



# *Regulatory Affairs Services for Life Sciences*

*We are your guide through the EU  
regulations for medical devices  
- focused and personal for your  
innovative products.*

- Do you need support in setting up a quality management system?
- Would you like to manufacture or place a medical device or in-vitro diagnostic medical device on the market under your own name?
- You do not have the expertise to cover the position of QMR or PRRC in your company?



***We support you in setting up a quality management system and in obtaining EU authorisation for your medical devices and in-vitro diagnostics.***

## **Our aim is:**

- Providing you with conceptual and consulting support
- Playing an operational role in setting up your documents and processes

## **Our services include:**

- Establishment of a quality management system according to ISO 13485:2021
- Document Review according to MDR 2017/745 or IVDR 2017/746
- Provision of external Person Responsible for Regulatory Compliance (PRRC) / Quality Management Representative (QMR)
- Provision of an authorised representative (EC-Rep) mandatory for manufacturers of medical devices / in-vitro diagnostic devices based outside the EU, with tasks such as:
  - Review of the issued EU Declaration of Conformity and the corresponding conformity assessment procedure
  - Review of the up-to-dateness of the technical documentation
  - Contact person for national authorities
- Review and advice on specific topics such as:
  - Risk Management | Clinical Evaluation | Usability
  - Software Lifecycle | Post Market Surveillance