

Quality Assurance Operations Specialist

Job ID
REQ-10078604
Июн. 22, 2026
Нидерланды
Available in: English

Сводка

#LI-Onsite
Location: Baarle Nassau, Netherlands

We are seeking a detail-oriented QA Operations Specialist to join our team. This position supports a 24/7 shift-based operation, so candidates must be comfortable working assigned shifts, which includes days, evenings, nights, weekends, and bank holidays as needed.

The Quality Assurance Operations Specialist provides QA support for all shopfloor GMP related activities. The main focus is linked to the on-time batch release process and all related operational activities to ensure that the batches are released according to regulatory compliance and the local quality system. This ranges from material release and batch record reviews, to deviation support and technical QA support (e.g. calibrations, interventions).

About the Role

Please note: This is a **100% on-site position** and is not eligible for remote or hybrid work. **Candidates must be available to work within a 24/7 shift schedule**

Major Accountabilities:

- Prepare and perform QA review of batch release documents and supports the Quality Responsible with the batch release process.
- On-site Quality support for operational activities including interventions.
- Guarantee the correct document lifecycle management (paper and electronic system). Ensures archiving of batch documentation.
- Release of starting materials and incoming goods.
- Perform Visual Monitoring on Surprise on-site inspections.
- Approve and review quality related documentation (operational procedures, protocols, and work instructions).
- Supports with deviation management. Ensures that the appropriate impact assessments are performed in a timely matter. Ensures that deviations are closed in a timely matter.
- Review and approve the investigations in case of analytical results out of specification (OOS), out of trend (OOT), out of expectation (OOE) or System Suitability Test failures.
- Supports with CAPA's and Actions and timely execution of defined actions.
- Supports with change controls and timely execution of defined actions.
- Support the preparation and execution of internal audits and Health Authorities inspections

Obligatory requirements:

- Education: MBO/HBO level, preferably in a scientific field.
- Experiences: Solid knowledge of quality system (GMP) and basic knowledge of regulatory requirements.
- Strong affinity with and awareness of quality issues.
- Good organizational skills including attention to details.
- Shows the appropriate sense of urgency around given tasks, work in team.
- Languages: English fluently, verbally and in writing.
- Work in shifts

Desirable requirements:

- Optional: Experience with radiation, PET or radiopharmaceuticals is highly valued.

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€44,100.00 - €81,900.00

Дивизион

Operations

Business Unit

Quality

Место

Нидерланды

Сайт

Baarle Nassau

Company / Legal Entity

NL42 (FCRS = NL042) IDB Holland BV

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

Job ID

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