



For further information on Harrison Clinical Research Group Services, see also in this series:

- ▶ Central Europe
- ▶ Eastern Europe, Poland, Ukraine and Russian Federation
- ▶ Japan
- ▶ Clinical Pharmacology Unit
- ▶ Clinic for Nutritional Medicine
- ▶ Data Management & Statistics
- ▶ Medical Writing



Harrison Clinical Research Group Services

- ▶ Development Strategy
- ▶ Clinical Pharmacology Unit
- ▶ Phase II-IV
- ▶ Clinic for Nutritional Medicine
- ▶ Quality Management Consultancy Services
- ▶ Auditing Services
- ▶ Data Management
- ▶ Statistical Analysis
- ▶ Medical Writing
- ▶ Training



The Harrison Clinical Research Group

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Other Harrison Clinical Research Group Offices

- ▶ Ely, United Kingdom
- ▶ Brussels, Belgium
- ▶ Rehovot, Israel
- ▶ Barcelona, Spain
- ▶ Levallois-Perret, France
- ▶ Milan and Rome, Italy
- ▶ Vienna, Austria
- ▶ Warsaw, Poland
- ▶ Moscow, Russia
- ▶ Kiev, Ukraine
- ▶ Princeton, USA

Harrison Clinical Research

Quality Assurance and Quality Management Consultancy Services



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General information

Harrison Clinical Research is a medically driven independent contract research organisation (CRO), founded in 1987. Harrison Clinical Research offers the full range of services required for the successful clinical development and registration of new pharmaceutical products and medical devices, from single studies to complete development programmes. Clinical trials from Phase I-IIa can be carried out in our own clinics, while Phase II-IV studies can be carried out either locally or globally, as required.

The head office of Harrison Clinical Research is located in Munich, Germany, where our Clinical Pharmacology Unit, the Clinic for Nutritional Medicine, Data Management and Statistics, Medical Writing and Quality Management departments are also based. There are Harrison offices in ten European countries, Israel and the USA.

All the activities of a Harrison Clinical Research office are performed in strict compliance with the relevant ICH-GCP guidelines. These comprehensive, quality services are performed to the highest international standards.

Quality Management and Auditing Services

Harrison Clinical Research was awarded the ISO 9001 certification in March 1998 for the Quality Management system applicable to the: *'Design and evaluation of clinical trials for the pharmaceutical and medical device industries, including conduct of Phase I/II/III/IV trials'*. The Harrison QM system has since been recertified tri-annually, confirming that we offer quality and comprehensive services to the highest international standards. The services offered by our Quality Management and Auditing Group are fully compliant with:

- ▶ ICH GCP, GLP, GMP
- ▶ ISO 9001
- ▶ ISO 19011
- ▶ ENGAGE Optional Guideline for GCP Compliance and Quality Systems Auditing (European Network of GCP Auditors)



Our Quality Management Group can assist you in evaluating your quality management systems. They routinely review the current structure and the policies, processes and documentation involved. The Quality Management Group can also support you in establishing a comprehensive and efficient system that will facilitate a consistent quality culture throughout your company. This includes identifying and initiating both corrective and preventive actions, in order to continually improve your processes.

We can assist you in writing, reviewing, updating and adapting Standard Operating Systems (SOPs) to your specific needs and can also provide advice on minimum requirements for SOP systems. Our services also include full training capabilities, both internally and externally. We can currently offer:

- ▶ Auditor training
- ▶ Quality management training and coaching
- ▶ Preparation of training plans
- ▶ Documentation for training.

Auditing Services

GXP Engaged

Auditing Services

Our auditing team involved in contract audits works independently from the internal Harrison Clinical Research QM personnel for all contract audit programmes. The team uses dedicated GXP Engaged Auditing Services tools, working procedures, own communication lines, which are usually actively agreed upfront with the audit client. The team has gained a vast amount of experience by conducting audits for over 500 studies in more than 20 countries since 1996. We provide a full range of auditing services including the preparation, conduct, documentation, follow-up and certification of site and systems audits. Depending on the scope and complexity of the programme, audits may be performed in teams, together with co-auditors from the client or from Harrison Clinical Research.

In compliance with either your SOPs or our own, we can audit:

- ▶ Trial sites
- ▶ Facilities
- ▶ Sub-contractors
- ▶ Study protocols
- ▶ Patient information/patient informed consent forms
- ▶ Case report forms
- ▶ Trial master files
- ▶ Data management
- ▶ Clinical reports.

Audit documentation includes:

- ▶ A peer-reviewed audit plan released from the Harrison lead auditor and the sponsor's representative
- ▶ For more complex audit projects, a project-specific audit SOP
- ▶ Tailored worksheets
- ▶ Communication of audit findings/audit follow-up plan
- ▶ Statistical evaluations on audit findings to help to prioritise preventative actions
- ▶ Audit certificates.

Our auditors have broadrange experience as well as offering expertise in specific areas, such as auditing:

- ▶ Analytical laboratories
- ▶ Clinical laboratories
- ▶ Phase I units
- ▶ Medical device studies
- ▶ Data Management
- ▶ Electronic data capture
- ▶ Qualification records/training documents.

Checklist

