White Paper

MedTech Trends Shaping 2026

Explore the key trends driving growth, uncertainty, and change in the MedTech market in the coming year

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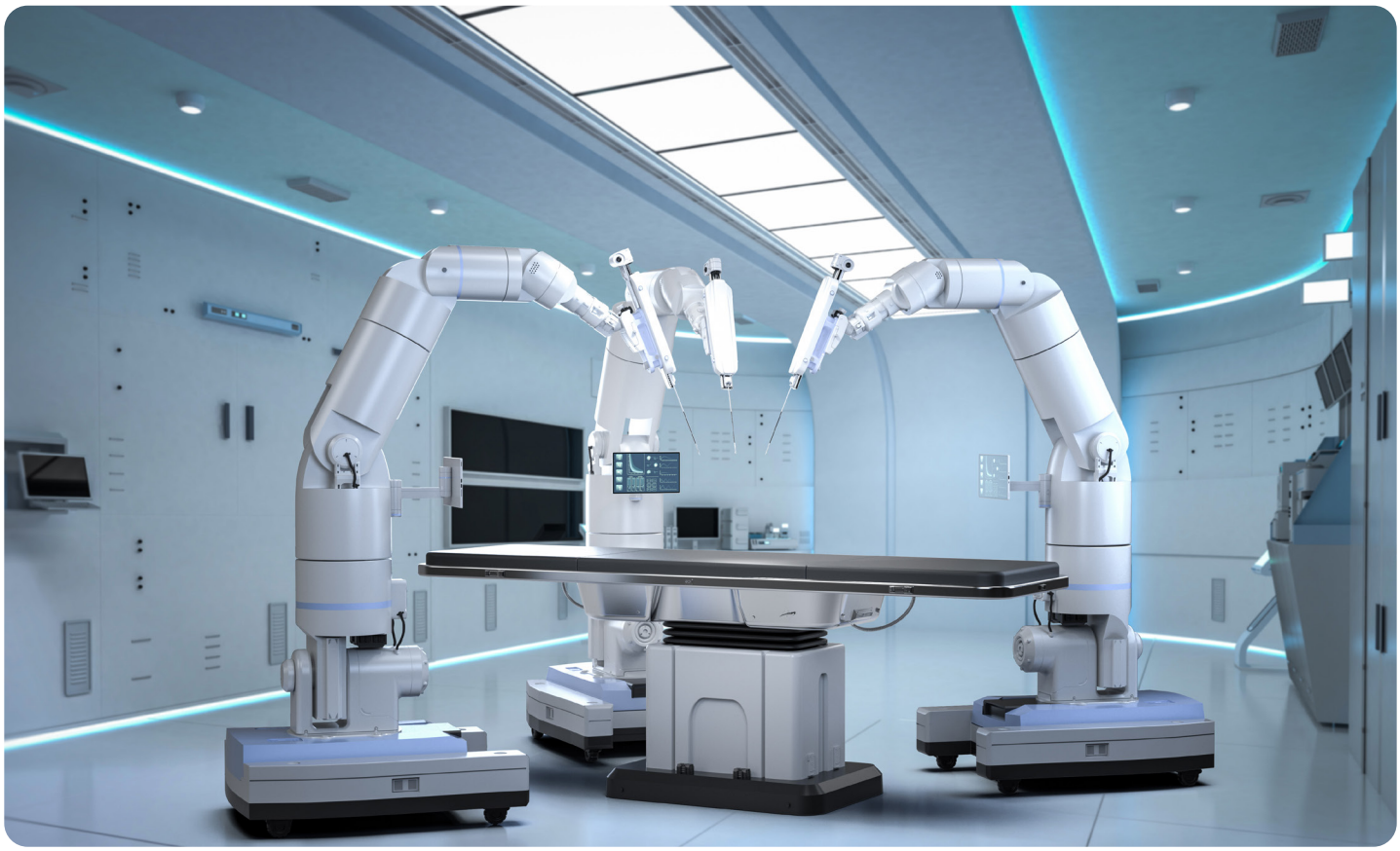
MedTech trends introduction

For the past 12 months, disruptions in the U.S. healthcare market have rippled throughout the global medical device industry. The dynamic situation has provided both challenges and opportunities, but market leaders remain cautiously optimistic that the field will continue to grow in 2026. Much of this confidence is tied to the enormous potential of AI to unlock even more healthcare innovation and the belief that regulators and payers will establish policies that enable this innovation. While uncertainty and rapid change is now the new normal, here are ten trends in the medical device industry that we are watching closely in 2026.



