CEHTRA

Your Specialties, Our Expertise

Medical Devices

As a legal manufacturer of Medical Devices or as a Supplier of components for Medical Device manufacturing, you may face unexpected challenges in applying the new quality and regulatory requirements. With over 20 years of combined experience, our passionate team has extensive knowledge in all aspects that will help you succeed in your market access strategy.

Key Services

Regulatory Affairs support

to ensure Business Performance through the whole lifecycle of technical files, from initiation to MDR/IVDR remediation

Quality support

to ensure Regulatory compliance based on the ISO 13485 requirements

Product-focused

to ensure user-oriented Safety and Performance of the Medical Devices

Manufacturing Process-focussed

to ensure consistent Quality of Products which are made available to the market

Value-added Services

- Holistic and transversal approach
- Data and bibliographic analysis for Biological Safety & Clinical Safety and Performance
- Training : Regulatory Affairs, Biological Safety
- Expert review of Technical Files
- Person rResponsible for Regulatory Compliance
- Benefit/risk Evaluation

Our Medical Devices expert

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