NOVARTIS

# Senior Expert Stability

Job ID
REQ-10026852
Nov 19, 2024
USA

## About the Role

Key Responsibilities:

- Participates in Stability strategy and protocol design for cell and gene therapy clinical products
- Oversight and coordination with internal partners or Contract Development & Manfacturing Organization (CDMO)/Contract Manufacturing Organization (CMO) for stability program management
- Writes technical reports; technical report generation (Expiry, Result Record, Investigations)
- Data management to support the Stability Programs including the administration and distribution of Quality Control (QC) stability samples, associated document coordination, and collection and evaluation of data.
- Owner of stability work processes supporting the stability programs.
- Participates in study design and ensures scheduling of stability lots.
- Tracks stability time points and evaluates stability data on a routine basis.
- Document owner for procedures and work instructions in support of stability processes.
- Owner and assessor of out of trend (OOT) and out of specification (OOS) events.
- Owner, assessor, and/or reviewer of deviations, change controls, and lab investigations and may generate metrics for stability programs. May also report risks related to stability programs to Quality System Owner(s).

Essential Requirements:

- Bachelors' and/or Masters' Degree in scientific discipline with a technical understanding of biopharmaceutical or Gene therapy production (gene and/or cell therapy development and manufacturing experience advantageous).
- Minimum of 5 years of Good Manufacturing Practice QC/QA lab experience.  Experience in Stability is highly preferred.
- Knowledge of Biologics and/or Gene therapy testing methods, validation and qualification.
- Knowledge of ICH, specifically stability guidelines.

- Excellent oral and written communication skills with technical writing experience, with expertise in use of MS suite of programs (outlook, excel, powerpoint, word, etc).
- Ability to work independently, collaboratively, and effectively.  Problem-solving aptitude with ability to prioritize and deliver on tight timelines.
- Understanding of Lab Information Management Systems (LIMS), database query, and data generation flow to reporting and visualization is beneficial.
- Experienced quality professional with knowledge of the drug development and quality control process and associated methods.

The pay range for this position at commencement of employment is expected to be between $118,400 and 177,600/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, 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.

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? https://www.novartis.com/about/strategy/people-and-culture

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

Commitment to Diversity & Inclusion: The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

## Role Requirements

**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? https://www.novartis.com/about/strategy/people-and-culture

**Join our Novartis Network:** Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

**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

Division
Development
Business Unit
Innovative Medicines
Location
USA
Site
East Hanover
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
Apply to Job

Job ID
REQ-10026852

## Senior Expert Stability

Apply to Job

---

**Source URL:** *https://prod1.jobapi.novartis.com/req-10026852-senior-expert-stability*

**List of links present in page**

1. https://prod1.jobapi.novartis.com/req-10026852-senior-expert-stability
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/careers/benefits-rewards
4. https://www.novartis.com/about/strategy/people-and-culture
5. https://talentnetwork.novartis.com/network
6. https://www.novartis.com/careers/benefits-rewards
7. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Senior-Expert--Stability_REQ-10026852-1
8. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/East-Hanover/Senior-Expert--Stability_REQ-10026852-1