QC Site Manager / Responsable CQ - pharmacien adjoint SCL - H/F

Job ID
REQ-10017562
Sep 03, 2024
Frankreich

Zusammenfassung

The Site Quality Control Manager is in charge of the maintenance at local level of the national quality management system as per GMP regulation and corporate guidelines as well as of all health regulated activities ensuring that all the relevant external and internal requirements are implemented, monitored for performance and adherence.

About the Role

Advanced Accelerator Applications Molecular Imaging a été créée en décembre 2022 en tant qu'activité distincte d'Advanced Accelerator Applications, société Novartis. Fondée en 2002, spin-off du CERN, elle axe son développement sur la fabrication de thérapies ciblées (RLT) et de radioligands destinés à l'imagerie de précision en oncologie. La société fait partie du groupe Novartis depuis 2018.

Notre mission est d'aider à sauver des vies grâce à un diagnostic de précision précoce de maladies parfois rares. L'imagerie moléculaire est une technologie de diagnostic capable d'identifier une maladie à ses premiers stades et de déterminer l'emplacement exact d'une tumeur, souvent avant l'apparition des symptômes ou des anomalies peuvent être détectées avec d'autres tests diagnostiques.

Travailler pour AdAcAp vous donnera l'opportunité de faire évoluer votre savoir-faire et de poursuivre une carrière scientifique dans une société de haute technologie en forte croissance.

Venez rejoindre une équipe engagée de 20 personnes, au sein d'un environnement motivant et formateur.

Major accountabilities:

- Raw materials, packaging materials, semi-finished products acceptance according to specifications;
- Manage, coordinate and approve the execution of the analytical activities for the batch release;
- Ensure that all quality control processes, equipment and software are validated/calibrated according to the Validation Master Plan;
- Ensure the maintenance of all quality control equipment according to the Validation Master Plan;
- Ensure that all methods used in QC analysis are validated according to SOPs, MA and cGMPs;
- Guarantee the cleanliness and tidiness and application of Good Laboratory Practice;
- Assure the adequacy of the SOPs of Quality Control department;
- Perform the audit trail review of the quality control equipment software;
- Verify the data integrity of the QC software;
- Maintain, review and approve the records of the QC activities;
- Ensure the existence of a system of procedures to guarantee the quality and efficacy of the QC

department;

- Ensure that all QC materials are properly and safely stored, identified, labelled recorded and monitored according to SOPs and specifications;
- Ensure that the stock of materials, reagents, standards is properly available and ordered;
- Ensure, in collaboration with QA department, that out of specifications, out of trend, deviations, CAPA, change controls related to the QC department are addressed and recorded according to cGMP and SOPs;
- Collaborate with other functions for the redaction of the stability programs and the annual product review according to the calendar;
- Ensure the initial and periodic training of QC analysts;
- Manage the presence, shifts and performances of the QC analysist;
- Act directly to the audits performed at the site by the France Quality Lead;
- Act participate during the Health Authorities (ANSM) and during the subcontractor inspections;
- Participate in the corrective actions at local level the follow up of the Health Authorities and the subcontractor inspections;
- Ensure the complete independence of the QC activities from the TechOps department;
- Assure the application of the recall procedure in case of critical issues impacting the products as per GMPs and Health Authorities requirements;
- Assure the escalation to the Site Quality Lead and to the France Quality Lead in case of critical issues.

Minimum Requirements:
Education:
Scientific Degree (Preferred qualification to Qualified Person)

Work Experience:
2+ years of experience in QC dept. Excellent organizational skills (time management, risk management) including attention to detail and multitasking skills
Open and clear collaboration and communication to make sure the daily operation runs smoothly
Shows the appropriate sense of urgency around given tasks
Reliable, present and able to transmit the energy necessary to continue an improvement process and consolidate the system
Preferred qualification to Qualified Person

Languages:
French, English fluently, verbally and in writing

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

Abteilung

Operations
Business Unit
Innovative Medicines
Ort
Frankreich
Website
Saint-Cloud
Company / Legal Entity
FR72 (FCRS = FR072) AAA Mol. Ima. France SAS
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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