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Learning from other Domains to Advance AI Evaluation and Testing

We are grateful to the authors of the enclosed expert report, which forms part of a broader series commissioned by Microsoft.

These reports were commissioned as part of Microsoft's effort to draw lessons from other domains to strengthen testing and evaluation as a cornerstone of AI governance.

The insights contained in this report reflect the authors' independent analysis and expertise. The views expressed are those of the authors alone.

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Medical Device Testing: History, Regulation, and Lessons for AI Governance

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1 Introduction

The field of medical devices exemplifies the transformative potential of technology in addressing healthcare challenges.

Testing in the medical device domain is intricately tied to regulatory requirements across jurisdictions. During the pre-market phase, medical testing establishes baseline safety and effectiveness metrics through bench testing, performance standards, and clinical studies. Post-market testing ensures that real-world data informs ongoing compliance and safety improvements. Testing is indispensable in translating technological innovation into safe and effective medical devices.

The regulation of medical devices plays a foundational role in safeguarding public health by ensuring that devices are safe, effective, and high-quality. In the global marketplace, the United States, the UK Medicines and Healthcare Products Regulatory Agency (MHRA), and the European Union represent some of the most influential regulatory jurisdictions, each with comprehensive frameworks: the U.S. Food and Drug Administration's (FDA) medical device regulations, the MHRA (MDD) and the European Union's Medical Device Regulation (EU MDR). While particular details of pre-market and post-market review procedures may slightly differ among countries, most developed jurisdictions regulate medical devices similarly to the US or European models (Minssen 2020).

Most jurisdictions with medical device regulation classify devices based on their risk profile, intended use, indications for use, technological characteristics, and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness (FDA 2018). In the U.S., the FDA uses a three-tier system: Class I for low-risk devices, Class II for moderate-risk devices, and Class III for high-risk devices that sustain or support life. Similarly, the UK MHRA (MDD) and EU MDR adopt a four-tier classification system: Class I, IIa, IIb, and III, with increasing regulatory requirements for higher-risk categories (Minssen 2020, Aboy 2024). This risk-based classification ensures that regulatory scrutiny and testing required are proportionated to the potential impact of a device on the patient. This classification determines the requirements a medical device must meet prior to market introduction, including the required testing.

Pre-market requirements in both jurisdictions are similar but differ in execution. In the U.S., Class I devices generally require adherence to general controls, while most Class II devices require a Premarket Notification (510(k)) to demonstrate substantial equivalence to an existing *predicate* device or go through the De Novo classification (Aboy 2024) to classify novel medical devices for which there is no legally marketed predicate. These can include specific controls for a particular product code, performance standards, and product specific guidance. Class III devices must undergo a rigorous Premarket Approval (PMA) process that includes extensive clinical testing and

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scientific review. In the EU, all devices require a CE marking to enter the market, signifying conformity with MDR standards. Higher-risk devices, including Class IIa, IIb, and III, are subject to evaluations by notified bodies, which audit technical documentation, performance standards and clinical evaluations.

Post-market requirements are also necessary. Both systems mandate adverse event reporting, recalls, and regular surveillance to monitor ongoing device performance. The EU MDR incorporates a lifecycle approach with its Unique Device Identifier (UDI) system and the European Database on Medical Devices (EUDAMED), enhancing transparency and traceability. Similarly, the FDA enforces post-market reporting and surveillance while embracing global harmonization efforts such as the Medical Device Single Audit Program (MDSAP) (Minssen 2020).

International consensus standards such as ISO 13485 for medical device quality management systems (MD-QMS) are central to both frameworks, streamlining compliance for manufacturers operating in multiple jurisdictions. Additionally, both the FDA and the EU have introduced regulatory pathways for emerging technologies like Software as a Medical Device (SaMD), ensuring adaptability to innovation while maintaining safety and efficacy (Minssen 2020).

Against this background, the following section examines the historical development of regulatory and testing regimes in the US and Europe. We then provide an overview of the medical testing landscape, detailing how it is conducted in these regions, and explore ongoing efforts to harmonize and standardize testing requirements across jurisdictions. Building on this foundation, we conclude by distilling key lessons from medical device testing and discussing their relevance to shaping effective governance frameworks for medical AI and AI in general.

2. The History and Evolution of Medical Device Regulation and Testing Regimes in the US and Europe

Testing as a cornerstone of medical device regulation emerged in the mid-20th century, driven by high-profile device failures and growing public demand for oversight. The 1976 Medical Device Amendments marked a turning point in the United States, establishing a comprehensive framework for device testing and approval. Since then, the regulatory landscape has evolved to address the complexities of digital health, software as medical devices (SaMD) and AI. Milestones such as the FDA's SaMD framework and the European Union's MDR underscore this shift toward accommodating software-driven innovations. Over time, testing has transitioned from primarily assessing physical device safety to also addressing software validation and the implications of real-world evidence.

The regulation of medical devices has evolved significantly over the past century, driven by technological advancements resulting in new opportunities and challenges, changing public health needs, and increasing complexities within the health and life science ecosystem. Against this background, the history of medical device regulation in the United States and Europe demonstrates how testing has become a critical component of this domain. In the following we briefly summarize the key changes in regulatory requirements over time, and the primary drivers behind these developments.

2.1 Early Developments in Medical Device Regulation

The origins of medical device regulation can be traced back to the early 20th century. In the United States, the establishment of the Food and Drug Administration (FDA) in 1906 marked a significant

milestone with the passage of the *Pure Food and Drugs Act*.[1] This Act aimed to ensure the safety of food and drugs. Although the Act did not specifically address medical devices, it laid the groundwork for future regulation by emphasizing the necessity of product safety standards.

In Europe, regulatory efforts were initially fragmented, with countries taking various approaches to medicinal products. The *UK's Medicines Act* of 1968[2] provided one of the first significant regulatory framework for medicines, highlighting the importance of safety and efficacy. However, a comprehensive and synchronized regulation of medical devices was lacking at this time.

2.2 The 1970s: The Emergence of Testing in Regulation

A seminal development for medical device regulation in the United States occurred in 1976 with the *Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act*.[3] This legislation formally established the FDA's authority over medical devices and categorized them into three classes based on their risk profiles: Class I (low risk), Class II (moderate risk), and Class III (high risk).

Testing began to take center stage as a core requirement of regulation during this period. Among other things, Class III devices, which present the highest risk to patients, were mandated to undergo a premarket approval (PMA) process—a rigorous evaluation requiring comprehensive clinical data and testing results. This marked the beginning of a more structured approach to testing within the regulatory framework and highlighted the necessity of demonstrating both safety and efficacy before devices could be introduced into the market.

