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# Quality Manual

Revision: **C** Effective: **03/01/10**

## 1.0 INTRODUCTION

We provide contract manufacturing services relating to medical, hard disc drive, automotive, consumer electronics and similar related industries.

### 1.1 APPROVALS

This Quality Manual represents our management policies. Management requires and directs their departments, associates, managers and contractors to comply with the policies and requirements stipulated in this document with diligence and willful attention.

Steve Gasparrelli-President

Bill Stout- Quality Director (Management Representative)

### 1.2 AMENDMENT RECORD

The Management Representative will process all authorized changes into the official distribution copies and ensure that all obsolete copies are withdrawn from use and disposed of to prevent unintentional usage.

Release Date: 6/04/08

Section(s) Affected	Revision		Description of Changes
	New	Replaces	
4.2.3	A	NC	Added permanent retention to records.

Revision: B Release Date: 8/01/08

Section(s) Affected	Description of Changes
3.0	Replaced Corporate Policy ( <i>non-value added</i> ) with "Left Intentionally Blank" statement to keep QAM numbering consistent with ISO.
4.2.3	Added documents of "Internal & External Origin" to further clarify.
5.6.1, 8.5.2 & 8.5.3	Added "Justification for non-action will be documented" statement
7.1	Added "Risk Management covered by OP 5.1" to further clarify.
8.2.1	Added "Customer Feedback per Op 7.2" to further clarify.
8.5.1	Added "Feedback" to further clarify.
4.2.2	Added Figure 1 reference & Figure 1 to final page.
5.2	Added "converting industry" to Quality Policy lead in statement.

Revision: **C** Release Date: **03/01/10**

Section(s) Affected	Description of Changes
Various	Changed ISO 9001:2000 to ISO 9001:2008 throughout
2.0, 4.1, 5.5.2, 6.1, 7.4.2	Added "statutory &/or regulatory" in alignment with ISO 9001:2008
4.2.2	Changed wording from "defines" to "outlines"
5.5.2 & 5.5.3	Mandated that MR must be member of Management per ISO 9001:2008 & listed Quality Director as MR
7.1	Simplified the Risk Management statement.
7.5 & 7.6	Changed Measurement "Devices" to "Equipment" in alignment with ISO 9001:2008
1.1	Revised COO title to President

## 2.0 SCOPE

This Quality Manual was developed in accordance with ISO 9001:2008 and *ISO 13485:2003* and is relevant to our organization, Customer, *statutory* and regulatory requirements.

The objectives of this manual are to provide our company personnel and Customers with a single source of information regarding our policies for assuring and controlling product quality, *maintaining* the effectiveness of the Quality Management System and the continual improvement of the Quality Management System.

### 2.1 EXCLUSIONS

Requirements of the ISO 9001:2008 and *ISO 13485:2003* standards that do not apply and are excluded from the scope of our Quality Management System are:

**SECTION 7.3- DESIGN AND/OR DEVELOPMENT DESIGN CONTROLS**

*We do not design or develop products. Our Customers specify product characteristics.*

**SECTION 7.5 & 7.5.1.2.3 - SERVICING**

*We do not service products.*

**Section 7.5.1.2.2 INSTALLATION ACTIVITIES**

*We do not install products.*

**Section 7.5.1.3 REQUIREMENTS FOR STERILE MEDICAL DEVICES**

*We do not sterilize products.*

**Section 7.5.3.2.2 & 8.2.4.2 REQUIREMENTS FOR IMPLANTABLE MEDICAL DEVICES**

*We do not provide implantable medical devices.*

**SECTION 7.5.2- VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION**

*We have no processes that subsequent monitoring or measurement cannot verify resulting output.*

