

TRD RLT Senior Expert Isotopes (m/f/d)

Job ID
REQ-10036969

Jan 17, 2025

Italy

Summary

Location: Ivrea, Italy

Role Purpose:

Act as Isotope Project Lead by providing the specialist knowledge and expertise as Subject Matter Expert (SME) of radioisotope production and purification with particular focus on assessing, developing, and optimizing new technologies that support RLT products Life Cycle Management (LCM).

Develop and optimize radioisotopes production and purification/separation processes. This is done in close collaboration with the relevant development centers, and Contract Manufacturing Organizations (CMOs).

About the Role

Major accountabilities:

- Contribute to the Radioisotope TRD-related activities. Ensure constant technological survey on the field of radioisotopes production. Apply scientific/technical expertise to identify new programs of interest for the company and support their development from early evaluation up late phase supply.
- Participate to development programs and activities around isotopes in adherence with global Isotope strategy and objectives within agreed timelines and budget, timely report key advancements and challenges.
- Identify strategic external partners for the activation of research collaboration agreement to develop new production technologies/ access to innovative isotopes.
- If required, setup new isotopes QC laboratory and pilot plant.
- Lead and/or monitor technical activities performed with CROs or External Collaborators
- Work according to appropriate procedures and guidelines (e.g., working instructions, SOPs, GMP, GLP)
- Ensure that the development work is properly documented, allowing independent review and understanding, external inspections and regulatory submission.
- Provide SME for assigned process technology for platform / sites following product / process transfer or handover from launch to commercial production.
- Benchmark new technologies and equipment relevant for platform
- Set standards to perform technical feasibility trials related to process improvement and implementation of new manufacturing technologies.
- Support clinical trial team to secure access to radioisotope material needed for clinical needs with the appropriate quality and regulatory packages.

Minimum Requirements:

Education:

- BSc. in Chemical Engineering, Pharmaceutical Technology, or equivalent scientific degree.
- Desirable MSc., PhD or equivalent experience.
- Desirable degree in Radiochemistry and strong scientific knowledge in nuclear medicine

Work Experience:

- Successfully demonstrated several years (minimum of 3 years) of directly related experience in a scientific area or Ph.D. or equivalent.
- Proven process understanding (Pharma, GMP, Validation and Regulatory aspects).
- Sound experience of data handling and applied statistics is a must.
- Strong understanding of risk assessment and risk management fundamentals/tools
- Quality-oriented with attention to details
- Excellent verbal and written communication skills
- Excellent problem solving and decision-making skills
- Defining and implementing productivity improvement measures.

Languages :

- Fluent in English and proficient in site local language.

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部門
Development

部門
Innovative Medicines

国
Italy

勤務地
Ivrea

Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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