

# QUALITY MANUAL



## **ISO 13485:2016** **Quality Management System**

## Approvals:



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**Management Representative**



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**President and CEO**

## Document Revision History

Rev	Date	Change Notice	Change Description
A			Original Release
B	1/5/2024		Updated Scope statement

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## 0 Introduction

### 0.1 General

At Millennium Precision LLC we know that an inferior component can cost you money, time and credibility. In high tech manufacturing, the only tolerance is zero defects. We understand the importance of prompt quote response, quality manufacturing and on time delivery. Millennium Precision has achieved customer loyalty by practicing a policy of strong communication and working closely with customers to deliver to their exact specifications.

Our investment in the best technology allows our engineering department to communicate with customers efficiently throughout the design, manufacturing and assembly processes.

#### **Millennium Precision LLC**

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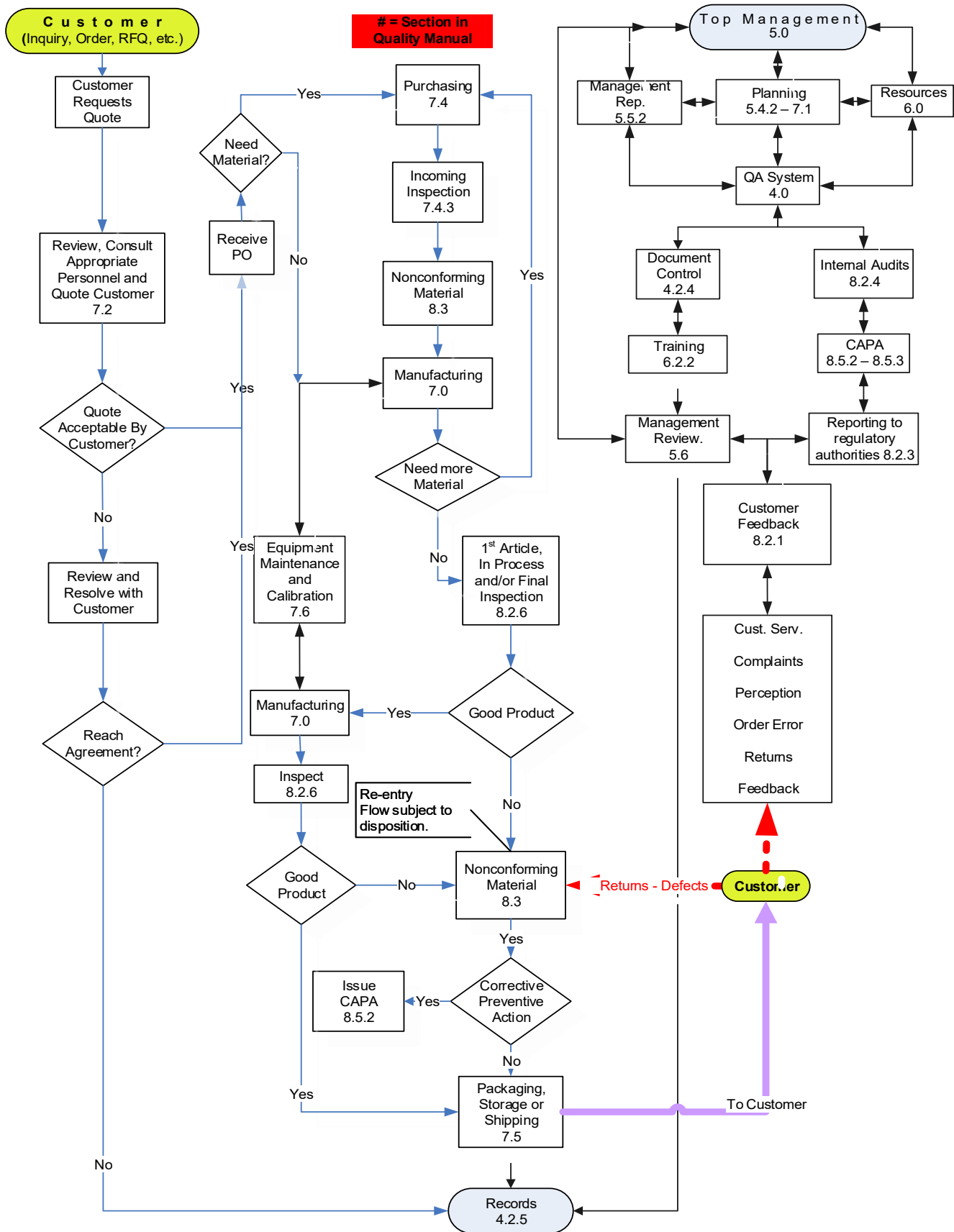
Phone: 603.644.1555    ♦    Fax: 603.644.2155