Trend 1: FDA resource constraints and shifting regulatory engagement for MedTech innovators

The FDA's recent operational challenges, including a government shutdown and staffing fluctuations, are influencing the regulatory landscape for MedTech innovators, making it essential to submit clear and focused materials to prevent delays.

During the shutdown, the FDA was unable to accept or review new submissions, and many staff were furloughed, resulting in an immediate halt to regulatory progress and a backlog of pending work. Even after operations resumed, the agency has prioritized meeting user fee agreement timelines, including formal review deadlines for submissions like 510(k)s and PMAs, while other interactions, such as pre-submission meetings and informal consultations, have experienced delays or resulted in less substantive feedback. Given this backlog, industry experts are observing a shift towards less collaborative engagement and receiving more "written response only" communications as the FDA manages internal bandwidth and seeks to keep processes moving.

De Novo and Breakthrough Device Designation reviews may be disproportionately affected, as these are often handled by senior staff (>20 years' experience) and probationary analysts from academia or research (<2 years' experience), who were most affected by recent layoffs and furloughs. Notably, submissions that are well constructed have experienced minimal impact, whereas weaker submissions may result in the deferral of complex issues and require multiple rounds of engagement to resolve matters that could be previously addressed within a single meeting.

For MedTech leaders, these dynamics highlight the need for well-prepared FDA submissions to reduce regulatory and time-to-market risks. The combination of backlog, staffing instability, and less bandwidth by the FDA for dialogue means sponsors must be especially diligent in framing questions and preparing submissions to elicit useful feedback. Extended cycles, particularly for innovative or non-standard approaches, can add months to development leading to downstream impacts on budgets, resource allocation, and commercial launch timing. While user fee agreement timelines for formal submissions remain largely protected, other regulatory interactions may be slower and less detailed, complicating strategic planning.

Leaders should invest in proactive engagement strategies where possible and ensure a level of rigor within submissions and communications to prevent more extended cycles, whilst anticipating that there may be additional rounds of feedback and less collaboration relative to what they have previously observed. Early alignment and clear communication with the FDA will be critical to navigating this evolving environment and minimizing delays.

Trend 2: System integration and data interoperability: The next frontier for connected devices

As medical devices become increasingly connected, the challenge of integrating device-generated data into clinical workflows and Electronic Health Records (EHRs) has emerged as a key factor for MedTech technology in 2026.

Recent innovations that have introduced integrations of their platforms with EMR such as Abbott's LibreView (Freestyle Libre CGM) and Baxter's DeviceBridge (Welch Allyn Connex 360 Vital Signs Monitor), demonstrate the expanding scope of connectivity, ranging from remote monitoring and programming of implants to cloud-based data storage and analytics. The real advantage of these technologies is unlocked when the clinical team can rapidly monitor patient data and seamlessly integrate it with other relevant information. However, device manufacturers and hospital IT teams face significant hurdles: Every EHR implementation is highly customized, technical integration is labor-intensive, and legal, cybersecurity, and biomedical engineering reviews add layers of complexity to account for the risk of integrations. Even with standards like SMART on FHIR, true interoperability is far from automatic.

This has created an environment where integration projects often take months to complete, or some technologies choose not to integrate at all and operate as independent platforms. As a result, data often exists in silos and the proliferation of data platforms has become increasingly difficult to manage. When EHR integrations occur, they are typically regarded as highly valuable.

For MedTech leaders, proactively considering system integration during product development can provide a competitive advantage. Hospitals and health systems increasingly demand proof of cybersecurity readiness such as SOC 2 or HITRUST certification and robust cyber insurance before allowing device data to integrate with their EHRs. Leaders should ensure that their devices are

designed with all applicable data security standards in mind depending on their intended geographies (e.g. ISO/IEC 27001, GDPR, DTAC in UK, HDS in France). This IT literacy and rigor can facilitate better integrations, creating a moat by making it easier to embed their solutions deeply into provider workflows and making it harder for competitors to displace them. Leaders should recognize that integration is not a one-time technical fix but an ongoing, resource-intensive partnership with provider IT teams. Success will require not only technical expertise but also a proactive approach to legal, regulatory, and security requirements.

