



- **The perfect start for successful medical device manufacturers!**
- **Regulatory Strategy Plan for further planning!**

en.co.tec Regulatory Strategy Workshop

In order to be successful as a manufacturer of medical devices or in-vitro diagnostics, the regulatory requirements (standards, laws, EU regulations, etc.) must be observed from the very beginning - in addition to a well thought-out business plan.

Requirements already taken into account during product development (design, material, etc.) save unnecessary detours and setbacks later on. You will work out the standards, laws and other requirements relevant to you, get important practical tips and an overview of the effects these requirements have on your product, your design, your schedule and possibly also on your financing plan.

Contents of the workshop

- Regulatory basics for medical devices
- Which standards, laws, directives apply to your product
- Inventory of existing documents and structures in the area of technical documentation and quality management
- Creation of a Regulatory Strategy Plan that shows you the impact on your product, your design, your schedule and possibly also on your financing plan.

With this plan you can much better estimate how much time, how many internal and external resources and costs you should plan for the approval.

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After that, you can use a solid basis to prepare funding applications or start detailed planning for such critical work packages as the

- Introduction of ISO 13485
- Clinical trial applications
- Preparation of technical documentation for the MDR/IVDR

We will be happy to provide you with individual offers for further support in the introduction of ISO 13485 or in the preparation of technical documentation for the MDR/IVDR!

Costs

- ✓ 1 day on your premises with one of our experts: Euro 3.890,-- (excl. VAT) incl. creation of an individual Regulatory Strategy Plan.

Date

Please allow approx. 4-6 weeks lead time for making an appointment!

Contact

Mag. (FH) Christa Bachinger-Hauk
Tel.: +43-1-886 34 91
Mobil: +43-650-886 34 91
Mail: christa.bachinger@encotec.at
Web: www.encotec.at