Hogan Lovells

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Biography

Scott Kaplan helps pharmaceutical and biotechnology clients achieve and maintain compliance with complex Food and Drug Administration (FDA) requirements.

Drawing on his deep understanding of the FDA's civil and criminal enforcement, Scott prepares clients for FDA inspections and works with them to respond to FDA 483s, Warning Letters, import alerts, investigations by the Office of Criminal Investigations, and other FDA enforcement actions.

Scott provides experienced counsel on Current Good Manufacturing Practice regulations, data integrity issues, product labeling, and Drug Supply Chain Security Act implementation, among others.

Before joining Hogan Lovells, Scott served as Associate Chief Counsel for Enforcement in the FDA's Office of the Chief Counsel. At the FDA, Scott helped the agency resolve seizures, injunctions, administrative detentions, and criminal prosecutions, in addition to serving as a Special Assistant U.S. Attorney. Scott also acted as counsel for compliance matters to the FDA's district offices. Prior to his tenure at the FDA, Scott clerked for the Hon. Helene N. White of the U.S. Court of Appeals for the Sixth Circuit.

Representative experience

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Cell, Tissue, and Gene Therapies

Education and admissions

Education

Assist pharmaceutical and biotech companies respond to FDA enforcement actions related to GMP, GTP, and data-integrity issues.

Draft responses to FDA 483s, Warning Letters, and Import Alert notifications.

Perform GMP and GTP assessments as well as internal investigations for domestic and global pharmaceutical and biotech companies.

Advise companies on CMC-related issues in IND, NDA, and BLA submissions.

Represent companies in FDA Consent Decree negotiations and at Regulatory Meetings.

Assist companies with DSCSA compliance and supply chain management.

Latest thinking and events

- News
  - FDA expands mutual reliance and harmonization with foreign regulators for inspectional oversight
- News
  - FDA issues guidance on conducting remote interactive evaluations during the COVID-19 pandemic
- News
  - Safeguarding drug development at academic institutions
- 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
- Hogan Lovells Events
  - Moving at warp speed: Are you ready to go to market?

J.D., University of Pennsylvania Law School, magna cum laude, Order of the Coif, 2009

M. Bioethics, University of Pennsylvania Center for Bioethics, 2009

B.A., University of Pennsylvania, cum laude, 2002

Bar admissions and qualifications

Massachusetts

District of Columbia

Pennsylvania