

## Quality Project Lead- FTC

Job ID  
REQ-10087796  
сен 11, 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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