NOVARTIS

Quality Assurance Specialist

Job ID
REQ-10087642
Sep 16, 2026
LOC_KR

About the Role

Major Accountabilities

- Accountable for product compliance to local/international regulations as well as Novar tis Corporate Quality Policy.
- Ensure that all drug products are released to the market in a timely manner in accordance with the registered specifications and with local/international regulations.
- Manage the effective Change Control process.
- Manages the documentations and archiving of QA data and records to be compliant with local regulations, Novartis Corporate guideline and GMP requirements.
- Conducts the review of the accordance between the analytical testing specifications/methods and registered product license.
- Performs management of analytical method transfer and analytical testing documents transfer complied with both Novartis QM/QD and relevant SOPs under pharmaceutical law.
- Manage external inspections, complaints, deviations, recalls, counterfeits and product tampering according to the Novartis Corporate Quality Manual and local written procedures and implement each CAPA timely.
- Manage technical complaints including reporting to appropriate investigation sites, managing investigation processes, and ensuring that appropriate corrective actions are taken.
- Identifies and reports any quality or compliance concerns and implementation of immediate corrective action as required
- Ensures the readiness for escalation including prompt decision and actions of recall / Market action.
- Report monthly Key Quality Indicators (KQIs) and monitor them and assure that gaps are addressed appropriately in order to mitigate risk.
- Establish a good working relationship with the Supply Chain Management (SCM) / RA departments as well as External Supply Organization (ESO) allowing to keep QA oversight on all partners (e.g. third-party activities).
- Ensures that returned and defective products are managed and disposed in accordance with GMP requirements.
- Ensure reporting and follow up of all spontaneous adverse events (AE) and technical complaints for all Novartis Corporate products according to respective SOP.

Key Performance Indicators (KPIs)

- Local GMP Quality System in place and continuously updated, as required
- GMP related risks proactively identified and effectively mitigated
- The number and severity of GMP issues identified during internal and external audits
- No regulatory problem/action due to inefficient local Change Control procedure
- Training conducted according to program

Education

- Degree in Life Sciences or related fields (Pharmacy preferred)

Language

- Good command in English (speaking and writing)

Experience

- Min. 3 year experience in the pharmaceutical industry in a relevant field such as quality assurance, quality control, registration, production or a directly related area
- Strong Interpersonal skills
- Strong Project Management and leadership skills
- Ability to work under pressure and matrix organization
- Highly proficient in negotiation skills
- Highly effective in influencing others

Role Requirements

Division
DIV_TO
Business Unit
Quality
Location
LOC_KR
Site
Seoul
Company / Legal Entity
KR01 (FCRS = KR001) Novartis Korea Limited
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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