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Editorial

MedTech Summit Berlin 2026: Where Innovation Meets Regulation

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INTRODUCTION

The medical technology sector entered one of the most transformative periods in its history in 2026. Artificial intelligence had moved from experimental pilot projects into clinical reality. Software had become as critical to patient outcomes as hardware. Digital evidence was reshaping clinical evaluation, while sustainability requirements were increasingly influencing product development decisions. At the same time, regulators across Europe and around the world were working to keep pace with technologies that were evolving faster than traditional regulatory frameworks had ever been designed to accommodate. Against this backdrop, the MedTech Summit 2026, held in Berlin, Germany, from 15-18 June 2026, brought together regulators, manufacturers, notified bodies, clinicians, researchers, legal experts, and technology leaders to address the industry's most pressing challenges. The event welcomed approximately 293 attendees, including 98 speakers, and featured representation from more than 150 organisations worldwide, as well as freelancers and independent consultants. Across four days of discussions, workshops, case studies, and roundtable sessions, a common theme emerged: the future of MedTech would belong to organisations that view regulatory integration by design as a strategic enabler, embedding regulatory, clinical, and quality considerations into innovation processes from the outset rather than treating compliance as a downstream activity. The summit provided a valuable platform for collaboration, knowledge exchange, and forward-looking discussions on the evolving regulatory, technological, and commercial landscape of the medical technology industry.

Artificial Intelligence Takes Centre Stage

No topic dominates the agenda more than Artificial Intelligence (AI). From keynote sessions exploring the relationship between the European Union's Medical Device Regulation (MDR) and the AI Act to discussions on explainable AI, software lifecycle management, AI risk governance, and post-market monitoring, the conference reflects the reality that AI has become a defining force in healthcare innovation. The industry's challenge is no longer whether AI will be adopted but how it can be implemented responsibly. Sessions examining AI-enabled medical devices, machine learning software, and generative AI solutions demonstrate that manufacturers are increasingly focused on establishing governance frameworks capable of supporting continuous learning systems while maintaining regulatory compliance. Particularly significant are discussions surrounding explainable AI and algorithm transparency. As healthcare professionals and patients rely more heavily on AI-driven decisions, trust becomes as important as technical performance. Regulators are demanding greater visibility into how algorithms function, while manufacturers must demonstrate that AI systems remain safe, effective, and understandable throughout their lifecycle. The emergence of sessions dedicated to AI drift, change management, and risk management under the AI Act highlights another critical reality: AI products are dynamic. Unlike traditional devices, software and machine learning systems evolve over time, creating new challenges for quality management systems, post-market surveillance, and regulatory oversight. The conference's focus on these issues reflects a broader shift in MedTech. Regulatory compliance is increasingly becoming an enabler of innovation rather than merely a barrier to market entry.

The Evolving European Regulatory Landscape

While artificial intelligence commanded significant attention throughout the conference, the backbone of the discussions remained European regulatory transformation. Nearly a decade after its adoption, the MDR continued to shape industry strategy and operational decision-making. Sessions examining MDR revisions, conformity assessment procedures, legacy device compliance, clinical evidence expectations, and EUDAMED implementation demonstrated that manufacturers were still adapting to a regulatory environment that continued to evolve. The conference took place at a particularly important moment for the industry. Proposed MDR revisions, implementation updates from European authorities, and ongoing efforts to reduce certification bottlenecks had created both opportunities and uncertainty. Industry leaders sought greater clarity on how future reforms would affect innovation timelines, resource planning, investment decisions, and market access strategies. Several sessions focused specifically on regulatory modernisation initiatives, including

