



*Cygnus Manufacturing Co.
Saxonburg, Pennsylvania
Quality Management System Manual*

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1.0 Introduction and Scope

1.1 Introduction

This section is intended to describe the scope of the quality management system (QMS). Subsequent sections describe the QMS and the elements of the system and set policies to be met by the organization.

The quality manual is intended to meet the needs of the organization and external parties. It is written as a directive to the organization including statements of things that “shall” be done by the organization. For readers outside the organization, these “shalls” should be read as actions that “will” be done (or are being done) by the organization.

1.2 Scope of Organization

This quality management system and this quality manual apply to the operations of Cygnus Manufacturing Company LLC (CMC), located at 491 Chantler Drive, Victory Road Business Park; Saxonburg, PA.

1.3 Scope of Compliance

The quality management system shall comply with the organization’s quality policy and with all applicable statutory and regulatory requirements, standards, and guidelines, including, but not limited to, the following:

- ISO 9001:2008, *Quality management systems – Requirements*
Note: 7.3 Design and Development is non-applicable to CMC as the organization is a contract manufacturer and currently does not have any design or development responsibility for any of the products or services provided to its customers.
- *Code of Federal Regulations (CFR), Title 21, Food and Drugs*
Note: The following section are non-applicable to CMC as the organization is a contract manufacturer and currently does not have any design or development, installation, Device Master Record maintenance, complaint filing or servicing responsibility for any of the products or services provided to its customers:
 - 820.30, Design Controls
 - 820.181, Device Master Record
 - 820.198, Complaint Files
 - 820.200, Servicing

2.0 Normative References:

ISO 9000:2005, Quality Management Systems - fundamentals and vocabulary

3.0 Terms and Definitions:

For the purpose of this document, the terms and definitions given in ISO 9000 apply.

- The following terms, used in ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:
supplier -> organization -> customer
- **the organization** refers to Cygnus Manufacturing Company LLC (CMC), and
- **supplier** refers to a third party organization that supplies a product or service that affects CMC’s quality management system.



4.0 Quality Management System

4.1 Quality Management System Overview

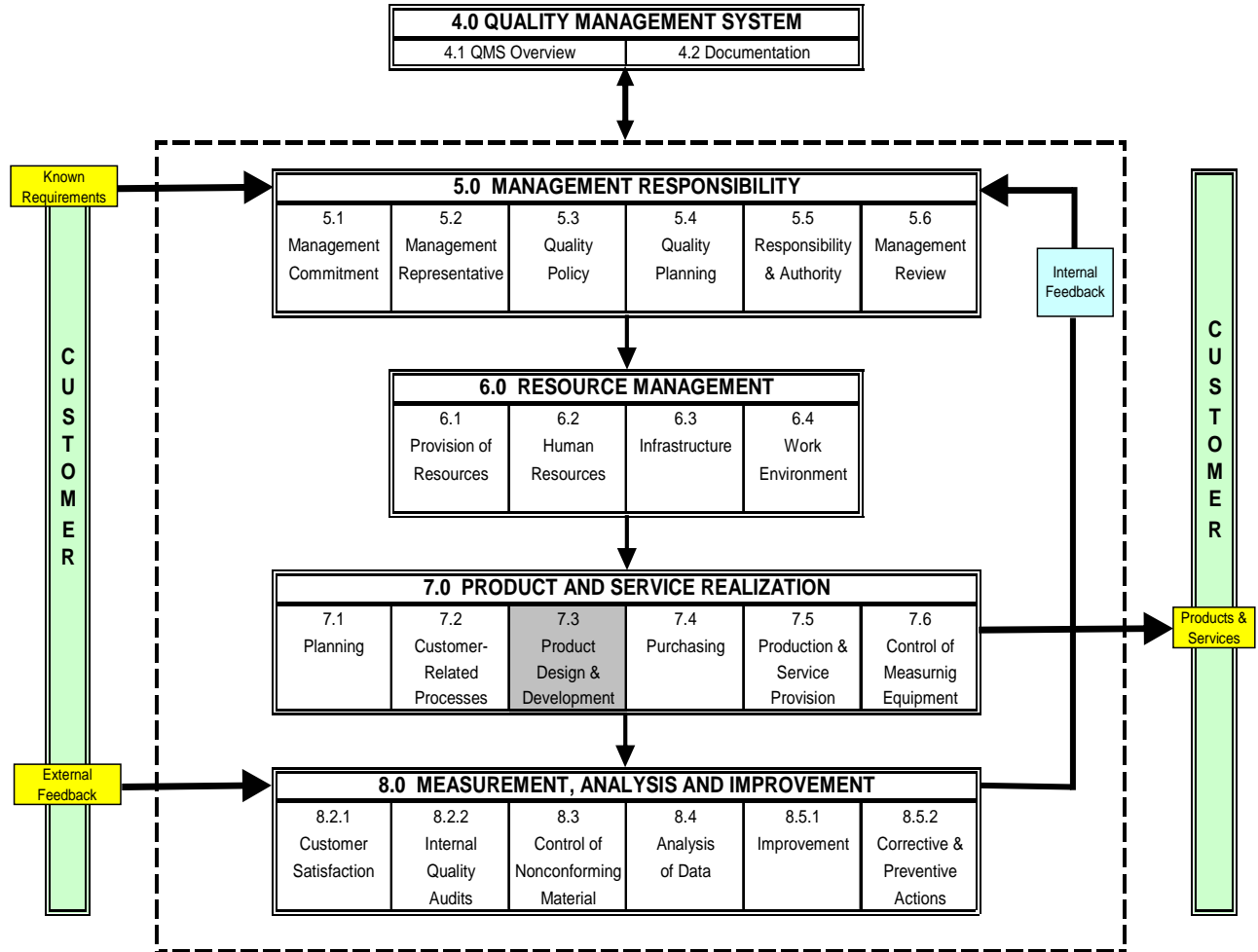
4.1.1 Introduction

This section describes the quality management system (QMS) in general terms. The requirements of this section establish a basic structure for the QMS in the form of documents and records. Subsequent sections describe the processes of the system and delineate policies to be met by the organization in implementing each process. The CMC quality system shall be appropriate for the specific devices manufactured for our customers as applicable. Note: Processes needed for the quality management system include processes for management activities, provision of resources, product realization, and measurement, analysis and improvement.

