NOVARTIS

ESO AS&T Manager

Job ID
REQ-10091445
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Сводка

Responsible for implementing and maintaining the ESO AS&T quality system including tools & processes. Responsible for analytical activities in the scope of ESO (e.g. QC activities and stability programs) and providing technical support to suppliers in scope.

About the Role

Major Accountabilities

- Lead, implement and reports on global AS&T requirements/programs in the assigned ESO QA Network. Supports defining and implementing business processes and SOPs/GOPS necessary to maintain a robust AS&T Quality System within External Supply (e.g. data integrity, analytical change management)
- Escalates any analytical issues or instances of instability per the Novartis escalation policy, initiates any market action as required.
- Owns and maintains testing monographs for products in scope of ESO
- Ensure Testing Monographs are state-of-the-art with respect to technique and technology, and in line with registration documentation. This includes, but not only, reviewing registration documents and being in line with pharmacopeia standards.
- Supports the accountable QAM to define and maintain the ESO Stability Program at CMOs, ensures that Stability Programs are state-of-the-art with respect to HA requirements and in line with registration documentation. Leads programs and initiatives to implement changes and remediation as required.
- Interprets stability data, analyses trends, and provides scientifically sound conclusions for product shelf life/re-test assessments, storage conditions and packaging and transport categories. Defines corrective actions to address immerging stability issues together with MS&T.
- Supports and drives analytical trouble shooting
- Owns and/or ensures analytical investigations are managed in agreement with cGxP standards and the right CAPAs are implemented.
- Acts as SPOC for analytical subjects in cross functional ESO AS&T project teams
- Owns tech transfer assessments for analytical method transfers or new analytical methods.
- Owns changes regarding analytics and/or provides the required assessments in regards to analytics during general change control activities. Defines studies/assessments needed to support changes regarding analytics.
- Supports implementation of guidelines at the assigned external partners and suppliers
- Provides the analytical input required for External Suppliers Qualification process
- Supports site readiness for Health Authority inspections & participate in audits on request.

Key Performance Indicators

- Number and severity of AS&T related cGMP issues identified during audits (internal, GCA, HA)
- ESO performance evaluated by the department KQIs
- State of the art of stability program for contractors and testing monographs

Specific Professional Competencies

- Deep knowledge of GMP and regulatory requirements (FDA, EU, MHRA, etc.)
- Good communication and interpersonal skills
- Stakeholder (internal and external) management

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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

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