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Quality Manager

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Company: Marken

Location: Lijnden

Category: computer-and-mathematical

Description

Title: Quality Manager **Job Purpose:** The Quality Assurance Manager (QAM) 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 QAM 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 and policies at the facility, in compliance with Marken's Global quality management system requirements and local requirements.

Effectively interact with other Marken department and stake holders to maintain quality and help introduce new quality improvements.

Agree standards and define quality processes and procedures through effective controlled document issue and management.

Interact with clients on Quality Assurance (QA)/ GxP related matters.

Write quality assurance procedures as required for GxP Compliance.

Participate and monitor the internal audit schedule and perform/ or delegate, including report

preparation, assessment and tracking of associated corrective and preventive actions (CAPA). To ensure that a self-inspection audit is done once a year in the local Marken facilities.

To maintain the vendor qualification program, this includes, but it is not limited to the QTA (Quality Technical Agreements) updates and performing Quality 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.

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

Maintain the oversight of review and release of incoming material receipts in accordance with product specification where applicable.

Perform QA role in qualification/validation activities.

Manage/Approve the change control.

Co-ordinate any product recall as required and ensure that a mock recall is carried out on an annual basis where applicable.

Prepare and acquire appropriate data to complete trending and KPI reporting requirements.

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

Requirements:

Comprehensive knowledge of Good Manufacturing Practice guidelines

At least 5 years held position as in Quality Assurance role within a GMP regulated position.

Good interpersonal skills

Organized, a methodical and efficient approach to work.

Proficient use of Microsoft Office.

Fluent in English and Dutch both written and oral.

Senior or Lead Auditor experience in self inspections, internal and external audit.

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.

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