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LIFE TO SCIENCE.
SCIENCE FOR LIFE.

biosaxony

# *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
- 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 (EU-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

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