U NOVARTIS

Automation Engineer

Job ID REQ-10010584 Juni 13, 2024 USA

Summary

Engineering support for automation systems, interfaces and equipment. Responsible for oversight of the automation systems across the facility (building/process/laboratory). Ensures the site's compliance with internal GMP's, CSV and external regulatory requirements.

About the Role

At Advanced Accelerator Applications, a Novartis company, we are committed to leading innovation in nuclear medicine and delivering the next generation of targeted radioligand therapy to cancer patients. We are looking for experienced Supply Chain professionals to help us reach our ambitious goals.

Location: Onsite

• Oversight of the automation systems at the site including building automation systems (BAS), room monitoring systems (RMS), process and laboratory equipment automation.

• Oversight of the overall automation asset care strategy for the site which includes performing upgrades, maintenance contracts and changes.

• Responsible for the support and execution of automation qualification as well as the resolution of all automation-related issues.

• Ensure cGMP, Data Integrity, and CSV compliance with all internal Novartis and external regulatory requirements.

• Update and develop User Requirement Specifications, Functional Specifications, Design Specifications, Operation and Maintenance for the new and existing control systems.

• Devise new approaches to complex problems through adaptations and modifications of standard automation technical principles.

• Work closely with manufacturing, engineering, utility operations, maintenance, quality assurance, and qualification to manage a diverse portfolio of projects.

- Lead, plan, and execute automation projects from start-up to completion.
- Develop Project Commission Plan / Strategy.
- Manage and resolve project deficiencies and deviations.

• Develop project execution strategy and execute project(s) according to customer needs (costs, schedule, functionality, quality).

• Assist in Preparing Project Initiation Documents (Business Requirements (PBR), Work Breakdown Structure (WBS); Cost Breakdown Structure (CBS), Project Scope Statement (PSS).

- Provide technical support to operations and support personnel.
- Own and close corrective actions related to the automation systems.
- Compliance with technical, quality and legal requirements.

• Reliable runtime of automation systems (minimum downtime).

Minimum Qualifications:

• Bachelor's degree in engineering, computer science, automation, or related field or equivalent relevant experience

• 2+ years of relevant engineering experience in Chemical, Pharmaceutical or Food & Beverage industry is required

• Good oral and written communication skills.

• Knowledge of FDA regulations, particularly 21 CFR part 11 and GMP systems.

• Familiarity with industry standards 21 CFR Part 11, Data Integrity, Validation, and GAMP. Must be able to work in controlled environments requiring special gowning.

• Extended interdisciplinary technical knowledge. Knowledgeable in a GMP regulated environment (pharmaceutical preferable).

• Experience with automation systems (Continuum, Siemens, DeltaV, PLCs, etc). Knowledge of IT infrastructure/networks related to automation systems. Strong oral and written communication skills.

• Must be able to work well with others in a team environment. Strong computer skills.

• Working knowledge of P&ID and loop diagram standards; temperature, pressure, flow, weight, humidity, and other instrumentation.

The pay range for this position at commencement of employment is expected to be between \$92,800 and \$139,200 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. 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 Advanced Accelerator Applications?

Thousands of people die of cancer around the world every day. At Advanced Accelerator Applications, a Novartis company, our mission is to transform lives through radioligand therapy in nuclear medicine to fight several leading types of cancer. How will we continue to be on the cutting edge of medicine? We believe new groundbreaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working. We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world's toughest medical challenges. Because the greatest risk in life, is the risk of never trying! Imagine what you could do here at Novartis!

Commitment to Diversity & Inclusion:

Novartis embraces diversity, equal opportunity, and inclusion. 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.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay

connected to learn more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

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

Division Operations **Business Unit** CTS Standort USA Site Indianapolis Company / Legal Entity U061 (FCRS = US002) Novartis Services, Inc. **Functional Area Technical Operations** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job

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EEO Statement :

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Major Accountabilities ~ Steigern Sie Ihr wettbewerbsfähiges Umsatzwachstum ~ Identifizierung und Priorisierung von Kunden mit hohem Potenzial durch Datenanalyse (HCPs und Stakeholder), die Verschreibungsentscheidungen beeinflussen ~ Steigern Sie die Vertriebsleistung durch die geschickte Orchestrierung positiver Kundenerlebnisse ~ Engagieren und Beziehungen aufbauen ~ Führen Sie wertorientierte Gespräche (persönlich und virtuell), um kritische Kundenherausforderungen, Entscheidungstreiber, Schwachstellen und Chancen zu verstehen ~ Personalisieren und orchestrieren Sie Customer Engagement Journeys für HCPs,

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List of links present in page

- 1. https://www.novartis.com/about/strategy/people-and-culture
- 2. https://talentnetwork.novartis.com/network
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