[www.millenniumprecisionllc.com](http://www.millenniumprecisionllc.com)

### 0.2 Process Approach

This Manual has adopted the process approach to quality management. [Figure 1](#), is a conceptual illustration of the process approach of the system aimed towards Consistent Compliance to the Standard and illustrates the process linkages presented in clauses 4 to 8 of ISO13485. References to procedures are made as applicable or to the section of the manual that applies to that activity.

**Figure 1: Millennium Precision LLC Corporation Processes Interrelationship:**



# 1 Scope

## 1.1 General

Millennium Precision LLC Corporation hereinafter referred to as “Millennium Precision LLC”, developed and implemented the Quality Management System (QMS) described in this manual to help our organization operate with increased effectiveness, consistency and to;

- demonstrate our ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services to regulatory requirements per ISO13485

**Scope of Millennium Precision LLC Quality Management system is:**

***Contract Manufacturer of Swiss style machined components for the medical device industry.***

## 1.2 Application

Millennium Precision LLC has developed and implemented the Quality Management System (QMS) described in this manual to help our organization operate with increased effectiveness, consistency and customer satisfaction. Our QMS utilizes the process approach and quality management principles contained in the international standard ISO13485 to create a customer focus while consistently meeting customer and regulatory requirements.

Our QMS encompasses all operations at our facilities. The following table identifies requirement(s) not applicable to our organization and provides a brief narrative justifying their exclusion from the scope of our QMS:

Clause or Sub-clause	Exclusion(s)	Justification
7.3	Design and development	Millennium Precision LLC builds product to customer's specification



Clause or Sub-clause	Non-Applicable Activities	Justification
6.4.2	Contamination control	Millennium Precision LLC does not manufacture any sterile medical devices
7.5.3	Installation Activities	Millennium Precision LLC does not perform any installation activities
7.5.4	Servicing Activities	Millennium Precision LLC does not perform any servicing activities after the sale of the product
7.5.5	Particular requirements for sterile medical devices	Millennium Precision LLC does not manufacture and sterile medical devices
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems	Millennium Precision LLC does not manufacture Sterile Medical Devices
7.5.9.2	Active Implantable Devices	Millennium Precision LLC does not manufacture Implantable Devices
8.2.3	Reporting to regulatory authorities	Millennium Precision LLC does not have any regulatory requirements

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015,	Quality management systems — Fundamentals and vocabulary
ISO 9001:2015,	Quality management systems — Requirements
ISO 13485:2016,	Quality management systems — Requirements for regulatory purposes
ISO 14971:2019	Medical devices – Application of risk management to medical devices
21 CFR 820 -	Quality Assurance System Regulation (QSR)

## 3 Terms and definitions

For the purposes of this manual, the terms and definitions given in ISO9000 and ISO13485:2016 apply, together with the following terms, used to describe the supply chain:

### SUPPLIER

Our Subcontractors



### ORGANIZATION



### CUSTOMER

Our Customers



Throughout the text of this QSM, wherever the term “product” occurs, it can also mean “service”.

Wherever requirements are specified as applying to “medical devices”, the requirements apply equally to related services as supplied by Millennium Precision LLC.

Definitions provided in national regulations can differ slightly and take precedence.

The term **Millennium Precision LLC** refers **Millennium Precision LLC Corporation Inc.**

## **4 Quality management system**

### **4.1 General requirements**

**4.1.1** Millennium Precision LLC documents a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.

Millennium Precision LLC establishes, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.