## 3.0 THIS SECTION LEFT INTENTIONALLY BLANK

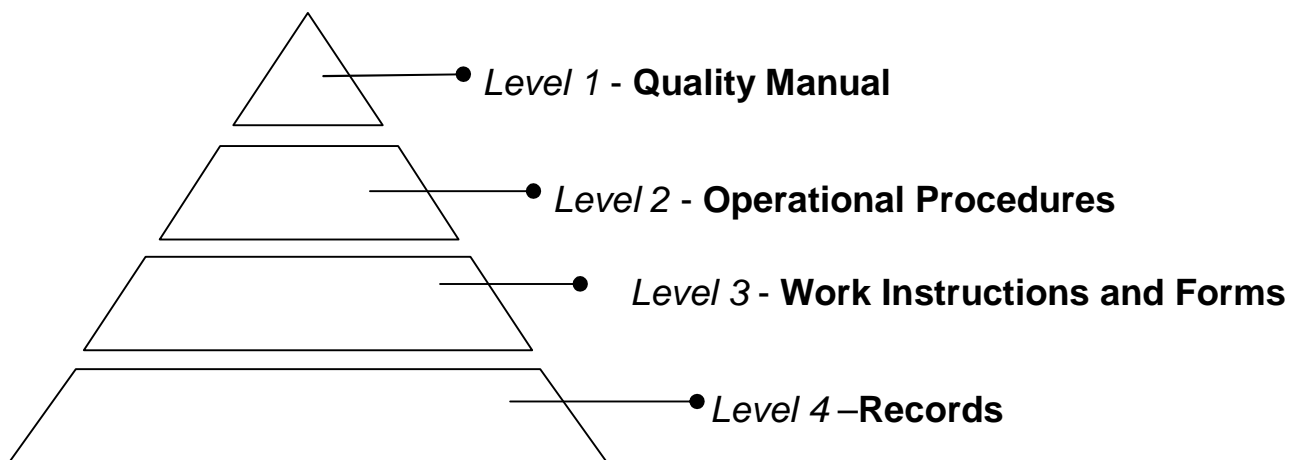
## 4.0 QUALITY MANAGEMENT SYSTEM

### 4.1 GENERAL

Our Quality Management System is documented per ISO 9001:2008, *ISO 13485:2003* and our own stated policies to ensure that products provided meet or exceed Customer requirements, [statutory and regulatory requirements](#).

### 4.2 DOCUMENTATION

4.2.1 The Quality Management System consists of 4 levels:



#### **Level 1 - QUALITY MANUAL**

Our policies with regards to the requirements of ISO 9001:2008 and *ISO 13485:2003*.

#### **Level 2 - OPERATIONAL PROCEDURES**

Established to ensure the effective planning, operation and control of processes defined in the Quality Manual.

#### **Level 3 - WORK INSTRUCTIONS AND FORMS**

Detailed instructions as to how specific tasks defined in Operational Procedures are performed.

#### **Level 4 - RECORDS**

Capture information or pertinent data resulting from the realization of Operational Procedures or Work Instructions.

#### **4.2.2 QUALITY MANUAL**

This Quality Manual [outlines our](#) Quality Management System. Details of and justification for exclusions are defined in Section 2.1. Sections were numbered to correspond with the sections of ISO 9001:2008 and *ISO 13485:2003*. The sequence and interaction of processes is illustrated in Figure 1.

## 4.2.3 CONTROL OF DOCUMENTS

Documents of internal & external origin required for the Quality Management System are controlled as defined in OP 4.1- *Document and Data Control*.

Documents are:

- Reviewed for adequacy and completeness and approved prior to issue
- Updated, re-reviewed and re-approved prior to issue by the same authorizations and approvals as the original
- Legible, readily identifiable and retrievable
- Identified as to the current revision status of each document to preclude the unintended use of obsolete documents
- Readily available to personnel
- Permanently maintained in the Paperless File system
- Promptly removed from all points of issue or use when they become obsolete
- Controlled as “Reference Only” when retained for the purposes of legal and/or knowledge-preservation

## 4.2.4 CONTROL OF RECORDS

Records prepared for or required by the Quality Management System that provide evidence of conformity to Customer requirements and effectiveness of the Quality Management System are legible, readily identifiable and retrievable. The methodology to be used and the personnel responsible for the identification, storage, protection, retrieval and disposition of Records are defined in OP 4.2- *Control of Records*.