4.1.2 Description of the Quality Management System

The quality management system consists of the quality policy, quality manual, quality objectives organizational structure, responsibilities, procedures, documents, records, specifications, processes, and resources that work together to identify, determine and meet the requirements of our quality policy, customers and applicable statutory and regulatory requirements. The QMS shall be monitored and analyzed to determine the effectiveness of the processes to ensure attainment of planned results. Where outsourcing of processes that affect product conformity with requirements occurs, CMC has established procedures that ensure control over these processes. The general structure of the quality management system is shown below.





4.2 Documentation

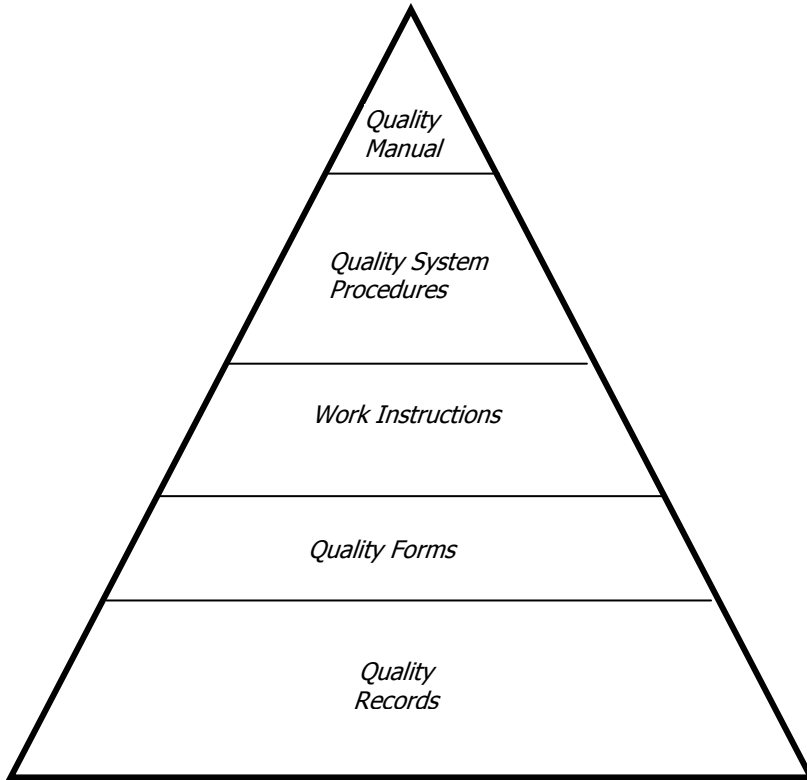
4.2.1 General Policy

The quality management system documentation consists of the quality policy and manual, quality objectives, documents and records required by international, national or regional requirements. Documents and data may be in the form of any type of media. Documents shall remain legible and be readily identifiable throughout all change, approval, and distribution processes. Personnel shall have access to QMS documentation and shall be aware of relevant procedures. All documents and data related to the QMS shall be controlled to ensure that the proper revision is provided for use and that changes are made only with the proper authorization prior to use. All documents and data that are part of the quality management system are considered proprietary and access may be restricted to third parties; however, CMC shall recognize the need to provide documentation to regulatory authorities and customers as required to maintain compliance as well as to support customer requirements relative to maintaining regulatory documentation.



4.2.2 Structure of the Quality Management System Documentation

The quality management system is documented by this quality manual, along with quality system procedures, work instructions, forms, and records as structured below.



- This **Quality Manual** describes the quality management system structure and specifies policy to the organization for each process of the system. To facilitate review of the system, an appendix provides traceability from key regulations and standards to sections of the manual.
- **Quality System Procedures** define the processes, assignment of responsibility and authority, establishment of review and approval mechanisms, and maintenance of records for non-product specific requirements of the QMS.
- **Work Instructions** are used where necessary for effective operation of the product specific elements of the QMS. These documents normally apply to the purchase, manufacture, maintenance, or servicing of specific devices, components, or equipment, or the performance of specific activities within a process, including computer operations.
- **Quality Forms** are used to document the accurate and efficient completion of procedural requirements. Any required forms are either made part of the implementing quality system procedure/work instruction or are controlled as separate documents.
- **Quality Records** are documents that furnish objective evidence of activities performed or results achieved. They include forms completed by hand or printed by a computer, as well as electronic records.



4.2.3 Document Approval and Change Control

Procedures shall be established and maintained to describe requirements and methods for control of quality management system documents including identification, format, document processing, retrieval, retention, periodic review, data control, distribution, and implementation. Procedures shall also define approval requirements for each type of QMS document including the coordination with customers and/or regulatory agencies according to contract or regulatory requirements. Records of approval shall be maintained. Records containing the current revision level of all quality system documents and data shall be maintained.

