Hogan Lovells

Sally Gu

Associate
Washington, D.C.

Phone
+1 202 637 6856

Fax
+1 202 637 5910

Email
sally.gu@hoganlovells.com

Biography

Sally Gu advises clients on Food and Drug Administration (FDA) advertising and promotion issues, compliance with current good manufacturing practices (cGMP), life cycle management, and product development issues.

She routinely advises pharmaceutical companies on pre-launch and post-marketing advertising and promotion issues and has served on multiple promotional review committees. She also assists pharmaceutical clients with responses to FDA enforcement actions and related government investigations, and advises on FDA regulatory issues arising in corporate transactional matters and filings with the Securities and Exchange Commission (SEC).

While at University of Michigan Law School, Sally was a Notes Editor for the Michigan Law Review, and the President of the Michigan Health Law Organization.

In addition to assisting clients in the life sciences and health care industry, Sally is also active in the firm's Pro Bono practice.

Representative experience

Counsel numerous pharmaceutical companies on pre-launch and post-marketing activities, including experience on promotional review committees.

Conduct internal audits for pharmaceutical companies of promotional materials, promotional review processes and investigator initiated study programs.

Languages

English

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Pharmaceuticals and Biotechnology

Advertising and Promotion Compliance

Controlled Substances and DEA

Regulatory Exclusivities, Hatch-

Assist multiple pharmaceutical companies in responding to FDA enforcement letters, Form FDA 483 inspectional observations, and related government investigations.

Latest thinking and events

- News
  - World Stem Cell Summit panel cautions over stepped up HCT/P enforcement, reimbursement issues
- Sponsorships and Speaking Engagements
  - 2022 World Stem Cell Summit
- News
  - PREVENT Pandemics Act to build pandemic capabilities and implications for medical product developers
- News
  - Meta ban on health-targeting ads will soon restrict clinical trial recruiters
- News
  - FDA RWD/RWE regulatory considerations in draft guidance highlight opportunities and challenges
- Announcements
  - Hogan Lovells assists EyePoint Pharmaceuticals on transformative follow-on public offering of common stock

Waxman, and Similar Statutes

Cell, Tissue, and Gene Therapies

Education and admissions

Education

J.D., University of Michigan Law School, cum laude, 2018

B.A., The University of Chicago, general honors, 2014

Bar admissions and qualifications

District of Columbia

California