



---

---

# Quality Manual

---

---




## Quality Manual

### Revision History

Revision #	Revision Date	Description of Revision	Originator
NA	12-22-03	Revised to address October 2003 BSI audit (ref. Report #4470363). Update organizational chart and title references throughout. Eliminate reference to ISO 9001 and EN 46001. Change Author to Originator on Revision page.	E. Verrall
NA	8-11-04	Revised to clarify multiple sections and reflect changes in practice.	E. Verrall
NA	1-25-05	Revise multiple sections that are inaccurate, add additional responsibilities, update org chart	C. LoTempio
1	8-9-05	Completely rewritten to reflect ISO 13485:2003 upgrade and to incorporate Ethox and STS Quality Manual into one document. The revision level is one (1) since the Ethox and STS Quality manual was merged.	C. Mocny
2	12-13-06	Updates to Quality Manual to include company division name changes; operation focus changes and reference changes.	J. Riggi
3	8-14-07	Update Quality Manual to include JPAL references and correct cross-reference table	J. Riggi
4	11-6-07	Added notation to step 2.1 to define that quality systems are assessed through the internal audit program in accordance to the listed regulations and standards. Added Reference to MHLW #169, Chapter 2 to the JPAL reference.	C. Dawson
5	3-18-09	Removed reference to Organization Charts (replaced with Attachment III) – it is not a requirement to include org charts in the Quality Manual. Added full titles to references Added Note to the References Section 2 Added Revision column to Revision History Table	C. Dawson
6	6-16-09	Revised Quality Policy and change in Management Representatives as a result of Ethox International, Inc. being acquired by MOOG Medical Devices Group (MMDG), added information to the company profile and updated processes to comply with current policies. Removed references to moist heat sterilization.	S. Marra C. Dawson

### Approvals:

S. Marra \_\_\_\_\_  \_\_\_\_\_ Date: 9/25/09  
 Management Representative

C. Dawson \_\_\_\_\_  \_\_\_\_\_ Date: 9-22-09  
 Management Representative  
 STS Life Sciences Division  
 MMC Sterilization Services Group



## Table of Contents

Company Profile	4	
1. Scope/Exclusions	5	
2. References	5	
3. Terms and Definitions	6	
4. Quality Management System	6	
4.1. General Requirements	6	
4.2. Documentation Requirements	7 & 8	
5. Management Responsibility	9	
5.1. Management Commitment	9	
5.2. Customer Focus	9 & 10	
5.3. Quality Policy	10	
5.4. Planning	10	
5.5. Responsibility, Authority, and Communication	11 & 12	
5.6. Management Review	12	
6. Resource Management	13	
6.1. Provision of Resources	13	
6.2. Human Resources	13	
6.3. Infrastructure	13	
6.4. Work Environment	14 & 15	
7. Product Realization	15	
7.1. Planning of Product Realization	15	
7.2. Customer-Related Processes	15 & 16	
7.3. Design and Development	16 & 17	
7.4. Purchasing	18	
7.5. Production and Service Provision	18 - 21	
7.6. Control of Monitoring and Measuring Devices	21 & 22	
8. Measurement, Analysis, and Improvement	22	
8.1. General	22	
8.2. Monitoring and Measurement	22 & 23	
8.3. Control of Nonconforming Product	23	
8.4. Analysis of Data	24	
8.5. Improvement (CAPA)	24 & 25	
Appendix I	Process Flow Chart	26
Appendix II	Quality Manual Cross-Reference Table	27 & 28
Appendix III	Responsibilities & Authorities Table	29 - 31



## Quality Manual

### **Company Profile**

Ethox International is a subsidiary of MOOG Medical Devices Group and includes the MMC Sterilization Services Group (MMC) and STS Life Sciences Division (STS). Ethox International operates a quality management system that satisfies the needs and meets or exceeds the expectations of our customers and regulatory bodies while maintaining and continuously improving the quality management system of Ethox International.

Ethox International specializes in the following business areas for medical, biotechnology, and pharmaceutical companies around the globe:

- Contract manufacturing of scientific and medical devices
- Ethylene oxide and moist heat contract decontamination and sterilization
- Laboratory services including analytical chemistry, microbiology, toxicology and packaging testing
- Design and manufacture of Ethox branded medical devices for use in Acute Care and Non-Acute care medical facilities throughout the world.

Ethox International's operations are divided as follows:

Buffalo, NY	Ethox medical products and contract manufacturing.
Erie, PA	Ethylene oxide sterilization and manufacturing services for Ethox medical and contract products.
Rush, NY	Laboratory services including microbiology, analytical chemistry, toxicology, and packaging testing.

Each operation maintains a quality assurance unit to ensure compliance with all requirements of the quality system that may be required in the facility.

### **History**

Ethox Corp. was established in 1966 and specialized in the design and manufacture of Ethox medical products and contract medical devices, contract sterilization and laboratory services (chemistry, microbiology, and packaging testing).

MMC became a wholly-owned subsidiary of Ethox Corp. in 1987 and provided 100% ethylene oxide sterilization services for Ethox Corp. as well as contract sterilization for the medical device industry

STS was acquired by Ethox Corp. in February 2005. STS was established in 1978, providing contract sterilization and validation services, as well as contract and support chemistry, microbiology, and toxicology testing. Early in the 1990's, STS acquired an assembly and packaging facility.

Ethox Corp. changed its name to Ethox International, Inc. in July 2005.

Ethox International Inc. became part of MOOG Medical Devices Group in January 2009.



## Quality Manual

### 1. Scope

- 1.1. The purpose of this manual is to define and describe the quality system, provide general procedures for all activities comprising the quality system, define the authorities and responsibilities of all personnel affected by the system and provide a vehicle to inform our customers of the specific controls that are in place at Ethox International to assure continued product and service quality.
- 1.2. The following requirements are not required based on Ethox International's current business practices:
  - 1.2.1. Post-Delivery Activities/Installation and Servicing (7.5.1.2.2 and 7.5.1.2.3)
  - 1.2.2. Post-Delivery Activities/Installation and Servicing are not required because Ethox supplies disposable devices that do not require post-delivery installation activities.

### 2. References

- 2.1. Ethox International's quality system (and assessed under the internal audit program) complies with the most recent revision of the following requirements and regulations which cover the design, product realization, sterilization, laboratory testing, delivery, and support of products and services:
  - 2.1.1. FDA 21 CFR Part 820 – Quality System Regulation
  - 2.1.2. FDA 21 CFR Part 58 – Good Laboratory Practice for Non Clinical Laboratory Studies
  - 2.1.3. FDA 21 CFR Part 210/211 – cGMP in Manufacturing, Processing, Packing, or Holding of Drugs and Finished Pharmaceuticals
  - 2.1.4. ISO 13485:2003 Medical Devices Quality Management Systems – Requirements for Regulatory Purposes
  - 2.1.5. ISO 11135:1994 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
  - 2.1.6. EN 550:1993 Sterilization of Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
  - 2.1.7. Council Directive 93/42/EEC
  - 2.1.8. Canadian Medical Devices Regulation (CMDR)
  - 2.1.9. Brazil Medical Devices Regulation
  - 2.1.10. Japan Pharmaceutical Affairs Law (JPAL) – MHLW Ordinance #169, Chapter 2.