In Europe, the *Medical Device Directive* (MDD), adopted in 1993[4], aimed to harmonize the regulation of medical devices across EU member states. While the MDD established essential requirements for safety and performance, it did not fully integrate a consistent framework for testing across all member states. Nevertheless, it set the stage for future developments in testing requirements.

2.3 The 1990s: Expansion of Testing Requirements

The 1990s brought significant developments in the regulation of medical devices, particularly concerning the role of testing. The FDA enacted the *Safe Medical Devices Act of 1990*[5], which expanded its authority to require post-market surveillance and mandated the reporting of adverse events linked to medical devices. This act recognized that testing should not only occur prior to market entry but should also extend throughout the device's lifecycle.

This shift towards ongoing monitoring and evaluation underscored the idea that a device's safety and efficacy could evolve post-approval, necessitating continual testing and data collection, as well as authorities that have the competence and capacity to monitor and assess a medical product

[1] 59th U.S. Congress (December 14, 1905). "S. 88, Draft bill of the Pure Food and Drug Act". Chapter 3915, cited 34 U.S. Stats. 768. U.S. Capitol Visitor Center. & 59th U.S. Congress (1906). "THE WILEY ACT". Public Law Number 59-384, 34 Stat. 768. U.S. Food and Drug Administration. Retrieved April 8, 2013.

[2] Medicines Act, UK Public General Acts 1968, Chapter 67, available at: **https://www.legislation.gov.uk/ukpga/1968/67** (accessed December 08, 2024). For even older medical legislation see: Ferner RE, Aronson JK. Medicines legislation and regulation in the United Kingdom 1500-2020. Br J Clin Pharmacol. 2023 Jan;89(1):80-92. doi: 10.1111/bcp.15497. Epub 2022 Sep 23. PMID: 35976677; PMCID: PMC10087031.

[3] U.S. Congress, House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, to accompany H.R. 11124, 94th Cong., 2nd sess., February 29, 1976, H. Rept. 94-853, pp. 8-9.; see also Appendix A. History of Laws Governing Medical Device Regulation: https://crsreports.congress.gov/product/pdf/R/R47374

[4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices *OJ L 169, 12.7.1993, p. 1–43, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31993L0042* .

[5] H.R.3095 - Safe Medical Devices Act of 1990, 101st Congress (1989-1990), see: https://www.congress.gov/bill/101st-congress/house-bill/3095

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throughout its lifecycle.[6] The emphasis on post-market testing became essential for understanding the long-term performance of devices and addressing any unforeseen issues that may arise after they were introduced to the market.

In Europe, the introduction of the *In Vitro Diagnostic Medical Devices Directive (IVDD)*[7] began to address testing requirements specific to diagnostic devices. This directive highlighted the increasing recognition of the importance of testing in ensuring that diagnostic devices met strict safety and efficacy standards.

2.4 The 2000s: Heightened Scrutiny and Globalization of Testing Standards

The early 2000s marked a period of heightened scrutiny regarding medical device regulation, particularly in terms of testing protocols. The Medical Device User Fee and Modernization Act (MDUFMA)[8], enacted in 2002, allowed the FDA to collect fees from manufacturers to expedite the review process for new devices. While this approach aimed to streamline approvals, it raised concerns about the thoroughness of safety evaluations and the adequacy of testing.

The need for more rigorous testing standards became increasingly evident in the wake of several high-profile device failures, which drew public attention to the importance of ensuring patient safety through effective regulation.[9] These included, for example, the Poly Implant Prothèse (PIP) breast implant scandal, controversies concerning metal on metal hip replacements, and complications following vaginal mesh implantation.[10] Consequently, the MDD was revised in Europe to improve the clarity and consistency of regulatory requirements, leading to calls for more comprehensive frameworks to address new medical technologies.[11]

2.5 The 2010s: Modernization of Testing Standards and Regulatory Reforms

As the medical device landscape evolved, so too did the regulatory frameworks governing it. The implementation of the *Medical Device Regulation* (MDR)[12] and the *In Vitro Diagnostic Regulation* (IVDR)[13], in Europe represented a significant shift towards more stringent testing requirements. These regulations and the changes that they brought about have been preceded and supported by seminal judgements by European Courts, such as the SNITEM decision by the Court of Justice of

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[6] Minssen T, Gerke S, Aboy,
M, Price N, Cohen G. Regulatory responses to medical machine learning. J Law Biosci. 2020 Apr 11;7(1):lsaa002. doi: 10.1093/jlb/lsaa002. PMID: 34221415; PMCID: PMC8248979.

[7] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices *OJ L 331, 7.12.1998, p. 1–37,* https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A31998L0079

[8] H.R.5651 - Medical Device User Fee and Modernization Act of 2002107th Congress (2001-2002), https://www.congress.gov/bill/107th-congress/house-bill/5651/text

[9] See for example Robert A. Byrne, Medical device regulation in Europe – what is changing and how can I become more involved?, https://eurointervention.pcronline.com/article/medical-device-regulation-in-europe-what-is-changing-and-how-can-i-become-more-involved .

[10] Id. (adding: "Although the PIP breast implant scandal appeared to be more a case of fraud than a failure of approval processes, the notified body responsible for the conformity assessment of the product was found liable for damages due to failures in monitoring of the manufacturer").

[11] See amendments made to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices *OJ L 169, 12.7.1993, p. 1–43,* https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31993L0042 .

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1–175 .

[13] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance.) *OJ L 117, 5.5.2017, p. 176–332* .

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the European Union on software as a medical device (SaMD).[14] The new regulations introduced stricter pre-market evaluation criteria, increased post-market surveillance, and emphasized the necessity for robust clinical evidence and thorough testing. The enhanced focus on testing was driven by several factors, including the increasing complexity of medical devices, the emergence of new technologies, and growing public scrutiny regarding device safety. The MDR and IVDR sought to address these challenges by ensuring that devices were subject to comprehensive testing protocols, thereby enhancing patient safety and restoring public confidence in medical technologies.

