Qt Group

From Conservative to Bold: **How MedTech is Transforming Itself**

2024

FOREWORD

It has long been argued that more regulation equals less innovation. Developers who prioritize innovation claim regulation deters innovation by increasing costs and restricting avenues for innovation. Conversely, those who prioritize regulation argue it plays a key role in creating checks and balances to protect consumers.

Balancing the two is a delicate art, especially in highly regulated industries like automotive, aviation, and medical devices, which are known for their long product development cycles and high R&D investments. Failure to comply with regulations can mean a product is simply not allowed onto the market, making it high-risk for technology companies.

The emergence of disruptive technologies like AI and quantum computing is making matters even more complicated. As tech companies use these new tools to shorten development time and innovate entirely new products and services, it raises pressure to shift regulatory goalposts, and regulators are left scrambling to put in place new guardrails to protect society without stifling innovation.

Is there a way out? Designing systems with adaptability and scalability in mind is one way to futureproof against evolving regulatory demands. The MedTech sector is a good example of how this could be done.

In this vision paper, we take stock of the factors driving MedTech innovation and envision the different forms it is expected to take.

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Disruption is Forcing MedTech's Evolution

The MedTech industry is rapidly evolving, and three factors are influencing its future development.

- The COVID-19 pandemic brought with it the need for medical devices to go beyond traditional roles. It accelerated the demand for remote and personalized care, transformed medical device connectivity, and highlighted the urgent need for cybersecurity. As the trend toward treating patients outside hospital settings continues, these connected devices are increasingly becoming an integral part of our homes.

- Modern consumers conditioned by personal technology devices have come to expect improved accessibility and seamless user experiences from the devices they use. There is growing demand for MedTech devices to replicate some of these features while ensuring they are reliable and robust enough to be used by non-professionals. Experts expect MedTech innovation to be focused on making next-gen healthcare devices intuitive health companions that are as comfortable to use as the latest smartphone.

- Big data, AI, quantum computing, and virtual and extended reality systems are unlocking new products and services in MedTech. In 2022, at least 91 new AI-related algorithms gained FDA approval in just the first 10 months, hinting at the rapid pace of development in this space (Source: EY Pulse of the Industrial Medical Technology Report 2023).

These shifts also introduce new challenges and opportunities from the perspective of user experience, interoperability, and security. By focusing on intuitive, secure, and accessible design, MedTech companies hope to drive innovation that improves patient outcomes while navigating the complex regulatory environment with confidence.

"While integrating modern user experiences into medical devices, we must balance innovation with regulatory compliance and patient safety. It requires careful planning and execution to deliver the best outcomes for both healthcare providers and patients."

- Roger Mazzella, Senior Product Lead, Medical at Qt Group

TREND: Intuitive UI/UX & Connectivity Will Enable Better Patient Care

"Doctors often have only about 90 seconds per patient to prepare before an appointment," notes Marc Caposino, Managing Director of Fuselab Creative, a US-based design studio. "A sophisticated, human-centered UX/UI-driven EHR system can significantly enhance their efficiency."

In healthcare, design has historically come second to the treatment or tool. Considering their relatively high costs and specialized use, devices usually run on UX/UI design that is built for purpose and unable to adapt to take into use new tech or comply with increasingly stringent regulations. All this leads to inefficiency in the system.

As MedTech devices increasingly move into home settings, B2B MedTech players are seeing competition from B2C manufacturers. The latter are bringing in modern UX/UI principles into the design and use of these consumer products, which have left device users spoilt for choice.

Going forward, we see these factors influencing heavy MedTech investments in UX/UI and interoperability. In the future, both hardware (Operational Technology) and software (Information Technology) will prioritize intuitive design principles that promise improved ease of use and accessibility.

"UI and UX are incredibly different in healthcare. In the ER or operating room, you can't go through multifactor authentication or wait for a code to hit your phone. You can't be locked out after three tries."