**Note:** Site work instructions define the specific requirements of FDA 21 CFR Part 58 and Part 210/211 for the STS Life Sciences Division and the MMC Sterilization Services Group that may not be defined in the Quality Manual

### 3. Terms and Definitions

- 3.1. Management with Executive Responsibility (MER) –Site Director and their direct reports.
- 3.2. Management Representative – Site Quality Manager for each location.
- 3.3. Department Head– Highest level of authority within a department. The term Team Leader is also used in Ethox documents with this definition.
- 3.4. Ethox International – Ethox, MMC, STS



## Quality Manual

- 3.5. Product – product or service (i.e., laboratory testing, contract sterilization) provided by Ethox International
- 3.6. FDA - Food and Drug Administration
- 3.7. CFR - Code of Federal Regulations
- 3.8. GLP - Good Laboratory Practice
- 3.9. GMP – Good Manufacturing Practice
- 3.10. QSR - Quality Systems Regulation
- 3.11. ISO - International Organization for Standardization
- 3.12. DMR - Device Master Record
- 3.13. S&T - Sterilization and Testing Protocol
- 3.14. BOM - Bill of Material
- 3.15. QCI - Quality Control Inspection Checklist
- 3.16. DHR - Design History Record
- 3.17. DHF - Design History File
- 3.18. STS - Sterilization Technical Services
- 3.19. EN - European Standard
- 3.20. Documented Procedure - specific way to carry out an activity or a process which is documented (i.e. SOP, WI, Traveler)
- 3.21. Record - states results achieved or providing evidence of activities performed.

### **4. Quality Management System**

#### **4.1. General Requirements**

- 4.1.1. Ethox International has established, maintains, and ensures the effectiveness of a documented quality management system designed and implemented to fulfill the requirements of standards and regulations described in section 2.1. Ethox International maintains the effectiveness of the quality management system through a range of activities such as internal audits, management review, corrective and preventive actions and external assessments.
- 4.1.2. Planning for quality is a cooperative effort amongst all of Ethox International's departments. All personnel who manage, perform, and verify work affecting quality are responsible for identifying the processes needed for the quality management system and for implementing the system throughout the organization.
  - 4.1.2.1. Appendix I provides a flow chart detailing the interaction between the processes of the quality management system.
- 4.1.3. Management determines the sequence and interaction of processes required to ensure that customer needs are met and all government regulations and quality requirements are effectively maintained and continuously improved.
- 4.1.4. Designation of key quality indicators and methods of verification for both purchased and produced components as well as the operation and control of quality management system processes are established to ensure effectiveness.
- 4.1.5. Resource allocation is primarily the responsibility of the Management with Executive Responsibility (MER), which ensures the availability of resources and information necessary to support the operation and monitoring of these processes.
- 4.1.6. The quality system is monitored, measured, and analyzed to identify and implement actions necessary to achieve planned results and maintain the effectiveness of quality management system processes.



## Quality Manual

4.1.7. Whenever outsourcing of resources is undertaken for processes that affect product conformity, appropriate controls are put in place to ensure requirements are met.

### 4.2. Documentation Requirements

#### 4.2.1. General

- 4.2.1.1. The quality management system documentation includes a four-tiered system as defined in the table below, which creates a framework that clearly defines the planned control of materials, processes, verification, and personnel qualification. This provides our customers with confidence that the design, manufacture, sterilization, and testing of company products and services are performed in a well-defined and controlled environment.
- 4.2.1.2. Ethox International has established and maintains the Quality Manual as the highest level document within the organization.
- 4.2.1.3. Appendix II provides a cross-reference between the Quality Manual, applicable standards references, and company documents, which describe the processes implemented within Ethox International.
- 4.2.1.4. Section 2 References; define all external standards and regulations Ethox International complies with.

Four Tier Quality Management System Documentation Structure

Tier	Document Type	Items Addressed	Document Owner
I	<b>Quality Manual</b>	Quality Policy and Quality Objectives	Ethox International Corporate
II	Standard Operating Procedures (SOPs)	Requirements of applicable standards and regulations	Ethox International Corporate
III	Work Instructions, Test Methods, Forms, Sterilization Agreements, Material Specifications, Drawings, DMR's, S&T's, BOM's, Travelers, QCI's, etc.	Effective planning, operation, and control of processes	Ethox International Site Documents
IV	Quality Records (e.g. DHR's, Validation reports, Test reports, Inspection reports, Computer Programs, Databases, DHF, Technical File, etc.)	Records required by applicable international, national, and regional standards & regulations	Ethox International Site Documents

#### 4.2.2. Control of Documents

The concise and accurate documentation of all procedures is essential to the effectiveness of the Ethox International quality management system. Document and data control procedures are necessary to provide efficient information management at all levels. The purpose of this section is to provide an overview of information management principles and policies.



## Quality Manual

- 4.2.2.1. The department management reviews and ensures that all relevant documents are adequate and accurate prior to issue. Approval of the document must include signature and date.
  - 4.2.2.2. Current issues of all relevant versions of the applicable controlled documents are made available at each specified point of use. Area management ensures employees are aware of the current procedure status at all times.
  - 4.2.2.3. Documents are reviewed and updated by the applicable department management as necessary and re-approved as required. Changes and current revisions are identified.
  - 4.2.2.4. Obsolete documents are removed from all issued locations or, if needed for process reference purposes, clearly marked as Obsolete or equivalent.
  - 4.2.2.5. Obsolete documents are kept for a defined period of time for legal, research, or other legitimate purposes.
  - 4.2.2.6. Documents that come into Ethox International from an outside source that become a record, are identified and controlled, including the distribution of such documentation.
  - 4.2.2.7. Any proposed changes to controlled documents are reviewed and approved prior to issuance. Any appropriate functional approvers, internal or external to Ethox International, are included in the review process. When approved, the changes are clearly identified in the new document.
- 4.2.3 Control of Records
- 4.2.3.1 Effectiveness of the quality management system depends on established and maintained efficient record keeping that provides evidence of conformity to requirements.
  - 4.2.3.2 All records are legible, readily identifiable, and retrievable
  - 4.2.3.3 Documented procedures have been established to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.
  - 4.2.3.4 Quality Department head or designee maintains an accurate list of all records and establishes specific record locations and document retention cycles. The retention times are established after consideration of potential product liability, civil statutes, and regulatory requirements.
  - 4.2.3.5 Ethox medical products documents are usually not supplied to any customer or customer's representative, except if such disclosure is a contractual agreement. Ethox International may; however, at its sole discretion, release such information on a case-by-case basis.

## 5 Management Responsibility

### 5.1 Management Commitment

- 5.1.1 Ethox International is a producer of high quality products and services that meet or exceed the customers' requirements and expectations. This goal is achieved through management's commitment to providing security for company employees as well as the financial viability of Ethox International.



## Quality Manual

- 5.1.2 MER which is ultimately responsible for establishing, implementing, maintaining, and continuously improving the quality system, realizes this objective by providing employees with the best tools, necessary training, and facilities to complete the job right the first time.
- 5.1.3 MER's responsibilities include:
- Establishing a quality policy
  - Communicating to the organization the importance of determining and meeting customer needs as well as statutory and regulatory requirements
  - Defining the organizational structure, assigning authorities and responsibilities
  - Creating an environment that encourages the involvement and development of people
  - Defining quality objectives
  - Appointing a Management Representative
  - Determining if the interaction of processes is effective, identifying hazards and managing risks, reviewing the quality system during Management Review
  - Making available the resources and personnel necessary to maintain and continuously improve the quality system's effectiveness.