Changes to documents or data shall be made with approval by designated individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Records of all changes to documents shall be maintained, containing the description of the change, identification of the affected document(s), approval signatures, approval date, and effective date of the change.

4.2.4 Document Release and Distribution

Procedures shall provide for the controlled release and distribution of new and revised documents. These procedures shall provide for distribution of current copies and for prevention of the use of outdated procedures or standards. Documents shall be approved prior to being issued. Distribution may be by issue of printed copies or through electronic media. In any case, methods shall be provided for clear distinction between controlled, uncontrolled, superseded and obsolete documents.

Distribution of documents shall be controlled to ensure that the proper versions of all documents are available in a timely manner to those requiring them. Document revision notifications shall be communicated to the appropriate personnel.

Reference copies of documents may be issued to outside parties having a need to review quality management system documentation or for internal training or informational purposes. Reference copies will be updated only by request. All copies of superseded or obsolete documents shall be promptly removed from the point of use or otherwise prevented from unintended use.

4.2.5 External Documents Control

Procedures shall be established and maintained to identify, obtain, and maintain current copies of applicable external standards related to the quality management system and to the design and evaluation of devices that are designed and manufactured under the quality management system. External standards shall be clearly identified and distributed through a controlled process to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution is controlled.

4.3 Control of Quality Records

A record is a document that furnishes objective evidence of activities performed or results achieved. The scope of records shall include records from regulatory agencies, suppliers, or other external parties where such records are necessary to demonstrate conformance to specific requirements or the effective operation of the quality management system. Quality Records include, but are not limited to:

- management reviews of the quality system;
- quality audits;
- customer contract review;
- advanced quality planning activities;
- product development activities;
- design and drawing reviews;
- results of any verification and validation activities;



- calibration results of M&TE;
- in-process and final inspection;
- customer complaints;
- corrective and preventive actions;
- nonconforming material concessions / approvals;
- employee training;
- supplier records; and
- process and equipment qualification results.

4.3.1 Preparation of Records

Records shall be prepared in a legible format, and appropriately identified.

In addition:

- Procedures and work instructions shall define specific record format and content requirements.
- Records, paper or electronic, shall be identified, collected, indexed, stored, and maintained for easy retrieval. Where applicable, records shall be maintained on approved forms.
- Records may be maintained in electronic form (of any appropriate media) if requirements for electronic records are met (see section 6.6).

4.3.2 Administration of Records

All quality records shall be maintained at the manufacturing location or be accessible to management and regulatory agencies. Records shall be maintained in an environment that prevents damage, deterioration, and loss. Quality records may be made available to customers or regulatory agencies for their inspection, subject to appropriate consideration of confidentiality of the records. Procedures shall define methods for record retention.

4.3.3 Quality System Record

CMC shall maintain a Quality System Record (QSR). The QSR shall contain or refer to the location of, the quality manual, quality system procedures, work instructions, templates and forms, and all other documentation that is associated with the quality management system but is not specific to a particular device or type of device.

5.0 Management Responsibility

5.1 Management Commitment

Executive Management shall demonstrate a commitment to the establishment, maintenance, and continuing improvement of the quality management system by:

- Establishing and communicating a quality policy
- Appointing a Management Representative
- Conducting regular Management Reviews
- Communicating the importance of meeting customer, regulatory and statutory requirements applicable to the product, and CMC's organizational requirements
- Maintaining a focus on customers and ensuring that customer requirements are determined and met to increase customer satisfaction through the effective application of the QMS, including processes for continual improvement of the QMS.
- Establishing and evaluating quality objectives
- Conducting quality management system planning



- Ensuring the availability of resources

The CMC Mission:

Our Mission, always carried out with unyielding integrity, is to meet or exceed the expectations of our customers in terms of quality, cost, delivery and service; ensure profitable growth for our company; and provide an environment of trust, rewards, opportunity and education for our employees.

The CMC Vision:

CMC will be known for excellence in contract manufacturing. We strive to be the first choice of engineers and purchasing professionals as they manage the intersection of function, design, manufacturing, schedule and budget.

5.2 Management Representative

A Management Representative shall be appointed; these appointments shall be documented. The Management Representative shall be a member of the organization and shall have the responsibility and authority to:

- Ensure that a quality management system is established and maintained in accordance with the requirements of this quality manual, applicable regulations and standards, and organization policies
- Regularly assess the quality management system
- Report to executive management regarding the compliance and performance of the quality management system
- Facilitate external agency audits, inspections, and visits relative to the quality management system
- Ensure the promotion of awareness of customer requirements and regulatory requirements throughout the organization

5.3 Establishment of Quality Policy

The CMC Quality Policy:

- Comply with mutually agreed upon valid requirements 100% of the time
- Minimize defects through a culture of prevention rather than detection
- Continually improve and maintain the quality of our products and services

Executive management regularly reviews the policy for suitability. The policy and its meaning is communicated to all levels of the organization through publication of the quality manual, quality system training, bulletin board postings, display of quality measurements, and periodic review at organization meetings.

5.4 Quality Planning

Management shall plan for any necessary changes to the quality management system to maintain the integrity of the QMS:

- As an integral part of business planning
- When making significant changes in responsibilities
- When significantly modifying facilities or processes
- In response to adverse findings from quality audits by external parties
- For significant changes in regulatory requirements
- To maintain and improve the effectiveness of the quality management system



Where appropriate, this planning shall be documented in the form of a quality plan. The quality plan for the manufacture of products shall specify quality requirements, resources and activities relevant to the devices that are manufactured.

