



Quality Assurance & Regulatory Affairs in **MedTech**

Foreword

QARA as a Strategic Lever in MedTech Innovation

Quality Assurance and Regulatory Affairs (QARA) have evolved from compliance checklists to strategic business drivers that affect MedTech profitability and competitive standing. Advanced QARA programs yield quantifiable returns on investment while moderating significant operational risk.

Incorporation of intelligent QARA functions throughout the product life cycle can make it possible to achieve quicker rollout and higher capacity for manufacturing through more responsive operations. These benefits are especially valuable since quality expenses in MedTech generally form a substantial portion of total revenue.

At the same time, the economic cost of poor quality management is equally persuasive. Organizations invest billions each year in quality assurance but lose twice that in issues surrounding poor quality control. Being able to meet quality and regulatory standards consistently without slowing down organizational agility is a competitive edge, with regulatory non-compliance costs escalating worldwide.

With AI-enabled optimization, insights and efficiencies, QARA experts improve product quality and patient safety while operating within cost constraints. These solutions avoid duplicative work and bring value across whole organizations rather than focusing on individual compliance pillars. This is where LTTS' Engineering Intelligence approach, representing the convergence of AI and engineering across Engineering AI, Agentic AI, Physical AI, and Industrial AI, makes its mark.

QARA departments should now be incorporated early in product development processes to navigate emerging challenges and ensure compliance with evolving international standards, transforming quality and regulatory functions into gateways for market access instead of barriers to entry.

Market Inflection Points

Regulatory Tightening

In the past few years, there has been a remarkable surge in the regulatory developments in the MedTech industry. With over 15 landmark regulations, more than 60 major guidelines around 100 technical amendments and at least 20 global and regional harmonization alignments, the requirements for medical device producers have evolved significantly.¹

The implementation of the MDR and IVDR will cause the manufacturers in the European Union to face increased regulatory burden and cost as compared to the previously applicable MDD. Manufacturers are now looking elsewhere to launch their devices as a result of the cumbersome regulatory compliance consuming substantial resources.

The UK presents an additional challenge for manufacturers post-Brexit. Those that want to access both the EU and UK markets are required to comply not only with the MDR but also with various UK regulations.

In order to identify the ideal pathways to regulatory approval in different markets, OEMs need to develop a comprehensive regulatory strategy covering all requirements and scenarios applicable to their product. Additionally, companies require knowledge on how to work with multiple stakeholders, including Notified Bodies in the EU and the FDA in the US, as well as other National Regulatory Agencies. Technical expertise is also necessary to take care of the growing scope of documentation in order to avoid costly errors and recalls.

Digital Acceleration

Forward-looking MedTech companies that have already integrated digital tools into their processes are now seeing these technologies come of age in many disruptive categories, including dynamic data analytics, AI, automation, precision engagement and orchestrated systems. The tangible benefits of digital acceleration have been evident in cost savings, enhanced operational efficiencies and improved stakeholder engagement.

Another innovation is the digital twin, which is potentially enabling MedTech companies to develop sustainable competitive advantage through accelerated time-to-market, improved product quality and safety and cost efficiency. McKinsey has shown that real-world applications of this technology already reduced time-to-market by 20 to 50% along with a 75% reduction in clinical trial costs.²

In order to drive a digital culture across every level of the organization, legacy businesses need to significantly redefine themselves or risk falling behind in a race that is already well underway.

Trade Uncertainties

The MedTech industry is highly integrated across the globe, with complex supply chains spanning many countries at times. Given this heavy reliance on global trade, the 'reciprocal tariffs' announced by the US government on several countries stand to disrupt global partnerships years or decades in the making. The short-term impact on MedTech manufacturers has been drastic.

In the long run, however, new trade partnerships are expected to evolve as global supply chains undergo major shifts. The number of bilateral trade deals also opens up new opportunities for exporters, while some manufacturers are focusing inwards on domestic markets. This means that OEMs need to keep track of evolving trade regulations and regulatory requirements of new markets for feasible pivots.

Cybersecurity

With the digital transformation of MedTech, the risk of cybersecurity threats impacts not only the medical products and healthcare infrastructure but also the health and well-being of the patients. It has become imperative, therefore, that robust security measures be integrated throughout the product lifecycle.

MedTech organizations first need to identify and address software vulnerabilities and review security controls using tools such as vulnerability scanning, malware scanning and static code analysis. As cyberattacks become more and more sophisticated, security measures must constantly evolve to remain one step ahead.

LTTS experts understand the intricacies of a wide range of cybersecurity issues in the context of MedTech. Our proven and robust framework ensures security deployment across each stage of the security development lifecycle while complying with all the regulatory standards mandated by the FDA, HIPAA, ARRA, PPACA and HL7.

LTTS' QARA-led Transformation Impact across Global MedTech Clients

LTTS' QARA solutions have transformed the medical device industry through end-to-end compliance solutions ranging from regulatory filings to quality management systems and post-market monitoring.

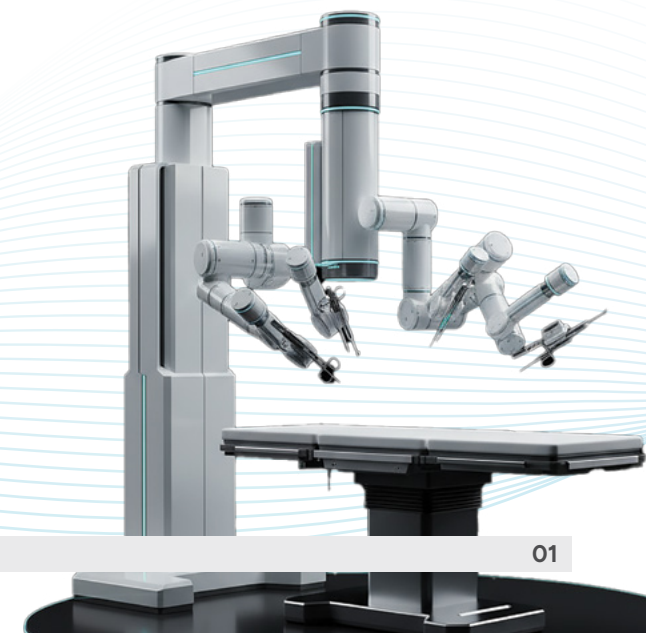
LTTS has formed strong partnerships with MedTech device manufacturers worldwide, providing comprehensive solutions ranging from design history file (DHF) remediation to regulatory compliance in multiple geographies. The QARA capability of the Company ranges from country-specific standard assessment through regulatory submissions, clinical evaluation, biocompatibility testing and full post-market support, including complaints management and CAPA remediation.

With more than 30 years of domain knowledge, LTTS has helped clients with predictive planning across the product lifecycle, helped reduce time-to-market, mitigated the risk of non-compliance and maximized approval processes while lowering costs. These outcomes are the direct expression of LTTS' EI approach — embedding AI across the entire engineering lifecycle instead of as an afterthought. In the QARA context, EI translates into combining more than three decades of medical-device domain expertise with GenAI, agentic and predictive capabilities, so that quality and regulatory intelligence is designed into the product from concept through post-market surveillance.

It is this fusion of engineering depth and applied intelligence, and not compliance tooling alone, that allows LTTS to convert QARA from a cost of doing business into a measurable source of speed, assurance and competitive advantage for medical device makers.

¹<https://www.iqvia.com/blogs/2025/05/the-future-of-medtech-compliance>

²<https://www.mckinsey.com/~media/mckinsey/business%20functions/operations/our%20insights/accelerating%20innovation%20the%20potential%20of%20digital%20twins%20in%20medtech%20r%20and%20d/accelerating-innovation-the-potential-of-digital-twins-in-medtech-r-and-d.pdf>



Introduction

The MedTech Moment & the QARA Imperative

In recent years, the global MedTech industry has expanded at an annual pace of at least 4%, supported by rapid technological innovation and increasing adoption of wearables. At the same time, minimally invasive therapies have gained widespread acceptance as healthcare providers and patients seek treatments that shorten recovery times and reduce procedural risks.

In the contemporary MedTech ecosystem, companies need to navigate a complex matrix of quality and regulatory requirements that encompasses every phase of a product's lifecycle. Patient safety is expected to be 'designed in' and not added on later. As products progress towards commercialization, companies must have strong, auditable quality management systems that govern everything from qualification of suppliers to change-control processes and prepare detailed technical documentation for worldwide submissions.

As the regulatory environment evolves, MedTech companies must align quality systems with agile development and continuous-monitoring requirements. The EU's Artificial Intelligence Act (effective 2024) categorizes AI elements of medical devices as 'high-risk' systems, requiring manufacturers to install strict risk management, transparency, human oversight, data governance measures in addition to existing conformity tests.

The UK Post-Market Surveillance Regulations require all UKCA- or CE-marked devices sold in Great Britain to enable active post-market surveillance. The Indian Medical Devices Rules seek to rationalize device testing and build local regulatory capability. The result of regulatory progress and recent technological advancements is expected to be safer, more effective innovations coming to market more rapidly while maintaining the highest standards of patient safety and regulatory compliance.

The MedTech Moment and the QARA Imperative

An Overview of QARA

Quality Assurance and Regulatory Affairs (QARA) is an integrated organizational function that combines two important disciplines of QA and RA. While Quality Assurance is a formal process aimed at preventing defects and ensuring that products or services comply with agreed requirements and standards, Regulatory Affairs is concerned with making products adhere to all legal and technical standards for sale and application.

Although QA and RA responsibilities have their own set of synergies, both domains involve distinct expertise and present their own set of challenges. The essential difference between Quality Assurance and Regulatory Affairs is their orientation and scope. QA is inwardly directed at avoiding quality issues through systematic process control, whereas RA is outwardly directed at avoiding regulatory noncompliance and obtaining market clearances. QA inquires, 'How do we make it right?' whereas RA inquires, 'How do we make it legal?' Both roles play a critical role in delivering safe and effective products to the market and proper coordination between them is critical for organisational success in regulated markets.

Understanding these differences allows organizations to effectively organize their quality and regulatory operations, such that they can provide sufficient resources and expertise to both critical domains. As the regulatory landscape grows more complex and global in nature, cooperation between QA and RA professionals becomes increasingly crucial to sustaining product quality, upholding patient safety and meeting business goals.

From Reactive Compliance to Strategic QARA as a Value Enabler

LTTS digital engineering optimizes medical product timelines and development costs by 20-30%.

Conventional View

Traditionally, quality has been regarded as a cost center. The cost of quality can be categorized as good or bad. The cost of good quality comprises the cost incurred on testing a new product or implementation of additional control measures in manufacturing. The cost of bad quality encompasses costs incurred due to product deviations, including mitigation of lower yield, scrap, or recall.

Contemporary View

The contemporary view of quality depicts it as a growth enabler. Quality is seen not merely as an insurance policy but as an investment to drive future yield. The aim is to nurture a quality culture where every functional unit takes accountability for quality control. A deeply imbibed quality culture greatly reinforces the possibility of detecting issues on the frontline.

The modern view of quality highlights the role of quality in enhancing the operational efficiency as well as the brand reputation of the organization. In the United States, quality is now regarded as an anticipatory, scientifically driven process that spans the entire product lifecycle. Similarly, the European Union's Better Regulation framework uses rigorous impact assessments, public consultations and regular fitness checks to ensure rules are evidence-based, proportionate, transparent and actively designed to facilitate innovation instead of hindering it.

In order to understand the journey from the traditional view of QARA to the modern view, let us delve into the history of 'quality' in the following section.

Evolution of Quality Assurance

Quality and regulatory assurance in MedTech has evolved from basic end-of-line inspections to end-to-end, risk-based systems controlling product design, production and post-market performance.

In the Middle Ages, European guilds upheld craftsmanship standards by examining goods and marking them with the seal of the craftsman. With the advent of the Industrial Revolution in the middle of the 18th century, Frederick W. Taylor advocated for factory inspection departments, which systematically inspected goods before shipping to detect flaws. During World War II, the US military used Walter Shewhart's statistical control charts and sampling plans (Mil-Std-105) to certify mass production to stringent standards.

Following the war, Japan revolutionized quality by adopting Total Quality Management (TQM). Companies focused on customer satisfaction and continuous improvement under the guidance of W. Edwards Deming and Joseph Juran. The Malcolm Baldrige National Quality Award and the first ISO 9000 standard codified excellence across sectors in the late 1980s.

Drugs and devices subsequently brought formal Good Manufacturing Practice (GMP) and Quality System Regulations (QSR). ISO 13485 appeared in 1996 to specifically adapt ISO 9001 processes to medical products, focusing on design controls, sterility and post-market monitoring. In 2016, its revision enhanced risk management, supplier control and harmony with changing regulations in Europe and the U.S.

The QA and RA activities of today have the shared mandate of patient safety and compliance but are slightly divided in purpose. QA integrates process controls, including document control, supplier qualification, CAPA and audits across the product life cycle under regulations such as ISO 13485 and 21 CFR 820. RA plans regulatory routes, prepares submissions (510(k), PMA, CE dossiers) and manages agency relationships to obtain and maintain market approvals.

As MedTech goes digital in health, with AI-based software and sustainability requirements, QA and RA functions are becoming increasingly overlapping. QA is now responsible for software lifecycle validation and cybersecurity, whereas RA incorporates real-world evidence into submissions and deals with intricate worldwide regulations. They become part of one cohesive QARA system to support innovation, safety and public confidence in contemporary medical technology. We discuss the convergence of QARA and EI in a later chapter.

Chapter 1

Adapting QARA to Today's Realities



MedTech firms have the potential to unlock up to \$105 billion in annual value through productivity gains and innovations in products and services.³

In the introductory chapter, we witnessed the evolution of QARA's perception—from being regarded as the traditional 'cost center' to being recognized as the modern 'value enabler.' In this chapter, we shall dive deeper into how QARA frameworks face the need to transform in view of the contemporary challenges and opportunities to drive value for MedTech organizations.

Why MedTech firms must rethink QARA amid SaMD, AI/ML and sustainability mandates?

With the rapid rate of technological advancement, enhanced regulatory scrutiny and expanding stakeholder expectations, patient safety in complex technologies depends on continuous risk management that addresses data bias, cybersecurity threats and algorithm drift. As MedTech embraces AI, digital health and sustainability, QARA must evolve into a strategic facilitator by leveraging digital platforms, cross-functional expertise and real-time analytics to meet requirements as a value driver for MedTech companies and pave the way for more user-friendly medical devices that improve the quality of life for patients.

QARA and SaMD

The rapid proliferation of Software as a Medical Device (SaMD) represents a fundamental paradigm shift that demands comprehensive recalibration of Quality Assurance and Regulatory Affairs (QARA) frameworks. SaMD is now a critical area of medical technology, supported by improvements in artificial intelligence, real-world data and digital health integrations. SaMD data released recently indicates that it represents about 70% of AI/ML-supported 510(k) clearances within the last five years⁴, emphasizing the increasing role of software in diagnostics, decision support and disease-management technologies. Radiology is at the forefront, with cardiology, neurology and remote patient monitoring immediately following. SaMD's diverse growth demonstrates the flexibility of software across clinical specialties.

The growth has encouraged regulators to release custom guidance. The US-Food and Drug Administration (US-FDA) has taken the initiative with AI/ML-based SaMD Action Plan (2021), bringing in Predetermined Change Control Plans, Good Machine Learning Practice and Real-World Performance monitoring to facilitate safe, transparent algorithm development. The International Electrotechnical Commission is planning to integrate AI concepts in the forthcoming editions of IEC 62304 standards for medical device software. Similarly, the International Medical Device Regulators Forum (IMDRF) has a dedicated AI/ML Working Group with an aim to harmonize international principles for the development of safe and effective AI/ML enabled medical device, in alignment with the Good Machine Learning Practice (GMLP). This can be summarized as primary drivers that directly address the patient safety and device effectiveness. Secondary drivers enable support, compliance and integration while tertiary drivers are based on harmonization, market realities and adaptability to technological advancements. Below are few examples of regulatory framework to achieve global compliance-

Regulatory Drivers

- FDA's AI/ML-Based SaMD Action Plan, introduced in 2021, recommends a Predetermined Change Control Plan (PCCP) comprising 'SaMD Pre-Specifications' and 'Algorithm Change Protocol' to govern anticipated model updates under total product-lifecycle oversight.

³<https://www.mckinsey.com/industries/life-sciences/our-insights/scaling-gen-ai-in-the-medtech-industry>

⁴<https://www.bcg.com/publications/2025/ai-and-machine-learning-stake-claim-on-MedTech>

- Article 1.4 under Annex VIII of the EU In Vitro Diagnostic Regulation (IVDR) 2017/746 extends definition of medical device to stand-alone software. This requires SaMD to comply with ISO 13485 QMS and Unique Device Identification (UDI) (Article 6.2.1).
- Task 12 of the Medical Device Single Audit Program (MDSAP) mandates the medical device software to be included in the design and development plan and its life cycle requirements and intended use to be defined.
- EU GMP Ch. 1 requires a state of control maintained by effective monitoring systems and continual improvement loops. Real World Performance (RWP) metrics mandated by FDA Action Plan translate this into dashboard-level surveillance for SaMD by defining reference data, performance thresholds and automated signal detection. The Agency will collaborate with volunteering stakeholders to support the piloting of real-world performance monitoring.
- The Action Plan also requires clear labelling of training-data characteristics, algorithm logic and performance evidence to be provided in device instructions for use in order to facilitate patient-centered transparency.
- FDA's updated cybersecurity guidance of 2025 governs SaMD innovation to focus on design security, continuous risk monitoring, vulnerability management to threats, thereby creating safer and robust medical software.
- Article 56.3 of the EU IVDR requires SaMD clinical evaluation to have three validation components, namely valid clinical association, analytical validation and clinical validation, to be audited as part of QARA technical files.
- Under Annex III, Article 3.1 of the EU IVDR mandates design information to include an overview of the entire system including a description of the algorithm used in the case of software.
- Article 16.1 under Annex I requires SaMD to function with reliability and consistency in line with its intended use. A single fault condition requires remedial action to be taken to eliminate or mitigate deviations as far as possible.
- According to Task 13 of the MDSAP, auditors will sample PCCPs, algorithm-change records and software-validation dossiers to verify QMS conformity across ISO 13485, FDA QSR and IVDR requirements.

SaMD compels MedTech vendors to take QARA from a device-oriented discipline to a software-lifecycle discipline regulated by ISO 13485, EU GMP, MDSAP and FDA AI/ML-specific guidance. Incorporating these formal software, data-integrity and change-control mandates into each

clause of the QMS is now a requirement for market entry and sustaining the public-trust dividend offered by digital health. Failure to re-calibrate will come quickly to the surface under the audit eyes of regulators, such as the combined MDSAP or by the FDA's PCCP guideline, leaving companies to face certification revocation and recall risk.

IEC 62304 Medical device software life cycle process



ISO 13485 Medical Devices-Quality Management Systems



ISO 14971 Application of Risk management for Medical devices



When LTTS was onboarded by a customer to ensure compliance across their entire range of Remote Progress Monitoring (RPM) and Clinical trial products, we faced the challenge of delivering support for the development of DHF files across multiple standards, including:

Our team of experts delivered QMS templates in line with regulatory requirements across the entire line of products for use in multiple geographies. Additionally, the team delivered:

- Validation across each phase of the software development life cycle with respect to relevant requirements, standards, norms and guidelines,
- Integration of risk analysis and DHF remediation from the design input planning to the aftermarket phase
- Evidence-based product checklists with gap analyses within the software architecture documentation, clearly describing boundaries and limitations, isolation and integration elements, as well as interactions with other components, including potential risks tied to their respective classes.
- Conduction of peer-reviewed change management (ECR/ECO), requirements analysis, risk/hazard analysis, verification and validation and implementation of a traceability matrix at each stage of the device lifecycle.
- End-to-end regulatory documentation support for Software as a Medical Device (SaMD), tailored to the device class and product requirements, and compliant with applicable standards and regulations (including ISO 13485:2016, ISO 14971, IEC 62304:2006, IEC 62366:2015, etc.).