## 5.2 Customer Focus

- 5.2.1 MER ensures that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction through the determination of requirements related to the product or service provided. This is typically achieved through the following:
- 5.2.1.1 Determining the requirements specified by the customer, including the requirements for delivery and post-delivery activities through past history, experience, and/or customer needs.
- 5.2.1.2 Determining the requirements not stated by the customer but necessary for specified use or known and intended use through past history, experience and/or customer needs.
- 5.2.1.3 Determining the regulatory requirements related to the product or service.
- 5.2.1.4 Monitoring information relating to customer perception as to whether Ethox International has fulfilled customer requirements through customer satisfaction, trend analysis, rejections, performance, on-time delivery, etc.
- 5.2.1.5 Promoting continual learning and skills training to employees for quality management system awareness.
- 5.2.1.6 Identifying customers and maintaining a balanced response to their needs.
- 5.2.1.7 Translating identified needs into requirements.
- 5.2.1.8 Communicating requirements throughout Ethox International.
- 5.2.1.9 Focusing on process improvement thus ensuring value.



## Quality Manual

### 5.3 Quality Policy

- 5.3.1 Ethox International's Quality Policy is stated below and is posted throughout the facilities to communicate the commitment to quality within the organization. The Quality Policy provides a framework for establishing and reviewing quality objectives and is reviewed periodically for continued suitability. The Quality Policy is a common policy across all of the MOOG Medical Devices Group's operating sites.

#### Quality Policy

The Medical Devices Group designs, produces, markets, sells and distributes medical related products, services, and technologies that improve the lives of the healthcare providers and patients who use them. We accomplish this by expertly designing and building dependable products and services, effectively applying world-class quality standards in a compassionate, collaborative work environment, continually improving our products, services and processes by empowering our employees. The products we sell, the services we provide and our operations fulfill the laws and regulations that relate to our business.

### 5.4 Planning

#### 5.4.1 Quality Objectives

- 5.4.1.1 MER ensures that quality objectives, including those needed to meet requirements for product or service, are established at relevant functions and levels of Ethox International. These requirements are communicated to employees through employee communication, training, announcements, and company meetings.
- 5.4.1.2 Quality objectives are measurable with appropriate time frames for completion and are consistent with the Quality Policy. Quality objective metrics are reported to MER on a consistent basis for review and determination if actions are necessary to address areas of concern.

#### 5.4.2 Quality Management System Planning

- 5.4.2.1 Quality management system planning consists of the implementation, updating, and maintenance of this Quality Manual and all supporting specifications and procedures. Customer and supplier feedback, as supplied through formal reports, performance reviews, during audits or through surveys are considered during the update reviews of this document. The approach and deployment of quality planning includes safeguarding the integrity of the quality management system to ensure the system is maintained effectively when changes are planned and implemented. These may include, as appropriate:
- 5.4.2.1.1 Short- and long-term plans with goals for improving quality and customer satisfaction. Performance of these goals are monitored and reported. Examples include: Product quality, cycle time, scrap costs, delivery commitments.
  - 5.4.2.1.2 Maintaining methods for disaster recovery
  - 5.4.2.1.3 Cross-functional teams



## Quality Manual

- 5.4.2.1.4 Inspection plans/test plans
- 5.4.2.1.5 Process validation
- 5.4.2.1.6 Equipment qualifications
- 5.4.2.1.7 Identification of customer specified characteristics
- 5.4.2.1.8 Internal audits
- 5.4.2.1.9 Strategic and business planning
- 5.4.2.1.10 Consideration of safety issues
- 5.4.2.1.11 Utilization of mistake proofing methodologies when planning processes, facilities, equipment and tooling
- 5.4.2.1.12 Regulatory and industry requirements

### 5.5 Responsibility, Authority, and Communication

#### 5.5.1 Responsibility and Authority

- 5.5.1.1 MER has established and communicated the organizational structure, including definitions of responsibilities and authorities.
- 5.5.1.2 A quality assurance unit is established with a definition of interrelations of all personnel who manage, perform, and verify work affecting quality. This quality unit has the independence and authority necessary to perform these tasks.
- 5.5.1.3 Appendix III is table that defines Responsibilities and authorities within the organization and provides an overview of Ethox International's management structure.

#### 5.5.2 Management Representative

- 5.5.2.1 The Management Representative for Ethox International is the Site Quality Manager.
- 5.5.2.2 The Management Representative has the authority and responsibility to ensure that the quality management system requirements are established, implemented, maintained, continuously improved, and effective; and that the systems complies with the requirements of standards and regulations described in section 2.1 and other applicable local, state, national, and international regulations.
- 5.5.2.3 The Management Representative reports on the effectiveness and any needs for improvement of the Quality System to the MER.
- 5.5.2.4 The Management Representative ensures the promotion and awareness of regulatory and customer requirements throughout the organization.

#### 5.5.3 Internal Communication

- 5.5.3.1 MER ensures that the appropriate communication processes are established and that communication takes place regarding the effectiveness of the quality management system.
- 5.5.3.2 Communication may be achieved through internal auditing, training, meetings, non-conformance reports, management reviews, and any other tools that may be developed and implemented to monitor the effectiveness of the quality system or employ continual improvements. The communication documentation may include any of the following: audit reports, analysis of data, employee training, management communication in working areas, bulletin boards, reports, etc.



## Quality Manual

### 5.6 Management Review

- 5.6.1 MER reviews various aspects of the quality system at planned intervals. More frequent reviews are made if determined necessary by operational conditions or systematic quality process failures. The purpose of these reviews is to assess the adequacy, effectiveness and continuing suitability of the quality system in meeting regulatory requirements, the quality policy, and quality objectives.
- 5.6.2 The review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.
- 5.6.3 Management Review is chaired by the Management Representative and attended by MER. The results of Management Review are documented and circulated to all members of the review team. Each is responsible for implementing remedial, corrective, or preventive action in areas under his/her control.
- 5.6.4 Inputs to Management Review include at a minimum information related to:
  - 5.6.4.1 Results of audits
  - 5.6.4.2 Customer feedback
  - 5.6.4.3 Process performance and product conformity
  - 5.6.4.4 Status of Preventive and Corrective Actions
  - 5.6.4.5 Follow-up actions from previous Management Reviews
  - 5.6.4.6 Changes that could affect the quality management system
  - 5.6.4.7 Recommendations for improvement, and
  - 5.6.4.8 New or revised regulatory requirements
- 5.6.5 Outputs from Management Reviews shall include any decisions and actions related to:
  - 5.6.5.1 Improvements needed to maintain the effectiveness of the quality management system and its processes (i.e. CAPA)
  - 5.6.5.2 Improvement of product related to customer requirements, and
  - 5.6.5.3 Resource needs.

## 6 Resource Management

### 6.1 Provision of Resources

- 6.1.1 Management determines and provides the resources needed to implement the quality management system to maintain and continually improve its effectiveness, enhance customer satisfaction by meeting or exceeding customer requirements, and meeting regulatory requirements.
- 6.1.2 Resource allocation is primarily the responsibility of the MER; and begins at the yearly budgeting process and continues throughout the year as the business climate changes. It is the responsibility of department management to ensure that they identify and allocate the appropriate resources for quality related activities.