In the United States, the FDA also recognized the need to modernize its approach to testing. Recent attempts to modernize and accelerate the FDA's premarketing clearance and classification process for medical devices have included both new device classifications and new ways of filing abbreviated applications.[15] The FDA's "De Novo" classification and "Breakthrough Devices" programs, in particular, allow applicants to create entirely new medical device "types," complete with their own fleet of standardized safety and effectiveness checklists, including sets of specifications on software, hardware, and energy sources.[16] The introduction of the 510(k) clearance process allowed manufacturers to demonstrate that their devices were "substantially equivalent" to existing devices, expediting the approval process for many Class II devices. However, this approach raised concerns about the depth of testing required to ensure safety, as the 510(k) pathway did not always mandate the same rigorous clinical evaluations as the PMA process for Class III devices.[17]

The FDA De Novo pathway was introduced in under the Food and Drug Administration Modernization Act (FDAMA) to address a critical regulatory gap for novel medical devices classified as moderate to low risk. Prior to its introduction, devices without a suitable predicate device were automatically designated as Class III, requiring a premarket approval (PMA) submission, even if their risk profile did not warrant such extensive scrutiny. The De Novo pathway offered an alternative, enabling manufacturers to request reclassification of their devices into Class I or Class II, provided sufficient evidence demonstrated the device's safety and effectiveness.

Initially, the De Novo process was triggered only after a Not Substantially Equivalent (NSE) determination through the 510(k) pathway, which created inefficiencies for manufacturers of innovative devices without predicates. This limitation was addressed with the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, which allowed manufacturers to submit direct De Novo requests, bypassing the need for an NSE determination. This reform streamlined the process, reducing unnecessary delays and fostering innovation.

The De Novo pathway has played a transformative role in accommodating novel devices that leverage emerging technologies or address unmet medical needs. It establishes device-specific special controls, such as labeling requirements, performance testing standards, and post-market surveillance obligations, which serve as a benchmark for future devices of the same type. Approved

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[14] Minssen T, Mimler M, Mak V. When Does Stand-Alone Software Qualify as a Medical Device in the European Union?-The CJEUs Decision in Snitem and What it Implies for the Next Generation of Medical Devices. Med Law Rev. 2020 Aug 1;28(3):615-624. doi: 10.1093/medlaw/fwaa012. PMID: 32607541.

[15] Aboy M, Sherkow JS., IP and FDA Regulation of De Novo Medical Devices. In: Cohen IG, Minssen T, Price II WN, Robertson C, Shachar C, eds. *The Future of Medical Device Regulation: Innovation and Protection*. Cambridge University Press; 2022:117-128.

[16] Id. citing: US Food & Drug Admin., Acceptance Review for De Novo Classification Requests: Guidance for Industry and Food and Drug Administration Staff (Sept. 9, 2019), https://www.fda.gov/media/116945/download [https://perma.cc/7YBQ-FWUM]; US Food & Drug Admin., De Novo Classification Process (Evaluation of Automatic Class III Designation): Guidance for Industry and Food and Drug Administration Staff (Oct. 30, 2017), https://www.fda.gov/media/72674/download [https://perma.cc/8US4-QEG7]; & 21st Century Cures Act, Pub. L. No. 144–255, 130 Stat. 1033 (2016).

[17] For further discussions see id.

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De Novo devices also create new classifications, paving the way for subsequent devices to enter the market via the less burdensome 510(k) pathway, provided they demonstrate substantial equivalence to the original De Novo device (Aboy 24).

Over the years, the FDA has introduced measures to enhance the efficiency and predictability of the De Novo process, including guidance documents and interactive review mechanisms. These efforts ensure the pathway remains a viable option for manufacturers while maintaining rigorous standards for safety and effectiveness. By bridging the gap between traditional 510(k) and PMA pathways, the De Novo process has become a cornerstone of the FDA's approach to regulating innovative medical devices, supporting their safe and timely introduction to the market.

2.6 Current Trends in Medical Device Regulation

Today, medical device regulation continues to evolve in response to rapid advancements in technology, particularly regarding digital health, artificial intelligence, and personalized medicine.[18] The FDA has established the Digital Health Center of Excellence[19] to promote innovation while ensuring the safety and efficacy of digital health technologies. Similarly, the European Commission has initiated efforts to adapt regulatory frameworks to address the unique challenges posed by digital health and software as a medical device (SAMD)[20], including particular challenges raised by generative AI.[21]

A major future challenge for sector specific medical device regulation in both Europe and in the US lies in its interplay with evolving regulatory landscape that regulates AI more generally. In the EU, for example, the recently adopted EU AI Act (AIA)[22] applies a comprehensive risk-based approach to regulating digital medical products. By aligning and interacting with existing regulations like the EU MDR/IVDR and the GDPR[23], the Act impacts AI across healthcare, focusing on patient safety, AI system efficacy, data governance, and ethical use.[24] This regulatory landscape aims to shape the future of AI in healthcare with the goal of fostering innovation while ensuring public trust and compliance. However, it remains to be seen whether the AIA in its currents form represents the gold standard in meeting this overarching goal.[25] Questions to explore include the EU AI Act's impact on innovation and SMEs, and the effectiveness of its 'measures to support innovation' such as AI regulatory sandboxes. Ensuring the Act is fit for purpose will likely require proactive and evidence-based scholarship, as well as the incorporation of such

[18] Cf. Cohen IG, Minssen T, Price II WN, Robertson C, Shachar C. Volume Introduction. In: Cohen IG, Minssen T, Price II WN, Robertson C, Shachar C, eds. *The Future of Medical Device Regulation: Innovation and Protection*. Cambridge University Press; 2022:1-10.

[19] https://www.fda.gov/medical-devices/digital-health-center-excellence

[20] Cf. Minssen T. European Regulation of Medical Devices: Introduction. In: Cohen IG, Minssen T, Price II WN, Robertson C, Shachar C, eds. *The Future of Medical Device Regulation: Innovation and Protection*. Cambridge University Press; 2022:47-114.

[21] Minssen T, Vayena E, Cohen IG. The Challenges for Regulating Medical Use of ChatGPT and Other Large Language Models. JAMA. 2023 Jul 25;330(4):315-316. doi: 10.1001/jama.2023.9651 (stressing - inter alia - concerns about open-source LLMs that maybe regarded as so-called software of unknown provenance if a third party adapts or uses them as a component in a medical device, which would trigger special compliance standards and require sufficient documentation that may not always be accessible. Device.

[22] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), PE/24/2024/REV/1, *OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj* .

[23] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 04/05/2016, p. 1–88.

[24] Aboy, M., Minssen, T. & Vayena, E. Navigating the EU AI Act: implications for regulated digital medical products. npj Digit. Med. 7, 237 (2024). https://doi.org/10.1038/s41746-024-01232-3 .

