NOVARTIS

# Associate Director ESP Quality

Job ID
REQ-10090202

十月 28, 2026

Ireland

## 摘要

#LI-Hybrid
Location: Dublin, Ireland
This role is based in Dublin, Ireland. Novartis is unable to offer relocation support for this role. Please only apply if this location is accessible for you.

As Associate Director External Service Provider QA, you will have an excellent opportunity to work as a liaison with the Novartis clinical trial teams and Third Parties to provide expert QA support during the Third-Party due diligence, qualification and on-going governance and monitoring.

The use of various types of technology (i.e., DHTs, Medical devices, AI) continues to evolve for use in clinical trials. As such, the approach to qualification and oversight continues to evolve and change, requiring adaptive approaches and specialized skills.

## About the Role

**Key Responsibilities:**

- QA support for technology-enabled (DHT, SaMD, SaaS) Third Party qualifications and governance oversight as a technical QA SME in the evolving digital and innovation landscape. This includes the initial qualification, routine risk monitoring and SME support during audits.
- Assist qualification and governance teams in identifying potential risks with new Third Parties, whether for GxP purposes or rapid ramp-up from exploratory to GxP use.
- As and when needed support the clinical trial team for trial specific assessment to ensure technology is fit for purpose based on specific study design.
- Responsible for review and approval of quality issues related to Third Party and ensure appropriate escalation of major and critical issues. Support assessment of serious breach and reporting to health authorities.
- Facilitate the ‘Quality with Technology’ discussions with Third Party management team other interested parties to promote greater understanding of quality challenges when working with tech enabled Third Parties and overcome them through improved collaboration and awareness
- Act as QA representative for cross-functional Digital Technology initiatives, managing the overall Third-Party Quality activities.
- Participate in the independent review of technology implementations ensuring inspection readiness and data integrity awareness.
- Ensure inspection readiness of outsourced related activities and support for internal and external audits and health authority (HA) inspections pertaining Third Party management.

**Minimum Requirements:**

- Extensive experience in pharmaceutical development and excellent knowledge of the quality management system, clinical operations processes and vendor management related activities is preferred.
- Minimum a bachelor’s degree in Life Sciences, Pharmacy or Medicine, M. Sc. IT/Engineering/Scientific discipline and/or Ph.D. in a Scientific and/or Engineering discipline preferred.
- Fluent English (both spoken & written)
- Working knowledge of GCP/GcLP, GVP, Medical Device regulations.
- Experience with clinical third-party management.
- Combination of computer system compliance and validation expertise associated with global IT systems development (SDLC) and implementation within the pharmaceutical and/or digital health technology (DHT).
- Broad knowledge of regulations and industry quality standards (GCP, ICH, FDA 21 CFR Part 11, FDA 21 CFR 820, ISO 13485).
- Expertise in implementing DHT/SAMD technology within innovative clinical trials preferred.
- Experience navigating complex problems and developing solutions within a matrixed environment.
- Demonstrated ability to partake in interdisciplinary projects with a wide range of business

functions and successfully work in a global cross-functional matrix.

**Benefits & Rewards**

At Novartis, we ' re committed to reimagining medicine together - and rewarding the people who make it happen.

**Expected Annual Base Salary Range for role: 72,800.00 -135,200.00 EUR**

The base salary offered is determined based on gender-neutral objectives, such as relevant skills, competencies and experience in accordance with the Novartis pay setting policy and upon joining Novartis will be reviewed periodically.

In addition to your base salary, you may be eligible for a performance-based bonus depending on certain performance parameters.

The rewards of being part of our team go far beyond base pay and incentives. We also offer a variety of competitive benefits in kind to help you thrive personally and professionally, such as insurance plans, retirement plans, wellbeing resources and global recognition programs. In addition, we provide flexible and hybrid working options, where possible, and minimum 14 weeks paid parental leave.

Pay equity is a fundamental principle of our employment policy and reflects our commitment to create a diverse, equitable and inclusive environment that treats all employees with dignity and respect, as outlined in our Code of Ethics.

Read our brochure to learn more about our global total rewards offering:

https://www.novartis.com/sites/novartiscom/files/novartis-life-handbook.pdf

*Note: Benefits and compensation may vary by country and are subject to local legal requirements, including provisions of collective bargaining agreements where applicable. A full overview of your compensation package, including any relevant collective bargaining agreement details applicable to your role based on your employment location and Novartis employer entity, will be communicated separately to you during the application process.*

**Commitment to Diversity and Inclusion / EEO paragraph**

Novartis is committed to building an outstanding, inclusive work environment and diverse teams ' representative of the patients and communities we serve.

**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)

Primary location salary range
€ 72,800.00 - € 135,200.00

部门
Development

Business Unit
Quality

地点
Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

var kPlayer = KalturaPlayer55802022 || KalturaPlayer; var config = { targetId: "kalturaplayer6ae1e7ecae216265060986", provider: { widgetId: "10m7rm1pm", partnerId: "2076321", uiConfId: "55802022" }, playback: { autoplay: false, autopause: false, muted: false, loop: false }, sources: { options: {}, startTime: 0 }, disableUserCache: "true", plugins: {}, sources: { options: {}, startTime: 0 }, ui: { showCCButton: false, settings: { showQualityMenu: true, showSpeedMenu: false }, components: { fullscreen: { disableDoubleClick: false } }, uiComponents: [ { presets: ['Playback', 'Live'], area: 'BottomBarRightControls', replaceComponent: 'Fullscreen', get: kPlayer.ui.components.Remove } ] } }; // Check and add plugins only if they exist if (kPlayer.plugins["download"]) { config.plugins.download = { disable: true }; } if (kPlayer.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 (kPlayer.plugins["preventSeek"]) { config.plugins.preventSeek = { preventSeekForward: false, preventSeek: false }; } config.plugins.floating = { disable: true }; if (kPlayer.plugins["navigation"]) { config.plugins.navigation = { position: "right", expandMode: "over", expandOnFirstPlay: false, visible: false }; } if (kPlayer.plugins["hotspots"]) { config.plugins['playkit-js-hotspots'] = { disable: true }; } if (kPlayer.plugins["moderation"]) { config.plugins['playkit-js-moderation'] = { disable: true }; } if (kPlayer.plugins["info"]) { config.plugins['playkit-js-info'] = { disable: true }; } if (kPlayer.plugins["share"]) { config.plugins.share = { disable: true }; } config.ui.uiComponents = []; if (kPlayer.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 } }; }

// Ensure the global player registry array always exists, regardless of embed type. window.kalturaPlayerVideos = window.kalturaPlayerVideos || []; try { var thumbEmbedPromise =

thumbnailEmbed({config, mediaInfo: {entryId: "1dgfvmafo"}}); // thumbnailEmbed() returns a Promise that resolves with the player instance // when the user clicks the thumbnail. Use .then() to capture the player directly. thumbEmbedPromise .then(function(player) { window.kalturaPlayerVideos.push(player); // Notify kaltura datalayer.js that a new player is ready so it can // attach custom event listeners immediately, regardless of when // the user clicked the thumbnail relative to page load. document.dispatchEvent(new CustomEvent('kalturaPlayerReady', { detail: { player: player } })); }) .catch(function(error) { console.error(error); }); } catch (e) { console.error(e.message) }

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