Hogan Lovells

Ted Lis

Counsel
Washington, D.C.

Phone
+1 202 637 5482

Fax
+1 202 637 5910

Email
ted.lis@hoganlovells.com

Biography

Ted Lis entered the practice of law after nearly a decade as a chemical engineer for a major American chemical company and is a senior member of the American Institute of Chemical Engineers. He uses his legal and engineering training to provide in-depth counsel to clients whose manufacturing processes are subject to current Good Manufacturing Practice (cGMP) regulation. Over the course of his career, Ted has assisted clients resolve cGMP issues pertaining to API, aseptic injectables, biologics, combination products, ophthalmic products, oral solid doses, medical devices, vaccines, and other regulated products.

Working with industry and company professionals, Ted applies his broad experience to advise quality and manufacturing managers and senior executives who face critical issues that are the focus of regulators. He assists clients with managing communications with regulatory agencies, preparing for pending site inspections, and training personnel. He also provides on-site support during inspections to assist subject-matter experts in cogently and succinctly presenting information that is relevant to investigators' requests.

During the COVID-19 public health emergency, Ted has assisted clients in preparing Emergency Use Authorization applications and communicating with FDA for medical devices that include in vitro diagnostic tests, personal protective equipment and ventilators. Ted also has experience in conducting internal investigations involving alleged FDA violations.

Practices

Pharmaceuticals and Biotechnology Regulatory

Medical Device and Technology Regulatory

Litigation Services

Industries

Life Sciences and Health Care

Manufacturing and Industrials

Areas of focus

Regulatory Inspections and cGMP

Compliance Readiness

Postmarket Compliance and Enforcement Actions

In addition to GMP regulation enforcement work, Ted is an experienced litigator. He has represented pharmaceutical companies when deposing plaintiffs, physicians and expert witnesses in support of dispositive motions and Daubert motions to exclude expert testimony.

Latest thinking and events

- Press releases
  - Hogan Lovells advises Perspective Therapeutics on a series of strategic transactions with Lantheus and a US$69 million follow-on public offering of equity securities
- News
  - Inside the FDA Advanced Manufacturing Technologies Designation Program
- Webinar
  - A Seat at the Table: Cell Cultured Foods: Considerations and recent developments
- News
  - Can sterile drug manufacturers implement EU GMP Annex 1 requirements before August?
- News
  - New FDA pilot offers expedited drug program sponsors expanded FDA meeting opportunities on manufacturing issues

Transaction and Securities Disclosure Support and Due Diligence

Education and admissions

Education

J.D., Georgetown University Law Center, 2002

B.S. Chemical Engineering, Drexel University, 1990

Memberships

Member, International Organization for Standardization (ISO)

Member, Parenteral Drug Association (PDA)

Senior Member, American Institute of Chemical Engineeers (AIChE)

Bar admissions and qualifications

District of Columbia

Virginia

Court admissions

U.S. District Court, Eastern District of Virginia

U.S. Bankruptcy Court, Eastern District of Virginia