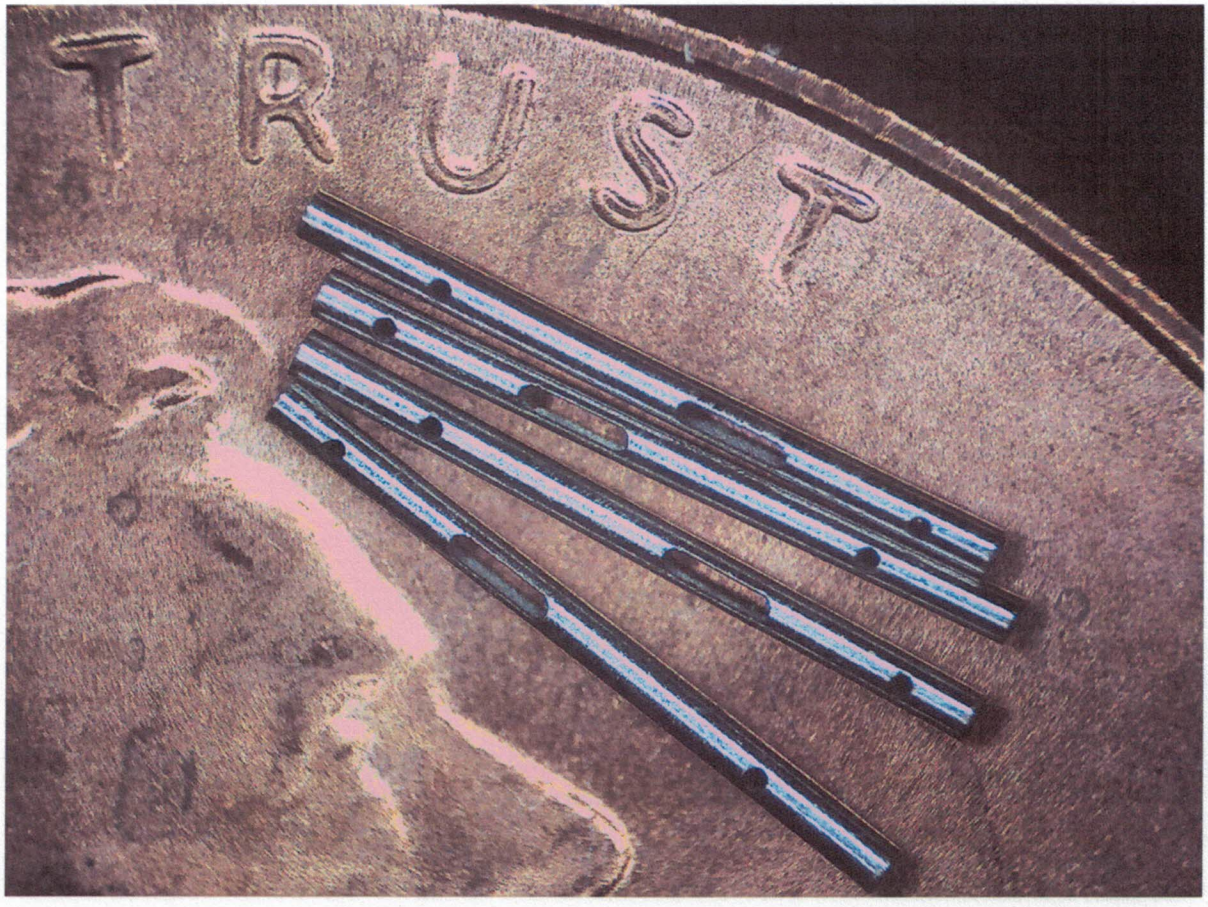
Precision™ MicroFab



ISO 9001:2015 & ISO 13485:2016

Quality Manual

Document: Quality Manual
Revision: L
Written By: Mark Prichep
Issue Date: October 3, 2024
Approved By:

Contents

1. Scope

1.1 General

Precision MicroFab was founded in 2002 and is based in Curtis Bay, MD. *Precision MicroFab provides products that meet customer and regulatory requirements applicable to medical devices and related products.* We take the time to understand our client's challenges and use our micro-manufacturing knowledge and experience to provide unique solutions to those challenges.

