Pilot Plant Manufacturing Technician

Job ID
REQ-10065391

10月 29, 2025

Italy

摘要

The Pilot Plant Manufacturing Technician performs end-to-end production of radiopharmaceuticals in strict adherence to current Good Manufacturing Practices and approved Standard Operating Procedures, ensuring quality, sterility, and regulatory compliance at every stage. It prepares, handles, operates, and documents materials and equipment according to validated procedures, maintaining accurate, traceable records and promptly escalating any deviations. The position follows an internal rotation plan with morning and afternoon shifts, requiring flexibility and consistent coordination to meet operational timelines and batch release objectives.

About the Role

Key responsibilities:

- Shift work for preparation, production, and packaging/shipping of sterile radioactive drugs in

compliance with HSE, EU GMP Annex 1/3, and applicable regulations
- Perform setup, cleaning, and environmental microbiological monitoring (viable and non-viable) of areas and equipment with GMP-based periodic cleaning
- Prepare raw materials and batch kits; manage stock and waste per Production Supervisor instructions and HSE SOPs
- Complete GMP documentation per ALCOA+ and promptly report deviations/OOS to Production Supervisor, Qualified Person, and HSE Manager
- Handle inbound logistics, restock areas, prepare shipping packaging; check for radioactive contamination and perform decontamination
- Manage proper radioactive waste disposal with related records and transport
- Support maintenance/qualification, train new personnel, contribute to the site quality system and continuous improvement in line with safety and GMP
- Perform technical tests and support process/product qualification and validation; drive feedback and improvements, tracking KPIs (successful batches, delays, OOS/deviations, audit findings, qualifications)

Essential requirements:

- Technical or scientific high school education required; university degree in Science (Pharmacy, Chemical Engineering, Pharmaceutical Technology) or equivalent experience desirable
- Minimum 2 years in GMP manufacturing support or technical roles, preferably in sterile injectables; radiopharmaceutical experience is a plus
- Strong scientific/technical understanding and quick grasp of production processes
- Quality and compliance mindset with knowledge of regulatory requirements across multiple health authorities
- Proficiency with manufacturing IT systems (e.g., SCADA, HMI) and good office software skills

- Team player with strong team spirit, adaptability, and change management
- Ability to work under pressure and maintain standards
- Language skills: Italian proficient; English desirable

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部门
Development

Business Unit
Development

地点
Italy

站点
Ivrea

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

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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