QUALITY CONTROL PLAN

Supply and installation for medical equipment at different hospitals and health centers

Introduction:

A medical device manufacturer distributing to markets worldwide, supplier required to comply with many regulations. These include the attached specifications and complying with the Ministry of Health, Royal scientific society standard regulations. These regulations form the basis of the Quality System requirements we place on our suppliers. The Quality System requirements we place on our suppliers ensures ongoing compliance to these regulations as well as ensuring systems are in place to support the manufacture of quality products and parts and delivery of quality service. QUALITY SYSTEM REQUIREMENTS Each supplier shall develop and maintain a quality management system to assure supplied product, parts or services consistently meet Healthcare requirements and specifications.

Quality management system

A quality system that conforms to ISO 9001:2008 or equivalent establishes a baseline Quality Management System. Although a certified Quality Management System is not required, suppliers are encouraged to have their Quality Management System confirmed by an independent audit such as third party certification. Management responsibility and review: Suppliers shall ensure that management responsibility and authorities are clearly defined, documented and communicated within its organization. Management shall ensure sufficient resources for an effective quality management system. Internal Audits: Suppliers shall ensure that periodic review of the effectiveness of the quality management system is undertaken and documented. Training: Suppliers shall have a documented training program in place to ensure staff have the necessary education, skills and knowledge to implement the requirements of their role. Training conducted should be documented and include training to the Quality Management System as it applies to the invidual roles of the employees. All employees should also be made aware of defects which may occur from the improper performance of their specific roles. DOCUMENT CONTROL & RECORDS The supplier shall have a process in place to control documents and records relating to the Quality Management System including manufacturing and distribution data. This should include storage conditions to prevent the deterioration, damage or loss of documents. This process shall also ensure documents are approved before use and outline how the documents are distributed..

QA & Assurance required:

Suppliers are responsible for their direct suppliers and supply chains to assure that raw materials and components used in the manufacture of their products, parts or provision of services meet above mentioned specifications. As such, suppliers shall apply appropriate supplier controls to ensure that their suppliers comply and are capable of meeting requirements and specifications. IDENTIFICATION & TRACEABILITY REQUIREMENTS Supplier shall have a system in place to identify product during all stages of receipt, production, and distribution. This system shall also ensure that product in different stages of the manufacturing process is properly identified to avoid mix ups. This includes any raw materials, in-process materials, inspected product, nonconforming product and product ready for shipping or storage. The system shall also ensure that the raw

material and components used to manufacture the product or part shipped to Mercy corps can be traced through their system throughout the production process from receipt to shipping. A unique traceability identifier, such as a lot or batch number should be included on the product labels. For all custom components, the label must also include the Mercy corps part number and revision. PRODUCTION & PROCESS CONTROLS Each supplier shall develop, conduct, control and monitor production processes to ensure parts manufactured conform to specifications. This includes documented instructions that define the production activities, approval of processes and equipment and any changes to those processes and equipment, monitoring and control of process parameters and component and device characteristics during production. Environmental Controls: Suppliers shall ensure product or parts are manufactured in an environment to reduce contamination. This may include applying environmental controls and processes for maintaining cleanliness and separation between areas where controls are in place and uncontrolled areas. This may also extend to personal

PERFORMANCE INDICATORS

This is to measure conformance of supplied parts, products, components and service to MOH &RSS requirements and specifications. It is monitored through the following processes:

- Incoming Goods Quality Control Acceptance (IGQCA). This is the measure of the number of units accepted in IGQC, as a percentage of total number of units delivered.
- Line Acceptance (LA). This is the measure of the number of units accepted in production, as a percentage of total number of units consumed.
- Supplier Non-conformance reports (SNCR). This is the number of SNCRs issued against a supplier. Delivery: This is to measure the continued ability of a supplier to meet Mercy corps business inventory delivery requirements.
- On-time Delivery (OTD). This is a measure of the number of deliveries received on time as a percentage of total deliveries expected. Additional performance indicators may be added at the discretion of Mercy Corps.

Responsible team

QC team from the biomedical department in MOH will be responsible to check, reject/accept, the performance indicators.