5.5 Responsibility and Authority

The implementation, maintenance, and improvement of the quality management system are the shared responsibility of all associates throughout the organization.

Process Ownership is defined within each quality system procedure. The Process Owner shall be responsible to:

- Establish and maintain procedures for the process, based on the requirements of the quality manual
- Continually improve the effectiveness of the process

The responsibility, authority, and interrelation of all associates who manage, perform, and verify work that affects quality shall be specified as part of the documented quality management system, including the quality manual, quality system procedures, and, if necessary, other documents. Management shall provide all such associates with appropriate independence and authority to perform these tasks.

When a position described in the quality system is vacant, or the incumbent is absent, any responsibility or authority assigned to that position shall normally be assigned to the next higher level of management.

Any changes of title, position, responsibility, delegation of responsibility, or significant changes in titles shall be communicated by the next level of management to all affected associates and the Management Representative. Any affected quality management system documents shall be revised within a reasonable time.

CMC maintains an Organization Chart to describe the organizational structure of the organization.

5.5.1 Internal Communication

The effectiveness of the Quality Management System will be communicated to executive management during Management Review Meetings. Communication to the organization is achieved verbally and through postings on organization bulletin boards, organization meetings, paycheck attachments, and the organization intranet site.

5.6 Management Review

Executive Management shall formally review and assess the suitability and effectiveness quality management system in planned Management Review meetings on a quarterly basis. During Management Review meetings, the management team shall consider opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Management Review inputs shall include the following:

1. Status of identified actions from previous Management Review Meetings
2. Internal and external quality audits
3. Corrective and preventive actions
4. Customer feedback
5. Product quality
6. Supplier performance
7. Performance of processes and associated quality measurements to defined goals and objectives.
8. Changes in external conditions or requirements that could affect the QMS
9. Recommendations for improvement
10. Infrastructure and business environment updates, changes or risks.

Management Review output shall include as applicable:



- The effectiveness of the QMS
- Improvements of processes
- Improvements of the product related to customer requirements
- Human, facility, or infrastructure resource needs
- Infrastructure and business environment updates, changes or risks.
- Other recommendations for improvement

Records of Management Review shall be maintained.

6.0 Resource Management

6.1 Provision of Resources

Management shall determine the need for and provide adequate human resources and infrastructure to achieve quality requirements including implementation, maintenance, effectiveness and continuous improvement of the quality management system, as well as maintenance of customer satisfaction by ensuring the fulfillment of customer requirements. This section describes requirements placed on various aspects of resources within the QMS.

6.2 Human Resources

For each job function, management shall provide sufficient personnel with appropriate background, education, and experience necessary. Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. The required competence to carry out those jobs affecting product quality shall be determined, and appropriate training or other action shall be performed to provide or ensure this competence. Each associate shall be provided with the necessary training or other actions to ensure that the assigned tasks are performed in accordance with the quality system and associated policies, procedures, and work instructions. Training shall include instruction on the importance of the associate's activities and their contribution to the quality objectives. Training records shall be maintained. The effectiveness of training shall be evaluated.

6.2.1 Hiring and Orientation

Requirements for hiring or promoting of associates shall include the background and education necessary to learn to perform the assigned tasks.

Each associate shall complete an orientation program. Records of all such orientation and training shall be maintained.

Any training mandated by federal, state, or local law shall be provided.

6.2.2 Training

Procedures shall be established and maintained to ensure that each CMC associate and temporary worker receive the training necessary to ensure proper performance in the assigned area(s) of responsibility. Management shall identify the training needs for each job function related to the quality management system and plan the training of associates accordingly. Records of all job-specific training shall be maintained.



6.3 Infrastructure

CMC shall determine, provide and maintain the infrastructure and supporting services (such as transport, communication, or information systems) required to comply with applicable product and customer requirements. Infrastructure includes, as applicable

- Infrastructure and business environment updates, changes or risks
- buildings, workspace and associated utilities,
- process equipment (both hardware and software), and
- supporting services (such as transport or communication).

All manufacturing and service processes shall be carried out under controlled conditions, including adequate buildings, process equipment, working conditions, and personnel, to ensure that all devices produced and released for distribution meet their intended requirements and are shipped free of contamination by any substances that could reasonably be expected to have an adverse effect on product quality.

6.3.1 Buildings

Buildings shall contain sufficient space and be adequately arranged to ensure orderly handling of all material and equipment and orderly execution of all processes that affect device quality, in order to enable maintenance and prevent mix-up. Buildings and grounds shall be designed and constructed and the environment of the building suitably controlled to prevent contamination by external environmental sources and pests. A suitable pest control program shall be established.

6.3.2 Processing Equipment

All process equipment, including hardware and software, shall be selected or designed to meet specified requirements and shall be constructed and installed to facilitate maintenance, adjustment, cleaning, and use.

Process equipment shall be regularly cleaned, maintained, inspected and adjusted as required to maintain product quality. A preventive maintenance schedule shall be established and shall be readily available to the associates who perform the maintenance activities or the associates' supervisor(s). A record of maintenance activities shall be maintained.

6.4 Work Environment

CMC shall determine and maintain the work environment required to meet applicable statutory, regulatory, product and customer requirements. All manufacturing and service processes shall be performed in compliance with applicable Environmental, Health, and Safety (EH&S) regulatory requirements. All employees shall receive appropriate safety training.

Components and devices that have been identified as sensitive to electrostatic discharge (ESD) shall be handled per approved procedures.

Smoking shall be prohibited in the building(s). Eating and drinking shall be limited to designated areas to prevent device contamination. Each associate shall be responsible to help maintain a clean and safe work environment.

