

Life Molecular Imaging GmbH (LMI) is the German based Research & Development (R&D) organization of Life Molecular Imaging S.A. Switzerland, a wholly owned subsidiary of Alliance Medical Group Limited. Our vision is to build our position as an innovator and leading player in the Molecular Imaging field. We aim to create value for patients & physicians by improving early detection and characterization of chronic and life-threatening diseases leading to better therapeutic outcomes and improved quality of life.

For our approved PET tracer NeuraCeq® and our pipeline of tracers in clinical development we offer the following full-time position, preferably at our Berlin site:

Scientist (m/f/d) Pharmaceutical & Kit Development PET-Radiopharmaceuticals

Main Tasks & Responsibilities:

- Lead all pharmaceutical development activities of LMI's commercial product NeuraCeq®
- Support pharmaceutical development activities of LMI's pipeline products
- Develop reagent kits for PET tracer production and setup kit manufacturing at CMOs
- Lead activities to select and qualify critical consumables (e.g. vials, cassettes, dispensing kits), reagents, and excipients
- Manage suppliers of beforementioned materials
- Technical writing and review of GMP and CMC documents (qualification/ validation/ stability plans and reports)
- Review of CMO manufacturing batch records incl. QA documents (deviations, OOS, change control)
- Coordinate interaction between external suppliers and internal functions (e.g. QA, GRA)

Skills:

- Ability to work effectively in a team environment
- Good communicator
- Attention to details and diligence
- Open-minded and motivating attitude
- Enable decisions
- Quality oriented
- Solid understanding of
 - regulated processes, in particular cGMP (Eudralex Vol. IV Annex 1, 3)
 - regulatory requirements of pharmaceutical (raw) materials and excipients
 - pharmaceutical guidelines and pharmacopoeias (in particular Ph.Eur. and USP)
 - pharmaceutical analytical methods
- Self-starter with a high degree of endurance, flexibility, and mobility (about 10% traveling)
- Computer skills, in particular Word, Excel and PowerPoint
- Fluency in English

Experience:

- University degree in Pharmacy, Chemistry or related discipline
- 7+ years of experience in development and manufacturing of parenteral drug products, incl.
 - Experience in qualifying materials for pharmaceutical use
 - Implementation of regulations for pharmaceutical materials, excipients, and products

If you want to become part of an entrepreneurial team, if you are prepared to assume a wide range of responsibilities and if your background and personal experience fits this profile, please send us your complete application (Cover letter detailing your interest in this position including your past relevant research and work experience, CV, publication list) as a single pdf document to:

Annekathrin Kirchner a.kirchner@life-mi.com

We are looking forward to receiving your application!