[25] Id.

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feedback for its continuous improvement to ensure it achieves its intended purpose. [26] Given the EU AI Act's potential impact on AI developments internationally and across sectors, including the medical device sector, it will be crucial to continuously monitor and analyze the European implementation if the AI.[27]

In addition to these general developments and concerns in AI regulation, key drivers of the evolution of sector-specific regulations, such as medical device regulation, also include increased public awareness of device safety, technological advancements that necessitate updated testing protocols, and the global nature of the medical device market. The COVID-19 pandemic further underscored the need for agile, adaptive and flexible regulatory frameworks, as both the FDA and European authorities expedited the approval of diagnostic tests, ventilators, and personal protective equipment. The urgency of these developments highlighted the importance of effective testing in safeguarding public health. In that context it is worth to note that the European Parliament has very recently adopted a resolution to update the MDR and the IVDR to avoid potential product shortages caused by what is perceived as a too rigid regulation.[28] The move comes as manufacturers have continued to voice concerns about too much bureaucracy and too little guidance affecting their ability to meet deadlines to transition their products to the new regulations.[29]

That too much bureaucracy, too little flexibility or adaptiveness of regulation, and overly high compliance thresholds can be problematic has become particularly evident in Europe, where discussion about the AIA, the MDR and other new regulation are ongoing within an increasingly complex regulatory ecosystem that has become difficult to navigate. Other jurisdictions should monitor these discussions closely before updating their own regulations, just has companies with market interests in Europe should actively participate in the debates.[30]

As the healthcare landscape continues to change, regulatory bodies must increase their capacities and navigate the delicate balance between fostering innovation and ensuring patient safety. It is a delicate task to find the right balance and trade-offs between fundamental values to maximize patients benefits and innovation in an increasingly fierce global competition, while minimizing the risks of medical technology.[31] The ongoing development of testing standards and regulatory frameworks will be crucial in addressing future challenges and opportunities posed by emerging medical technologies in a sustainable and responsible manner, ensuring that patients receive safe and effective medical devices in an increasingly complex healthcare environment.

3 The Medical Device Testing Landscape

In the medical device domain, devices are evaluated not only for their technical functionality but also for their safety, reliability, and usability in specific clinical contexts to satisfy the regulatory requirements.

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[26] Id.
[27] Id.
[28] See: European Parliament resolution of 23 October 2024 on the urgent need to revise the Medical Devices Regulation (2024/2849(RSP)) https://www.europarl.europa.eu/doceo/document/TA-10-2024-0028_EN.html
[29] See also: Ferdous Al-Faruque, EU Parliament passes resolution citing 'urgent need' for MDR/IVDR revision, https://www.raps.org/news-and-articles/news-articles/2024/10/eu-parliament-passes-resolution-citing-%E2%80%98urgent-nee
[30] Aboy, M., Minssen, T. & Vayena, E. Navigating the EU AI Act: implications for regulated digital medical products. npj Digit. Med. 7, 237 (2024). https://doi.org/10.1038/s41746-024-01232-3
[31] Id.

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3.2 Standards, stakeholders, testing types and testing phases

Standards play a foundational role in medical device testing. The development of testing standards is a collaborative process. International bodies like ISO and IEC, alongside regional regulators such as the FDA and European Commission, provide the foundational frameworks.

Testing is conducted by various entities, including manufacturers, independent third-party laboratories, and regulatory agencies. It occurs throughout the device lifecycle, beginning with iterative testing during research and development, advancing to pre-market evaluations, and continuing into post-market monitoring. The outcomes of these tests directly impact regulatory approvals, market access, and device design refinements. Testing results are typically shared with regulatory authorities and, in some cases, with healthcare providers and the broader public to enhance transparency and trust.

Testing occupies a central role in the governance and regulation of medical devices, serving as a critical mechanism to ensure safety, efficacy, and regulatory compliance. As such, medical device testing is first and foremost a tool for ensuring compliance with regulatory standards. That said, testing not only satisfies regulatory requirements but also underpins public trust and technological progress by establishing performance benchmarks to be met and exceed by new medical devices.

In the pre-market phase, manufacturers must demonstrate that their devices conform to safety and performance benchmarks defined by regulatory authorities. For example, in the United States, the Food and Drug Administration (FDA) requires evidence of evidence of conformity through pathways such as Premarket Notification (510(k)), De Novo or Premarket Approval (PMA). Similarly, in Europe, the Medical Device Regulation (MDR) mandates that devices undergo testing to validate their safety and performance before receiving a CE marking. These pre-market evaluations include functional bench testing, biocompatibility assessments, and software validation, all of which are integral components of a manufacturer's submission (Minssen 2020).

Beyond regulatory approvals, testing plays a vital role in the broader governance of medical devices by serving as a cornerstone of risk management. The ISO 14971 provides a globally recognized framework for managing risks throughout the lifecycle of a device. Testing supports this framework by supplying empirical evidence to identify and mitigate risks. For example, environmental testing evaluates device performance under stress conditions such as extreme temperatures, humidity, or mechanical vibrations. This ensures that devices are not only safe in controlled laboratory conditions but also reliable in the diverse clinical settings where they are deployed.

Equally important, testing sets objective thresholds for safety and performance, often defined through international consensus standards. Standards such as IEC 60601-1 for electrical safety and IEC 61000 for electromagnetic compatibility (EMC) provide harmonized criteria that manufacturers must meet. Adhering to these standards facilitates interoperability and simplifies market access across jurisdictions, as testing results are recognized by regulators worldwide. This harmonization reduces the duplication of testing efforts, thereby lowering costs and accelerating the time to market. For devices with software components, standards like IEC 62304 offer guidelines for software development and validation, ensuring that these increasingly complex systems are robust and reliable.

Testing also extends into the post-market phase, where it continues to ensure device safety and efficacy. Post-market surveillance, as outlined in ISO 13485, relies on testing to monitor real-world performance and identify emerging risks. By integrating real-world evidence into ongoing

assessments, manufacturers can address unforeseen issues, update devices as needed, and maintain compliance with evolving regulatory expectations. This iterative process ensures that devices continue to meet the high standards set during their initial approval, thereby reinforcing confidence among patients, healthcare providers, and regulators.