6.5 Information Systems

6.5.1 General Policy

Information systems shall be provided as necessary to achieve conformity to product requirements and to support business processes. Information systems and computer-related systems that support the quality



management system shall be developed, operated, and maintained under controlled conditions, including adequate equipment, environment, software, operating procedures, and personnel.

6.5.2 Equipment and Environment

All computer-related equipment shall be selected or designed to meet specified requirements.

Computers shall be located in areas that contain sufficient space and be adequately arranged to assure orderly execution of all processes and to enable maintenance. When environmental controls are necessary to ensure that computers perform reliably, procedures shall be established and maintained to adequately control the environmental conditions and the functioning of the environmental controls shall be verified by documented inspections.

6.5.3 Computer Operations

Procedures shall be established to ensure secure and reliable operation of computer-related systems, encompassing the following:

- Maintenance of the computer system and associated network equipment
- Periodic back up of programs and records

6.5.4 Process Validation

Where computers or automated data processing systems are used as part of a manufacturing process or for any purpose in the quality management system, computer software shall be validated for its intended use. All software changes shall be validated before approval and use.

7.0 Product and Service Realization

7.1 Planning

Management shall plan, define, implement, and maintain processes and documents to meet customer, regulatory and statutory requirements applicable to the product, and CMC's organizational requirements, with due consideration for quality objectives, compliance with the requirements of the quality management system, and any unique requirements of the products. In the event that assistance with documented risk management activities is provided throughout the product realization process, as required by customer contract, these activities shall be performed according to specific procedures. Similarly, if contract requires CMC to identify the resources to support operation and maintenance of the product, procedures will be developed to support this requirement.

7.2 Customer-related Processes

7.2.1 Determination of requirements

Processes shall be established to ensure effective interfaces with customers, including regulatory and statutory requirements applicable to the product, and CMC's organizational requirements, the receipt and entry of customer orders and capturing the requirements for delivery, quantity, terms and any additional requirements considered necessary by the organization.

Within the policy of this section and supporting procedures, the use of the word "order" shall also mean "contract," such that entry of a customer order constitutes review and acceptance of a contract.



7.2.2 Review of requirements

Contracts and orders shall be reviewed prior to acceptance, to ensure that the customer's product requirements are clearly defined and documented, and that the organization is capable of meeting those requirements within a reasonable time. Where appropriate, a formal contract review is held. This review includes a review and communication of any additional regulatory requirements necessary to support the contract, an evaluation of risks, as well as any different or new requirements to existing contracts. Records of contract review shall be maintained.

The order entry and contract review process(es) shall ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction. Any differences between specified customer requirements and the manufacturer's capability to meet the requirements should be resolved prior to acknowledgement of the order.

7.2.3 Customer Communication

Management shall establish effective methods for communicating with customers on product information, quotes, pricing, inquiries, contracts, order entry, order status, and any changes affecting the products and services. Processes shall be established for the recording of customer complaints and for the collection of customer feedback.

7.3 Product Design and Development

CMC offers technical assistance to our customers in the form of manufacturing engineering support for the initial design phase, prototype production, and manufacturing problem resolution. CMC does not have design and development responsibility for any of the products provided to our customers. Verification and validation approval of all designs remain the responsibility of the customer.

7.4 Purchasing

Processes shall be established and maintained to manage the supply of material and outsourced products and services. Procedures shall provide for the evaluation and control of purchased products, the identification of potential sources for purchased materials, the development of suppliers or partners, and the evaluation and re-evaluation, as necessary, of their ability to supply the required products. These processes shall ensure that all purchased or otherwise received products, components, and services conform to specified requirements.

7.4.1 Purchasing Processes

CMC shall evaluate and select suppliers based on their ability to supply products or services in accordance with the specified requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of the results of supplier evaluation and any necessary actions arising from the evaluation shall be maintained.

The type and extent of control applied to the supplier and the purchased product or outsourced service shall be defined and shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. Supplier performance shall be reviewed and monitored according to established criteria. Suppliers of goods or services that do not directly affect the quality management system or the quality of CMC-supplied product or services may be deemed acceptable based solely on their ability to meet purchase order requirements. NOTE: An outsourced process is identified as one being needed for the organization's quality management system but chosen to be performed by a party external to the organization.



7.4.2 Purchasing Information

Purchasing information shall clearly describe or refer to the requirements for the product or service to be purchased, including where appropriate requirements placed on the supplier for:

- Requirements for approval of product, or supplier procedures, processes, and equipment
- Qualification of supplier personnel
- Supplier's quality management system
- Traceability requirements as defined by customer contract.

The adequacy of specified purchase requirements shall be reviewed prior to their communication to the supplier.

7.4.3 Verification of Purchased Product

CMC shall established and implement activities to ensure that purchased or otherwise received material conforms to specified requirements by inspecting, testing, or otherwise verifying the material prior to acceptance. In the event that CMC or a customer intends to perform verification at a supplier's premises, the intended verification arrangements and method of product release shall be stated in purchasing information.

Material shall not normally be made available for manufacturing use until all acceptance procedures have been completed and the authorized personnel have released the material. Procedures may however allow for the release of material for manufacturing use prior to completion of receiving inspection, provided that control is maintained over the unapproved material such that it could be retrieved prior to distribution of the associated finished product.

Where specified in the contract, Cygnus Manufacturing Company's customers (or customers' designee) shall be permitted to verify, at the supplier's premises and/or at CMC, that subcontracted product conforms to specified requirements; however, this inspection does not absolve CMC from providing acceptable product.

