

# Job Description

<b>Division/Department</b>	Medical Horizons, NUTRAScriptives		
<b>Position Title</b>	Quality Lead		
<b>Reports To Title</b>	Operations Manager, CEO		
<b>*Full Time Pay Class</b>	X	<b>Exempt</b>	SL/SB, Exemption: Administrative
			<b>Non-Exempt</b>

\*PT Roles default to Non-Exempt, Hourly

## POSITION OVERVIEW

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

## RESPONSIBILITIES

### Essential Job Functions

#### General Responsibilities

- Has ultimate responsibility for cGMP compliance
- Participates in the development of continuous improvement plans, including processes and guidelines for efficient and compliant systems and operations
- Works effectively with team members in all other areas of the company, including regulatory, purchasing, customer service, shipping, sales, marketing and quality
- Builds relationships with external vendors and leverages outside expertise in order to work together effectively on quality issues

#### Manufacturing Processes

- Reviews and approves specifications, master manufacturing and batch records, and other quality documents used by contract manufacturing partners
- Reviews all SOPs regularly according to the schedule dictated by the SOPs and, when necessary, updates all SOPs in a timely manner to ensure they are always current and valid

#### Regulatory Audits

- Is responsible for leading and overseeing an FDA audit whenever initiated by the FDA
- Maintains audit readiness by preparing the team to host the FDA and performing internal audit GAP analysis as outlined in SOPs
- Leads audits from other regulatory agencies

#### Document and Product Reserve Control

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

#### Internal Investigations

- Conducts Customer Complaint Investigations, per SOP requirements and cGMP regulations
- Conducts Out of Specification/Deviation Investigations when required, and works to remedy the OOS for future production runs
- Conducts Corrective Action/Preventative Action (CAPA) plans where applicable

#### Vendor Qualification

- Qualifies all contract manufacturers and third-party labs according to SOP requirements and cGMP regulation
- Audits all contract manufacturers and labs according to SOP requirements and cGMP regulations
- Performs post-audit work with vendors to remedy any deficiencies or non-conformities
- Builds and maintains strong relationships with vendors through effective communication

#### Inventory, Receiving and Release

- Manages the disposition of expired products in a manner consistent with current SOPs and cGMP regulations
- Oversees the receipt, sampling, inspection and quarantine of all incoming product
- Manages the disposition of reviewing and releasing product to inventory in a manner consistent with current SOPs and cGMP regulations
- Ships bulk products and intermediate goods to manufacturers, vendors and clients
- Works with Nutrascriptives Shipping Clerk to manage physical inventory of all Nutrascriptives products, White Stock and labels, and assists with destruction of expired or otherwise unusable inventory

#### Testing

- Facilitates third-party lab testing for finished products and for stability study modeling
- Documents all lab results according to SOPs and cGMP regulations

#### Training

- Trains all Medical Horizons employees on SOPs and cGMP guidelines pertinent to their jobs, and retrain employees as required to keep the entire team current with cGMP and SOP standards
- Acts as a company-wide resource for quality processes and procedures

#### Facility

- Sets up and manages pest control according to SOP requirements and cGMP regulations
- Manages all other facility maintenance according to SOP requirements and cGMP regulations
- Operates forklift occasionally to move product to different areas of warehouse

#### Marketing and Strategy

- Helps ensure that label claims and customer communication materials are accurate and in compliance with regulations
- Participates in exhibiting, presenting product information and providing customer support at various events to promote Medical Horizons and product lines

#### **Additional Duties**

- Cross-trains and maintains proficiency in various job functions of other Medical Horizons team members, and performs these duties as needed when they are on leave or out of the office
- Is available to work in conjunction with MedQuest Pharmacy's regulatory compliance department to perform vendor qualifications and audits
- Participates in strategic planning and marketing initiatives
- Evaluates opportunities for growth through increased efficiencies, improved client service levels, and reduced operational risk
- Participates in analysis of potential new products and product lines, including market demand/saturation and pricing, and assist in development of marketing campaigns aimed at target audiences

#### **REQUIREMENTS**

- Bachelor of Science Degree preferred
- In-depth knowledge and understanding of cGMP desired
- Minimum two years of experience in the QA/QC field required, three+ years of experience preferred
- Good written and verbal communication skills, with the ability to tailor effective written and verbal communications across a variety of audiences
- Detail oriented, thorough documentation skills
- Excellent time management and organization, able to successfully prioritize and manage a wide variety of critical and/or time-sensitive job duties
- Self-driven and self-directed, works well independently
- Computer proficiency with G Suite and MS Office applications, specifically email, document and spreadsheet programs
- Travel, extended hours and/or weekend work may be required occasionally

<b>Date Reviewed</b>		
<b>Employee Name/Signature</b>		
<b>Manager Name/Signature</b>		