### 6.2 Human Resources

- 6.2.1 It is Ethox International's policy to determine the necessary competence level and ensure that all personnel possess the necessary training, skills, experience, and education to perform their assigned responsibilities adequately. Written job descriptions for each position contain the minimum education and skills requirements of that position.
- 6.2.2 Competence, Awareness, and Training



## Quality Manual

- 6.2.2.1 The training program is designed to clearly determine the competence of personnel performing work that affects product quality. Department management identifies and organizes training for his or her respective employees and is responsible to ensure that each employee receives this training and that the training is appropriately documented.
- 6.2.2.2 All employees are thoroughly oriented and properly trained in the tasks and functions they are expected to perform. It is a management responsibility to ensure personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and to provide or arrange all necessary on the job training. A quality failure attributed to a lack of employee training is unacceptable under any circumstances.
- 6.2.2.3 All new employees undergo an orientation session to generate an awareness of Ethox International's commitment to quality management, including its Quality Policy and procedures and to indoctrinate new employees of the benefits of working within the quality system.
- 6.2.2.4 Employees are trained in the Quality System Regulation and relevant international quality system standard requirements applicable to their specific job functions
- 6.2.2.5 Training records including education, skills, and experience are maintained for all employees including contract and temporary employees who are hired for short-term, long-term or significant assignments.
- 6.2.2.6 All actions taken toward training are evaluated for effectiveness through observance of daily job performance, appropriate on-the-job training documentation, and quizzes given during classroom training or annual job performance evaluations.

### 6.3 Infrastructure

- 6.3.1 Management determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes:
  - 6.3.1.1 Buildings, workspaces, and associated utilities
  - 6.3.1.2 Process equipment, both hardware and software, and
  - 6.3.1.3 Supporting services such as transport or communications.
- 6.3.2 The process for defining the infrastructure necessary for achieving effective and efficient product realization can include the following:
  - 6.3.2.1 Provision of an infrastructure defined in terms such as objectives, function, performance, availability, cost, safety, security, and renewal.
  - 6.3.2.2 Design, development, construction of equipment which is installed and located to facilitate proper operation, adjustment and maintenance.
  - 6.3.2.3 Development and implementation of maintenance methods to ensure that the infrastructure continues to meet Ethox International's needs, these methods consider the type and frequency of maintenance and verification of operation of each infrastructure element based on its criticality and usage. Records of maintenance activities are maintained.
  - 6.3.2.4 Evaluation of the infrastructure against the needs and expectations of interested parties.
  - 6.3.2.5 Consideration of environmental issues associated with infrastructure such as conservation, pollution, waste, and recycling.

## **6.4 Work Environment**

- 6.4.1 Management determines and maintains the work environment needed to achieve conformity to product requirements. The work environment shall have a positive influence on motivation, satisfaction, and performance of people in order to provide continuity in performance and development.
- 6.4.2 Requirements for the work environment are determined by any of the following:
  - 6.4.2.1 Processes in a given location.
  - 6.4.2.2 Requirements for health, cleanliness, and clothing of personnel if contact between personnel and product or work environment could have a negative affect on the quality of the product or service.
  - 6.4.2.3 Documented procedures for monitoring and controlling the work environment where conditions could have an adverse affect on product or service quality.
  - 6.4.2.4 Requirements for appropriate training and supervision for personnel required to work temporarily under special environmental conditions within the work environment.
  - 6.4.2.5 Where appropriate, special arrangements are established and documented to control potentially contaminated or contaminated product to prevent contamination of other products, work environment, or personnel.
  - 6.4.2.6 Level of skill and number of employees working in a given area.
  - 6.4.2.7 Type of environment, heat, humidity, light, and air
  - 6.4.2.8 Cost of equipment
  - 6.4.2.9 Safety factors associated with process or equipment
  - 6.4.2.10 Levels or supervision
  - 6.4.2.11 Ergonomics
- 6.4.3 Department managers and personnel are expected to maintain their work areas and, if areas are found unsuitable or have changed in any way that is considered unfit, they shall be corrected immediately and restored back to their intended use and level of functioning.

## **7 Product Realization**

### **7.1 Planning of Product Realization**

- 7.1.1 Processes needed for product realization are planned and developed. Planning of product realization is consistent with the requirements of other processes of the quality management system.
- 7.1.2 When planning product realization, Ethox International determines the following as appropriate:
  - 7.1.2.1 Quality objectives and requirements for the product.
  - 7.1.2.2 The need to establish processes, documents, and provide resources specific to the product.
  - 7.1.2.3 Required verification, validation, monitoring, inspection, and test activities specific to the product acceptance.
  - 7.1.2.4 Records needed to provide evidence that the realization process and resulting product fulfill requirements.
- 7.1.3 Outputs of planning are documented appropriately for Ethox International's method of operations and controlled through documentation requirements.



## Quality Manual

7.1.4 Where appropriate, documented requirements for risk management throughout the product realization process are established and records are maintained.

### 7.2 Customer Related Processes

7.2.1 Determination of Requirements related to the Product – Management determines and ensures that:

7.2.1.1 Requirements specified by the customer can be met, including requirements for delivery and post delivery activities

7.2.1.2 Requirements not stated by the customer but necessary for specified use or known and intended use to the final product can be met.

7.2.1.3 Statutory and regulatory requirements related to the product can be met.

7.2.1.4 Additional requirements determined necessary by Ethox International based on experience, knowledge, and history of the product can be met.

7.2.2 Review of Requirements

7.2.2.1 The purpose of contract review is to define and document customer requirements in order to identify and resolve any differences in the customer's expectations and Ethox International's ability to meet those expectations. It is also to guarantee that Ethox International has the resources to meet the contract or order specifications. Departmental management ensures the technical and quality requirements are reviewed.

7.2.2.2 All proposals and contracts are reviewed prior to the submission of Ethox International's commitment to supply a product/service to the customer and ensure:

7.2.2.2.1 Product requirements are defined and accepted, including special requirements.

7.2.2.2.2 Contract or order requirements differing from those previously expressed are resolved and accepted.

7.2.2.2.3 Ethox International has the ability to meet the defined requirements.

7.2.2.2.4 The delivery schedule and pricing has been agreed to.

7.2.2.2.5 Any use of subcontractors has been pre-approved by the customer.

7.2.2.2.6 Any special skills or training of personnel have been identified.

7.2.2.3 Where the customer provides no documented statement of requirements, the customer requirements are confirmed by management and the customer and documented before accepting the order.

7.2.2.4 Any contract change, order amendments, specification changes, product requirements, or delivery variations to an existing order or contract, are subjected to the contract review stated above. The changes received from the customer are clearly identified, documented, and forwarded to the respective department(s) and/or subcontractors.

7.2.2.5 Records of the results of the review and actions arising from the review are maintained.

7.2.3 Customer Communication

7.2.3.1 Management determines and implements effective arrangements for communicating with customers relative to product information; inquiries, contacts or order handling, including amendments; customer expectations, special requirements, or arrangements that may be



## Quality Manual

necessary; customer feedback, including customer complaints; advisory notices.

- 7.2.3.2 Communication with customers is documented as required and these communications become part of the records. Communications requiring documentation are those requiring a change to product or process, procedures, corrective action, scheduling changes.

### 7.3 Design and Development

#### 7.3.1 Design and Development Planning

- 7.3.1.1 Ethox International has established documented procedures for design and development. Ethox International plans and controls the design and development of products.
- 7.3.1.2 During the design and development planning, Ethox International determines the design and development stages; input, output, the review, verification, validation, and design transfer activities that are appropriate for each design and development stage, and assigns responsibilities and authorities for design and development projects.
- 7.3.1.3 Ethox International manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
- 7.3.1.4 Planning output is documented and updated as appropriate during the progression of design and development projects.

