GE HealthCare

Product safety, quality, and regulatory compliance

Patient-centered innovation grounded in rigorous standards for safety, quality, and governance

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Our commitment

At GE HealthCare, we are committed to delivering innovative products, solutions and services that prioritize patient safety and clinical effectiveness. Our approach to quality excellence is guided by the GE HealthCare Quality Policy, which defines clear expectations for patient safety, regulatory compliance, and continuous improvement.

This commitment is executed through a global framework comprising one Quality Management System (QMS) for Medical Devices and one QMS for Drugs, each designed to meet regulatory requirements across approximately 160 countries. Together, these QMSs enable consistent global compliance and support the safe and reliable performance of our technologies and products for healthcare providers and the patients they serve.

Across our business, we foster a culture of accountability, collaboration and continuous learning to advance product safety and quality throughout the product lifecycle.

Delivering safe, high-quality products is central to our social responsibility and long-term sustainability. By prioritizing patient safety, regulatory compliance and continuous improvement throughout the product lifecycle, we strengthen trust in our technologies and support enduring value for healthcare systems, communities and investors.

Governance

The GE HealthCare Board of Directors oversees the safety and quality of our products and services through its Nominating and Governance Committee. The Committee and full Board receive regular updates on quality management performance, regulatory developments and significant quality matters.

Management accountability is reinforced through a global quality structure with dedicated quality and regulatory leaders embedded within each business segment and region. These leaders report to the Chief Quality and Regulatory Officer, a member of the Executive Leadership Team. This governance framework supports consistent implementation of the QMS processes and procedures across the enterprise and ensures leadership visibility into quality priorities, regulatory risks and continuous improvement initiatives.

External certifications

All global sites within the scope of our QMSs – one for Medical Devices and one for Drugs – are certified to applicable global quality standards, such as ISO 13485 and/or ISO 9001 and/or operate in alignment with internationally recognized current Good Manufacturing Practices and current Good Clinical Practices, as applicable.

Quality Management Systems

Our QMSs incorporate internationally recognized standards and regulatory frameworks. These include but are not limited to:

- ISO 13485 and/or ISO 9001
- U.S. FDA 21 CFR Parts 820 and 211
- National Medical Products Administration Decree 739
- European Union Medical Device Regulation
- EudraLex Volume 4 Good Manufacturing Practice
- Applicable Health Authority requirements worldwide

The QMSs establish governance, processes, and controls to guide the development, manufacture, distribution, servicing, and monitoring of our products. This includes regular quality management reviews across sites and regions for oversight of patient safety and quality matters. These reviews are conducted with senior leadership and help:

- Evaluate QMS effectiveness
- Highlight continuous improvement opportunities
- Support escalations to the Board, when appropriate.

Regular quality audits at GE HealthCare facilities play a central role in confirming our adherence to applicable requirements and identifying opportunities for continuous improvement. Insights from these audits, paired with ongoing regulatory intelligence, help us support patient safety and quality compliance and enhance operational efficiency.

Quality management training

Colleagues receive structured training to support consistent execution of our Medical Device and Drug QMSs. All colleagues complete foundational training upon hire and participate in annual refresher training. Programs emphasize:

- The impact of individual responsibilities on patient safety and product quality
- Regulatory expectations across markets
- Documentation, compliance and risk awareness

Role-specific training provides deeper technical and regulatory knowledge aligned with individual responsibilities.

In addition, The Spirit & The Letter, our Code of Ethics and Integrity, empowers colleagues to stop work and raise concerns if a potential issue could compromise patient safety, quality or regulatory compliance. Daily management practices reinforce readiness and encourage teams to prioritize safety and quality before beginning work.

Working with suppliers

A resilient, high-performing supply chain is essential to product quality and regulatory compliance. Our QMSs include risk-based purchasing controls governing supplier qualification, change management and ongoing performance monitoring.

Using defined performance indicators and risk assessments, we evaluate supplier criticality, scope of work and quality performance. Through audits, capability assessments and continuous engagement, we collaborate with suppliers to maintain compliance, enhance operational performance and drive improvement across the value chain.

Continuous improvement

Continuous improvement is integral to our approach to delivering safe and reliable products. Our post-market surveillance systems integrate:

- Product tracking
- Complaint handling
- Adverse event reporting
- Pharmacovigilance
- Literature review
- Customer feedback
- Facility registration and inspection readiness

We systematically evaluate post-market data to identify early indicators of potential patient safety or product quality risks. When trends or signals emerge, we apply structured problem-solving methodologies through our Corrective and Preventive Action process.

Some examples of inputs include, but are not limited to, customer feedback, production and service data, internal assessments and external literature. Actions may include design modifications, process improvements, enhanced training, or field actions such as product corrections or recalls, based on risk assessments informed by our comprehensive risk management framework.

More information about our commitment to patient safety, quality and regulatory compliance is available in our Sustainability Report.

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