QA Specialist -Categoria Protetta L.68/99

Job ID
REQ-10014057
Jul 15, 2024
Italia

Resumen

The Quality Assurance Specialist is responsible to support the maintenance at local level of the quality management system as per GMP regulation and corporate guidelines as well as of health regulated activities ensuring that all the relevant external and internal requirements are implemented, monitored for performance and adherence.

About the Role

Major accountabilities:

- · Assure the respect of the GMPs and Health Authorities requirements at local level.
  · Contribute to maintain the local quality system as per GMPs and corporate guidelines.
  · Redaction and review of SOPs, records, protocols and reports according to GMPs, National/ Corporate Guidelines and health authorities' requirements.
  · Registration and archive of the documentation at local level.
  · Manage the GMP logbooks (distribution, archiving and revision).
  · Collaborate in the management of Annual Product Reviews (redaction and review).
  · Manage of training records, execution at local level of staff GMP training and redaction of the Training Annual Plan.
  · Support the Quality Site Head during escalation case in case of critical issues occurred.
  · Participate to the self-inspections as per approved annual plan and to the external audits (Health Authorities, Certified Bodies, Supplier).
  · Support in management and redaction of Out of Specifications, System Suitability Test failure, Out of Trend, Deviations, CAPA, Change Controls, Complaints according to cGMP and reference SOPs.
  · Collaborate in the annual suppliers' qualification in accordance with related SOPs.
  · Fill in the KQIs files.
  · Prepare and print the batch documentation.
  · Support the QPs in the batch record review.

- Support at local level the QA Department:

  - in assuring the execution of qualification, maintenance, calibration and revalidation programs;
  - in managing the external inspections follow up;

  to follow the training annual plan.

Key performance indicators:

- Inspection management (no critical observations during Health Authorities inspections).

  Completion of all relevant quality records within applicable time frame, with measured overdues.

Minimum Requirements:
Work Experience:

- Functional Breadth.
- QC/ QA in pharmaceutical ind./ biotech with environmental monitoring &.
- Collaborating across boundaries.
- cleanliness zones.

Skills:

- Continuous Learning.
- Dealing With Ambiguity.
- Gmp Procedures.
- Qa (Quality Assurance).
- Quality Control (Qc) Testing.
- Quality Standards.
- Self Awareness.
- Technological Expertise.
- Technological Intelligence.

Languages :

- English.

Education: Pharmaceuticals, Chemical or biological degree

Languages: Fluent English verbally and in writing

Experiences:

- 1+ years of experience in a Quality dept.
- Strong affinity with and awareness of quality issues
- Good organizational skills including attention to details
- Knowledge of quality system (GMP)
- Basic knowledge of regulatory requirements
- Shows the appropriate sense of urgency around given tasks
- Work in team

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