#### 7.3.2 Design and Development Inputs

- 7.3.2.1 Ethox International has established documented procedures for design input. Inputs related to product requirements are determined and records maintained. Inputs are reviewed for adequacy and approved. Requirements are complete, unambiguous, and not in conflict with each other. Inputs include:
  - 7.3.2.1.1 Functional, performance, and safety requirements according to the intended use.
  - 7.3.2.1.2 Applicable statutory and regulatory requirements.
  - 7.3.2.1.3 Information derived from previous similar designs, where applicable.
  - 7.3.2.1.4 Other requirements essential for design and development.
  - 7.3.2.1.5 Outputs of risk management.

#### 7.3.3 Design and Development Outputs

- 7.3.3.1 Ethox International has established documented procedures for design output. Outputs of design and development are provided in a form that enables verification against the design and development input and are approved prior to release.
- 7.3.3.2 Outputs will meet the input requirements for design and development, provide appropriate information for purchasing, production, and service provision (if applicable), contain or reference product acceptance criteria and specify the characteristics of the products that are essential for its safe and proper use.
- 7.3.3.3 Records of design and development outputs are maintained and may include specifications, manufacturing procedures, engineering drawings, and engineering or research log books.

#### 7.3.4 Design and Development Review



## Quality Manual

- 7.3.4.1 Ethox International has established documented procedures for design review. Systematic reviews of design and development are performed at suitable stages in accordance with planned arrangements to evaluate the ability of the results of design and development to meet requirements and to identify any problems and propose necessary actions.
- 7.3.4.2 Review participants include representatives of functions concerned with the design and development stages being reviewed as well as other subject matter experts.
- 7.3.4.3 Records of results of reviews and any necessary actions are maintained.
- 7.3.5 Design and Development Verification
  - 7.3.5.1 Ethox International has established documented procedures for design verification. Verification is performed in accordance with planned arrangements to ensure that the design and development outputs meet the input requirements. Records of the results of verification and any necessary actions are maintained.
- 7.3.6 Design and Development Validation
  - 7.3.6.1 Ethox International has established documented procedures for design validation. Design and development validation is performed in accordance with planned arrangements prior to the delivery or implementation of the product to ensure that the resulting product is capable of meeting the requirements of the specified application or intended use.
  - 7.3.6.2 As part of design and development validation, clinical evaluations and/or evaluation of performance of the medical device as required by national or regional regulations are performed.
  - 7.3.6.3 Records of validation results and any necessary actions are maintained.
- 7.3.7 Control of Design and Development Changes
  - 7.3.7.1 Design and development changes are identified, reviewed, verified, validated, as appropriate, and approved prior to implementation with records being maintained to include any necessary actions as a result of these activities. This review shall include evaluation of the effect of the changes on constituent parts and product already delivered.
- 7.3.8 Design Transfer
  - 7.3.8.1 Ethox International has established documented procedures for design transfer. Design transfer is provided in a form that enables verification that the device design is correctly translated into production specifications
- 7.3.9 Design History File (DHF)
  - 7.3.9.1 Ethox International establishes and maintains a DHF for each type of device in which Ethox is responsible for the Design Controls.

## 7.4 Purchasing

- 7.4.1 Purchasing Process
  - 7.4.1.1 Ethox International has established documented procedures to ensure purchased product conforms to specified purchase requirements.
  - 7.4.1.2 The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on the final product realization.
- 7.4.2 Purchasing Information



## Quality Manual

- 7.4.2.1 Purchasing records describes the product to be purchased including, where appropriate, requirements for approval of the product, procedures, processes, and equipment; requirements for the qualification of personnel; quality management system requirements.
- 7.4.2.2 Purchase orders are reviewed and approved by specified personnel prior to transmission to establish that all information is correct and to ensure the adequacy of the specified purchase requirements.
- 7.4.2.3 Ethox International maintains relevant purchasing information to ensure appropriate traceability activities.
- 7.4.3 Verification of Purchased Products
  - 7.4.3.1 Ethox International has established and implemented the necessary inspection activities to ensure that purchased product meets specified purchase requirements.
  - 7.4.3.2 If Ethox International, or a customer, intends to perform verification at a supplier's premises, Ethox International will state the intended verification arrangements and method of product release in the purchasing information.
  - 7.4.3.3 Records of product verification are maintained.

## 7.5 Production and Service Provision

- 7.5.1 Control of Production and Service Provision
  - 7.5.1.1 General Requirements – Ethox International plans and carries out production and service provision under controlled conditions which include, as applicable:
    - 7.5.1.1.1 The availability of information to describe the characteristics of the product.
    - 7.5.1.1.2 The availability of documented procedures, requirements, work instructions, reference materials, and reference measurement procedures as necessary.
    - 7.5.1.1.3 The use of suitable equipment.
    - 7.5.1.1.4 The availability and use of monitoring and measuring devices.
    - 7.5.1.1.5 The implementation of monitoring and measurement.
    - 7.5.1.1.6 The implementation of release, delivery, and post-delivery activities (if applicable).
    - 7.5.1.1.7 The implementation of defined operations for labeling and packaging.
    - 7.5.1.1.8 Ethox International establishes and maintains a record for each batch of medical devices to provide traceability and to identify the amount manufactured and amount approved for distribution. The batch record is verified and approved.
  - 7.5.1.2 Control of Product and Service Provision – Specific Requirements
    - 7.5.1.2.1 Cleanliness of Product and Contamination Control – Ethox International has established documented requirements for cleanliness of product if: product is cleaned by Ethox International prior to sterilization and/or its use, product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, product is supplied to be used non-sterile and its cleanliness is of significance in use, or



## Quality Manual

- process agents are to be removed from the product during manufacture.
- 7.5.1.2.2 Installation Activities – Does not apply, see section 1.2
  - 7.5.1.2.3 Servicing Activities – Does not apply, see section 1.2
  - 7.5.1.3 Particular Requirements for Sterile Medical Devices – Records of the process parameters for sterilization processes used for each sterilization cycle are maintained and are traceable to each production batch of medical devices.
  - 7.5.2 Validation of Processes for Production and Service Provision
    - 7.5.2.1 General Requirements – Ethox International validates processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. Ethox International has established arrangements for these processes including as applicable:
      - 7.5.2.1.1 Defined criteria for review and approval of the processes
      - 7.5.2.1.2 Approval of equipment and qualification of personnel
      - 7.5.2.1.3 Use of specific methods and procedures
      - 7.5.2.1.4 Requirements for records and revalidation
      - 7.5.2.1.5 Documented procedures are established for the validation of the application of computer software and changes to such software and/or its application for production and service provision that affect the ability of the product to conform to specified requirements. Such software shall be validated prior to initial use.
      - 7.5.2.1.6 Records of validation shall be maintained.
    - 7.5.2.2 Particular Requirements for Sterile Medical Devices – Procedures are established for the validation of sterilization processes. Sterilization processes are validated prior to initial use. Records of validation of each sterilization process are maintained.
  - 7.5.3 Identification and Traceability
    - 7.5.3.1 Identification – Ethox International has procedures for identifying product throughout the product realization process. Procedures are implemented which ensure that medical devices returned to Ethox International are identified and distinguished from conforming product.
    - 7.5.3.2 Traceability
      - 7.5.3.2.1 General - Documented procedures are implemented to define the extent of product traceability and the records required. Where traceability is required, Ethox International controls and records the unique identification of the product.
      - 7.5.3.2.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices – Records for traceability are documented for all components, materials, and work conditions that could cause medical devices not to satisfy their requirements. Where agents or distributors are used in the distribution of any Ethox medical products in this category, Ethox International requires that records be maintained to allow



## Quality Manual

traceability and that these records are available for inspection by Ethox International. Records of the name and address of the shipping package consignee are maintained.