Table 1 provides a structured overview of this framework, dividing it into the key phases of Research & Development, Pre-Market (Regulatory), and Post-Market. During the Research & Development phase, activities like feasibility testing, bench testing, and risk analysis are conducted to verify conceptual viability and identify potential hazards. The Pre-Market phase focuses on regulatory compliance, with detailed performance testing that includes clinical studies, biocompatibility assessments, and software validation to confirm safety and efficacy under both bench-, simulated- and real-world-conditions. The Post-Market phase ensures continued safety and performance through activities like post-market surveillance and real-world evidence collection, addressing unforeseen risks and informing ongoing compliance. This lifecycle approach, as illustrated in **Table 1**, underscores the iterative nature of medical device testing and its critical role in robust device governance and public health protection.

Table 1 – Typical medical device tests conducted during the R&D, pre-market and post-market phases

Phase	Type of Testing	Description	Purpose
Research & Development	Feasibility Testing	Initial evaluations of the design and basic functionality.	Ensures the concept is viable and meets preliminary design requirements.
	Bench Testing	Controlled environment testing to assess device mechanics, electronics, and safety.	Evaluates core functionality, mechanical integrity, and basic safety.
	Risk Analysis	Identification and evaluation of potential risks using a systematic approach (e.g., ISO 14971).	Identifies hazards and plans risk mitigation strategies.
	Software Verification	Code reviews, unit tests, and integration testing of software components.	Ensures software functions as intended without errors.
	Prototyping and Iterative Testing	Continuous evaluation and refinement of device prototypes.	Optimizes design and addresses early-stage performance issues.
Pre-Market (Regulatory)	Functional Bench Testing	Detailed evaluation of the device's design and performance in a controlled environment.	Confirms adherence to specifications and early-stage safety.
	Medical Device-Specific Performance Testing	Testing device performance against intended use-specific criteria and standards.	Verifies the device meets defined performance standards under expected conditions.
	Biocompatibility Testing	Assessment of materials for biological compatibility (e.g., ISO 10993).	Ensures materials are safe for contact with human tissues.
	Electrical Safety Testing	Evaluation of electrical systems for compliance with safety standards (e.g., IEC 60601-1).	Verifies safety from electrical hazards and electromagnetic interference.
	Software Validation	Comprehensive testing of software systems to ensure reliability and compliance (e.g., IEC 62304).	Validates that software performs as intended in the clinical context.
	Packaging and Sterilization Testing	Assessment of packaging durability and sterilization effectiveness.	Ensures the device is delivered safely and remains sterile.
	Environmental Testing	Evaluation of device durability under environmental stresses (e.g., heat, cold, vibration).	Confirms device performance in extreme or variable conditions.

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	Clinical Testing	Human trials under controlled conditions to evaluate safety and efficacy.	Confirms the device's effectiveness and safety for its intended use.
Post-Market	Post-Market Surveillance	Monitoring real-world use of the device to identify safety or performance issues.	Ensures continued compliance and identifies unforeseen risks.
	Real-World Evidence (RWE) Collection	Gathering data from real-world usage (e.g., registries, observational studies).	Supports ongoing safety and efficacy claims.

The types of testing conducted for medical devices are essential for addressing specific safety and performance requirements, ensuring both reliability and user safety. **Table 2** builds upon the lifecycle perspective introduced in **Table 1** by providing a detailed examination of these testing types. It includes functional testing, environmental testing, and usability evaluations, each serving a distinct purpose in validating device design and performance. These testing methodologies align with internationally recognized standards, such as those established by ISO and IEC, which provide a framework for ensuring consistency and compliance across the industry. Together, the lifecycle approach of Table 1 and the targeted testing methodologies in **Table 2** illustrate a comprehensive strategy for achieving robust device validation and meeting regulatory expectations.

Table 2 – Overview of types of testing for medical devices and their purpose.

Testing Type	**Description**	**Purpose and Best Practices**	**Testing and Certification**
Functional Testing	Evaluates whether the medical device performs its intended functions accurately and reliably.	Ensures the device operates as designed and meets all specified requirements. Develop detailed test plans, simulate real-world scenarios, and document findings.	Performed by manufacturers' internal QA teams or independent testing laboratories. Results included in regulatory submissions and reviewed by regulators (e.g., FDA) and notified bodies.
Performance Testing	Assesses the device's performance under various conditions to verify it meets predefined standards and criteria.	Confirms the device consistently delivers the expected performance. Use calibrated equipment, adhere to standardized protocols, and conduct repeated trials.	Conducted by manufacturers with oversight from regulatory or notified bodies. Results included in regulatory submissions and reviewed by regulators (e.g., FDA) and notified bodies.
Safety Testing	Examines the device for potential hazards, including electrical, mechanical, and thermal risks.	Identifies and mitigates risks to ensure safety. Conduct thorough risk assessments, comply with relevant safety standards, and implement safety features.	Accredited safety labs (e.g., TÜV, UL) or in-house safety testing teams. Results included in regulatory submissions and reviewed by regulators (e.g., FDA) and notified bodies.
Biocompatibility Testing	Tests the interaction between the device materials and biological tissues to ensure compatibility.	Ensures no adverse reactions. Follow ISO 10993 standards, select biocompatible materials, and conduct required in vitro and in vivo tests.	Performed by specialized labs accredited for biocompatibility testing (e.g., NAMSA, Eurofins). Results included in regulatory submissions and reviewed by regulators (e.g., FDA) and notified bodies.
Usability Testing	Evaluates the device's user interface and interaction to ensure it can be used safely and effectively.	Reduces user errors and enhances usability. Involve end-users, simulate real-use environments, and iterate based on feedback.	Conducted by human factors engineering teams or usability testing specialists. Results included in regulatory submissions and reviewed by regulators (e.g., FDA) and notified bodies.
Software Validation and Verification	Assesses the software components of the device to ensure they function correctly and securely.	Confirms software performance and security. Implement rigorous code reviews, conduct unit/integration testing, and	Internal software QA teams or specialized third-party software testing firms. Results included in regulatory submissions and reviewed by

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		ensure compliance with IEC 62304.	regulators (e.g., FDA) and notified bodies.

Horizontal standards form the backbone of medical device testing and certification, providing a consistent framework for evaluating safety and performance across diverse device types and stages of development. **Table 3** highlights specific testing methodologies focusing on these foundational standards. Examples include ISO 13485, which defines quality management systems, and ISO 14971, which establishes processes for risk management. These standards underpin device development by ensuring adherence to key principles of safety, efficacy, and quality. Additional standards, such as IEC 60601 for electrical safety and IEC 62304 for software lifecycle processes, address essential performance requirements that are broadly applicable and require specific tests that must be conducted and reported.

