ALSTON & BIRD

Zimu Yang

Associate

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Zimu Yang is an associate in Alston & Bird's Health Care Group and a member of the Food, Drug & Device/FDA Team. Zimu counsels life sciences clients on regulatory, compliance, and enforcement issues related to clinical trials, marketing authorization, manufacturing, market access, promotion and sales, product safety, imports/exports, and cybersecurity. He has extensive experience assisting clients in complex government enforcement actions and internal investigations, especially in the fields of current good manufacturing practice (CGMP) and data integrity. Zimu also supports litigations and regulatory due diligence in transactions involving FDA regulated products, and counsels biotechnology and medical device companies in collaboration and licensing transactions.

Before joining the firm, Zimu was an associate at another global law firm, where he practiced FDA law in both Washington, D.C. and Shanghai. Zimu is well-versed on Chinese medical product regulations and has helped multi-national corporate clients navigate local laws and policies.

Representative Experience

- Represented domestic and overseas pharmaceutical and medical device manufacturing facilities to manage FDA inspections, respond to Form FDA-483s and Warning Letters, and prepare for FDA Regulatory Meetings and subsequent status reports.
- Counseled a NASDAQ-listed biotechnology company on requesting Breakthrough Therapy Designation for its biologic product candidate.
- Counseled a Chinese company on the 510(k) submission for a medical device product candidate with artificial intelligence (AI) features.
- Led an internal investigation of data falsification allegations by a whistleblower at a multinational pharmaceutical company's aseptic processing site.
- Assisted a multinational medical device company's internal investigation of its overseas CMO's CGMP violations.
- Served as an FDA counsel in a BPCIA patent litigation.
- Counseled a NASDAQ-listed biotechnology company on strategic reorganization to reduce FDA enforcement risks.
- Represented a multinational biologics manufacturer in China's NMPA inspections and subsequent response drafting and corrective actions.
- Represented biotechnology and medical device companies in collaboration and licensing transactions, including contract manufacture and quality agreement drafting.

Publications & Presentations

Publications

- "What FDA's Digital Health Innovation Plan Means for Digital Diagnostics," *Medical Device and Diagnostic Industry*, August 11, 2017.

Education

- The University of Chicago (J.D., 2016)
- Columbia University (M.S., 2013)
- Columbia University (B.S., 2012)
- DePauw University (B.A., 2012)

Languages

- Mandarin

Admitted to Practice

- District of Columbia
- New York

Related Services

Health Care | FDA/Food, Drug & Device | Life Sciences | FDA Compliance & Enforcement