



Quality Assurance Associate - Auditing

The Centre for Probe Development and Commercialization (CPDC) is a Centre dedicated to fostering the development, translation, and commercialization of molecular imaging probes and associated technologies.

Overview:

The Quality Assurance Associate - Auditing will specialize in GMP auditing and general compliance assessment and readiness. They will work internally with quality assurance management and peers in other functional areas, primarily Manufacturing, Quality Control, Regulatory Affairs and Quality Assurance to continually assess and improve the Centre's quality system. Externally, they will work with partner manufacturing sites, vendors and subcontractors. The position will require periodic travel totaling up to 25% of the time in year one and up to 50% in year two. **NOTE: This is a 12-18 month contract position.**

Key responsibilities/requirements include:

- Manage an audit program to assess compliance with:
 - Local standard operating procedures and policies
 - Health Canada Good Manufacturing Practices (GMP) Guidances
 - Annex 3 – Schedule C Drugs (GUI-0026)
 - Annex 5 – Positron Emitting Radiopharmaceuticals (PER's) (GUI-0071)
- Conduct audit closeout presentations and draft timely audit reports and follow-ups
- Maintain close contact with partner sites to assist in close-out of audit findings in a timely fashion
- Work with fellow Quality Assurance team members to:
 - Conduct proactive gap analysis of quality systems within the Centre and develop improvement plans
 - Work with the Manufacturing and Product Development groups to improve efficiency of the quality system
 - Monitor changes to assess impact on compliance and efficiency
- Review SOPs, protocols and other controlled documents for compliance with all pertinent GMP regulations and internal policies
- Perform review of raw material, production and testing documentation as needed
- Develop raw material, equipment and finished product specifications as needed
- Participate in qualification audits of vendors and subcontractors as needed
- Provide support during government/agency or client inspections as needed
- Participate in quality assurance projects as needed
- Perform all other related duties as assigned.

Qualifications:

- Bachelors degree (BSc or Engineering) or equivalent, preferably a post-graduate degree in quality assurance
- Minimum of 4 years experience in an auditing role at a GMP regulated company
- Requires comprehension of complex regulations and guidance documents with the ability to apply critical thinking skills to evaluate compliance with procedures, standards and regulations
- Consistently demonstrate reliable communication skills, initiative, self starting and attention to detail

To apply please submit a cover letter and CV to: careers@imagingprobes.ca

Attention: Joe McCann, PhD
Director, Product Development & Quality

We thank all
their interest, but
selected for



Centre for Probe Development and Commercialization

be contacted

applicants for
only those
interview will