Millennium Precision LLC documents the role(s) undertaken by Millennium Precision LLC under the applicable regulatory requirements.

#### **4.1.2 Millennium Precision LLC:**

- a) determines the processes needed for the quality management system and the application of these processes throughout Millennium Precision LLC taking into account the roles undertaken by Millennium Precision LLC;
- b) applies a risk based approach to the control of the appropriate processes needed for the quality management system;
- c) determines the sequence and interaction of these processes.

#### **4.1.3 For each quality management system process, Millennium Precision LLC:**

- a) determines criteria and methods needed to ensure that both the operation and control of these processes are effective;
- b) ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- c) implements actions necessary to achieve planned results and maintain the effectiveness of these processes;
- d) monitors, measure as appropriate, and analyses these processes;
- e) establishes and maintains records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).

**4.1.4** Millennium Precision LLC manages these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes will be:

- a) evaluated for their impact on the quality management system;
- b) evaluated for their impact on the medical devices produced under this quality management system;
- c) controlled in accordance with the requirements of this International Standard and applicable
- d) regulatory requirements.

**4.1.5** When Millennium Precision LLC chooses to outsource any process that affects product conformity to requirements, monitors and ensures control over such processes. Millennium Precision LLC retains responsibility of conformity to this International Standard and to customer and applicable regulatory

requirements for outsourced processes. The controls are proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4 The controls will include written quality agreements.

**4.1.6** Millennium Precision LLC documents procedures ([P-024](#)) for the validation of the application of computer software used in the quality management system. Such software applications will be validated prior to initial use and, as appropriate, after changes to such software or its application.

The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

Records of such activities shall be maintained (see 4.2.5).

## **4.2 Documentation requirements**

### **4.2.1 General**

The quality management system documentation includes

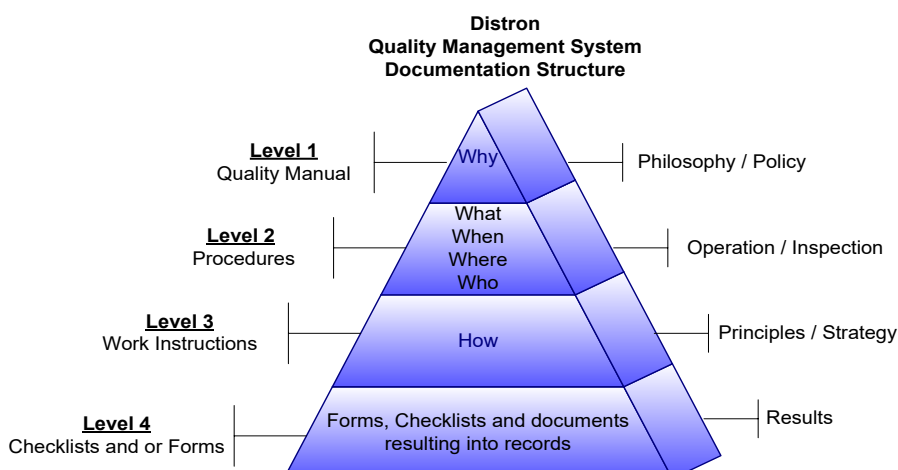
- a) documented statements of a [quality policy](#) and [quality objectives](#),
- b) a quality manual,
- c) [documented procedures](#) required by ISO13485,
- d) documents, including records, determined by Millennium Precision LLC to be necessary to ensure the effective planning, operation, and control of its processes
- e) other documentation specified by applicable regulatory requirements

### **4.2.2 Quality manual**

Millennium Precision LLC establishes and maintains a quality manual that includes

- a) the [scope](#) of the quality management system, including details of and justification for any exclusion and/or non-application (see [1.2](#)),
- b) the [documented procedures](#) established for the quality management system, or reference to them, and
- c) a description of the [interaction](#) between the processes of the quality management system.
- d) The structure of the documentation used in the quality management system is as shown below.

