



# QUALITY MANUAL

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## List of Referenced Procedures

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SOP1000 - Document Control  
SOP1010 - Quality Records  
SOP1020 - Management Responsibility  
SOP1030 - Job Descriptions  
SOP1040 - Competence, Awareness, and Training  
SOP1050 - Quotation Process  
SOP1060 - Sales Orders  
SOP1070 - Customer Complaints  
SOP1080 - Returned Goods Authorization  
SOP1100 - Qualification – Validation  
SOP1110 - FMEA  
SOP1120 - Pre-Production Quality and Planning  
SOP1130 - Vendor Evaluation  
SOP1140 - Purchasing  
SOP1150 - Receiving and Inspection  
SOP1160 - Scheduling  
SOP1170 - Manufacturing  
SOP1180 - Part Number Assignment  
SOP1200 - Product Labeling  
SOP1210 - Customer Property  
SOP1220 - Control of Monitoring & Measuring Devices  
SOP1230 - Customer Satisfaction  
SOP1240 - Internal Quality Audits  
SOP1250 - Monitoring & Measurement of Process  
SOP1260 - Control of Nonconforming Product  
SOP1270 - Data Analysis and Continual Improvement  
SOP1275 - Statistical Techniques  
SOP1280 - Corrective Action  
SOP1290 - Preventive Action

Notice:

Device Master Records are called “Engineering Project Folders” in the above Standard Operating Procedures, and are maintained by the Engineering Dept.  
Device History Records (DHRs) are called “Job Folders” in the above Standard Operating Procedures, and are maintained by the Production Dept.

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## **1.0 PURPOSE**

The purpose of this Quality Manual is to establish and state the general policies governing Medbio's Quality Management System (QMS). These policies define management's intended arrangements for handling our operations and activities in accordance with the framework established by ISO 13485:2016 in conjunction with FDA 21 CFR part 820. These are the top-level policies representing the company's plans for achieving quality assurance and customer satisfaction.

All departmental or functional policies and procedures written must conform and parallel these policies. All changes to policies and procedures are required to be reviewed to ensure that there are no conflicts with the policies stated in this Quality Manual (QM).

## **2.0 SCOPE**

The policies stated in this manual apply to all QMS-related operations and activities at Medbio. The scope of our quality system is as follows:

Contract Manufacturer of Medical and Biotech Components and Devices Including Injection Molding, Part Decorating, Assembly and Packaging.

It is the responsibility of all department managers to help define, implement and maintain the procedures required by this manual and to ensure all processes conform to these requirements. It is the responsibility of all employees to follow procedures that implement these policies and to help strive for continual improvement in all activities and processes of Medbio, Inc.

### **2.1 EXCLUSIONS**

Medbio does not own any design of any product; to that effect, ISO 13485 Section 7.3 Design and Development is excluded.

Medbio does not perform cleaning of product, installation activities, servicing activities, or sterilization. Therefore, ISO 13485 Sections 7.5.3, 7.5.4, and 7.5.5 are not applicable.

Also, Medbio does not manufacture *finished* implantable medical devices. Therefore, ISO 13485 Section 7.5.9.2 is not applicable.

## **3.0 RELATION TO ISO 13485:2016**

For ease of reference, the sections of this manual are numbered to coincide with the equivalent section numbers of the ISO 13485: 2016 standard. Going forward, the ISO standard will be referred to as "ISO".

