U NOVARTIS

Digital Data Systems and Applications Sr. Manager, Engineering

Job ID REQ-10054253 Jun 26, 2025 USA

Summary

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."

Novartis is a world-leading healthcare company that provides solutions to address the evolving needs of patients worldwide. Our TRD Cell & Gene Therapies Engineering department is looking for an experienced Digital Data IT/OT Systems and Applications Sr. Manager. The ideal candidate will have a proven track record in managing and overseeing digital data systems and computer system validation activities for lab-based instrumentation and equipment relevant to the field of Cell & Gene Therapies. The candidate will be responsible for DQP & GMP compliance relating to, but not limited to, workstation applications, network and server compliance and will assume role as "Super User" for data systems such as SAP S4 HANA. #LI-Onsite

Key Responsibilities:

• Act as the Senior local IT/OT and business system applications manager, builds cross-functional relationships between the business and various, global operational groups to ensure success of Digital Data IT projects.

• Partner with the Lean Digital Core team on IT/OT Projects in the pipeline, (e.g. – SAP S4, MES, CMX, KNEAT, GLIMS), and assume Super User responsibilities for site digital data systems. The candidate shall have the capabilities and experience to assist with installation and integration processes, security issues, and program upgrades, system administration, networking and digital data regulatory compliance and lifecycle support.

• Compliance: Owns / ensures IT/OT systems and procedures (DQP & GMP) follow established regulatory standards, local and global policies and procedures and acts a lead facing internal and external inspectors/auditors during regulatory inspections and owns the training curriculum for own Job Profile, as well as supporting resources. Owns OT related compliance actions including change controls, deviations and quality events.

• Problem Solving: Go beyond fixing the problem - identify root causes, evaluate, and recommend optimal solutions, to prevent future issues, Identifies key compliance issues and appropriate solutions together with the system owners/experts to collaboratively eliminate Data Integrity, Data Security, Data Compliance and cGMP technical problems.

• Lead IT/OT Systems and Applications: Oversee the development, implementation, and use of technology throughout the CGT organization, to include collaboration across sites, managing internal and external staff, 3rd party vendors, and liaising with department managers to ensure optimal use of IT/OT systems and 1/4

applications.

• Project Management: Coordinate IT/OT projects, from managing system updates to implementing new technologies. This includes defining project scope, goals and deliverables that support business goals in collaboration with senior management and stakeholders.

• Business Advocacy / Strategy: Develop and execute an IT/OT strategy that aligns with the organization's digital data goals and objectives. Act as an advocate for CGT ensuring high availability of IT/OT services for manufacturing, Laboratories, and supporting site functions.

About the Role

- Bachelor's degree in Engineering IT or Computer Systems discipline or Engineering Data Systems related field with significant prior experience (5+ years) or equivalent preferred
- 5+ years of cGMP Pharmaceutical IT/OT system and applications, or equivalent industry experience required.
- Good working knowledge of cGMPs and DQPs with a solid 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, as they relate to digital data and information technology
- 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 to include internal direct reports, contract service providers, vendors, and regulatory agencies.
- Interpersonal and operational Savvy, collaborating across boundaries, managing people challenges and stakeholder engagement.
- Continuous Learning (Knowledge Development)

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$114,900yr 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.

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

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 <u>us.reasonableaccommodations@novartis.com</u> 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 State New Jersey 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 Apply to Job

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