Consequently, the customer was able to reduce the time spent on regulatory approvals for product deployment by 60% and streamline future regulatory requisites by leveraging their improved documentation procedures.

QARA and AI/ML

Impact of AI and ML on MedTech

AI and ML are altering medical devices by discovering valuable information in huge volumes of health data that we all create every day. Device manufacturers employ this technology to develop innovative products, which assist healthcare professionals and result in improved patient care. The strongest aspect of this technology is its capacity for learning from real-world experience, progressively enhancing its own performance over a period of time.

⁵<https://web-assets.bcg.com/pdf-src/prod-live/MedTech-can-improve-quality-regulatory-processes-gen-ai.pdf>

⁶Large Language Models are AI systems trained to understand and generate human language by processing vast amounts of text data. RAG (Retrieval-Augmented Generation) is a technique that enhances Large Language Models (LLMs) by integrating them with external knowledge sources.

⁷Markey, Nigel & El-Mansouri, Ilyass & Rensonnet, Gaetan & Langen, Casper & Meier, Christoph. (2025). From RAGs to riches: Utilizing large language models to write documents for clinical trials. Clinical Trials. 10.1177/17407745251320806.

The MedTech industry stands at an inflection point where traditional Quality Assurance and Regulatory Affairs (QARA) approaches are becoming increasingly obsolete in the face of AI/ML integration.

Current Landscape

The MedTech industry stands at an inflection point where traditional approaches are giving way to Engineering Intelligence-led QARA.

The resolution is not less technology but better-directed technology. This is the premise of Engineering Intelligence: applying domain-trained AI across design, validation, submission and surveillance so that QARA keeps pace with the very algorithms it must govern. Where conventional processes struggle to manage predetermined change control, real-world performance monitoring and continuous algorithm updates, an EI-led approach treats these as engineering problems — instrumented, modelled and automated — rather than as manual documentation burdens. It is precisely this gap that leaves only one in ten MedTech companies able to create value from generative AI today, and precisely the gap EI is built to close.⁵ AI-driven documentation has demonstrated increased efficiencies since the adoption of generative AIs. Although human supervision is still required, AI models (RAG-enabled LLMs) are able to reduce the time taken for end-to-end document creation for clinical trials by 25-50%.⁷

AI has also accelerated and increased the accuracy of documentation related to changes in technical filings during the product's lifecycle due to product updates or changes in the regulatory environment. By consolidating inputs from different departments, AI has facilitated cross-functional collaboration, thereby enhancing employee experience. QARA systems need to evolve to bridge the gap between traditional and modern approaches, integrating AI across QMS processes, unlocking operational efficiencies. By keeping Human-in-the-loop (HITL), that is, combining AI systems with human review, experts can step in to guide and correct the AI, especially in the case of complex or sensitive tasks, such as those common in human healthcare, where mistakes can have severe consequences.

AI systems are, however, not without their shortcomings. There are over 20 different known data biases, which have found their way into AI algorithms too. This makes the data validation process even more critical. During the Covid-19 pandemic, the pulse oximeter's incorrect readings on some skin colors highlighted the severe consequences of inadequate bias management.⁸ QARA experts are implementing and monitoring AI-integrated data management systems to minimize known biases and limit deviations to acceptable risks.

The European Union's AI Act has introduced unprecedented complexity for MedTech companies, requiring dual compliance with AI Act requirements and existing Medical Device Regulation (MDR)/In Vitro Diagnostic Medical Device Regulation (IVDR) frameworks. Many existing AI solutions integrated into medical technologies will qualify as high-risk AI systems under the AI Act, creating a complex regulatory landscape that demands sophisticated QARA capabilities. The challenge extends beyond simple compliance addition. Medical technology manufacturers must ensure that AI Act requirements do not contradict, misalign, or compromise existing MDR/IVDR requirements. This necessitates a unified approach to quality management systems that can simultaneously address both regulatory frameworks while maintaining operational efficiency.

In order to promote 'safe, effective, and high-quality' application of AI and ML enabled medical devices, the US FDA, Health Canada and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) have jointly identified 10 guiding principles for the development of Good Machine Learning Practice (GMLP).

QARA experts are implementing and monitoring AI-integrated data management systems to minimize known biases and limit deviations to acceptable risks.

Specific use case applications for AI/ML in QARA

Quality Management Applications:

-  Automated Medical, Legal, Regulatory (MLR) reviews with cross-referencing capabilities
-  Complaint handling and classification with pattern recognition
-  Quality document creation for SOPs and validation protocols
-  Deviation handling with automated root cause analysis
-  CAPA generation and effectiveness tracking

Regulatory Affairs Applications:

-  Technical documentation writing with regulatory standard compliance
-  Product manual drafting with multi-language translation capabilities
-  Regulatory intelligence monitoring with automated impact assessment
-  Submission preparation with template-based automation

Spotlight

QAssure.ai, LTTS' proprietary EI offering, automates QARA workflows through AI, streamlining documentation and monitoring—transforming compliance into a predictable, ROI-driven advantage.

QARA and Sustainability

QARA functions must evolve to imbibe environmental requirements across the device lifecycle, impacting design controls, risk management, documentation, supplier oversight, training, CAPA and post-market surveillance, meeting emerging sustainability regulations and procurement expectations.

Broadening Risk Management Framework to include Environmental and Social Risks

Historical QARA risk models (e.g., ISO 14971) were patient-centered, which need to be expanded to include environmental and social risks amidst the prevailing sustainability mandate. The EMA's 'Guideline on Environmental Risk Assessment of Medicinal Products for Human Use' defines the stepwise procedure, endpoints and reporting format for ERAs in marketing-authorization dossiers. By incorporating ERA requirements, QARA teams must expand traditional Common Technical Document (CTD) preparation and dossier writing processes to include environmental fate, ecotoxicity and risk mitigation measures in addition to patient-safety data.

Life-Cycle Emissions Risk

Organizations must measure and reduce greenhouse gas emissions for Scopes 1-3, working with suppliers and end-users to enhance activity-based information.

Circularity Hazards

Product and material designs must be evaluated for end-of-life effects, such as single-use plastic vs. bio-based drapes, minimizing waste without the loss of sterility.

Social-Value Risks

Work standards across the supply chains and fair-access considerations should be integrated into QARA risk analysis, in compliance with UN SDGs.⁹

CAPA systems must be expanded to record and investigate environmental nonconformities (e.g., failure in waste-handling procedures, packaging-recyclability lapses).

Circularity in Design Principles

MedTech generates considerable unrecycled waste owing to single-use disposable products and packaging. Medical device companies can make their products easier to recycle and use resources more efficiently by designing them with interchangeable parts, using materials that are easy to take apart and creating programs to take back old devices from customers.

⁸U.S. Food and Drug Administration, Center for Devices and Radiological Health (2024). Performance evaluation of pulse oximeters taking into consideration skin pigmentation, race and ethnicity: Executive summary.

⁹The Sustainable Development Goals (SDGs) were adopted by the UN in 2015 to alleviate global issues. SDG 13 calls for 'urgent action to combat climate change and its impacts.'

High-value instruments such as MRI machines and ultrasound equipment are being retrofitted and refurbished to extend their operational lives, reducing demand for new materials and lowering lifecycle environmental impact.

Sterile and Biocompatible Devices

Medical devices that have contact with the patient (direct or indirect) undergo sterilization to make them infection-free. Depending on the case, the sterilization methodologies can vary with Ethylene Oxide (EtO) sterilization being the most widely used sterilization technique for major medical devices.

Various health issues have often been associated with EtO sterilization, however, including a heightened risk of white blood cell cancers. These health concerns have driven international regulators to closely monitor the use of EtO sterilization while reducing dependency through alternatives.

The U.S. Environmental Protection Agency (EPA) has finalized rules that include an immediate ban on EtO for specific, non-essential uses, including museum and archival materials, cosmetics, musical instruments and beekeeping equipment. The new rules are aimed at limiting community exposure to EtO and ensuring worker protection by lowering exposure limits to EtO and requiring enhanced safety measures.

Next generation medical devices are also becoming increasingly biocompatible highlighting the industrial and regulatory commitment toward patient-centred healthcare. Besides being safer, these biocompatible devices use biodegradable materials which minimizes the environmental impact by reducing waste through easier disassembly and end-of-life processing of the devices.

Updating IFUs for Disposal/Recycling

EU MDR 2017/745 mandates that instructions for use (IFUs) describe validated, safe disposal or recycling pathways. QARA must revise technical files and IFUs to document post-use cleaning, decontamination and circular-design measures facilitating end-of-life processing. Most IFUs of single-use medical devices (SUDs) currently provide instructions for cleaning and recycling of batteries in the product, if present, but not for the actual device itself. This must be amended to allow for safe and validated cleaning of the whole product. Thus, the pathway must be reflected in the IFU for clarity on how to process the device for the hospitals and decontamination services. Annex I,

General Safety and Performance Requirements, Section 14.7 of Regulation (EU) 2017/745 requires that devices be 'designed and manufactured to facilitate their safe disposal and the safe disposal of any related waste substances by the user, patient or other person,' with 'identified and tested procedures and measures for disposal' described in the Instructions for Use. Section 23.4(v) requires the IFU to include those tested disposal procedures, including handling contaminated items and sharps.

Environmental Standards

Clause 4.4 (Environmental Management System) of the ISO 14001:2015 requires organizations to establish, implement, maintain and continually improve an EMS, including processes for procurement. The top management is required to maintain an environmental policy, which is consistent with the nature, scale and context of the organization according to clause 5.2. Clause 8.1 (Operational Control) expects organizations to implement, control and maintain the processes needed to meet environmental management system requirements as well as control outsourced processes that can have significant environmental aspects.

Spotlight

LTTS helps OEMs move beyond EtO with validated, ISO-compliant, future-ready sterilization solutions.

Similarly, ISO 50001:2018 focuses on the organization's energy management system and continual improvement of its energy performance. Clause 4.3 requires the establishment of an energy policy which shall guide the organization's commitment to achieving energy performance improvement through design and through purchase of energy-efficient products and services. The organization is required to establish objectives and targets consistent with the energy policy and define action plans to facilitate achievement of these targets.

Evolving Regulatory Landscape

QARA processes must align with evolving EU directives, including the Corporate Sustainability Reporting Directive (CSRD), the Eco-design for Sustainable Products Regulation, the EU Green Deal and national supply chain due-diligence laws (e.g., the German Lieferkettengesetz), ensuring unified technical documentation templates that satisfy both safety and environmental requirements.

Strategic Benefits

Medical technology companies face a big challenge in meeting their environmental and social goals. However, the initial investment is small and could even pay for itself over a period of time. Organizations can cut their emissions by 20% to 30%, which could save them money and reducing emissions by as much as 80% might not cost them anything in the long run.¹⁰ By embracing sustainability mandates, organizations can strengthen their reputation, while simultaneously attracting the finest talent.

Manufacturers of medical devices are becoming increasingly concerned with minimizing the environmental impact of their products. To facilitate this, there must be new regulations to mandate sustainable practices for the entire lifecycle of a device, from design through disposal.

Embracing such green strategies also has major payoffs. Businesses can find new sources of revenue, create a better brand reputation that brings them customers and investors and improve employee retention. They also gain more resilient supply chains and remain ahead of upcoming environmental regulations, while at the same time contributing considerably to the battle against climate change and ensuring global well-being.

Globally, 5% of total climate emissions come from the healthcare sector.¹¹

¹⁰<https://www.bcg.com/publications/2023/how-MedTech-ceos-can-meet-esg-goals>

¹¹<https://www.who.int/westernpacific/news/item/18-09-2025-up-to-5--of-climate-emissions-come-from-healthcare.-a-new-coalition-of-asia-pacific-countries--backed-by-who--plans-to-change-that>

Chapter 2

QARA's expanding scope: lifecycle integration, speed-to-market and digital-first frameworks



Spotlight



LTTS leverages Gen AI to automate the creation of technical documents, literature reviews, and clinical evaluations—reducing production time by up to 50%.

The adaptation imperatives discussed in the previous chapter have fundamentally expanded QARA's scope beyond traditional boundaries. Chapter 2 explores how this expansion manifests across the product lifecycle.

Lifecycle Integration

QARA functions are transitioning from discrete checkpoints to end-to-end, lifecycle disciplines, starting right from conception to the final product retirement. This is because the MedTech products of today, particularly SaMD, are highly advanced and constant vigilance is required to ensure safety, effectiveness and regulatory adherence at every level.

Starting early, QARA functions begin in the design phase when risk management and regulatory strategy are integrated along with engineering requirements. With the integration of quality and compliance objectives in product requirements, QARA teams facilitate design-for-compliance into device design. Quality Lifecycle Management (QLM) develops a systematic approach through all the stages of the value stream, such as planning, assurance, control and improvement activities from concept to disposal.

While products move into the market, QARA's function is also extended to encompass post-market surveillance and real-world performance monitoring. At this stage, RWP data like device usage patterns or software performance metrics are collected and analyzed by QARA teams to identify early safety signals and initiate swift CAPA or design

optimization. QMS platforms must be able to facilitate iterative software updates, thus enabling MedTech firms to launch improved versions and iteratively enhance the performance of products years after initial approval.

Finally, QARA has expanded further to include product retirement and environmental responsibility. End-of-life process planning for device take-back, recycling, or decommissioning software must be achieved in order to comply with more stringent sustainability regulations. By combining regulatory compliance, quality controls and environmental goals, QARA protects products from being withdrawn from the market safely and responsibly while maintaining patient confidence and company reputation.

With this end-to-end integration, QARA has moved from discrete quality checks to specially tailored aggregation of quality, regulatory and safety programs, thereby enhancing product excellence, regulatory resilience and sustainable innovation across the full MedTech lifecycle.

Speed-to-Market

QARA's increasing function in propelling speed-to-market depends upon a number of interrelated capabilities, including digitally integrated systems, automation through artificial intelligence and forward-looking regulatory strategy.

Integrated QMS and RIM solutions now eliminate handoffs and data silos, cutting months-long submission cycles to weeks. QARA unifies document control, change management, supplier quality and registration-information management into a single platform, enabling real-time technical file and regulatory dossier updating. This end-to-end visibility not only ensures quality and regulatory output consistency but also reduces manual effort by as much as 60%, cutting time-to-market directly, while preserving compliance integrity.

Generative AI also accelerates QARA efficiency through automated repetitive outputs. This means faster preparation for submission and quicker response to agency queries, with weeks saved in securing approvals.

Finally, future-proof regulatory foresight and scenario planning allow QARA teams to anticipate evolving requirements and modify development roadmaps ahead of time. Global regulatory changes, which are tracked automatically and integrated into eQMS processes allow companies to respond instantly by reworking templates and processes, avoiding redesigns at late stages or submission delays. Data-driven agility turns regulatory complexity into a strength, bringing innovative medical technology to patients faster and more reliably.

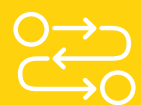
Digital-First Frameworks

QARA is striding ahead towards a digital-first approach, leveraging Industry 4.0 technologies and analytics-based big data to embed quality and compliance across every step of the product life cycle. This transformation is supported by Quality 4.0, which the American Society for Quality (ASQ) has defined as the implementation of quality disciplines to digital and disruptive technologies.¹² Quality 4.0 evolves the role of the quality professional from being an inspector to that of a strategist by bringing people, process and technology together:



Individuals

QA and RA staff are converted into 'data stewards', analytics, AI and IoT-trained individuals to enable decision-making instead of just performing inspections.



Process

Existing processes are re-engineered for automation. Manual verification gives way to sensor-based monitoring and computerized processes enforce strict process adherence in real time.



Technology

Technologies like blockchain for auditability, machine learning for predictive quality and digital twins for process simulation ensure systems learn at 'ten times' the pace of today's technology.

Quality 4.0 digitizes the quality function; Engineering Intelligence advances it. Where Quality 4.0 connects data, dashboards and workflows, EI adds a layer of domain-trained intelligence on top. This means models that understand medical-device engineering, not just generic text or data.

In practice this is the difference between a digital QMS that surfaces information faster and an EI-enabled QMS that interprets it. The latter is able to predict

nonconformities before they occur, drafting compliant documentation for human review, and remapping controls automatically as regulations evolve. For MedTech organizations, EI is therefore the natural next step beyond digital-first. It is the point at which the quality system stops merely recording engineering decisions and begins actively strengthening them.

How Does It Work?

End-to-end eQMS solutions put quality and regulatory capabilities onto a single AI platform. eQMS puts document control, CAPA, supplier quality, change management, training and post-market surveillance onto a single cloud platform. Its AI powers adverse-event coding detects nonconformities and delivers a 'single source of truth,' minimizing manual handoffs by over 60 per cent and accelerating market access while maintaining compliance.

Generative AI brings a second level of efficiency. Boston Consulting Group research indicates that MedTech firms using GenAI to author regulatory filings, labelling and risk plans can cut first-pass draft time by 65% and compliance errors by 75%, if rigorous human review is in place.¹³ This capability converts dull, document-heavy procedures into high-speed, iterative procedures that enable faster agency inquiry response times and shorter approval cycles. Together, these digital-first elements facilitate a proactive, data-driven QARA model that:

- Ensures continuous compliance by providing regulatory intelligence streams to automated processes that remap controls as rules evolve.
- Enables real-time risk management through predictive analysis to identify potential quality or safety issues prior to their occurrence.
- Facilitates cross-functional collaboration by giving all interested stakeholders—R&D, manufacturing, clinical affairs, supply chain—role-based, secure access to real-time quality and regulatory data.

By embracing Quality 4.0 practices, integrated eQMS solutions and GenAI-driven automation, MedTech companies can transform QARA into an engaged, digital-first capability from its present passive, document-based function. This will enable innovation, patient safety and regulatory compliance in a dynamic healthcare landscape.



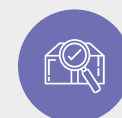
LTTS' Positioning and Capabilities Snapshot

Understanding the intricacies of a dynamic environment, LTTS has evolved over its more than three decades of operations, delivering value to our customers in the following areas-



Regulatory Compliance

Country-specific standards assessment; dossier/technical-file preparation; new-market registration; change notifications; hazardous-substances evaluation; clinical and biocompatibility evaluations.



Product Quality Assurance

Design quality; Design History File/Technical File (DHF/TechFile) creation; functional testing; reliability assessments; pre-compliance and compliance testing.



Quality Management System

Gap assessments; QMS design and deployment; SaMD/SiMD process definition; QMS harmonization and integration; work-instruction development for QMS tools and processes.



Process and Supplier Quality

New-line setup; line transfers; process validations; computerized-system validations; TMV; supplier qualification and audits; multi-organization integration.



Post-Market Support

Complaint management; CAPA; change management; lifecycle-sustenance support; Post-Market Surveillance (PMS) and risk management; remediation (e.g., MDD to MDR transition).

Differentiated Positioning in QARA for MedTech

End-to-End Lifecycle Support

From initial gap assessment to clinical-evaluation support and Post-Market Clinical Follow-up (PMCF), LTTS integrates Quality Assurance with Regulatory Affairs in a unified QARA framework.

Centre of Excellence Model

Dedicated QARA centers leverage domain experts (200+ SMEs) to manage compliance for specialized areas (biocompatibility, C.E.R., hazardous substances), ensuring up-to-date alignment with evolving regulations.

Training and Knowledge Repository

MedTech Academy provides ongoing training, certifications and a centralized knowledge base to ensure teams remain current on ISO 13485, EU MDR/IVDR, FDA QMSR and MDSAP requirements.