### **Documentation Structure**



The extent of the quality management system documentation is to be referenced in the Documentation System and can be in any form or type of medium. The quality system structure is as follows;

- a) Level I Document – Is the Quality Management System Quality Manual which establishes Millennium Precision LLC's philosophy and policy. i.e. QMAN-XXX
- b) Level II Documents – Are the required procedures to support the ISO13485:2016 implementation. i.e. DQP-XXX
- c) Level III Documents – Are those work instructions that provide the details utilized by each department when following the Level II document procedures. i.e. DWI-XXX
- d) Level IV Documents – are those documents that provide the day to day instructions, data, checklist or forms and records. i.e (DF-XXX)

### 4.2.3 Medical device file

For each medical device type or medical device family, Millennium Precision LLC establishes and maintains one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of this International Standard and compliance with applicable regulatory requirements.

The content of the file(s) include, but is not limited to:

- a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use;
- b) specifications for product;
- c) specifications or procedures for manufacturing, packaging, storage, handling and distribution;
- d) procedures for measuring and monitoring;
- e) as appropriate, requirements for installation;
- f) as appropriate, procedures for servicing.

### 4.2.4 Control of documents

Documents required by the quality management system are controlled. Records are a special type of document and are controlled according to the requirements given in 4.2.4.

A documented procedure ([P-001](#)) has been established to define the controls needed

- a) to review and approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) ensure that documents of external origin, determined by Millennium Precision LLC to be necessary for the planning and operation of the quality management system, are identified and their distribution controlled
- g) prevent deterioration or loss of documents;
- h) prevent the unintended use of obsolete documents and apply suitable identification to them.

Millennium Precision LLC ensures that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.

Millennium Precision LLC defines the period for which at least one copy of obsolete controlled documents shall be retained. This period ensures that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by Millennium Precision LLC, but not less than the retention period of any resulting record (see [4.2.4](#)), or as specified by relevant regulatory requirements.

#### **4.2.5 Control of records**

Records are maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. ([P-001](#))

Millennium Precision LLC documents procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

Millennium Precision LLC defines and implement methods for protecting confidential health information contained in records in accordance with the applicable regulatory requirements.

Records remain legible, readily identifiable and retrievable. Changes to a record remain identifiable.

Millennium Precision LLC retains the records for at least the lifetime of the medical device as defined by Millennium Precision LLC, or as specified by applicable regulatory requirements, but not less than two years from the medical device release by Millennium Precision LLC.

## **5 Management responsibility**

### **5.1 Management commitment**

Top management provides evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by

- a) communicating to Millennium Precision LLC the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews,

- e) ensuring the availability of resources.

## 5.2 Customer focus

Top management ensures that customer requirements and applicable regulatory requirements are determined and met.

## 5.3 Quality policy

Top management ensure that the quality policy

- a) is appropriate to the purpose of Millennium Precision LLC,
- b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within Millennium Precision LLC.
- e) is reviewed for continuing suitability.

### Organization Quality Policy Is:

**TO ENSURE QUALITY IS PRESENT FROM INCEPTION TO COMPLETION IN  
ALL THAT WE DO...**

As a Service Driven Contract Manufacturer, Millennium Precision Provides and Continually Improves Quality-of-Product, On-Time Delivery and the Overall Service Experience While Meeting or Exceeding the Requirements and Expectations of Our Customers. Millennium Precision Commits to Review the Continued Suitability of This Policy, Promotes this Throughout the Organization, Assures Compliance with All Requirements and Continually Maintains the Effectiveness of the QMS while complying with ITAR/EAR requirements.

## 5.4 Planning

### 5.4.1 Quality objectives

Top management ensures that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within Millennium Precision LLC. The quality objectives are measurable and consistent with the quality policy.

### 5.4.2 Quality management system planning

Top management ensures that

- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

## **5.5 Responsibility, authority and communication**

### **5.5.1 Responsibility and authority**

Top management ensures that responsibilities and authorities are defined, documented and communicated within Millennium Precision LLC.

Top management establishes the interrelation of all personnel who manage, perform and verify work affecting quality, and ensures the independence and authority necessary to perform these tasks. This is achieved via any or combination of the Quality Systems Manual, Procedures, Work Instructions, Job Descriptions, Organizational Chart, and other means suitable for Millennium Precision LLC.