As the value of connected devices grows, so does the importance of building integration capabilities that are aligned with the evolving demands of healthcare.

Trend 3: A wave of divestitures across the medical device industry

2025 saw announcements and executions of divestitures of relatively large divisions from prominent MedTech manufacturers. These divestitures are poised to reshape notable MedTech markets and shift portfolios.

Notable divestitures executed in 2025:

- Stryker finalized the sale of non-core spine assets to Viscogliosi Brothers, LLC
- Baxter finalized the sale of its Kidney Care business to Carlyle

Notable upcoming divestitures (expected completions in 2026):

- Announced: BD announced its intention to spin off the Biosciences and Diagnostic Solutions business and subsequently merge it with Waters Corp, with the transaction anticipated to be completed by February 2026 (Company Announcement, January 2026)
- Announced: Philips announced its intent to sell its Emergency Care business to Bridgefield Capital (Company Announcement, January 2025)
- Announced: J&J MedTech announced its intent to separate its orthopedics business into an independent company, DePuy Synthes (Company Announcement, October 2025)
- Announced: Medtronic announced its intent to separate its diabetes business into a new standalone company (Company Announcement, May 2025)
- In Consideration: Siemens is considering divesting its diagnostics arm and has held exploratory discussions with private equity firms (Bloomberg, Sept 2025)

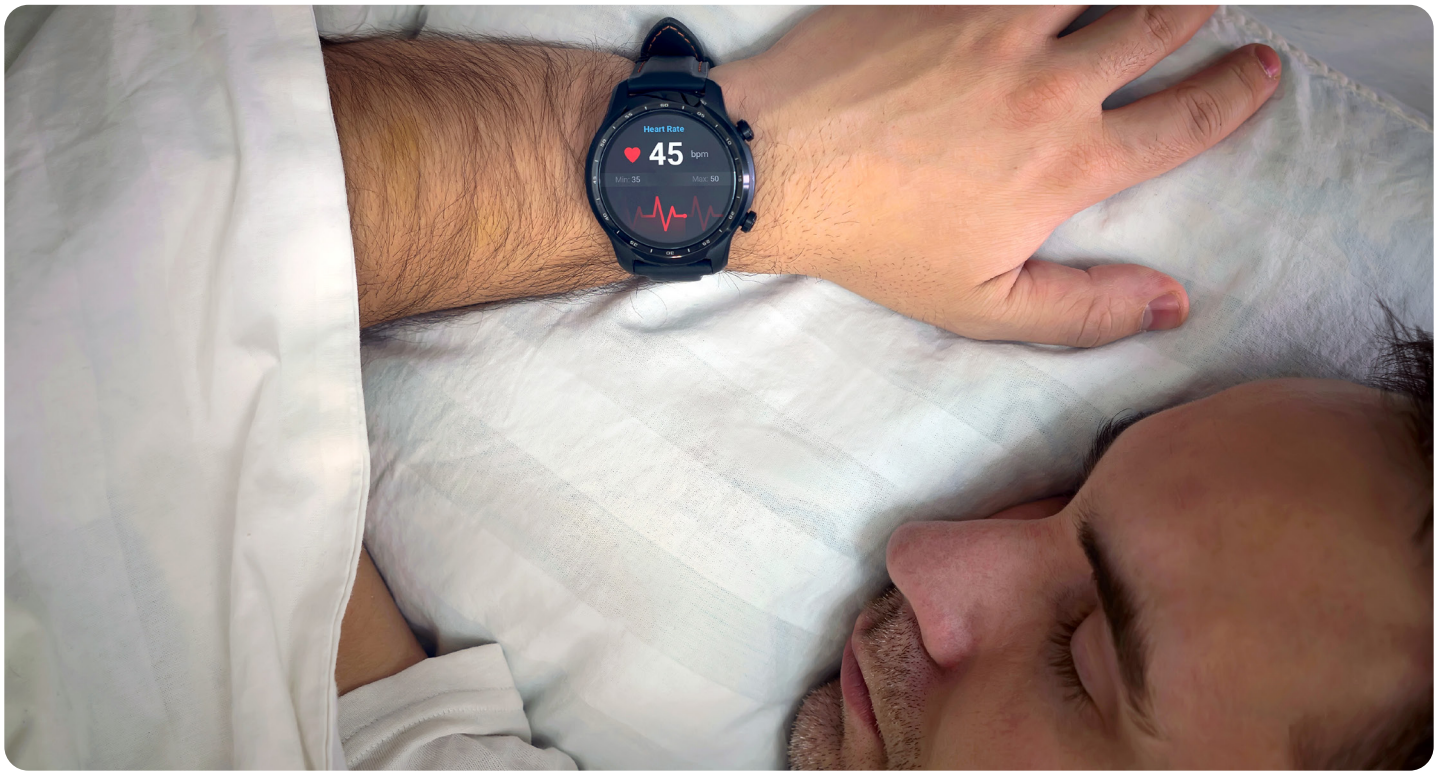
Each of these divestitures is driven by its own unique circumstances, but there are some consistent factors. For the parent organizations, these divestitures allow shedding of lower growth segments, produce liquidity for critical innovations or acquisitions, and simplify portfolios for greater focus and reduced operational burden. For the divested group, they enable a more narrow strategic focus that was not practical when part of the parent organization, allow for acquisitions that may not have been viable when part of the parent company, and remove some barriers to deeper collaborations with companies that may have been a competitor to the parent organization (See Medtronic diabetes and Abbott below). A contributing factor driving this surge in divestitures is the growing interest from private equity in acquiring medical device manufacturers. Many of these acquisitions by private equity seem poised to be bundled with other smaller organizations or merged with other divestitures to build efficient organizations with powerful portfolios.