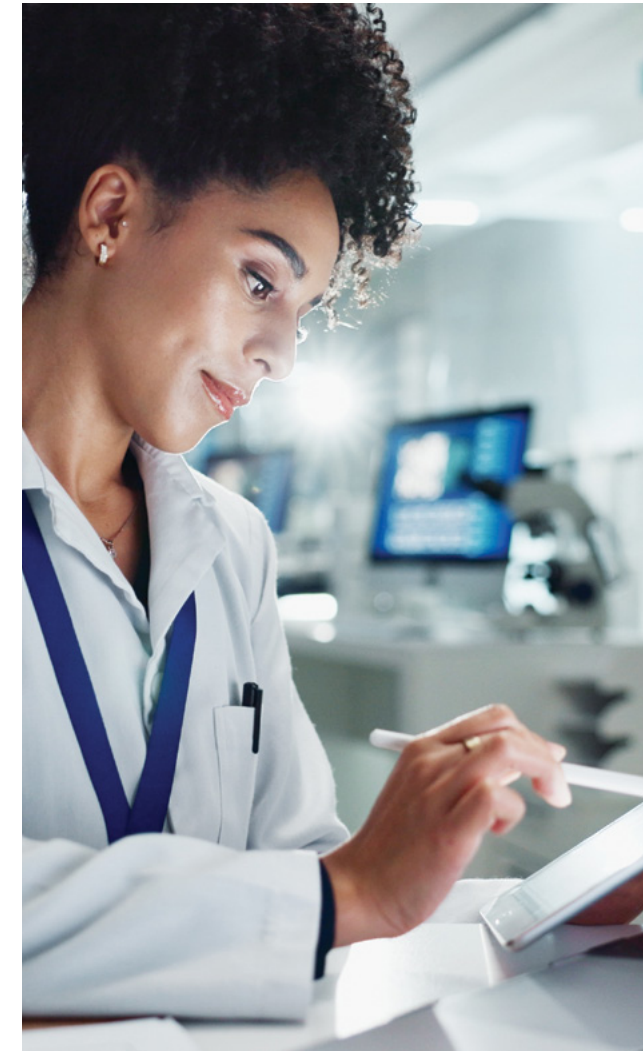


¹²<https://asq.org/quality-resources/quality-4-0>

¹³<https://www.bcg.com/publications/2025/MedTech-can-improve-quality-regulatory-processes-gen-ai>

Chapter 3

The Foundation of Quality Assurance



In a digital MedTech world, standards alone aren't enough—intelligent QARA drives real outcomes

While QARA's scope has expanded dramatically, its effectiveness still depends on solid foundational principles. Understanding these quality assurance fundamentals is essential before diving into regulatory complexities.

What underpins Quality Assurance?

Quality Assurance guarantees products repeatedly achieve established standards of safety, efficacy and performance throughout their life cycle. It has evolved from statistical process control in the 1920s to current risk-based management systems that include leadership commitment, customer focus and data-driven decision-making. QA essentially integrates process control, documentation and ongoing improvement to avoid defects instead of finding them after production.

In MedTech, QA has evolved from manual record-keeping and end-of-line testing to complex, technology-driven Quality Management Systems (QMS). Contemporary QMS platforms, driven by modern quality standards, consolidate document control, CAPA, change management and supplier management onto a single, technology-driven platform. This consolidation minimizes manual labor while expediting adverse-event reporting and empowering cross-functional collaboration. The efficiencies achieved through modern QMS enable organizations to unlock new growth opportunities while aligning with international 'quality standards' and allow teams to concentrate on high-value activities such as product development and strategic planning.

What are Quality Standards?

Quality standards are writings that provide the requirements, specifications, guidelines or features that are used consistently to make sure that materials, products, processes and services are appropriate for their intended use.

Regulatory agencies such as the US FDA, UK MHRA and EU EMA all impose stringent quality management system requirements. FDA regulation 21 CFR Part 820, for example, mandates specific controls for a QMS. With the rising noncompliance cost, the necessity for an effective QARA framework is amplified for all organizations.

Core QA Principles Anchored in ISO 13485, GMP and GAMP5

Regulatory frameworks have advanced to keep pace with the rapid technological shifts. Software as a Medical Device (SaMD) has prompted further developments with the introduction of the FDA's AI/ML-Based SaMD Action Plan in 2021.

In Europe, MDR 2017/745 and IVDR 2017/746 replaced legacy directives, mandating CE marking, Unique Device Identification (UDI) and enhanced post-market surveillance via European Database on Medical Devices (EUDAMED) modules as they come online. The AI Act and Corporate Sustainability Reporting Directive (CSRD) embed environmental risk assessments and ESG reporting into technical documentation, extending QARA's remit to AI and sustainability. The creation of EUDAMED will enhance accessibility for healthcare professionals by collating information on medical devices across member states and promoting mutual collaboration. The EU also has guidelines in place for product manufacturing and testing known as the Good Manufacturing Practices. The aim of GMP is to reduce the risk of injury from product contamination, failures or errors in the manufacturing or packaging process. The manufacturer is responsible for designing protocols and ensuring compliance.

ISO 13485 is the global standard for medical device quality management systems established by the International Standards Organization (ISO). ISO 13485:2016 emerged from the recognition that medical devices required specialized quality management systems beyond the general framework provided by ISO 9001. The ISO 13485 standard was first published in 1996 and underwent significant revisions, with the most recent version published on March 1, 2016.

Meanwhile, the Medical Device Single Audit Program (MDSAP) enables a single audit to satisfy US, Canadian, Australian, Japanese and Brazilian requirements, harmonizing ISO 13485, FDA QSR and EU MDR standards and reducing inspection burdens.

As device complexity increases and software permeates almost every product, QARA teams must shift from sequential, submission-focused work to continuous, lifecycle-oriented oversight. Under the EU's Corporate Sustainability Reporting Directive, MedTech companies will need to demonstrate lifecycle environmental performance, mandating integration of ISO 14001/50001 audits and post-market environmental surveillance into existing QMS frameworks. The core QARA principles based on all the above-mentioned quality standards are discussed below:



Risk-Based Approach

Clause 4.1.2 of the ISO 13485:2016 deems 'the organization shall apply a risk-based approach to the control of appropriate processes needed for the quality management system.' Organizations must apply risk-based decision-making in both QMS processes and device safety, integrating ISO 14971 risk-management principles throughout design, production and service.

According to EU GMP (Clause 1.12) 'Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively.' The GMP guides the organization to evaluate risk based on scientific knowledge and prior experience and to carry out documentation and quality risk management proportionate with the quantum of risk.

GAMP 5 suggests the typical use of risk-based decision making—during the initial stages of planning operational activities, during functional risk assessment and during implementation, verification and monitoring of risk controls.

In the EU MDR, the 3rd section of the 1st Chapter under Annex 1 mandates the manufacturer of medical devices to establish, implement, document and maintain a risk management system. It includes identification of risks, continuous monitoring and documentation throughout the life cycle of the device, as well as risk elimination or control measures conforming to safety principles (sections 4 and 5).



Continuous Monitoring and Improvement

Quality assurance is a continuous process involving detecting nonconformities, driving corrective/preventive actions and refining processes. Clause 10.3 in ISO 9001:2015 describes continuous improvement and corresponds to the clauses 5.6.1, 8.5.1 and 8.5.3 in ISO 13485:2016. Quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review enable continued adequacy of both the quality management system and the safety and performance of the medical device.

Clause 1.8 of the EU GMP states that 'Good Manufacturing Practice is that part of Quality Management which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use

and as required by the Marketing Authorization, Clinical Trial Authorization, or product specification.' All critical manufacturing steps and significant process changes require validation to demonstrate consistent production of quality medical products. The standardized quality controls ensure that quality is monitored and documented throughout the manufacturing process and in line with clearly defined and systematically reviewed standards.

The GAMP5 lifecycle model includes periodic revalidation, change-control assessments and periodic performance checks to ensure ongoing system compliance. It adopts a risk management framework involving continuous improvement in operations.

Manufacturers are required to establish, document and implement a quality management system as described in Article 10(9) of the EU MDR and maintain its effectiveness throughout the life cycle of the devices concerned as stated in Chapter 1 of Annex IX. Manufacturers of medical devices are also required to implement and keep up to date the post-market surveillance system in accordance with Article 83 of the EU MDR. Manufacturers of class IIa devices are required to prepare a Periodic Safety Update Report (PSUR) for each device or category of devices (if applicable) when necessary or at least bi-annually. Manufacturers of class IIb and class III devices are required to update the PSUR at least annually. PSURs summarize the results and analyses of the post-market surveillance data, with the description and rationale for corrective actions taken.



Customer Focus

The primary aim of quality management according to the ISO standard is 'to meet customer requirements and to strive to exceed customer expectations.' By assessing current and future needs of the customers, organizations can provide more value for them which translates into long-term success of the organization. In order to identify needs, quality systems must first identify the direct and indirect customers as those who receive value from the organization.

The organization's objectives should be aligned with the customer needs and expectations and this should be clearly communicated throughout the organization. Quality systems should constantly measure and monitor customer satisfaction and take appropriate actions when required. ISO encourages an active customer relationship management to underpin continued success.



Process-oriented Approach

Quality systems consist of inter-related processes which need to be optimized to deliver consistent and predictable results. Besides consistent delivery, a process-oriented approach enables organizations to identify key processes and opportunities for improvement. Additionally, effective process management results in breaking down of organizational silos and optimized use of resources.

ISO recommends defining objectives of the quality system and the inter-related processes which form the system. Before modifying an individual process, the organization should assess its capabilities and resource constraints and analyze process interdependencies to determine the outcome on the system as a whole. Operational hierarchy and accountability for managing processes should be clearly established to manage risks and ensure that the organization achieves its quality objectives.



Traceability

Maintaining end-to-end linkage between requirements, activities and outcomes to enable root-cause analysis and effective recalls is important for an effective QMS. Article 7.5.9 of the ISO 13485:2016 defines the extent of traceability to be maintained in documentation, in compliance with the applicable regulatory requirements. The components, materials and working conditions for manufacture of medical devices must be recorded if these factors can affect the specified safety and performance requirements of the device. The organization must further ensure the maintenance of records for distribution of medical devices to allow for traceability in the event of an inspection.

Section 4.3 of the EU GMP requires that the documents are uniquely identifiable and their effective date is clearly defined. Section 4.8 states that records are established and maintained in such a way that all significant activities concerning manufacturing of medicinal products are traceable.

In the EU MDR, Article 25 of Chapter 3 mandates the cooperation between manufacturers or authorized representatives and distributors and importers to ensure an adequate level of traceability of devices. The UDI System described in Part C of annex VI allows for identification and facilitates the traceability of devices. The UDI consists of two components— the UDI Device Identifier (UDI-DI) and the UDI Production Identifier (UDI-PI). It comprises a distinct numeric or alphanumeric code created using a globally accepted standard for device identification and coding.

Documentation and Record Keeping

Every activity affecting quality must follow approved, controlled procedures, with records maintained to demonstrate compliance. Clauses 4.2 (Documentation requirements), 7.3 (Design and development) and 8 (Measurement, analysis and improvement) of ISO 13485:2016 require a Quality Manual, controlled documents and Medical Device Files capturing design inputs/outputs, validation reports and post-market data.

Chapter 4 (Documentation) of the EU GMP deals with establishing, controlling, monitoring and recording all activities, which directly or indirectly impact all aspects of the quality of medicinal products. GMP documentation requires a Site Master File, instructions (requirements), manufacturing formulae, processing, packaging and testing instructions and Standard Operating Procedures (SOPs), protocols, technical agreements, records and reports. Good documentation practice should be implemented and suitable controls should be applied to ensure the accuracy, integrity, accessibility and legibility of documents.

Technical documentation is required to be maintained as per Annex II of the EU MDR, including device description and specification, manufacturing process and its validation, product testing data, general safety and performance requirements, risk management and all verification and validation tests undertaken to highlight the adherence of the device to the requirements of the regulation. Under Article 10(8), manufacturers are obligated to keep the technical documentation and the EU Declaration of Conformity, along with any amendments and supplements issued under Article 56, accessible to competent authorities. This obligation lasts for a minimum of 10 years, starting from the date that the final device covered by that specific declaration of conformity was placed on the market.

Change Control

A robust change control mechanism ensures that any modification to processes, equipment, documents, or systems is evaluated, approved and documented before implementation. Clause 4.1.4 of the ISO 13485:2016 mandates the changes made to the processes to be evaluated for their impact on the QMS, on the medical devices produced under the QMS and controlled in accordance with the requirements of this international standard.

The EU GMP states under Annex 15 (Qualification and Validation) that any 'planned changes to facilities, equipment, utilities and processes which may affect product quality should be formally documented and the impact on the validated status or control strategy assessed.'

The Second Edition of GAMP 5 introduced the concept of low-risk standard/routine changes as part of its updated guidance on computerized system validation and lifecycle management. Low-risk standard/routine changes are changes that are well-understood, have a low potential impact on patient safety, product quality and data integrity and are unlikely to introduce new risks. For low-risk changes, GAMP 5 suggests a streamlined or reduced validation approach potentially involving less extensive documentation or testing.

Article 10(9) of the EU MDR mentions that any modifications to a device's design or characteristics, as well as any changes to the harmonized standards or Common Specifications referenced for its declaration of conformity, must be appropriately addressed in a timely manner.

Supplier Control

The manufacturer is responsible, according to the ISO 13485:2016 (Article 7.4.1), for the evaluation and selection of suppliers based on the suppliers' performance, ability to fulfill the manufacturing requirements, effect of the purchased product on the quality of the medical device and risk proportionate to the concerned medical device.

The EU GMP, in its section 2.9 (under chapter 'Personnel'), qualifies the duty of quality control to include the approval and monitoring of the suppliers of materials. Sections 27 to 30 have been amended with the addition of a new section on the qualification of suppliers, ensuring the legal obligation of manufacturing authorization holders to ensure that active substances are produced in accordance with GMP.

According to article 10(d) of the EU MDR, the quality management system must address resource management, including selection and control of suppliers and sub-contractors. In case the manufacturer cannot demonstrate adequate control over suppliers or if the activity of the suppliers is significantly responsible for the conformity of the medical devices to the regulation, the notified body may audit the process controls on the premises of the suppliers.

Design Control

Article 7.3 of the ISO 13485:2016 lays down the procedure for planning, controlling and maintaining records of performance, regulatory and safety requirements, along with review and verification of design and development. According to section 7.3.9, design and development changes must be monitored and their significance verified based on the functionality, safety and regulatory requirements of the medical device and its intended use. Further, the organization is required to maintain a design and development file for each medical device type or medical device family, as mentioned in section 7.3.10.

EU MDR Annex IX section 2.2(c) reinforces design-control phases by requiring monitoring, verifying, validating and controlling design, covering regulatory-compliance strategy, applicable legal requirements and general safety and performance requirements conformity throughout development.

The GAMP5 in paragraph 3.3.5 (Life Cycle Requirements) of appendix D1 defines phases from user requirements specification (URS) to be addressed, including mandatory design methods and documentation from the supplier on design specification.

Management Review

Quality assurance ensures top-management oversight of QMS performance, resource adequacy and driving continuous improvement. ISO 13485:2016 requires top management to review the organization's QMS at documented planned intervals, ensuring its adequacy, suitability and effectiveness. Article 5.6 (Management Review) also mandates the assessment of changes required and opportunities available to update the QMS, quality policy and quality objectives.

According to article 10 of the EU MDR, which enlists the general obligations of manufacturers, point 9 dictates that the quality management system must address the responsibility of the management. For medical devices falling under class I, the responsibility of the conformity assessment procedure also lies with the manufacturer due to the low risk associated with the application of such devices.

Section 2.4 (Personnel) of Part 1 of EU GMP places the responsibility of ensuring the effectiveness of the QMS according to the quality objectives on the senior management. They are also responsible for defining, communicating and implementing the roles, responsibilities and authorities of personnel, in relation to quality, throughout the organization and monitoring overall GMP compliance. The organization's quality policy should describe the overall intentions and direction of the company regarding quality.

Corrective and Preventive Action (CAPA)

Systematic investigation of nonconformities and implementation of corrective actions to eliminate causes and avert recurrence is a fundamental part of good quality practice. Article 8.5.2 lists corrective action measures, including reviewing of nonconformities, determining root causes, evaluating the need for action to avoid recurrence and reviewing the effectiveness of the corrective action while maintaining documentation and ensuring compliance. Similarly, Article 8.5.3 deals with the preventive action required to eliminate causes of potential nonconformities, including identification of potential nonconformities, planning and implementation of required action and reviewing the effectiveness of the action while maintaining documentation and ensuring compliance.

Chapter 8 (Complaints, Quality Defects and Product Recalls) of the EU GMP discusses the application of quality management principles to the assessment of quality defects and determination of corrective and preventive action in relation to product recall. Section 8.9.ix lays down the need for appropriate CAPAs to be identified and implemented along with evaluation of their effectiveness.

The EU MDR's general obligation of manufacturers, covered under Article 10, requires the QMS to address management of corrective and preventive actions and verification of their effectiveness.

QMS Framework with Digital Overlays—Illustrated with LTTS-led Implementations

LTTS demonstrates strong capabilities in technology transfer from development to the manufacturing level, ensuring a seamless transition from design to production while maintaining QMS compliance.

Agile Development Approach

LTTS adopts an agile, iterative development approach in understanding that QMS with digital overlay is 'not a single product and will not be built in one go.' The guiding principles are:

- Interoperability and integration focus
- Iterative and agile development cycles
- People-centric stakeholder alignment

Competitive Advantage

- Broad domain experience across the product lifecycle
- Full integration capabilities with legacy infrastructure
- Regulatory compliance and standardization focus
- Integration of advanced analytics and AI-driven insights
- Cloud-based, scalable infrastructure to support global reach

Analyst firm ISG has recognized L&T Technology Services as a leader among 21 providers in their Life Sciences Digital Services for MedTech Digital Transformation Services report.



Case Study

A multinational medical device manufacturer sought to transform their existing business frameworks beset by the challenges of the shifting market dynamics and new regulatory requirements. Amidst growing global demand for innovative devices and wearables, the customer looked to recalibrate their digital transformation journey and accelerate their go-to-market strategy by deploying robust digital Product Lifecycle Management (PLM) solutions.

Challenges

- Integrating all the tools and platforms (such as Adlib and Prisms 360) to avoid surprise delays in the production rollout
- Implementing UDI (Unique Device Identifier) according to FDA's 21CFR803.20 guidelines
- Deployment of Prisms 360 upgrades on time to ensure project timelines
- Implementation of strict regulatory guidelines and review cycles for standardization of regulatory filing processes
- Flexible healthcare service delivery with the supplier to implement Prisms 360 upgrades based on project timelines
- Assisting growth in emerging markets

LTTS' Solution

Beyond the core PLM implementation, LTTS implemented a comprehensive digital overlay that included:

1 Prisms 360 Enhancement Integration:

Non-disruptive integration to push data from the PLM to label software to maximize label design, accelerate approval and speed up printing, with product labelling according to GS1 standards

2 Global Regulatory Submission (GRS) Standardization:

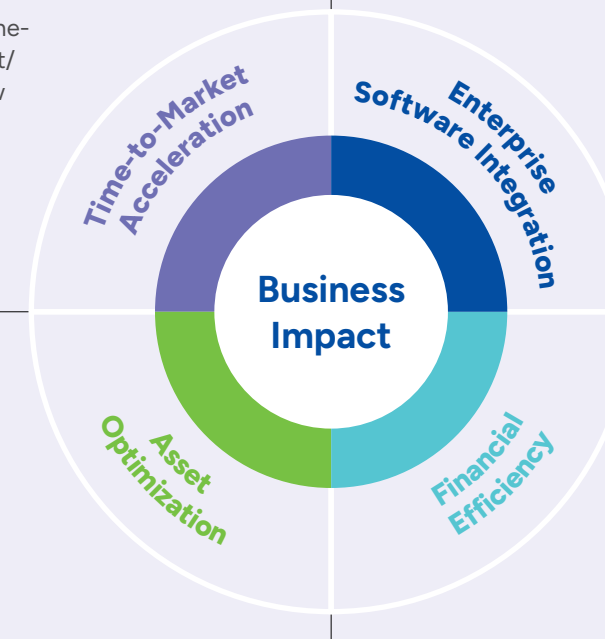
Deployment of one GRS system for efficient and trustworthy regulatory submission worldwide

3 UD Management Integration:

The team facilitated the implementation of the GS1-128 barcodes, in addition to the Global Trade Identity Number (GTIN) with Design Identifier (DI) and Production Identifier (PI) definitions for all products worldwide, with the process aiding to enhance design changes to drive changes directly on labels and UDI management.