The purpose of this quality assurance policy is to assure Precision MicroFab delivers a product which exceeds our client's specification, *regulatory and statutory requirements. This level of quality is achieved through the adoption of the ISO 13485 standards and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Our 13485 process excludes the design process because that aspect is always taken upon by our customers. The primary objective of this International Standard is to facilitate harmonized medical device regulatory requirements for quality management systems.* Non-medical devices are subject to the ISO 9001 Standard. To achieve and maintain the required level of assurance the President accepts responsibility for the quality manual with routine operation controlled by the quality management representative. Our experienced team offers intelligent solutions to your micro-design challenges. We specialize in manufacturing parts no one else can make.

Services:

- Design and Manufacturing Consulting
- Rapid Response Prototyping
- Contract Micro-Manufacturing
- Micro-Manufacturing Systems

Industries:

Our clients include physicians, inventors, scientists, engineers and researchers in the medical device, life sciences, microelectronics and aerospace industries.

1.2 Customer Satisfaction

We achieve customer satisfaction when all of our customer's requirements are clearly restated in our quote and agreed upon in the purchase order they send. We maintain good communication and show we have a high competency level in order provide them the type of quality and end result they desire. We turnaround parts that meet all specifications they have stipulated in their drawing in timely fashion that meets their deadline. We show our customers that we care about our work by following up with a customer survey asking how they liked their experience and if there are ways we can improve. We truly feel we have met customer satisfaction is when they give us repeat business and recommend us to others.

Quality Policy- PMF' s employees take personal commitment to understand our customer' s requirements, comply *and maintain the effectiveness of the QMS.* We are dedicated to deliver defect free *medical devices and* other products on-time, at the most competitive cost possible.

Quality Objectives are:

a) 70% of all products are shipped on time.
b) Customer satisfaction is 70% or higher.
c) Zero customer returns.
d) Discuss ways to improve upon complaints and returns.

1.3 Organization Strategic Direction

OUR GOALS are to provide our customers great service of micro-fabricating quality parts with tight tolerances with a timely turnaround and at a price that reflects the quality they should expect. We stand by the quality of our work and hope our customers are satisfied enough to come back to us. We hope if they do come back we can improve upon the services they enjoyed.

OUR SUCCESS comes from our knowledge and skill in a small market. We can meet tight tolerances and perform many services with a vast number of materials for a wide variety of applications.

OUR PRIORITIES are to continue to grow our resources and skillset. To be a lean company that can still meet many tasks from our customers. We want to expand our resources and equipment in order to stay current on technology and new capabilities. We want to spread by word of mouth and grow our reputation that we are a high quality company and reach more people in tight knit industries. We want to expand into more medical component and medical device manufacturing.

External Factors:

External factors can arise from legal, technological, competition, market development, weather, environment, and economy, whether they are international, national, regional or local.

External Issues:

1) Economic factors such as money exchange rates, economic situation, inflation forecast, credit availability;

2) Social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;

3) Political factors such as political stability, public investments, local infrastructure, international trade agreements;

4) Technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;

5) Market factors such as competition, including the organization's market share, similar products or services, market leader trends, customer growth trends, market stability, supply chain relationships;

6) Statutory and regulatory factors which affect the work environment

7) The organization has determined environmental sustainability or climate change is a relevant issue

due to possible impacts regarding abnormal weather events, power disruptions, disruptions to transit (deliveries and commutes), supply chain disruptions, and being able to attract talent to the area.

Internal Factors:

Internal factors may be related to employees, equipment, software, quality, knowledge, performance, organization structure, and the business model of the organization.

Internal Issues:

1) Overall performance of the organization;
2) Resource factors, such as infrastructure (see ISO 9001:2015, 7.1.3), environment for the operation of the processes (see ISO 9001:2015, 7.1.4), organizational knowledge (see ISO 9001:2015, 7.1.6);
3) Human aspects such as competence of persons, organizational behavior and culture, and management effectiveness.
4) Operational factors such as process or production and service provision capabilities, performance of the quality management system, monitoring customer satisfaction;
5) Factors in the governance of the organization, such as rules and procedures for decision making or organizational structure.
6) Practicing environmental sustainability by minimizing energy consumption, recycling materials, using recycled materials, and applying a maintenance plan to maximize life cycles of equipment.

