Quality Operations Specialist - Supplier Quality Management

Job ID
REQ-10049917

4月 24, 2025

Mexico

摘要

Support for preparation of documents such as (but not limited to) Initial Quality Questionnaires (QQ), Quality Assurance Agreement (QAA), Quality Risk Assessment (QRA), Annual Monitoring Report (AMR), Audit CAPA management (creation, monitoring and closure), Audit Request Change Form required for the Quality Management of suppliers. Additional responsibilities include the training of employees, compiling, analyzing, and reporting of metrics and strategies that will continuously improve the processes.

About the Role

**Major Accountabilities

Responsible for the preparation of documents required through the complete lifecycle of a supplier such as but not limited to the Supplier Initial Quality Questionnaires (QQ), Quality Assurance Agreement (QAA) and Quality Risk Assessment (QRA), as per agreed third party products in

accordance with company and regulatory requirements, as per internal and external guidance.

- Responsible for the Audit CAPA Plan uploading and actions follow up with Suppliers.

- Responsible to draft and submit Audit Request Change Form.

- Support and guide risk experts to evaluate and complete third party Risk Assessment for suppliers within defined timelines.

- Responsible for writing and updating applicable SOPs. - Monitor KPIs agreed with the customer on each deliverable.

- Responsible for scheduling meetings with the team/quality manager to determine and assign follow-up action items, if required.

- Support QA Manager responsible for the review of documentation required through the complete lifecycle of a supplier such as QAA and QRA to ensure compliance with Novartis requirements.

- Communicate with internal stakeholders or third parties as required

**Key Performance Indicators

- Manage Quality aspects and projects within the area.
- Applicable process KPIs and KQIs.

- Partner satisfaction/responsiveness.

- Adherence to projects timelines and proactive management of upcoming issues.

- Generation/delivery of reports related to owned activities.

- No issues due to non-observance of cGMP, SOPs and no critical deviations/findings

**Work Experience
- At least 3 years in the Pharmaceutical Industry or similar.

- Solid experience in data analysis and reporting.

**Skills

- Quality Assurance

- Continuous Improvement

- Good Manufacturing Practices

- Local/international Health Regulations

- Solution oriented behaviour

- Self organization
- Stakeholder Engagement
- Effective communication

**Language
- English
- Portuguese, according to needs

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部门
Operations

Business Unit
Innovative Medicines

地点
Mexico

站点
INSURGENTES

Company / Legal Entity
MX06 (FCRS = MX006) Novartis Farmac é utica S.A. de C.V.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Ajustes de accesibilidad

Novartis tiene el compromiso de trabajar y proporcionar adaptaciones razonables para personas con discapacidad. Si, debido a una condici ó n m é dica o discapacidad, necesita una adaptaci ó n razonable para cualquier parte del proceso de contrataci ó n, o para des empe ñ ar las funciones esenciales de un puesto, env í e un correo electr ó nico a las.mexico@novartis.com y perm í tanos conocer la naturaleza de su solicitud y su informaci ó n de contacto. Incluya el n ú mero de posici ó n en su mensaje.

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