20-30% improvement in time-to-market and development/enhancement costs for new medical products through digital-powered product engineering services

30-40% increase in asset utilisation effectiveness



Smooth rollout of enterprise software from top suppliers

Enhanced working capital efficiency and significant decrease in maintenance expenses

LTTS' comprehensive approach to implementing QMS frameworks with digital overlay reflects the Company's capabilities that extend from core PLM systems to advanced healthcare digital transformation, connected health solutions and comprehensive test infrastructure.

QA Traceability Models and Audit Preparedness Best Practices

QA traceability

Traceability in Quality Assurance (QA) provides the 'digital thread' from requirements, design inputs/outputs and verification/validation activity to post-market data. Effective traceability models ensure that every requirement is fully implemented, thoroughly tested and followed throughout the product life cycle.

The Main Principles of QA Traceability

End-to-end linkage

Establishing a connection from customer needs via design, manufacturing and after-market input.

Convergence in regulations

Ensuring traceability schemes meet ISO 13485:2016 Clause 7.5.9 documentation requirements and EU MDR/IVDR device history record requirements.

Risk-based depth

Scaling the level of traceability to product risk class. High-risk implantables require extensive linkages, whereas low-risk accessories can afford to have weaker controls.

Examples of Traceability Models

1 Forward Traceability

- Maps each requirement to the respective QA artifacts (test steps, design outputs, inspection reports).
- Makes sure that all needs, which are outlined make it into actual implementation and are not left out.
- ISO 13485 mandates 'procedures... to define the extent of traceability' from requirements onwards.

2 Backward (Reverse) Traceability

- Binds QA artifacts, specifically test cases and nonconformities, back to original requirements.
- Prevents scope creep since tests and corrections are only allowed to touch sanctioned requirements.
- Enables audit readiness by revealing the source of regulation for every document.

3 Bidirectional Traceability

- Combines the forward and backward procedures into one matrix.
- Offers end-to-end coverage: all requirements give rise to tests and all tests give rise to requirements.
- Appropriate for high-risk and regulated devices to demonstrate extensive QA coverage.

4 Vertical Traceability

- Extends bidirectional links between different layers of artifacts: requirements ⇄ design ⇄ code/configuration ⇄ test scripts ⇄ deployment packages.
- Most important in Software as a Medical Device (SaMD), as safety is influenced directly by source-code modification.
- Complies with Good Automated Manufacturing Practice (GAMP5) by aligning computerized-system requirements through qualification processes.

5. Closed-Loop (Lifecycle) Traceability

- Covers post-market surveillance: field reports, complaint handling and CAPA actions feedback to design and risk-management records.
- Enables continuous improvement by balancing real-world performance data with upstream requirements and design controls.
- According to ISO 13485 and EU MDR lifecycle risk management and Device History Records regulations.

Implementation Strategies

- Requirements Traceability Matrix (RTM) software (enterprise QMS modules, for example) creates links automatically and manages them with coverage and gap analysis dashboards.
- Model-based paradigms employ metamodels (e.g., SysML, UML) with trace models for transformation to preserve relations among design and test artifacts.
- Physical and informational traceability are combined in barcode/UDI systems so that serialized products are traceable to production records and QA documentation.

Benefits of Sound Traceability Models

- Complete QA coverage, avoiding the risk of untested functionality or untracked changes.
- Streamlined audits and regulatory reporting, with verifiable proof of compliance.
- Quick impact analysis and change control to address changing requirements or regulations.
- Enhanced patient safety through quick identification and removal of non-conforming devices.

By adopting a multi-model traceability strategy, MedTech organizations can offer full QA control, comply with stringent regulatory demands and maintain agile, resilient operations in a complex environment.



Audit Preparedness Best Practices

Audit preparedness under Quality Assurance relies on embedding audit preparedness into day-to-day operations rather than as a one-time occurrence. Best practices include:

Integrated Audit Planning and Governance

Organizations must establish an audit governance framework that delineates clear roles, responsibilities and control of audit activities. A centralized team of auditors, supported by senior management, maintains control over audit scope, frequency and use of resources. Audit processes and charters must be recorded, sanctioned and made known within the organization to exercise oversight and accountability.

Risk-Based Audit Programs

Organizations must use risk-based scheduling and depth of audit with a focus on high-risk processes, major suppliers and new systems introduced. They must use CAPA trends, customer complaints and real performance data as inputs to drive audit targets and prioritize them. This enables audit resources to be utilized where highest potential quality or compliance gaps with the greatest patient safety risk need to be addressed.

Standardized Audit Criteria and Tools

MedTech companies must ensure development of controlled checklists and scoring requirements using applicable regulations (e.g., ISO 13485, 21 CFR 820, EU MDR) and internal procedures. They must store such requirements in a controlled document store and update them from time to time to accommodate regulatory changes. Electronic export/import of checklists ensures auditors apply up-to-date standards with every audit.

Mock Audits and Self-Assessments

MedTech companies must conduct regular internal mock audits or 'dry runs' to simulate external inspections. They should utilize FDA inspection-readiness checklists and scenario planning for stress document retrieval, SME readiness and back-room support procedures. Further, organizations must identify and fix gaps in real time and validate effectiveness through follow-up audits. This rigor lends confidence and reveals hidden defects before the regulators arrive.

Seamless CAPA Integration

Organizations must feed direct audit results into the CAPA system for prompt investigation and closure. Low-risk results initiate immediate corrective action and high-risk results feed into formal CAPA procedures. Track CAPA plans, status of completion and performance in the eQMS and review metrics (e.g., time to closure, recurrence rates) at management review meetings to support continuous improvement.

Qualified Auditors

Audit teams must comprise of competent auditors with no direct responsibility for what they audit. Regular training in risk-based auditing techniques, regulatory guidelines and emerging technologies (e.g., digital-tool validation) is indispensable.

Real-Time Audit Analytics and Reporting

MedTech companies must utilize eQMS dashboards to monitor audit program health, including audit close-out rates, nonconformity trends and CAPA performance. Auto-reporting gives leaders real-time visibility into critical audit results, enabling them to recognize underlying issues and reassign resources ahead of time. Integration with supplier scorecards guarantees external audit results influence vendor performance metrics.

Inspection Readiness Culture

Organizations must embed audit readiness in the corporate culture by emphasizing the 'day-one readiness' mindset. Both regulatory and quality teams should take part in sharing audit expectations widely, recognizing audit success and sharing lessons. According to BCG, organizations with strong quality cultures view audits as opportunities for improvement rather than as punitive measures, allowing collaboration between auditees and auditors.

MedTech companies should embrace these best practices to ensure they are always ready for internal and external audits in order to protect product quality as well as adhere to regulatory mandates.

AUDIT ANALYTICS REAL-TIME OVERVIEW

All Sites

All Processes

May 1 – May 31, 2024

TOTAL AUDITS

128

+12% vs last month

AUDITS IN PROGRESS

35

+8% vs last month

OPEN FINDINGS

62

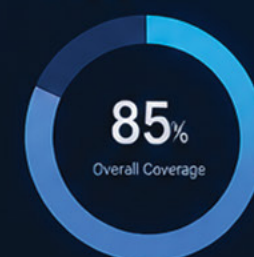
-5% vs last month

OVERDUE CAPAs

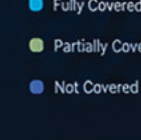
18

+15% vs last month

AUDIT COVERAGE



FINDINGS BY SEVERITY



AUDIT TREND



FINDINGS BY PROCESS



AUDIT HEALTH SCORE



AUDIT COVERAGE HEATMAP



OVERDUE CAPAs BY AGE



Chapter 4

Understanding Regulatory Affairs



The functions of RA include product approvals, labeling, submissions and extending to product lifecycle compliance.

Regulatory Bodies across Regions

United States	Food and Drug Administration (FDA)
European Union	European Medicines Agency (EMA)
Canada	Health Products and Food Branch (HPFB)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)
Australia	Therapeutic Goods Administration (TGA)
South Africa	Medicines Control Council (MCC)
Africa (Tanzania)	Tanzania Food and Drugs Authority (TFDA)
Latin America (Brazil)	Agência Nacional de Vigilância Sanitária (ANVISA)
CIS Regional Group (Russia)	Federal Service for Surveillance in Healthcare (ROSZDRAVNADZOR)
Asian Region (Hong Kong)	Department of Health (DOH)
GCC Regional Group	National filing handled by specific independent regulatory agencies

Quality standards provide the foundation, but regulatory affairs translate these standards into market-specific compliance requirements. Regulatory Affairs is concerned with making products comply with all legal and technical standards for sale and application. This means navigating the complicated regulatory environment, providing required

documentation to regulatory authorities and keeping pace with compliance throughout the product's life cycle.

The functions of RA include product approvals, labeling, submissions and extending to product lifecycle compliance. Some of the regulatory requirements for medical devices are discussed later in the chapter.

Under different jurisdictions, MedTech organizations are required to comply with different standards for establishing and sustaining operations. Let us dive into the evolution of the regulatory landscape in MedTech over the years to have a better understanding of the various differences and points of convergence under different jurisdictions.

Regulatory Bodies Overview

The evolution and history of the major medical-device regulatory agencies are close to a century old, reflecting progressively advanced control to safeguard patients. Some of the prominent international organizations regulating and monitoring medical devices are:

Food and Drug Administration

In the US, the Federal Food, Drug and Cosmetic Act of 1938 gave the Food and Drug Administration (FDA) jurisdiction over 'drugs, devices and cosmetics,' including factory inspections and misbranding laws. Responding to increasing concern regarding the safety of medical devices, Congress passed the Medical Device Amendments on May 28, 1976 (Public Law 94-295), which created a risk-based classification scheme (Classes I-III) and the 510(k) premarket notification process. The FDA combined its medical-device and radiological-health responsibilities in 1982 to create the Center for Devices and Radiological Health (CDRH), the primary FDA center currently responsible for device safety and effectiveness.

International Organization for Standardization

Globally, quality-management standardization commenced with ISO 13485:1996, initially published by the International Organization for Standardization to unify QMS requirements for medical devices. Its latest revision, ISO 13485:2016, was published on March 1, 2016 to highlight risk-based decision-making and regulatory conformity.

Medical Device Coordination Group

Three 'New Approach' directives in Europe—Directive 90/385/EEC (AIMDD) for active implantable devices (20 June 1990), Directive 93/42/EEC (MDD) for general medical devices (14 June 1993) and Directive 98/79/EC (IVDD) for in vitro diagnostics (27 October 1998)—were

replaced by two directly applicable regulations. Regulation (EU) 2017/745 (MDR) came into effect on 25 May 2017 and was fully applied on 26 May 2021 and Regulation (EU) 2017/746 (IVDR) came into application on 26 May 2022.

Central Drugs Standard Control Organization

In India, the Central Drugs Standard Control Organization (CDSCO) published the Medical Devices Rules 2017 (G.S.R. 78(E)), effective from 1 January 2018. The rules provided risk-based classification (Classes A-D), notified bodies and ISO 13485-conformant QMS requirements under the Drugs and Cosmetics Act of 1940.

Therapeutic Goods Administration

Australia's Therapeutic Goods Act 1989 created the Therapeutic Goods Administration (TGA) as the national regulator of therapeutic goods (including devices). This was followed by complementary legislation in 1990 and device-specific regulation in 2002. The TGA oversees the Australian Register of Therapeutic Goods (ARTG) to provide quality, safety, efficacy and control over supply.

Together, these agencies and regulations have increasingly tightened device quality and safety standards, from the first manufacturing regulations in 1938 to today's coordinated, risk-based and harmonized international system, ensuring medical devices are designed, made and inspected under strict standards protecting patient well-being.



Ongoing Regulatory Challenges

The EU regulatory environment for medical devices is still evolving and deadlines have now been pushed far beyond 2024 with additional requirements to ensure patient protection without unnecessarily impacting supply. Manufacturers are still beset by challenges despite extensions and revisions, including having to satisfy more stringent timelines, availability of Notified Body capacity and reconciling various regional frameworks. Additionally, lack of clear guidance on what constitutes sufficient clinical evidence for conformity assessments remains a major concern for manufacturers.

EU MDR/IVDR Transition

The Medical Device Regulation (MDR 2017/745) implementation has created substantial burdens for manufacturers worldwide. Originally, the transition period for all legacy devices from the earlier MDD (Medical Devices Directive) to MDR was set to end by May 26, 2025. However, this has been extended to 31st December 2027 for Class IIb and III devices and 31st December 2028 for lower-risk devices. Applicants have to sign a written agreement with a Notified Body (NB) and transfer appropriate surveillance to an MDR NB by 26th September 2025, to meet the conditions required to avail the new transition timelines.

Notified Body

Under the New Approach Notified and Designated Organizations (NANDO) Information System, organizations that have been authorized to carry out conformity assessments for medical devices are known as Notified Bodies. Although Notified Body capacity for the EU MDR has increased from 18 in 2020 to 50 in 2025,¹⁴ their capacity to handle the rising workload remains strained amidst a wave of applications to meet registration deadlines for legacy devices. However, according to Team NB, the association representing Notified Bodies, delays in technical documentation submissions and slow manufacturer responses are primarily responsible for the massive gap in certifications.

Documentation Delays

In a survey conducted by the organization MedTech Europe in 2022, covering 475 EU companies and international companies operating in Europe, 33% of the existing medical devices were slated for discontinuation as an effect of MDR implementation.¹⁵

In a subsequent survey conducted by the same organization in 2024, 86% of large and 91% of SME medical device manufacturers reported facing difficulties in securing qualified regulatory affairs employees.¹⁶ In the same survey, more than half of the total conformity assessment time was reported to be expended on activities outside the review phase, including the pre-review and certificate issuance phases. Expert consultation can streamline these processes, thereby expediting assessment.

IVDR Implementation

Similar to MDR, the transition of legacy IVD devices from IVDD (In Vitro Diagnostic Directive) to IVDR (In Vitro Diagnostic Regulation) poses acute challenges despite timeline extensions. The transition period is extended from May 26, 2024, to December 31, 2027, 2028 and 2029, based on their risk class.

Loper Bright and Corner Post Rulings

The 2024 US Supreme Court ruling in the case of Loper Bright Enterprises v. Raimondo has placed the right to interpret statutes in the hands of the courts. This overturns the earlier norm of deference to the agency interpretations in such cases.¹⁷

The Corner Post Ruling has changed the statute of limitations for challenging agency regulations from 6 years after the creation of such regulation to 6 years after the company is injured by a regulation. The implications of these rulings are an uncertain regulatory environment.¹⁸

Global Harmonization Barriers

Different countries face unique public health challenges leading to divergent regulatory agendas and priorities. These differences can create hurdles for achieving alignment on product safety and effectiveness standards.

Technology and infrastructure gaps further exacerbate the challenges since not all regulatory bodies have access to the same level of technology or infrastructure needed to implement standardized frameworks.

Over the years, the FDA has made efforts to harmonize the US standards with international regulations. The organization played a key role along with its counterparts from the EU, Japan and Canada to form the Global Harmonization Task Force (GHTF) in 1993. The GHTF worked in association with member states from the EFTA, the CEN, the CENELEC, the TGA, the ISO and the WHO to converge global regulatory practices. In 2011, the IMDRF was established by the regulatory authorities of Australia, Brazil, Canada, China, Japan, the EU and the US to carry forward the foundational work by the GHTF. The IMDRF now comprises a dozen member states and 25 affiliate member states.

The European Commission has also made concerted efforts to drive pan-European harmonization of methodologies to evaluate DMDs. The Regulation on HTA (HTAR) became active in January 2022 with the aim to standardize methodologies and approaches for Joint Clinical Assessments (JCAs) and Joint Scientific Consultations (JSCs).

In April of the same year, the European Taskforce for Harmonized Evaluation of Digital Medical Devices was launched, under the stewardship of France. The taskforce engages in a voluntary association of countries aimed at harmonizing nomenclature and taxonomy of DMDs.

Despite this progress, administrative fragmentation and lack of mutual recognition plague submission processes. Most Mutual Recognition Agreements cover GMP inspections but exclude device approvals. Manufacturers must duplicate dossiers, often in multiple languages and manage inconsistent e-labeling, UDI formats and portal requirements (EUDAMED, FDA eSTAR, TGA's eBS).

On 31st January 2024, the FDA replaced the existing QSR with the new QMSR, which is slated to come into effect from 2026. The new rule aims to harmonize requirements with the ISO 13485.

¹⁴<https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>

¹⁵<https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf>

¹⁶<https://www.medtecheurope.org/wp-content/uploads/2025/01/mte-ivdr-mdr-survey-report-highlights-final.pdf>

¹⁷https://www.supremecourt.gov/opinions/23pdf/22-451_7m58.pdf

¹⁸https://www.supremecourt.gov/opinions/23pdf/22-1008_1b82.pdf

How Should QMS Programs Adapt to FDA QMSR?

The forthcoming implementation of the QMSR provides MedTech companies with an opportunity to strategize and stay ahead of the new regulatory requirements.

Non-ISO 13485 certified companies, which are following the current QSR should benchmark the FDA 21 CFR Part 820 with the ISO 13485:2016 to assess the gaps with the impending QMSR requirements. Further, they may undertake the additional step of obtaining an ISO 13485:2016 certification, which would help them align their existing framework with the anticipated requisites.

ISO 13485 certified companies will still need to make adjustments to comply with the QMSR owing to the FDA's newer additions in the form of sections—820.7 (Incorporation by Reference), 820.10 (Requirements for a Quality Management System), 820.35 (Control of Records) and 820.45 (Device Labeling and Packaging).

To help manufacturers navigate the complex landscape of ongoing FDA QMSR and ISO 13485 harmonization efforts, LTTS leverages deep domain expertise and technical knowledge to deliver comprehensive solutions. Our team of specialists offers guidance throughout each step of the compliance process, ensuring the products are able to surpass the quality benchmarks laid down by these regulatory standards.

How Will Organizations Stay EU MDR/IVDR Compliant?

The EU MDR/IVDR transition has made it compulsory for all devices to undergo conformity assessments as per the new regulations. This means that legacy devices will be required to conduct repeated post-market surveillance as well as update the existing data for each device in the EU database.

For a smooth transition, manufacturers have implemented technological solutions, including analytical tools, cloud computing and product engineering. These organizations have discovered the added benefits of accelerated time to market, reduced product development costs, labeling and UDI integrated within the supply chain and ensured seamless connectivity.

LTTS' Proven Track Record of Helping Manufacturers Remain Compliant

LTTS' deep experience across MedTech, robust test support and capabilities around AI, cloud computing and advanced analytics, which facilitate the Internet of Medical Things (IoMT), interoperability and smart connected products, have helped clients across the world in ensuring compliance across the product life cycle. Our examples of successfully overcoming compliance challenges for our clients include:

Achieving REACH Compliance in Surgical Instruments

LTTS assisted a customer in the identification of dangerous chemicals in surgical instruments exported to Europe. Through close collaboration with stakeholders and thorough analysis, LTTS enhanced product safety, reduced documentation and coordination and facilitated REACH compliance.

Obsolescence Management and RoHS Compliance for a Urine Monitor

LTTS assisted a customer in redesigning outdated boards and eliminating non-RoHS components in a urine monitor with no change in the form factor. With gap analysis, design refinement and testing, LTTS ensured RoHS compliance, improved performance, streamlined the device profile, enhanced connectivity and enabled 10% cost savings per unit.

Compliance for Microbiology and Haematology Devices

LTTS assisted a customer to review and convert over 10,000 parts in microbiology and haematology devices to RoHS-3. Through BOM clean-up, alternate part documentation and close collaboration with suppliers, LTTS managed obsolescence efficiently, reduced paperwork and ensured RoHS-3 compliance.

