

Senior Engineer, Automation

Job ID
REQ-10064030
Июн. 22, 2026
США
Available in: English

Сводка

The Senior Automation Engineer reports to the AD Process Automation and is responsible for providing automation design team leadership and serving as a technical subject matter expert for a Novartis Aseptic Drug Product facility.

About the Role

Location: This position will be located in Durham, NC and will be an On-Site role.

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

Key Responsibilities:

- Ensure automation aspects of new equipment are appropriately designed, meet Novartis standards and are appropriately commissioned and qualified.
- Provide oversight for automation aspects of projects including integration of 3rd party equipment to other standard plant systems, e.g., DCS, BMS, Historian, Infrastructure.
- Provide design, configuration, installation, and maintenance of automation software and associated hardware for existing equipment and processes.
- Prepare scopes of work for large projects, lead small teams and manage automation contractors as required to complete required work within project timelines.
- Lead discussions with internal business partners on priorities, timelines and transparent sharing of information.
- Develop, review and approve lifecycle documentation, e.g., User Requirements (URS), Functional Specification (FS) and Detail Design Specifications (DDS/HDS/SDS).
- Develop and maintain procedures to meet GMP requirements, CFR's and internal company policies.
- Participate and/or lead new product implementation processes to ensure smooth transition from process development into GMP manufacturing.
- Drive operational excellence and continuous improvement.
- Partner with Quality to ensure a quality and compliant manufacturing environment including participation in regulatory audits as an automation SME.
- Solve technical related issues impacting production.
- Support 24x7 site-based operations including rotating on-call responsibilities.
- Support investigations of non-conformances related to automation systems.
- Other related duties as assigned.

Essential Requirements:

- B.S. degree in Engineering, Computer Science, or related technical field.
- 8 years work experience in pharmaceutical or biopharmaceutical based GMP manufacturing operations, or equivalent work experience (12 years) in pharmaceutical or biopharmaceutical based GMP manufacturing operations.
- Excellent oral and written communication skills, including demonstrated technical writing skills.
- Experience programming, troubleshooting, and maintaining various site automation systems including DCS, BMS, PLC, SCADA, historian, infrastructure, including use of various industrial protocols.
- Experience in development and execution of system level qualification testing including providing guidance on qualification plans in conjunction with C&Q department.
- Proven experience applying S88 in an automated environment and development of control system standards aligning with S88 methodology.
- Experience in field wiring practices and panel design, experience with troubleshooting and start-up of control systems, and experience with instrumentation.
- Experience writing and executing complex change controls.
- In-depth knowledge of FDA regulations particularly 21 CFR part 11 and GMP systems.
- Strong project management skill set with extensive experience in strategic / tactical planning, demonstrated ability to perform long-term project planning.
- Ability to prepare contingency plans and logically work through complex issues in a pressure filled atmosphere.
- Provide technical support on all manufacturing issues when driving towards issue resolution.
- Up to 10% travel may be required.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$108,500 and \$201,500 annually.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

#LI-Onsite

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: Learn about all the ways we'll help you thrive personally and professionally.

[Read our handbook \(PDF 30 MB\)](#)

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.

Дивизион

Operations

Business Unit

Production / Manufacturing

Место

США

Состояние

North Carolina

Сайт

Durham

Company / Legal Entity

U061 (FCRS = US061) Novartis Services, Inc.

Functional Area

Technical Operations

Job Type

Full time

Employment Type

Regular

Shift Work

No

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