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EUDAMED, digital technical documentation, and streamlined conformity assessment processes. These discussions reflected a growing recognition that regulatory systems themselves would need to become more digital, connected, and efficient if they were to support increasingly complex healthcare technologies. A recurring theme throughout the conference was the challenge posed by the highly decentralised nature of the EU MDR and IVDR ecosystem. Manufacturers continued to navigate a fragmented landscape involving multiple competent authorities, notified bodies, expert panels, and national implementation approaches, often resulting in inconsistencies, duplicated effort, and extended regulatory timelines. Participants highlighted how variations in interpretation and assessment practices across the European regulatory network continued to create uncertainty and increase compliance burdens, particularly for small and medium-sized enterprises. The absence of a fully integrated digital regulatory infrastructure was also identified as a significant barrier to efficiency. While initiatives such as EUDAMED represented important progress toward greater transparency and coordination, stakeholders noted that the broader regulatory ecosystem remained dependent on a combination of disconnected systems, manual processes, and fragmented data exchanges. Many speakers advocated for a more unified digital platform capable of supporting end-to-end regulatory workflows, improving data interoperability, facilitating real-time information sharing, and reducing administrative complexity across the product lifecycle. At the same time, legal experts examined the implications of the revised Product Liability Directive, highlighting the expanding responsibilities facing manufacturers of software-driven and AI-enabled medical devices. The intersection of liability, patient safety, cybersecurity, data governance, and algorithmic decision-making emerged as one of the most significant regulatory debates of the coming decade. Several legal and regulatory experts also advocated for greater alignment through horizontal EU legislation, arguing that the growing overlap between the MDR, IVDR, AI Act, Cyber Resilience Act, Data Act, GDPR, and Product Liability Directive risked creating an increasingly complex and fragmented compliance environment. Speakers emphasised the need for more harmonised, cross-cutting regulatory frameworks and coordinated implementation mechanisms to streamline the European regulatory landscape, reduce duplication of requirements, improve legal certainty, and enable innovation while maintaining high standards of safety, performance, and public trust.

Clinical Evidence in the Digital Age

Another dominant theme throughout the summit was the evolution of clinical evidence generation. Traditional approaches to clinical investigations were increasingly being supplemented, and in some cases challenged, by emerging methodologies. Sessions dedicated to Real-World Evidence (RWE), Post-Market Clinical Follow-Up (PMCF), systematic literature reviews, and digital evidence generation demonstrated how manufacturers were seeking more efficient and scalable pathways to demonstrate safety, performance, and clinical benefit. Perhaps one of the most transformative areas of discussion was the growing focus on *in silico* trials. Once viewed as a future possibility, computational modelling and simulation were increasingly being explored as practical tools for medical device evaluation. Multiple sessions examined how virtual testing could complement, augment, or partially replace conventional clinical studies. The potential benefits were substantial. *In silico* methodologies offered opportunities to reduce development costs, accelerate innovation cycles, optimize study design, and improve patient safety by identifying potential risks earlier in the development process. However, participants acknowledged that widespread adoption would depend on regulatory acceptance, internationally recognised standards, robust validation frameworks, and greater confidence in the reliability and reproducibility of simulation-based evidence. The conference's extensive exploration of these topics highlighted that evidence generation itself was undergoing a profound digital transformation. Manufacturers were moving beyond traditional clinical studies toward integrated evidence ecosystems that combined clinical investigation data, real-world evidence, simulation outputs, post-market surveillance findings, and advanced analytics to support regulatory and clinical decision-making throughout the product lifecycle. Discussions also highlighted the particular challenges faced by developers of orphan and paediatric medical devices within the current European regulatory framework. Several speakers noted that, unlike the pharmaceutical sector, the EU regulatory system provided limited dedicated incentives for the development of devices targeting rare diseases or small paediatric populations. The high costs of clinical evidence generation, combined with stringent MDR and IVDR requirements and relatively small commercial markets, often created significant barriers to innovation in these areas. Stakeholders expressed concern that the current regulatory and economic environment could discourage investment in devices intended for underserved patient populations, potentially limiting patient access to innovative technologies. Many participants therefore called for greater regulatory flexibility and targeted policy measures to support orphan and paediatric device development, including proportionate evidence requirements, enhanced use of real-world evidence, adaptive regulatory pathways, and incentives that recognise the unique challenges associated with generating clinical data in small patient populations. For regulators and industry alike, the challenge was no longer simply generating more evidence, but ensuring that emerging evidence paradigms maintained scientific rigour, transparency, and patient safety while enabling innovation and improving access to technologies for all patient groups, including those with rare diseases and unmet clinical needs.

