

Engineer I

Job ID: 00414523

Job Function

Production & Manufacturing

Schedule

Full-time

Location

United States-California
Vacaville

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

Provide automation support for biopharmaceutical manufacturing operations as part of the Vacaville Technology Upstream Frontline Group. Support will primarily be focused on the manufacturing production Distribution Control Systems (DCS) system involving cell culture manufacturing including fermentation, media prep, and harvest operations. Candidate must be a self-starter who can independently drive day-to-day work tasks to completion according to schedule and must be able to work well with others as a team member in an informal results oriented environment.

Responsibilities: Automation design and support to the manufacturing Distributed Control System (Siemens APACS, APS, Orchestra) as well as providing support to implement automation changes. This person is expected to perform troubleshooting of process, equipment, and system malfunctions or failures involving the DCS system, including after-hours on-call support on a rotational basis. Ability to initiate corrective or preventative actions to ensure continued compliant operation including emergency change records as needed. Provide technical assessments and evaluations for discrepancies that occur during manufacturing operations, as well as provide technical input for investigation and/or developing and implementing corrective action plans. A key part of this person's role will be to redline automation functional specifications for automation lead review/approval,

troubleshoot the DCS system and software, prepare automation software change work plans and perform off-line and on-line coding and testing. This person will support automation projects with activities such as detailed design, design review, implementation, testing/debug, and troubleshooting. This position includes working with the Manufacturing, BSI, Quality, Facilities, and Technology departments to implement software changes. This person will be expected to clearly communicate across functional departments at various levels to drive efficient issue resolution and change implementation. The position may involve the cross-training in another discipline within Upstream Frontline, such as Validation, Process Engineering, or Manufacturing Sciences where business needs allow.

Who You Are

Job Requirements:

- Minimum of 2 years as a practicing professional with work experience in cGMP biopharmaceutical production or equivalent combination of education and experience. Work experience specific to automation design, implementation and/or support involving instrumentation and control systems, preferably in the biopharmaceutical, pharmaceutical, food or other batch processing industries.
- BSc. /MSc. in Engineering such as Automation, Chemical, Electrical, or equivalent preferred, BA/BSc/MSc degree in life/physical sciences also considered.
- Candidate should have working experience with the configuration of automation systems including IEC 61131-3 programming languages. Experience with Siemens APACS, Wonderware ArchestrA, and/or InBatch configuration is desirable as well as work experience with Batch Control Standard S88.01.
- Experience with programming languages and applications such as C, C# Visual Basic and Microsoft SQL Server is a plus.
- Thorough understanding of Good Manufacturing Practices (GMPs) as they apply to bioprocess manufacturing.
- Thorough understanding of Good Automated Manufacturing Practice (GAMP) as it applies to automation design, implementation, and testing.
- Technical knowledge of upstream processes, fermentation, media prep, CIP, SIP and harvest preferred.
- Demonstrated drive for results and a passion for learning.
- Strong mechanical aptitude and problem solving skills.
- Demonstrated training ability, communication skills, and initiative.
- Strong written and verbal communication, interpersonal, leadership, and team skills.
- Must be flexible for after-hours call support rotation and floor support of 24/7 operations.

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