1.4 Understanding the needs and expectations of interested parties

Interested Parties	Requirements and Expectations
Customers (and their customers)	Products and services are quality and on time.
Owners / Investors	Sustained profitability / Return on investment, Reduce expenses or energy consumption. Customer satisfaction, Use great communication
Employees / Contractors	Safe and pleasant work environment; good compensation; adequate tools and equipment to complete tasks, adhere to the quality policy.
External providers (Suppliers / ISO Registrar)	Continuous operations; Sustainable markets and business
Competitors	Be more competitive and innovative; Use ethical behavior (impacts all in the industry)
Society / Regulators	Ethical behavior / Compliance with regulations / Environmentally friendly

NOTE: Relevant interested parties can have requirements related to climate change.

1.5 Application

All requirements of this International Standard apply to non-medical (ISO 9001:2015) and medical (ISO 13485:2016) products and services. .

2. Exclusions:

Design and Development controls 7.3 through 7.3.10, *ISO 13485:2016 only
PMF does not design and develop medical devices. PMF is a subcontractor to medical device companies who have already established the design. The drawings are sent to PMF's engineers for manufacturing work. Manufacturing of a medical device can include, making radial cuts through walls of thin tubing, translating the tubes axis and rotary.

Installation activities 7.5.3, *ISO 13485:2016 only
Non-applicable: PMF does not install nor verify the installation of medical devices. PMF's customers are not patients but clients who design medical devices.

Servicing Activities 7.5.4, *ISO 13485:2016 only
Non-applicable: PMF does not perform servicing activities. When medical devices are finished being manufactured by PMF, the device is shipped to the purchasing client and servicing is done by the client.

Particular requirements for sterile medical devices 7.5.5, *ISO 13485:2016 only
Non-applicable: PMF does not sterilize medical devices. Passivation is performed to clean the medical devices after deburring and debris removal is finished. Sterilization is performed by the purchasing client.

Particular requirements for active implantable medical devices and implantable medical devices 7.5.9.2, *ISO 13485:2016 only
Non-applicable: PMF does not have agents or distributors. Traceability is only used between PMF and its client. The client is responsible for maintaining distribution records and traceability from whom received the medical devices. PMF also does not have any personnel testing the medical devices. Inspection is performed by PMF only to verify the manufacturing requirements, not to inspect the device by means of implanting.

2.1 Normative References

BS EN ISO 13485:2016
BS EN ISO 9001-2015
ISO 9001 2015 Amd 1 2024(en)
The latest edition of the referenced documents applies.

3. Terms and Definitions

Active implantable medical device: Active medical device is intended to be totally or partially introduced, surgically or medically, into the body and is intended to remain after the procedure.

Risk: A negative effect of uncertainty. *ISO 9001:2015 Only

Risk: Combination of the probability of occurrence of harm and the severity of that harm. ISO 13485:2016

Opportunity: A positive effective of uncertainty.

Uncertainty: A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

Risk Assessment: a systematic investigation and analysis of potential risks, combined with the assignment of severities of probabilities and consequences. These are used to rate risks in order to prioritize the mitigation of high risks.

Risk Mitigation: a plan developed with the intent of addressing all known or possible risks and preventing their occurrence.

FMEA (Failure Mode Effects Analysis): a specific risk treatment method which ranks risks by probability and consequence.

Interested Parties: A person or group that can either affect or be affected by the actions of the organization relevant to its quality management system.

For the purposes of this document, the terms and definitions given in ISO 9001:2015 apply together with ISO 13485:2016. Blue Italics identifies specific requirements of ISO 13485:2016.

PMF= Precision MicroFab

Active implantable medical device: Active medical device is intended to be totally or partially introduced, surgically or medically, into the body and is intended to remain after the procedure.

Active medical device: Medical devices relying on a source of electrical energy or any other source of power other than that directly generated by the human body or gravity.

