Medicines Evaluation Unit
Job Description

Job Title: Quality Assurance Officer

Reports To: Quality Manager

Hours of work: 37.5hrs

Job Purpose:

To assist the Quality Manager in all aspects of Quality Assurance Services

To ensure compliance to EU and UK Clinical trials legislation and ICH GCP in all Medicines Evaluation Unit studies

To assist with system for the control of Standard Operating Procedures

Specific Duties:

1. **Quality Assurance Processes**

To assist the QA manager in the following MEU QA processes:

a) To perform facility and system audits on an ongoing basis.
b) To perform audits of third party providers.
c) To perform frequent in-depth GCP audits of data, study documentation, including source data verification, informed consents, clinical reports, and ethical submissions at pre-study, study and post-study stages as appropriate.
d) Reporting findings to the Management Team and provide feedback to the study teams initiating any training requirements as appropriate.
e) Provide advice and interpretation of new regulations and regulatory issues as they occur.

2. **Standard Operating Procedure (SOP) systems**

To assist the QA Manager with

a) The administration of SOP process.
b) The coordination of the review and update of SOP's.
c) Ensure documentation of training in SOP's is maintained.
d) Oversee the implementation of new SOP's.

3. **To ensure compliance to EU and UK Clinical Trials legislation and ICH GCP in all Medicines Evaluation Unit Studies**

a) To ensure compliance to ICH GCP using systems described above.
b) As part of quality assurance function to ensure that all Medicines Evaluation Unit staff have comprehensive training records to include documentation of general and study specific training.
c) Assist Quality Manager with training of staff

4. To assist the QA Manager in the set up and management of ISO 9001 quality management system

a) To monitor quality systems and initiate appropriate actions in order to meet standards in order to gain accreditation for ISO 9001
b) Promotion of ISO9001 compliance to potential sponsor companies

5. Responsibility of adherence to EU and UK Clinical Trials legislation and ICH GCP

a) Maintain personal training record
b) Attend training sessions as appropriate
c) Perform role in accordance with company policies and Standard Operating Procedures.

6. HEALTH AND SAFETY

a) Take care of own safety and others who may be affected by their actions or omissions.
b) Adhere to Medicines Evaluation Unit Health and Safety policies and use any equipment or personal protective equipment provided to ensure safety.
c) Adhere to trust health and safety policies where applicable.
d) Co-operate with their managers to maintain safe systems and safe workplaces.
e) Report any accidents/incidents or ill health failings in premises and equipment or personnel protective equipment.
f) Not interfere with any equipment provided to ensure Health & Safety.
g) Not attempt to carry out tasks or repairs beyond their competence.
h) Failure to adhere to the above may result in disciplinary action.

This role specification indicates the main functions and responsibilities of the post and is subject to regular review and amendment.