RA's Regulatory Responsibilities

Now that we have an idea of the international regulatory bodies and the prevailing headwinds, let us understand the role of the RA professionals in ensuring that devices and organizations comply with the relevant requirements and processes are validated according to statutory standards while navigating the complex and evolving regulatory environment. As mentioned earlier, this encompasses a broad spectrum of responsibilities, ranging from classification and documentation to approval and post-market survey, resulting in lifecycle compliance. Some of the regulatory responsibilities are described in detail below:

Classification

Before applying for medical device certification, the organization must first establish the classification of the device under the relevant jurisdiction. Depending on its risk profile, performance, or application, the device may be classified into one of many categories under established standards, with each classification dictating a distinct pathway for certification. Below are some of the classification standards under respective jurisdictions:

FDA

Under the Federal Food, Drug and Cosmetic Act, section 513, each medical device filed for approval is classified under three classes:

Class I devices are low-risk devices that provide reasonable assurance of safety under general controls. Most Class I devices are exempt from premarket submission.

Class II devices are moderate-risk devices where general controls are unable to provide reasonable assurance of safety and effectiveness. In such cases, special controls are established, including premarket notification submissions in accordance with section 510(k).

Class III devices are high-risk devices, which are generally life-supporting or life-sustaining, or carry risk of potential injury or illness. For these devices, pre-market approval is mandated under section 513 and special controls are applicable.

EU MDR

In the EU MDR, definitions are set out for invasive, non-invasive and active devices before classifying each under one of the four classes. Under the MDR Annex VIII, devices are classified as under:

Non-Invasive

Class I

includes all non-invasive devices, which do not belong to the second or third class.

Class IIa

includes all non-invasive devices, which function as a storage medium, facilitating the introduction of blood, body fluids, cells and organs into the body or if they are connected to class IIa, IIb or III active devices. Blood bags are an exception under this rule and are classified as class IIb.

Class IIb

includes high-risk non-invasive devices, including devices that alter the biological or chemical composition of human cells or tissues.

Class III

includes all non-invasive devices that find application through direct contact with human cells or tissues or human embryos.

Invasive

Medical devices that penetrate the body through a body orifice or through the surface of the body, either partially or wholly, are termed as invasive devices.

Devices that are not surgically invasive are termed as class I. However, reusable surgical instruments with transient application are also included in this category.

All non-surgical invasive devices that are used for a short term or surgically invasive devices that are intended to be used for a transient term are classified as class IIa.

Labeling

FDA

The labeling regulations are complex and often unique to the product. The FD&C Act prohibits misbranding through the restriction of false, misleading, or improper packaging or labeling. The absence of required information, illegibility of information and lack of special packaging with respect to the Poison Prevention Packaging Act are also prohibited.

EU MDR

Chapter III lists the information required to be mentioned on the label of the devices including name of the device, name and address of the manufacturer, the lot number or the serial number the UDI carrier, date of use, warnings and precautions, etc. The labelling must include a symbol to indicate sterilization and distinguish between identical or similar devices. Article 7 of Chapter 1 further prohibits the use of misleading text, names, trademarks, pictures or other any signs, with respect to the intended use or performance of the device.

ISO 13485

According to ISO 13485:2016, organizations are required to establish and maintain labeling, including instructions for use, for each medical device or medical device family to ensure conformity with the standards.

IMDRF

The IMDRF takes over from the rule prescribed in GHTF/SG1/N70:2011, which lists the requirements for medical device labelling.

Approval/Accreditation Process

ISO 13485

ISO does not directly provide certification to organizations. The body has developed a Committee on Conformity Assessment (CASCO) which lays down certification standards followed by third party certification bodies. These third parties then conduct conformity assessments in line with CASCO standards. ISO 13485 accreditation is achieved through a third a controlled, three-phase process of initial certification, regular surveillance and complete recertification over a three-year period.

Initial Certification

Preparation

As soon as the contract for certification is established, the auditor plans and schedules the audit.

Stage 1 (Readiness Review)

Performed on-site, this stage reviews your written quality system, assesses the effectiveness of your staff's understanding of the standard's requirements, checks for the internal audits and management review procedures to be in place, and ensures you are ready for the more detailed Stage 2. Any identified gaps have to be filled before going ahead.

Stage 2 (Implementation Audit)

The auditor reviews on-site how well your system complies with ISO 13485 requirements—interviewing personnel, observing operations and examining records. At the end, a closing meeting shows findings and any non-conformities needing corrective action.

Certificate Award

Upon examination of audit reports and approval of any corrective-action plans, the certification body awards your ISO 13485 certificate.

Surveillance Audits

Once certified, you undergo at least one surveillance audit each calendar year (except the recertification year) to verify the effectiveness of quality and document changes. The first surveillance audit must occur within twelve months of the certificate issue date.

Recertification Audit

Prior to the three-year certificate's expiration, a re-certification audit is conducted on-site to re-evaluate requirements, including the resolution of past nonconformities.

Other Audit Types

Extension Audits

To extend the certificate's scope, an extension audit can be merged with surveillance or recertification visits.

Unannounced Audits

Followed by severe incidents or complaints, these unannounced visits determine current compliance.

Multi-site Sampling

For organizations spread over numerous locations under one management system, auditors can visit a representative set of sites.

Transferred Certifications

Accredited certificates issued by other organizations can be brought forward upon a document review and, if necessary, a site visit to verify compliance.

Nonconformity Management

Any audit nonconformity is required to be resolved by root-cause analysis and corrective-action planning. Evidence of completion is generally within six weeks. Inability to close issues may delay certification or result in withdrawal.

FDA

Regulatory controls for medical devices under Code of Federal Regulations (CFR), Title 21 Subchapter H, post classification, includes:

Substantial Equivalence

Devices under 510(k) need to establish proof of substantial equivalence with a legally marketed (prior to May 28, 1976) medical device of the same class. Most class II devices follow this route to market. Examples include x-ray machines, catheters and tongue depressors. For these devices, pre-market approval is not required.

Pre-market Approval

For class III devices and devices which cannot establish substantial equivalence through 510(k) process, pre-market approval is required. PMA establishes the safety and effectiveness of these devices by determining through scientific evidence that the benefits from the use of the device outweigh the risks associated with its use and that it will help a large section of the intended population. Examples include implanted defibrillators and digital mammography.

Orphan Devices

Orphan devices are medical devices designed to diagnose, treat or prevent rare diseases or conditions affecting a small patient population. Such devices do not have to follow the above pathways for regulatory approval. In the US, the FDA has implemented a unique pathway for such devices which involves:

- ▶ **Humanitarian Use Device Designation-** The FDA conducts an initial assessment to determine that the device meets the criteria related to a small population of affected people and how its development aims to remedy their affliction. To qualify, the related condition must affect not more than 8000 people in the US per year. Upon successfully meeting the criteria, the device is designated as a Humanitarian Use Device by the FDA opening the Humanitarian Device Exemption pathway for marketing the device.
- ▶ **Humanitarian Device Exemption-** In contrast to the Pre-market approval pathway which also requires demonstration of device effectiveness, HDE pathway only requires devices to establish their safety and demonstrate probable benefits to a limited population. However, this pathway requires the absence of comparable devices and may have associated restrictions on profits earned through its sale.

While the EU does not have a direct counterpart legislation for orphan devices, the MDCG has recognized the need for separate pathways for such devices by issuing dedicated guidance. As per the MDCG guidance, an orphan device is specifically intended to treat, diagnose or prevent a disease or condition affecting not more than 12,000 individuals in the European Union per year and having no comparable alternatives. The move aims to simplify market approval for orphan devices amid the strict pre-market clinical evidence requirements of the MDR.

EU MDR/IVDR

The EU MDR (Medical Device Regulation 2017/745) and IVDR (In Vitro Diagnostic Regulation 2017/746) established a comprehensive certification framework requiring manufacturers to demonstrate compliance with General Safety and Performance Requirements (GSPR) before placing devices on the European market. The process culminates in CE marking, which indicates conformity with EU regulations.

- 1 Pre-Application Phase** involving contacting a Notified Body for conformity assessment and preliminary verification to classify the device. Complete information minimizes delays and enables accurate quotation preparation.
- 2 Formal Application** including Quality Management System (QMS) documentation per Annex IX or technical documentation per Annex X requirements.
- 3 Conformity Assessment Procedures**
 - For Class I Devices (Non-sterile, non-measuring): Self-certification through EU Declaration of Conformity without NB involvement.
 - Higher Risk Devices: Require NB assessment through one of three routes:
 - **Annex IX:** QMS assessment combined with technical documentation review
 - **Annex X:** Type examination followed by production quality assurance
 - **Annex XI:** Product conformity verification.
- 4 Technical Documentation Requirements** include device description, labeling information, design and manufacturing details, GSPR compliance evidence, benefit-risk analysis and verification/validation data under MDR (Annex II). Under IVDR (Annex II & III), device specifications, performance evaluation reports, analytical and clinical performance data and post-market surveillance plans must be included.
- 5 Special Procedures for certain High-Risk Devices** require expert panel consultation before certificate issuance. Competent authority consultation is mandatory for companion diagnostics, devices with ancillary medicinal substances and devices made from systemically absorbed substances.

- 6 Certificate Issuance** follows successful conformity assessment and the NB issues CE certificates enabling manufacturers to:
 - Prepare EU Declaration of Conformity
 - Affix CE marking with NB identification number
 - Register devices in EUDAMED (when fully functional)
- 7 Post-Market Obligations** encompass annual QMS audits, assessment of Periodic Safety Update Reports (PSURs) and ongoing monitoring of post-market performance. Reporting of serious incidents and corrective actions through national competent authorities and eventually EUDAMED is mandatory.



RA's Evolving Role in Lifecycle Compliance

Regulatory Affairs in medical device organizations has evolved from a primarily submissions-focused discipline into an end-to-end lifecycle compliance function that integrates design, production, post-market surveillance and perpetual improvement.

The role of RA begins right at the conception of the device, ensuring that the design inputs remain compliant. In an instance of compliance gap, a global OEM with an urgent FDA-mandated recall engaged LTTS' QARA experts to complete DHF remediation within a three-month window. LTTS assembled a specialized team to review tens of thousands of design documents, perform gap analyses and implement a remediation plan that secured regulatory compliance and cleared the way for product requalification. Additionally, the OEM was able to identify all possible flaws in the design process while incurring minimal burden on their resources.

During the post-market phase, RA leads complaints handling and remedial action in conjunction with the engineering and service teams. When one of the world's largest conglomerates producing a wide range of medical and healthcare devices faced a voluntary recall under

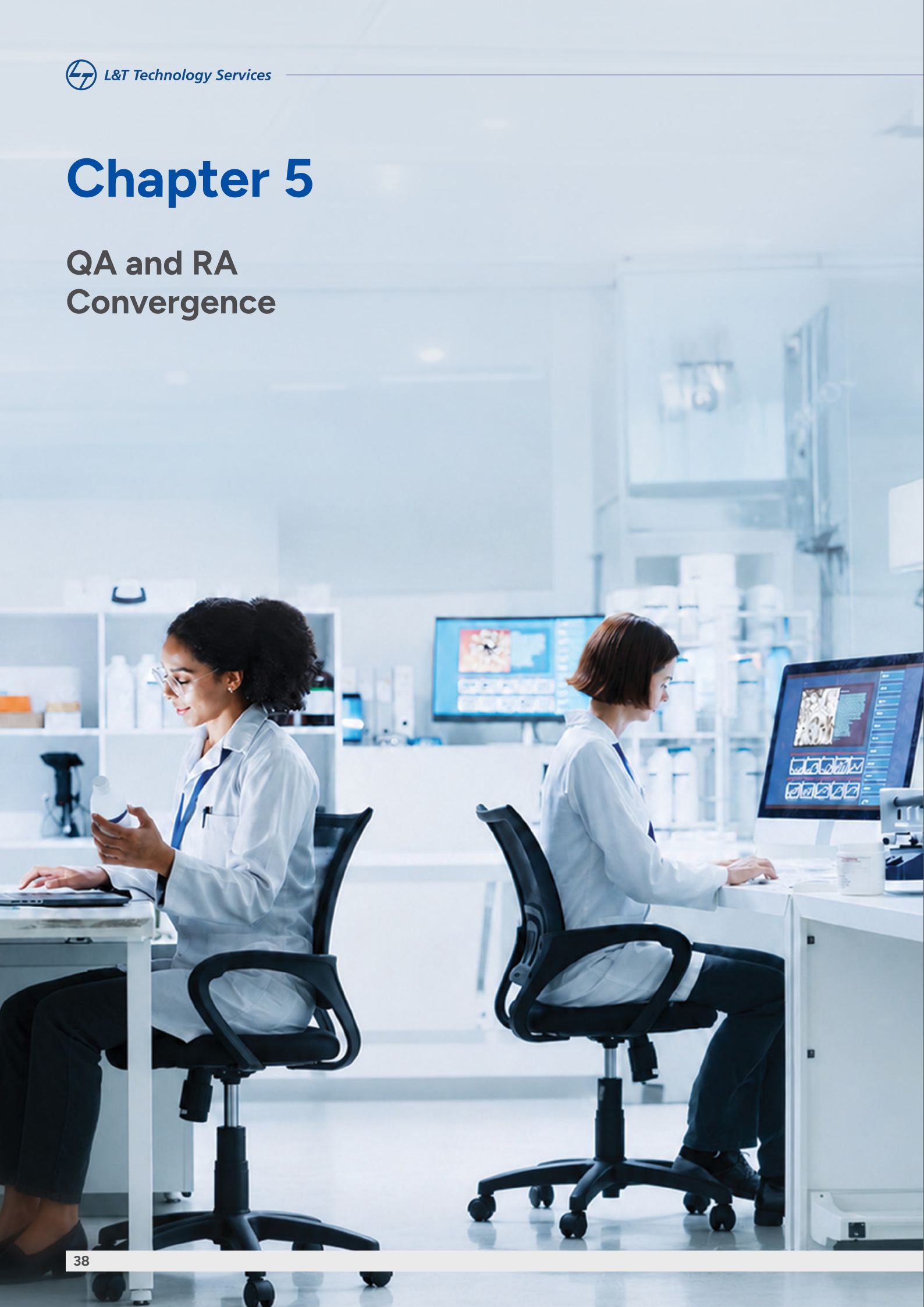
FDA's Section 21 CFR 7, they called upon LTTS to review a staggering **2,40,000 complaints** for submission to the USFDA. To tackle the stringent timeline, LTTS had to come up with a strategic approach. LTTS' QARA team undertook the training and onboarding of **70 offshore team members** in just **two days**. Along with dedicated regulatory affairs and medical device subject matter experts and mentors, the team delivered 100% success across all the required metrics within a short turnaround time, while maintaining complete transparency.

RA also drives data-driven maintenance and trend analysis. In another instance, LTTS successfully reduced the time in failure reporting for a customer, thereby reducing maintenance efforts and enhancing workflow efficiency. In this case, the client's legacy failure reporting database was facing challenges due to the large number of the failure codes generated and their genericness. The team at LTTS implemented a New Failure code Architecture (NFCA), reducing the number of **failure codes** from **300** to **75-100**. This resulted in person hours being saved for the customer's field engineers leading to **1,40,000 complaints** being redressed in the **first month** of deployment of the NFCA alone.



Chapter 5

QA and RA Convergence



RA secures legal market access for the product, while QA guarantees consistent adherence to quality standards during production.



Regulatory Affairs (RA)	VS	Quality Assurance (QA)
Adhering to external legal requirements and regulations	Primary Focus	Meeting internal standards for quality and compliance
Acquiring and upholding necessary market authorizations	Main Objective	Averting product flaws and guaranteeing consistent output quality
Outward-facing: Engaging directly with official regulatory bodies	Primary Orientation	Inward-facing: Coordinating with manufacturing, Quality Control, and R&D teams
Creating strategies and drafting documentation for submissions; Following established regulatory instructions; Formulating and filing Marketing Authorization Applications (MAAs)	Core Responsibilities & Skills	Verifying Good Manufacturing Practices (GMP) compliance; Conducting audits and validating production processes; Reviewing and authorizing batch documentation prior to product release

Merging QA and RA Throughout the Device Lifecycle

Quality Assurance and Regulatory Affairs have unique responsibilities, but their close collaboration in every step of the device lifecycle, including New Product Development (NPD), validation, post-market surveillance (PMS) and change control, is now critical to speed up approvals, improve the safety of products and maintain compliance.

QA provides the formal processes that embed quality into products and RA translates shifting regulations and ensures market access. Convergence exists where both functions work on common artifacts (risk files, design dossiers, validation protocols, PMS plans and change records) in a way that the evidence produced by QA meets the data required by regulators.

Convergence During New Product Development (NPD)

Early regulatory influence on design controls: RA defines intended use, risk class and target markets, while influencing R&D on the extent of clinical and bench evidence needed. QA then infuses these regulatory requirements into design plans, traceability matrices and gated reviews so that compliance is 'designed-in,' and is not an afterthought.

Unified risk management: QA-maintained ISO 14971 risk files are the basis for regulatory submission. RA ensures that risk-benefit wording conforms to FDA and EU MDR expectations to avoid rework when dossiers are assembled.

Iterative documentation: Agile teams depend on QA to impose document control (specifications, DHF/DMR), while RA ensures that every iteration remains in conformance with the selected regulatory path to avoid last-minute surprises.

Convergence in Process and Software Validation

Protocol development QA develops Installation/ Operational/Performance Qualification (IQ/OQ/PQ) or software validation protocols. RA ensures that acceptance criteria align with regulatory guidance and that data formats are compatible with submission requirements.

Execution oversight QA reviews test execution to ensure completeness and integrity of data, while RA ensures that any deviation is evaluated for regulatory impact and properly justified in the technical file.

Evidence packaging Validation reports direct input to FDA 510(k)/PMA or EU Annex II technical documentation, preventing redundant testing.

Convergence in Post-Market Surveillance (PMS)

Unified PMS strategies During PMS, QA has ownership of complaint management and CAPA processes, while RA supplements reporting triggers and timelines required by FDA MDR, EU MDR/IVDR PSUR and other vigilance regulations.

Why Convergence Matters

In the chart below, we illustrate the shared outcomes of QA and RA convergence across different stages of the product lifecycle:

Lifecycle Stage	QA Deliverable	Lifecycle Stage	Lifecycle Stage
NPD	DHF, risk matrix	Regulatory pathway, predicate/device classification	More accurate, faster-first-time submissions
Validation	IQ/OQ/PQ reports, software validation	Module-specific guidance alignment	Evidence accepted without retest
PMS	Complaint trending, CAPA logs	PSUR, vigilance reports	Real-time monitoring and continuous improvement of safety
Change Control	Impact-assessed, closed change records	Updated filings, agency communications	Compliant, traceable product development

Analytics on data Trending dashboards managed by QA supply RA with real-world evidence that supports periodic safety update reports and renewal filings.

Feedback loop Design or labelling improvements are driven by field data. QA governs the CAPA; RA decides if updates need filings or NB notifications.

Convergence in Change Control

Cross-functional evaluation Engineering logged change requests flow to QA for risk and validation effect analysis and at the same time, to RA for regulatory effect reviews (e.g., 'significant change' according to MDR).

Aligned approval structure QA ensures product quality and QMS integrity; RA ensures filing strategy and informs authorities when necessary.

Post-implementation verification QA ensures implementation success while RA maintains registrations, declarations of conformity, or FDA listings, keeping records audit-ready.

Role of DHFs, TFs and CERs

DHF

The goal of the DHF is to maintain a record of all the actions and steps involved in designing a medical device. The FDA mandates every manufacturer to establish and maintain a Design History File (DHF) for each type of device. According to FDA 21 CFR 820.30(j), the DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

The 2016 update of ISO 13485 requires organizations to establish 'design and development files'. To converge to the ISO standards, the QMSR (effective 2026) also replaces the term DHF along with other documents, including the Device Master Record (manufacturing and testing records) and the Device History Record (archival records of manufacturing), with a single Medical Device File encompassing all requirements.