Customer complaint: If manufactured medical devices are alleged deficient related to identity, quality, durability, reliability, safety or performance by a customer, PMF will follow their corrective action procedure. PMF is a contractor to a medical supplier and does not place medical devices on the market.

Implantable medical device: Implantable medical device differs from active implantable medical device. Implantable medical devices are intended to be totally or partially introduced into the human body to replace an epithelial surface or the surface of an eye by surgical intervention which remains after a procedure for at least 30 days and can only be removed by medical or surgical intervention.

Medical Device: A medical device is any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material, or related article, intended by the manufacturer to be used alone or in combination, for human beings for one or more specific purposes:

a) Diagnosis, prevention, monitoring, treatment or alleviation of disease,
b) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
c) Investigation, replacement, modification, or support of the anatomy or of a physiological process,

d) Supporting or sustaining life,
e) Control of conception,
f) Disinfection of medical devices,
g) *Providing information for medical purposes by means of in vitro examination of specimens derived from the human body.*

These medical devices do not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

4. Management Responsibility

Management commitment

Top management stays committed to the development and implementation of the quality system and *maintains its effectiveness* by:

a) Communicating to the employees the importance of meeting customer, statutory *(safety and performance of medical devices only)* and regulatory requirements,
b) Notifying employees of the company quality policy and quality objectives,
c) By conducting management reviews,
d) Ensuring availability of resources

Top Management ensures the processes operate as an effective network. Top management shall ensure processes achieve planned results, inputs and outputs which are clearly defined. Top management has the ability to identify risks, conduct data analysis and manage processes to achieve objectives. Top management shall demonstrate leadership and commitment to understanding current and future customer needs, promoting policies and objectives to increase awareness, motivation and involvement of personnel.

4.1 Environmental Sustainability

Our organization is committed to integrating environmental sustainability into our quality management system and addressing environmental impacts proactively. We aim to enhance our resilience, demonstrate responsibility, and foster a forward-thinking approach. This involves complying with legal regulations, using renewable materials, and adapting products and services to mitigate climate change. We strive to reduce energy consumption, are mindful when disposing of hazardous materials, and extend equipment lifecycles. Additionally, we must evaluate our vulnerability to natural disasters, ensure supply chain sustainability, and stay informed on market trends to maintain our competitive edge.

5. Quality Management System

5.1 General Requirements & Context of the organization

PMF establishes, implements, documents and maintains a quality management system and *maintains its effectiveness* in accordance with the requirements of the ISO 9001 and *ISO 13485* International Standards. *Identification of the processes needed (formal procedures) for the quality management system is listed under 4.2.2.* Their application throughout the organization is identified through the quality manual. Management reviews are conducted throughout the course of each year to ensure procedures are set in place. All levels of employment follow the controlled procedures implemented by the President. Internal audits are conducted to ensure the quality management system is *effective.* Interaction of these processes is carried out from upper level to lower level positions. Procedures and work instructions are sequenced in a way to give step by step instructions or guidelines on how to operate or meet the customer's requirements. Our criteria and methods are tested to make sure our processes are effective by customer feedback, management review and internal audits. Available resources can be found within our customer feedback questionnaires to support customer satisfaction and the operation of our processes. Records are maintained such as management reviews, audits, preventive and corrective action taken, and inspections performed. All resources are used to monitor these processes. Regular monitoring of these feedbacks will determine if changes needed to be made within the organization. During management reviews PMF will analyze data to determine how to achieve improvement *or maintain effectiveness.* Necessary actions to achieve planned results are implemented and maintained in product realization and measurement processes. If PMF decides to outsource any process that affects product conformity with requirements, PMF will ensure control over such process. When outsourcing occurs, PMF will select suppliers who are ISO certified and ensure the supplier is held to the ISO standards by filling out a supplier survey.

