NOVARTIS

**Novartis Technical Operations**

**Country: France**

# ROLE PROFILE

## General

**Business Title:** QA Specialist, Operations
**Job/SAP Title:** QA Specialist, Operations
**GJFA:** 06
**Job Family / Sub Job Family:** PD (Production)/QA
**Reports to (Job Title):** PD (Production)/QA

## Job Purpose:

The incumbent will have responsibility to ensure that all aspects of the operational business comply with cGMP legal and regulatory requirements, the Novartis Pharma Corporate Quality Manual and Policies, and site procedures and business requirements.

## Major Accountabilities:

This position will be expected to work a 4 day/10 hr. work shift. (Sunday through Wednesday or Wednesday through Saturday)

- The role is responsible for the final release of product
- Ensures review and quality decision of all batch related documentation and performs the batch disposition
- Timely and robust product disposition in accordance with GMP and license requirements
- Coordinates and performs batch disposition of raw materials and media.
- Reviews and approves manufacturing and QC related documents for batch disposition.
- Reviews and approves QC/BioAnalytics data in support of testing performed for batch record disposition.
- Participate in “On the Floor” Manufacturing activities, such as Quality Oversight for Aseptic Process Validation and Operator Qualification activities and “Real Time” Batch Record Review, etc.
- Initiates, Reviews and approves deviations, CAPAs, change controls, facility Work Orders, and any other site/product related documents ensuring adequate levels of documentation are adequate and compliant to existing procedures
- Coordinates activities associated with event resolution and CAPAs with a focus on organizing and attending cross-functional meetings to lead/facilitate investigations and to provide updates on discrepancy investigations; publish notes and action items from meetings; provide support to the investigation process and follow-up to assure timely discrepancy closure.
- Performs independent quality evaluation of deviation reports including root cause analysis cause/preventive action identification, CAPA effectiveness check and trending.
- Develops meaningful site KPI’s and prepares and presents trend reports for Quality Management Reviews.



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- Implementation and ensures adherence of appropriate Health Authority regulations and Novartis quality standards.
- Write, review and approve Standard Operating Procedures (SOPs) and associated Work Procedures (WPs) and Forms (FRMs) Quality Risk Assessments (QRAs), Campaign Quality Plans, specifications, Batch Production Documents (BPDs), Manufacturing Production Documents (MPDs), or other documentation, as needed.
- Provide support for self-inspections and external audits.
- Interact with FDA, partner and /inspectors, as needed.
- Support regulatory filings.
- Provide cGMP and associated OJT training to QA and other departments to improve right the first time (RTFT) initiatives, high quality performance.
- Control costs within department to meet budget.
- Represent QA at corporate and site operational and cross-functional meetings, providing QA input and disseminating information back to QA as needed.
- Complete job-related training in electronic database system along with GMP, safety, and Ethics & Compliance course requirements.
- Perform or support any other tasks necessary to maintain the product quality and site cGMP compliance, as needed.

## Ideal Background:

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| **Education**: | BS/BA in Biological Sciences or equivalent relevant career experience |
| **Experience:** | Minimum of 7 years GMP manufacturing and/or QA related experience, at least 5 years of which are in the area of quality assurance and/or compliance or equivalent experience. |

## Signatures:

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|---|---|
| **Name of Job Holder (printed):** | **Name of Supervisor (printed):** |
| **Signature/Date:** | **Signature/Date:** |