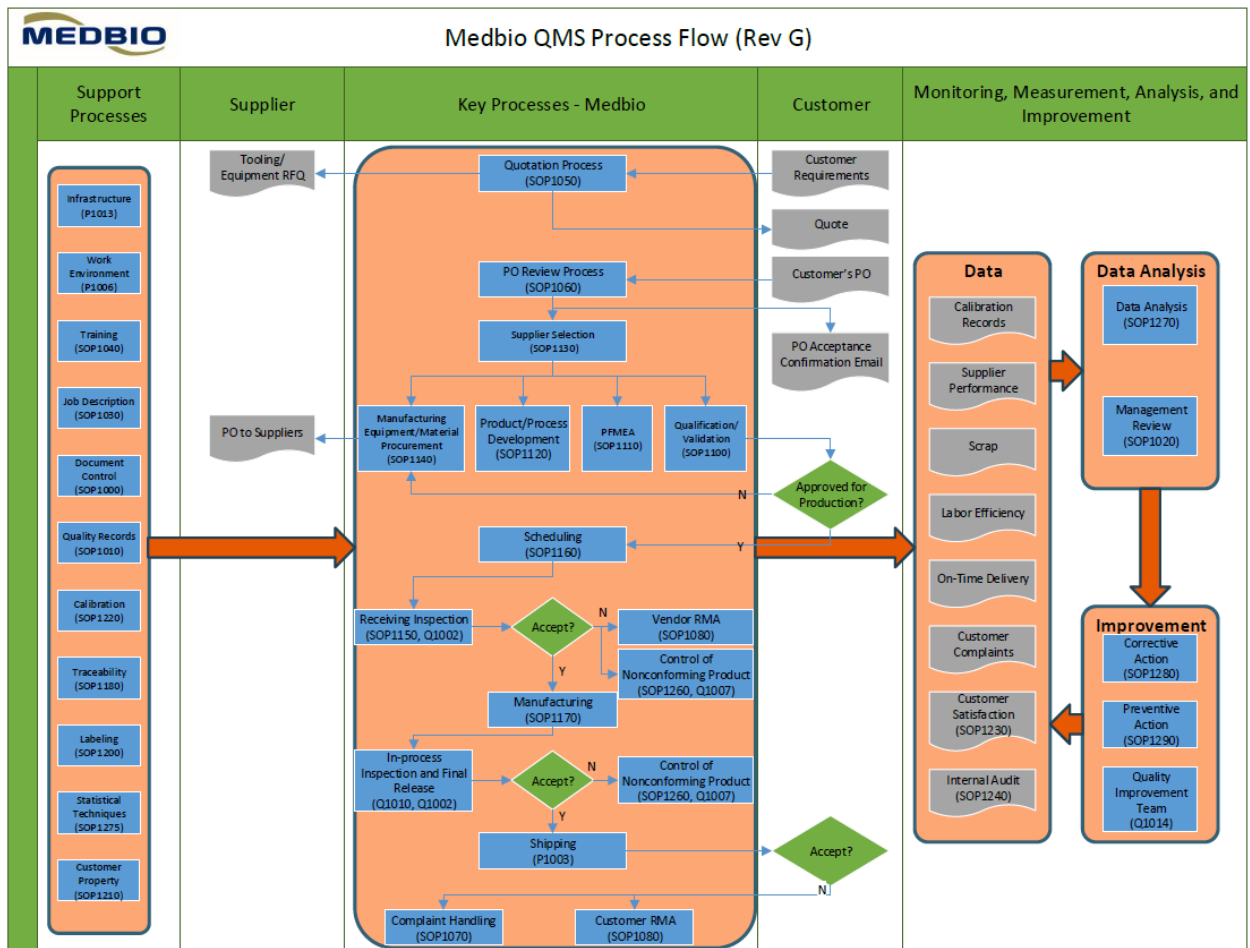
## **4.0 MEDBIO QUALITY MANAGEMENT SYSTEM**

### **4.1 GENERAL REQUIREMENTS**

4.1.1 Through this manual and associated procedures and documents, Medbio has established, documented, and implemented a Quality Management System conforming to ISO requirements and FDA 21 CFR part 820. The system is designed to result in continual improvement of the QMS and in our ability to satisfy our customers' requirements.

Maintenance of this system is the responsibility of the ISO Management Representative in conjunction with all Department Managers.

4.1.2 This Quality Manual identifies the processes and their interactions needed for the QMS at Medbio (see Medbio General Process Flow). As defined in Q1011 – Risk Assessment, all relevant procedures have inherent methods for assessing and/or mitigating risk to both the patient safety/product performance, as well as the organization itself.



4.1.3 The ISO Management Representative maintains a document that identifies the sequence of these processes and, in conjunction with the appropriate department managers, defines the interactions of the processes within the procedures defining these processes. Processes for management activities, provision of resources, product realization, and measurement are included. Procedures shall include the methods needed to ensure the operation and control of processes are effective. These processes will be managed in accordance with the requirements of ISO and FDA requirements.

Top Management will ensure the availability of resources to support the operation and monitoring of processes through regular interaction with department managers and through review activities at Management Review meetings. Department Managers and the Management Representative will monitor, measure, and analyze processes and implement any actions necessary to achieve intended results and continual improvement of the processes. These results will also be monitored at Management Review meetings.

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4.1.4 Changes to existing processes will be made in accordance with the regulatory standards, in that they will be evaluated for their impact on the QMS and any related product. These changes will be controlled through the DCN process.

4.1.5 Any processes that are outsourced that may affect the products' conformity to requirements shall be controlled; the processes that Medbio outsources are fabrication, calibration and testing, and part measurement. The Quality Manager and appropriate department manager(s) are responsible for defining the methods to control outsourced processes in procedures.

4.1.6 Medbio has established procedures for the categorization and validation of software applications used within the QMS. Any new software applications that have been introduced after September 15, 2017, will conform to the procedure, though the organization will prioritize and retroactively assess applications that did not initially conform to the requirements.

## **4.2 DOCUMENTATION REQUIREMENTS**

4.2.1 (General) - This Quality Manual and the associated procedures are intended to satisfy the FDA and ISO documentation requirements for a quality manual, procedures and statements of the quality policy and quality objectives. Records required by the standards are identified in the appropriate procedures or the Quality Records procedure.

Department managers and/or supervisors are responsible for identifying any additional documents needed to ensure the effective planning, operation and control of processes. Procedures may vary in detail based on the size of the department or organization involved and the type of activity performed. Procedure developers shall consider this as well as the complexity of the processes and interactions, and the competence of the personnel involved. Where competence is used to minimize the content in procedures, records must support the decision.