## 5.0 MANAGEMENT RESPONSIBILITY

### 5.1 MANAGEMENT COMMITMENT

The Management Team is committed to the development, *maintenance* and continual improvement of the effectiveness of Quality Management System.

To reinforce this commitment, Management will ensure that:

- The importance of meeting Customer, statutory and regulatory requirements as applicable is effectively and consistently communicated throughout the organization
- The quality policy continues to remain consistent with organizational policies
- Objectives are identified for Quality Management System processes and where required
- Management review of the Quality Management System are conducted
- All necessary resources to implement, *maintain* and improve the Quality Management System processes are made available

### 5.2 CUSTOMER FOCUS

Management ensures that Customer requirements are identified and satisfied through the implementation of the Quality Management System.

## 5.3 QUALITY POLICY

We are dedicated to achieving Customer satisfaction and attaining market leadership in the converting industry. Towards that end we are committed to the following Quality Policy:

We will Monitor and Strive to Improve:

- **Customer Satisfaction**
- **Our Quality Management System**

## 5.4 PLANNING

### 5.4.1 OBJECTIVES

Objectives are established for each Quality Management System process and are consistent with the Quality Policy as defined in OP 5.1- *Quality Planning*.

### 5.4.2 QUALITY MANAGEMENT SYSTEM PLANNING

Management ensures that the planning of the Quality Management System is carried out and that objectives are achieved as defined in OP 5.2- *Management Review*. Changes to the Quality Management System are reviewed and approved by the Management Team to ensure Quality Management System integrity is maintained.

## 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

### 5.5.1 RESPONSIBILITY AND AUTHORITY

The Organizational Chart defines the reporting structure of functional units. Responsibility and authority for Quality Management System processes is defined in each Operational Procedure and each Process Diagram.

### 5.5.2 MANAGEMENT REPRESENTATIVE

**The Management Representative must be a member of Management.** The **Quality Director** is the Management Representative and has responsibility and authority to:

- Ensure the establishment, implementation and maintenance of the processes needed for the Quality Management System
- Report to top management on the performance of the Quality Management System including needs for improvement
- Promote awareness of Customer, **statutory** & **regulatory** requirements throughout the organization

## 5.5.3 INTERNAL COMMUNICATION

The **Management Representative** is responsible for ensuring that the effectiveness of the Quality Management System processes and accomplishment towards objectives are properly communicated to the organization through team briefings, departmental meetings, postings, quality training sessions and any other methods as required.

## 5.6 MANAGEMENT REVIEW

### 5.6.1 GENERAL

The Management Team reviews the Quality Management System to ensure its continuing suitability, adequacy and *effectiveness*. These reviews include a review of the Quality Policy. The methodology to be used to review the Quality Management System and the personnel who make up the Management Team are defined in OP 5.2– *Management Review*. Justification for non-action will be documented as applicable.

### 5.6.2 REVIEW INPUT

Inputs to Management Reviews will include the following sources of information:

- Audit data (*internal and external*)
- Customer feedback
- Process performance data
- Product performance data
- Supplier performance data
- Preventive and corrective action data
- Previous Management Review data
- Changes that could affect the Quality Management System
- Potential opportunities for improvement
- *New or revised statutory or regulatory requirements*

### 5.6.3 REVIEW OUTPUT

Outputs from Management Reviews will be documented in Management Review Minutes and will include decisions made and actions taken related to:

- *Maintain*/improve the effectiveness of the Quality Management System
- Objective generation and/or revision
- Improvement of product/processes related to Customer requirements
- Determination and allocation of additional resource needs

## 6.0 RESOURCE MANAGEMENT

### 6.1 PROVISION OF RESOURCES

The Management Team provides, evaluates and monitors the resources needed to:

- Implement, *maintain the* effectiveness of and continually improve the Quality Management System
- Enhance Customer satisfaction by meeting Customer, *statutory* and *regulatory* requirements

Methodologies and responsibility for the provision of resources is defined in OP 6.1– *Personnel Competency*, OP 6.2- *Preventive Maintenance* and OP 7.1- *Product Planning*.

