

QA Operations Specialist

Job ID
REQ-10034964

1月 23, 2025

Netherlands

摘要

We are seeking a QA Operations Specialist to help us with 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 role will work directly with the Quality and Operations Team, and reports to the QA Operational Manager.

About the Role

Major accountabilities:

- Prepare and perform QA review of batch release documents and supports the Quality Responsible with the batch release process, as well as guarantee the correct document

- lifecycle management (paper and electronic system).
- Release of starting materials and incoming goods.
 - On-site Quality support for operational activities including interventions.
 - Approve and review quality related documentation (operational procedures, protocols, and work instructions), and ensures archiving of batch documentation.
 - Supports with deviation management. Ensures that the appropriate impact assessments are performed in a timely matter as well as the deviations are closed promptly.
 - 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, change controls, preparation and execution of internal audits and Health Authorities inspections, and also support in improvement projects.

Minimum Requirements:

- MBO/HBO level, preferably in a scientific field.
- Knowledge of quality system (GMP), and basic knowledge of regulatory requirements.
- English fluent, verbally and in writing

Desirable Requirements:

- Experience with radiation, PET or radiopharmaceuticals.

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部门

Operations

Business Unit

Innovative Medicines

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
Temporary (Fixed Term)

Shift Work
No

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