7.5.3.3 Status Identification – Ethox International identifies the product status with respect to monitoring and measuring results. This identification is maintained throughout production and storage to ensure that only product that has passed the required inspections and tests or authorized concession is released.

7.5.3.4 Label Control –

7.5.3.4.1 Integrity - Labels are printed and applied so as to remain legible and affixed during processing, storage, handling, distribution, and use.

7.5.3.4.2 Inspection – Labeling is not released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage and handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination is documented.

7.5.3.4.3 Storage – Labeling is stored in a manner that provides proper identification and is designated to prevent mix-ups.

7.5.3.4.4 Operations – Labeling and packaging operations are controlled to prevent mix-ups and labeling used for each production unit, lot, or batch is documented.

7.5.3.4.5 Control Number – Where a control number is required by 21 CFR 820.65, that control number will be on or will accompany the batch of devices through distribution.

7.5.4 Customer Property

7.5.4.1 Ethox International exercises care with customer property including intellectual property or confidential health information while it is under the control of Ethox International. Ethox International identifies, verifies, protects, and safeguards customer property provided for use or incorporation into the product. If customer property is lost, damaged, or otherwise found to be unsuitable for use, this will be reported to the customer and records maintained.

7.5.5 Preservation of Product

7.5.5.1 Ethox International has established documented procedures for preserving conformity of product during internal processing and delivery to the intended destination.

7.5.5.2 This preservation includes identification, handling, packaging, storage, and protection and also applies to the constituent parts of a product.

7.5.5.3 Documented procedures are established for the control of product with limited shelf-life or requiring special storage conditions. Such special storage conditions are controlled and recorded.

## 7.6 Control of Monitoring and Measuring Devices

7.6.1 Ethox International determines the monitoring and measurement to be undertaken and the monitoring and measuring devices required to provide evidence of conformity of product to determined requirements.



## Quality Manual

- 7.6.2 Documented procedures are implemented to ensure that monitoring and measurement is carried out in a manner that is consistent with these requirements.
- 7.6.3 To ensure valid results, necessary equipment will be:
  - 7.6.3.1 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 is recorded.
  - 7.6.3.2 Adjusted or re-adjusted as necessary.
  - 7.6.3.3 Identified to enable the calibration status to be determined.
  - 7.6.3.4 Safeguarded from adjustments that would invalidate the measurement result.
  - 7.6.3.5 Protected from damage and deterioration during handling, maintenance and storage.
- 7.6.4 The validity of previous measuring results shall be assessed and recorded when equipment is found not to conform to requirements and appropriate action is taken on the equipment and any product affected.
- 7.6.5 Records of results of calibration and verification are maintained.
- 7.6.6 When computer software is used in the monitoring and measurement of specified requirements, its ability to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

## **8 Measurement, Analysis, and Improvement**

### **8.1 General**

- 8.1.1 Ethox International plans and implements the monitoring, measurement, analysis, and improvement of processes needed to:
  - 8.1.1.1 Demonstrate conformity of the product,
  - 8.1.1.2 Ensure conformity of the quality management system and,
  - 8.1.1.3 Maintain the effectiveness of the quality management system.
- 8.1.2 This includes a determination of applicable methods, including statistical techniques, and the extent of their use.

### **8.2 Monitoring and Measurement**

- 8.2.1 Feedback
  - 8.2.1.1 As one of the measurements of the performance of the quality management system, Ethox International determines the methods and monitors information relating to whether the organization has met customer requirements.
  - 8.2.1.2 A documented procedure for customer feedback is implemented to provide early warning of quality issues and input into the corrective and preventive action system.
  - 8.2.1.3 Where national or regional regulations require Ethox International to gain experience from the post-production phase, the review of this experience forms part of the feedback system.
- 8.2.2 Internal Audit
  - 8.2.2.1 Ethox International conducts internal audits at planned intervals to determine whether the quality management system conforms to the applicable external regulations and requirements as well as to internal



## Quality Manual

- quality management system requirements and is effectively implemented and maintained.
- 8.2.2.2 The audit program is planned taking into consideration the status and importance of processes and areas to be audited as well as the results of previous audits. Audit criteria, scope, frequency, and methods are defined and the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work.
  - 8.2.2.3 A documented procedure is in place that defines the responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records.
  - 8.2.2.4 Management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.
- 8.2.3 Monitoring and Measurement of Processes
- 8.2.3.1 Suitable methods are applied for monitoring and measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective and preventive action is taken to ensure conformity of the product.
- 8.2.4 Monitoring and Measurement of Product
- 8.2.4.1 General Requirements – Documented procedures are implemented to monitor and measure the characteristics of the product to verify that product requirements are met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Evidence of conformity with the acceptance criteria is maintained and records indicate the person(s) authorizing release of product. Product release shall not proceed until the planned arrangements are satisfactorily completed.
  - 8.2.4.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices – The identity of personnel performing any inspection or testing is recorded.

### 8.3 Control of Nonconforming Product

- 8.3.1 Documented procedures are implemented to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined.
- 8.3.2 Nonconforming product is processed in one of the following ways:
  - 8.3.2.1 Action is taken to eliminate the detected nonconformity.
  - 8.3.2.2 Authorization of use, release, or acceptance is under concession only when regulatory requirements are met with records of the personnel authorizing the concession being maintained.
  - 8.3.2.3 Action is taken to preclude its original intended use or application.
- 8.3.3 Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.
- 8.3.4 Where nonconforming product is corrected, it is subjected to re-verification to demonstrate conformity to the requirements.



## Quality Manual

- 8.3.5 When nonconforming product is detected after delivery or use has started, appropriate action is taken to the effects or potential effects of the nonconformity.
- 8.3.6 If product is reworked one or more times, the rework process is documented and subject to the same approval and authorization as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effects of the rework upon the product is made and documented.

### 8.4 Analysis of Data

- 8.4.1 Documented procedures are implemented to determine, collect, and analyze the appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.
- 8.4.2 This includes data generated as a result of monitoring and measurement and from other relevant sources.
- 8.4.3 Analysis of data provides information relating to: feedback, conformity to product requirements, characteristics and trends of processes and products including opportunities for preventive action, and suppliers.
- 8.4.4 Records of the results of analysis of data are maintained.

### 8.5 Improvement

- 8.5.1 General
  - 8.5.1.1 Ethox International identifies and implements changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.
  - 8.5.1.2 Documented procedures are established for the issue and implementation of advisory notices; these can be implemented at any time.
  - 8.5.1.3 Records of customer complaint investigations are maintained. If an investigation determines that the activities outside the organization contributed to a customer complaint, relevant information is exchanged between the organizations involved.
  - 8.5.1.4 If a customer complaint is not followed by corrective and/or preventive action, the reason is authorized and recorded.
  - 8.5.1.5 Documented procedures are in place to address notification to regulatory authorities where national and regional regulations require notification of adverse events that meet specified reporting criteria.
- 8.5.2 Corrective Action
  - 8.5.2.1 Documented procedures are implemented to ensure that appropriate action to eliminate the cause of nonconformities in order to prevent recurrence is taken.
  - 8.5.2.2 Documented procedures are established which define the requirements for:
    - 8.5.2.2.1 Reviewing nonconformities including customer complaints.
    - 8.5.2.2.2 Determining the causes of the nonconformities.
    - 8.5.2.2.3 Evaluating the need for action to ensure that nonconformities do not recur.



