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Biography

Joshua Yao focuses his practice on medical device regulation, leveraging his background in biomedical engineering to solve complex regulatory issues concerning a broad range of clinical applications. Joshua advises clients on both pre-market strategy and post-market compliance.

Prior to joining Hogan Lovells, Joshua served as a biomedical engineer and lead regulatory reviewer at the Center for Devices and Radiological Health (CDRH) of the U.S. Food and Drug Administration (FDA), where he evaluated various pre-market submissions in the respiratory technologies landscape, including Premarket Approval (PMA) applications, Investigational Device Exemption (IDE) applications, 510(k) Notifications, 513(g) Requests for Information, Breakthrough Designation Requests, and more. Joshua capitalizes off his valuable insights on FDA's internal review policies and nuances to help clients optimize entry-to-market timelines.

Joshua was also a duly accredited FDA investigator working closely with the CDRH Office of Regulatory Affairs (ORA) as a Ventilator Subject Matter Expert. He performed on-site manufacturer inspections of Quality Systems Regulations (QSR) compliance, classified high-profile Class 1 medical device recalls, and provided technical review of the adequacy and feasibility of risk mitigation strategies. Joshua offers a first-hand

Languages

English
Chinese

Education and admissions

Education

M.S. Biomedical Engineering, Tulane University, 2019

B.S. Biomedical Engineering, Tulane University, Cum Laude, 2018

understanding of FDA's perspectives on post-market regulation when assisting clients with compliance strategy.

Joshua completed his Bachelor of Science and his Master of Science, both in biomedical engineering, at Tulane University, where he published cross-cutting research in pulmonary health and computational quantification ventilator-induced lung injury.

Latest thinking and events

- News
  - Update to biocompatibility policy for medical devices in contact with intact skin