

Quality Project Lead- 3 Months FTC

Job ID
REQ-10087796
сен 14, 2026
Южноафриканская Республика

Сводка

Project lead for Analytical Method transfers and post-importation testing exemption application management

About the Role

Major Accountabilities:

- Establish and maintain a prioritised tracker for all post importation exemption applications. Coordinate supporting documents from manufacturing sites and relevant functions. Compile and quality-check submission packages. Coordinate submission applications, proof of payment and respond to Health Authority queries. Escalate overdue inputs through established governance channels.
- Analytical Method transfer: 1) Lead end-to-end method transfer schedules between sites and the local laboratory, 2) Draft, review, and approve method transfer plans, protocols, comparative testing strategies, acceptance criteria, and final reports. 3) Act as the Subject Matter Expert (SME) to resolve out-of-specification (OOS) results, deviations, and analytical challenges, 4) Ensure equipment and reference standards are available
- Complete an orderly handover at the end of the project.

Key Performance Indicators:

- Adherence to cGMP and SOPs
- Project targets are met
- Quality related processes carried out in a timely way
- GxP risks proactively identified and effectively mitigated
- Timely close out of deviations, out of specifications and corrective and preventative actions
- Compliance with all aspects of the Code of Conduct/ Novartis Policies and Procedures

Minimum Requirements:

Work Experience:

- Managed health authority submissions and applied guidelines to ensure compliance.
- Engaged with SAHPRA on regulatory, quality, and compliance-related matters.
- Post-importation testing exemption and analytical method transfer.
- Collaborated with Quality Control (QC) laboratories to support testing, investigations, and compliance requirements.

Skills:

- Knowledge and understanding of GMP, quality systems and quality and regulatory practices
- Understanding and interpretation of regulations & guidelines
- Document management
- Analytical thinking and problem solving
- Project management
- Planning & organizing
- Good time management
- High compliance
- Communication and interpersonal skills.
- Self Awareness

• English.

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Дивизион
Operations
Business Unit
Quality
Место
Южноафриканская Республика
Сайт
Midrand
Company / Legal Entity
ZA01 (FCRS = ZA001) Novartis SA (Pty) Ltd.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

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