Hogan Lovells

Regulatory Inspections and cGMP

Handling an inspection is a critical event for your company. You want a team with strong relationships with FDA. You need support during inspections and the right response to the agency.

We have almost 30 lawyers devoted to pharmaceutical regulation, many of whom worked at FDA before joining Hogan Lovells, a number with extensive experience handling GMP enforcement, both while at FDA and at the firm. Our GMP practice is truly global, and our team is regularly onsite providing clients with real-time support at manufacturing facilities around the world.

We advise clients on all aspects of GMP compliance, including:

- Conducting internal compliance assessments and data integrity investigations;
- Counseling on manufacturing obligations;
- Helping prepare for FDA inspections and interacting with the agency during inspections;
- Responding to Form FDA 483 observations;
- Resolving Warning Letters, Import Alerts/Import Bans, and other FDA enforcement actions;
- Leading complex investigations and remediation activities involving significant GMP deviations, data integrity violations, non-conforming product, and FDA inquiries;
- Helping develop and implement global corrective action plans;

Contacts

James (Jim) R. Johnson,
Washington, D.C.

Christopher A. Fanelli,
Washington, D.C.

Xin Tao,
Washington, D.C.

Practices

Pharmaceuticals and Biotechnology Regulatory

- Preparing for and conducting meetings with FDA;
- Advocating before FDA in person and in written submissions;
- Developing strategies and facilitating FDA engagement to avert drug shortages related to manufacturing issues; and
- Addressing drug approval issues and FDA complete response letters related to manufacturing and GMP concerns.

Representative experience

Provided onsite FDA inspection and GMP/data integrity support to manufacturing sites around the world, including in the United States, China, India, Japan, Europe, and South America.

Helped pharmaceutical companies, large and small, around the globe successfully resolve Form FDA 483 observations and Warning Letters.

Conducted privileged investigations of alleged significant GMP compliance and data integrity deviations.

Negotiated consent decrees on behalf of manufacturers and individual defendants.

Successfully assisted companies and individual defendants in vacating GMP consent decrees.

Provided regulatory and white collar investigation support to pharmaceutical companies in responding to qui tam (whistleblower) actions involving GMP and data integrity allegations.

Helped develop and implement GMP policies and procedures and related training.

Developed briefing materials and prepared CEOs and senior executives for “make or break” meetings with FDA.

Successfully counseled numerous foreign manufacturers through the process of lifting GMP Warning Letters and Import Alerts (Import Bans).

Negotiated civil and criminal settlements involving government investigations into GMP violations.

Developed responses and strategies to address drug approval issues and FDA complete response letters related to manufacturing and GMP concerns.

Engaged FDA on averting drug shortages due to manufacturing constraints.

Negotiated many GMP-related consent decrees with FDA, and defend criminal prosecutions of companies and executives under the Park doctrine.

Latest thinking and events

News
COVID-19: Daily Report for Life Sciences and Health Care Companies

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (29 June - 3 July 2020)

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (22 - 26 June 2020)

News
USPTO Alert – New fast track for certain COVID-19 trademark applications

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (15 - 19 June 2020)

News
COVID-19: Daily Report for Life Sciences and Health Care Companies (15 - 19 June 2020)