

en.co.tec Consulting



- ✓ The perfect start for medical device manufacturers!
- ✓ Help from experts!
- ✓ Answers to your regulatory questions!

en.co.tec Regulatory Kick Start

In order to be successful as a manufacturer of medical devices or in-vitro diagnostics, regulatory requirements (standards, laws, EU regulations, etc.) must be taken into account 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.

Content of the consultation

- Clarify your individual questions about technical documentation, quality management and the new EU regulations (MDR / IVDR).
- In an one-and-a-half hour consultation, we offer you a basic assessment for the regulatory path to approval of your medical product / in vitro diagnostic.
- For this purpose, please send us a product presentation in advance, as well as a maximum three specific questions that we will address in the course of the meeting.

We would be pleased to provide you with individual offers for further support in the implementation of ISO 13485 or the preparation of technical documentation!

en.co.tec Consulting

CHARGES

- ✓ 1.5 hours of on-site or remote consultation with one of our experts: Euro 750,- (excl. VAT) including preparation
- ✓ plus travel expenses outside Vienna

DATE

Please calculate with approx. 4-6 weeks lead time for the meeting!

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