### **5.5.2 Management representative**

Top management appoints a member of management who, irrespective of other responsibilities, has responsibility and authority that includes

- a) ensuring that processes needed for the quality management system are documented
- b) reporting to top management on the performance of the quality management system and any need for improvement, and
- c) ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout Millennium Precision LLC

### **5.5.3 Internal communication**

Top management ensures that appropriate communication processes are established within Millennium Precision LLC and that communication takes place regarding the effectiveness of the quality management system.

## **5.6 Management review**

### **5.6.1 General**

Millennium Precision LLC documents procedures for management review. Top management reviews Millennium Precision LLC's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. (see [P-007](#))

Records from management reviews are maintained

### **5.6.2 Review input**

The input to management review includes, but is not limited to, information arising from

- c) feedback;
- d) complaint handling;
- e) reporting to regulatory authorities;
- f) audits;
- g) monitoring and measurement of processes;
- h) monitoring and measurement of product;

- i) corrective action;
- j) preventive action;
- k) follow-up actions from previous management reviews;
- l) changes that could affect the quality management system;
- m) recommendations for improvement;
- n) applicable new or revised regulatory requirements.

### **5.6.3 Review output**

The output from the management review includes any decisions and actions related to

- a) improvements needed to maintain the suitability, adequacy and 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

## **6 Resource management**

### **6.1 Provision of resources**

Millennium Precision LLC determines and provides the resources needed to

- a) implement the quality management system and to maintain its effectiveness
- b) meet applicable regulatory and customer requirements.

### **6.2 Human resources**

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

Millennium Precision LLC documents the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

Millennium Precision LLC

- a) determines the necessary competence for personnel performing work affecting product quality,
- b) provides training or take other actions to achieve or maintain the necessary competence
- c) evaluates the effectiveness of the actions taken,
- d) ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,
- e) maintains appropriate records of education, training, skills and experience (see 4.2.5)

### **6.3 Infrastructure**



Millennium Precision LLC documents the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport or communication or information systems).

Millennium Precision LLC document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.

Records of such maintenance are maintained

## **6.4 Work environment and contamination control**

### **6.4.1 Work environment**

Millennium Precision LLC documented the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment can have an adverse effect on product quality, Millennium Precision LLC will document the requirements for the work environment and the procedures to monitor and control the work environment.

Millennium Precision LLC will:

- a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance;
- b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person.

### **6.4.2 Contamination control**

As appropriate, Millennium Precision LLC will plan and document arrangements for the control of contaminated or potentially contaminated product to prevent contamination of the work environment, personnel, or product.

For sterile medical devices, Millennium Precision LLC will document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.

## **7 Product realization**

### **7.1 Planning of product realization**

Millennium Precision LLC plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system.

Millennium Precision LLC documents one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).

In planning product realization, Millennium Precision LLC determines the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment;
- c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5).

The output of this planning is documented in a form suitable for Millennium Precision LLC's method of operations.

## **7.2 Customer-related processes**

### **7.2.1 Determination of requirements related to the product**

Millennium Precision LLC  
determines

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer but necessary for specified or intended use, as known;
- c) applicable regulatory requirements related to the product;
- d) any user training needed to ensure specified performance and safe use of the medical device;
- e) any additional requirements determined by Millennium Precision LLC.

### **7.2.2 Review of requirements related to the product**

Millennium Precision LLC reviews the requirements related to the product. This review is conducted prior to Millennium Precision LLC's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and ensures that

- a) product requirements are defined and documented;
- b) contract or order requirements differing from those previously expressed are resolved;
- c) applicable regulatory requirements are met;
- d) any user training identified in accordance with 7.2.1 is available or planned to be available;
- e) Millennium Precision LLC has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained (see 4.2.5). When the customer provides no documented statement of requirement, the customer requirements are confirmed by Millennium Precision LLC before acceptance.

When product requirements are changed, Millennium Precision LLC ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

### **7.2.3 Communication**

Millennium Precision LLC plans and documents arrangements for communicating with customers in relation to:

- a) product information,
- b) enquiries, contracts or order handling, including amendments,

- c) customer feedback, including complaints
- d) advisory notices.