The inspection of labeling shall include an examination for accuracy. The record of this review shall include the signature of the person who examines the labeling.

7.4.4 Inspection Records

Records shall be maintained of the acceptance or rejection of each lot of received components. They shall include, at a minimum:

- Date inspected
- Supplier name
- Results
- Where appropriate, the equipment used
- Signature of the associate performing the acceptance

7.5 Production and Service Provision

All manufacturing processes, inspection, and testing shall be performed under controlled conditions in accordance with written instructions or drawings by qualified and trained personnel to assure that the devices conform to the approved original or modified design. These instructions shall include assembly procedures, work instructions, and any necessary controls on the process. Records of these processes shall be maintained.



7.5.1 Process Control

All manufacturing processes shall be performed in accordance with drawings and documented instructions, where applicable, that define and control the process and identify the characteristics of the product. These may include or make reference to criteria for workmanship, which may be expressed in work instructions, documented standards or by means of identified and approved representative samples. These documents may be CMC documents or customer drawings, as applicable.

Process monitoring and measurement systems shall be utilized to evaluate product quality in the manufacturing process. Information derived from these systems shall be available and used to initiate corrective or preventive action as appropriate.

Where deviations from device specifications could occur as a result of the manufacturing process, process control procedures shall be established and maintained to describe any process controls necessary to ensure that the device conforms to specifications.

Each process of applying a label to a medical device or of using packaging that includes medical device labeling shall be controlled to prevent labeling errors and mix-up.

Records shall be maintained to ensure that all manufacturing and inspection operations have been performed as planned. Changes or deviations to any manufacturing process, method, procedure, equipment or tools shall be documented, reviewed and approved and the appropriate associates notified of the change.

7.5.2 Inspection Testing and Product Release

Procedure(s) shall be established and maintained for acceptance activities including receiving, in-process, final inspection and final acceptance, implementation of product release, delivery, and post delivery activities.

CMC will support the documented requirements of medical device customers related to final release for distribution as required by contract.

7.5.3 Rework and Reprocessing

Procedures shall be established and maintained to provide for the rework as necessary of nonconforming material, including components, subassemblies, and finished devices. All rework shall be performed in accordance with written instructions unless the rework is an obvious repetition or reversal of another documented process. Reworked material shall be identified as nonconforming and shall be segregated from conforming material until disposition, to prevent mix-up. The rework shall be documented on the forms controlling nonconforming material, on the device history record, or on a corrective action document.

Rework instructions shall identify any limitations on the amount or the nature of the rework. Procedures shall include re-testing and re-evaluation of the nonconforming material after rework to ensure that it meets its current approved specification. Rework and re-evaluation activities, including the determination of any adverse events from the rework on the product, shall be documented.

7.5.4 Medical Device History Record

The Medical Device History Record (DHR) is a compilation of records containing the production history of a device or a batch of medical devices. CMC will support the documented requirements of medical device history records as required by contract.



7.5.5 Process Validation

A procedure shall be established and maintained to define the requirements for Process Validation. A special process is one in which the product quality characteristic cannot fully be verified in the finished product by inspection or testing. Any special processes shall be identified and validated.

Any computers or software used in a manufacturing or service process shall be validated.

If a change is made to a process the process shall be revalidated as appropriate.

7.5.6 Product Identification and Traceability

7.5.6.1 Material Identification

Materials shall be identified by material number and, as necessary, by status with respect to monitoring and measurement requirements, or by other appropriate method throughout all stages of product realization.

Material returned for rework or reprocessing shall be identified to distinguish them from normal production.

7.5.6.2 Device and Component Traceability

Where stipulated by contractual requirements, when traceability is required CMC shall control the unique identification of the product (devices and components) and maintain records. Records shall be maintained to provide traceability of all such items from the supplier, through manufacturing, and to finished goods items in order to facilitate corrective action. The responsibility for component traceability may be assigned to suppliers.

7.5.7 Preservation of Product

Procedures and practices shall provide for the identification, handling, storage, cleaning, labeling, packaging, protection of materials and prevention, detection and removal of foreign objects while in the warehouse, production process, distribution, or servicing as applicable. These procedures shall also address shelf-life for products, special handling for any hazardous materials and any necessary special storage guidelines for sensitive product such as electrostatic sensitive components and products labeled as sterile. The procedures for handling, storage and distribution preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Any documentation required by the contract shall be attached to the product for delivery and are protected against loss or damage.

7.5.8 Labeling

Product labels, package labeling, and user instructions shall be treated as components in document control, purchasing, and product validation.

7.5.9 Customer Property

Customer property shall be identified, verified and protected while it is in CMC's care. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the customer shall be notified and records maintained. Note: Customer property can include intellectual property and personal data.

7.6 Control of Measuring Equipment

All measuring equipment used to provide evidence of conformity to determined requirements shall be controlled to ensure that it is suitable for its intended use and to assure confidence in the measurements. These controls shall comprise, as appropriate, selection, qualification, identification, preservation, calibration, and corrective



action and shall meet requirements of international standards on quality assurance requirements for measuring equipment. This shall include any such items that are owned by another organization or by a CMC associate. Any custom software shall be verified and the associated measurement system shall be validated.

7.6.1 Selection and Qualification

Measuring equipment shall be qualified to establish that it is suitable for its intended use. When computer software is used to monitor or measure specified requirements, the ability of the computer software to satisfy the intended application shall be confirmed prior to initial use at appropriate stages as necessary to satisfy the intended application. The quality plan for development of a new product or implementation of a new process shall include consideration of measuring equipment selection and qualification. Any custom software shall be verified and the associated measurement system shall be validated.

