Lab Operational Technology Engineer

Job ID
REQ-10015312
oct 22, 2024
Etats-Unis

Résumé

Onsite

About the 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.

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, contractemployees, and regulatory agencies.
- Interpersonal and operational Savvy, collaborating across boundaries, managing people challenges and stakeholder engagement.

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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 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.

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