Centre for Probe Development and Commercialization

Job Description
Quality Assurance Supervisor

Under the direction of the Director of Radiopharmaceutical Development and Manufacturing Quality Manager, the Quality Assurance (QA) Supervisor ensures that quality standards and current procedures meet or exceed Canadian and international regulations for Good Manufacturing Practices as well as the standards set by Contract Manufacturing clients. Where necessary, works with other CPDC departments to establish GxPs within the quality system.

The responsibilities listed can be delegated to team members at the discretion of the Quality Assurance Supervisor.

- Accomplishes Quality Assurance human resource objectives by recruiting, selecting, orienting, training, assigning, scheduling, coaching, counseling, and disciplining employees; communicating job expectations; planning, monitoring, appraising, and reviewing job contributions; supporting career development activities; enforcing policies and procedures. Human Resources issues are raised to the Director in a timely manner to avoid inefficiencies within the group
- Achieves Quality Assurance operational objectives by monitoring and assigning day-to-day activities, identifying and addressing gaps and problems; completing audits; implementing change and providing regular feedback to the Director and stakeholders regarding system performance and issues
- Performs the project management function for the group including resource planning, objective setting, communication of issues and reporting project progress to stakeholders
- Serves as the Quality Assurance liaison with external clients for projects in all stages of clinical development, as well as for products having marketing authorization
- Perform gap analysis through regular audits of Quality Systems and proposes plans to the Director and stakeholders to close gaps with the aim to continually improving the performance of Quality System to meet recognized industry standards for radiopharmaceuticals
- Work with Product Development and Production personnel to analyze and trend product performance through completion of Annual Product Quality Reports (Health Canada), Annual Product Reports (FDA) and Quality Reports (Contract Manufacturing)
- Host regulatory and client audits, and assumes responsibility for ensuring that stakeholders are included in proposals for corrective actions and that proposed corrective actions are completed in a timely manner
- Work closely with the departmental managers to ensure staff are working in compliance with internal policies and procedures, external client expectations and GxPs
- Update job knowledge by studying trends in and developments in quality management; participating in educational opportunities; reading professional publications; maintaining personal networks; participating in professional organizations
- Meet weekly with the Director to track and set team priorities, and address issues and problems
- Oversee the day to day running of the group, monitoring and assigning tasks to meet the needs of QA, RA, Clinical, PD and manufacturing
- Runs weekly team meetings and prepare minutes for distribution to stakeholders
- Complete all other duties as required to support the mission of the centre

QA Supervisor

Educational Qualifications:

- BSc or equivalent with a minimum of 5 years experience in the pharmaceutical, radiopharmaceutical or biopharmaceutical industry

Experience:

- Pharmaceutical industry experience or experience within a highly regulated technical environment (e.g. GMP)
- Demonstrated ability to think strategically and identify a vision along with the plans which need to be implemented to meet the end goal
- Ability to develop and maintain relationships with internal and external business partners
- Strong communication skills with various levels of the organization
- Proven ability to assess and make risk-based decisions while keeping stakeholders appraised
- Experienced in assessing a situation, identifying issues and developing solutions that result in efficiencies or process improvements
- Demonstrated leadership capability (ie. takes initiative to lead self and others, lead by example and follow through to completion often with minimal direction)
- Ability to work with a sense of urgency, prioritize work, meet objective / deadlines with strong organizational capability
- Successfully demonstrated ability to coach others with a strong self awareness (both strengths and opportunities) and ability to self develop
- Ability to adapt to change and work flexibly to overcome boundaries
- Strong project management skills with the ability to work independently and within a team
- Ability to adjust work schedule based on business requirements

To apply please submit a cover letter and resume to: careers@imagingprobes.ca
Attention: Joe McCann, PhD

Centre for Probe Development and Commercialization (CPDC)
1280 Main Street West, NRB-101
Hamilton, ON L8S 4K1

We thank all applicants for their interest, but only those selected for interview will be contacted