Documents may be any medium including: software programs, electronic text files, or hardcopy documents, for example.

4.2.2 (Quality Manual) - This Quality Manual includes the scope of the Medbio quality system. Exclusions are documented in QM section 2.1. Each section of the manual references appropriate implementing procedures. Interactions between processes are defined in the manual or in the referenced procedures.

4.2.3 (Medical Device File) – Though not the owner of any medical device, Medbio stores product information provided by the customer, and references the product-specific information on the associated work instructions.

4.2.4 (Control of Documents) - All Documents required by the quality management system shall be controlled; these include the Quality Manual, the SOPs, P-specs and Q-specs (Level II documents), and part-specific work instructions (Level III documents). Where department-specific instructions are deemed necessary for training purposes, the department manager may choose to create 'Departmental Specifications', which will not be released through Document Control, but will be available for reference by associated personnel.

The Document Control Procedure defines the controls needed to:

- a) Approve documents for adequacy prior to issue
- b) Review and update as necessary and re-approve documents
- c) Ensure that changes and the current revision status of documents are identified



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- d) Ensure that relevant versions of applicable documents are available at points of use
  - e) Ensure that documents remain legible and readily identifiable
  - f) Ensure that documents of external origin are identified and their distribution controlled
  - g) Prevent deterioration or loss of documents
  - h) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose

4.2.5 (Control of Records) - Procedures define appropriate records to be maintained in order to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. The Quality Records Procedure defines the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records. No confidential health information is created or stored at Medbio.

4.2.6 Referenced Procedures:

SOP1000 - DOCUMENT CONTROL

SOP1010 - QUALITY RECORDS

SOP1130 – VENDOR EVALUATION

P1008 – ELECTRONIC DATA BACKUP – RECORD RETENTION

## **5.0 MANAGEMENT RESPONSIBILITY**

### **5.1 MANAGEMENT COMMITMENT**

Top Management at Medbio shows its commitment to the quality management system through the development and implementation of this quality manual. Additionally, management commitment is demonstrated through the Medbio Quality Policy, the specific objectives that are set and reviewed during Management Review Meetings, and by providing the resources required to meet our objectives for continually improving the effectiveness of our operations and quality system.

The management team, consisting of all department managers and above, is charged with ensuring our products and services meet customer as well as statutory and regulatory requirements.

### **5.2 CUSTOMER FOCUS**

Top management ensures that customer specifications and applicable regulatory requirements will be identified and met for each production item. The focus on improving customer satisfaction is maintained by setting and reviewing objectives related to customer satisfaction at Management Review Meetings.

### **5.3 QUALITY POLICY**

Medbio has established a Quality Policy that we feel is appropriate to our organization and meets the requirements set forth in ISO and CFR 820. This policy is communicated throughout the company. Department managers and/or supervisors are responsible for ensuring all employees understand the policy. To ensure our policy remains appropriate, it is reviewed at Management Review meetings.

The Medbio Quality Policy:

**The employees of Medbio are committed to providing our customers with products of high quality and value, while complying with applicable regulations.**

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**By utilizing robust and efficient systems and processes, we will manufacture safe and effective products, delivered on-time, and at a reasonable cost. We will build strong relationships with our customers, and strive for continual improvement in everything we do.**

## **5.4 PLANNING**

5.4.1 (Quality Objectives) - Medbio shall establish quality objectives which shall be measurable and consistent with the Quality Policy and the regulatory standards; these metrics will be reviewed, and updated as necessary, at Management Review meetings.

5.4.2 (Quality Management System Planning) - As part of annual strategic planning meetings, Medbio establishes strategic objectives for improvement of our products, processes and customer satisfaction. These objectives are supported by specific measures that track performance against those objectives. Department managers, in turn, set departmental objectives with specific performance measures and targets that support the company objectives. These metrics will be specified in SOP1020-Management Responsibility, to be reported monthly to the Management team, and discussed at Management Review Meetings.

Action levels will be assigned at Management Review Meetings for the specified departmental metrics. These levels provide a point at which correction and corrective action shall be taken, as appropriate, to ensure conformity to the product or to company goals. Charts or graphs for the specified metrics will contain an 'action level' line, to reflect the chosen action levels. It is important to distinguish other information that may be reported to Medbio employees, since these additional charts or graphs are for informational purposes, and the data is not 'actionable'.

As situations arise that demand changes to the quality management system, either to meet objectives or because of changing business conditions, all changes will be reviewed by the management team to ensure the integrity of the quality system is maintained.

## **5.5 RESPONSIBILITY, AUTHORITY, AND COMMUNICATION**

5.5.1 (Responsibility and Authority) – Responsibilities, authorities, and interrelations at Medbio are defined in the Organization Chart and each Job Description as well as the Management Responsibility procedure. Job Descriptions are posted on the company shared drive and are also used during annual performance reviews.

