

# Meet with ZWIERS!

## As a Person Responsible for Regulatory Compliance, Zwiers Regulatory Consultancy:

- Reviews or creates the QMS (or relevant procedures)
- Reviews, creates and/or maintains the technical dossier for your device
- Checks the conformity assessment of the device
- Communicates with the competent authority and/or Notified Body
- Handles customer complaints
- Performs post-market surveillance activities
- Evaluates and reports incidents and/or product recalls (field safety corrective action)
- Advises on changing EU regulations and guidelines

## Documents created by Zwiers:

- Complete set of QMS Documents including procedure post market surveillance, vigilance, complaint handling, clinical and biological safety evaluations
- Template for technical dossier reports and plans as indicated above