The DHF's outputs and processes serve as the foundational source of design and manufacturing information for the Technical File. It is where the initial risk management and design control data are generated.

Technical File

The EU MDR requires an organization to maintain a technical file for a period of at least 10 years¹⁹ after the market launch of the last EU-certified device for review by the competent authorities. The manufacturer should be able to service the technical document or its summary upon request of the authorities during the above period.

The Technical File relies on the DHF for core design and manufacturing data. It also directly references or incorporates the CER to provide evidence of the device's clinical safety and performance.

CERs

In the EU MDR, clinical evaluation is prescribed as a part of the technical documentation, under Annex XIV, including its planning, continuous conduction and documentation. The manufacturer is required to maintain a Clinical Evaluation Report (CER) to demonstrate conformity

with the general safety and performance requirements. Clinical evaluation is mandatory for all medical devices (except custom-made devices) to obtain a CE (Conformité Européenne) marking, which allows them to be sold in Europe.

The CER provides the clinical evidence that demonstrates the device's safety and performance claims, which is a required element of the Technical File for market approval. The CER may also guide updates to the DHF, particularly concerning risk management.

STED

The GHTF in 2008 had established the guidelines titled Summary Technical Documentation (STED) as a subset of mandatory technical documentation. This abridged version contains documentation necessary to present adequate evidence to the RA/CAB (Regulatory Authorities/ Conformity Assessment Bodies) that the device is in conformity with the Essential Principles²⁰. The STED enables manufacturers to harmonize documentation with international requirements, resulting in wider access and unlocking of cost efficiencies.

Cross Functionality in QARA Governance

- ISO 13485 places the responsibility for effective quality management system on the top management. However, the organization is required to determine the QMS processes and its application throughout the entire organization. Cross-functional communication is prescribed to disseminate regulatory requirements and QMS requirements across the organization.
- FDA requires that the quality policy is "understood, implemented and maintained at all levels of the organization."
- The MDSAP audit model brings together QA, RA and manufacturing under one audit scope. It enforces a single audit team reviewing design controls, purchasing, production and regulatory submissions in one review.

¹⁹15 years in the case of implantable devices
²⁰Essential Principles of Safety and Performance of Medical Devices (SG1/N020 of June 30, 1999) was introduced by the GHTF initially in 1999. It was later updated in 2005 to include in vitro devices before being adopted by the IMDRF and updated in 2012 and finally in 2024.

Chapter 6

Building a QARA-Centered Organization



LTTS supports top 10 global MedTech OEMs, delivering QARA programs with 90% automation and 80% lower certification effort.

The QA-RA convergence that we have examined naturally leads to a couple of fundamental questions—how should organizations structure themselves to maximize QARA value and why is it necessary for MedTech companies to develop QARA-centered organizational capabilities?

Let us first look at the latter question. As a value driver, quality can have a direct impact on unlocking cost efficiencies. Product recalls can lead to billions of dollars in spending for the manufacturers and in some cases, loss of reputation and market share. Manufacturers are adopting a risk-based approach for quality management systems, aligning with the ISO requirements and ensuring design and building accuracy for life-critical machines.

The proliferation of connected devices has encouraged widespread incorporation of predictive maintenance protocols. Manufacturers are leveraging risk-based approaches like Design in quality, Failure Mode and Effects Analysis (FMEA), Digital Twins, Traceability and documentation, building accuracy into life-critical machines. Process validation protocols now involve detailed software-based frameworks to ensure installation qualification, operational qualification, performance qualification and revalidation. This forms the foundation of a QARA-centered organization.

A defining feature of a QARA-centered organization lies in embedding quality into its very DNA, i.e., the culture of the organization. According to the Medical Device Innovation Consortium (MDIC), a culture of quality in medical device organizations is one that ‘transcends compliance and serves as a clear competitive differentiator.’ This highlights the contrast between the conventional view and the contemporary view of quality as discussed earlier.

QARA-centered organizations can be characterized by the following-



Strategic Integration

QARA functions are embedded at the strategic planning level and not relegated to downstream compliance activities. McKinsey’s research on ‘smart quality’ establishes a strong correlation between adopting a quality culture and quality performance.²¹



Cross-functional Ownership

Rather than quality being the sole responsibility of quality departments, QARA-centered organizations ensure that quality metrics, risk assessments and regulatory considerations are integrated into every role’s responsibility. McKinsey also emphasizes that ‘everyone owns quality,’ concluding that ‘quality outcomes improve when non-quality employees are involved in quality work.’



Predictive Compliance

These organizations have transitioned from reactive ‘firefighting’ to predictive compliance models using AI and data analytics. Dynamic data strategies are enabling organizations to proactively mitigate regulatory risks by adjusting processes before issues arise.

In order to instill a culture of quality within the organization, these values must be aligned with the leadership development of the human capital while encouraging process ownership. Let us understand how these forces shape the culture of a QARA-centered organization.

²¹<https://www.mckinsey.com/industries/life-sciences/our-insights/embedding-smart-quality-culture-and-capabilities-in-the-organization>

Leadership Alignment

Commitment of the Top Management

As mentioned in the 3rd chapter of this book, ISO 13485:2016 and EU MDR requires top leadership to actively oversee and accept responsibility for QMS effectiveness. Leadership must ensure that QMS aligns with the company's goals, regulatory obligations and evolving product portfolios.

In a 2021 survey conducted by the MIDC, 90% of organizations reported that their leaders actively promote quality across processes. A similar survey from ASQ and Forbes Insights from 2014 found that only 60% of the organizations reported that their management unequivocally supported quality values. The notable increase in the role of top management in defining and sustaining quality culture in the organization is evident from these two studies.

Establishing Quality Values and Vision

Effective leadership begins with establishing a clear quality policy that reflects the company's mission and commitment to product safety, customer satisfaction and regulatory compliance.

Leading organizations invest in leadership development programs that help leaders successfully embody the values of the organization. When leaders walk the talk by consistently prioritizing quality in decision-making, employees at every level follow suit, creating an organizational alignment and momentum in the same direction.

Breaking Down Organizational Silos

One of the challenges of establishing quality culture arises at the middle management level, where quality initiatives often struggle to gain traction. This problem is addressed through cross-functional collaboration with clearly defined responsibilities across departments. QARA professionals, therefore, must act as facilitators instead of enforcers. Each function needs to understand its quality responsibilities throughout the product lifecycle.

Process Ownership

Building a quality culture that is sustainable means turning individual employees into product outcome owners who feel personally responsible for the results. Research from leading organizations proves that process ownership—where employees own responsibility for quality in addition to their immediate job tasks, plays an important role in constructing world-class quality systems.

Clear Accountability and Recognition

Leading medical device companies build ownership by defining specific, measurable quality targets linked to personal performance reviews. This extends beyond the traditional model of inspection-based quality control and aligns with integrating quality considerations into everyday decision-making. Strong quality cultures in companies ensure that production targets and quality metrics complement each other instead of competing with one another.

Training and Development

Comprehensive development and training programs are the most important factors in motivating employees to embrace process ownership. When employees understand the purpose that their work serves, their emotional investment increases, leading to improved quality outcomes.

Continuous Improvement Mindset

Product ownership in QARA-centered organizations includes recognizing that every failure is an opportunity for improvement. Organizations deploy cross-functional teams to identify root causes and implement effective corrective and preventive actions that prevent recurrence. This systematic approach to problem-solving becomes embedded in the organizational culture rather than being treated as isolated incidents.

Our Approach

Over three decades of expertise in medical product development and a robust R&D infrastructure drive LTTS' quality culture, which is reflected throughout the organization. Our diverse range of solutions across various segments has delivered consistent customer satisfaction for some of the biggest players in the healthcare industry and resulted in over 100 successful product launches and over 50 patents to our credit.

Core QARA Organizational Design

LTTS provides comprehensive QMS organizational design services, including

Gap Assessment

Evaluating current organizational structures against regulatory requirements

Quality System Design and Deployment

Creating integrated quality frameworks across global operations

QMS Harmonization and Integration

Streamlining quality processes across multiple sites and geographies

Work Instructions Development

Designing QMS tools and processes for organizational implementation

SaMD/SiMD Process Integration

Specialized capabilities for SaMD and SiMD organizational frameworks, helping customers integrate software quality processes into their broader QARA organizational structure.



Integrated Change Management Approach

LTTS employs a holistic advisory methodology combining—

Process Excellence

- Gap assessment methodologies for existing organizational structures
- Risk-based change management aligned with regulatory requirements
- Continuous improvement frameworks for sustainable transformation

Technology Integration

- Digital engineering solutions for process optimization
- AI-driven analytics for change impact assessment
- Automated compliance monitoring for regulatory adherence

People and Culture Transformation

- Cross-skilling and upskilling programs for organizational capability building
- Culture change initiatives supporting quality-first mindsets
- Leadership development programs for change champion identification

Our advanced change management capabilities are reflected as we help medical device manufacturers transition to PFAS-free products.

Per- and poly-fluoroalkyl substances (PFAS) are a class of synthetic chemicals, which are used by various industries and are found in a large number of consumer products. However, concerns over their potential harmful effects and virtually indestructible nature have led to impending regulations and restrictions on these chemicals from the EU and other jurisdictions.

Our advanced change management capabilities are reflected as we help medical device manufacturers transition to PFAS-free products.

- Assisting in the preparation of comprehensive public comments in line with the European Chemicals Agency (EHCA) guidelines or other specific regulatory requirements
- Collecting further information as required by the EHCA, including social and economic impact assessments and recycling or disposal mechanisms
- Partnering with specialized and accredited test labs to determine the concentration of PFAS in medical devices
- Conducting feasibility analysis to identify and evaluate alternative materials and how they impact device design and performance while ensuring compliance
- Ensuring regulatory compliance throughout the product lifecycle, including assessment, documentation and filing of regulatory documents in relation to changes in materials, components or designs of the product.

Our proven track record of successful change management includes identification of hazardous chemicals in surgical devices for a European manufacturer. Our team performed BoM scrubbing, gathered information from suppliers and manufacturers, coordinated for CoC, tested the product for compliance, generated ECOs, modified the drawings and suggested replacement parts without compromising functionality.

As a result, we were able to deliver EU's REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) compliance while ensuring product safety and streamlining documentation and coordination processes.

For another customer, we undertook obsolescence management by redesigning obsolete boards and other components in a urine monitor to make it RoHS compliant. Our team of experts conducted gap analysis and made design modifications for compliance. We performed EMI/EMC, safety testing and alarm testing, replacing the EL backlight with LED backlight and adding a communication module. Our efforts resulted in improved device performance and efficiency along with RoHS compliance without altering the form factor of the existing device.

In the healthcare industry, PFAS have long been used due to their heat resistance, lubrication and biocompatibility. It is important to recognize, however, that not all PFAS are identical. Out of a group of 15,000 chemicals, typically small molecules are responsible for the known adverse effects and end up in human drinking water, according to the FDA.

Given the evolving nature of research around the adverse effects of these chemicals, it is imperative for medical device manufacturers to ensure that their devices are compliant with the regulatory requirements for safe use of PFAS and minimize the use of potentially harmful PFAS.

LTTS offers comprehensive solutions for medical device manufacturers to assist in their transition to PFAS-free and PFAS-compliant products. Our services include—

- Identification and confirmation of PFAS presence in the product portfolio
- Determining the type and extent of PFAS usage in medical devices via chemical composition analysis
- Delivery of actionable insights from the analysis of data collected from the stakeholders

LTTS supported a client in assessing and converting more than 10,000 components used in microbiology and hematology instruments to comply with RoHS 3.

LTTS supported a client in assessing and converting more than 10,000 components used in microbiology and hematology instruments to comply with RoHS 3.

By performing detailed BOM scrubbing, documenting qualified alternates and coordinating closely with suppliers, LTTS enabled robust obsolescence management, simplified documentation workflows and successfully delivered RoHS 3 compliance for the client.

Our service scope in change-management includes—

- Evaluation and conversion/upgrading of products to the latest EU Regulations
- BOM scrub and gap analysis followed by compliance information gathering (CoC)
- Report hazardous substances to the SCIP (Substances of Concern in articles as such, or in complex objects (Products)) portal when present beyond the allowable limit
- Identifying drop-in replacements for Non-compliance/EOL parts
- Alternate solutions and Impact Analysis
- Document update (Drawing/BOM/Scheme)—through change management (ECR/ECO)
- Testing support:
 - Material compliance testing for RoHS 3 and REACH through tie-ups with testing agencies (such as TUV)
- Additional compliance services:
 - Conflict minerals, CA prop 65, China RoHS, WFD



Chapter 7

LTTS Tools and Accelerators



QARA-centered organizations require sophisticated tools and accelerators to deliver on their strategic promise. At LTTS, these are not standalone point solutions but the applied expression of Engineering Intelligence – AI embedded across the engineering and compliance lifecycle. AiCE brings intelligence to clinical evaluation; AiKno® to complaint handling and document optimization; EvQUAL to validation and test; DigiServe and uALM to service and lifecycle management; and i3PDS® to digital-twin-based prediction. Each addresses a distinct QARA challenge, but together they form a single EI toolkit that turns quality and regulatory work from a manual, reactive burden into a predictive, engineered capability. The pages that follow explore each in turn.

AiCE

As mentioned earlier, MedTech organizations are required to prepare a Clinical Evaluation Report by the EU MDR for approval of medical devices. Within this process, clinical literature review has emerged as a critical challenge, given its time-consuming, labor-intensive and error-prone nature. LTTS leverages its Artificial Intelligence Clinical Evaluation (AiCE) solution to improve the speed, efficiency, accuracy and cost-effectiveness of clinical evaluation research.

AiCE's successful contribution has resulted in a reduction of opportunities for errors by 30%, increased CER approval for equipment, improved productivity by 30% and enabled swift and regulatory-compliant decision-making.

How Does AiCE Function?

The tool scans existing literature, clinical experience and clinical trials to identify relevant clinical data. AiCE then articulates the conclusion based upon the data collected.

AiCE's other features include:

- Bias minimization
- Algorithm customization
- Auto-translation of sources into other languages
- Automatic screening of literature and highlighting 2-3 crucial sentences under different methods of screening.
- Second pass screening on full-text articles
- PRISMA chart
- User role-based access management
- Pre-set criteria customization
- Project creation and workflow management
- PICO entity recognition
- Pre-set criteria customization



LTTS Supplier Quality Engineering Framework

Medical device companies must follow strict rules from the US FDA and ISO standards when working with suppliers. Despite having dedicated teams for managing suppliers, most companies still struggle to meet all the regulatory requirements. Companies need assistance in finding suppliers, categorizing associated risks and validating and onboarding them to the ecosystem.

LTTS Solution

LTTS created the SQEFM framework to solve these problems. It covers four main areas:

Finding and Choosing Suppliers

How to pick the right suppliers

Getting Suppliers Ready

How to qualify and bring new suppliers into the system

Watching Supplier Performance

How to monitor if suppliers are doing good work

Managing Supplier Risks

How to handle problems and end relationships when needed

Benefits of SQEFM

- Better supplier performance
- More efficient operations
- Less risk
- Cost savings

Our Deliverables

- Approved supplier lists and risk checks
- Supplier audits (in-person and online)
- Help with supplier agreements
- Management of problems and fixes
- Better supplier relationships
- Improved compliance with regulations
- Automated reporting dashboards to track progress

The framework helps medical device companies meet regulatory requirements while working more efficiently with their suppliers.

AiKno®

LTTS' award winning proprietary cognitive intelligence framework, AiKno®, delivers a range of solutions, including predictive maintenance and document optimization. The advanced system is also able to extract metadata from complex documentation, digitalize physical data and undertake auto corrections without any need for re-engineering.

How Does It Work?

AiKno® developed AI framework includes



Machine Learning - advanced learning algorithms for greater effectiveness



Image Processing - extraction and analysis of visual content



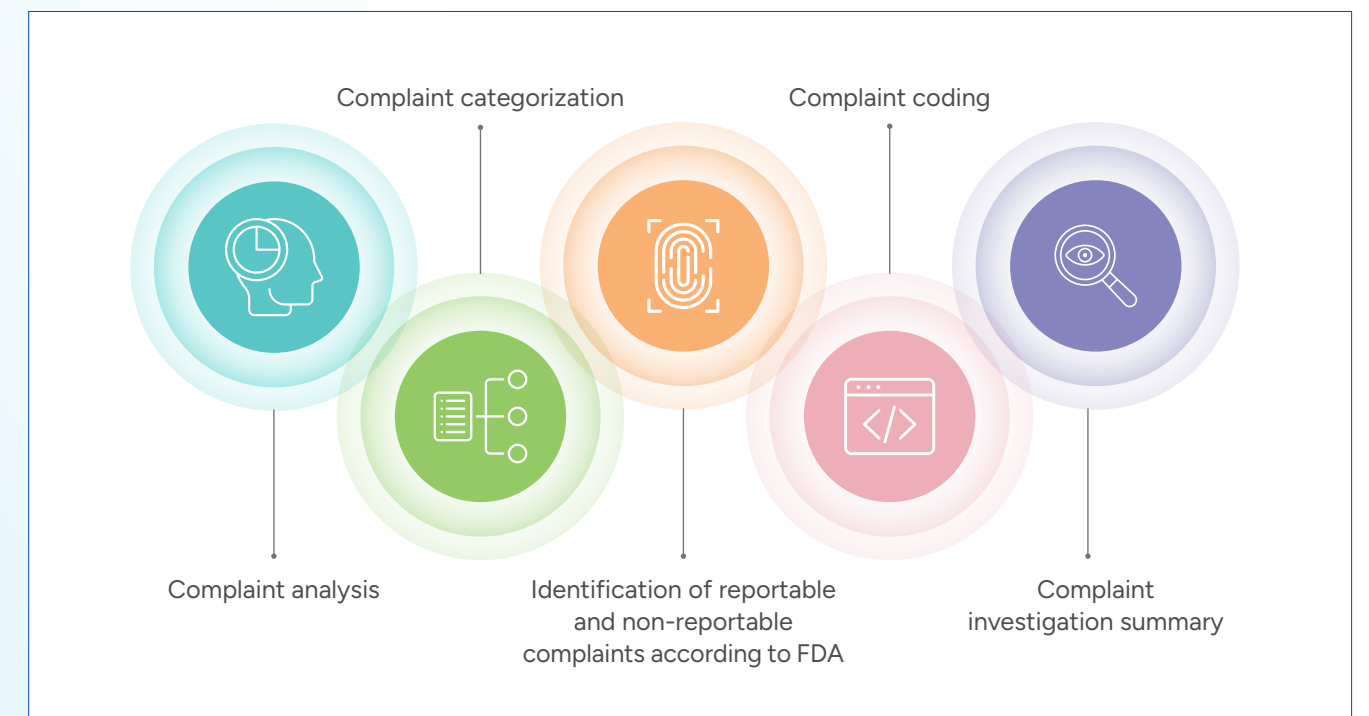
Natural Language Processing - enhanced and customized human-machine interactions

Our AiKno® tool was able to analyze unstructured logs in ultrasound machines for a client and convert them into a structured format. AiKno® is able to detect erroneous logs using machine learning and parse unstructured data using automated algorithms, streamlining the troubleshooting process for medical devices. LTTS was thus able to help the client identify log patterns, predict the fault type and implement corrective action.