5.2 Quality Manual

This manual is part of our quality management system that defines the scope of our system, documents the policy, procedures and processes we have implemented to achieve our quality objectives *and list any exclusions or non-applications (see 1.2).*

Our quality management system contains:

1. Procedures
2. Work Instructions
3. Forms
4. Records

6. Documented Procedures

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion
1 Scope 4.1.1 (no title)	1 Scope 4.3 Determining the scope of the quality management system	Quality Manual P104 Management Review Procedure
4 Quality management system	4 Context of the organization 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.4 Quality management system and its processes	Quality Manual P104 Management Review Procedure
4.1 General requirements	4.4 Quality management system and its processes 8.4 Control of externally provided processes, products and services	Quality Manual P104 Management Review Procedure
4.2 Documentation requirements	7.5 Documented information	P101 Document Control Procedure P102 Master Document List P103 Control of Records Procedure P103A Control of Records Table P104 Management Review Procedure
4.2.2 Quality manual	4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes 7.5.1 General	Quality Manual P126 QMS Process Flow Chart
4.2.3 Medical device file	No equivalent clause, must be in place without exception	P101 Document Control Procedure
4.2.4 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented information	P101 Document Control Procedure P102 Master Document List P103 Control of Records Procedure P103A Control of Records Table
4.2.5 Control of records	7.5.2 Creating and updating 7.5.3 Control of documented information	P103 Control of Records Procedure P103A Control of Records Table
5 Management responsibility	5 Leadership	Quality Manual P104 Management Review Procedure
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General	Quality Manual P104 Management Review Procedure

5.3 Quality policy	5.2 Policy 5.2.1 Establishing the quality policy 5.2.2 Communicating the quality policy	F508 Policy & Objectives P104 Management Review Procedure
5.4 Planning	6 Planning	P107 Product of Realization P129 System Shipping and Installation F507 Production Sheet
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them	P104 Management Review Procedure F508 Policy & Objectives
5.4.2 Quality management system planning	6 Planning 6.1 Actions to address risks and opportunities 6.3 Planning of changes	P107 Product of Realization F507 Production Sheet
5.5 Responsibility, authority and communication	5 Leadership	P107 Product of Realization F507 Production Sheet
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities	R703 Employee Duties
5.5.2 Management representative	5.3 Organizational roles, responsibilities and authorities	R703 Employee Duties
5.5.3 Internal communication	7.4 Communication	P104 Management Review Procedure
5.6 Management review	9.3 Management review	P104 Management Review Procedure
5.6.2 Review input	9.3.2 Management review inputs	P104 Management Review Procedure P112 Internal Audit F514 Customer complaint F502 Corrective Action Request F513 Preventive Action Request F503Nonconformance Report
5.6.3 Review output	9.3.3 Management review outputs	P104 Management Review Procedure
6 Resource management	7.1 Resources	P104 Management Review Procedure P105 Employee Training P129 System Shipping and Installation

6.1 Provision of resources	7.1.1 General 7.1.2 People	P104 Management Review Procedure P105 Employee Training R707 Training Log
6.2 Human resources	7.2 Competence 7.3 Awareness	F509 Competency upon hiring W319 Human Resources New Hire Candidate Screening
6.3 Infrastructure	7.1.3 Infrastructure	P100 Flow Chart P126 QMS Process Flow Chart R705 Organization Chart
6.4 Work environment and contamination control	7.1.4 Environment for the operation of processes	W309 Work Environment
7 Product realization	8 Operation	P107 Product of Realization F507 Production Sheet
7.1 Planning of product realization	8.1 Operational planning and control	P107 Product of Realization F507 Production Sheet
7.2 Customer-related processes	8.2 Requirements for products and services	F507 Production Sheet
7.2.1 Determination of requirements related to product	8.2.2 Determining the requirements for products and services	F507 Production Sheet
7.2.2 Review of requirements related to product	8.2.3 Review of the requirements for products and services 8.2.4 Changes to requirements for products and services	F507 Production Sheet
7.2.3 Communication	8.2.1 Customer communication	F507 Production Sheet P120 Advisory/Recall Notice F516 Customer Survey F514 Customer Complaint W306 Customer Feedback

