

# **Qualification & Maintenance Specialist**

Job ID REQ-10063620

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## 摘要

The role is responsible for ensuring the qualification, calibration, and maintenance of laboratory equipment in full compliance with cGMP, GLP, and Novartis Quality standards. It also covers oversight of computerized systems, preparation and execution of qualification documentation, coordination with vendors, and support during audits and inspections. Furthermore, the role drives continuous improvement initiatives, ensures data integrity, and contributes to both global and local projects within the AS&T Hub and Nitrosamines.

#### About the Role

Key Responsibilities:

- To ensure that MoH and Novartis Manuals are carried out effectively
- · Ensuring that all equipment is used correctly and carefully
- · Managing the computerized systems

- Managing various DQC projects
- Managing various NETLAB projects
- · Performing Repair, Maintenance, calibration and validation processes to equipments
- Creating annual Validation Master Plan
- Writing maintenance, calibration and validation procedures
- Purchasing spare parts and equipments
- Writing and updating quality assurance documents
- Evaluating the new scientific technologies/equipment and preparing CAR
- Continuously improving quality and data integrity standards of laboratory equipment
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt
- Reviewing and approving of production, QC, and AS&T records
- Define and implement CAPAs
- SOP revision
- Perform local training and monitor training status

#### Key performance indicators:

- On time maintenance activity
- On time qualification/calibration activity
- Improvement and development in the qualification department of DQC and Netlab project
- Adapting to CAPEX and OPEX budgets

### **Essential Requirements:**

- Knowledge of computerized system validation and data integrity principles
- Experience with audit/inspection processes
- Sound technical & scientific knowledge of pharmaceutical/ chemical
- Analytics/QC/ equivalent
- Strong Documentation & Reporting Skills
- Audit/Inspection Readiness & Communication
- Problem-Solving & Solution-Oriented Mindset
- Stakeholder Management & Cross-functional Collaboration
- Communication Skills
- Continuous Learning
- Decision Making Skills
- Gxp
- Laboratory Equipment
- Laboratory Excellence
- Self-Awareness
- Total Quality Management
- English

#### Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to

become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

#### Benefits and Rewards:

Read our handbook to learn about all the ways we'll help you thrive personally and professionally: Novartis Life Handbook

Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to learn more about Novartis and our career opportunities, join the Novartis Network here: <a href="https://talentnetwork.novartis.com/network">https://talentnetwork.novartis.com/network</a>

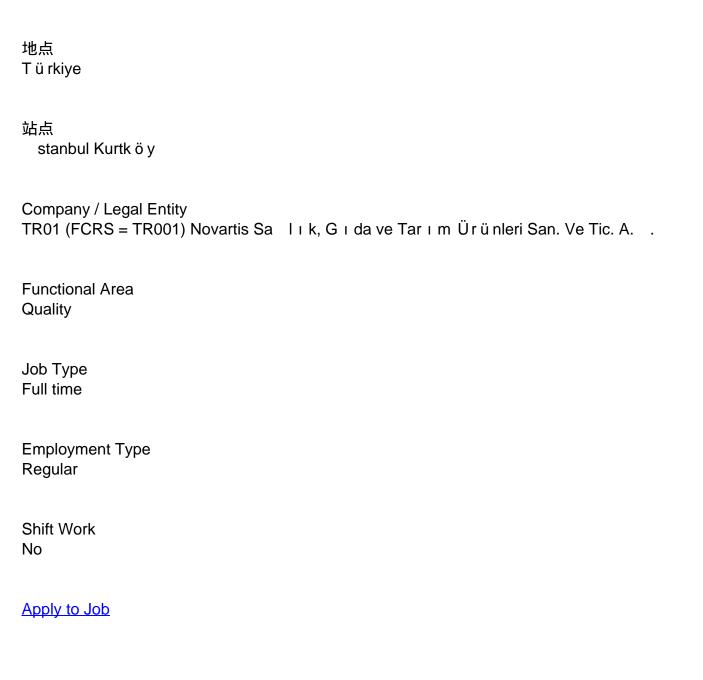
Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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部门 Operations

Business Unit Innovative Medicines



Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



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