

# Specialist, Quality Operations

Job ID  
REQ-10026565  
nov 05, 2024  
Inde

## Résumé

-Manages Quality aspects and projects within area of responsibility. -Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

## About the Role

### Key Responsibilities:

- The QA Specialist will serve as QA technical subject matter expert for CSV process, such as MES, KNEAT, DCS, including but not limited to GMP enterprise systems, manufacturing systems and computerized equipment, laboratory systems and computerized equipment and validation software tools.
- The role will also provide QA oversight for MES qualification activities such as URS, IQ, OQ and any qualification activities by supporting review, and approval (as applicable) of QA records including SOPs, site deviations, CAPAs and change control records related MES project.
- Hands on experience with MES, KNEAT and DCS
- Experience with Agile, 1QEM system
- Ability to work with tight deadlines as well as strong planning, organizing and time management skills. Attention to details, dedication to accuracy
- Reliable and with high sense of accountability. Ability to work independently
- Strong problem solving and analytical skills.
- Reliable team-player with strong competence in leading cross-functional teams and operating within a matrix organizational structure.

### Essential Requirements:

- Minimum of 3 to 5 years of experience in quality assurance and GMP in the pharmaceutical / biotech industry is preferred .
- Minimum Bachelor degree in a scientific discipline (e.g. pharmacy, chemistry, engineering, life science) or similar education; advanced degree in natural or applied sciences preferred
- Enhanced Computer skills
- Proficient in English Required

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Division

Operations

Business Unit

Innovative Medicines

Emplacement

Inde

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area

Qualité

Job Type

Full time

Employment Type

Regular

Shift Work

No

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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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