- **Chad Holmes**, Cybersecurity Evangelist at Cynerio

Image credit: Clarius Mobile Health

A well-designed interface will streamline access to patient records and test results, thus improving care and clinical workflows. Effective UI/UX design will play a key role in making these interactions less intimidating for both patients and caregivers. Improving the overall user experience will increase accessibility to critical patient information and data. Various MedTech companies are already pursuing this.

Take the Clarius HD3 portable handheld ultrasound scanner by Clarius Mobile Health. By replacing the complex knobs and buttons used in traditional ultrasound systems with AI and adding automation, it has “created a very fluid and intuitive user experience”, says Kris Dickie, the company’s CTO, allowing it to automatically deliver high-quality ultrasound images. This eliminates the need for sonographers and eMed physicians to manually perform tasks, improving efficiencies across the board.

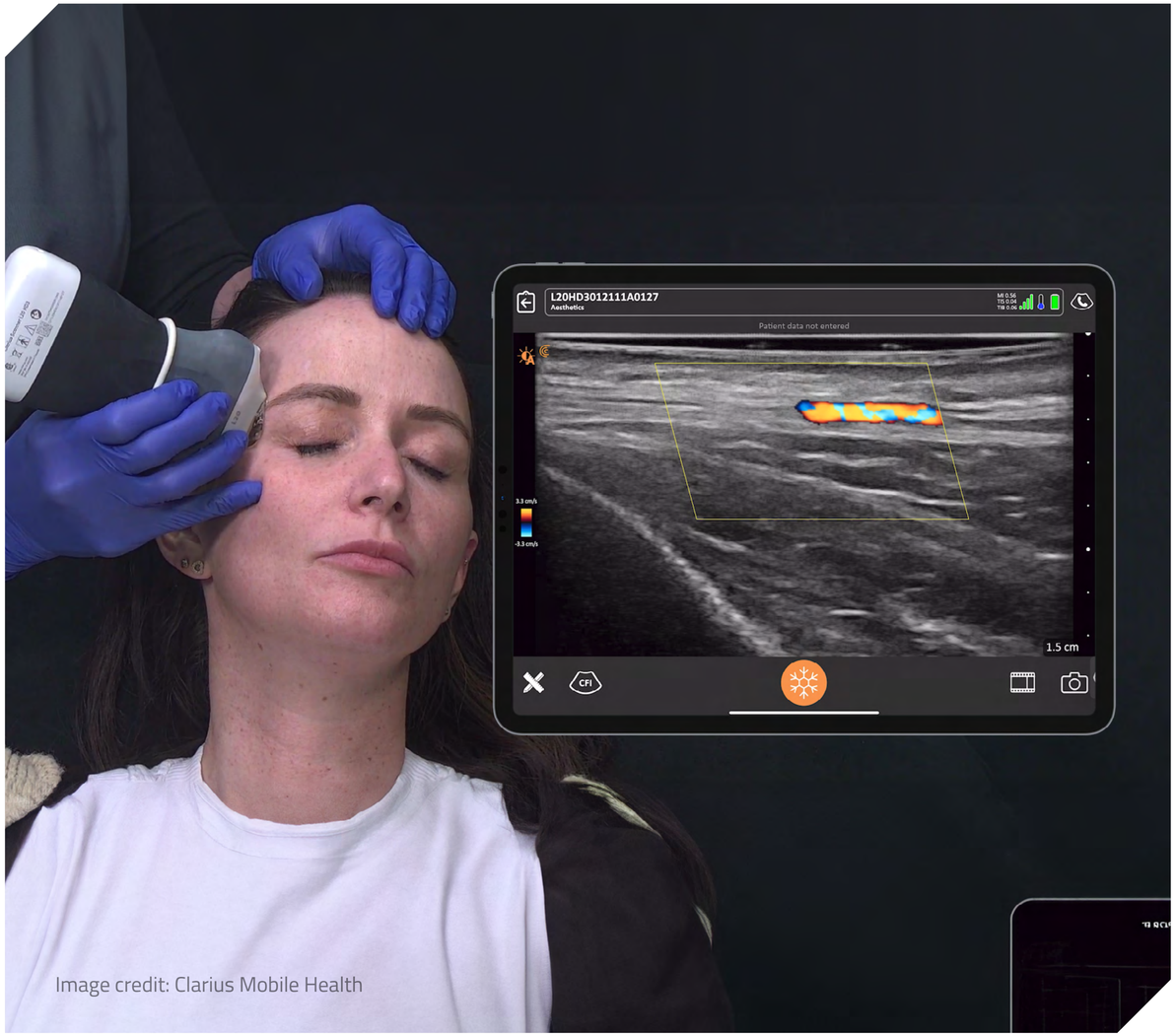

Image credit: Clarius Mobile Health

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CASE Robotic Dentists Are Coming, UI/UX is Paving The Way

Would you let a robot assist your doctor in dental surgery? Introducing the Yomi robot by Neocis, the only FDA-approved robotic system for dental surgeries.

The process is straightforward. A preoperative CT scan creates a 3D reconstruction of the teeth and mouth, ensuring that patients feel more informed and involved in their treatment. The surgeon then plans the surgery digitally - ensuring everything is clear from start to finish. Operational software prevents the robot from going off plan during surgery, and a user-friendly UI allows providers to execute the procedure.

Yomi is the most accurate implant treatment modality offered today—more accurate than freehand, guides, or navigation.

Yomi surgical robots have performed more than 60,000 implant surgeries so far. The US-based firm has an expansive list of approved indications, including full arch implant treatments and bone reduction. The company partnered with Qt to incorporate functional UX and UI solutions that ensured their new system was cross-functional and could run on different operating systems and platforms.

Beyond technical precision, innovations such as robotic-assisted surgeries will further enhance the customer experience by providing patients with valuable information throughout their care journey. This improves surgical outcomes and treatment. Intuitive and reliable UI/UX design will remain crucial in helping to bring the next generation of medical technology to life.

