Life Molecular Imaging GmbH (LMI) is a German based Research & Development (R&D) organization focused on developing PET imaging solutions to diseases with high unmet medical need. As a division of the Alliance Medical Group, we are a fully integrated pharmaceutical company with research and development laboratories, access to a network of cyclotrons, radiopharmacies and imaging facilities. 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. Our emphasis is on the development and marketing of new innovative Positron Emission Tomography (PET) tracers.For our approved PET tracer NeuraCeq and our pipeline of tracers in clinical development we offer the following position in Berlin, Germany:

CMC Documentation Manager (m/f/d)

Main Tasks & Responsibilities:

- Technical writing, review and revision of GMP and CMC documents (Technical Registration Documents for drug dossiers, risk assessments, CMC review of documents for submission)
- Coordination of packaging information
- Revision of CMS documentation (MBR, QC SOPs) during Technology Transfer and revision cycles
- Creation/updates of CMC dossier documents
- Act at an interface between Supply chain, Regulatory Affairs, CMC and Quality Assurance
- Oversee supply status of sites
- Support LMI's global partners and collaborators in the generation of local GMP and CMC documents as well as CMC documents for local competent authorities
- Authoring of protocols for testing and implementation of new procedures
- Issuance and coordination of Change Control workflows related to CMC documentation
- Review of Change Requests for impact on other LMI documents
- Coordination of document revisions

Skills:

- Ability to work effectively in a team environment
- Work in a global environment across multiple groups
- Attention to detail and diligence
- Multitasking and prioritization of workload/tasks
- Good communicator
- Open-minded and motivating attitude
- Quality oriented
- Solid understanding of
- regulated processes, in particular cGMP (Eudralex Vol. IV Annex 1, 3, 21 CFR Parts 210-212)
- pharmaceutical guidelines and pharmacopoeias (in particular Ph.Eur. and USP)
- Computer skills, in particular Word, Excel and PowerPoint
- Fluency in English

Experience:

- University degree in Pharmacy, Chemistry or related discipline
- Work within a regulated environment pharmaceutical environment
- At least two years of experience in technical writing, review and revision of CMC documents
- IND documentation, work in GMP environment (QMS experience or exposure)
- Experience in CMC regulatory desired

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 jobs@life-mi.com
Life Molecular Imaging GmbH
Tegeler Str. 6-7
13353 Berlin

We are looking forward to receiving your application!