**ROLE TITLE:** **SENIOR CLINICAL QUALITY ASSURANCE MANAGER**

**Valid from November 2020**

**LOCATION:** **Head Office-Welwyn Garden City, Hertfordshire**

**REPORTS TO:** **MANAGING DIRECTOR**

## 1. PURPOSE OF ROLE

Primary responsibility for this position will be managing the ongoing Clinical Quality Assurance (CQA) activities for the Organisation, supporting our Good Clincial Practice (GCP) and Clincial Trial obligations, reporting to the Managing Director.

Ensure planning, coordination, and control, of processes and methods are established to control the quality of studies conducted at PHARMExcel.

Develop the QA department, focusing on continuous improvement ,using approved tools, design control, validations, and ensuring adherence to the agency regulations, GxP, Industry Guidelines, local regulations, along with PHARMExcel policies and procedures for the conduct of clinical trials.

Work closely with Clinical Operations, Information Technology, and other supporting areas/ teams, to drive a culture of Quality within PHARMExcel

Be proactive in developing and implementing procedures and work with a high degree of autonomy.

Organise workload to ensure that role and Company objectives and deadlines are met. To adhere to PHARMExcel's information governance and confidentiality policies.

Will be required to attend a Good Clinical Practice (GCP) course/undertake GCP training within 3 months of starting if he/she has not already done so.

## 2. KEY AREAS OF RESPONSIBILITY

- Develop and maintain GCP/ICH compliant processes which control the quality of work and clinical trials conducted at PHARMExcel.
- Actively lead in the areas of Internal Quality Audits, CAPA (Corrective and Preventive Actions), Quality Management Reviews and Quality Audits.
- Lead the organisation during regulatory agencies and Sponsor/Client audits.
- Lead with identifying non-conformancesagainst requirements, provide suitable recommendations and facilitate ongoing improvements using risk-based methodology while maintaining compliance with applicable study protocols, Quality System Regulations and or ISO standards where applicable.
- Communicate any critical compliance risks noted from these activities to senior management.
- Responsible for management of contract auditors.
- Responsible for conducting vendor audits and work with vendors and service delivery personnel in eliminating problems via root cause analysis techniques, to ensure that service delivery continuously improves.
- Assist in providing training to PHARMExcel Clinical staff.
- Prepare, review and approve external and internal QA reports and other documentation required by regulatory agencies, or clients, to support the quality assurance function.
- Manage and maintain databases for the quality system.
- Update and maintain CQA Standard Operating Procedures (SOPs) that support the Quality Systems.
- Prepare and assist in preparing annual reports and quality trending reports.
- Keep up to date with all related quality legislation and compliance issues.
- Utilise guidance documents, international standards, or consensus standards and interpret for guidance.
- Provide leadership and strategy in line with global QA strategic objectives.
- Co-operate with colleagues in Clinical, Regulatory, and Medical departments to increase the overall effectiveness of the Quality role, and instil a Quality Improvement approach in all activities.
- Sit on the Senior Leadership team and contribute to operational excellence initiatives, both in the department and companywide, which result in the overall improvement in both areas.

**General duties**

- Complete time-sheets
- Encourage a team culture that fits within PHARMExcel's work ethos creating a team environment which supports process improvement, innovation and personal accountability
- Undertake any other duties commensurate with the position

**NB. The role description is a reflection of the current position and may change emphasis or detail in the light of subsequent organisation developments, in consultation with the post holder.**

## 3. INTERFACES AND INTERDEPENDENCIES

### Internal

- Reports to Managing Director
- Member of Senior leadership Team
- Works cross functionally to deliver CQA activites for the organisation

### External

- Regulatory Authorities
- Client/Sponsor
- Clinical Research Sites
- Vendors
- External QA personnel

## 4. PERSON SPECIFICATION

### Knowledge and skills

Essentials

- Minimum degree (BSc) in Life Science or related discipline.
- 5 years + of demonstrated CQA experience in regulated industry such as pharma, biotech, CRO.
- Full understanding of ICH/FDA GCP guidelines, with an extensive knowledge of GCP.
- Broad knowledge of risk-based quality systems approaches consistent with ICH E-6 for Good Clinical Practice.
- Understand device regulations, development processes and FDA / EMA inspection procedures is also required.
- Experience with effectively managing FDA / EMA inspections, working with regulators and customer audits.
- Experience developing SOPs, reviewing internal clinical, regulatory and medical processes to ensure they are accurately represented in current SOPs.
- Demonstrated ability to lead by example and to encourage team members to seek solutions independently
- Ability to work independently.
- Ability to manage conflicting priorities and deadlines
- Ability to negotiate and liaise with clients/vendors in a professional manner.
- Ability to present to staff at all levels.

**Values and behaviours**

- Professional
- Self-motivated
- Organised, ability to multi-task, ability to motivate and organise others.
- Flexible and proactive approach with a “can do” attitude
- Delivers high quality work
- Willingness to accept and make changes in a fast paced environment.
- Strong leadership and motivational skills
- Able to work independently whilst also being a strong ‘team player’

## 5. IMPACT

- Will quickly get to know the organisation ethos and study workload
- Will build good working relationships with other team members and clients
- Will provide senior level QA support
- Will identify areas for quality improvements within the clinical are of the Company and intiate business cases for implementation of new systems and processes
- Will work independently to prioritise workload under pressure and work to changing business needs
- Will have confidence in own abilities and know when to be assertive and diplomatic
- Will work to challenge the status quo and improve on current best practice