5.5.2 (Management Representative) - The President appoints the ISO Management Representative. Irrespective of other responsibilities, the ISO Representative has the responsibility and authority to:

- a) Ensure that processes needed for the QMS are established, documented, implemented and maintained
- b) Report to top management on the effectiveness of the QMS and any need for improvement
- c) Ensure the promotion of awareness of customer, regulatory, and QMS requirements throughout the organization

5.5.3 (Internal Communication) - In line with a policy of leadership through employee involvement, Medbio's personnel policies have established open communication throughout the organization.

The effectiveness of our quality management system is evident through Internal Audit results, Quality Alerts, Corrective and Preventive Actions, and the departmental performance measures.

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Other than confidential information, company and departmental performance measures will be posted throughout Medbio. Internal Audit results and Corrective and Preventive Actions are shared at departmental meetings as appropriate. Part-specific information will be addressed with Communication Travelers in the Advisory Notice procedure.

5.5.4 Referenced Procedures

- SOP1020 - MANAGEMENT RESPONSIBILITY
- SOP1030 - JOB DESCRIPTIONS
- SOP1120 – PRE-PRODUCTION QUALITY AND PLANNING
- SOP1240 – INTERNAL QUALITY AUDITS
- SOP1280 – CORRECTIVE ACTION
- Q1008 – ADVISORY NOTICES

**5.6 MANAGEMENT REVIEW**

5.6.1 (General) - The President and management team shall review Medbio’s QMS on a semi-annual basis, and more frequently if needed, to ensure its continuing suitability, adequacy, and efficacy. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The ISO Management Representative is responsible for maintaining records from management reviews.

5.6.2 (Review Input) - The ISO Management Representative and department managers provide the information for Management Review meetings as defined in SOP1020.

5.6.3 (Review Output) - Records shall include the output from the management review and shall include any decisions and actions related to:

- a) Improvement of the effectiveness of the quality management system and its processes
- b) Improvement of product related to customer requirements
- c) Changes needed to respond to applicable new or revised regulatory requirements
- d) Resource needs

5.6.4 Referenced Procedures:

- SOP1020 - MANAGEMENT RESPONSIBILITY
- SOP1030 - JOB DESCRIPTIONS

**6.0 RESOURCE MANAGEMENT**

**6.1 PROVISION OF RESOURCES**

During planning and budgeting processes, and as needed throughout the year, the President and management team determine and ensure the appropriate resources are available to maintain the quality management system to meet regulatory requirements, and continually improve its effectiveness and enhance customer satisfaction by meeting or exceeding customer requirements.

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## **6.2 HUMAN RESOURCES**

Personnel performing work affecting product quality shall be competent based on appropriate education, training, skills and experience.

The minimum competencies required for each position at Medbio are defined in each position's Job Description. Human Resources and department managers and/or supervisors are responsible for ensuring job descriptions are current.

Where otherwise-qualified personnel require additional training or other action to meet the minimum competency requirements, these needs are identified. The department provides task-specific training. General training or education is provided or coordinated by Human Resources. The department or Human Resources evaluate the effectiveness of training or other actions taken as appropriate for the applicable level of risk for the position.

The department generates records of task-specific training. Human Resources maintains records of all general or department-based training and education, skills and experience. Document Control maintains records of document-based training (DCNs and Temporary Deviations).

Department managers are responsible for ensuring their employees are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

### **6.2.1 Referenced Procedures**

SOP1030 - JOB DESCRIPTIONS

SOP1040 - COMPETENCE, AWARENESS, AND TRAINING

P1046 - NEW EMPLOYEE HIRE PROCEDURE

## **6.3 INFRASTRUCTURE**

Medbio provides the infrastructure necessary to achieve conformity to product requirements. During the annual budgeting and strategic planning processes, buildings, workspace, production and measurement equipment, information systems, and associated utilities are evaluated and provided. When new personnel are added, Human Resources coordinates activities to ensure appropriate process equipment including hardware and software (if required) and supporting services such as telephones, etc., are available.

Equipment maintenance procedures, for standard equipment types used in production, include required activities and frequencies. All manufacturing SOPs indicate the requirement for line clearance to prevent part mixups, and the full spectrum of documents combine to ensure the orderly handling of product through the facility, including measurement and monitoring.

### **6.3.1 Referenced Specifications**

P1013 PREVENTIVE MAINTENANCE

P1008 ELECTRONIC DATA BACKUP – RECORD RETENTION

P1038 GENERATING AN MRO WORK ORDER AND PACKING SLIP IN IQMS

P1065 EMERGENCY ACTION PLAN

P2026 – MANUFACTURING-MOLDING

P2027 – MANUFACTURING-ASSEMBLY

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## **6.4 WORK ENVIRONMENT AND CONTAMINATION CONTROL**

6.4.1 (Work Environment) - The management team determines and manages the work environment to ensure Medbio provides a safe and desirable place to work. They ensure the environment is appropriate for achieving conformity to product requirements, including a facility with positive pressure to resist ingress of pollutants, the establishment of controls on the manufacturing areas, and requirements for personnel hygiene and gowning.

