# Quality services for clinical trials

- MHRA-accredited clinical trials unit
- ISO 9001-certified since 1999


**HMR**

www.hmrlondon.com

## Quality services at HMR

HMR's well established quality services comprise numerous quality control functions and an experienced, independent quality assurance team, which:

- maintains and oversees our ISO 9001-certified quality management system (QMS);
- audits our systems, facilities and trials; and
- provides an independent monitoring service

## Key features of ISO 9001:2015

Our mature ISO 9001-certified quality management system (QMS) is based on GCP and GMP, and ensures the safety of our trial subjects and the integrity of our data.

- Customer-focussed approach
- Control from design through to delivery and reporting
- Emphasis on continual improvement, regulatory compliance and best practice
- 'No blame' culture, seeking to learn from mistakes and improve procedures
- Compliance monitoring
- Management review

## Quality control (QC)

- Dedicated Data Quality Team for eCRF data entry and risk-based quality review
- Quality Coordinators in each ward team
- QC checks of all key documents and data across all functions
- Automated QC checks of eCRF data

## Quality assurance (QA)

- Audit programme tailored for each trial
- Risk-based approach
- Comprehensive scope:
  - data, documents and procedures
  - clinical, laboratory, pharmacy and data management
  - systems and facilities
  - subcontractors

## Monitoring

- Independent monitoring of trials at HMR and external sites
- Blinded and unblinded monitoring
- Comprehensive risk-based monitoring plan and detailed reports
- Site initiation, training and close-out

## Third party audits

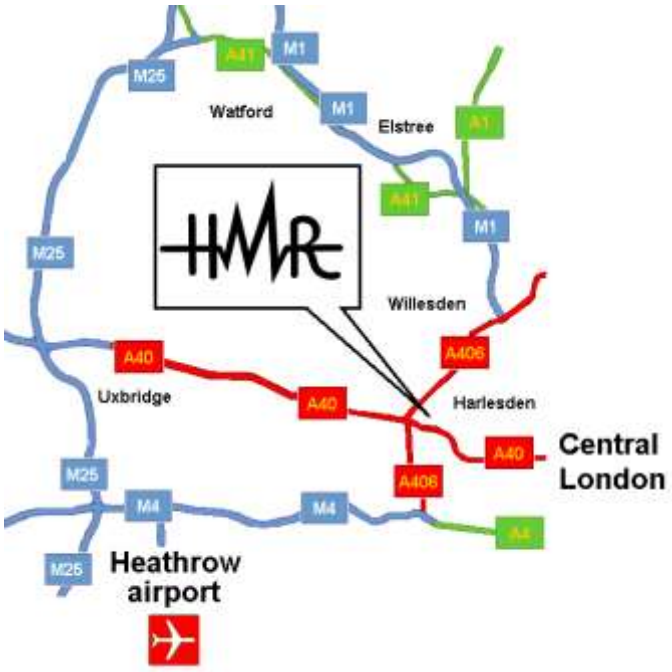
We've successfully undergone:

- > 15 inspections by the MHRA, and an FDA Bioequivalent Clinical bioresearch monitoring (BIMO) inspection
- > 20 ISO 9001 inspections
- > 250 sponsor audits
- 2 ISO 17025 inspections
- 4 General Pharmaceutical Council audits
- 3 Environment Agency radiation compliance inspections

QA host all sponsor audits, ensure that relevant staff and documents are available, and oversee HMR's response to your audit report and implementation of any CAPA.

## Accreditations

- MHRA phase 1 accreditation
- MHRA Manufacturer's Authorisation for IMP
- ISO 9001 certified QMS
- ISO 17025 accredited laboratory
- Registered pharmacy
- Licence to possess, supply and destroy controlled drugs (schedules 2, 3 and 4 (part 1 and 2))
- Employer and practitioner licences under IR(ME)R 2017 for clinical studies of radiolabelled compounds
- Health and Safety Executive consent for manufacture and administration to humans of radioactive substances




**HMR**
**Cumberland Avenue**
**London NW10 7EW**
**UK**

**www.hmrlondon.com**

**Contact:**

**Malcolm Boyce**

**Phone: 020 8961 4130**
**Fax: 020 8961 8665**
**Email: EnquiriesTeam@hmrlondon.com**