Medical Device Consulting

Our Quality Policy

Easy Medical Device is a consulting firm that helps Medical Device manufacturers all over the world to place compliant Medical Devices on the market.

To support the needs of its customers, **Easy Medical Device** constantly deliver up-to-date information about the Medical Device Regulation.

Our mission is to support Medical Device manufacturers with their objectives of design, development, manufacturing, maintainance, distribution, representation in diverse region and monitoring its device in the market.

For that **Easy Medical Device** has partners in its network to be able to reach these goals of compliance. We also help you during your discussion with the Notified Bodies or Competent authorities.

This policy is applied within all **Easy Medical Device** locations (Europe, Swiss, United Kingdom, India). We are here to make your Quality and Regulatory life EASY.

Do have only the growth of your Business in mind, we will take care of your Quality & Regulatory Affairs activities.

Easy Medical Device milestones

2017: Easy Medical Device website was created to provide information about QA RA for Medical Devices.
2018: The Youtube Channel and the Podcast were born
2019: The company Easy Medical Device GmbH opened in Basel-Switzerland
2020: Due to Brexit, Easy Medical Device opened an office in Manchester-UK
2021: Service as Swiss Representative due to Swixit

Message from Monir El Azzouzi

Hi everyone, in this message I wanted to tell you few words about me and my commitments to you.

From the beginning of my career, I have always worked on Medical Devices Quality and Regulatory affairs for small and big companies.

After leaving Johnson & Johnson in Switzerland, I have decided to open Easy Medical Device as I have seen the need to support Medical Device manufacturers for this big transition.

I also decided to offer free content to make this transition more easy with Blog, Videos, Podcast episodes, Comics, Training, Calls, LinkedIn Lives... My team and I are really dedicated to helping you reach your objectives.

My only mission is to make Easy Medical Device your preferred partner for any tasks related to Medical Device Quality and Regulatory affairs.

So don't hesitate to contact us. We will organize a meeting with you to review your needs and help you place compliant devices on the market.

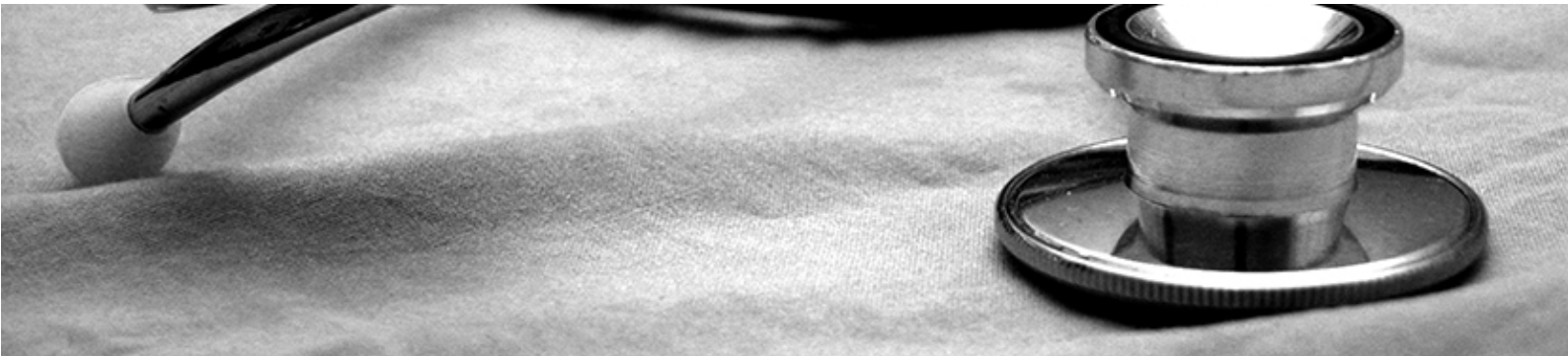
Monir El Azzouzi

List of Activities Proposed

Here are some examples of activities that can be proposed by **Easy Medical Device.** But don't hesitate to share your needs and we can evaluate the possibility to help you:

- EU MDR & IVDR certification
- Quality Management System creation following ISO 13485:2016
- FDA 510k, PMA, 21 CFR part 820, 21 CFR part 11
- Risk management following ISO 14971:2019
- Usability following IEC 62366
- Software Lifecycle management following IEC 62304
- Training of your personal
- Realization of your audit activities (Internal, Supplier, Due Diligence)
- Technical Writing (Clinical Evaluation, Performance Evaluation, PMCF)
- Backoffice staff for your company
- SaMD development support
- Registration in different countries (USA, India, Brazil, Mexico, South East Asia, Middle East, Africa)
- PMS activities
- Labelling and IFU creation and review
- Review of your documentation prior submission
- UK-EU-Swiss Authorized Representative
- Employee Coaching
- PRRC

All these tasks will be supported by qualified consultants. Don't hesitate to request a meeting to discuss your project. We will then be able to provide you all the information needed so you can be successful.



Contact us

Why should you work with us? Because we want to be part of your success and would be really happy to support you until the finish line. I think Monir meant it when he asked me to write that here. So give him a chance to show you.

For any question you can contact us at

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- **Website:** EasyMedicalDevice.com

Let's Work Together