6.4.2 (Contamination Control) - The management team provides procedures and training for the protection of personnel and product, in all manufacturing and warehouse spaces. Where sterile product is returned to Medbio for further processing, part-specific handling procedures will be established.

6.4.3. Referenced Specifications

P1006 CONTROLLED ENVIRONMENT AREA (CEA)

P1043 WASTE MANAGEMENT

P1049 SPILL CONTAINMENT

P1052 BLOODBORNE PATHOGENS PROGRAM

P1055 CEA CLEANING SCHEDULE

P1059 PEST CONTROL

Q1006 CLEANROOM CLASSIFICATION AND TESTING

## **7.0 PRODUCT REALIZATION**

### **7.1 PLANNING OF PRODUCT REALIZATION**

Medbio has planned and developed the processes needed to provide our customers with products and services that meet their requirements. The results of this planning are the processes and procedures defined in our QMS documentation. These processes and procedures include the quality objectives and requirements for our products, the method of assessing potential failure modes, the required verification, validation, manufacturing, monitoring, traceability, inspection and test activities specific to our customers' products, and the criteria for product acceptance verification. The records needed to provide evidence that these processes and resulting product meet requirements are defined in the procedures. Consideration is given for the need to establish processes and documents, and obtain resources specific to new products as they are developed or during contract review.

7.1.1 Referenced Procedures

SOP1100 – QUALIFICATION/VALIDATION

SOP1110 – FMEA

SOP1120 – PRE-PRODUCTION QUALITY AND PLANNING

SOP1170 – MANUFACTURING

SOP1180 - PART NUMBER / CLASSIFICATION / LOT NUMBER ASSIGNMENT

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## **7.2 CUSTOMER RELATED PROCESSES**

7.2.1 (Determination of Requirements Related to the Product) - Product requirements at Medbio are typically defined during the quotation process, where Sales and Engineering confer with the customer to identify the unique requirements for each part/product.

During the quotation process, requirements specified by the customer, including delivery and post-delivery activities are defined. Requirements not stated by the customer but necessary for specified or intended use, where known, are identified by both Sales and Engineering. Quality Engineering also identifies statutory and regulatory requirements related to the product. Medbio does not perform any user training on finished devices. Any additional requirements determined by internal organizations are normally communicated at design review meetings.

7.2.2 (Review of Requirements Related to the Product) - Before committing to the customer, Medbio personnel review the customer's requirements related to the product to ensure all requirements can be met.

These include reviews of quotations before submission, and reviews of orders or change orders before acceptance.

The purpose of these reviews is to determine if the product requirements are adequately defined, any requirements differing from those previously agreed to are resolved, applicable regulatory requirements are met, and that Medbio has the ability to meet the defined requirements for both the product and delivery. Verbal orders for production-intent parts are not accepted by Medbio.

Sales and Engineering process change orders or contract amendments to ensure these items are reviewed by the appropriate departments and that work orders, sales orders and any other documents are updated and affected personnel are made aware of the changes. These reviews are defined in the Quotation and Contract Review procedures, and monitored with Phase Reviews. Required records are also defined in these processes.

### **7.2.3 Communication**

In keeping with our commitment to customer satisfaction, Medbio views effective customer communication as an essential element of customer satisfaction. Appropriate handling of communications can reduce customer dissatisfaction in situations and in many cases turn a dissatisfying scenario into a satisfying experience.

The Sales department is responsible for establishing communication methods to ensure inquiries, contracts or order handling (including amendments), advisory notices, and customer feedbacks, including customer complaints, are handled expeditiously and professionally. Sales also has primary responsibility for developing product information and literature, and manages the corporate web site. Where necessary, the Regulatory group will communicate with regulatory authorities and the organization will work with customers to address any applicable field actions.

### **7.2.4 Referenced Procedures**

SOP1050 - QUOTATION

SOP1060 - SALES ORDERS

SOP1070 - CUSTOMER COMPLAINTS

SOP1080 - RETURNED GOODS AUTHORIZATION

SOP1120 – PRE-PRODUCTION QUALITY AND PLANNING

### **7.3 DESIGN AND DEVELOPMENT**

N/A – No product design will be performed at Medbio, Inc.

### **7.4 PURCHASING**

7.4.1 (Purchasing Process) - The purchasing process is essential to provide our customers with products that meet their requirements. Medbio ensures that purchased product conforms to specified purchase requirements; we accomplish this by controlling our supplier base and inspecting purchased product as required. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

It is the responsibility of the Purchasing Department and the Quality Manager to evaluate and select suppliers based on their ability to supply product in accordance with specified requirements, and based on the risk of the supplied product on the finished devices. Engineering may be called on to assist as required. Criteria for selection, evaluation and re-evaluation are defined in the Vendor Evaluation procedure. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

7.4.2 (Purchasing Information) – Medbio uses purchase orders (POs) to describe the product to be purchased, including where appropriate:

- Product specifications and their corresponding revisions
- Requirements for approval of product, procedures, processes and equipment
- Requirements for qualification of personnel
- Quality management system requirements

The reviewers of specifications at the time of release are responsible for ensuring the adequacy of specified purchase requirements before their communication to the supplier.