Reimagining Biological Safety Evaluation

A significant portion of the summit was devoted to biological evaluation and biocompatibility, reflecting the continued importance of foundational safety science in medical device development. Numerous sessions examined ISO 10993 implementation, toxicological risk assessment, chemical characterization, biological evaluation plans, and emerging standards development. These discussions underscored how biological safety evaluation continued to evolve in response to scientific advances, emerging technologies, and changing regulatory expectations. One particularly noteworthy trend was the growing emphasis on reducing animal testing. Industry experts explored alternatives such as advanced *in vitro* methods, computational toxicology, New Approach Methodologies (NAMs), and AI-driven assessment approaches. This reflected broader societal, ethical, scientific, and regulatory pressures to identify scientifically robust alternatives to traditional animal testing models while maintaining high standards of patient safety and regulatory confidence. The increasing integration of computational methods into biological safety assessments mirrored developments occurring elsewhere in the MedTech sector. Digital tools were not only transforming software-based products but were also reshaping fundamental scientific and regulatory processes across the product lifecycle. As regulatory authorities continued to evaluate and validate alternative testing strategies, biological evaluation was increasingly being viewed as one of the next major areas of innovation within regulatory science. Another important area of discussion focused on per- and Polyfluoroalkyl Substances (PFAS), a large group of more than 10,000 synthetic chemicals often referred to as "forever chemicals" due to their persistence in the environment and resistance to degradation. Given the widespread use of PFAS in certain medical devices and healthcare applications because of their unique performance characteristics, participants examined the potential impact of evolving European regulatory initiatives aimed at restricting or more tightly controlling these substances. Speakers highlighted the need for regulatory approaches that balanced environmental and public health objectives with the continued availability of safe and effective medical technologies. Discussions explored challenges related to PFAS identification, chemical characterisation, risk assessment, substitution strategies, and supply chain transparency. Many stakeholders advocated for clearer regulatory guidance, risk-based implementation pathways, and greater coordination between medical device regulations and broader European chemicals legislation to avoid unintended consequences for healthcare systems and patient access. Overall, the discussions demonstrated that biological evaluation was expanding beyond traditional biocompatibility assessments to encompass broader considerations of chemical safety, environmental sustainability, material innovation, and lifecycle risk management. This evolution reflected a growing recognition that future regulatory science would need to integrate patient safety, environmental responsibility, and technological innovation within a more holistic framework for medical device evaluation.

Global Regulatory Convergence and Market Access

Although European regulations remained central to the conference, the agenda highlighted the increasingly global nature of medical device regulation and the growing interconnectedness of healthcare markets. Dedicated sessions explored regulatory pathways and emerging policy developments in China, Japan, the United States, Switzerland, the United Kingdom, and other key international markets. These discussions reflected the reality that regulatory decision-making could no longer be viewed through a purely regional lens, as manufacturers increasingly developed products for simultaneous access across multiple jurisdictions. Industry leaders, regulators, and market access experts examined the challenges associated with navigating diverse regulatory frameworks amid ongoing supply chain disruptions, geopolitical uncertainties, evolving trade relationships, and increasing demands for resilience in global healthcare systems. Participants shared experiences on managing parallel regulatory submissions, coordinating post-market obligations across jurisdictions, and addressing differing expectations for clinical evidence, cybersecurity, software validation, quality management systems, and lifecycle compliance. The emphasis on global harmonisation reflected a growing strategic priority across the medical technology sector. Manufacturers increasingly recognised that regulatory divergence created significant operational, financial, and innovation-related burdens. Differences in evidence requirements, approval pathways, terminology, technical documentation expectations, and post-market surveillance obligations often resulted in duplicated effort, delayed market access, and increased development costs. As a result, considerable attention was devoted to initiatives aimed at strengthening international regulatory cooperation, expanding reliance mechanisms, promoting convergence through international standards, and advancing the work of organisations such as the International Medical Device Regulators Forum (IMDRF). Particularly significant were discussions comparing European MDR and IVDR requirements with regulatory approaches adopted by the U.S. Food and Drug Administration (FDA) and major Asian regulatory authorities. Speakers examined areas of both convergence and divergence, highlighting how differences in classification systems, clinical evidence expectations, software regulation, cybersecurity requirements, and AI governance frameworks could create substantial challenges for globally marketed products. The emergence of artificial intelligence as a transformative healthcare technology further amplified the importance of international regulatory alignment. Multiple sessions explored how regulators around the world were approaching AI-enabled and adaptive medical devices, including issues related to algorithm transparency, performance monitoring, change management,