For MedTech leaders, the ongoing wave of divestitures and spinouts presents both uncertainty and opportunity. As newly independent entities, it may take time before companies fully settle and are able to leverage their strategic positions and operational flexibility. Leaders should closely monitor how private equity engages with these divisions, as investment strategies and operational changes can significantly influence the value creation potential for future buyers.

Trend 4: A moment for the MedTech sleep market

Clinicians have long known that the pillars of good health are nutrition, exercise, and sleep, yet sleep has been overshadowed by the public health focus on obesity and metabolic disease. Most expert guidance and innovation have centered on calorie intake and expenditure, relegating sleep to a distant third priority. This dynamic is changing rapidly, as mounting evidence links sleep quality to a wide spectrum of health outcomes, from cardiovascular risk and dementia to overall life expectancy. Historically, research in sleep has lagged due to the subjectivity, complexity, and expense of traditional sleep studies, leaving manufacturers hesitant to invest in the space. However, the proliferation of smaller, more accessible sleep monitoring tools and wearables that allow monitoring outside of a sleep lab is transforming the landscape, generating unprecedented volumes of sleep data and enabling new insights across therapeutic areas. Investor enthusiasm has driven major funding rounds, such as Beacon Biosignals' recent $86M Series B. This company offers a wearable EEG device powered by advanced AI that generates objective, quantitative biomarkers of brain function during sleep. Another example is Eight Sleep's $100M Series D, which aims to advance their vision for AI-powered sleep optimization through leveraging their technology that tracks cardiovascular and respiratory patterns during sleep, with some applications seeking FDA approval.

The implications for MedTech are significant and extend well beyond the immediate sleep market. As consumers increasingly track their sleep with wearables, demand for better sleep tools and actionable insights is accelerating. Medical device companies are poised to benefit not only from direct opportunities in sleep health, but also from the ripple effects in related fields where sleep data is becoming a sought-after metric for product development, clinical research, and patient management. The surge in sleep data will drive continued investment and innovation, with stakeholders across the healthcare ecosystem seeking to understand and leverage the impact of sleep on health outcomes.



Trend 5: Speed, access, and insight: The next chapter for diagnostics

Two notable diagnostic trends have been building in recent years, with 2026 poised to be an impactful year: the progression of Point-of-Care testing and the growth of liquid biopsies into a substantial market.

Point-of-Care (POC) diagnostics have evolved into a core element of modern healthcare. Rapid platforms now span emergency departments, clinics, pharmacies, and homes, driving a 6-7% annual market growth. Adoption surged during the pandemic, but long-term momentum stems from demand for timely decisions, telehealth expansion, and at-home testing. North America leads in size, while Asia Pacific shows the fastest growth as decentralized testing improves access.

