

Quality Assurance Operations Specialist

Job ID
REQ-10078604
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Нидерланды

Сводка

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

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.

Desirable requirements:

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

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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

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