### 6.2 HUMAN RESOURCES

#### 6.2.1 GENERAL

We select Personnel on the basis of appropriate education, training, skills and experience, as individually applicable.

#### 6.2.2 COMPETENCY, AWARENESS AND TRAINING

The competency needs for personnel are defined in Job Descriptions. Employees are evaluated to determine competency. Identified gaps will be identified and corrected. Methodologies and responsibility for identifying competency gaps and coordinating training for personnel are defined in OP 6.1- *Personnel Competency*.

### 6.3 INFRASTRUCTURE

The Management Team determines, provides, reviews and maintains infrastructure as required to ensure effective operations as defined in OP 5.2- *Management Review*.

### 6.4 WORK ENVIRONMENT

Work environment requirements are determined as defined in OP 7.2- *Customer Processes* and OP 7.1- *Product Planning*. Work environments are controlled to ensure effective operations as defined in OP 6.2- *Preventive Maintenance* and OP 7.5- *Production Control*.

## 7.0 PRODUCT REALIZATION

### 7.1 PRODUCT PLANNING

Processes are planned to ensure product conformance throughout the manufacturing cycle. The methodology to be used and the personnel responsible for product planning are defined in OP 7.1– *Product Planning*.

***Risk management activities are defined in OP 5.1- Quality Planning.***

## 7.2 CUSTOMER PROCESSES

### 7.2.1 DETERMINATION OF PRODUCT REQUIREMENTS

Upon receipt of a Customer's request for quotation, Customer requirements will be determined as defined in OP 7.2- *Customer Processes* with consideration given to:

- Customer-specific product requirements
- Requirements for delivery and post-delivery activities
- Product requirements not specified by the Customer but, considered essential for intended or specified use, where known
- What process development activities are involved
- If any statutory or regulatory requirements would apply
- What personnel, materials, costs and facilities are required to perform the work
- What lead time is necessary to ensure on-time delivery
- That we have the ability to meet the requirements specified
- Any additional requirement determined relevant

### 7.2.2 REVIEW OF PRODUCT REQUIREMENTS

Customer Request for Quotes/ Orders are evaluated and reviewed as defined in OP 7.2- *Customer Processes* to determine:

- That product requirements are defined
- That no differences exist between the quote and the order received

#### 7.2.2.1 CONTRACT OR ORDER AMENDMENTS

Changes to orders initiated internally or by Customers are reviewed and approved as defined in OP 7.2- *Customer Processes*. Customers will be advised of any cost or schedule impact and documented approval of these changes from the Customer will be obtained prior to acceptance and implementation.

### 7.2.3 CUSTOMER COMMUNICATION

The identification of requirements for communication with Customers is defined in OP 7.2- *Customer Processes* relating to:

- Product information
- Inquiries, contracts or order handling, including amendments
- Customer feedback, including Customer complaints
- *Advisory notices (as applicable).*

## 7.3 DESIGN AND DEVELOPMENT

*Not applicable. We do not design products.  
See Section 2.1 for exclusion statement.*

## 7.4 PURCHASING

### 7.4.1 PURCHASING PROCESS

Purchasing activities are conducted and controlled as defined in OP 7.4- *Purchasing*. The type and extent of controls exercised over Suppliers and purchased products is dependent upon the effect of the purchased product on subsequent processes, or on the final deliverable to the Customer as defined in OP 7.4- *Purchasing*.