"Robotic-assisted surgeries are set to become standard practice, augmenting surgeons—particularly older ones—with steadier and more precise movements. This advancement promises to significantly enhance surgical outcomes by minimizing human error."

- Roger Mazzella, Senior Product Lead, Medical at Qt Group

Image credit: Neocis

TREND: MedTech Innovation Will Prioritize Cyber Resilience

The World Health Organization estimates there are two million different kinds of medical devices categorized into over 7,000 generic device groups.

A 2023 study published by professors from the University of Rome Tor Vergata found that numerous medical devices purchased by national health services possessed or still possess 661 distinct vulnerabilities— more than half of which were deemed critical or high-severity with the potential to impact data confidentiality, integrity, and accessibility negatively.

As MedTech innovation connects these devices, builds data ecosystems, and provides more digital experiences, the risk of cyber threats and attacks increases. As such, we see the sector facing increasingly sophisticated cyber threats driven by financial motives.

Ransomware attacks will persist, and cybercriminals will continue to target electronic protected health information (ePHI) due to its high black-market value. Additionally, generative AI will increase phishing and social engineering attacks by simulating human interactions, such as fake doctor authorizations or prescriptions. Safeguarding patient data will be crucial as healthcare advances technologically. Encryption alone won't be enough.

"Hackers will always be there; we're not going to eliminate them. The goal is to secure hospital environments so they're not the easiest, most profitable targets. Let's force hackers to go elsewhere rather than putting patients at risk," says Chad Holmes, a cybersecurity evangelist at Cynerio.

Both the U.S. Food and Drug Administration (FDA) and the EU are enhancing the cybersecurity resilience of next-generation medical devices through uncompromising standards and regulations. The Consolidated Appropriations Act of 2023, for instance, amends the Federal Food, Drug, and Cosmetic Act, granting the FDA increased authority to enforce cybersecurity requirements for medical devices.

This means the MedTech sector will have to invest more in building cyber resilience by incorporating 'Secure-by-Design' principles, enabling advanced IoT protections and standardization that ensures cyber security across a device's lifecycle and the ecosystem it operates in.