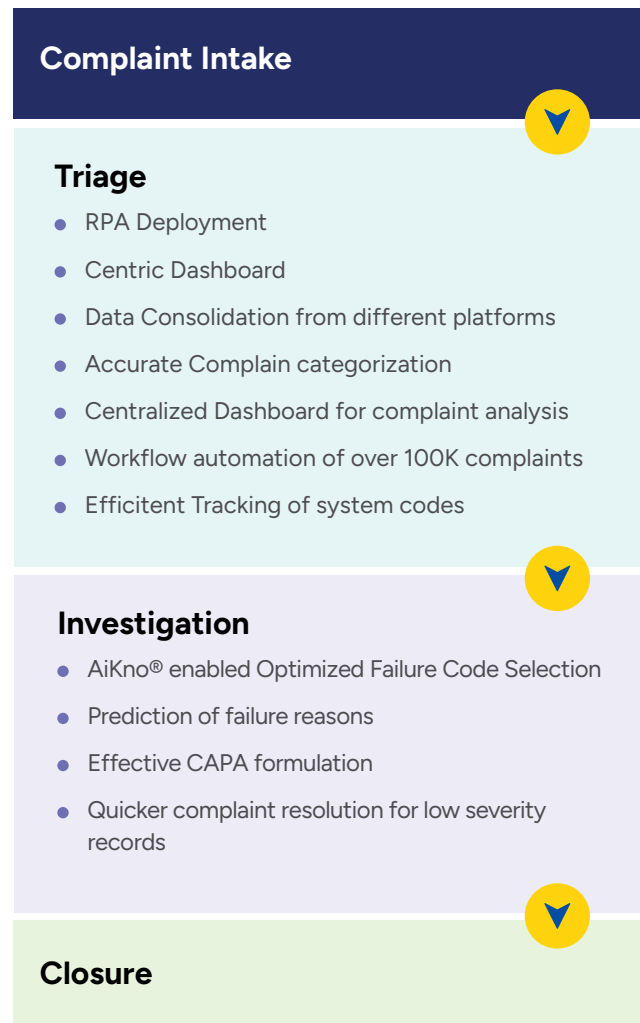
In another instance, a multinational healthcare and technology conglomerate required a quality and complaint management system that would conform related functions across its global operations and improve efficiency and productivity while adhering to compliance requirements and maintaining customer satisfaction.



Our team stepped in with a multi-faceted approach involving:



LTTS' combined Robot Process Automation and AiKno® deployment delivered the following framework for the customer for effective complaint redressal:



The combined AiKno® and RPA deployment can help the client achieve:

- 15% improvement in overall productivity
- 10% improvement in quality of deliverable resulting in cost optimization

LTTS also brings extensive expertise in building and deploying enterprise-grade RPA solutions using UiPath, Automation Anywhere, Blue Prism and Python. These platforms have helped leading global companies streamline critical operations, including data extraction, data classification, complaint handling and quality inspections.



EvQUAL

With the rapid proliferation of digital devices, there is a growing imperative for an advanced test strategy to reinforce product validation. Our solution—EvQUAL—presents an industry-agnostic platform for remote test orchestration to eliminate faults and project delays. Our EvQUAL platform offers:

Remote Test Orchestration

- Remote and Multi-Geo, Cloud-enabled Test Orchestration, Management and Control
- Manual and Automation Testing integrated with CI/CD pipeline

Scalability and Performance Precision

- Cloud enabled Master-Agent approach to scale parallel test executions
- Accurate validation even at high-scale testing

Reusable and Customizable Components

- Extensive test bank, keywords and test scripts to reduce development time
- Reusability and easy maintenance of test scripts

Modularity

- Loosely Coupled and Modular Tech Stack agnostic components
- Easy API based integration with existing tools and Tech stack/frameworks

AI-driven Testing

- AI/NLP driven auto-script generation and self-heal against UI changes
- Smart Continuous Testing with relevant test selection and distribution

**Our solution—
EvQUAL—presents
an industry-
agnostic platform
for remote test
orchestration to
eliminate faults
and project delays.**

Value Delivered

- Cloud-mediated remote testing across geographically distributed test infrastructure delivers up to 80% higher utilization of test assets
- A repository of existing scripts and keywords, combined with a platform-agnostic smart script capability, saves 30% effort in script development
- Enterprise-scale testing with on-demand parallel executions reduces test cycle time by 20%.

DigiServe



DigiServe is aimed at solving the problems of

- Inconsistent service data availability
- Non-availability in service data availability
- Lack of visibility, consistency or availability of service content
- High service delivery cost



The End-to-End Service Lifecycle Management (SLM) framework facilitates

- Material Traceability across the product lifecycle
- Service Part Management
- Service Info Management using AI/ML
- IoT enabled field equipment monitoring for failure prediction



Business value delivered

~40%

Customer complaints resolution time reduced

99%

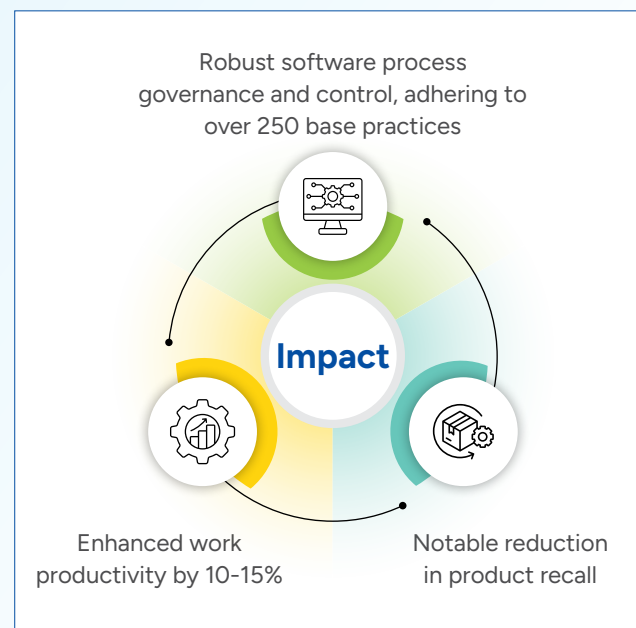
First time fix rate

30%

Service costs reduced

uALM

Our Unified Application Lifecycle Management deploys and maintains robust governance and control of the software development lifecycle process. In medical device manufacturing, the uALM framework takes care of complex mechatronics data management across the product development lifecycle. In addition, it facilitates Compliance Data Management and reporting in line with standards such as CFR 21 and ISO 14671.



AICH

In MedTech, customer complaints are critical quality and safety signals that require timely, accurate, and compliant resolution. Yet, managing complaints across fragmented legacy systems and global platforms can be complex and resource-intensive.

Consequently, LTTS developed AICH, an AI-enabled complaint-handling solution combining domain expertise, RPA, and a proprietary AI engine. AICH consolidates complaints from multiple platforms, automates classification, and provides a unified dashboard for efficient monitoring and resolution.

Powered by AIKno, the solution supports investigations by predicting failure codes, automating root-cause analysis, and generating Kappa recommendations. This enables faster resolution, improved decision-making, and reduced human intervention.

AICH delivers 15-25% productivity improvement, 10% better quality outcomes, and up to 95% validated AI accuracy. It also reduces complaint resolution time from eight days to three days, a 62% improvement in turnaround time, while enabling timely regulatory submissions and stronger quality management.

By accelerating complaint resolution and delivering 20-25% overall productivity gains, AICH helps MedTech organizations enhance quality, strengthen compliance, and ultimately drive safer, smarter outcomes for patients.

A digital twin can be used to analyze data collected from various interpretations to deliver 'what-If' scenarios, behavioral insights, predictions and deep visualizations.

Innovation Spotlight

LTTS Digital Twin

A digital twin is a virtual replica of a product, system, or operations in a digital environment. It is used to simulate real-life scenarios, which can help to better understand the behavior of the object in diverse conditions. A digital twin can be used to analyze data collected from various interpretations to deliver 'what-If' scenarios, behavioral insights, predictions and deep visualizations.

According to McKinsey & Company, over two-thirds of C-suite executives across the world are already exploring digital twins to improve operational efficiency and reduce errors. The rapidly growing adoption of the technology indicates a market growth of around 60% annually till 2027, when it will reach \$73.5 billion.²²

Cloud-enabled digital twins enhance operational flexibility, scalability and security, cutting downtime by 30% and boosting productivity by 20%.

²²<https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-digital-twin-technology>

LTTS leverages its i3PDS® (Integrated 3D Plant Digitization Services) platform to help organizations build digital twins of plant assets using pragmatic principles.

Our capabilities span smart 3D modeling, 2D digitization, laser scanning and the development of 4D and 5D services. The platform enables information of any type, from any source, to be stored in a secure cloud environment. It also supports software rationalization, allowing resources to scale flexibly based on project needs.

Our innovative digital twin for line operations can offer invaluable insights in predictive analysis of critical failures and root-cause analysis. The system helps identify First-of-Fault points resulting in avoidance of critical equipment failures before they occur. With a 3D environment for testing and a live feed for critical assessment, maintenance teams can plan accordingly, addressing issues in scheduled downtime instead of during unexpected breakdowns.

Users can implement the digital twin solution over the cloud or on-site close to their operations. With cloud-based solutions, customers can enjoy additional flexibility, accessibility, scalability and security in their operations.

Business Impact

LTTS' digital twin solution offers enhanced quality and productivity resulting in-

Up to
30%

Improvement in Mean Time to Diagnose (MTD) and Mean Time to Failure (MTTF)

20%

Increase in Critical Equipment Time

Up to
2%

Increase in Right First Time



Chapter 8

LTTS' differentiators demonstrated through examples



Spotlight



LTTS labs maintain globally recognized certifications including ISO 9001, AS 9100D, and ISO 13485

LTTS' journey in the medical products domain began in 1987. Nearly four decades later, the team has accumulated expertise in conceptualization, design, development, compliance and commercialization of medical products. Leveraging this depth of experience, the team was able to convert a three-line brief, along with its interdependencies and complexities, into actionable design inputs. These are core domain credentials that a typical software vendor cannot match. Our deep medical-domain knowledge has ensured that we remain a leading player in integrated hardware, embedded systems and software development.

LTTS' tools and accelerators come to life through real-world applications. Next, we take a look at some of the examples, which highlight how we stand apart in our value delivery for medical OEMs across the globe.

Centers of Excellence (CoEs)

LTTS' multiple Centers of Excellence focus on specific technologies and industries, serving as global hubs for innovation, research and development. Our CoE knowledge helps us provide innovative solutions to our clients.

When a major healthcare manufacturer required labeling solutions across its global operations in various languages for existing as well as new products, LTTS relied on its Centre of Excellence approach for quick and efficient results.

We delivered end-to-end labeling solutions in this case, reducing cycle time and costs while ensuring consistency, accuracy and quality. Our innovative approach involved—

LTTS' differentiators demonstrated through examples



CoE Expertise

Our team leveraged their CoE knowledge to deliver an adaptable and resilient solution



Quick Turnaround

Our innovative NPD labelling procedure is capable of ensuring quicker time to market for years to come



Innovative Labeling

We explored various applications, including a software-driven display for labelling, aiming to align with the Device Master Record specifications and enhance the labeling process while ensuring full regulatory compliance



Linguistic Diversity

Translation in every required language along with modern writing systems was delivered while maintaining accuracy



Optimum Compliance and Security

We simplified the labelling process while making it more secure and compliant with the regulatory requirements

Value Delivered

- Accelerated Time to Market by 40%
- Reduction in Complaint Resolution time and footprint by 40%
- Enhanced Operational Efficiency by 30%
- Cost Reduced by 35%
- Improved Revenue Generation and faster ROI

Connected Health

Connected Devices

LTTS helps leading MedTech companies re-imagine their solutions by integrating next-generation platforms, which facilitate device monitoring, management and monetization. Our connected platform offers a one-stop solution for tracking and monitoring multiple devices across multiple facilities. Predictive maintenance and usage pattern analytics drive continuous improvement.

LTTS connected platforms find use in—



Surgical devices -
Connectivity Platforms



Cloud based Remote Diagnostics -
Predictive Maintenance



MRI -
Data based Selling



Medical Modalities -
Analytics and Business Intelligence Solution



Our next-gen platforms for device monitoring, management and monetization facilitate—

- Tracking and monitoring of multiple devices across multiple facilities via a single platform
- Servitization of assets and central usage patterns
- Predictive maintenance and analytics on usage patterns

We have helped global manufacturers in the implementation of the Digital Imaging and Communications in Medicine (DICOM) Standard. The DICOM standard is followed by hospitals and medical institutes for handling, storing, printing and transmitting patient information related to medical imaging. We assisted our customers with significant cost savings using—

- DICOM Imaging Modality Equipment interaction with HIS or RIS
- DICOM Echo to verify network and connectivity
- DICOM Worklist to retrieve the patient records from HIS Updating the patient procedure details and MPPS details to HIS or RIS
- DICOM Imaging Modality Equipment interaction with PACS Server
- Storage commitment for patient-acquired Images and Structured Reports to the PACS/Image Server
- Sending Patient Query or Study Root level Information to PACS Server
- Retrieving the queried DICOM Images and information from PACS Server
- Displaying the retrieved DICOM 2D Images and datasets in Workstation Copying DICOM Images to CD and USB
- Printing of DICOM Images
- DICOM Messages logging details.



Connected Hospitals

LTTS' smart offerings for hospitals include

- Remote monitoring and operation of hospital beds
- Edge analytics on patients' vital signs for anomaly detection
- Stable software application over 150 different test scenarios

Our connected solutions find use cases in—



Ophthalmology -
Enabling EMR Connectivity



Sleep Diagnostics and Neural Analysis Software –
EEG Data EMR



Hospital Bed Management



Patient Monitoring –
Caregiver and Physicians

Connected Patients

Our offerings include

- IoT-integrated smart devices, including the facilities of sensors, connectivity, cloud and mobility
- Remote monitoring and diagnosis of patients
- iOS and Android platform development

MRI and CT- Cloud-based Healthcare SaaS

Virtual Patient Monitoring

Portal for Airway Clearance Therapy Management

A large American multinational technology conglomerate wanted to get its first Android-based wearable tested and certified.

A large American multinational technology conglomerate wanted to get its first Android-based wearable tested and certified. The solution we provided using our in-house accelerators, EvQUAL, Dashboard and Log Analyzer, was

- Using our EvQUAL tool, we facilitated functional and stability tests on Android 11 and 12 based wearables covering aspects, such as PIM, multimedia, menu navigation, real-time text, telephony, connectivity, etc.
- Multi-loop iterative stability tests according to particular specifications from AT&T, Verizon and T-Mobile

- EvQUAL tool customizations to pull RAM-dumps, Heap-dumps, Logcats etc. as per requirements from the development team
- Parallel rack-based testing and VM-based testing for scalability
- Web-based cloud-hosted dashboard was customized and enabled with access to test results anytime, anyplace and on any device
- Live test results as well as historical trends streaming on the dashboard with test-category-based grouping
- Dashboard enabled test results report generation leveraging statistics on all or select (the best performing) devices
- Our in-house developed machine learning algorithm enabled failure classification and root cause analysis.

Value Delivered

- EvQUAL backed test automation reduced test execution time by 50%.
- Advanced dashboarding and ML-powered log analysis accelerated issue triaging, cutting cycle time by 30%.



Airway Clearance Therapy

- We have developed web-based application that connects to a Therapeutic system for Cystic fibrosis
- Data analysis and visualization are delivered on the basis of therapy data collected from the device
- Therapy progress is shared with the relevant stakeholders, including the patient, the care giver and the healthcare professionals involved.
- Our solution is compatible with the Health Insurance Portability and Accountability Act (HIPAA).

LTTS helps manufacturers with comprehensive biocompatibility assessments, including breathing gas pathways, in compliance with the ISO 18562 standards. This involves testing for particulate matters, VOCs and leachable condensates to assess associated risks and develop worst-case scenarios. Our team of experts leverage their design and application knowledge, working directly with product manufacturers for biological safety evaluation. The comprehensive process starts from initial risk assessment and introduction of device, materials, processing, patient contact, areas of risk and mitigation steps and is followed by testing and finally a summary report concluding if the device is biocompatible as per the ISO 18562 standards.

Successful Product Launches

Customizable Knee Implant Design

When a healthcare OEM wanted to choose the right innovation partner for the design and development of customized knee implants, LTTS stepped in with our talented pool of technical associates and QARA experts. We designed 3D customizable implants from 2D CT images and submitted a proposal for AI techniques to improve the quality of implants while complying with DICOM and STL standards.

New Product Development in Ultrasound Scanners

LTTS partnered with a leading ultrasound manufacturer—offering a turnkey development solution by designing and developing a next-gen ultrasound scanning device. We met the client's need for an aesthetically pleasing design with the functional advantage of lower floor area occupancy. The design needed to adhere to a wide array of regulatory requirements in order to be ready for the client's target markets.

We ensured that the device remained compliant with the following:

DICOM Digital Imaging and Communications in Medicine

60601-1 3rd edition Standards for the safety and essential performance of medical electrical equipment

62304 Standard specifying the requirements for developing new software e2e within medical devices

ISO 14971 Standard for the application of risk management to medical devices

62366 Standard that specifies usability requirements for the development of medical devices

We completed the project in less than 24 months, with the result for the customer being a 20% increase in productivity. Alignment with multiple regulatory standards generated several growth opportunities for the product.

Linear Surgical Stapler for Emerging Markets

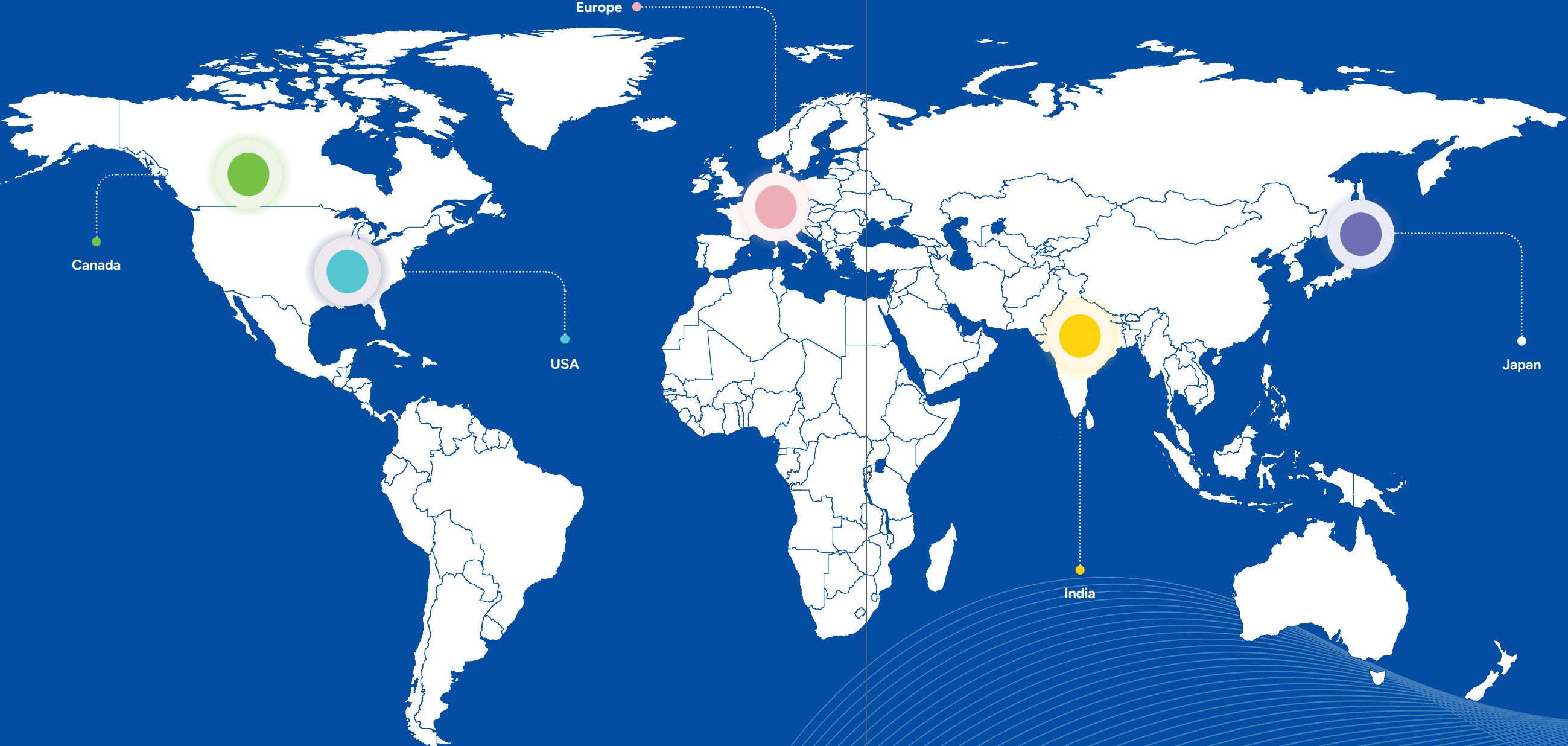
We designed and developed a reusable linear surgical stapler for emerging markets, maintaining the safety and efficacy standards of its disposable predicate device. Our efforts resulted in reduced procedural and compliance costs.

