NOVARTIS

Pilot Plant Manufacturing Expert

Job ID
REQ-10062437

9月 22, 2025

Italy

摘要

Responsible for technology transfer activities and front line technical and scientific expert support for all process-specific issues to ensure execution of processes on-time (business continuity); in compliance to cGMPs, SOPs and applicable guidelines and functional standards and to allow continuous improvement in quality, productivity efficiency.

About the Role

Key responsibilities:

- Provides frontline SME support on manufacturing on TRD RLT Pilot Plant, including hot-cell operations, radiolabeling, aseptic handling, and time-critical troubleshooting on the shop floor.
- Design processes for RLT production campaigns to meet short half-life constraints and just-in-time release, ensuring adherence to GMP, HSE/SSE, radiation protection rules, and 5S; performs real-time batch follow-up and technical record review.

- Leads investigations for RLT-specific deviations and complaints, drives RCA and CAPAs; manages change control and inspection readiness, aligns with site and corporate QMs/GOPs, and monitors RLT portfolio KPIs and trends (APQR, CPV/OPV).
- Partners with QA, QC and Regulatory for RLT dossiers and audits; maintains GMP documentation and master records for radionuclide precursors, conjugates, and final drug product.
- Drives Operational Excellence for RLT: cycle-time and yield improvements under decay constraints, 5S in controlled areas, data analytics and control charts; defines technical needs, URS, and functional specs for manufacturing suites in collaboration with Engineering.
- Manages end-to-end Technical Transfers for RLT assets from development laboratory and across sites: recipes/sequences for synthesis and labeling equipment, manufacturing instructions, equipment and process qualifications, technical batches, OPV, change control, and site readiness.
- Promotes Quality, HSE, and radiation safety culture; enables upskilling of operators and technicians in RLT-specific procedures; ensures effective communication of technical, quality, HSE, and radiation impacts. Manage manufacturing documentation life-cycle.
- Aligns all activities with the RLT portfolio strategy and timelines, ensuring manufacturing readiness, inter-site coordination, and process innovation to support clinical and commercial RLT programs.

Essential requirements:

- Language: English fluent; Italian proficient.
- Experience: 2+ years in GMP manufacturing support/technical roles; or 8+ years in field for lower education levels.
- Strong scientific and technical understanding with rapid grasp of pharmaceutical production processes. Radio-pharma knowledge/experience would be a plus.
- Quality, compliance, and pharma regulatory awareness.
- Team player with strong collaboration, negotiation, influencing, and persuasion skills.
- Change management, adaptability, and resilience under pressure.
- Knowledge of MES and ERP systems (e.g., MES, SAP) and related manufacturing IT.
- Solid command of office productivity software.

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部门
Development

Business Unit
Innovative Medicines

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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