bias mitigation, clinical validation, and post-market oversight. Participants acknowledged that while regulatory innovation was occurring across many jurisdictions, inconsistent requirements risked creating barriers to global deployment and slowing the adoption of technologies that could benefit patients worldwide. Greater consistency in regulatory expectations was therefore viewed as essential for supporting innovation, investment, and equitable access to AI-driven healthcare solutions. Beyond regulatory compliance, discussions also highlighted the growing importance of global market intelligence and strategic regulatory planning. Regulatory affairs professionals were increasingly expected to understand not only the requirements of individual jurisdictions but also the interactions between regulatory systems, reimbursement frameworks, health technology assessment processes, and broader healthcare policies. This shift reflected the expanding role of regulatory functions within organisations, moving from a primarily compliance-focused discipline to a strategic capability that directly influences product development, market entry, commercialisation, and long-term business growth. The conference ultimately demonstrated that regulatory affairs professionals were no longer merely regional specialists responsible for obtaining approvals in individual markets. They had become global strategists, tasked with coordinating compliance, evidence generation, market access, and lifecycle management across increasingly interconnected regulatory ecosystems. As healthcare technologies continued to transcend national boundaries, the ability to navigate and influence the global regulatory landscape emerged as a critical competitive advantage for the medical technology industry.

Digital Transformation Beyond the Product

While much of the attention focused on digital health products and emerging technologies, the conference also examined the digital transformation of MedTech organisations themselves. Sessions addressing quality management systems, regulatory information management, technical documentation, software development integration, data interoperability, and automated information extraction revealed how companies were modernising their internal regulatory and operational processes to meet the increasing demands of a complex compliance environment. The emergence of AI-powered compliance and regulatory intelligence tools illustrated a broader industry trend: organisations were beginning to apply the same digital technologies they were developing for healthcare applications to their own quality, regulatory, and business operations. Discussions highlighted the growing adoption of automation for literature reviews, clinical evidence management, regulatory submissions, post-market surveillance activities, and technical documentation generation. Digital quality management platforms and connected regulatory information systems were increasingly being viewed as essential enablers of efficiency, consistency, and scalability. Speakers also emphasised that digital transformation was extending beyond simple process automation. Many organisations were moving toward integrated digital ecosystems capable of connecting product development, clinical evidence generation, quality management, regulatory affairs, and post-market activities through shared data environments. Such approaches were seen as critical for supporting the concept of regulatory integration by design, enabling regulatory and quality considerations to be embedded throughout the product lifecycle rather than addressed as separate downstream activities. At the same time, participants acknowledged that these technological advances introduced new governance challenges. The use of AI and automation within regulated processes raised important questions regarding system validation, data integrity, transparency, traceability, cybersecurity, human oversight, and accountability. Regulators and industry leaders alike recognised that confidence in digital tools would depend not only on their efficiency gains but also on their ability to operate within robust governance frameworks that ensured reliability and regulatory compliance. As regulatory requirements continued to expand and product technologies became increasingly data-driven, the conference highlighted a growing consensus that digital transformation was no longer merely a source of competitive advantage. Rather, it had become a strategic necessity for organisations seeking to manage regulatory complexity, improve operational resilience, and maintain compliance while accelerating innovation in an increasingly demanding global MedTech environment.

