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# **Pilot Plant Manufacturing, Team Head**

Job ID REQ-10037249 Jan 28, 2025 Italy

### Summary

The Pilot Plant Manufacturing Team Head is responsible to establish and manage the Production unit and ensures the manufacturing program is achieved efficiently within the framework of regulatory compliance and operating within high standards of GMP, HSE, environmental protection and good working practices as well as high level of flexibility needed by the Pilot Plant nature.

Identify and implement the necessary programs and actions in order to ensure sustainable, reliable execution of manufacturing operations at the RLT Pilot Plant.

# About the Role

#### Key responsibilities:

- Responsible to establish and maintain a Production unit and team in full cGMP, HSE and radioprotection compliance.
- Establish, optimize and maintain workflows, methods, procedures and guidelines for manufacturing.
- Ensure and maintain qualified status of production equipment and methods for intended use in Production lines.
- Ensure adequate management of Production related validations, transfers, investigations related activities (deviations, OOS, OOE, OOT, CAPAs, trending), and Change Control systems.
- Procure site validation and qualification support, support site launches of manufacturing products.
- Prepare and participate to health authorities' inspections and internal audits in his/her area.
- Ensure that Production personnel is duly qualified, and manufacturing is properly conducted and documented for all performed activities. Evaluate and approve Production records as required.
- Manage the staff objectives, performance and development. Ensure team members are empowered to develop in the plant and company organization through an open mindset without losing focus on Pilot Plant strategic objectives.
- Support the Director pilot plant for the Production area budget planning, execution and adherence
- Responsible to ensure that production planning and raw material planning are established and executed as needed to follow manufacturing demand.
- Guarantee that warehouse management, waste management as well as finished product shipment management are executed timely, safely and reliably ensuring best Pilot Plant efficiency.
- Ensure analysis of trends in deviations and other events are performed and facilitate resolution defining action plans.
- Follow-up on actions to ensure timely execution. Ensure needed flexibility is guaranteed by production team and manufacturing procedures and routines.
- Help promote an unbossed culture supporting ownership, innovation, speak-up, and accountability.

#### **Essential requirements:**

- PhD or MSc in Pharmacy, Biotechnology, Engineering (industrial fields) or Chemistry
- Fluent in Italian. Good knowledge of English (C1).
- English: fluent (oral and written)
- at least 7 years experience in the pharmaceutical industry with direct experience with sterile manufacturing, or similar, 2+ years of leadership experience.
- Related experience should be in GMP-regulated industries in Manufacturing.
- Proven ability to plan and manage operational process for maximum efficiency and productivity.
- Must have an understanding of pharmaceutical industry trends and practices. Broad cGMP experience is required with knowledge and understanding of manufacturing and validation requirements and activities.
- Radiation safety education
- Strong affinity with and awareness of quality issues
- Strong leadership skills (communication, team-working with other departments, drive to enable problem solving)
- Exploitation of new technology and techniques to eliminate non-value adding activities and improve productivity / performance through new processes

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Division International Business Unit Innovative Medicines Location Italy Site 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 Apply to Job

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