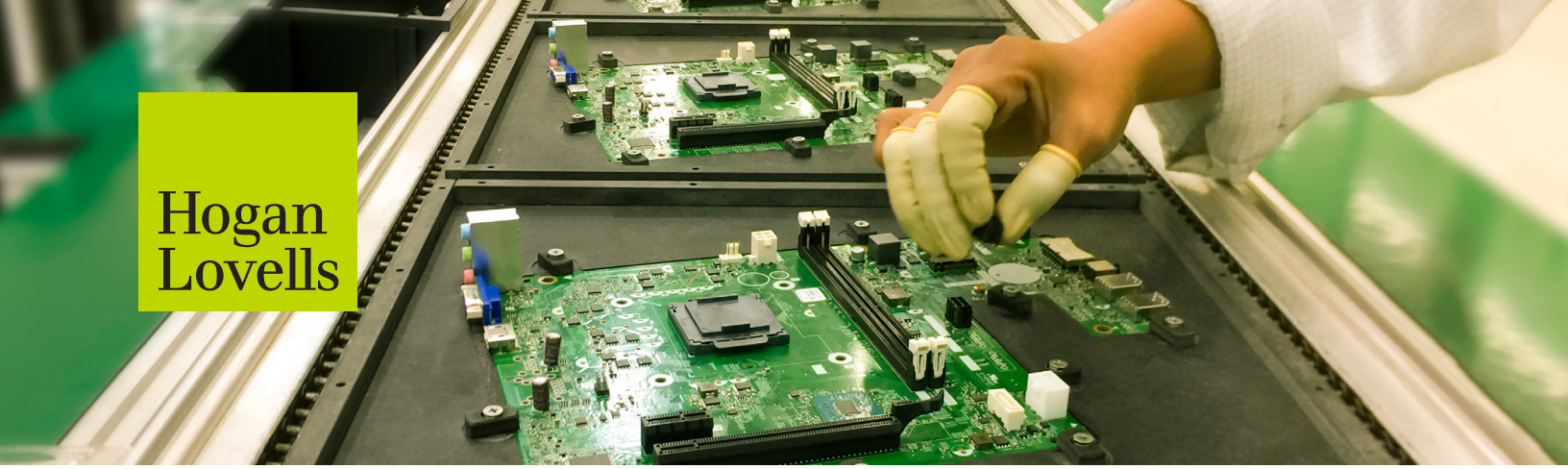

Hogan Lovells

Medical Device and Technology

QMS eAudits and remote inspections

The global spread of COVID-19 has resulted in the imposition of quarantine orders and travel restrictions that are affecting the ability of the U.S. Food and Drug Administration (FDA), notified bodies and MDSAP Auditing Organization to perform on-site audits. Further, limitations on personnel and staffing are creating challenges to completing scheduled internal audits or preparing for preapproval or postmarket surveillance inspections.

In an era where adaptability, flexibility, and creative use of technology have been crucial to ongoing business operations, the regulators and notified bodies are similarly finding ways to continue to perform their work; so too must the medical device industry.[1]

The requirements under the U.S. *Quality System Regulation* (21 CFR Part 820), and the quality management system requirements in the Medical Device Directives and ISO 13485 *Medical devices — Quality management systems — Requirements for Regulatory Purposes to conduct annual internal Quality Audits* continue to be in effect as we are not aware of any broad waivers. As such, companies need to evaluate alternative ways to perform internal audits, not only to satisfy the annual audit requirements, but to also ensure that your Quality Management System is ready for the next inspection or audit — whether it happens virtually or in person. Perhaps even most importantly, continuing to perform internal audits provide the necessary data for management to monitor the health of your quality system and ensure ongoing effectiveness.

Hogan Lovells can help. Our Medical Device and Technology Compliance team has received ISO 13485 auditor certification and has developed a plan for conducting remote Quality System Audits of most elements of your Quality Management System. We are able to use numerous platforms, including Web-Ex, Zoom, Skype, Google Meet and others. We also can utilize secure file transfers to ensure confidentiality and data protection.

Why use a law firm to satisfy your auditing needs? Our medical device practice started with the 1976 Medical Device Amendments. We were practicing in the medical device space when the U.S. *Quality System Regulation* requirements were implemented. Collectively, our U.S./EU team has hundreds of years of experience helping companies prepare for and defend audits/inspections and, when needed, respond to the government and notified bodies strategically. Our Medical Device and Technology Compliance team has depth and experience in the issues that are unique to medical device manufacturers and we've seen and evaluated hundreds of quality systems. Because of this experience, we are able to exercise the type of judgment that comes with experience and help you improve and protect your quality system. We also work very closely with our premarket submission teams to ensure that companies are appropriately addressing regulatory and quality issues throughout the total product life cycle.

Below is a proposed sample agenda for a QMS audit, but we certainly have flexibility to adapt the agenda so that we satisfy your audit needs. If you need more or less or to adjust the focus, we can do that. We will work with you to develop a plan and schedule that works for you.

We would be delighted to help you complete your internal audits.

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1. On March 10, and 18, 2020, FDA announced that it was postponing most foreign facility inspections and domestic routine surveillance facility inspections, respectively. In a May 11, 2020 Update, the agency explained that it will continue to utilize and implement additional alternative inspection tools and approaches while postponing domestic and foreign routine surveillance inspections.

On March 24, 2020, a transmittal issued by the MDSAP Assessment Program Managers proposed interim extraordinary measures to address the challenges posed by COVID-19 quarantine orders and travel restrictions that allowed for eAudits and Virtual Audits.

In April 2020, the Medical Device Coordination Group (MDCG) issued a new guidance (MDCG 2020-4) on temporary extraordinary measures related to medical device notified body audits during COVID-19 quarantine orders and travel restrictions. In the Guidance, the MDCG provides that, for certain audits, notified bodies may introduce temporary alternative extraordinary measures in place of on-site conformity assessment audits that have been impacted by COVID-19 restrictions.

Sample agenda

Day 1
Introductory Meeting • Introductions and Objectives • Company Presentation • Organization and Responsibilities (Organization Chart) • Overview of Production Flow (including responsibilities of key subcontractors/contract manufacturers) • Quality Manual
• Management Responsibility • Quality Audits • Personnel/Training
• Design Controls, including design transfer to any key subcontractors/contract manufacturers that are used in the manufacture of the finished device
Day 2
• Purchasing Controls and Acceptance Activities, including acceptance of product from any key subcontractors/ contract manufacturers that are used in the manufacture of the finished device
• Corrective and Preventive Action (CAPA), including review of findings/observations from prior third party audits/inspections
Day 3
• Nonconforming Product and Rework • Customer Complaint Handling • Medical Device Reporting/Vigilance • Recalls (Corrections and Removals)
• Aspects of Production and Process Controls, including process validation and inspection, measuring, and test equipment • Depending on capability, virtual tours of the manufacturing facility may allow for other aspects of production and process controls to be covered
Day 4
• Document Controls • Final Release of Product • Device History Record Review • Device Master Record • Unique Device Identification
Close out meeting

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[See our Medical Device and Technology team.]