7.6.2 Preservation

Measuring equipment shall be handled, transported, stored, and maintained in a manner to preserve its accuracy and fitness for use. When necessary, measuring equipment shall be maintained, calibrated, and used in a controlled environment. Measuring equipment shall be protected from any adjustments, software changes, or tampering that would adversely affect its accuracy or invalidate the measurement results.

7.6.3 Calibration

Processes shall be established to provide for the inspection, maintenance, adjustment and re-adjustment, as necessary, of measuring equipment at periodic intervals to ensure that it meets the intended accuracy and precision. Equipment calibration status shall be identified.

7.6.4 Calibration Standards

Calibration standards shall be used for inspection, measuring and test procedures. If national or international standards are not available, CMC shall use an independent reproducible standard. In the event that no applicable standard is available, CMC shall establish and maintain an in-house standard. Calibration procedures ensure that environmental conditions are suitable and specified, if appropriate.

7.6.5 Calibration Records

Equipment calibration records shall include: equipment identification, calibration dates, the individual performing each calibration and the next due date. Calibration records shall be displayed on or near each piece of equipment or readily available to the individual using or calibrating the equipment.

7.7 Distribution

Procedures and practices for handling, storage, preservation, and distribution of finished goods shall prevent damage, mix-up, and contamination and provide for product traceability.

7.7.1 Storage of Finished Goods

Storage areas for finished devices shall be designed to prevent mix-up, damage, deterioration, or other adverse effects and to facilitate location and withdrawal for shipment. Finished goods shall be identified with a part number, at a minimum, to facilitate storage and withdrawal.

Procedures shall be established to account for the inventory of material and to verify accuracy of inventory accounting, as well as for the maintenance of necessary records.



7.7.2 Distribution Activities

Procedures for the distribution and control of finished goods shall illustrate that distribution occurs only after devices have been authorized for release. The traceability of required finished goods is maintained in the distribution records.

7.7.3 Distribution Records

Distribution records shall be maintained for all finished medical devices. Distribution records shall include:

- Name and address of consignee
- Identification of material
- Quantity shipped
- Date shipped
- Control number, if required

7.7.4 Processing of Returned Materials

Procedures shall provide for the segregation, identification, evaluation, and disposition of material returned by the customer and should ensure timely resolution to any customer issues arising from such returns. The return process shall ensure that obsolete or non-conforming products resulting from customer returns are identified and are not re-introduced into the distribution process and do not contaminate other product, the work area, or personnel. Returned goods that are received without prior notice from the customer shall be resolved through communication with the customer to ensure that any customer's issues related to the return are addressed.

7.8 Servicing and Installation

If servicing or installation is required by contract, CMC shall establish documented procedures, as necessary, for performing servicing activities and verifying that they meet the specific requirements.

8.0 Measurement, Analysis, and Improvement

8.1 General

CMC shall utilize measurement, analysis and improvement to demonstrate conformity of product, ensure the conformity, maintain effectiveness and continually improve the Quality Management System.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Information relating to customer perception will be routinely gathered during customer visits and customer service calls to determine if CMC is meeting customer requirements. If this information indicates that requirements are not being met, corrective or preventive action will be initiated as necessary.

8.2.2 Internal Quality Audits

Internal quality audits shall be conducted at planned intervals to ensure that all aspects of the quality management system are effectively implemented and maintained and to identify areas for improvement. Procedures provide for the performance of audits at planned intervals based on the status and importance of the activity and results of previous audits. Note: When determining suitable methods, CMC considers the type and



extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.3 Control of Nonconforming Material

A procedure shall be established and maintained to provide for the identification of nonconforming material and prevent its inadvertent use or delivery, including reviews and controls over products that are not yet distributed and those already distributed. All nonconforming material shall be clearly identified and appropriately segregated from acceptable material. In the event of a process nonconformity, CMC shall determine whether the product was affected and if so, disposition the product per the requirements of this action. Further, action shall be taken to correct the process nonconformity.

8.4 Analysis of Data

Appropriate data related to customer satisfaction, conformity to product requirements, corrective and preventive action and suppliers shall be collected, maintained and reported for the purposes of management review. (See section 5.6.)

Statistical techniques shall be identified, developed, and used to draw inferences from data when establishing, controlling, and verifying evaluations of product characteristics and manufacturing processes and customer feedback.

When appropriate, procedures shall be established and maintained to identify and provide for appropriate use of statistical techniques in those cases where required for measurement, evaluation, and improvement, and for effective implementation of the quality management system.

8.5 Improvement

8.5.1 Continual Improvement

CMC shall use the evaluations and measurement processes of the QMS to continually improve the effectiveness and adequacy of the system through the use of the quality policy, quality objectives, audit results, analysis of data corrective and preventive actions, customer feedback and management review.

8.5.2 Corrective and Preventive Action Process

Corrective and preventive action procedures shall be documented and maintained to ensure that the causes or potential causes of nonconforming product, material or processes are identified, evaluated, documented, and corrected, to prevent recurrence of the problem or to prevent the problem from initially occurring. Provisions shall be made for review and control of products that may be nonconforming, including those distributed and those not yet distributed.

The corrective action processes shall provide a systematic, problem-solving approach to continuous quality improvement with the primary objective of determining and eliminating all causes of nonconforming product, material, and processes. The preventive action process shall help prevent the occurrence of nonconforming material, product, and conditions by identifying, analyzing, and eliminating potential quality problems, and analyzing and trending information on quality. Identified quality problems and the status and effectiveness of corrective and preventive actions shall be reported as part of Management Review.