## Quality Manual

8.5.2.2.4 Determining and implementing action needed including, if appropriate, updating documentation.

8.5.2.2.5 Recording the results of any investigation and action taken.

8.5.2.2.6 Reviewing corrective action taken and its effectiveness.

### 8.5.3 Preventive Action

8.5.3.1 Ethox International determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

8.5.3.2 A documented procedure is implemented to define requirements for:

8.5.3.2.1 Determining potential nonconformities and their causes.

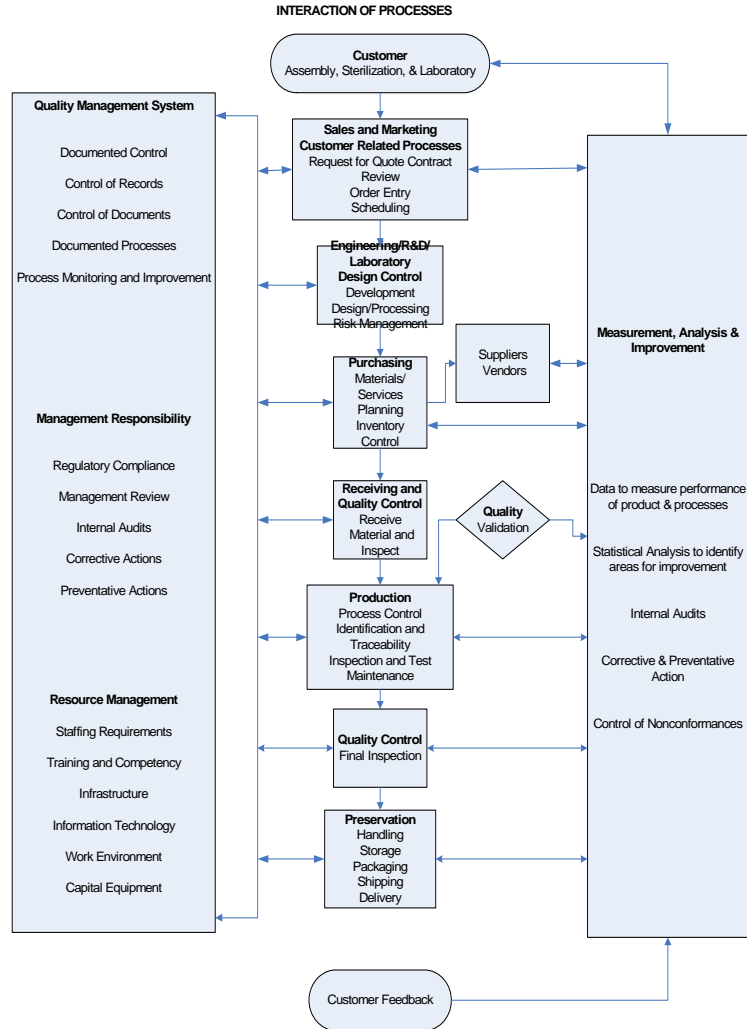
8.5.3.2.2 Evaluating the need for action to prevent occurrence of nonconformities.

8.5.3.2.3 Determining and implementing action needed.

8.5.3.2.4 Recording the results of any investigations and actions taken

8.5.3.2.5 Reviewing preventive action taken and its effectiveness.

**Appendix I – Process Flow Chart**



**Appendix II – Quality Manual Cross-Reference Table**

<b>ISO 13485:2003 Requirements</b>	<b>21 CFR 820</b>	<b>Ethox International Document</b>
<b>1. SCOPE</b>	5	Quality Manual
<b>4. QUALITY MANAGEMENT SYSTEM</b>	5	Quality Manual
4.1 General requirements	20(e) & 40	ESOP-0003
4.2 Documentation requirements	40	ESOP-0003
4.2.3 Control of documents	40	ESOP-0003
4.2.4 Control of records	180,181,184,186	ESOP-0005
<b>5. MANAGEMENT RESPONSIBILITY</b>	20	
5.1 Management commitment	20	ESOP-0001
5.2 Customer focus		ESOP-0001
5.3 Quality policy	20(a)	Quality Manual
5.4 Planning	20(d)	Strategic Initiatives
5.5 Responsibility, authority, & communication	20(b).1	ESOP-0001 Quality Manual
5.6 Management review	20(c)	ESOP-0001
<b>6. RESOURCE MANAGEMENT</b>		
6.1 Provision of resources	20(b).2 & 25	ESOP-0001
6.2 Human resources	25	ESOP-0012
6.3 Infrastructure	70	ESOP-0019
6.4 Work environment	25, 70	ESOP-0017
<b>7. PRODUCT REALIZATION</b>		
7.1 Planning of product realization		ESOP-0021
Risk Management	30(g)	ESOP-0022
7.2 Customer-related processes	50	ESOP-0023
7.3 Design and development	30	ESOP-0020
7.3.1 Design & development planning	30(b)	EWI-0463
7.3.2 Design & development inputs	30(c)	EWI-0464
7.3.3 Design & development outputs	30(d)	EWI-0465)
7.3.4 Design & development review	30(e)	EWI-0466
7.3.5 Design & development verification	30(f)	EWI-0467
7.3.6 Design & development validation	30(g)	EWI-0468
7.4 Purchasing	50	ESOP-0007
7.4.3 Verification of purchased product	80(b)	ESOP-0008
7.5 Production and service provision	70	



## Quality Manual

ISO 13485:2003 Requirements	21 CFR 820	Ethox International Document
7.5.1 Control of production and service provision	70	ESOP-0010
7.5.2 Validation of processes for production and service provision	75	ESOP-0013
7.5.2.2 Validation Requirements for Sterile Products	75	ESOP-0013
7.5.3 Identification and traceability	60, 65	ESOP-0011
7.5.4 Customer property		
7.5.5 Preservation of product	70,80,86,120,130,140,150,160	ESOP-0018
7.6 Control of monitoring & measuring devices	72	ESOP-0016
<b>8. MEASUREMENT, ANALYSIS AND IMPROVEMENT</b>		
8.1 General	250	ESOP-0014
8.2 Monitoring and measurement		
8.2.1 Feedback	198	ESOP-0015
8.2.2 Internal audit	22	ESOP-0004
8.2.4 Monitoring & measurement of product	80	ESOP-0008
8.3 Control of nonconforming product	90	ESOP-0009
8.4 Analysis of data		ESOP-0002
8.5 Improvement	100	
8.5.1 General	100	ESOP-0015
8.5.2 Corrective action	100	ESOP-0006
8.5.3 Preventive action	100	ESOP-0006



