MD squared

Bringing Medical Technology Innovations Sustainably and Quickly to Market

MD squared, based at HighTech Campus Eindhoven and New Babylon in The Hague, helps bring innovative medical technologies to market with speed and sustainability. The company uses a unique, multidisciplinary approach that covers clinical, technological, regulatory, and quality aspects of product development for MedTech companies.

"We serve start-ups and scale-ups with meaningful innovations in the medical devices industry. Our multidisciplinary approach helps these companies make informed choices at the intersection of clinical issues, technical and budgetary possibilities and regulatory constraints on the road to market approval." says Claus Schaffrath, founder and partner at MD squared. With a background in medicine and engineering, Schaffrath brings 25 years of experience in hospitals and the MedTech industry. "Early on, I realised that blending different expertise is essential for a successful market launch. That's why we use multidisciplinary teams for every project, whether it's interventional oncology, robotics, AI in medical products, or resorbable implants," he explains. Schaffrath emphasizes that MD squared's approach focuses on identifying the areas where a new technology has the best chance of shifting the standard of care. "We carefully assess each new technology to determine its potential impact. We then examine the necessary clinical studies, followed by regulatory issues and budget considerations. This thinking forms the foundation of MD squared since our start in 2017. Our job is done when the product is approved, adopted, and used in the market."

Comprehensive Consultancy Portfolio

MD squared's portfolio includes a range of consultancy programs for different stages of growth, structured as a "roof-tile" system:

- PathFinder Program: Tailored for start-ups and scale-ups, PathFinder answers key questions on product definition, regulatory and clinical strategy, development, and quality management, all critical for entering the MedTech market.
- Voyager Program: This program provides embeds specific expertise in growing companies, providing supporton clinical evaluation, development documentation and validation, as well as risk management, regulatory matters, and quality management.
- QuickScout: QuickScout is designed to examine a critical area of attention, arising on the way to market or during a product's life cycle. Here, MD squared works with clients to develop informed choices for a timely response. MD squared also works internationally, assisting clients in the European, American, and Asian markets (especially China and Japan). "This international focus means we're familiar with diverse regulatory frameworks. Often, a regulatory question is just the beginning, followed by questions about which studies align with these requirements. We collaborate with partners who specialize in regulations for different countries," Schaffrath says.

Risk Classes, Certification, and Artificial Intelligence

One example is developing an algorithm for a device to monitor patients' need for respiratory support. Schaffrath explains: "We examine the


Managing Director Claus Schaffrath, MD MSc

intended use and clinical application, considering its risk level. An algorithm in a Clinical Decision Support System (CDSS) might inform medical staff via an app, or by directly monitoring a patient in a wearable device and alerting if intervention is required. The same principle could also adjust ventilation in a device for a critically ill patient. Each use may be supported by the same algorithm, but has different risk levels, therefore different design, clinical evaluation, and documentation requirements. The business case, development cost, and time to market is also fundamentally different. We help clients understand these implications to make informed decisions."

AI is increasingly central to MD squared's work, especially in cancer detection and diagnosis, but Schaffrath stresses the need for caution. "AI feedback requires thorough interpretation by professionals to ensure reliable insights. Over-reliance on AI without professional oversight can lead to incorrect conclusions," he notes.

Key Takeaways

- *"With clients, we examine where their innovation has the best chance to shift the standard of care, balanced against the clinical and regulatory evidence needed."*
- *"Innovation value arises at the intersection of clinical need and technical implementation, while meeting regulatory standards. We help ensure all stakeholders speak the same language and understand each other's work."*

Through its comprehensive approach, MD squared guides MedTech companies in accelerating market entry while maintaining regulatory compliance, ultimately supporting innovations that advance healthcare.