Table 3 – Selection of general (horizontal) medical device standards, testing, and certification

Standard	Title	Description	Purpose/Scope	Testing and Certification
ISO 13485	Medical Devices - Quality Management Systems	Specifies requirements for a quality management system for medical devices.	Ensures consistent design, development, production, and post-market activities of devices.	Audits conducted by notified bodies (e.g., TÜV, BSI, SGS). Certificates issued by the notified body.
ISO 14971	Medical Devices - Application of Risk Management	Provides a framework for risk management during the lifecycle of a medical device.	Identifies, evaluates, and mitigates risks associated with medical devices.	Risk management audits by manufacturers or independent auditors. Results included in regulatory submissions.
IEC 60601-1	Medical Electrical Equipment - General Requirements	Standard for basic safety and essential performance of electrical medical equipment.	Ensures electrical, mechanical, and functional safety of devices.	Testing by accredited labs (e.g., UL, Intertek, TÜV). Certificates of conformity issued by the testing lab.
IEC 62304	Medical Device Software - Software Lifecycle Processes	Establishes requirements for software development and maintenance processes for medical devices.	Ensures safety and reliability of medical device software.	Testing conducted by software teams or independent labs. Results reviewed by notified bodies or regulators.
ANSI/AAMI ES60601-1	Medical Electrical Equipment - General Requirements for Basic Safety and Performance	U.S. adaptation of IEC 60601-1 with additional requirements specific to North America.	Ensures electrical safety and performance of devices in North American markets.	Testing by accredited labs (e.g., UL, Intertek). Certificates issued by labs or certification bodies.

Electromagnetic compatibility (EMC) testing plays an important role in ensuring that medical devices function reliably and safely in environments with electromagnetic interference. **Table 4** outlines the key EMC tests required for medical devices, including Electrostatic Discharge (ESD) immunity, radiated emissions testing, and conducted immunity assessments, all of which are governed by internationally recognized standards such as IEC 61000-4-2 and IEC 61000-4-3. These tests are critical for verifying that devices maintain performance integrity while coexisting with other electronic systems, preventing disruptions and ensuring patient safety. Positioned within the broader lifecycle framework presented in **Table 1** and complementing the specific testing methodologies described in Table 2, EMC testing emerges as a vital component of the overall validation process.

Table 4 – Selection of electromagnetic compatibility (EMC) testing for medical devices.

EMC Test Type	Description	Applicable Standard/Subsection	Purpose/Scope	Testing & Certification
Electrostatic Discharge (ESD)	Tests device immunity to electrostatic discharges from human contact or surfaces.	IEC 61000-4-2	Ensures the device can withstand static electricity without malfunctioning.	EMC accredited labs (e.g., TÜV, SGS, Intertek)
Radiated Immunity	Assesses the device's resistance to electromagnetic fields from nearby devices or antennas.	IEC 61000-4-3	Ensures device functionality near sources of electromagnetic radiation.	EMC accredited labs
Conducted Immunity	Tests immunity to RF signals conducted through power or signal lines.	IEC 61000-4-6	Ensures device performance under RF interference through cables.	EMC accredited labs
Electrical Fast Transients (EFT)	Simulates disturbances caused by switching transients or relay operations in electrical systems.	IEC 61000-4-4	Verifies device resilience to rapid, short-duration electrical bursts.	EMC accredited labs
Surge Immunity	Evaluates device immunity to high-energy power surges, such as lightning strikes or faults.	IEC 61000-4-5	Protects against damage or malfunction from high-energy transients.	EMC accredited labs
Radiated Emissions	Measures electromagnetic emissions radiating from the device.	CISPR 11 (EN 55011)	Ensures the device does not emit harmful electromagnetic interference.	EMC accredited labs
Conducted Emissions	Measures emissions conducted through power or signal cables.	CISPR 22 (EN 55022)	Ensures emissions do not interfere with other equipment connected to power lines.	EMC accredited labs
Magnetic Field Immunity	Tests immunity to low-frequency magnetic fields, such as those from power transformers.	IEC 61000-4-8	Ensures device performance near magnetic field sources.	EMC accredited labs
Voltage Dips and Interruptions	Assesses device behavior during power interruptions or voltage fluctuations.	IEC 61000-4-11	Ensures device functionality during and after power disruptions.	EMC accredited labs
Harmonic Current Emissions	Measures the harmonics generated by the device on AC power lines.	IEC 61000-3-2	Limits interference with power grid harmonics.	EMC accredited labs

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Horizontal and vertical standards serve distinct but complementary roles in the regulation of medical devices. Horizontal standards provide broad, foundational requirements applicable across a wide range of devices, ensuring consistency in areas such as quality management and risk assessment. Vertical standards, on the other hand, are tailored to the specific needs of particular device categories, addressing unique safety and performance requirements.

Table 5 categorizes a selection of standards into horizontal and vertical groups. Horizontal standards, such as ISO 13485 for quality management systems and ISO 14971 for risk management form the foundational framework applicable to a broad range of devices, ensuring consistent approaches to safety, performance, and compliance. In contrast, vertical standards -such as IEC 60601-2-47 for ambulatory ECG systems, ISO 81060-2 for non-invasive blood pressure monitors and the ANSI/AAMI SP10 for blood pressure monitors- address the unique requirements of specific device categories. This dual categorization highlights the interplay between universal regulatory frameworks and the tailored standards necessary for addressing the complexity and diversity of medical devices.

Table 5 – Categorization of horizontal and vertical medical device standards

Standard Type	Standard	Title	Scope
Horizontal	ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes	Specifies requirements for a quality management system applicable to all medical devices.
	ISO 14971:2019	Medical devices—Application of risk management to medical devices	Provides a process for managing risks associated with medical devices throughout their lifecycle.
	ISO 10993-1:2018	Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process	Offers guidance on evaluating the biocompatibility of medical device materials.
	IEC 60601-1:2005+A1:2012	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance	Specifies general safety and performance requirements for medical electrical equipment.
	IEC 62304:2006+A1:2015	Medical device software—Software life cycle processes	Defines life cycle requirements for medical device software.
Vertical	IEC 60601-2-47:2012	Medical electrical equipment—Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	Specifies safety and performance requirements for ambulatory ECG (Holter) recorders.
	IEC 60601-2-34:2011	Medical electrical equipment—Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	Details requirements for invasive blood pressure monitoring equipment.
	ISO 81060-2:2013	Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type	Provides protocols for clinical validation of automated non-invasive blood pressure monitors.
	ANSI/AAMI EC38:2007	Ambulatory Electrocardiographs	Specifies requirements for ambulatory electrocardiographs, including performance and safety standards.

