# Senior Engineer / Equipment Qualification

Job ID
REQ-10058385

8月 13, 2025

USA

## 摘要

This position will be located at East Hanover, NJ site and will not have the ability to be located remotely.
“Please note that this role would not provide relocation and only local candidates will be considered.”

The Equipment Qualification Engineer is responsible to ensure the qualification program for facilities, utilities, equipment and analytical instrumentation at the Novartis, Cell and Gene Therapy East Hanover,
NJ facility is executed in accordance with internal policies, procedures and regulatory agency compliance. The Equipment Qualification Engineer recommends and implements improvements of the
qualification process and performs a variety of routine and non-routine tasks related to the GMP compliance for facilities, utilities, equipment, and analytical instrument qualification. Responsibilities also
include oversight of qualification program service provider deliverables, projects, and program changes.
Reviews and approves qualification documents such as installation, operational, performance qualification (IOPQ) and computer software validation (CSV) protocols, reports, traceability matrix

(TM).
Prepares and/or approves risk and impact assessments, validation master plans (VMP) and other evaluations. Supports Production Unit (PU), Operations (OPS), Quality Control (QC) and Quality Assurance (QA) departments. Plans and manages qualification activities of manufacturing equipment,
laboratory instruments, facilities, and utilities. Ensures efficient, timely, GMP and compliant execution of
qualification activities

#LI-Onsite

Key Responsibilities:

- Manage qualification activities in compliance with corporate policy, local procedures, and regulatory expectations.
- Determines qualification requirements based on a worst-case matrix approach for the site. Manage and
develops with PU, OPS, QC and QA teams' qualification projects and plans and identifies the “critical to
quality”parameters impacting qualification activities.
- Prepares and or approves Qualification Master Plans, risk and impact assessments, protocols and summary reports and coordinates review and approvals of the documents.
- Approves executed of installation, operational, performance qualification and computer system validation (CSV) protocols.
- Authors/reviews/updates/assists in developing departmental standard operating procedures (SOPs) and qualification programs.
- Assists PU, OPS, QC and QA colleagues, as necessary. Ensures that all activities are in compliance
with cGMP, Health Authority regulations and the Novartis Policies.
- Supports/assists 3rd party/ vendor qualification activities, if applicable. Assists in investigation of Out of
Specification (OOS), Out of Expectations (OOE), product deviations or rejects related to equipment, laboratory instruments, facilities, and utilities in area of responsibility.
- Trains colleagues and external employees on qualification and validation practices, as applicable

## About the Role

**Requirements:**

- 7+ years of GMP equipment and laboratory instrument qualification and CSV experience in the Cell & Gene Therapy industry or applicable experience in a related pharmaceutical
- Knowledge and thorough understanding of the concepts of GMP, GLP, FDA and Health
- Authority guidelines, applicable regulations and standards routinely used in the industry
- (ANSI, ISO, GAMP, ATMP) to include 21 CFR Part 11 compliance.
- Proficiency in Change Control, CAPA, Deviations, HLRA, SIA, Protocols, SOPs, WPs, etc
- Functional Breadth.
- Collaborating across boundaries.

- project Management.

**Novartis Compensation and Benefit Summary:** The pay range for this position at commencement of employment is expected to be between $114,100/yr and $211,900/yr; ***however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.*** The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Company will not sponsor visas for this position.

*Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.*

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**Benefits and Rewards:** Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

**EEO Statement:**

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

**Accessibility & Reasonable Accommodations**

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Universal Hierarchy Node

地点
USA

状态
New Jersey

站点
East Hanover

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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