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion
7.3 Design and development	8.3 Design and development of products and services	P121 Design and Development
7.3.2 Design and development planning ***Exempt**	8.3.2 Design and development planning	P121 Design and Development
7.3.3 Design and development inputs ***Exempt**	8.3.3 Design and development inputs	P121 Design and Development
7.3.4 Design and development outputs ***Exempt**	8.3.5 Design and development outputs	P121 Design and Development
7.3.5 Design and development review ***Exempt**	8.3.4 Design and development controls	P121 Design and Development
7.3.6 Design and development verification ***Exempt**	8.3.4 Design and development controls	P121 Design and Development
7.3.7 Design and development validation ***Exempt**	8.3.4 Design and development controls	P121 Design and Development
7.3.8 Design and development transfer ***Exempt**	8.3.4 Design and development controls	P121 Design and Development
7.3.9 Control of design and development changes ***Exempt**	8.3.6 Design and development changes 8.5.6 Control of changes	P121 Design and Development

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion
7.3.10 Design and development files ***Exempt**	7.5.3 Control of documented information	P121 Design and Development
7.4 Purchasing	8.4 Control of externally provided processes, products and services	P108 Purchasing Information F517 Supplier Survey R713 Supplier List
7.4.1 Purchasing process	8.4 Control of externally provided processes, products and services 8.4.1 General 8.4.2 Type and extent of control	P108 Purchasing Information F517 Supplier Survey R713 Supplier List
7.4.2 Purchasing information	8.4.3 Information for external providers	P108 Purchasing Information R713 Supplier List F507 Production Sheet
7.4.3 Verification of purchased product	8.4.2 Type and extent of control 8.4.3 Information for external providers 8.6 Release of products and services	P108 Purchasing Information P124 Inspection
7.5 Production and service provision 8.5 Production and service provision	8.5 Production and service provision	F507 Production Sheet
7.5.1 Control of production and service provision 8.5.1 Control of production and service provision	8.5.1 Control of production and service provision	F507 Production Sheet
7.5.6 Validation of processes for production and service provision	8.5.1 Control of production and service provision	P125 Equipment and Software Validation
7.5.8 Identification	8.5.2 Identification and traceability	P109 Identification and Traceability P107 Product of Realization
7.5.9 Traceability	8.5.2 Identification and traceability	P109 Identification and Traceability
7.5.10 Customer property	8.5.3 Property belonging to customers or external providers	P110 Customer Property P122 Preservation of Product P127 Shipping Customer Orders

