QA Manager

Job ID
REQ-10001512

四月 17, 2024

Taiwan

Summary

-Assurance that the product quality conforms with specifications and that production activity is compliant with Novartis quality policy and GxP requirements. Ensure that relevant documentation is up-to-date and archived correctly. Ensure “state of the art” GxP know-how and future trends in the field of GxP

About the Role

Major accountabilities:

- Ensure that all aspects of the handling, manufacturing and distribution of pharmaceutical products in the country comply with the requirements of the Novartis Quality Manual and Policies and meet all relevant cGMP regulatory and legislative requirements.
- Ensure that a local Quality System and Standard Operating Procedures are in place for all GMP/GDP related activities and that compliance with cGMP/GDP regulations is maintained

through training and internal audits.
- Maintain current knowledge of local and international regulatory and legislative requirements and trends to ensure that technical support on all quality related matters is provided to the country.
- Establish a good working relationship with the Supply Chain Management (SCM) and RA departments.
- Ensure that coordinated contact is maintained with the Regulatory Authorities, the local partners (suppliers, third parties, licensees, and distributors) and Global Quality Assurance.
- Ensure that all drug products are released to the market in accordance with the registered specifications and with local/international regulations. Ensure that an effective Change Control process is in place.
- Audit, supervise and co-ordinate third party activities and ensure that third party manufacture, (re-)packaging, (re-)labelling, storage and/or distribution of Novartis products is in compliance with Novartis Standards.
- Ensure NCQ readiness for all GMP regulatory inspections.
- Manage external inspections, complaints, recalls, counterfeits and product tampering according to the Novartis Corporate Quality Manual and local written procedures. Support / participate in NEM cases as required.
- Ensure conduct of adequate training at the NCQ for all GMP and GDP related activities by defining, planning and supporting training activities.
- Handling and follow-up customer complaint investigations.
- Controlled drug monthly on-line reporting.
- Engagement in NCQ project, initiatives and plan.
- Other: tasks assignment by manager.

Key performance indicators:

- Fully support business priorities
- Ensure successful inspection and audits by good readiness and process management
- External engagement
- Meet all relevant Quality KQIs and take appropriate corrective actions in case of missed
- Ensure 3rd party business partner /service provider sustainable and updated compliance

Minimum Requirements:

Education

Degree in Life Sciences or related fields

Language

English fluent in speaking and writing

Experience

Min. 5 years experience in the pharmaceutical industry in a relevant field such as quality assurance, quality control, registration, production or a directly related area

Work Experience:

- Participating in volunteer / community projects.
- Functional Breadth.
- Collaborating across boundaries.
- Operations Management and Execution.

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Division
Operations

Business Unit
Pharmaceuticals

國家
Taiwan

Site
Taipei

Company / Legal Entity
TW03 (FCRS = TW003) Novartis (Taiwan) Co. Ltd

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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