

**GXP
Engaged**

**Auditing
Services**

GXP Engaged Auditing Services

Quality Management Consultancy,
Quality Assurance and
Auditing Services



Auditing Standards

Services related to the following GXP areas:

- ▶ GCP
- ▶ GLP
- ▶ GMP
- ▶ ISO 9001
- ▶ ISO 14155
- ▶ ISO 13485
- ▶ Pharmacovigilance
- ▶ FDA standards
- ▶ EMA standards
- ▶ WHO standards
- ▶ National Regulatory Requirements

Countries covered

GXP Engaged Auditing Services has provided assistance in the following countries:

Australia, Austria, Belgium, Bulgaria, Canada, China, Croatia, Czech Republic, Estonia, France, Germany, Hungary, India, Italy, Israel, Latvia, Lithuania, Netherlands, Poland, Portugal, Romania, Russia, Slovenia, Spain, UK, Ukraine, USA

Experience

See www.gxp-engaged.com

Do give as a call on **++49 (89) 51 30 51 37** or e-mail us at info@gxp-engaged.com or contact us via www.gxp-engaged.com and discuss with us how GXP-Engaged Auditing Services can be of help to you.



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Quality
Management
Consultancy
Quality
Assurance
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GXP Engaged Auditing Services is a management buy-out company of the auditing and QM consultancy service brand of the ISO 9001 certified Harrison Clinical Research Group. The company provides services for the industry that require full independence from other service providers involved in clinical research.



DR. BARBARA SCHNURR,
MANAGING DIRECTOR

GXP Engaged Auditing Services headquarters is located in Munich, Germany. It provides global QM Consultancy and Auditing services through its network of QM personnel. The QM team involved in the execution of GXP Engaged Auditing Services contracts has provided this type of service for companies in the pharmaceutical, biotechnology, medical device, nutrition and related industries, since 2003.

Quality Control and Quality Assurance are a legal requirement for sponsors. Audits follow the standards of ISO 19011 and the ENGAGE Optional Guideline for GCP compliance and Quality Systems Auditing from the European Network of GCP auditors and other GCP experts. These stipulate that all audits follow a defined audit plan. The audit plan for a contracted audit is always peer-reviewed and released from the lead auditor and the audit client, reflecting that the scope and objectives of the audit are agreed to and the areas to be addressed are known and accepted by both, in advance.

The Quality Management market is a growing market corresponding to increased requirements from regulatory authorities and the trend to outsource work, particularly if it requires very specific experience and expertise.

The most critical deliverable of the performance of GXP Engaged Auditing Services is the quality and experience of its QM professionals. QM consultancy activities are usually single activities which require very specific experience and, ideally, a professional who is located in the geographical area of the auditee and/or sponsor. We take great care in the selection of our contract staff and have documented tools and processes used to ensure high standards.

Consistent Quality Structure

GXP Engaged Auditing Services Clients

- ▶ Any company from the pharmaceutical, biotechnology, medical device, nutrition or related areas with QM support requirements for clinical trials or company systems and procedures
- ▶ Clinical Research Organisations (CROs)
- ▶ Public companies
- ▶ Regulatory or QM service providers who need resources in this field

Our Core Services

- ▶ Revising and/or setting up and implementing QM systems in client companies, including writing or support with writing SOPs
- ▶ Independent full or partial Quality Management or Quality Assurance coverage of client companies who need additional resources in QM/QA
- ▶ Definition and/or execution of Quality Management and Auditing plans for clinical trials conducted by companies who need or wish to have a strong oversight of their projects
- ▶ Preparation of and participation in audits and due diligences at client companies
- ▶ Conduct of Audits for clients covering all areas of clinical studies including ...
 - critical suppliers
 - investigational sitesand key activities like ...
 - investigational study site management
 - clinical monitoring
 - safety management
 - regulatory affairs
 - data management, biometricsand essential documents, such as ...
 - protocols, informed consent documents
 - trial master files
 - clinical study reports

Consistent Compliance Level

Our Service Packages

Continuous QM coverage of internal client systems

- ▶ QM tasks for smaller companies that do not have their own QM staff, however, QM systems to be maintained.
- ▶ Support to companies with external, fully independent QM to evaluate compliance of operations and QM and support QM including system maintenance

Provide QM services for outsourced projects

- ▶ To companies who have no presence in the participating countries
- ▶ Surveillance of trial specific QM plans, non-compliance/CAPA follow-up and regular (e.g. monthly) report of trial compliance situation

Trial specific QM plans

- ▶ Defined quality metrics/KPIs selected in mutual agreement with the client
- ▶ Evaluation of new and ongoing issues recorded on study tracker system
- ▶ Review of final monitoring reports
- ▶ Review of suggestions for corrective and preventative actions (CAPAs)
- ▶ Surveillance of audit CAPA progress and confirmation of CAPA close out

Audits

- ▶ To critical suppliers
- ▶ To investigational sites
- ▶ Of essential documents

Quality Emergency Hotline

Questions related to ICH-GCP and other applicable regulatory standards relevant for the target countries and the trial under investigation, answered within 24 hours

