

Quality Control Team Coordinator

Job ID
REQ-10013924

9月 03, 2024

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摘要

-Responsible for managing quality aspects within area of responsibility and to ensure that the operational business is in compliance with cGMP (Current Good Manufacturing Practices), the Quality Assurance Agreement, regulatory requirements and the Novartis Quality Manual and is conducted according to the relevant Standard Operating Procedures

About the Role

QUALIFICATIONS AND JOB DESCRIPTION

- •Ensure that GMP/GLP requirements defined by MOH, Novartis Global Procedures completely and effectively implemented
- Lead and coach the product control analyst team
- •Prepare and update SOPs, ensure that actions are managed according to SOPs and give the trainings of the revised SOPs

- Control and approve all documents associated with Product Control Laboratory
- Prepare weekly analysis plan for drug products and follow up
- ·Control raw data and worksheets
- •Make usage decision in SAP system for drug products in accordance with the KPI (key performance indicator) and target release date
- Report and investigation of all OOS, OOE OOT and deviations according to the Novartis SOPs
- •Performing of all ''Change Control Process'' evaluation and execution actions regarding Product Control Lab on time
- •Provide and apply SOP rules about HSE requirements security preventions on time
- Define and take the necessary precautions in terms of working safety
- •Define and provide IQP projects. Identify productivity opportunities within the Product Control lab and support the implementation

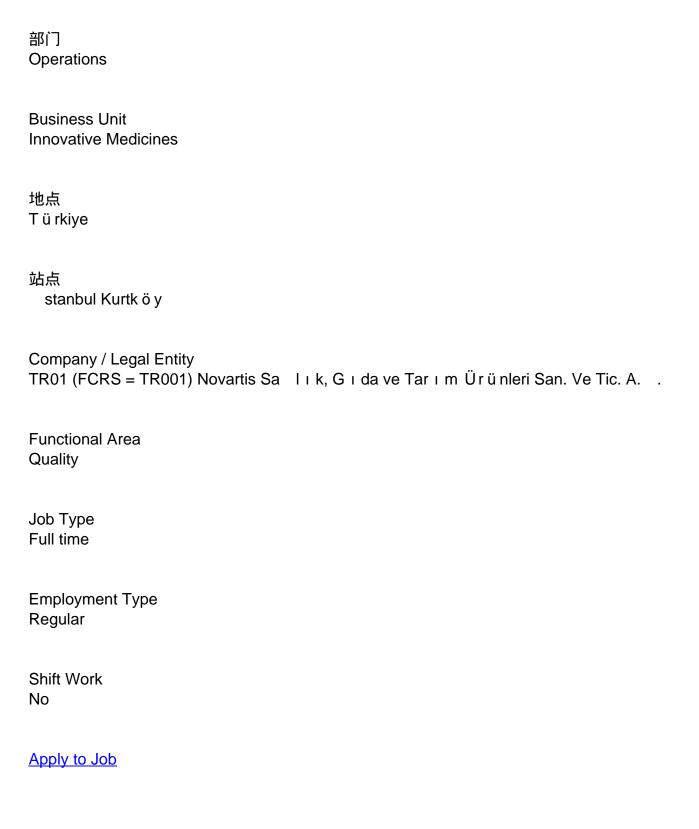
Minimum Requirements

- University degree in Pharmacy, Chemical Engineering or Chemistry
- •Minimum 6 years of Laboratory experience with equipment e.g. HPLC, GC, UV/Vis and Wet Chemistry at a pharmaceutical company. Non-sterile oral dosage form drug product test experience is preferred
- Knowledge of cGMP& cGLP and SAP
- Good command of English is required
- Strong communication skills and leadership presence
- Ability to work in a fast-paced changing environment
- ·Team working and customer oriented mindset
- ·Good analytical thinking skills
- Good knowledge of MS Office applications

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