The corrective and preventive action process shall include the analysis and investigation of the causes of nonconforming material, product, and conditions. The process shall also provide for identifying, documenting, evaluating the need for action to prevent recurrence of the issue, determination and implementation of necessary actions and records of the results of the actions taken.



9.0 Appendix A: Trace from Regulations and Standards to the Quality Manual

This section is provided to assist internal and external auditors and other users in the review of the quality manual and the quality management system. Each section or clause of the key regulations and standards is listed, along with a reference to the section of the quality manual that is intended to specify compliance with that clause.

This section is considered advisory and is not a formal part of the documented quality management system.



9.1 ISO 9001:2008 Quality management systems – Requirements

Quality Manual Section & Paragraph Title	ISO 9001:2008 Sections
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2.0 Normative References	2
4.0 Quality Management System	4
4.1 General Requirements	4.1
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5.1 Management commitment	5.1
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5.3 Quality Policy	5.3
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5.2 Management Representative	5.5.2
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6.0 Resource Management	6
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7.0 Product Realization	7
7.1 Planning of product realization	7.1

Quality Manual Section & Paragraph Title	ISO 9001:2008 Sections
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7.2.1 Determination of requirements related to the product	7.2.1
7.2.2 Review of requirements related to the product and Order Entry	7.2.2
7.2.3 Customer Communication	7.2.3
N/A	7.3
7.4 Purchasing	7.4
7.4.1 Purchasing Process	7.4.1
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7.5 Production and Service Provision	7.5
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7.4.5 Monitoring of Suppliers	
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7.5.5 Process Validation	8.2.3
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8.3 Control of Nonconforming Product	8.3
8.4 Analysis of Data	8.4
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8.5.1 Continual Improvement	8.5.1
8.5.2 Corrective and Preventive Action	8.5.2
8.5.2 Corrective and Preventive Action	8.5.3



9.2 21 CFR 820, Quality System Regulation (2009)

Quality Manual Section or Paragraph	Section #	Quality Manual Section or Paragraph	Section #
1.0 Introduction and Scope	820.1	7.6.1 Selection and Qualification	820.72(a)
Not applicable; no requirements	820.3	7.6.2 Preservation	
4.0 Quality Management System	820.5	7.6.3 Calibration	820.72(b)
5.0 Management Responsibility	820.20	7.5.5 Process Validation	820.75
5.3 Establishment of Quality Policy	820.20(a)	7.4.1 Purchasing Processes	
5.5 Responsibility and Authority	820.20(b)	See sections below.	820.80
5.5 Responsibility and Authority	820(b)(1)	See sections below.	820.80(a)
6.0 Resource Management	820(b)(2)	7.4.3 Verification of Purchased Product	820.80(b)
5.2 Management Representative	820(b)(3)	7.5.2 Inspection and Testing	820.80(c)
5.6 Management Review	820.20(c)	7.5.2 Inspection and Testing	820.80(d)
5.4 Quality Planning	820.20(d)	See sections above.	820.80(e)
4.2.2 Structure of the Quality Management System	820.20(e)	7.5.2 Inspection and Testing	820.86
8.3 Internal Quality Audits	820.22	8.3 Control of Nonconforming Material	820.90
6.2 Human Resources	820.25	8.3.1 Identification and Control of Nonconforming Product	820.90(a)
6.2 Human Resources	820.25(a)	8.3.2 Review and Disposition of Nonconforming Product	820.90(b)
6.2.2 Job Specific Training	820.25(b)	8.5.2 Corrective and Preventive Action	820.100
N/A	820.30	See sections below.	820.120
N/A	820.30(a)	7.4.3 Verification of Purchased Product	820.120(b)
4.2 Documentation	820.40	7.5.8 Labeling	820.120(c)
4.2.3 Document Approval and Change Control	820.40(a)	7.5.1 Process Control	820.120(d)
4.2.4 Document Release and Distribution		7.5.6.2 Device and Component Traceability	820.120(e)
4.2.3 Document Approval and Change Control	820.40(b)	7.7 Distribution	820.140
7.4 Purchasing	820.50	7.7 Distribution	820.150
7.4.1 Purchasing Processes	820.50(a)	7.7.1 Storage of Finished Goods	820.150(a)
7.4.5 Monitoring of Suppliers		7.5.7 Preservation of Product	
7.4.2 Purchasing Information	820.50(b)	7.5.2 Inspection and Testing	820.150(b)
7.5.6.1 Material Identification	820.60	7.7 Distribution	820.160
7.5.6.2 Device and Component Traceability	820.65	7.7.2 Distribution Activities	820.160(a)
7.5 Production and Service Provision	820.70	7.7.3 Distribution Records	820.160(b)
7.5 Production and Service Provision	820.70(a)	N/A	820.170
7.5.1 Process Control	820.70(b)	4.3 Control of Quality Records	820.180
6.4 Working Environment	820.70(c)	N/A	820.181
6.4 Working Environment	820.70(d)	7.5.4 Medical Device History Record	820.184
6.4 Working Environment	820.70(e)	4.3.3 Quality System Record	820.186
6.3 Infrastructure	820.70(f)	N/A	820.198
6.3.2 Processing Equipment	820.70(g)	N/A	820.200
7.5.1 Process Control	820.70(h)	8.4.1 Statistical Techniques	820.250
6.5.6 Process Validation	820.70(i)		
7.6 Control of Measuring Equipment	820.72		



Revision History:

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5	3/6/08	B. Marshall, N. Spaniel	0097
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