Network-level protections like segmentation and micro-segmentation will become essential in minimizing exposure. Advanced technologies like Network Detection and Response (NDR) will be deployed for monitoring traffic and identifying anomalies. Improved cyber resilience will involve action from all stakeholders in the MedTech space.

"Securing healthcare environments must involve private industry and those providing care. The regulatory environment should then provide guidance and funding. If we can get these three working together, we can make significant progress."

- **Chad Holmes**, Cybersecurity Evangelist at Cynerio

TREND: Data Will Unlock New Opportunities for MedTech Personalization

The seemingly unstoppable rise of wearables and rising consumer desire to record and analyze their healthcare statistics is resulting in a boom in data. Paralleling trends seen in the consumer electronics space, we see the MedTech sector using this data to create products and solutions that provide greater personalization and drive a more proactive approach to healthcare.

Superior UI/UX experiences will ensure that this personalization translates well across different touchpoints and devices. More manageable regulatory barriers could also see AI integrated into wearables, promoting greater flexibility and innovation in personal healthcare.

This is set to revolutionize accessibility and equity, democratizing medical technology. Imagine more precise adjustments to treatment plans through ongoing monitoring and feedback. For example, consider a scenario involving a wearable glucose monitoring device paired with a small insulin infusion pump.

By connecting the two devices and using AI, an artificial pancreatic device could be developed that monitors and predicts blood sugar levels and delivers insulin as required to keep them constant and normal. Such use cases are being explored and could vastly improve patients' quality of life.

Consequently, patient outcomes will improve as adverse reactions are minimized and therapeutic efficacy is optimized. Devices that once required hospital visits will now be managed remotely, granting improved healthcare access.

If you were diagnosed with a rare cancer and told no treatments are available, would you consider using a medical company in Qatar or China and managing your care via telemedicine? This scenario highlights a crucial shift with telemedicine revolutionizing healthcare delivery.

Advanced EHR systems would aid remote treatment and healthcare by transforming decades of medical history into actionable insights. Critical data, such as recent lab results and imaging reports, would be readily accessible to healthcare providers anywhere in the world.

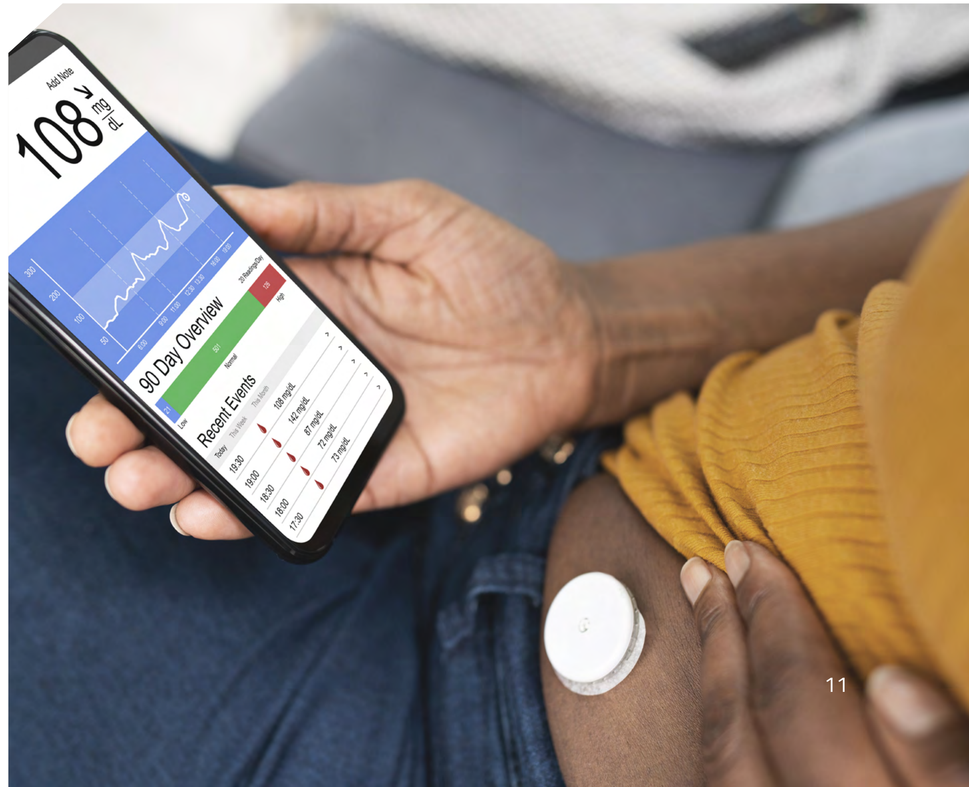
Advances in digital technologies will further blend MedTech and pharmaceuticals. For example, genomic data will enable customized treatments, resulting in medications tailored to an individual's unique genetic profile. In the future, data provided by connected medical devices could be used by authorities to better target pre-emptive medical care and well-being services to at-risk populations.

