Specialist, Quality Operations

Job ID
REQ-10028520

11月 05, 2024

India

摘要

Provide quality services in compliance with cGMP requirements and Novartis Quality Management System as defined and agreed between QOP and business partners. Manage Quality aspects & projects within area of responsibility.

About the Role

- Support in updating and maintenance of APQR (Annual Product Quality Review) schedule.
- Perform review of APQR report/ data as applicable to ensure it is complete and correctness.
- Collect contributory reports for product related evaluations.
- Interact with CMOs and / or manufacturing sites as required.

- Complete APQRs within defined timelines.

- Extract data from relevant sources in IT tools/ applications.

- Interpret and compile external supplier APQR and/ or extracted data from Internal Novartis systems into a pre-defined template and draft conclusion of product quality review.

- Archive the approved APQR as applicable

- Communicate with external suppliers to provide applicable APQR to QOP.

- Create and review GxP documents including SOPs, working procedures, trend reports, qualification reports and technical investigations, as and when needed

- Support in maintenance of MAH/BRS review / PQR schedule

- Coordinate with NCQ SPoCs and/ or manufacturing/ packaging/ testing/ batch releasing sites as required to draft MAH/BRS checklist

- Extract data from relevant sources and compile MAH/BRS as per the requirements in a predefined format

- Interpretation and consolidation of the data

- Review for accuracy and completeness of compiled data and/or information

- Submit the drafted MAH/BRS reviews for approval to respective Country/ team

- Archive the approved MAH/BRS review documents

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部门
Operations

Business Unit
Innovative Medicines

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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