Press Release

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From idea to approval: regulatory expertise for founders

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TÜV SÜD publishes white paper for medtech start-ups

Munich. MedTech start-ups are under pressure to innovate, but between prototype and patient lies a regulatory maze. A new white paper from TÜV SÜD shows how young companies can set the course for safe and successful market entry at an early stage and avoid typical regulatory pitfalls.

As one of the world's leading testing, certification and training partners in the medical technology sector, TÜV SÜD brings together experience from supporting numerous start-ups – from digital health solutions and AI-based diagnostics to traditional medical devices.

Regulatory maturity as the key to market success

Dynamism, creativity and speed are among the greatest strengths of start-ups. But in medical technology, that alone is not enough. To be successful in this field, you need to be just as confident in mastering regulatory requirements as you are in your own innovation process. This is precisely where TÜV SÜD's new white paper ‘What MedTech start-ups need to know’ comes in.

It highlights seven key topics that young companies in medical technology should consider from the outset: from intended use and classification to quality management and clinical evaluation to market surveillance and strategic approval (CE vs. FDA). The white paper thus offers a structured roadmap that can be directly applied to development and approval processes.

“Many start-ups underestimate how closely technological innovation and regulatory requirements are intertwined,” says Prof. Dr. Max D. Singh, expert in regulatory affairs and innovation for medical devices at OTH Regensburg and author of the white paper. “Those who integrate regulatory expertise from the outset avoid delays and also gain the trust of investors and notified bodies.”

Seven topics for the regulatory roadmap

The white paper provides practical guidance on how young medtech companies can integrate regulatory requirements into their product development and which typical pitfalls to avoid. Among other things, it explains:

- **Intended use:** How it defines the regulatory framework of a product and why imprecise wording leads to delays.
- **Classification according to MDR:** Which rules apply in particular to software as a medical device. Digital and AI-based start-ups in particular benefit from specific information on the MDR classification of software.
- **Quality Management System (QMS):** Why ISO 13485 is crucial even in the early stages of development.
- **Design Control:** How structured development and traceability ensure investor confidence and auditability.
- **Clinical evaluation:** Why the Clinical Evaluation Report (CER) should be planned at an early stage.
- **Post-market surveillance and PMCF:** How continuous learning and data feedback create regulatory stability.
- **Market access CE vs. FDA:** What strategic differences need to be considered in international growth plans.

Between innovation and regulation

Finding the balance between speed of innovation and regulatory thoroughness is a particular challenge for founders. Venture capital, time-to-market and scaling are often the focus. But a lack of compliance can delay market launch by months or unsettle investors.

“Regulatory excellence is not a luxury, but a prerequisite for sustainable success,” emphasises Max Singh. “The new white paper aims to show start-up teams how they can strategically use regulatory requirements as a competitive advantage instead of seeing them as a brake on innovation.”

Free download and further training

The white paper “What MedTech start-ups need to know” is now available for free download on the TÜV SÜD website. In addition, TÜV SÜD offers the compact course “MedTech Start-up Innovator – TÜV” (currently only in German, English coming soon), which provides practical in-depth information on the contents of the white paper – from the initial idea to clinical evaluation and CE certification. The course is aimed in particular at start-up teams who want to increase

their regulatory maturity in a short period of time and avoid typical mistakes in the early stages of development.

Further information:

- Medical devices

Note for editorial staff: The press release is available on the Internet at: tuvsud.com/newsroom.

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