Sustainability Moves Into the Mainstream

Sustainability emerged as an increasingly prominent topic throughout the summit. Sessions focused on PFAS (Per- and Polyfluoroalkyl Substances) reporting, environmental legislation, circular economy initiatives, and sustainability-driven value creation demonstrated how environmental considerations were becoming deeply embedded within MedTech strategy and decision-making processes. Historically, sustainability initiatives had often operated separately from regulatory, quality, and product development functions. Discussions at the conference indicated that this separation was rapidly disappearing. New reporting obligations, evolving chemical restrictions, climate-related disclosures, and environmental regulations were directly influencing product design decisions, material selection, manufacturing processes, supply chain management, and long-term market access strategies. As a result, sustainability was increasingly being viewed not simply as a corporate responsibility initiative, but as a strategic business and regulatory requirement. Particular attention was given to the evolving regulatory landscape surrounding PFAS, with stakeholders assessing the potential impact of future restrictions on medical devices and healthcare products. Participants discussed the challenges of balancing environmental objectives with patient safety and device performance, especially in applications where PFAS materials currently provide critical technical and clinical benefits. These

discussions reinforced the growing need for proactive material assessment, supply chain transparency, and the development of suitable alternatives where feasible. Speakers also highlighted the increasing convergence of sustainability, regulatory compliance, and innovation. Environmental considerations were becoming integrated into product lifecycle planning, risk management activities, supplier qualification processes, and design control frameworks. This shift reflected a broader movement toward lifecycle-based thinking, where manufacturers were expected to consider not only the safety and performance of products but also their environmental impact from raw material sourcing through end-of-life management. The integration of environmental considerations into regulatory and strategic discussions highlighted a wider trend toward holistic product stewardship. Throughout the summit, there was a growing recognition that future success in the MedTech sector would depend not only on clinical performance, technological innovation, and regulatory compliance, but also on an organisation's ability to demonstrate environmental responsibility, resource efficiency, and sustainable value creation across the entire product lifecycle.

Supporting Innovation for SMEs

The agenda also acknowledged the unique challenges facing Small and Medium-Sized Enterprises (SMEs), which continue to play a vital role in driving innovation across the medical technology sector. Dedicated sessions explored regulatory planning, clinical evidence generation, market access strategies, resource optimisation, and common compliance pitfalls encountered by emerging companies navigating increasingly complex regulatory environments. These discussions recognised that while regulatory requirements under frameworks such as the MDR and IVDR continued to expand, smaller organisations often had significantly fewer financial, technical, and regulatory resources available to manage compliance obligations. Participants highlighted how rising certification costs, increasing clinical evidence expectations, limited notified body capacity, and prolonged regulatory timelines could disproportionately affect SMEs, placing additional pressure on innovation and commercial viability. At the same time, speakers emphasised that SMEs remained a critical source of technological advancement within the MedTech ecosystem. Many breakthrough technologies, novel digital health solutions, and disruptive medical innovations originated from startups, university spinouts, and emerging companies rather than large multinational organisations. Preserving this innovation pipeline was therefore viewed as essential for maintaining the long-term competitiveness of the European medical technology sector and ensuring continued access to innovative healthcare solutions for patients. A recurring theme throughout these sessions was the need to strike an appropriate balance between patient protection and innovation. Participants discussed how regulatory frameworks must continue to uphold high standards of safety, performance, and clinical evidence while avoiding unnecessary barriers that could discourage investment, delay market entry, or limit the ability of smaller companies to scale and compete effectively. Discussions on SME success factors, regulatory strategy, and evidence generation reflected a growing awareness among regulators, policymakers, and industry leaders of this delicate balancing act. Many speakers advocated for greater regulatory predictability, improved access to guidance, enhanced support mechanisms, proportionate regulatory approaches, and increased use of digital tools to reduce administrative burden. These measures were seen as important steps toward fostering an environment where SMEs could continue to innovate while successfully navigating an increasingly demanding regulatory landscape.

