Hogan Lovells

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Biography

Daniel J. Roberts successfully guides domestic and international clients in the preparation for and management of U.S. Food and Drug Administration (FDA) pre-approval and systems-based inspections.

Daniel evaluates and assesses pharmaceutical quality systems and specializes in detecting and remediating data integrity concerns and evaluating compliant automated manufacturing processes and related computerized systems.

He provides guidance and assists clients in responding to FDA-483 observations, correspondence with regulatory agencies, and mock FDA facility audits.

Daniel has over 18 years of government regulatory and pharmaceutical/biopharmaceutical industry experience. He was an FDA investigator for eight years, including two years as the primary point of contact for conducting pharmaceutical inspections at the FDA India office located at the U.S. Embassy in New Delhi. As a former investigator, Daniel has conducted pre-approval inspections (PAIs) and for-cause investigations and inspections of pharmaceutical manufacturers of human and veterinary sterile and non-sterile finished dosage forms of active pharmaceutical ingredients (APIs) worldwide. He was also the first lead investigator for the first biosimilar

Languages

English

Practices

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Education and admissions

Education

inspection conducted by the FDA in India.

Prior to joining the FDA, Daniel worked in the biopharmaceutical / biotechnology industry for eight years, specializing in quality control analysis for large molecule biotherapeutics.

Latest thinking and events

- News
  - FDA expands mutual reliance and harmonization with trusted foreign regulators for inspectional oversight
- News
  - FDA issues guidance on conducting remote interactive evaluations during the COVID-19 pandemic
- Hogan Lovells Publications
  - Life sciences and health care horizons 2021
- News
  - Increased use of virtual tools, optimized inspectional activities, & enhanced supply chain oversight
- News
  - FDA updates industry on what drug & biologic inspections will occur during COVID-19 pandemic
- News
  - New FDA inspection program released for “streamlined approach” for combination product cGMP

B.S., Molecular Biology, University of California, Santa Cruz