

# Laboratory Operational Technology and Applications Engineer

Job ID

REQ-10015312

Jul 21, 2024

USA

## Summary

Onsite About the role: (Editable Section unique to each role) The Senior Expert Laboratory IT/OT Systems and Applications Engineer, provides the technical expertise and operational support for laboratory equipment automation and digital data, networking technology and laboratory system applications at our Cell & Gene Therapy Technical Research and Development Clinical Facility. This role will be responsible for driving automation and IT solutions to integrate new clinical development equipment and systems, as well as new quality control systems into the Operational Technology infrastructure by working with system owners, equipment manufacturers, and Novartis IT. This role will work in liaison with the Development and Analytical Operations teams to meet the requirements and timelines to support new Cell & Gene Therapy projects, programs and (LDC) Lean Digital Core initiatives and programs. Your Key Responsibilities: • Lead the design, configuration, installation, and maintenance of automation software (Supervisory Control and Data Acquisition) and associated hardware, including interacting with other teams as necessary. Provide oversight or participation on all automation aspects of projects including, but not limited to, integration of SAP, CMX, GDLIMS systems to include data concentration, batch reporting, and data retention. • Maintains, troubleshoots and ensures compliance of the GMP and non-GMP control systems utilized for processing equipment, analytical instrumentation, and system database infrastructure. • Prepares scope of work and manage automation and OT Network contractors as required, completes work within project timelines, determines equipment or system specifications and most cost-effective technology to be implemented. • Acts as liaison between the local East Hanover CGT organization and local & global IT organizations. • Participates in discussions with internal business partners on priorities, timelines and transparent sharing of information. • Establishes equipment specifications and standard documentation – User Requirements (URS), Functional Specification (FS) and Detail Design Specifications (DDS/HDS/SDS). • Responsible for maintaining procedures to meet GMP & DPQ requirements, FDA Code of Federal Regulations (CFR's), internal company policies and Support site-based operations outside business hours as needed. • Problem Solving: Go beyond fixing the problem - identify root causes, evaluate, and recommend optimal solutions, to prevent future issues.

## About the Role

### Role Requirements:

- B.S. degree in Engineering, Computer Science, or equivalent related technical experience.
- General, 5+ years of cGMP Pharmaceutical IT system and applications, or equivalent industry experience required.
- Good working knowledge of cGMPs and 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) including 21 CFR Part 11.

- Project management experience; may include leading teams or projects with demonstrated leadership skills in team building and accomplishing complex projects.
- Must demonstrate excellent communication and team building skills when interacting with personnel at all levels and with contract service providers, vendors, contract employees, and regulatory agencies.
- Interpersonal and operational Savvy, collaborating across boundaries, managing people challenges and stakeholder engagement.

**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?

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**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.

**Novartis Compensation and Benefit Summary:** The pay range for this position at commencement of employment is expected to be between \$107,200-\$160,800/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.

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### **EEO Statement:**

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### **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](mailto: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.

Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

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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