

Quality Assurance Associate

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Company: Marken

Location: Lijnden

Category: farming-fishing-and-forestry

Description

Title: Quality Assurance Associate **Job Purpose:** The Quality Assurance Associate is responsible for the oversight and implementation of the Marken Quality Management System (QMS), Marken Standard Operating Procedures (SOPs), processes and policies required to manage and control Marken's Storage, Distribution and Transportation, Kit Production Facility. The QAA also need to ensure compliance with applicable regional and local regulations and requirements, and customer requirements as appropriate, but not limited to: current Good Manufacturing Practice (GMP), Good Distribution Practices (GDP), Good Storage Practices (GSP), ISO 13485 and ISO 9001 **Main Duties and Responsibilities:**

- Implement, communicate and maintain company's quality systems at the facility, in compliance with Marken's Global Quality Management System (QMS) requirements
- Interact with clients on Quality Assurance (QA)/ GxP related matters.
- Effectively interact with Marken Departments and stakeholders to maintain that all QA tasks are appropriately supported by QA.
- Oversee an internal audit schedule and perform internal audits including report preparation and assessment and tracking of associated corrective and preventive actions (CAPA).
- Perform audits of external service providers as part of the vendor selection process. Tracking and overseeing all commitments for actions or changes made by Marken from previous audits.
- Host client audits and regulatory inspections, manage the audit report responses and act

as Marken's main representative, including and preparing of appropriate materials required within those audits when applicable.

Manage issues and CAPA plans, collate CAPA metrics, and identify and implement quality improvement initiatives. Oversee activities that conclude on the appropriate close-out of all CAPA entries.

Identify relevant GxP/ Quality related training needs and deliver or make they are deliver where required.

Manage the change control.

Ensuring that the Marken Quality System and GxP Program are implemented and maintained.

Assisting in the evaluation of Marken-designated vendors and/or out-sourced activities.

Ensuring the accuracy and quality of records and documents.

Monitor that training for all personnel is conducted and documented.

Coordinating and promptly performing any recall activity.

Participate actively in all the internal Quality and/ or designated meetings.

Keep informed of regulatory changes in Country/Region and prompt updates to SOPs as needed.

The duties below may vary depending on the activities performed by the facility:

Perform QA visual/physical inspection of pharmaceutical products in accordance with internal procedure and client specific requirements.

Perform a review and release of incoming material receipts in accordance with relevant SOPs.

Perform verification and approval of label printing process and additional labelling/ repackaging activities.

Perform the QA activities required Solo (warehouse movement, inventory status control) for the facility.

General

Perform activities assigned by the QA Management.

Travel as reasonably requested by the Line Manager to the performance of duties.

Support your line manager, that a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management.

Requirements:

Knowledge of Good Manufacturing Practice, Good Storage Practice and Good Distribution Practice guidelines.

2+ years of relevant experience working in a Quality Assurance role within a GSP/GMP/GDP regulated position.

Associate degree and/or equivalent university degree/ certifications.

Knowledge of local regulations. ·

Previous experience in Quality Management Systems with an eye for details.

Excellent written and oral communication skills. ·

Fluent in English and Dutch.

Good interpersonal skills ·

Organized, methodical and efficient approach to work. ·

Proficient use of Microsoft office.

Marken is a wholly owned subsidiary of UPS and is a critical part of UPS Healthcare. Marken offers a state-of-the-art GMP-compliant depot network and logistic hubs for clinical drug product storage and distribution worldwide, and supports cell and gene therapy logistics services from clinical to commercial, while maintaining the leading position for Direct-to-Patient and Home Healthcare services, biological sample shipments and biological kit production. **Moving Our World Forward by Delivering What Matters. #LI-AD1 IND123**

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