

Process Engineer III

Job ID
REQ-10074913

3月 31, 2026

USA

摘要

#LI-Onsite
#Engineering #ProcessEngineering

Location: Durham, NC

This role is based in Durham, NC. Novartis is unable to offer relocation support: please only apply if accessible.

As a Process Engineer III, you 'll ensure new laboratory equipment is appropriately designed and qualified and that lab operations run in a compliant manner throughout the equipment lifecycle. You 'll help define and optimize equipment qualification strategy, own changes needed to maintain equipment in a validated state and lead complex equipment investigations and CAPA 's. You 'll partner closely with Laboratory Operations and Manufacturing Sciences on new assay/product introductions and lab fit evaluations, provide mentorship to other engineers, and contribute to strategic equipment and technology roadmaps that keep the lab ready for what 's next.

About the Role

Key Responsibilities:

- Provide engineering, validation, and maintenance support to laboratory equipment, lab support systems, and utilities at the site; equipment may include chromatography systems (HPLC), capillary electrophoresis (CE) instruments, incubators, freezers, biosafety cabinets, centrifuges, balances, and other offline bench-top instruments and lab utility systems.
- Ensure new equipment is appropriately designed and qualified and that existing processes run in a compliant manner through the equipment lifecycle; help define and optimize the equipment qualification strategy.
- Own and manage changes to laboratory equipment and lab utility/support systems to maintain equipment in a validated state; where applicable, contribute to cross-site consistency of engineering/validation approaches.
- Investigate laboratory equipment deviations and instrument performance issues and develop corrective actions to prevent recurrence; provide technical expertise for complex equipment investigations.
- Participate in FDA and internal audits as a subject matter expert (SME) for laboratory areas and laboratory equipment; support inspection readiness and respond to observations.
- Develop and implement equipment reliability and maintenance strategies that are compliant, effective, and cost appropriate.
- Establish equipment specifications in standard documentation (e.g., User Requirements, Functional Specifications, and Detailed Design Specifications) and author/review associated protocols, reports, and SOPs.
- Independently lead or provide SME support on capital projects, including scope definition, vendor engagement, installation/commissioning, qualification, and handover to Operations.
- Work closely with Laboratory Operations and Manufacturing Sciences to evaluate new assay/product introductions and lab fit/readiness; translate current and future testing needs into laboratory equipment, utilities, and space requirements at the site.
- Apply engineering principles and best practices to ensure robust solutions; provide mentorship to other process engineers; lead small teams to optimize engineering systems and processes; lead evaluation of new technologies/equipment platforms; and help define and advance facility/equipment changes aligned with 5- and 10-year strategic plans.

Essential Requirements:

- B.S. degree in Chemical, Electrical, or Mechanical Engineering (or related technical field) with 5 years of work experience in pharmaceutical or biopharmaceutical GMP manufacturing operations; or equivalent work experience (9 years) in pharmaceutical or biopharmaceutical GMP manufacturing operations.
- Excellent oral and written communication skills; strong technical writing ability required.
- Ability to work effectively in a team environment with strong communication and organizational skills.
- In-depth knowledge of FDA regulations and GMP systems, and experience providing engineering support in a highly regulated pharmaceutical/biotech facility.
- Strong project management skill set with experience in strategic and tactical planning,

including long-term project planning.

- Ability to prepare contingency plans and logically work through complex issues in a high-pressure environment; uses professional concepts to solve complex problems in creative and effective ways.
- Demonstrated ability to lead cross-functional teams (including across manufacturing locations) in a fast-paced, dynamic environment; demonstrates good judgment in selecting methods and techniques to obtain solutions and networks with senior internal/external personnel in area of expertise.

Desirable Requirements:

- Diverse experience in the development, automation, and manufacture of gene therapy products, medical devices, instruments, or biotechnology.
- Demonstrated experience mentoring engineers and leading small teams to standardize practices, optimize engineering systems/processes, and drive continuous improvement.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$98,700.00 - \$183,300.00 per year.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

To learn more about the culture, rewards and benefits we offer our people click [here](#).

Company will not sponsor visas for this position.

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally. [Read our handbook \(PDF 30 MB\)](#)

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 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.

部门

Operations

Business Unit

Production / Manufacturing

地点

USA

状态

North Carolina

站点

Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
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false, allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: {},
sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true,
showSpeedMenu: false }, css : "/modules/custom/arcticnckalturaaddon/css/kalturavideo.css",
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if
(KalturaPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if
(KalturaPlayer.plugins["transcript"]) { config.plugins["playkit-js-transcript"] = { position: "right", //
Default: bottom;('left', 'right', 'top', 'bottom') to enable transcript. expandMode: "over", // Default:
alongside;('alongside', 'hidden', 'over') expandOnFirstPlay: false, showTime: true, downloadDisabled:
false, printDisabled: false, disable: true }; } if (KalturaPlayer.plugins["preventSeek"]) {
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config.plugins.floating = { disable: true }; if (KalturaPlayer.plugins["navigation"]) {
config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible:
false }; } if (KalturaPlayer.plugins["hotspots"]) { config.plugins["playkit-js-hotspots"] = { disable: true }; }
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(KalturaPlayer.plugins["info"]) { config.plugins["playkit-js-info"] = { disable: true }; } if
(KalturaPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents =
[]; if (KalturaPlayer.plugins["googleAnalytics"]) { config.plugins.googleTagManager = {};
config.plugins.googleTagManager.customEventsTracking = {};
config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
false, playlistEvents: false, castEvents: false } }; }
```

```
try { var kalturaPlayer = KalturaPlayer.setup(config); // Add the player to the global array. if (typeof kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other media. kalturaPlayer.loadMedia({entryId: "1_dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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