and cGMP

through intricate due diligence matters relating to FDA compliance and enforcement, including pre-acquisition quality assessments and post-acquisition quality integration.

Representative experience

Assist multiple Chinese pharmaceutical companies in responding to FDA enforcement.

Draft responses to FDA 483s and Warning Letters.

Conduct GMP assessments and data integrity investigations in the U.S., China, India, Japan, and Europe.

Resolve multiple Warning Letters for global pharmaceutical companies.

Latest thinking and events

- Blog Post
  - FDA and EMA Address Quality and Manufacturing Challenges for Breakthrough Therapies Undergoing Expedited Approval
- Sponsorships and Speaking Engagements
  - Legal, Business, and Technical Considerations for International Crisis Management: General Principles and Case
- Hogan Lovells Publications
  - Good Manufacturing Practice and the global supply chain
- Hogan Lovells Publications
  - U.S. drug inspections in China: Staying ahead of FDA enforcement trends
- Blog Post
  - FDA Finalizes Data Integrity Guidance, With Some Noteworthy Changes
- Hogan Lovells Publications
  - FDA schedules public hearing on solutions to drug shortages *Pharmaceuticals and Biotechnology*

Education and admissions

Education

J.D., Boston University School of Law, cum laude, 2011

B.A., Juniata College, magna cum laude, 2006

Bar admissions and qualifications

District of Columbia

New York

Alert