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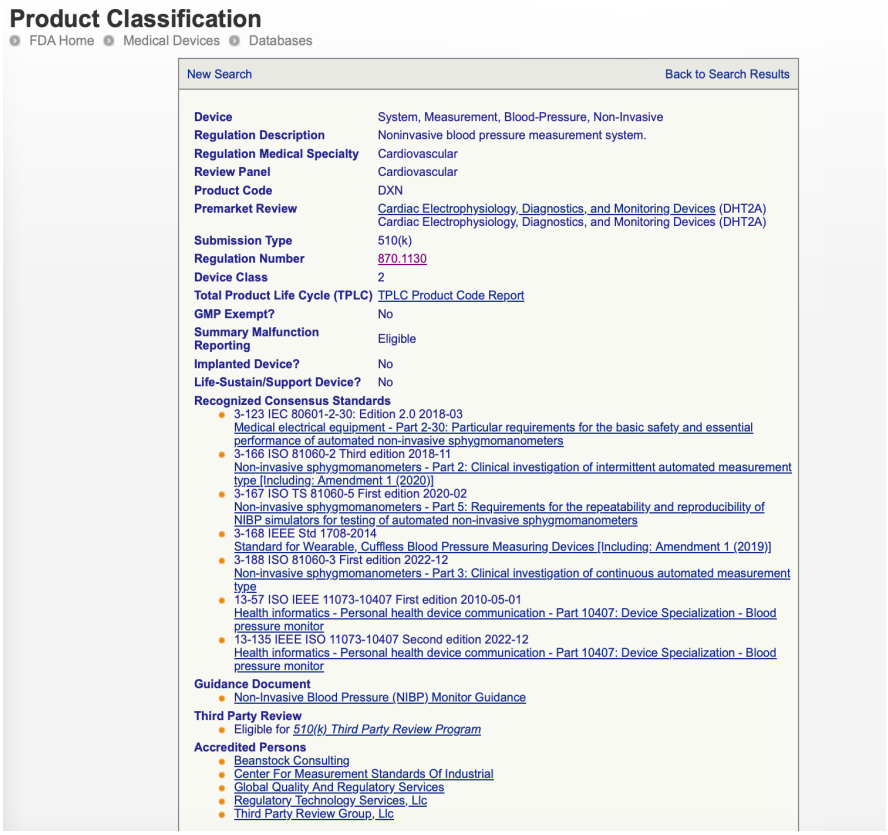
As an example of the device-specific (vertical) performance standards, **Fig. 1** shows a screenshot from the FDA Product Classification Database (510(k) Premarket Notification) for a non-invasive blood pressure monitor. Specifically, it shows 1) the regulatory description and CFR number (870.1130), 2) review panel (cardiovascular), 3) product code (DXN), 4) device class (Class 2), 5) submission type (510(k), 6) specific vertical standards for this type of device including the IEC required testing for safety and essential performance, 7) guidance documents, and 8) accredited persons to review the regulatory file.

Fig. 1 Screenshot from the FDA Product Classification Database (510(k) Premarket Notification) for a particular type of device, non-invasive blood pressure monitor showing the specific vertical standards for this type of device including the IEC required testing for safety and essential performance, guidance documents, and accredited persons to review the regulatory file.



Product Classification

FDA Home › Medical Devices › Databases

New Search | Back to Search Results

Device	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Description	Noninvasive blood pressure measurement system.
Regulation Medical Specialty	Cardiovascular
Review Panel	Cardiovascular
Product Code	DXN
Premarket Review	Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A) Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A)
Submission Type	510(k)
Regulation Number	870.1130
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No

Recognized Consensus Standards

- 3-123 IEC 80601-2-30: Edition 2.0 2018-03
  Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- 3-166 ISO 81060-2 Third edition 2018-11
  Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type [Including: Amendment 1 (2020)]
- 3-167 ISO TS 81060-5 First edition 2020-02
  Non-invasive sphygmomanometers - Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers
- 3-168 IEEE Std 1708-2014
  Standard for Wearable, Cuffless Blood Pressure Measuring Devices [Including: Amendment 1 (2019)]
- 3-188 ISO 81060-3 First edition 2022-12
  Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type
- 13-57 ISO IEEE 11073-10407 First edition 2010-05-01
  Health informatics - Personal health device communication - Part 10407: Device Specialization - Blood pressure monitor
- 13-135 IEEE ISO 11073-10407 Second edition 2022-12
  Health informatics - Personal health device communication - Part 10407: Device Specialization - Blood pressure monitor

Guidance Document

- Non-Invasive Blood Pressure (NIBP) Monitor Guidance

Third Party Review

- Eligible for *510(k) Third Party Review Program*

Accredited Persons

- Beanstock Consulting
- Center For Measurement Standards Of Industrial
- Global Quality And Regulatory Services
- Regulatory Technology Services, Llc
- Third Party Review Group, Llc

Ultimately, testing is far more than a regulatory hurdle—it is the foundation of medical device governance. It bridges the gap between innovation and compliance, enabling manufacturers to bring novel technologies to market while ensuring they adhere to rigorous safety and performance standards.

4 International Coherence and Interoperability

The coherence of testing requirements across jurisdictions significantly influences the medical device industry. And while regulatory frameworks like the FDA's and EU MDR's share common principles, differences in specific requirements can still pose challenges for global manufacturers.

Variations in regulatory requirements across jurisdictions often present challenges to manufacturers, such as increased costs, delays in market entry, and duplicative testing requirements. Organizations like the International Medical Device Regulators Forum (IMDRF) and its predecessor, the Global Harmonization Task Force (GHTF), have played an important

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role in addressing some of these challenges by promoting harmonization and fostering international collaboration through the adoption of international consensus standards.

International consensus standards from ISO and IEC promote international coherence and harmonization. The ISO 13485, the internationally recognized standard for medical device quality management systems, has become a foundational standard to increase harmonization and regulatory coherence since the standard is incorporated by reference by regulation to satisfy the medical device quality management system requirements. It establishes a consistent framework for designing, developing, manufacturing, and maintaining medical devices, providing manufacturers with an international harmonized standard for compliance across multiple jurisdictions. Its alignment with IMDRF principles underscores its pivotal role in global harmonization. Programs like the Medical Device Single Audit Program (MDSAP), spearheaded by the IMDRF, leverage ISO 13485 as a foundational requirement, enabling manufacturers to undergo a single audit that satisfies quality management expectations across several regulatory jurisdictions, including the United States, Canada, Australia, Brazil, and Japan. This program demonstrates the transformative potential of consensus standards in reducing duplicative efforts and facilitating global market access (Minssen 2020).