#### 7.4.1.1 EVALUATION AND SELECTION OF SUPPLIERS

Suppliers are selected based on their ability to provide products and/or services to specified requirements. The methodology to be used and the personnel responsible for evaluating and selecting Suppliers is defined in OP 7.4- *Purchasing*.

### 7.4.2 PURCHASING INFORMATION

Procurement documents for raw material, equipment, parts or services are generated, reviewed and issued as defined in OP 7.4- *Purchasing* and include or reference any or all of the following as applicable:

- Requirements for approval of product, processes, personnel or equipment
- Quality Management System, Customer, [statutory and/or regulatory](#) requirements
- Traceability requirements as applicable

Amendments to procurement documents are processed and reviewed in the same manner as the original document.

### 7.4.3 VERIFICATION OF PURCHASED PRODUCT

All procured material and products are verified at receipt *and evidence of this verification* is as defined in OP 7.4- *Purchasing*.

## 7.5 PRODUCTION AND SERVICE PROVISION

### 7.5.1 PRODUCTION CONTROL

Production processes are developed as defined in OP 7.1- *Product Planning* and include information pertaining to product characteristics and acceptance criteria. Production processes are controlled per OP 7.5- *Production Control* including:

- Process equipment is maintained as defined in OP 6.2- *Preventive Maintenance*
- Valid, calibrated measuring **equipment** are used to verify production processes and products as defined in OP 7.6- *Measuring Equipment*.
- Work in progress is monitored as defined in OP 8.4- *Product Measurement*
- Products are inspected as defined in OP 7.5- *Production Control*
- Products are inspected and tested during manufacture and prior release as defined in OP 8.4- *Product Measurement*
- Product delivery and post-delivery activities is performed and monitored in accordance with OP 7.2- *Customer Processes* and OP 7.5- *Production Control*

7.5 & 7.5.1.2.2 *Not applicable. We do not service products.*

7.5.1.3 *Not applicable. We do not sterilize products.*

*See Section 2.1 for exclusion statements.*

### 7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION

*Not applicable. We have no processes that subsequent monitoring or measurement cannot verify resulting output.*

*See Section 2.1 for exclusion statement.*

### 7.5.3 IDENTIFICATION AND TRACEABILITY

Product status, identification and traceability of all products are maintained throughout product realization as defined in OP 7.5- *Production Control*.

7.5.3.2.2 *Not applicable. We do not provide implantable medical devices.*

*See Section 2.1 for exclusion statement.*

### 7.5.4 CUSTOMER PROPERTY

Customer furnished property/materials are:

- Examined for completeness, identification, transit damage and identified as Customer property as defined in OP 7.4- *Purchasing*
- Handled and protected in the same manner as internally owned property/material as defined in OP 7.5- *Production Control* and any applicable contract requirements
- Inspected in the same manner as internally purchased materials
- Brought to the immediate attention of the Customer for disposition as defined in OP 8.5- *Nonconforming Material Control*

## 7.5.5 PRESERVATION OF PRODUCT

Purchased product are identified, handled, packaged, stored and protected as defined in OP 7.4– *Purchasing*.

Manufactured products are identified, handled, packaged, stored and protected as defined in OP 7.5– *Production Control*.

## 7.6 CONTROL OF MEASURING EQUIPMENT

Measuring **equipment** used to determine product conformity are calibrated and controlled as defined in OP 7.6– *Measuring Equipment*.

## 8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

### 8.1 GENERAL

Activities to assure product conformity, Quality Management System conformity, Customer Satisfaction and the continual improvement of the effectiveness of the Quality Management System are defined within this section of this manual.

### 8.2 MONITORING AND MEASUREMENT

#### 8.2.1 CUSTOMER SATISFACTION

Customer Satisfaction levels are measured and monitored to identify areas for improvement and to determine that Customer requirements have been met as defined in OP 8.1– *Customer Satisfaction*.

