Hogan Lovells

W. Alex Smith

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Biography

Alex Smith understands the pressure pharmaceutical and medical device companies around the world face when working with the U.S. Food and Drug Administration (FDA) to resolve compliance and CMC concerns.

From small start-up companies to large multi-national corporations identified as leaders within the pharmaceutical and medical device spaces, Alex frequently works with companies to avoid further enforcement from the FDA. From developing corrective action plans to responding to FDA Form 483 inspectional observations, Untitled Letters, and Warning Letters; assisting companies through FDA-requested certified audit programs; and preparing recall plans, Alex is able to help companies navigate through the myriad of FDA regulations, requirements, and expectations.

Alex maintains a Regulatory Affairs Certification (RAC) by the Regulatory Affairs Professional Society (RAPS). RAC is the only credential for regulatory professionals in the healthcare product sector.

Alex has traveled the world in preparing, assisting, and defending companies before routine and directed FDA inspections. Alex has also prepared and assisted in the execution of global remediation plans to help ensure

Languages

English
French
Spanish

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

that all company sites act in accordance with company expectations and FDA requirements.

Previously, Alex held several roles in research development, manufacturing process engineering, software development, and GMP facility commissioning at several pharmaceutical and contract manufacturing firms.

Latest thinking and events

- Press Releases
  - Hogan Lovells advises Lucira Health in securing Emergency Use Authorization for over the counter at-home COVID-19 test
- News
  - HHS proposal to exempt medical devices from 510(k) process halted
- News
  - Five highlights from FDA's new AI device regulation Action Plan
- Press Releases
  - Hogan Lovells advises Lucira Health in obtaining the first FDA Emergency Use Authorization for an at-home COVID-19 testing kit
- News
  - New FDA inspection program released for "streamlined approach" for combination product cGMP
- Sponsorships and Speaking Engagements
  - The 3rd Annual Pharmaceutical Manufacturing Execution Systems Conference

Postmarket Compliance and Enforcement Actions

Combination Products

Controlled Substances and DEA

Regulatory Exclusivities, Hatch-Waxman, and Similar Statutes

Medical Devices

Pharmaceuticals and Biotechnology

Education and admissions

Education

M.B.A., University of Maryland, 2013

B.A. History, University of Maryland, 1999

B.S. Computer Science, University of Maryland, 1999