Quality Management System (QMS)

A Quality Management System defines how the vendor of Health Software should have its business processes organized in order to have an effective way of working and meet customer and regulatory requirements.

Examples of what has to be implemented:

- sufficient management commitment,
- adhering to a suitable quality policy,
- training of personnel in order to have competent personnel
- document and record control,
- sales, purchase, design, development, production and service processes,
- control of measurement tools
- supplier control,
- suitable work environment
- and last but not least: measuring and improving above mentioned processes.

The ISO13485 standard details out all requirement for a QMS for medical devices. Be aware that an accredited third party has to certify the QMS in order to have evidence of compliance. This will include an initial audit and a yearly re-audit. For start-up companies is it a good strategy to first get the CE mark (see chapter CE Marking) on their first product and next start the ISO13485 certification trajectory.