***Customer feedback is managed as a Customer Process as outlined in section 7.2.3 and as defined in OP 7.2 Customer Processes.***

Customer satisfaction reports are distributed, reviewed and analyzed during management reviews as defined in OP 5.2– *Management Review*.

#### 8.2.2 INTERNAL AUDITS

Internal auditing of each Quality Management System process is conducted annually at a minimum as defined within OP 8.2– *Internal Audits* to determine:

- The effectiveness and continued suitability of the Quality Management System
- If the Quality Management System conforms to planned arrangements

#### 8.2.3 MONITORING AND MEASUREMENT OF PROCESSES

The definition, sequence and interaction of the processes of our Quality Management System are defined in this Quality Manual and in the Operational Procedures.

The methodology to be used and the personnel responsible for the monitoring and measurement of processes will be in accordance with OP 8.3– *Process Measurement*. Corrective action will be taken for processes that are not meeting objectives as defined in OP 8.6– *Corrective and Preventive Action*.

## **8.2.4 MONITORING AND MEASUREMENT OF PRODUCT**

Product monitoring, measuring, testing and verification activities required by contract and essential to ensure product conformance are conducted as defined in OP 8.4– *Product Measurement*.

*8.2.4.2 Not applicable. We do not provide implantable medical devices. See Section 2.1 for exclusion statement.*

## **8.3 CONTROL OF NONCONFORMING MATERIAL**

Materials that do not conform to requirements will be identified as nonconforming and controlled to prevent unintended use or delivery as defined in OP 8.5– *Nonconforming Material Control*.

### **8.3.1 REVIEW AND DISPOSITION OF NONCONFORMING PRODUCT**

As defined in OP 8.5– *Nonconforming Material Control*:

- Nonconforming product is dispositioned as rework, scrap, return to vendor or submit to Customer for concession
- Nonconformances requiring rework are verified and/or retested according to the disposition provided once work has been completed
- Customers will be notified immediately if a nonconformance is detected and/or suspected after delivery. Disposition will be as directed by the Customer

## **8.4 ANALYSIS OF DATA**

Data relating to the performance of processes, products and objectives will be collected as defined in OP 8.3– *Process Measurement*. Data collected will be reviewed and analyzed as defined in OP 5.2- *Management Review*.

## **8.5 IMPROVEMENT**

### **8.5.1 CONTINUAL IMPROVEMENT**

The Management Team will expend efforts to continually improve the effectiveness of the Quality Management System as defined in OP 5.2– *Management Review*.

*Processing, review and implementation of Public Health Advisory Notices and/or regulatory standards when/if applicable is defined in OP 8.7- Advisory Notices.*

*Customer complaints/ feedback unrelated to products will be investigated and addressed as applicable as defined in OP 7.2– Customer Processes and OP 8.6– Corrective and Preventive Action as applicable.*

*Customer Complaints related to defective product will be processed as defined in OP 7.2– Customer Processes, OP 8.5– Nonconforming Material Control and OP 8.6– Corrective and Preventive Action as applicable.*

## **8.5.2 CORRECTIVE ACTION**

Nonconformances and conditions adverse to quality will be investigated in order to:

- Determine the root cause of the nonconformity
- Evaluate the need for action to prevent recurrence
- Determine and implement required corrective action
- Record and review results of action taken to ensure resolution was achieved

The methods to be used and the personnel responsible for determining the steps required for corrective action is defined in OP 8.6– *Corrective and Preventive Action*. Justification for non-action will be documented as applicable.

## **8.5.3 PREVENTIVE ACTIONS**

Potential nonconformities are investigated in order to:

- Determine the root cause of the potential nonconformity
- Evaluate the need for action to prevent occurrence
- Determine and implement required preventive action
- Record and review results of action taken to ensure risk was nullified

The methods to be used and the personnel responsible for determining the steps required for preventive action is defined in OP 8.6– *Corrective and Preventive Action*. Justification for non-action will be documented as applicable.