#### **7.4.3 Verification of Purchased Product**

Purchased items and materials are verified for correctness by the Receiving Department. If additional inspection is required, it is noted on the purchased component specification and the item is sent to Quality Assurance for inspection. Engineering will develop the purchased-component specification considering the risk of the item on the associated medical device(s). Any subsequent changes to purchased products will be similarly assessed prior to release into the Document Control system.

Should Medbio or any of our customers decide to perform verification at the supplier's premises, the verification arrangements and method of product release shall be stated in the purchasing information. Records of all purchasing activities will be maintained per the procedures.

#### **7.4.4 Referenced Procedures:**

SOP1000 – DOCUMENT CONTROL

SOP1130 - VENDOR EVALUATION

SOP1140 - PURCHASING

SOP1150 - RECEIVING AND INSPECTION

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## 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 (Control of Production and Service Provision) - Medbio plans, carries out, and monitors production activities under controlled conditions. Controls shall include, as applicable:

- Documented procedures for the control of production
- Qualification of infrastructure
- Documented inspection and testing requirements and procedures
- The availability and use of monitoring and measuring devices
- Documented labeling and packaging requirements and procedures
- Documented product release and delivery requirements and activities

All applicable manufacturing-related and part-specific documents will be maintained in batch records (Job Folders) that provide traceability, as well as the amount manufactured and approved for distribution. All production records will be verified and approved.

7.5.2 (Cleanliness of Product) – Medbio identifies general cleanliness and part handling requirements for all manufactured product, and where necessary, identifies additional requirements in the part-specific work instructions.

7.5.3 (Installation Activities) – Excluded

7.5.4 (Servicing Activities) – Excluded

7.5.5 (Particular requirements for sterile medical devices) – Excluded

7.5.6 (Validation of Processes for Production and Service Provision) - Engineering and Quality Engineering are responsible for ensuring any production-intent processes (i.e. non-prototype) are qualified or validated prior to running sale-able units. This is especially true for any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Qualification/Validation shall demonstrate the ability of these processes to achieve planned results.

Qualification/Validation documentation for these processes will include, as applicable:

- Defined criteria for review and approval of the processes
- Qualification of equipment and training of personnel
- Use of specific methods, procedures, testing, and acceptance requirements
- Where appropriate, statistical techniques and rationale for sample sizes
- Requirements for records
- Requirements for process changes and revalidation activities



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Medbio has procedures for the validation of computer software applications used in production, ensuring validation that is proportionate to the risk of the software on the business, the process, or the product. Reference Section 4.1.6 of this QM.

7.5.7 (Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems) – Medbio doesn't 'own' any sterilization cycles, and doesn't design the sterile barrier system for any product. As dictated by our customers, we may be required to seal trays or pouches, but all sterilization validations and package-design and shipping validations are the responsibility of the customer.

7.5.8 (Identification) - All personnel are responsible for identifying product, throughout the process, from receipt of material through shipment of the final product. Product identification will be provided by using the company's part numbering system to assign unique identification for all components and internally-manufactured parts. For all production-intent materials in the warehouse or production areas, labels are used as appropriate to clearly identify products and materials throughout the manufacturing process and in storage.

Personnel performing monitoring and measuring activities are responsible for clearly identifying the product status. To ensure that only items, assemblies, or final products that have passed required tests and/or inspections proceed to the next operation or process, all products or assemblies will be appropriately labeled, tagged, or stamped to properly indicate their inspection status. The inspection status shall clearly indicate RELEASED, REJECT, or HOLD as appropriate.

7.5.9 (Traceability) –

7.5.9.1 General - In products where component traceability is a requirement, the Lot Number will be used to record the unique identification of the traceable components used in the final product.

7.5.9.2 Particular Requirements for Implantable Medical Devices – Excluded

7.5.10 (Customer Property) - Medbio personnel shall exercise care with customer property while it is under our control or being used. The SOP for managing Customer Property identifies three primary categories: Customer-supplied materials, Customer-supplied tooling/fixtures, and Intellectual Property. The customer will be contacted if any of their property is lost, damaged, or found to be unsuitable. Records of these situations may be a letter to the customer or a memo to the customer file.

7.5.11 (Preservation of Product) - All personnel shall handle materials, components, and products in a manner that preserves the conformity of product during internal processing and up to the point of loading onto the shipping vehicle, where our responsibility ends. This preservation shall include identification, handling, packaging, storage, and protection.

Preservation shall also apply to the constituent parts of a product and includes items such as special storage requirements, Electro-Static Discharge (ESD) protection, and monitoring of shelf life. Details of appropriate preservation controls are included in Receiving procedures, Purchased Component Specifications, and where necessary in part-specific work instructions.

