Hogan Lovells

Leif E. Olsen

Director of Regulatory Sciences
Washington, D.C.

Phone
+1 202 637 5801

Fax
+1 202 637 5910

Email
leif.olsen@hoganlovells.com

Biography

Leif Olsen assists clients throughout the life cycle of medical device and diagnostic product development in assessing FDA quality system regulation (QSR) requirements and implementation of post-marketing strategies.

He assists clients in achieving and maintaining compliance with the FDA's Current Good Tissue Practice (CGTP) regulation for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps). He also assists clients in obtaining FDA marketing approvals and clearances for diagnostic tests and medical devices. Leif is attuned to the needs of large corporations and start-up companies in formulating practical solutions to address FDA regulatory requirements.

He has deep insight into the FDA's QSR and CGTP regarding the design, development, and manufacturing of biologics and medical device requirements, including various radiological health devices, in vitro diagnostics (IVD) assays, and related laboratory instruments and accessories.

Previously, Leif held various operations and executive management positions in regulatory and quality for IVD, medical device, and biologic product companies and was responsible for development of regulatory

Practices

Medical Device and Technology Regulatory

Pharmaceuticals and Biotechnology Regulatory

Industries

Life Sciences and Health Care

Areas of focus

Adverse Event Reporting Vigilance Reporting

Premarket Review

Medical Devices

strategies and premarketing submissions to the FDA and international authorities, as well as establishment and monitoring of good manufacturing practice programs compliant with FDA regulations.

Representative experience

Utilizes 28 years of experience working with life science manufacturing companies regulated by the FDA.

Led the team at one device company in achieving ISO 13485 and ISO 9001 certification.

Managed the start-up of an in vitro diagnostic company's manufacturing laboratory for microbiological and immunological diagnostic products.

Key contact during FDA communications regarding product submissions and compliance related matters, including inspections, MDR, and corrections and removals.

Representative of the company regarding trade association activities, e.g., AdvaMed and AMDM.

Awards and rankings

- Certificate of Appreciation, *Food and Drug Administration Center for Devices*
- Food and Drug Administration, Group Recognition

Latest thinking and events

- Hogan Lovells Publications
  - DuPont's Upgraded Manufacturing Process Regarding Their Tyvek® Material and Impact on Medical Device Manufacturers *Medical Device Alert*
- Hogan Lovells Publications
  - FDA issues new draft guidance on distinguishing medical device recalls from product enhancements *Medical Device Alert*

Education and admissions

Education

Graduate Studies, Biomedical Sciences, Hood College, 1978

B.S., Milligan College, 1973

Memberships

Member, Board of Directors, Association of Medical Diagnostic Manufacturers

Member, Editorial Advisory Board, *IVD Technology*

Past President, Association of Medical Diagnostic Manufacturers