Building the Future Regulatory Workforce

An often-overlooked aspect of industry transformation was talent development. The summit addressed this through networking initiatives, leadership discussions, and dedicated opportunities for emerging regulatory professionals. As MedTech became increasingly interdisciplinary, the discussions highlighted that future leaders would require expertise spanning engineering, data science, clinical research, quality systems, cybersecurity, sustainability, and regulatory affairs. The traditional regulatory specialist role was evolving into something significantly broader and more integrated. Participants noted that tomorrow's professionals would need to understand both technology and policy, innovation and compliance, global strategy and local implementation, while also navigating increasingly complex regulatory frameworks such as the MDR, IVDR, and emerging digital health legislation. This shift underscored the growing need for continuous upskilling and cross-functional collaboration across the sector. At the same time, the conference highlighted the particular challenges faced by smaller notified bodies operating within the European regulatory system. These organisations were under increasing pressure due to rising workloads, more complex technical assessments, evolving designation requirements, and stringent oversight expectations. Limited capacity and resource constraints often made it difficult for smaller notified bodies to recruit and retain specialised expertise across all high-risk and emerging technology areas, including software, AI-enabled devices, and advanced materials. Speakers noted that this imbalance in capacity across the notified body ecosystem could contribute to bottlenecks in conformity assessment, longer certification timelines, and variability in review depth. It also placed additional strain on manufacturers, particularly SMEs, who depended on timely and consistent assessments to bring innovative products to market. The conference therefore emphasised the importance of strengthening the overall regulatory ecosystem through targeted capacity building, improved training pathways, and greater collaboration between regulators, notified bodies, and industry. Initiatives aimed at harmonising competencies, supporting knowledge transfer, and

enhancing digital tools for assessment were seen as key enablers for addressing these challenges. Ultimately, the summit served as a platform for cultivating the next generation of industry leadership while also recognising that sustainable regulatory performance would depend not only on innovation in technology, but also on investment in people, institutional capacity, and cross-sector expertise.

Looking Ahead

The MedTech Summit 2026 arrived at a pivotal moment for the healthcare technology sector. Artificial intelligence, digital evidence generation, computational modelling, sustainability requirements, and global regulatory evolution were converging simultaneously, reshaping both industry strategy and regulatory practice. Rather than viewing regulation and innovation as opposing forces, the conference presented a more sophisticated perspective. The future, as discussed in Berlin, belonged to organisations capable of integrating technological advancement with robust governance, scientific rigour, and patient-centred design throughout the product lifecycle. The discussions suggested that the industry was moving beyond the initial disruption caused by MDR implementation and the rapid emergence of AI-enabled technologies. Attention was increasingly shifting toward optimisation, scalability, and long-term sustainability, as stakeholders sought to stabilise regulatory approaches while enabling continued innovation. Medical technology was entering a new era, one in which software, data, and intelligent systems played a central role in healthcare delivery and decision-making. Yet the core mission remained unchanged: improving patient outcomes while ensuring safety, reliability, and public trust. The conversations at MedTech Summit 2026 reflected an industry actively defining how that mission would be achieved in the years ahead. From AI governance and regulatory integration by design to clinical evidence modernisation, biological safety innovation, sustainability requirements, and global regulatory harmonisation, the summit offered a comprehensive view of the forces shaping the future of healthcare technology. Discussions highlighted how these domains were becoming increasingly interconnected, requiring more holistic and coordinated approaches across regulatory, clinical, and technical disciplines. For regulators, manufacturers, clinicians, and innovators alike, Berlin served not only as a meeting place but also as a lens into the next chapter of MedTech evolution, one defined by convergence, digitalisation, and a growing emphasis on system-level thinking across the global healthcare technology landscape.

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