Strategic moves, including bioMérieux's agreement to acquire SpinChip for ~$150M, Hamershlag Private Capital's $150M venture structured investment into Patho Care, and several smaller $5-10M investments in the space signal investor confidence, while market penetration from Abbott's ID NOW, BD's Veritor Plus, and Siemens' CLINITEST highlight continued innovation and execution from strategics. This excitement is well-justified, as the advancement of POC diagnostics is enabling real-time results that reshape clinical decisions by providing faster and more accurate diagnoses, while also extending the reach of diagnostics across various care pathways. Additionally, the ongoing conversation regarding down classification of many oncology companion diagnostics from Class III to Class II (expected in 2026) may bring more players into the market and entice more companies to bring their tests through the FDA. These advancements are fueling the strong momentum seen in the diagnostics field heading into 2026, making POC solutions an increasingly integral part of modern healthcare delivery.

In a parallel trend, the liquid biopsy market is on a strong growth trajectory. Currently an approximately $7–8 billion market globally, it is expected to expand further, fueled by the appeal of fast, non-invasive tests that deliver insights across a wide range of biomarkers and can be easily repeated for ongoing patient monitoring or tracking of disease progression. As enabling platforms advance and the scientific community deepens its understanding of complex biomarker-driven insights, these tests are becoming increasingly impactful, standardized, and widely accepted. Liquid biopsies are often commercially intertwined with small molecule and biopharmaceutical oncology treatments, a connection that will continue to drive innovation and market growth. Notable developments in 2025 include GRAIL's PATHFINDER 2 and SYMPLIFY studies for its Galleri early detection test, as well as expanded applications for Guardant360 Liquid and Reveal.

For more on this trend, read The future of diagnostics: Key trends that will shape point-of-care testing by 2030.

Trend 6: AI adds fuel to the fire of RWE in MedTech

The growth of Real-World Evidence (RWE) in MedTech has been accelerating, with AI advancements set to further enhance data analysis for RWE applications in 2026.

An FDA announcement in December 2025 encouraged broader use of large datasets with de-identified patient information in regulatory processes and included finalized guidance that clarified device manufacturers' use of RWE. AI tools are transforming RWE research by revealing patterns, forecasting outcomes, and offering insights previously attainable only by expert coders or data scientists. Large Language Models (LLMs) now make data analysis more efficient and accessible to a wider range of professionals such as clinicians, engineers, and marketers who may not have previously engaged directly with data tasks. New agent-based analytics can eliminate manual coding entirely by enabling researchers to use natural language queries for their analyses. As medical datasets expand through record linkage and the addition of device-generated information, sophisticated AI analysis will be vital for MedTech companies to more effectively leverage their datasets for RWE applications.

For MedTech leaders, the proliferation of AI-powered analytical tools is reshaping how evidence is generated and used for regulatory, clinical, and commercial decision-making. Traditional AI approaches like Natural Language Processing (NLP) enable higher-grade evidence by extracting specific device information, clinical data points, and patient factors from unstructured healthcare records. For example, wound care studies often rely on generic diagnosis codes and surrogate measures like infections or repeat treatments; however, NLP makes it possible to capture nuanced parameters such as wound size, healing rates, and specific wound characteristics for more robust real-world research. As these tools become more widely available, it is increasingly important to ensure datasets are constructed with rigorous standards for quality, traceability, and governance so that they may be leveraged for evidence strategies. Maintaining trustworthy and verifiable RWE will be essential for all stakeholders, as the industry moves toward richer, more actionable data to support innovation and patient outcomes in 2026 and beyond.

Trend 7: Tech talent — the new battleground for MedTech innovation

As connected devices, interoperability standards, digital health applications, and AI-driven solutions become more prevalent in MedTech, the demand for skilled technology professionals is growing.

Companies increasingly need experts in software engineering, data science, cybersecurity, artificial intelligence, cloud infrastructure, and integrations. However, Big Tech and digital startups are also actively hiring in these fields, often with far greater financial resources than traditional MedTech firms and operating without the constraints of strict regulations. Several strategics including Stryker, Medtronic, Abbott, and BD have recently referenced this war for tech talent in quarterly shareholder meetings and earnings calls. While some recent layoffs in the software sector have created a pool of available talent, expertise in fields such as AI continue to be highly sought after, making it challenging for MedTech companies to compete with larger technology firms.

