

Job Description Form



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| Division/Department | Medical Horizons |
| Position Title | Quality Manager |
| Reports To Title | Director of Medical Horizons |

GENERAL DESCRIPTION

The Quality Manager reports to the Director of Medical Horizons and is responsible for administration of the company’s quality systems, improvement of quality systems and maintaining regulatory compliance. The Quality Manager is responsible for all cGMP compliance, FDA audits, and vendor audits.

POSITION FUNCTIONS

- General**
- Have ultimate responsibility for all cGMP compliance
 - Manage all FDA audits
 - Participate in the development of continuous improvement plans, including processes and guidelines for efficient and compliant systems and operations
 - Work effectively with team members in all other areas of the company including product development, regulatory, purchasing and quality
 - Work effectively with external vendors on quality issues
 - Become cross-trained in and perform job functions of other Medical Horizons team members when they are on leave or out of the office. This includes, but is not limited to responsibilities of the Director of Medical Horizons, Product Specialist, Customer Service and Shipping
- Manufacturing Processes**
- Review specifications, master and batch records, and other quality documents used by our contract manufacturing partners
 - Review all SOPs regularly according to the schedule dictated by the SOPs and, when necessary, update SOPs in a timely manner to ensure that they are constantly current and valid
- Training**
- Train all Medical Horizons employees on SOPs and cGMP guidelines pertinent to their jobs; retrain employees as required to keep the entire team current with cGMP and SOP standards
- Testing**
- Facilitate third-party lab testing for finished products and for stability study modeling
 - Document all lab results according to SOPs and cGMP regulations
- Inventory, Receiving and Release**
- Manage the Expiration Dating of each product and the disposition of expired products in a manner consistent with current SOPs and cGMP regulations
 - Receive, quarantine, and release to inventory all incoming product in a manner consistent with current SOPs and cGMP regulations
 - Review and release products to clients, manufacturers, and other vendors according to SOP guidelines and cGMP regulations
 - Ship bulk products and intermediate goods to manufacturers, vendors, or clients
- Internal Investigations**
- Conduct Customer Complaint Investigations, when required, per SOP requirements and cGMP regulations

- Conduct Out of Specification / Deviation Investigations when required and work to remedy the OOS for future production runs

Regulatory Audits

- Be available to lead an FDA audit whenever initiated by the FDA
- Prepare the team to be ready to host an FDA audit at all times
- Assign the teammates their appropriate roles and responsibilities for audits
- Lead audits from regulatory agencies

Document and Product Reserve Control

- Oversee and perform all document control, keeping all documents up-to-date for an FDA audit or other audit
- Manage all reserve samples according to current SOPs and cGMP regulations

Vendor Qualification

- Qualify all suppliers and contract manufacturers according to SOP requirements and cGMP regulations
- Audit all suppliers and contract manufacturers according to SOP requirements and cGMP regulations
- Perform post-audit work with vendors to remedy any deficiencies or non-conformities

Facility

- Oversee, manage, and have ultimate responsibility that Facility security is in line with current SOPs and cGMP regulations
- Set up and manage pest control according to SOP requirements and cGMP regulations
- Manage and/or perform all other facility maintenance according to SOP requirements and cGMP regulations
- Operate forklift occasionally to move product to different areas of warehouse

Marketing and Strategy

- Participate in strategic planning and marketing initiatives
- Execute on marketing projects as determined in collaboration with the Medical Horizons management team
- Help ensure that label claims and customer communication materials are accurate and in compliance with regulations

EDUCATION REQUIREMENTS/SPECIAL TRAINING, CERTIFICATIONS, SKILLS

- Bachelor of Science Degree preferred but not required (preferably in a health science field)
- cGMP or Quality Systems experience required
- Ability to occasionally travel for short periods of time
- Strong verbal and written communication skills
- Detail-oriented nature and strong organizational skills
- Ability to be self-driven and self-directed

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| Date Reviewed | | |
| Employee Name/Signature | | |
| Manager Name/Signature | | |