7.5.12 Referenced Procedures

SOP1100 - QUALIFICATION - VALIDATION

SOP1150 - RECEIVING AND INSPECTION

SOP1160 - PRODUCTION SCHEDULING

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SOP1170 - MANUFACTURING

SOP1180 - PART NUMBER CLASSIFICATION / LOT NUMBER ASSIGNMENT

SOP1200 - PRODUCT LABELING

SOP1210 - CUSTOMER PROPERTY

P2008 – RECEIVING PURCHASED GOODS

Q1002 – PRODUCT RELEASE PROCEDURE

## **7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT**

Engineering or our customers define monitoring and measuring requirements on product and component drawings and specifications. Monitoring and measuring requirements are also defined by Manufacturing and Engineering for process characteristics where required for process validation.

Personnel performing monitoring and measurement activities shall determine the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. The Quality department will provide assistance in selecting the appropriate device as required.

The Quality Department is responsible for the Calibration activities at Medbio. They are responsible for establishing and maintaining processes to ensure that monitoring and measurement can be carried out per product requirements, while taking into account the tolerances required for the measurement and the accuracy and precision of the instrument.

Where necessary to ensure valid results, measuring equipment shall be included in the calibration program. The calibration program ensures measuring equipment is:

- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded
- Adjusted or re-adjusted as necessary, and recorded
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance and storage

In addition, the Quality Department shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action (corrective and preventive) on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken before initial use and reconfirmed as necessary. Records of this confirmation shall be maintained along with calibration records through SOP1100 .

### 7.6.1 Referenced Procedures:

SOP1100 - QUALIFICATION / VALIDATION

SOP1220 - CONTROL OF MONITORING & MEASURING DEVICES

SOP1280 – CORRECTIVE ACTION

SOP1290 – PREVENTIVE ACTION

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## **8.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT**

### **8.1 GENERAL**

As part of our quality system and our commitment to continual improvement, Medbio, has planned and implemented the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the QMS , and to continually improve the effectiveness of the QMS. This includes determination of applicable methods, including statistical techniques, and the extent of their use, with the intention of converting data to information and presenting it in a suitable format for decision-making.

### **8.2 MONITORING AND MEASUREMENT**

8.2.1 (Feedback) - As one of the measurements of the performance of the QMS, Medbio monitors information relating to customer perception as to whether we have met their requirements. The methods for obtaining and using this information are defined in the Customer Satisfaction procedure. Customer-based metrics and production metrics are defined in the Management Responsibility procedure. Where trends indicate problems, resources will be assigned in relation to the risk posed on product safety and/or the organization.

8.2.2 (Complaint Handling) – Medbio has documented a procedure for handling all customer complaints, in a timely manner, including requirements for:

- Receiving and recording information
- Investigating the complaint and recording the results
- Handling of affected product
- Determination of need for formal corrective action

8.2.3 (Reporting to Regulatory Authorities) – While it is expected that Medbio’s customers will identify and communicate any medical device reporting events, Medbio has an advisory notice procedure in the event that a non-conformity is identified on product that has been shipped to the customer.

8.2.4 (Internal Audit) – Medbio conducts internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements for product realization, to the requirements of the ISO and FDA standards, and to the quality management system requirements; and to determine if the QMS is effectively implemented and maintained.

The Internal Audit Procedure details the requirements for the audit program including requirements that the audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The ISO Management Representative is responsible for the Internal Audit Program. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are further detailed in the Internal Audit Procedure.

The manager responsible for the area being audited shall ensure that actions are taken without undue delay to address findings.

8.2.5 (Monitoring and Measurement of Processes) - Department Managers and the ISO Management Representative are responsible for monitoring the effectiveness of the processes under

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their control to demonstrate the ability of the processes to achieve planned results. Correction and corrective action will be taken, as appropriate, to ensure conformity of the product when planned results are not achieved. Information from process monitoring will also be considered for continual improvement efforts.

Each process may require different measures depending on its nature. Examples of potential measures include: process capability, cycle times, efficiency and effectiveness measures, or cost reduction.

8.2.6 (Monitoring and Measurement of Product) – Medbio quality planning defines points at which the characteristics of products are monitored and measured to verify that product requirements have been met (see 7.1).

Inspection records will show evidence of conformity with the acceptance criteria. Appropriate sample sizes are to be inspected, as dictated by SOP1275 – STATISTICAL TECHNIQUES, or as dictated by the customer. Records will indicate the test equipment used and the person(s) authorizing release of product.

Release of our products or delivery of services shall not proceed until the activities defined in the quality plan have been satisfactorily completed. Any exceptions must be approved by management and, where applicable, by the customer.

#### 8.2.7 Referenced Procedures

SOP1020 – MANAGEMENT RESPONSIBILITY

SOP1070 – CUSTOMER COMPLAINTS

SOP1150 - RECEIVING AND INSPECTION

SOP1170 - MANUFACTURING

SOP1230 - CUSTOMER SATISFACTION

SOP1240 - INTERNAL QUALITY AUDITS

SOP1250 - MONITORING & MEASUREMENT OF PROCESS

SOP1270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT

SOP1275 - STATISTICAL TECHNIQUES

SOP1280 - CORRECTIVE ACTION

Q1002 – PRODUCT RELEASE PROCEDURE

### **8.3 CONTROL OF NONCONFORMING PRODUCT**

8.3.1 (General) - All product that does not conform to requirements shall be identified and controlled to prevent its unintended use or delivery. The Nonconforming Product Procedure, coupled with the MRB procedure, defines controls and related responsibilities and authorities for dealing with nonconforming product, including identification, documentation, segregation, evaluation, and disposition methods.

