TRD Pilot Plant Quality Control Head

Job ID
REQ-10033339
Dic 10, 2024
Italia

Resumen

To lead the Ivrea TRD RLT Pilot plant Quality Control (QC) team by developing and executing strategic plans, providing direction for organizational structure, GMP and safety strategy, lean and continuous improvement initiatives, and people training and development. The QC Head is responsible for ensuring that the lab unit meets all agreed-upon objectives and Key Performance Indicators (KPI), specifically related to Compliance and Quality-related topics.

About the Role

Productivity:

- Full end-to-end responsibility, ownership, and accountability for the entire process from sample receipt to result release, including equipment ownership.
- Formulate strategies and make decisions to ensure the efficient and compliant operation of the Ivrea Site.
- Establish long-term strategy and resource requirements, periodically reviewing progress towards goals.
- Write and/or approve laboratory-relevant SOPs and review guidelines, Quality Modules, and all analytical work-related documentation.
- Ensure that all components, in-process materials, and test results are released in accordance with local/international regulations.
- Formulate KPIs to support strategic and quality objectives.
- Ensure lab processes follow compliant processes, including a high degree of Data Integrity assurance.
- Ensure method validations and other GMP analytical activities in support of IND/IMPD are planned and executed according to protocols and under the guidance of RLT development team.

Cost:

- Partner with the Director Pilot Plant RLT to establish operating and capital budgets; manage operating expense budget in the laboratory area.

Quality:

- Ensure all activities are performed according to the local Quality system and SOPs.
- Ensure that OOE, OOT, and OOS are properly and timely escalated to QA.
- Own investigation of all QC-relevant deviations and collaborate closely for all OOE/OOT/OOS investigations, ensuring they are conducted in a scientifically sound and timely manner according to SOPs.
- Define and implement appropriate corrective/preventative actions in due time.
- Support internal audits and external inspections according to the Novartis Corporate Quality Manual.

People/Culture:

- Act as a role model in accordance with the Novartis Values and Behaviors.
- Provide leadership, direction, and support to team members, ensuring they are adequately qualified and trained to achieve a high level of competence and are motivated to excel.
- Transfer knowledge and expertise to further empower lab team members.
- Drive for the internalization of a lean and quality-beyond-compliance culture.
- Create a positive working environment by providing honest and immediate feedback and coaching to resolve conflicts.
- Participate in the recruitment process to contribute to hiring the right people.
- Actively work at retaining and developing talents, identifying and responding to their technical and interpersonal development needs.
- Ensure the performance review process for all team members is executed.
- Effectively deal with poor performers in the laboratory.

HSE:

- Ensure changes and significant process steps within the area of responsibility are risk assessed according to standards and periodically reviewed.
- Ensure high level of attention for handling radioactive materials within the area of responsibility, running operations in full compliance with HSE guidelines (internal/external).
- Serve as a role model for HSE at the entire site by addressing HSE topics ad-hoc in the entire Site, including areas of indirect responsibility.
- Provide support to inspections carried out by Safety in the laboratory.

Key Performance Indicators

- No critical audit findings and audit actions completed on-time to root cause level, both in own area and across processes.
- Timely close out of corrective actions implemented for deviations.
- Demonstrated positive trends in key quality management process measures (Overdue deviations, Overdues, CAPA effectiveness, etc.).
- Testing and technical release of results according to agreed delivery times.
- Active contribution to compliance activities.
- Cost and budget adherence.
- GMP and technical training conducted, registered, and followed up.
- Achieve KPIs with regard to quality, cost, people, and productivity (lead time adherence).
- Retention, absenteeism, compliance with succession plans.

Job Dimensions

Number of associates: 10

Financial responsibility: Manage operating expense budget in the laboratory area

(Budget, Cost, Sales, etc.,)

Impact on the organisation: High.

Ideal Background

Education (minimum/desirable): University degree in natural sciences / Chemistry/ Biologic

Languages: Fluent written and spoken Italian and English

Experience: At least 5 years of Quality Control/AS&T experience within the pharmaceutical industry. Sound knowledge in GMP and related activities, analytical technology and equipment, incl. qualification and calibration.

Good know-how in common computer applications, e.g. MS Office, as well as in laboratory specific applications, e.g. LIMS, Chromeleon, 1QEM.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

División
International
Business Unit
Innovative Medicines
Ubicación
Italia
Sitio
Ivrea
Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10033339

TRD Pilot Plant Quality Control Head

Apply to Job

Source URL: *https://www.adacap.com/careers/career-search/job/details/req-10033339-trd-pilot-plant-quality-control-head*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Ivrea/TRD-Pilot-Plant-Quality-Control-Head_REQ-10033339
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Ivrea/TRD-Pilot-Plant-Quality-Control-Head_REQ-10033339