NOVARTIS

QA Manager, ESO SRT China

Job ID
REQ-10091448
Ноя. 01, 2026
Китай

Сводка

Responsible for managing quality aspects at external suppliers for Pharmaceuticals and/or Devices and to ensure that the operational business is in compliance with cGMP, the Quality Assurance Agreement, regulatory requirements and the Novartis Pharma Quality Manual and is conducted according to the relevant SOPs.

About the Role

Major Accountabilities:

- Lead External Suppliers Qualification process.
- Acts as Single Point of Contact / SPOC for all quality related activities at the External Supplier.
- Ensure that all aspects of the handling, manufacturing and distribution of biopharmaceutical / pharmaceutical products are in compliance with the Novartis Pharma Quality Manual, the effective Quality Agreement that they meet relevant cGMP regulatory requirements and are conducted according to local SOPs.
- Responsible for driving / initiating External Supplier Quality Risk assessments to be carried out for all External Suppliers. Gaps are Quality Systems to be identified with an evaluation of the associated risks. Remediation plans are to be defined and execution is to be monitored to ensure that issues are suitably addressed.
- Provide the quality presence and in-put to Technical meetings with the External suppliers and establish good working relationships with clear communication and defined actions and goals.
- Ensure that a valid QA agreement defined in line with the requirements of the Global template is in place which clearly defines cGMP roles and responsibilities between Novartis and the External Supplier, as well as Product details and requirements.
- Request, review and process GMP documentation as defined by the Quality Agreement and Novartis SOPs. Manage the quality aspects of the relationship in accordance with the effective Quality Agreement. Perform the required periodic review and make recommendations for amendments to the agreement based on identified needs and issues.
- Responsible for coordinating and ensuring that Quality auditing of External suppliers is carried out according to the Novartis Quality Manual - maintain an annual auditing program, participate in and/or lead audits, manage action plans and follow up on agreed upon CAPAs. Ensure site readiness for regulatory inspections at External suppliers where appropriate.
- Manage critical quality issues (deviations, complaints, recalls, counterfeits and product tampering, stability failures, etc.) according to the Quality Agreement and the Novartis Quality Manual. Ensure investigations are correctly executed.
- Escalate any issues or instances of instability per the Novartis escalation policy, and initiate any market action that is required. Support / participate in Novartis Emergency Management cases as required.
- Cooperate at the preparation of change requests, either from the External Supplier or from Novartis, and ensures they are managed according to the Quality Agreement and Novartis SOPs from receipt, through to the implementation and closure.
- Responsible for assessing quality trends and driving continuous improvement for process and product quality performance.
- Stability reports and PQR's: support ensuring that the External Supplier provides the required product review or the data as specified in the relevant Quality Agreement on an annual basis. Critically assess the performance of the product and process and provide the assessment to the report annually.
- Support launch process: QA evaluation, QA checklist handover, review of new SKUs and alignment with different functions if needed.
- Ensures that the QA Lead and the Supplier Relationship Manager is kept informed of all critical and major issues which may have an adverse affect on the quality of the product at an External Supplier.
- Together with the Supplier Relationship Manager provide direction, formulate strategies and make decisions which ensure the efficient operation of the External Supplier Business as a whole.
- Participation in the Business review of External Suppliers.
- Participate in the reporting on QA External Supplier activities. This is to include Risk Assessment, reporting and managing of defined KPI's.
- Ensure that the coordinated contact is maintained with other functions within Novartis also dealing with External suppliers namely Purchasing, Legal, Supply Chain, Regulatory CMC, Drug Regulatory Affairs, Group Quality Operations (GQO), etc.
- Participate in projects as defined and ensure that all aspects are implemented and followed up.

Key performance indicators:

- Other tasks determined during the annual objectives setting process and by KPIs

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
Китай
Сайт
Changshu (Jiangsu Province)

Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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