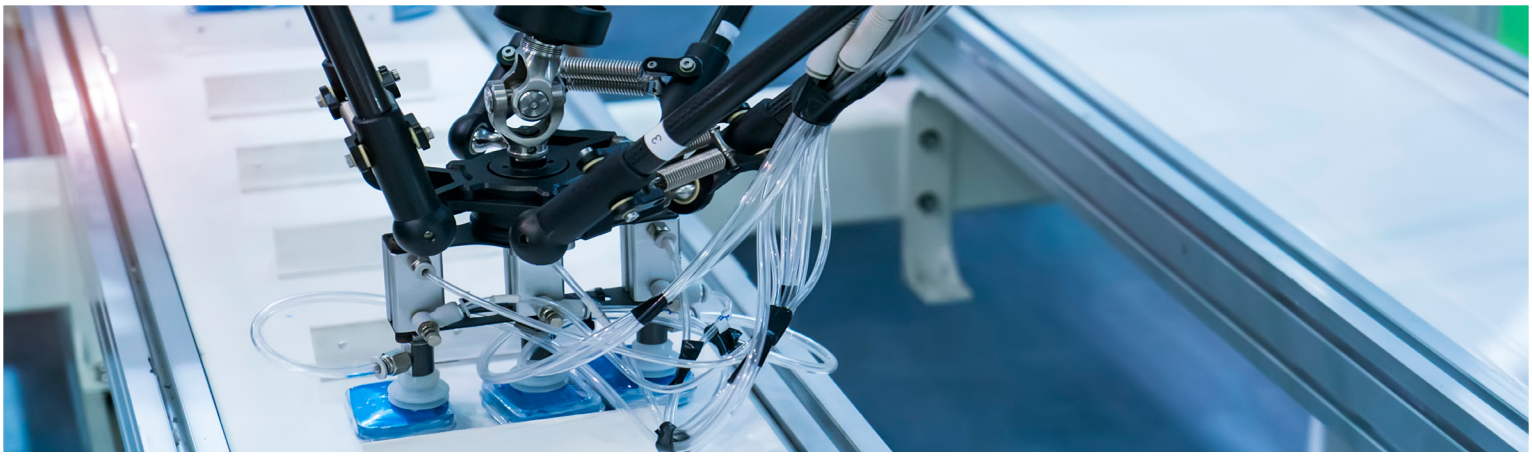

Medical Device and Technology

Your QMS supports your global operations and we are prepared to support you

Our FDA compliance team has received ISO 13485 auditor certification

Satisfying ISO 13485[1] is important for U.S. and international medical device firms. Companies selling in the EU must operate their quality management systems (QMS) in compliance with applicable QMS requirements laid down in the relevant Medical Device Directives or the new Medical Device Regulations (EU MDR and EU IVDR) through meeting the requirements of ISO 13485. Companies selling in the United States must still comply with 21 C.F.R. Part 820, the Quality Systems Regulation (QSR), but the U.S. Food and Drug Administration (FDA) has indicated an intention to move toward harmonization with ISO 13485 as the compliance standard of choice. Additionally, FDA has joined Brazilian, Canadian, Australian, and Japanese regulators in participating in—and in some geographies mandating—audits conducted through the Medical Device Single Audit Program (MDSAP).

Our medical device lawyers and regulatory science professionals have extensive experience in designing and implementing robust quality management systems for medical device manufacturers. With our deep bench and extensive knowledge of your industry and regulators, we are uniquely positioned to help your company refine existing systems to align with evolving regulatory obligations while supporting your growing operations. We have helped hundreds of clients prepare for both domestic and international inspections, supported them during those inspections, and advised them on taking appropriate corrective and preventive action. All of this means that we can help you in these business critical areas: (1) implementing a QMS that is designed to improve your products and processes; (2) recognizing opportunities for improvement; and (3) taking remedial action to mitigate the potential for findings during a regulatory audit. We also regularly represent clients before regulators and notified bodies to find workable solutions to complex health, safety, quality, and regulatory matters.

Our experience and training puts us in a unique position to assist our clients with the challenges that face medical device companies of all sizes around the globe. Our team of compliance lawyers and regulatory science professionals has over 100 years combined experience working with medical device companies. To complement our extensive real-world, practical experience, our team of compliance lawyers has received ISO 13485 auditor certification and enhanced MDSAP training. We understand how the international standard and QSR interact, and we can help you plan and manage for the interplay of the two because we know you operate only one QMS.

“The firm is notable for its all-encompassing regulatory practice, for which it receives top rankings across the board”

— *LMG Life Sciences*, 2018

1 ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

Hogan Lovells

Members of our team reside in the United States and Brussels, and understand medical device businesses and the priorities and initiatives of U.S. and EU regulators. In other critical geographies, we have lawyers ready to assist who have developed relationships with in-country legal counsel to help in the global markets where you operate.

Representative experience

- Conducted numerous QMS (QSR and ISO 13485) audits both domestically and internationally to help companies make their processes more robust and to prepare them for inspections by regulators and audits by notified bodies.
- Assisted numerous companies in taking remedial actions related to FDA Warning Letters and 483 Notices of Observation, including situations that were considered by FDA to be of high public health importance.
- Assisted clients in preparing robust 483 responses following inspections with significant findings for which FDA noted the strength of the response was instrumental in the agency's decision not to issue a Wanting Letter.
- Evaluated quality systems and identified strategic opportunities to make improvements in advance of expected inspections.
- Assisted various medical device clients in addressing the quality management system non-conformities identified by their notified bodies.
- Prepared and built out a quality system tailored to the needs of a client entering the medical device space for the first time.
- Attended numerous foreign inspections to help facilitate communication between our client and FDA and assist the client in managing the inspection.
- Conducted third-party audits to certify to the FDA that our client had taken the necessary corrective actions to address FDA's inspectional observations.
- Helped a company develop and monitor a corrective action plan designed to address systemic issues with the client's quality systems.
- Prepared and supported an international client, by drafting their PMA manufacturing section and supporting them on site through their PMA inspection for their first product, resulting in no observations.
- Drafted and negotiated numerous quality agreements, supply agreements and contract manufacturing agreements focusing on quality and regulatory issues.

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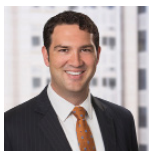

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