This trend is further intensified by global factors, including the proposed increase in H1-B fees for new petitions and tighter visa requirements in the U.S. The EU has already enacted policies such as lowered and standardized salary thresholds, lowered experience requirements, and shorter contract minimums to make EU entry more accessible in shortage occupations (e.g., IT/AI/engineering). India and China are scaling tech talent pools rapidly, with India a prime location for MedTech digital centers and Global Capability Centers (GCCs).

Proactively navigating challenges with sourcing, developing, and retaining tech talent is a top priority for leaders as digital transformation becomes increasingly relevant for maintaining a competitive advantage in MedTech. The risks of high turnover and talent poaching by Big Tech or well-funded startups can disrupt product roadmaps and erode institutional knowledge. To compete, leaders must rethink their employer value proposition by offering competitive compensation, career development, and workplace flexibility that rivals the software sector.

Other techniques to leverage may include partnerships with academic facilities, upskilling programs, broadening recruitment to non-traditional backgrounds, and hybrid/remote options. Subsets of tech talent may be attracted to an emphasis on the mission-driven focus of MedTech, while others may find appeal in the cross-disciplinary nature of roles within MedTech (e.g., a role may combine biomedical + clinical + regulatory + AI expertise) or the opportunity to work on novel applications and cutting-edge research. MedTech organizations can also consider adopting more flexible, borderless recruitment strategies that make use of available visa programs where globally applicable, investing in global partnerships, and leveraging remote collaboration tools to build teams.

Trend 8: Co-development and device integration partnerships

As medical devices and technologies become more complex and connected, a trend is emerging regarding collaborations between medical device companies to co-develop or integrate their expertise.

This trend gained momentum in 2024 when Medtronic Diabetes announced its insulin delivery systems/pumps would be integrated with Abbott FreeStyle Libre to enable automated insulin delivery. Beyond its significant clinical implications, this collaboration was noteworthy due to the overlapping diabetes portfolios of the involved companies, as well as their broader competition across multiple clinical markets. While partnerships have long existed in MedTech, they were typically focused on distribution or bundling. The current wave reflects a shift toward product co-development and integration. Some recent collaborations and announcements have included:

- Philips and Edwards: 'DeviceGuide AI' to bring AI into cardiac repair procedures
- GE Healthcare and Volta Medical: AI solution with electrophysiology recording system
- Stryker and Siemens Healthineers: Co-develop a robotic system for neurovascular interventions
- Siemens Healthineers and Cook Medical: Co-develop a radiation free iMRI suite
- Abbott and Tandem Diabetes Care/Beta Bionics/Sequel Med Tech/Ypsomed: Integration of insulin delivery systems with monitoring sensors

For MedTech leaders, this new era of collaboration is both a strategic opportunity and a necessity. These collaborations reflect the degree to which complex innovation has necessitated specialization of data, skillsets, platforms, and sales channels. A key driver of

this trend is the recent AI boom, as it is likely no single manufacturer has access to high volumes of data, AI expertise, and a platform through which AI capabilities can deliver value. Therefore, collaborations to leverage complementary strengths are often required to bring an AI offering to market. Similarly, the momentum around innovation with wearables and robotics require highly complex design and manufacturing skillsets, sales channels, and product platforms. As the pace of announcements continues to accelerate, expect even more cross-company collaborations in 2026, with successful partnerships likely to set new standards in value creation.

Trend 9: MedTech global quality convergence: FDA's 21 CFR 820 harmonizes with ISO 13485

Global regulatory harmonization continues to progress, with the FDA's Quality Management System Regulation (QMSR) set to take effect on February 2, 2026, replacing the legacy QSR (Quality System Regulation). This update formally aligns 21 CFR 820 with ISO 13485 for manufacturers selling in the U.S., allowing companies to leverage a single, internationally recognized quality management system.

The QMSR changes include (but are not limited to): greater emphasis on integrating complaint handling data, clarification of definitions, and requirements for manufacturers to demonstrate that risk-based Quality Management System (QMS) concepts are incorporated throughout the entire QMS, not solely within ISO 14971 design control focused risk management activities.