Documentation Support

Our dedicated team has implemented Unique Device Identification (UDI) across multiple locations in the US, Europe and Asia, addressing region-specific UDI rules and timelines, harmonizing label content and ensuring device data was published to the correct regulator databases (e.g., FDA GUDID in the US, EUDAMED in the EU as applicable). We maintained adherence to the GS1 standards (for both 1D and 2D barcodes), providing SAP-integrated labelling solutions. Our documentation support extends to installation guides, work instructions and artwork labeling.

Our complete ownership of change management documentation resulted in a comprehensive analysis of 3 years of complaint data for a customer to identify failure modes. Based on field failures, we updated the risk files for two micro catheter products and guidewire.

LTTS Global Regulatory Capabilities



USA

NIST framework 21 CFR Part 11
FDA QSR-21CFR820 21 CFR 820
HIPAA

Canada

SOR/98-282

Europe

ROHS, MDR,
IVDR, EUMDR 2017/745

India

CDSCO
Drug and Cosmetic Law

Japan

Pharmaceutical
Affair Law

Chapter 9

Future-Ready QARA



The European Union's AI Act has introduced unprecedented complexity for MedTech companies, requiring dual compliance with AI Act requirements and existing MDR/IVDR.

Understanding the Strategic Value of QARA

We have seen how QARA functions have evolved from transactional back-office activities into strategic enablers of business success. We have also witnessed how QARA teams not only safeguard patient safety but also accelerate time-to-market, enhance company reputation and unlock new revenue streams by ensuring that products meet ever-changing global standards. In today's complex MedTech environment, agile QARA capabilities can be a significant competitive advantage, reducing recall risks through predictive monitoring and enabling first-time-right regulatory submissions that reduce costs and minimize effort.

With regulatory requirements for MedTech products becoming increasingly complex, manufacturers are struggling to manage go-to-market activities while being cost-conscious. In this environment, the role of QARA professionals in guiding OEMs navigate the modern regulatory maze has become crucial.

MedTech organizations now recognize the importance of automation and AI-enabled technology in medical products. With rules governing the integration of AI in medical devices still at a formative stage, QARA experts remain abreast of the emerging statutory frameworks and technological developments in the domain.

Innovation Aligned with Compliance

The current rate of innovation in the MedTech industry demands that the regulations keep pace. The emergence of clinical AI and large-scale dynamic databases pose new regulatory risks. Insufficient security measures when dealing with AI-enabled dataflows threaten breaches of confidential information. The EU GDPR (General Data Protection Regulation), implemented in 2018, is aimed at securing strong privacy and security rights for individuals over their personal data.

Training models for generative AI can introduce bias into the system, resulting in inaccurate responses and reinforcing unfair stigmas. GMLP includes a suggestion for the implementation of appropriate controls to mitigate the risks of unintended biases or model degradation.

Advanced AI systems offer limited understanding of the way that they operate, leading to questions around transparency of the overall process. The FDA's AI/ML based action plan addresses this concern by suggesting a patient-centric approach while incorporating transparent labeling to provide clarity and visibility to the users about the functioning of the device.

In its current state, AI is prone to errors and inaccuracies, leading to costly false positives or dangerous false negatives in some cases. In this case, the FDA's Predetermined Change Control Plan (PCCP) for AI-enabled devices recommends maintaining and updating the Modification Protocol to keep track of data uses. The recommended device monitoring plan includes tracking of misdiagnosis due to device errors.

Limited AI literacy breeds skepticism and resistance in organizations towards the adoption of the technology.



From Reactive to Proactive: AI Imperative in QARA

Dynamic data-driven systems and AI-integrated workflows are driving QARA from maintenance orientation to proactive governance. AI facilitates unified global dashboards, which can keep track of application status and compliance gaps across markets in real time. AI-based predictive models can pre-empt audit findings, supply gaps and product recalls.

Necessity of Human Intervention

The EU AI Act builds upon the existing MDR and IVDR to include AI systems, ensuring that users are able to understand the logic, limitations and behavior of AI components within a medical device. Such devices are required to include clear and comprehensible instructions for use.

GMLP addresses the transparency issues related to the AI 'black box' by emphasizing human interpretability of the model outputs, i.e., keeping 'humans in the loop.'

While the hype around Generative AI (GenAI) is ubiquitous with considerable and demonstrable advantages, the above concerns highlight that it is no panacea. A customer-centric framework should be adopted where the AI solution is tailored to the requirements of the organization.



What Does the Future Hold?

GenAI systems will continue to become more sophisticated, however, playing an increasingly significant role in product risk documentation, product failure mode identification and help in developing strong risk mitigation plans. GenAI models could engage in predictive maintenance, identifying potential failures or safety risks before they occur. Through real-time monitoring and post-market performance analysis, these models can accelerate safety interventions and minimize the impact of regulatory actions on the operations.

With the EU MDR transition, modern QARA systems must integrate proactive PMS, advanced signal detection and rapid response capabilities. Environmental factors are also expected to play an increasingly important role in the regulatory and competitive agenda. The success of global harmonization efforts will go a long way in expanding access to wider international markets for medical product manufacturers.

As the regulatory environment incorporates digital technologies, AI and data-driven tools, LTTS will continue to guide MedTech firms on integrating Good Machine Learning Practices (GMLP), maintaining total product lifecycle documentation and preparing for real-time performance auditing in AI and Software as a Medical Device (SaMD) contexts. Our commanding regulatory intelligence, digital system expertise and adaptability will continue helping our clients maintain compliance, expedite innovation and stay ahead in a competitive global market.

The trajectory of QARA, from reactive documentation to proactive, data-driven governance, is ultimately a trajectory toward Engineering Intelligence. As clinical AI, dynamic databases and Software as a Medical Device reshape the regulatory landscape, the organizations that thrive will be those that meet intelligent products with intelligent quality systems. LTTS is investing to lead this shift, from dedicated Engineering Intelligence centers of excellence to one of the industry's deepest AI and GenAI patent portfolios, all directed at a single outcome for our clients: compliance that keeps pace with innovation. In an environment where today's best practices lead to dead ends, EI is how MedTech makers build the paths that are new, defensible and safe.

Appendix A

Key QARA Terms and Definitions

Quality Assurance (QA) Terms

- **CAPA** - Corrective and Preventive Actions: Systematic processes to eliminate causes of nonconformances and prevent recurrence
- **Design History File (DHF)** - Compilation of records containing design output, design review results and design verification and validation procedures
- **IQ/OQ/PQ** - Installation Qualification/Operational Qualification/Performance Qualification: Sequential validation phases ensuring equipment and processes function as intended
- **Quality Management System (QMS)** - Framework of policies, processes and procedures for achieving quality requirements and continuous improvement
- **Technical File** - Documentation demonstrating that a medical device conforms to regulatory requirements
- **TMV** - Tool, Method, Validation: Framework for ensuring manufacturing tools and methods meet quality standards
- **Traceability** - Ability to trace the history, application, or location of items through documented identification

Digital and Emerging Technology Terms

- **AI Act** - European Union regulation governing artificial intelligence systems, including high-risk AI in medical devices
- **GMLP** - Good Machine Learning Practices: Framework for AI/ML development in medical devices
- **IVDR** - In Vitro Diagnostic Medical Device Regulation (EU 2017/746): European regulation for diagnostic devices
- **SaMD** - Software as a Medical Device: Software intended for medical purposes without being part of hardware
- **SiMD** - Software in Medical Device: Software that is integral to a medical device's operation
- **Engineering Intelligence (EI)** - LTTS' approach of embedding AI across the entire engineering and product lifecycle, combining deep domain engineering expertise with GenAI, agentic, multimodal and physical AI to move organizations from AI experimentation to scalable, real-world outcomes. In QARA, EI enables predictive, lifecycle-wide quality and regulatory management.

Regulatory Affairs (RA) Terms

- **510(k)** - FDA premarket submission demonstrating substantial equivalence to a legally marketed device
- **CE Marking** - Conformity marking indicating compliance with EU health, safety and environmental protection standards
- **Clinical Evaluation Report (CER)** - Document demonstrating clinical safety and performance of medical devices
- **Declaration of Conformity** - Document declaring that a product meets specified requirements
- **EUDAMED** - European database on medical devices for regulatory oversight and transparency
- **MDR** - Medical Device Regulation (EU 2017/745): European regulation governing medical device safety and performance
- **Notified Body** - Organization designated to assess conformity of products before placing on EU market
- **Post-Market Surveillance (PMS)** - Systematic process to collect and review experience with devices after-market release
- **Predicate Device** - Legally marketed device used as comparison for demonstrating substantial equivalence
- **PSUR** - Periodic Safety Update Report: Regular safety report for marketed medical devices
- **UDI** - Unique Device Identification: System for identifying medical devices through distribution and use
- **Vigilance** - System for collecting and evaluating information on incidents involving medical devices

Sustainability and Environmental Terms

- **CSRD** - Corporate Sustainability Reporting Directive: EU legislation requiring sustainability disclosure
- **ESG** - Environmental, Social and Governance: Framework for measuring sustainability impact
- **ISO 14001** - International standard for environmental management systems
- **PFAS** - Per- and polyfluoroalkyl substances: Chemical compounds regulated in medical device manufacturing
- **RoHS** - Restriction of Hazardous Substances: Directive limiting hazardous materials in electrical equipment

Appendix B

Global Regulatory Submission Portals

United States

- **FDA CDRH** - Center for Devices and Radiological Health
- **Portal:** FDA Unified Registration and Listing System (FURLS)
- **Website:** www.fda.gov/medical-devices
- **Submission Types:** 510(k), PMA, De Novo, HDE

European Union

- **EUDAMED** - European Database on Medical Devices
- **Portal:** eudamed.ema.europa.eu
- **Key Functions:** Device registration, economic operator registration, UDI database
- **Status:** Modules being implemented progressively

Individual EU Member States

- **Germany:** BfArM (Federal Institute for Drugs and Medical Devices)
- **France:** ANSM (National Agency for Medicines and Health Products Safety)
- **Netherlands:** CIBG (Central Information Point for Healthcare Professions)
- **Italy:** Ministry of Health - Medical Devices Office

United Kingdom (Post-Brexit)

- **MHRA** - Medicines and Healthcare products Regulatory Agency
- **Portal:** www.gov.uk/guidance/medical-devices-regulation-and-safety
- **Requirements:** UKCA marking, UK Responsible Person

Asia-Pacific

Japan

- **PMDA** - Pharmaceuticals and Medical Devices Agency
- **Portal:** www.pmda.go.jp/english/
- **Requirements:** JFRL certification, QMS certification

Australia

- **TGA** - Therapeutic Goods Administration
- **Portal:** www.tga.gov.au
- **Requirements:** ARTG listing, conformity assessment

India

- **CDSCO** - Central Drugs Standard Control Organization
- **Portal:** cdscoonline.gov.in
- **Classification:** Classes A-D based on risk

China

- **NMPA** - National Medical Products Administration
- **Portal:** www.nmpa.gov.cn
- **Requirements:** NMPA registration, clinical trials for higher-risk devices

Canada

- Health Canada
- **Portal:** www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices
- **Requirements:** Medical Device License (MDL), Quality System Certification

Brazil

- **ANVISA** - National Health Surveillance Agency
- **Portal:** www.gov.br/anvisa
- **Requirements:** ANVISA registration, GMP certification

Appendix C

Global Regulatory Timelines

FDA (United States) Timelines

510(k) Standard Review: 90 FDA days (approximately 4-6 months total)	510(k) Standard Review: 90 FDA days (approximately 4-6 months total)
510(k) Expedited Review: 60 FDA days (for breakthrough devices)	De Novo Request: 120 FDA days
PMA Standard Review: 180 FDA days (6 months) + potential advisory panel	PMA Expedited Review: 150 FDA days (for breakthrough devices)
Quality System Inspection: 30-90 days depending on facility size	

EU MDR Timelines

Class I Self-Declaration: 1-3 months (internal assessment)	EUDAMED Registration: Ongoing as modules become available
Class III Notified Body Review: 210 days + additional assessment time	Clinical Investigation Approval: 60 days (with possible 35-day extension)
Notified Body Audit: 45-90 days depending on scope	Class IIa/IIb Notified Body Review: 210 days maximum (7 months)

Major Markets' Comparison Table

Region	Low Risk (Class I)	Medium Risk (Class II)	High Risk (Class III)
US (FDA)	30-90 days	4-6 months (510k)	6-12 months (PMA)
EU (MDR)	1-3 months	7-12 months	12-18 months
UK (MHRA)	2-4 months	8-12 months	12-18 months
Japan (PMDA)	3-6 months	10-14 months	14-20 months
Canada	2-4 months	6-10 months	12-16 months
Australia (TGA)	1-3 months	6-9 months	10-14 months

Critical Timeline Factors

Pre-submission Meetings:
Add 2-3 months
to overall timeline

Clinical Studies:
6-24 months
depending on scope and complexity

Quality System Certification:
3-12 months
for initial certification

Post-Market Surveillance Setup:
1-3 months
for system implementation

Multi-jurisdictional Submissions:
Stagger submissions by
3-6 months
for optimal resource utilization

LTTS Accelerated Timeline Capabilities

DHF Remediation:
Completed within
3 months
FDA mandate (Chapter 4)

Complaint Processing:
240,000 complaints
reviewed within regulatory deadline (Chapter 4)

Failure Code Architecture:
Implemented NFCA resulting in
140,000 complaints
resolved in first month (Chapter 4)

RoHS 3 Compliance:
10,000+ components
assessed and converted (Chapter 6)

Timeline Optimization Strategies

I

Parallel Processing:

Conduct clinical evaluations alongside technical documentation

II

Early Engagement:

Pre-submission meetings to clarify regulatory pathway

III

Resource Scaling:

Deploy specialized teams for urgent timelines (LTTS model)

IV

Digital Tools:

AI-powered clinical evaluation (AiCE) for faster literature reviews

V

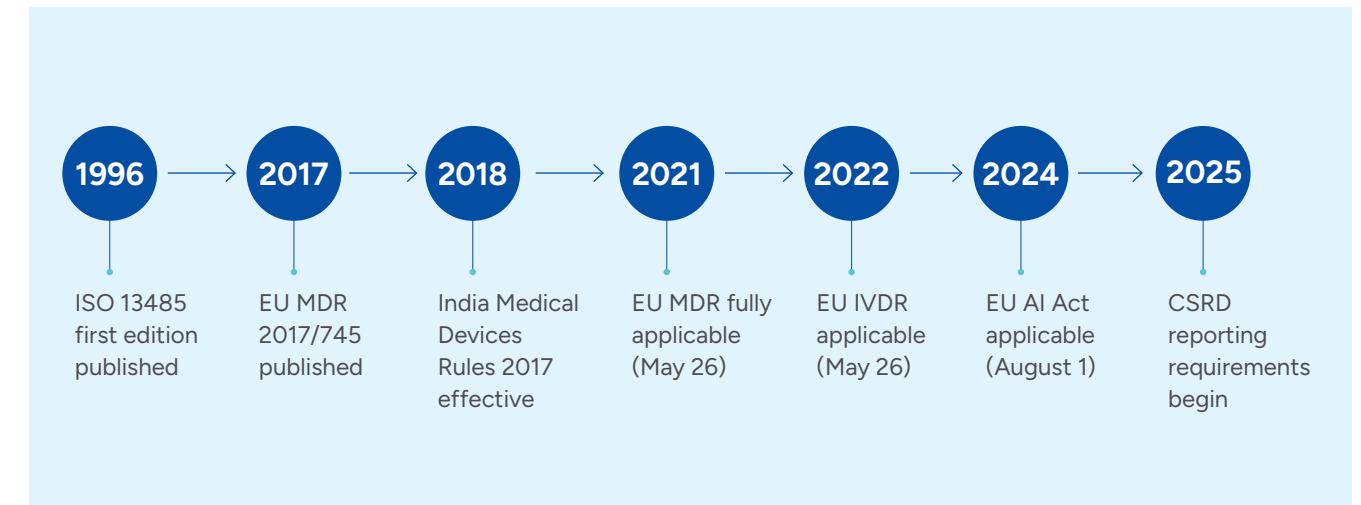
Supplier Coordination:

SQEFM framework for streamlined supplier qualification

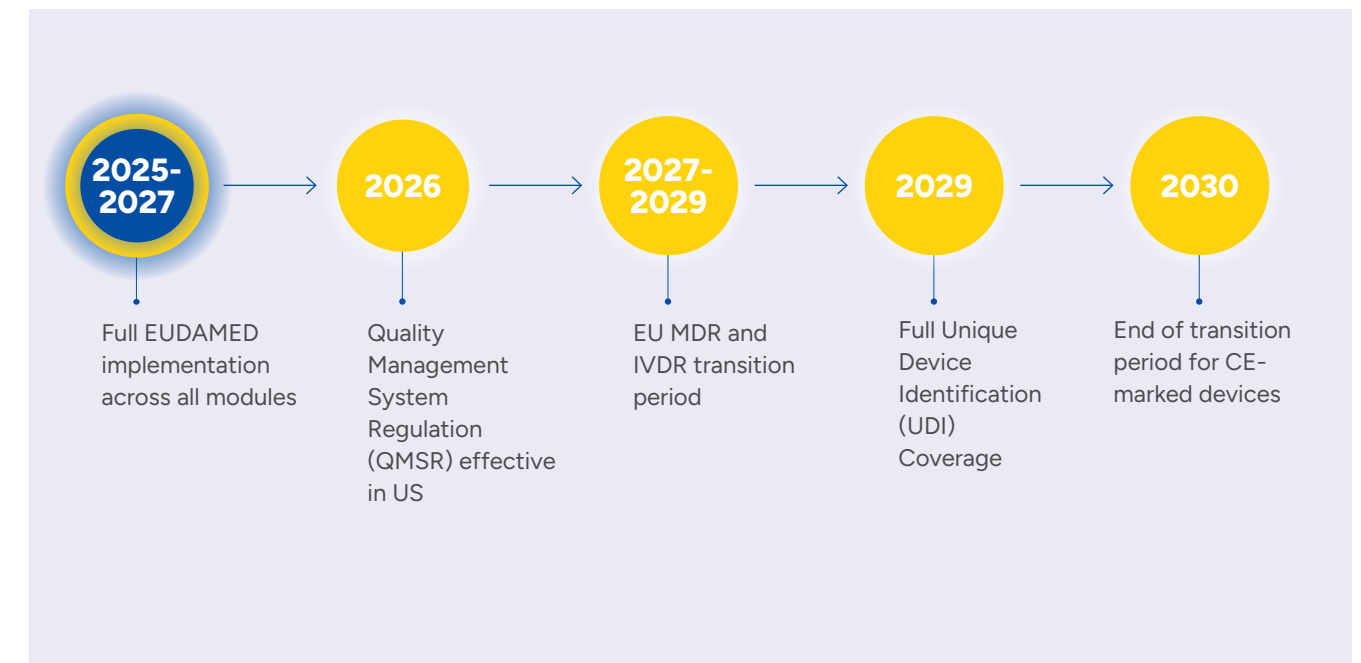
Appendix D

Regulatory Framework Evolution Timeline

Historical Milestones



Future Regulatory Milestones





ENGINEERING **THE CHANGE**

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