



Life Molecular Imaging (LMI) is a global and innovative biotech company focusing on the development and commercialization of molecular imaging radiopharmaceuticals. Currently, for our approved F-18 amyloid PET tracer Neuraceq® and pipeline of PET tracers in clinical development we offer the following full-time position in the United States:

PET-Radiopharmaceuticals Specialist

The PET-Radiopharmaceuticals Specialist (PRS) will be the primary contact for contract manufacturing sites (CMS) regarding, troubleshooting, the technology transfer of new and on-going implementation, testing and training of the manufacturing and QC devices to ensure proper processing of LMI products. Create and/or review SOP, GMP and CMC documents while assisting with other Quality Assurance compliance.

Key Tasks and Responsibilities:

- Serve as first technical support contact for contract manufacturing sites (CMS)
- Perform and / or support troubleshooting of manufacturing and QC devices
- Support technology transfer projects (implementation of manufacturing and testing procedures to new CMS) related to the manufacturing and testing of current and new fluorine-18 radiopharmaceuticals
- Train staff at CMS on manufacturing and / or testing methods
- Ensure implementation of manufacturing and testing procedures at CMS
- Support preparation and review of SOP and GMP relevant documentation
- Review validation documents and batch records
- Support Quality Team in ensuring compliance with GMP
- Preparation and revision of CMC documents
- Implement process changes and provide input to continuously improve manufacturing and / or QC processes

Experience:

To be successful in this role, the incumbent must be able to work remotely while being responsible for a large territory across the US and occasionally internationally, and therefore must be able to travel frequently (up to 50%) and work hours outside their home time zone.

This position will be the primary point of contact for contract manufacturing sites and must be knowable in the field. Candidates will need to have a degree in Chemistry, Pharmacy, or a related discipline with a minimum of three years of experience with automated manufacturing and/or quality control of fluorine-18 radiopharmaceuticals.

The PRS must have good knowledge of CFR 21 Part 212 GMP guidelines and regulatory standards and the ability to comprehend the issues and to analyze situations fully and accurately to reach a productive resolution. Be able to understand the necessity and value of accuracy and attention to detail while processing information and then working collaboratively with others both internally and externally until resolution.

LMI is seeking candidates who are up for a challenge while being supported by their coworkers, managers, and other divisions of a global company. LMI offers competitive salary and outstanding benefits.

Life Molecular Imaging, Inc. is an Equal Opportunity Employer and drug-free workplace. All applicants are considered for all positions without regard to race, religion, color, sex, gender, sexual orientation, pregnancy, age, national origin, ancestry, physical/mental disability, medical conditions, military/veteran status, genetic information, marital status, ethnicity, alienage, or any other protected classification, in accordance with applicable federal, state and local laws.

Please send resume and cover letter to: hr.us@life-mi.com