Additionally, the FDA is retiring its legacy QSIT inspection guide and will implement new compliance programs, meaning internal audit reports, supplier audit reports, and management review reports will now be subject to FDA inspection and emphasis will be placed on integration of processes and process-based narratives. For a deeper dive into the changes, RAPS held a webinar on February 5th, 2026. The replay can be found here: Sponsored Webcast: QMSR Final Rule: Navigating Implementation and Demonstrating Compliance | RAPS

For MedTech leaders, this harmonization offers both opportunity and complexity. While potential exists to streamline compliance processes and establish a more integrated QMS, achieving this requires thorough transition planning, comprehensive gap assessments, and focused training to ensure organizational preparedness for updated audit requirements and terminology. For manufacturers operating only in U.S. markets, this will proactively assist them in creating an ISO 13485 compliant QMS and enable opportunities for international growth. However, they will still need to obtain notified body certification and complete the required submissions and obtain approvals for their respective global markets, as the FDA will not certify products for other countries' markets.

Organizations that can understand these impacts and efficiently navigate these changes will be better positioned to accelerate product launches, expand internationally, and maintain compliance in an increasingly complex global landscape.

Trend 10: The ever exciting and evolving surgical robotics space

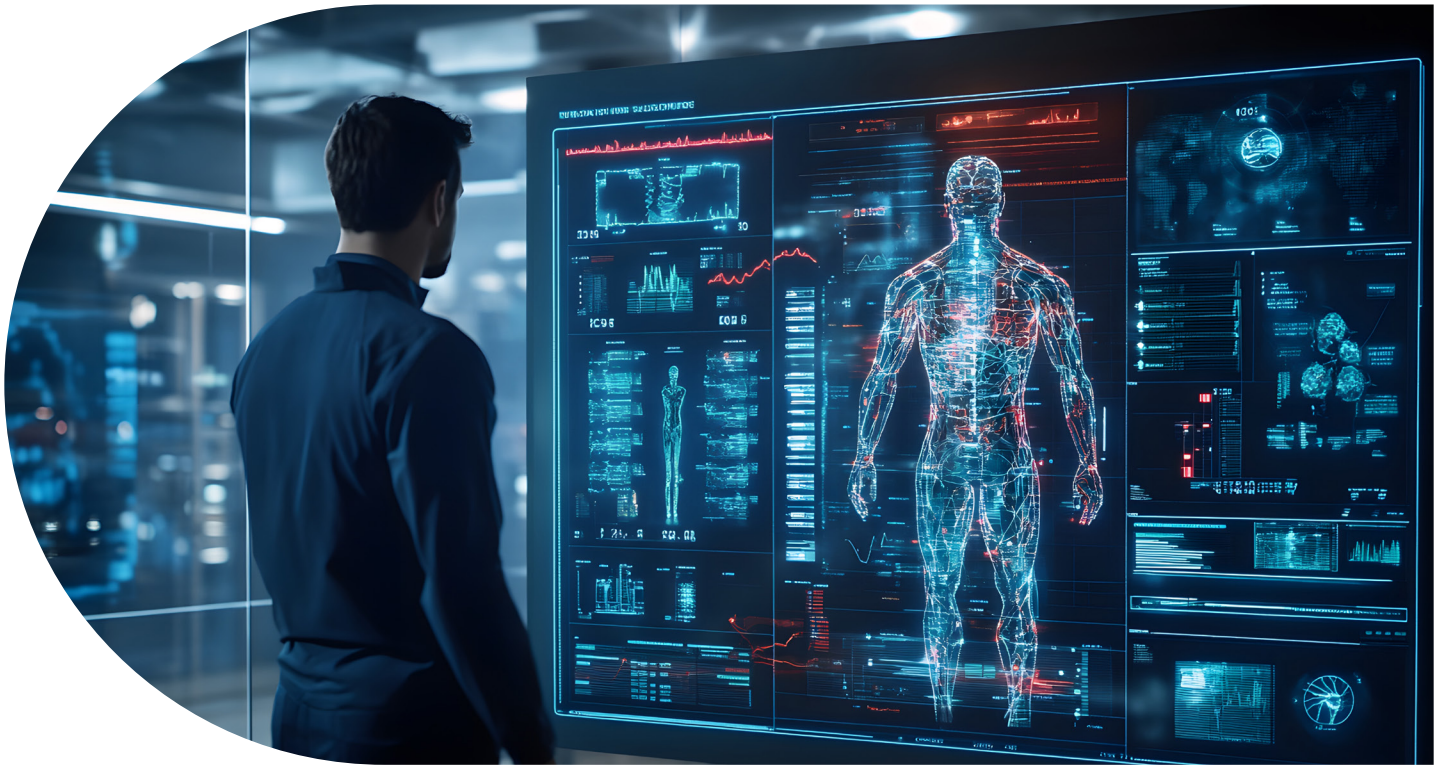
Surgical robotics is shifting into a complex and competitive marketplace, with 2026 set up as a pivotal window for new product entry and use case expansion.