That said, care must be taken in how this data is collected, managed and used to protect against cyber threats and unethical use. While regulations that govern the use of such data are still evolving, patient-centric technologies could be used to empower individuals by giving them greater control over how their health data in healthcare ecosystems, allowing them to make informed decisions.

We see an opportunity for MedTech companies to innovate in this regard by learning from the experiences of the consumer electronic sector. By prioritizing patient-centricity, ethical use of data, and transparency through effective UX/UI design and cyber security, MedTech will ensure that patients can easily access, understand, and utilize their health data. Patients will transform from passive recipients into active participants in their health journey.

"Patients should own and control their private data. Traditionally, doctors have had all the data, but with devices like the Apple Watch and Fitbit, it's time to democratize access."

- **Ben Cyprian Sindram Müller**, Founder and Managing Director of Silberpuls



MedTech's Challenge: Balancing Innovation and Regulation

The growth of the MedTech sector is bringing exciting innovations that can change patient care and improve how healthcare operates. However, achieving these breakthroughs requires careful navigation through complex regulations. In highly regulated industries, it is essential to find a balance between advancing technology and following strict rules. Regulations are not barriers to innovation but essential guides that shape its development and keep people safe.

To stay ahead, we see MedTech companies integrating compliance into their processes early on, designing systems that can adapt while constantly monitoring changing regulations. They will also focus on greater OT and IT convergence, ensuring the two work in tandem to unlock new business models and innovative productions and solutions.

Over the next five to six years, key technology and regulations will determine just how much the MedTech space can innovate and whether it can emerge as agile and disruptive as the B2C consumer electronics space.

"MedTech companies will focus on two fronts. On the hardware side, keeping things nimble. Providing high performance while keeping the device small. On the software side, having a stack to develop the capabilities you want to integrate into the system in the future. AI, machine learning, better UI, etc."

- **Remi Roux**, Head of Applications at Witekio

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ROADMAP: Medtech’s Path To Transformation By 2030

We spoke to key stakeholders to understand the milestones and pathways that will lead to the MedTech industry’s transformation by 2030. Here is what they expect.

2024-2025

- AI tools will be adopted in diagnostics and personalized treatment protocols
- Increased funding for MedTech startups, especially in AI and telemedicine
- More focus on accelerating regulatory approval processes
- Enhanced cybersecurity in medical devices

2026-2028

- Expansion of digital health ecosystems
- Significant progress in wearable technology for chronic disease management
- Enhanced remote monitoring solutions becoming standard practice
- Streamlined regulatory pathways for rapid approval of MedTech solutions

2029-2030

- Significant breakthroughs in disease prevention and early detection
- Leveraging advanced diagnostics and personalized treatments
- Establishment of global standards for MedTech interoperability
- Interoperability across healthcare systems will become standard

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Our customers are in more than 70 different industries in over 180 countries. Qt Group is headquartered in Espoo, Finland, and employs over 800 people globally.