Compliance & Qualification Specialist A.I.

Job ID
REQ-10026620
Nov 05, 2024
Italy

Summary

Provide the knowledge and skills to guarantee engineering operations (in Equipment, procedures, and maintenance) to comply with GMP standards and Novartis internal quality and safety policies.
In the same way, to meet expectations in internal audits and external audits (Health authorities and HSE).
To support initiatives of continuous improvement of the processes from the point of view of Engineering, as well as to manage the internal and external needs of training for the engineering department.
Ensure the implementation of the HSE by design program.
Provide support functions to the administrative management of the engineering department.
In compliance with corporate law, corporate policies and procedures in the field of HSE, GMP, Protection of Company Assets, Code of Conduct.

About the Role

Il dipartimento di Ingegneria a Torre Annunziata Operations apre la candidatura per la posizione temporanea di Compliance and Qualification Specialist.

Major accountabilities:

- Governance of AGILE records (CAPA, Actions, Quality Events) for Eng Dpt
- Strict activities tracking in order to ensure NO OVERDUE
- Support to record owners
- Link with Compliance department to solve any issues
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- Support to investigators team about deviation records for Eng Dpt
- ESOP monitoring. Governance of SOPs for Eng. Dpt.
- Activities coordination in order to ensure NO OVERDUE
- Support to SOPs authors whether required
- SOPs compliance review
- Governance and development strategy of Validation Master Plan.
- Governance (Activities coordination in order to ensure NO OVERDUE)
- Develop and define together with the owners of each stream of Validation master plan (EQ-VMP. CSV-VMP and F&U-VMP) the strategy and the annual implementation plan. Assuring the inventory list, the action plan and the adherence to previous plan Leading and upgrading the Master Equipment Inventory (MEI)
- Support the documents authors whether required and making the documentation compliance review.
- Develop the role of Training Coordinator for Eng Dpt.
- Training manager for Eng Dpt (Internal and external team) Take care of logistics and organizational

aspects (ATP, ATR, LMS Registration-UP4GROWTH migrazione)
- Suporting the teacher and the students.
- Assuring an tracking the training status in order to give support the Engineering Head in case of Audit.
- Representing Eng. Dept. to Training Council meetings + QRB data.
- Develop and execute the HSE by Design program together with the PM Coordinator in order to fulfill all HSE requirements.
- SPOC IGM of Eng Dpt.
- Governance and responsible of technical documentation archiving for Eng Dpt. .
- Representing Eng. Dept. to Council meetings.
- Responsible of annual and trimestral plan.
- Guarantee the training to AUB (Acceptable user Baseline) of Eng. Dpt.
- Conduct release meeting at the end of the project.
- Conduct Site Regular analysis through Rolling Engineering assurance to strengthen and improve Engineering Compliance on Site.
- Enables and facilitates sharing and the ability to make best use of best practices in the respect of technical compliance
- Provide support the Engineering Head in management of administrative functions like job profiles, Euhreka support, adherence to holiday plan, travel and expense note.
- Active participation in the definition of new process and procedures, periodic review of them and work for their improvement.
- Suggests to all concerned people the changes from legal and regulatory requirements.
- Participate, when required, on quality audits of suppliers or on internal quality controls
- **Key Performance Indicators :**
- Number of Overdue in compliance activities within the engineering team.
- Number and severity of GMP observations identified during internal and external audits related to engineering equipment.
- No deviation and overdue in the governance of the Validation Master Plan.
- Governance and development strategy of Validation Master Plan
- No deviation and overdue in the training plan.
- No deviation in the HSE by design plan.
- No deviation in the IGM plan.
- Adherence of local procedures to internal cGMP and HSE policies

Minimum Requirements :

Experience/Backgorund in Quality & Compliance

Education:

Master degree in Engineering or equivalent, CTF, Chemistry, Scientific Degree

Languages:

English

Experience:

Preferred 2-3 years of experience in the engineering field.

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

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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

Division
Operations
Business Unit
Innovative Medicines
Location
Italy
Site
Torre Annunziata
Company / Legal Entity
IT08 (FCRS = IT008) Novartis Farma S.p.A.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
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