Medtronic's Hugo recently secured FDA clearance for urologic procedures bringing long anticipated competition to Intuitive in the soft tissue space and giving hospitals new choice on platform, pricing, and digital ecosystem integration. J&J's OTTAVA progressed through first U.S. clinical cases in April 2025 (post IDE) and was recently submitted to the FDA for De Novo classification. However, its commercial timing remains uncertain, leaving observers to speculate whether J&J can translate its integrated table arm architecture into near term market impact.

Meanwhile, several emerging companies are seeking to find a niche within soft tissue by leveraging smaller and less costly form factors, specialized indications, and hybrid robotic surgical support models (e.g. Moon Surgical, Distalmotion, CMR Surgical — among others). Intuitive's durable moats, including technical innovation for a wide range of indications, installed base, training, and commercial strategy will make it hard to unseat; however, a growing number of companies are eager to claim a share of the market.

Beyond multi port soft tissue and the increasingly crowded orthopedics space, momentum is building in a diverse range of novel robotic applications such as endoluminal GI (e.g. EndoQuest, Swan EndoSurgical, Neptune Medical, Virtuoso), vascular (e.g. Siemens Healthineers (Corindus), Stryker/Siemens Healthineers, Telos Health, XCath) and the already established area of bronchoscopy (e.g. Intuitive, J&J (Auris), Noah Medical). There is also the emerging category of nonmechanical "robotics adjacent" disruption: HistoSonics' $250M financing for incisionless histotripsy and new entrants like Petal Surgical for acoustic liquefaction, which recently emerged from stealth mode with $20M of funding, broadening the interventional playbook to potentially shift portions of care from cutting to energy based, image guided therapies. Investor confidence remains high in these applications: Fred Moll, considered a leading pioneer of robotic surgery, committed ~$100M to next gen startups across high precision and high volume procedures, setting the tone for continued category expansion.

Potential for cost disruption is also rising: India's SS Innovations recently filed a US 510(k) for the lower cost SSi Mantra system (Dec 2025), while China's MicroPort MedBot gained NMPA approvals and touted commercial tele robotic capabilities. It is anticipated that U.S./Europe/Japan will anchor the premium segments while India/China scale value-oriented robots globally. These value-based systems may be especially compelling for Ambulatory Surgery Center (ASC) sites. While surgical robotics have historically focused on hospital settings due to capital intensity and infrastructure needs, ASCs continue to gain share of the outpatient procedure market, especially in the U.S. ASC uptake of robotic surgical systems currently remains constrained by capital burden and reimbursement, but manufacturers are more aggressively exploring ideas around financing options to reduce capital outlay. Reimbursement still remains the white whale — in the U.S., the leading market for robotics, there's still no national separate add-on payment for robotic assistance (e.g., S2900 routinely non-payable; robotic technique treated as integral to the primary procedure under payer policies and OPPS packaging), which keeps return on investment grounded in outcomes, efficiency, and service line strategy rather than per case premiums. It is likely this challenge will persist as new robotic platforms are launched with clearance for a diverse range of procedures.



Conclusion

The advent of AI, the astonishingly rapid increases in available data, and the evolving regulatory environment will undoubtedly generate even more impactful events that we have covered here, but we are confident that the talent and innovation that has always been the hallmark of MedTech will continue to adapt and overcome any challenges that emerge. For any questions or additional information about the topics presented above, please email us at meddevice@IQVIA.com.

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