

Qualified Person (QP)

Job ID
REQ-10072955

6月 12, 2026

Netherlands

摘要

The Qualified Person is responsible for batch release, ensuring product quality and compliance with applicable regulatory requirements, including cGMP, Dutch legislation, and relevant European pharmaceutical regulations.

This role provides quality oversight of operational activities and ensures the effective implementation, monitoring, and maintenance of a GMP-compliant quality system. The Qualified Person is also responsible for supporting a reliable supply chain through the timely release of radiopharmaceutical products.

Key responsibilities include the review and release of batch analysis in accordance with applicable requirements, the relevant Marketing Authorisation, and European Union pharmaceutical legislation, including Directive 2001/83/EC for medicinal products for human use.

About the Role

Major Accountabilities:

- Responsible for the release of the radiopharmaceutical products manufactured on site. Partner with Supply Chain to ensure timely release in support of a reliable supply chain.
- Release of batch analysis in accordance with the relevant requirements and the European Union pharmaceutical regulation Directive 2001/83/EC for medicinal products for human use and the National law.
- Ensure that deviations, CAPAs, Change Controls and Product Quality Complaints are timely and properly investigated by providing quality, compliance and technical expertise such that the internal and external customer expectations are met.
- Ensure that deviations and complaints with potential impact on patient safety and/or product supply are properly handled and escalated.
- Responsible for the quality oversight for the operational activities on site. Support the quality oversight process of the operational activities by ensuring QA review (for example maintaining the validation/qualification status of the production site, equipment, training of personnel, and management of quality management system). Additionally, write, review and approve GMP documentation such as procedures, work instructions, protocols and reports.
- Serve as Subject Matter Expert for assigned Quality Processes. Be the SME during Health Authority inspections and other internal- or external audits.
- Maintenance of the Quality Manual including internal audits.
- Establish and maintain strong working relationships with Business and Quality partners to ensure alignment of objectives and results.
- Strengthen the quality culture in the supporting departments by providing coaching and/or training on cGMP requirements.
- Work in shifts or provide on-call support with the team to supervise the quality assurance and quality control activities. Replace the Quality Operations Manager in case of absence.

Essential requirements:

- Master ' s degree in a scientific discipline. Pharmacy is preferred.
- 3+ years of experience in a similar role or in a Quality Assurance position within the pharmaceutical or biotechnology industry.
- Strong knowledge of GMP requirements and applicable pharmaceutical regulations.
- Hands-on and proactive working style, with the ability to take ownership and drive tasks forward.
- Demonstrates an agile mindset by setting clear priorities, collaborating openly, and using feedback to drive continuous, step-by-step improvements, reflecting the core elements of Agile culture within the Dutch organization.
- Fluent in English, both written and spoken.

Commitment To Diversity And Inclusion

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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>

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部门

Operations

Business Unit

Quality

地点

Netherlands

站点

Baarle Nassau

Company / Legal Entity

NL42 (FCRS = NL042) IDB Holland BV

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

```
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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
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(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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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
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config.plugins.googleTagManager.containerId = 'GTM-57RJQ5';
config.plugins.googleTagManager.customEventsTracking.custom = [];
config.plugins.googleTagManager.customEventsTracking = { preset: { coreEvents: true, UIEvents:
false, playlistEvents: false, castEvents: false } }; }
```

```
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kalturaPlayerVideos !== 'undefined') { kalturaPlayerVideos.push(kalturaPlayer); } else { var
kalturaPlayerVideos = []; kalturaPlayerVideos.push(kalturaPlayer); } // Load the Player for other
media. kalturaPlayer.loadMedia({entryId: "1dgfvmafo"}); } catch (e) { console.error(e.message) }
```

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