

Specialist, Quality Control Microbiology

Job ID
REQ-10068269

1月 26, 2026

USA

摘要

The Specialist, Quality Control Microbiology, assists and supports the organization with initial compliance and ongoing preparation, testing and monitoring of conformance to established quality processes and standards for manufacturing and production.

The Specialist, Quality Control Microbiology performs Environmental Monitoring and Microbiological testing in support of manufacturing at the assigned GMP Manufacturing facility, data review and report writing.

About the Role

Location: Durham, NC

#LI-Onsite

Please note this role is on-site 5 days a week and does not have the ability to work remotely. This role is based in Durham, NC. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Major accountabilities:

- Executes routine and non-routine analysis, may include, but not limited, to cGMP release and characterization testing using microbial techniques such as environmental and utilities monitoring in clean rooms, bioburden, endotoxin, growth promotion, sterility, and cell culture assays.
- Assists in the evaluation of internal controls, communications, risk assessments and maintenance of documentation as related to compliance with internal and external safety, quality, and regulatory standards.
- Reviews data obtained for compliance to specifications and reports abnormalities. Performs trend analysis of methods / environmental data / assay controls & standards and draws conclusions.
- Capable of delivering to assigned work schedule with attention to detail and accuracy.
- Ensure schedule adherence aligns with department goals and manufacturing support. Escalate as needed.
- Support department risk assessments and participates in audit walk-throughs.
- Compiles data for documentation of test procedures that may include stability program testing and formulation studies.
- Escalate issues with multiple solutions to management when timelines are at risk
- Supports Quality Control department at QMR by preparing slide deck and presenting laboratory metrics.
- Proficient in investigations, summaries and reports. Reviews data obtained for compliance to specifications and reports Investigates and resolves non-conforming test results by completing thorough Deviation, OOS/OOT/OOE and Investigation.
- Authors new/revise Standard Operating Procedures, Protocols / Summary Reports /Trend Reports for QC.
- Oversees special projects on microbial and instrument problem solving. May develop testing and analysis methods and procedures in accordance with established guidelines.
- Performs training of departmental personnel in appropriate technique and related topics.
- Mentor Analyst/Sr. Analyst level to ensure strong teamwork.
- Champion 's continuous improvement projects both internal and cross-functional, to maximize laboratory/site efficiencies and to strengthen compliance.
- Other related job duties as assigned.

Minimum Requirements:

Experience:

- Bachelor's degree in scientific disciplines such as Biochemistry, Biology, Microbiology or related field
- Minimum 5 years ' experience in a GMP environment.
- Excellent interpersonal, verbal, and written communication skills with strong technical writing experience.
- Possess a strong understanding of QC testing technique.
- Proficient in Microsoft Word, Excel, Power Point and other applications.
- Extensive knowledge of GLP and GDocP principles.
- An understanding of FDA/EMEA regulations.

Skills:

- Proactively raise concerns to management with multiple solutions.
- Acts as SME on cross functional teams and inspection support.
- Full understanding of area of specialization; resolves a wide range of issues in creative ways.
- Works on problems of diverse scope where analysis of data requires evaluation of identifiable factors.
- Demonstrates good judgment in selecting methods and techniques for obtaining solutions.
- Ability to receive little instruction on day-to-day work, general instructions on new assignments.
- Networks with senior internal and external personnel in own area of expertise.

Languages:

- English.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between \$85,400 and \$158,600 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.

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
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

```
function adjustKalturaPlayer() { var deviceWidth = window.innerWidth ||
document.documentElement.clientWidth || document.body.clientWidth; var mediaElement =
document.getElementById("kalturaplayer697f77699fed6860235811"); var mediaContainer =
mediaElement.closest('.nc-kaltura-media'); var originalWidth = "1200px"; var originalHeight = "674px";
var originalWidthValue = parseFloat(originalWidth); var originalHeightValue =
parseFloat(originalHeight); var mediaType = "video"; var isResponsive = false; // Get computed styles
of the container element. var parentStyles = window.getComputedStyle(mediaContainer); var
finalWidth = parseFloat(parentStyles.width); if (finalWidth < originalWidthValue) {
var config = { targetId:
"kalturaplayer697f77699fed6860235811", provider: { widgetId: "10m7rm1pm", partnerId:
"2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false,
allowMutedAutoPlay: false, loop: false }, sources: { options: {}, startTime: 0 }, plugins: { download: {
disable: true }, "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 } }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false },
components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback',
'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get:
KalturaPlayer.ui.components.Remove } ] } }; config.plugins.preventSeek = { preventSeekForward:
false, preventSeek: false }; config.plugins.floating = { disable: true }; config.plugins.navigation = {
position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; config.plugins['playkit-
js-hotspots'] = { disable: true }; config.plugins['playkit-js-moderation'] = { disable: true };
config.plugins['playkit-js-info'] = { disable: true }; config.plugins.share = { disable: true };
config.ui.uiComponents = []; 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: "1dgfvmafo"}); setTimeout(() => {  
setupAutoPause(kalturaPlayerVideos); }, 500); function setupAutoPause(players) {  
players.forEach((currentPlayer) => { currentPlayer.addEventListener('play', () => {  
players.forEach((otherPlayer) => { if (otherPlayer !== currentPlayer && typeof otherPlayer.pause ===  
'function') { otherPlayer.pause(); } })); }); }); } catch (e) { console.error(e.message) }
```



VIDEO

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