Millennium Precision LLC communicates with regulatory authorities in accordance with applicable regulatory requirements.

## 7.3 Design and development

**Not applicable since Millennium Precision LLC don't design their own product** (see 1.2 Application)

## 7.4 Purchasing

### 7.4.1 Purchasing process

Millennium Precision LLC establishes documented procedures to ensure that purchased product conforms to specified purchase requirements.

Millennium Precision LLC establishes criteria for the evaluation and selection of suppliers. The criteria are:

- a) based on the supplier's ability to provide product that meets the organization's requirements;
- b) based on the performance of the supplier;
- c) based on the effect of the purchased product on the quality of the medical device;
- d) proportionate to the risk associated with the medical device.

Millennium Precision LLC plans the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product are monitored. The results of the monitoring provide an input into the supplier re-evaluation process.

Non-fulfilment of purchasing requirements are addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.

Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities are maintained (see 4.2.5).

### 7.4.2 Purchasing information

Purchasing information describes or references the product to be purchased, including as appropriate:

- a) product specifications;
- b) requirements for product acceptance, procedures, processes and equipment;
- c) requirements for qualification of supplier personnel;
- d) quality management system requirements.

Millennium Precision LLC ensures the adequacy of specified purchasing requirements prior to their communication to the supplier.

Purchasing information includes, as applicable, a written agreement that the supplier notify Millennium Precision LLC of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.

To the extent required for traceability given in 7.5.9, Millennium Precision LLC will maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).

### 7.4.3 Verification of purchased product

Millennium Precision LLC establishes and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities are based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When Millennium Precision LLC becomes aware of any changes to the purchased product, Millennium Precision LLC determines whether these changes affect the product realization process or the medical device.

When Millennium Precision LLC or its customer intends to perform verification at the supplier's premises, Millennium Precision LLC will state the intended verification activities and method of product release in the purchasing information.

Records of the verification are maintained (see 4.2.5).

## **7.5 Production and service provision**

### **7.5.1 Control of production and service provision**

Production and service provision are planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls include but are not limited to:

- a) documentation of procedures and methods for the control of production (see 4.2.4);
- b) qualification of infrastructure;
- c) implementation of monitoring and measurement of process parameters and product characteristics;
- d) availability and use of monitoring and measuring equipment;
- e) implementation of defined operations for labelling and packaging;
- f) implementation of product release, delivery and post-delivery activities.

Millennium Precision LLC establishes and maintains a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record is verified and approved.

### **7.5.2 Cleanliness of product**

Millennium Precision LLC documents requirements for cleanliness of product or contamination control of product if:

- a) product is cleaned by Millennium Precision LLC prior to sterilization or its use;
- b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use;
- c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use;
- d) product is supplied to be used non-sterile, and its cleanliness is of significance in use;
- e) process agents are to be removed from product during manufacture.

If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.

### **7.5.3 Installation activities**

Millennium Precision LLC does not perform any installation activities (see 1.2 Application)

### **7.5.4 Servicing activities**

**Millennium Precision LLC does not perform any serving activities. The requirement of the standard is not applicable (see 1.2 Application)**

#### **7.5.5 Particular requirements for sterile medical devices**

Millennium Precision LLC does not manufacture any sterilized devices. **The requirement of the standard is not applicable (see 1.2 Application)**

#### **7.5.6 Validation of processes for production and service provision**

Millennium Precision LLC will validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, therefore, 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 consistently.

Millennium Precision LLC documents procedures for validation of processes, including:

- a) defined criteria for review and approval of the processes;
- b) equipment qualification and qualification of personnel;
- c) use of specific methods, procedures and acceptance criteria;
- d) as appropriate, statistical techniques with rationale for sample sizes;
- e) requirements for records (see 4.2.5);
- f) revalidation, including criteria for revalidation;
- g) approval of changes to the processes.

Millennium Precision LLC will document procedures for the validation of the application of computer software used in production and service provision. Such software applications is validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation is proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation are maintained (see 4.2.4 and 4.2.5).

