Choose certainty.
Add value.

Assessments of clinical evaluations for high-risk medical devices

Pre-assessment of submitted documentation at a very early stage.

Your challenges

Incidents mean harm for patients and also endanger your business. Therefore, it is essential that clinical trials address all risks and demonstrate the clinical performance and safety of your devices before they are placed on the market. Medical device manufacturers are often caught off guard by new or emerging developments. They are constantly challenged on safety or performance issues that could easily have been avoided, sometimes losing ground to competitors as a result.

What are assessments of clinical evaluations for medical devices?

TÜV SÜD's experts assess your documentation, such as the clinical investigation plan, and provide impartial pre-assessment of the submitted documentation at a very early stage. Our assessments of clinical evaluations play a crucial role in the successful launch of new combination products, devices, diagnostic products and treatment protocols intended for human use.

Why are assessments of clinical evaluations important for your business?

TÜV SÜD's assessments of clinical evaluations identify early deficiencies in your submitted report. The results of the assessment determine the safety and performance of your device before formal clinical assessment. Our expert reports allow you to correct missing information, enabling you to submit your product for clinical trials confident in the knowledge that it will meet industry-specific requirements and helping you avoid pitfalls that often result in costly and significant delays. This improves business planning while minimising your exposure to regulatory risks prior to the scheduled product launch.

TÜV SÜD's expertise in assessing clinical evaluations

Nearly 75 per cent of the world's largest medical companies use TÜV SÜD for evaluating new and high-risk treatment technologies. We have a dedicated

Regulatory Foreign Affairs & Clinical Department specialising in market access and worldwide regulations. By testing products in compliance with the latest directives, we help you avoid product recalls as a result of obsolete regulations.

Our clinical services

We support your company throughout the whole certification process, from initial technical meetings with our experts, during design dossier assessment through to final certification.

- **Scientific assessment screening**
  TÜV SÜD's experts will audit your certification readiness with your team and assess your investigation plan and respective clinical study documents in the early stages of your product's certification.
- **Pre-assessment**
  We can assess regulatory documents at a very early stage. Our experts will provide you with a detailed evaluation report including the deficiency points. This allows you to correct failure early to ensure that the new device will meet its essential requirements.
- **Combination products**
  In Europe, a Notified Body has to request a competent authority to provide an opinion concerning a medicinal substance and its application. TÜV SÜD can aid you during the whole process for combination products with expert gap analysis on how to apply for such a process and pre-assessment of the clinical evaluation report.
- **Evaluation of medical devices**
  TÜV SÜD's team of experienced experts can assess the evaluation reports of any new innovative medical device to verify that it will meet the essential requirements of the directive.

Your business benefits

- **Save costs** – by identifying product deficiencies at an early stage, which are easier and cheaper to rectify during the initial certification phase prior to production launch rather than on a finalised product.
- **Increase speed to market** – with our experts who check step-by-step compliance during all pre-assessment activities, removing the threat of costly and time-consuming rework.
- **Gain a competitive edge** – by anticipating future healthcare trends and requirements, and nurturing relevant industry skills with our knowledge services and training programmes.
- **Benefit from an expert partnership** – that ensures optimum results with TÜV SÜD's independent services.

Why choose TÜV SÜD?

TÜV SÜD has the highest number of medical experts, with a team of over 400 international specialists situated in major markets around the world. Our experts serve on many standards development committees, giving them insight into the industry's technical standards. We also employ a group of medical doctors for assessing evaluations of new treatment methods and products, as well as a scientific advisory board comprised of scientists from world-class universities. You can rely on our comprehensive in-house medical competencies and thorough understanding of regulations worldwide to serve your needs.

Choose certainty. Add value.

TÜV SÜD is a premium quality, safety and sustainability company that specialises in testing, inspection, auditing and certifications. Represented in over 800 locations worldwide, we hold accreditations in Europe, the Americas, the Middle East, Asia and Africa. By delivering services to our customers, we add tangible value to businesses, consumers and the environment.

Related services

TÜV SÜD provides the following related services:

- Design dossier assessment
- ISO 13485 – Quality management system certification for medical devices
- Medical device market assessment and certification
- Medical device testing

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