NOVARTIS

Quality Assurance Specialist

Job ID
REQ-10087642
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Южная Корея

Сводка

Ensure the quality of the finished products that are imported and distributed by Country Organization is complied with both a) Korea Pharmaceutical Law and the related regulation and b) Novartis Corporate Quality Manual and Policies (Quality manual and the relevant SOP) including cGxP requirements

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

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

Дивизион
Operations
Business Unit
Quality
Место
Южная Корея
Сайт
Seoul
Company / Legal Entity
KR01 (FCRS = KR001) Novartis Korea Limited
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Novartis are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

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