#### **7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems**

Millennium Precision LLC does not manufacture any sterilized devices. The requirement of the standard is not applicable (see 1.2 Application)

#### **7.5.8 Identification**

Millennium Precision LLC documents procedures for product identification and identify product by suitable means throughout product realization.

Millennium Precision LLC identifies product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status is maintained throughout production, storage, installation and servicing of product to ensure that only product that has passed the required inspections and tests or released under an authorized concession is dispatched, used or installed.

If required by applicable regulatory requirements, Millennium Precision LLC will document a system to assign unique device identification to the medical device.

The organization documents procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product.

## **7.5.9 Traceability**

### **7.5.9.1 General**

Millennium Precision LLC documents procedures for traceability. These procedures define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained (see 4.2.5).

### **7.5.9.2 Particular requirements for implantable medical devices**

Millennium Precision LLC does not manufacture implantable medical devices (see 1.2 Application)

## **7.5.10 Customer property**

Millennium Precision LLC will identify, verify, protect, and safeguard customer property provided for use or incorporation into the product while it is under Millennium Precision LLC's control or being used by Millennium Precision LLC. If any customer property is lost, damaged or otherwise found to be unsuitable for use, Millennium Precision LLC will report this to the customer and maintain records (see 4.2.5).

## **7.5.11 Preservation of product**

Millennium Precision LLC will document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation applies to the constituent parts of a medical device.

Millennium Precision LLC will protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:

- a) designing and constructing suitable packaging and shipping containers;
- b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.

If special conditions are required, they are controlled and recorded (see 4.2.5).

## **7.6 Control of monitoring and measuring devices**

Millennium Precision LLC will determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

Millennium Precision LLC will establish documented procedures (See P-012) to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

As necessary to ensure valid results, measuring equipment will:

- a) be 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;
- b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall be recorded
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

Millennium Precision LLC will perform calibration or verification in accordance with documented procedures. In addition, Millennium Precision LLC will assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Millennium Precision LLC will take appropriate action in regard to the equipment and any product affected.

Records of the results of calibration and verification are (see 4.2.5).

Millennium Precision LLC will document procedures for the validation of the application of computer software used for the monitoring and measurement of requirements. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the validation are maintained (see 4.2.4 and 4.2.5).

## **8 Measurement, analysis and improvement**

### **8.1 General**

Millennium Precision LLC will plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity of the product,
- b) to ensure conformity of the quality management system, and
- c) to maintain the effectiveness of the quality management

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

### **8.2 Monitoring and measurement**

#### **8.2.1 Feedback**

As one of the measurements of the performance of the quality management system, Millennium Precision LLC will gather and monitor information relating to whether Millennium Precision LLC has met customer requirements. The methods for obtaining and using this information is documented. The methods for obtaining and using this information are determined.

Millennium Precision LLC will document procedures for the feedback process. This feedback process includes provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process serves as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require Millennium Precision LLC to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process

### 8.2.2 Complaint handling

The organization documents procedures for timely complaint handling in accordance with applicable regulatory requirements.

These procedures include at a minimum requirements and responsibilities for:

- a) receiving and recording information;
- b) evaluating information to determine if the feedback constitutes a complaint;
- c) investigating complaints;
- d) determining the need to report the information to the appropriate regulatory authorities;
- e) handling of complaint-related product;
- f) determining the need to initiate corrections or corrective actions.

If any complaint is not investigated, justification is documented. Any correction or corrective action resulting from the complaint handling process is documented.

If an investigation determines activities outside Millennium Precision LLC contributed to the complaint, relevant information shall be exchanged between Millennium Precision LLC and the external party involved.

Complaint handling records are maintained (see 4.2.5).

### 8.2.3 Reporting to regulatory authorities

Millennium Precision LLC does not have any regulatory authorities' requirements (see 1.2 Application)

### 8.2.4 Internal audit

Millennium Precision LLC will conduct internal audits at planned intervals to determine whether the quality management system:

- a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
- b) is effectively implemented and maintained.

Millennium Precision LLC will document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program is planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods are defined and recorded (see 4.2.5). The selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors will not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, are maintained (see 4.2.5).

The management responsible for the area being audited ensures that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.