## Quality Manual

### Appendix III – Responsibilities & Authorities

Function	Responsibilities & Authorities
Management with Executive Responsibility (MER)	<ul style="list-style-type: none"> <li>• Develops and reviews quality policy</li> <li>• Provides resources necessary to maintain and continuously improve the effectiveness of the quality system</li> <li>• Participates in Management Reviews of the quality system</li> <li>• Oversees overall financial, legal, and shareholder issues; strategic planning and business goals; policies that effect company image, financial health or liability; expenditures beyond the annual approved budget; financial structure; risk management; daily operations with responsibility for staffing, training, recognition, and communication within Ethox International</li> </ul>
Marketing, Sales and Customer Service	<ul style="list-style-type: none"> <li>• Market research to establish the desired quality characteristics of products or services</li> <li>• Establishes functional specifications of products and services</li> <li>• Advertises and promotes company products and services emphasizing quality</li> <li>• Monitors industry views of competitive products and services</li> <li>• Reviews contracts and orders</li> <li>• Provides customer liaison and service</li> <li>• Coordinates RFQ's</li> <li>• Complies with requirements for distribution of CE marked product to designated countries (company branded sales only)</li> <li>• Communicates requirements for international distribution to shipping</li> <li>• Collects field performance, post-market surveillance, and reliability data</li> <li>• Acts as initial recipients for customer complaint information</li> </ul>
Engineering	<ul style="list-style-type: none"> <li>• Prepares material and product specifications from customer-supplied requirements</li> <li>• Identifies manufacturing processes</li> <li>• Control engineering drawings</li> <li>• Investigates customer complaints</li> <li>• Provides contract manufacturing design control (with input from customer)</li> <li>• Provides technical support manufacturing and contract customers</li> <li>• Maintains engineering change and DMR files</li> <li>• Qualifies material/process changes</li> <li>• Identifies/recommends suppliers for materials</li> <li>• Provides technical support to quality</li> <li>• Verification and validation of manufacturing processes</li> <li>• Designs products</li> <li>• Initiates design reviews</li> <li>• Documents design outputs</li> <li>• Design control activities of proprietary products</li> <li>• Customer complaints/feedback</li> </ul>



## Quality Manual

Function	Responsibilities & Authorities
	<ul style="list-style-type: none"> <li>• Qualifies mall/process change</li> <li>• Provides technical support</li> <li>• Prepares material and product specifications</li> <li>• Identifies and recommends suppliers</li> </ul>
Operations	<ul style="list-style-type: none"> <li>• Determines production personnel and equipment requirements</li> <li>• Controls production flow and timing</li> <li>• Executes defined manufacturing processes</li> <li>• Assists with verifying specifications</li> <li>• Initiates process improvement efforts</li> <li>• Prepares production plan and schedules</li> <li>• Oversees inventory control function</li> </ul>
Laboratory Services	<ul style="list-style-type: none"> <li>• Completes contract and order reviews to ensure customer requirements can be met</li> <li>• Provides customer liaison and service</li> <li>• Responsible for sterility assurance program</li> <li>• Controls and monitors laboratory processes</li> <li>• Performs Microbiology, Toxicology, and Analytical Chemistry testing in accordance with quality plans and relevant standards</li> </ul>
Materials	<ul style="list-style-type: none"> <li>• Selects qualified supplies and suppliers with input from Engineering and Quality</li> <li>• Prepares and approves purchasing documents</li> <li>• Assesses supplier performance</li> <li>• Controls receipt, issuance, storage and handling of products and materials</li> <li>• Supervises shipping and receiving</li> </ul>
Human Resources	<ul style="list-style-type: none"> <li>• Employment and staffing</li> <li>• Employee relations</li> <li>• Wage and salary administration</li> <li>• Policy development and interpretation</li> <li>• Benefit administration</li> <li>• Affirmative Action/Equal Employment Opportunity</li> <li>• Employee orientation</li> <li>• Employee services</li> <li>• Payroll</li> <li>• Coordinates and tracks training activities</li> <li>• EEOC/OSHA compliance</li> </ul>
Quality Systems/ Regulatory Affairs	<ul style="list-style-type: none"> <li>• Receiving and in-process inspection</li> <li>• Establishes, maintains, and continually improves the effectiveness of the quality system</li> <li>• Completes technical files</li> <li>• Coordinates supplier quality surveys and audits</li> <li>• Performs inspections and testing in accordance with the quality plans</li> <li>• Manages Nonconforming material processes</li> <li>• Conducts employee cGMP/ISO and GLP training</li> </ul>



## Quality Manual

Function	Responsibilities & Authorities
	<ul style="list-style-type: none"> <li>• Maintains and controls quality documents and quality records (i.e., procedures, DHR's, etc.)</li> <li>• Corrective and Preventive Action Process</li> <li>• Ensures compliance with ISO and FDA requirements, Canadian Medical Device Regulation, and Council of European Communities' Directives for medical devices</li> <li>• Prepares new product FDA submissions</li> <li>• Manages Customer Complaint/Feedback system</li> <li>• Maintains Internal and External quality audit records</li> <li>• Final product disposition</li> <li>• Establishment/product registrations and licenses</li> <li>• EPA, DEC, DEA reporting, permits, and licenses</li> <li>• Quality control function in lab and sterilization areas</li> <li>• Verification and validation of manufacturing processes</li> <li>• Manage validation system</li> <li>• Manage calibration program</li> </ul>
Finance	<ul style="list-style-type: none"> <li>• Financial statements and tax returns</li> <li>• Accounts receivable</li> <li>• Accounts payable</li> <li>• Cost accounting</li> <li>• Banking</li> <li>• Insurance</li> </ul>
Sterilization	<ul style="list-style-type: none"> <li>• Processing scheduling</li> <li>• Customer liaison and service</li> <li>• Monitors and evaluates non-conformances</li> <li>• Initiates investigation of customer complaints</li> <li>• Assists in supplier performance assessments and audits</li> <li>• Maintains calibration of equipment traceable to NIST</li> <li>• Ensures compliance with company Quality System requirements</li> <li>• Performs sterilization services to industry standards and customer specifications</li> <li>• Performs documented preventive maintenance to written procedures</li> <li>• Assures adequate and trained personnel available to perform required functions</li> <li>• Hosts customer and regulatory audits</li> <li>• Inspects incoming material</li> <li>• Provides a clean, safe, and comfortable environment for employees and visitors</li> </ul>
Information Technology Systems	<ul style="list-style-type: none"> <li>• Responsible for all computer systems including the Local Area Network (LAN) and Wide Area Network (WAN), remote access, internet access, file servers, personal computers, operating systems and applications</li> <li>• Maintains reliable server backups and restoring operations</li> <li>• Maintains internal network security and external system security</li> <li>• Responsible for answering questions and solving technical problems for end users on desktop technical issues</li> </ul>



## Quality Manual

Function	Responsibilities & Authorities
	<ul style="list-style-type: none"> <li>• Designs, develops, validates, and implements in-house developed applications</li> <li>• Responsible for company telephone system, copiers, network printers and fax machines</li> <li>• Maintains EDI systems and services</li> <li>• Responsible for purchasing, configuring and implementing new computers, network hardware, operating systems, applications and replacement parts</li> <li>• Maintains anti-virus systems</li> </ul>
Facilities	<ul style="list-style-type: none"> <li>• Responsible for providing a clean, safe, and comfortable environment for all users of the facilities</li> <li>• Maintenance and operation of all facilities and support utilities</li> <li>• Project management related to renovations, construction, and installations</li> <li>• Maintenance of all facilities-related equipment per the preventive maintenance program schedule</li> <li>• Responsible for insuring the facility meets all standards required for air quality in a medical manufacturing facility</li> <li>• Maintenance of interior/exterior of buildings and grounds</li> <li>• Responsible for housekeeping activities</li> <li>• Performance of equipment and utility installation qualifications</li> </ul>
Mechanical Services	<ul style="list-style-type: none"> <li>• Maintain all production equipment in good operating condition including preventive maintenance</li> <li>• Setting up production equipment</li> <li>• Maintain tooling in good condition</li> <li>• Assist engineering in the design and development of new products, tooling, and processes</li> <li>• Performance of equipment installation qualifications</li> </ul>