8.3.2 (Actions in Response to Nonconforming Product Detected Before Delivery) - Medbio deals with nonconforming product by one or more of the following ways:

- By taking action to eliminate the detected nonconformity;
- By authorizing its use, release or acceptance under Temporary Deviation or approval by Engineering and, where applicable, by the customer.

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Product accepted under Temporary Deviation must have documented justification, approval from customer for product-requirement variances, and meet regulatory requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained according to the Quality Records Procedure.

8.3.3 (Actions in Response to Nonconforming Product Detected After Delivery) - When nonconforming product is detected after delivery or use has started, Medbio will take action appropriate to the effects, or potential effects, of the nonconformity, and communicate with the customer(s) per the Advisory Notice procedure.

8.3.4 (Rework) - Medbio will perform rework and re-inspection per the documented procedures, taking into account the potential adverse effects of the rework on the product. When nonconforming product is corrected with a non-standard process, it shall be subject to re-verification to demonstrate conformity to the requirements. Records of reworks and re-inspections will be maintained per procedures.

8.3.5 Referenced Procedures:

SOP1260 - CONTROL OF NONCONFORMING PRODUCT

SOP1010 - QUALITY RECORDS

SOP1100 – QUALIFICATION / VALIDATION

Q1007 – MATERIAL REVIEW BOARD

Q1008 – ADVISORY NOTICES

## **8.4 ANALYSIS OF DATA**

The ISO Management Representative and department managers are responsible for determining, collecting and analyzing data using appropriate statistical techniques to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made.

This shall include data generated as a result of monitoring and measurement and from other relevant sources, including input from:

- Feedback
- Conformity to product requirements
- Characteristics and trends of processes and products including opportunities for improvement
- Suppliers
- Audits

Where analysis of data shows the QMS is not suitable, adequate, or effective, Medbio will use the data to make appropriate improvements, and maintain records of related analyses and activities.

8.4.1 Referenced Procedures

SOP1010 - QUALITY RECORDS

SOP1070 - CUSTOMER COMPLAINTS

SOP1230 - CUSTOMER SATISFACTION

SOP1260 - CONTROL OF NONCONFORMING PRODUCT

SOP1270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT

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## SOP1275 – STATISTICAL TECHNIQUES

### 8.5 IMPROVEMENT

8.5.1 (General) - Medbio personnel shall continually improve the suitability, adequacy, and effectiveness of the QMS (and the safety and performance of our customers' products where possible) by using the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review programs.

8.5.2 (Corrective Action) - The ISO Management Representative is responsible for managing the Corrective Action Program. As defined in the Corrective Action Procedures, all personnel are responsible for taking action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be implemented without undue delay, and be appropriate to the effects of the nonconformities encountered.

The Corrective Action Procedure defines requirements for:

- Reviewing nonconformities (including customer complaints)
- Determining the causes of nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur
- Determining, documenting, and implementing actions needed
- Verifying that corrective actions taken do not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the products we manufacture
- Reviewing the effectiveness of the corrective action taken
- Documenting and maintaining records of investigations and actions taken.

8.5.3 (Preventive Action) - The ISO Management Representative is responsible for managing the Preventive Action Program. As defined in the Preventive Action Procedures, all personnel are responsible for taking action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

The Preventive Action Procedure defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining, documenting, and implementing actions needed
- Verifying that preventive actions taken do not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the products we manufacture
- Reviewing effectiveness of the preventive action taken
- Documenting and maintaining records of investigations and actions taken.

8.5.4 Referenced Procedures

SOP1270 - DATA ANALYSIS AND CONTINUAL IMPROVEMENT

SOP1280 - CORRECTIVE ACTION

SOP1290 - PREVENTIVE ACTION

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## Quality Manual - Revision History

<b>Revision</b>	<b>DCN</b>	<b>Description of changes</b>	<b>Requested By</b>
A	051001	Initial Release	Patrick Eddy
B	061159	Chg ref ISO9001:2000 to ISO 13845:2003	John Kotwick
C	071038	Change Tillman Industries to Medbio, Inc.	Chris Williams
D	111344	Revise to reflect changes since last revision and issues raised as the result of the 2011 ISO13485 re-certification audit.	John Kotwick
E	141374	Improve the consistency/accuracy overall	Joe Szyperski
F	161523	Update/Clarify verbiage in Quality Policy and create as a separate form	Joe Szyperski
G	171582	Update QM to reflect 13485:2016 req'ts	Joe Szyperski
H	171602	Add outsourced processes in 4.1.5; add reference to security of records in 4.2.5	Joe Szyperski