In addition to quality management frameworks, international consensus standards govern the key tests that medical devices must undergo to ensure safety and performance. For example, the IEC standards outlined in the testing tables—such as IEC 60601 for electrical safety and IEC 61000 for electromagnetic compatibility (EMC)—are globally recognized benchmarks. These standards not only provide detailed methodologies for evaluating device performance but also ensure that testing results are consistent and comparable across borders. By adhering to these standards, manufacturers can demonstrate that their devices meet universally accepted thresholds for safety and efficacy, further streamlining the regulatory process. These consensus standards ensure alignment across markets, reducing the need for redundant testing and facilitating quicker access to global markets.

The IMDRF has also advanced international coherence by addressing emerging technological paradigms, such as Software as a Medical Device (SaMD). Recognizing the distinct regulatory and technical challenges posed by SaMD, the IMDRF has published several key documents, including the "SaMD: Key Definitions" and "SaMD: Clinical Evaluation" guidance. These documents establish a unified framework for defining, evaluating, and regulating SaMD, offering practical tools for regulators and manufacturers alike. By setting internationally agreed-upon criteria for risk categorization, clinical evaluation, and post-market surveillance of SaMD, the IMDRF has facilitated a more coherent approach to this rapidly evolving domain (Minssen 2020).

Despite these advancements, achieving full interoperability remains an ongoing challenge. Programs like MDSAP and the IMDRF's continued advocacy for the adoption of international standards offer practical solutions for bridging these divides. And as the medical device industry continues to evolve, the role of international consensus standards becomes ever more critical. By aligning regulatory requirements with these standards and fostering collaboration among stakeholders, the global regulatory framework can achieve greater coherence and interoperability. This not only ensures consistent safety and performance across markets but also supports innovation and timely access to life-saving medical technologies, including emerging areas like SaMD and AIaMD.

In general aligning testing practices and regulatory requirements with international consensus standards supports global interoperability and it is beneficial for the global medical device industry and users of these devices.

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5 Lessons Learned and Recommendations

The examination of testing frameworks, international standards, and regulatory practices for medical devices offers several critical lessons for advancing both governance and innovation in this sector. These insights not only reinforce the importance of rigorous testing but also highlight opportunities for enhancing international harmonization, regulatory coherence, stakeholder engagement, and adaptability to emerging technologies.

The evolution of medical device testing and regulation highlights a few key lessons for improvement. Table 6 organizes these emphasizing the importance of lifecycle-based testing to validate safety and efficacy at every stage, from development to post-market use. It also notes the importance of international standards such as ISO 13485 and ISO 14971 for global harmonization. Similarly, international technical standards, such as IEC 60601 for electrical safety and IEC 61000 for electromagnetic compatibility, play an important role in aligning global testing and benchmarking practices and reducing duplicative efforts. Programs like the Medical Device Single Audit Program (MDSAP) demonstrate the value of regulatory harmonization. To address challenges posed by emerging technologies, adaptive regulatory pathways must evolve, incorporating innovative testing approaches for Software as a Medical Device (SaMD) and AI. Greater reliance on real-world evidence (RWE) in post-market surveillance, coupled with enhanced public-private collaboration, can further strengthen risk management and foster innovation.

Together, these lessons and recommendations underscore the importance of a comprehensive, internationally harmonized approach to medical device governance that leverages organizations such as ISO, IEC and IEEE.

Table 6 - Lessons Learned from Medical Device Testing and Governance for Medical AI Governance

Category	Lessons Learned	Recommendations
Lifecycle-Based Testing	Testing across the entire lifecycle ensures comprehensive safety and efficacy validation. Iterative evaluations, guided by standards like ISO 13485 and ISO 14971, address risks at every stage.	Ensure testing frameworks integrate lifecycle-based approaches, emphasizing iterative evaluation during Research & Development, Pre-Market, and Post-Market phases.
International Consensus Standards	Global standards like ISO 13485, IEC 60601 (electrical safety), and IEC 61000 (EMC) enable consistent, interoperable testing and reduce duplicative efforts.	Broaden adoption of international consensus standards as the foundation for regulatory submissions, particularly for emerging technologies.
Regulatory Harmonization	Programs like the Medical Device Single Audit Program (MDSAP) demonstrate the benefits of aligned audits, though regional differences (e.g., FDA vs. EU MDR) pose ongoing challenges.	Expand global harmonization efforts by aligning pre-market and post-market regulatory priorities, addressing gaps between regions, and enhancing mutual recognition programs.
Emerging Technologies	Innovations such as Software as a Medical Device (SaMD) and artificial intelligence require new testing approaches. IMDRF frameworks for SaMD provide examples of adaptability.	Develop adaptive regulatory pathways for innovative devices, including AI-driven technologies and dynamic software systems, ensuring risk-appropriate evaluation methods.
Real-World Evidence (RWE)	Post-market testing and surveillance provide critical insights into long-term safety and performance. Emphasizing RWE ensures ongoing device reliability.	Increase focus on real-world evidence in post-market surveillance to identify long-term trends and address unforeseen risks throughout the device lifecycle.
Public-Private Collaboration	Collaborative efforts between regulators, industry, and stakeholders enhance testing methodologies, risk management, and innovation without compromising safety.	Foster public-private partnerships to drive the development of robust testing practices, align on risk management strategies, and support technological advancements in healthcare.

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Beyond the medical device industry, the testing of medical devices offers valuable insights for the broader governance of AI. First, the development of globally harmonized standards for AI-specific testing could mitigate fragmentation and streamline innovation. Second, collaborative mechanisms that include regulators, industry, and other stakeholders can enhance the relevance and fairness of testing frameworks. Third, regulations must be agile and adaptable to address the unique challenges of continuously learning AI systems, ensuring that oversight evolves alongside technological advancements (Aboy 2024b).

6 Conclusion

In conclusion, the lessons learned from existing testing and regulatory practices underscore the importance of a collaborative and adaptive approach to medical device governance. By embracing global standards, fostering harmonization, and addressing emerging challenges, the medical device industry and regulators can promote innovation as well as greater medical device safety and effectiveness. These lessons are applicable to AI/ML-enabled medical devices as well as AI governance in general.

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