

Summary of Quality Management responsibilities:

- Legal conformance of quality assurance by the established quality management system and handbook based on ICH-GCP and DIN EN ISO 9001:2008
- Complete process referencing by Standard Operating Procedures (SOP)
- Supervision of all internal operational procedures and systems
- Conducting of audits
- Monitoring of audits and inspections
- Documentation of further training
- Conducting of training courses

The Clinical Trials Unit possesses a quality management system which complies with the high international quality standard of Good Clinical Practice (ICH-GCP). In this way, the conformity of Clinical Trials Unit services with the effective national and international laws and requirements is secured. This is reflected in its clearly delineated organisational structure, definite accountability regulations and fixed operational procedures.

In the quality management handbook of the Clinical Trials Unit the aims, legal bases, the leadership and management processes, as well as the allocation of resources and responsibilities for the quality-relevant processes are transparently established.

The methods of operation of the Clinical Trials Unit are regulated through a system of Standard Operating Procedures (SOPs) and Technical Procedures (TPs), which are adapted to legal regulations.

The internal operational procedures and systems of the Clinical Trials Unit are regularly reviewed by internal audits. In addition, the conducting of audits by clients serves as a means of checking the efficiency and acceptability of the quality management system. The results of these audits and measures are continuously leaving their mark on the refinement process.

The further development of all employees through participation in internal and external training courses is monitored by the quality management representatives.

Through involvement in the quality management system of the Freiburg University Medical Center the quality management system of the Clinical Trials Unit also complies with the requirements of the KTQ (Cooperation for Transparency and Quality in Hospitals).

The quality management representatives are qualified in the area of Good Clinical Practice (ICH-GCP), DIN EN ISO 9001:2008 and KTQ (Cooperation for Transparency and Quality in Hospitals). By means of regular further training it is assured that the quality management representatives always are competent contact persons for the employees and clients.

The Clinical Trials Unit has introduced a quality system in accordance with [DIN EN ISO 9001:2008](#) in July 2009 for the scopes: project coordination clinical trials, clinical monitoring and pharmacovigilance/medical science, biometry/data management, cooperations and networks, continuing education, IT Development and Support, Quality Management.