### **8.2.5 Monitoring and measurement of processes**

Millennium Precision LLC will apply suitable methods for monitoring and, as appropriate, 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, correction and corrective action are taken, as appropriate.

### **8.2.6 Monitoring and measurement of product**

Millennium Precision LLC will monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.

Evidence of conformity to the acceptance criteria are maintained. The identity of the person authorizing release of product is recorded (see 4.2.5). As appropriate, records identify the test equipment used to perform measurement activities.

Product release and service delivery will not proceed until the planned and documented arrangements have been satisfactorily completed.

For implantable medical devices, Millennium Precision LLC will record the identity of personnel performing any inspection or testing.

## **8.3 Control of nonconforming product**

### **8.3.1 General**

Millennium Precision LLC will ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Millennium Precision LLC will document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation and disposition of nonconforming product. (P-004)

The evaluation of nonconformity includes a determination of the need for an investigation and notification of any external party responsible for the nonconformity.

Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions is maintained (see 4.2.5)

### **8.3.2 Actions in response to nonconforming product detected before delivery**

Millennium Precision LLC will deal with nonconforming product by one or more of the following ways:

- a) taking action to eliminate the detected nonconformity;
- b) taking action to preclude its original intended use or application;
- c) authorizing its use, release or acceptance under concession.

Millennium Precision LLC will ensure that nonconforming product is accepted by concession only if the justification is provided, approval is obtained and applicable regulatory requirements are met. Records of the acceptance by concession and the identity of the person authorizing the concession are maintained (see 4.2.5).

### **8.3.3 Actions in response to nonconforming product detected after delivery**

When nonconforming product is detected after delivery or use has started, Millennium Precision LLC will act appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken are maintained ([see 4.2.5](#)).

Millennium Precision LLC will document procedures for issuing advisory notices in accordance with applicable regulatory requirements. These procedures are capable of being put into effect at any time. Records of actions relating to the issuance of advisory notices are maintained (see 4.2.5).

#### **8.3.4 Rework**

Millennium Precision LLC will perform rework in accordance with documented procedures that considers the potential adverse effect of the rework on the product. These procedures undergo the same review and approval as the original procedure.

After the completion of rework, product is verified to ensure that it meets applicable acceptance criteria and regulatory requirements.

Records of rework are maintained (see 4.2.5).

### **8.4 Analysis of data**

The organization documents procedures to determine, collect and analyze appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures include determination of appropriate methods, including statistical techniques and the extent of their use.

The analysis of data includes data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:

- a) feedback;
- b) conformity to product requirements;
- c) characteristics and trends of processes and product, including opportunities for improvement;
- d) suppliers;
- e) audits;
- f) service reports, as appropriate.

If the analysis of data shows that the quality management system is not suitable, adequate or effective, Millennium Precision LLC will use this analysis as input for improvement as required in 8.5.

Records of the results of analyses are maintained (see 4.2.5).

### **8.5 Improvement**

#### **8.5.1 General**

Millennium Precision LLC will identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance using the quality policy, quality objectives, audit results, post- market surveillance, analysis of data, corrective actions, preventive actions and management review.

#### **8.5.2 Corrective action**

Millennium Precision LLC will take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions are taken without undue delay. Corrective actions are proportionate to the effects of the nonconformities encountered.

Millennium Precision LLC documented a procedure (P-005) to define requirements for:

- a) reviewing nonconformities (including complaints);

- b) determining the causes of nonconformities;
- c) evaluating the need for action to ensure that nonconformities do not recur;
- d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- f) reviewing the effectiveness of corrective action taken.

Records of the results of any investigation and of action taken are maintained (see 4.2.5).

### **8.5.3 Preventive action**

Millennium Precision LLC will determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are proportionate to the effects of the potential problems.

Millennium Precision LLC documented a procedure (P-006) to describe requirements for:

- a) determining potential nonconformities and their causes;
- b) evaluating the need for action to prevent occurrence of nonconformities;
- c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
- d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
- e) reviewing the effectiveness of the preventive action taken, as appropriate.

Records of the results of any investigations and of action taken are maintained (see 4.2.5).