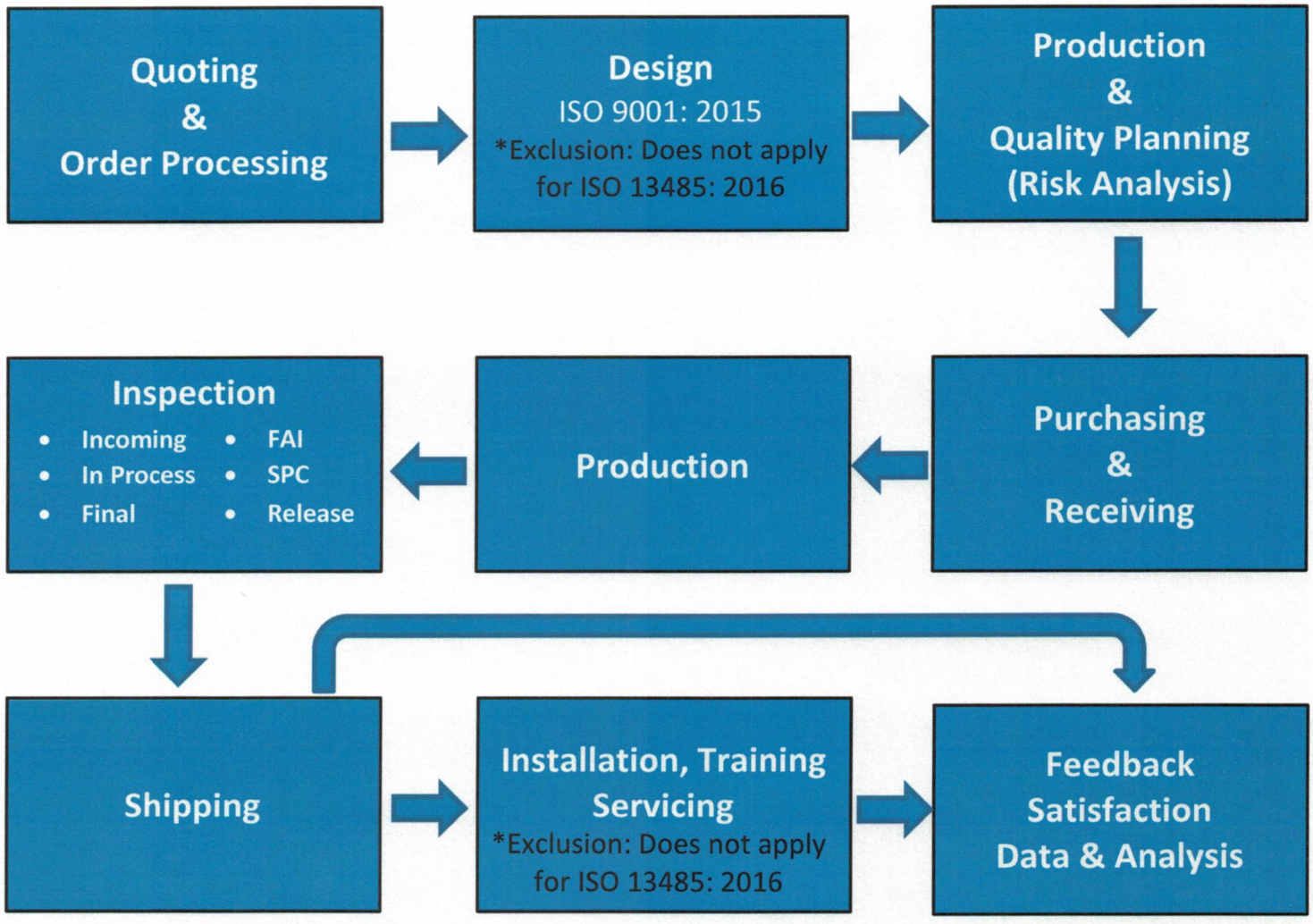
7.5.11 Preservation of product	8.5.4 Preservation	P122 Preservation of Product
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources	R701 Equipment List W316 Methods of Calibration
8 Measurement, analysis and improvement	9 Performance evaluation 9.1 Monitoring, measurement, analysis and evaluation	P124 Inspection R701 Equipment List W316 Methods of Calibration
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation	P111 Calibration and Measurement P114 Analysis of Data
7.5.3 Installation activities ***Exempt** 7.5.4 Servicing activities***Exempt** 8.2.1 Feedback	8.5.5 Post-delivery activities 9.1.2 Customer satisfaction	P129 System Shipping and Installation F516 Customer Survey
8.2.2 Complaint handling	9.1.2 Customer satisfaction	P113 Control of Nonconformances
8.2.3 Reporting to regulatory authorities	8.5.5 Post-delivery activities	P119 Vigilance System
8.2.4 Internal audit	9.2 Internal audit	P112 Internal Audit
8.2.5 Monitoring and measurement of processes	9.1.1 General	F514 Customer complaint F516 Customer Survey
8.2.6 Monitoring and measurement of product	8.6 Release of products and services	P124 Inspection
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs	P113 Control of Nonconformances
8.3.1 General	10.2 Nonconformity and corrective action	P113 Control of Nonconformances
8.3.2 Actions in response to nonconforming product detected before delivery	8.7 Control of nonconforming outputs	P113 Control of Nonconformances
8.3.3 Actions in response to nonconforming product detected after delivery	8.7 Control of nonconforming outputs	P113 Control of Nonconformances

Clause in ISO 13485:2016	Clause in ISO 9001:2015	Evidence/Reference/ Documented Exclusion
8.4 Analysis of data	9.1.3 Analysis and evaluation	P104 Management Review Procedure F501 - Management Review Check List P111 Calibration and Measurement P114 Analysis of Data SUP-EVAL Supplier Evaluation
8.5 Improvement	10 Improvement	P104 Management Review Procedure
8.5.1 General	10.1 General 10.3 Continual improvement	P104 Management Review Procedure
8.5.2 Corrective action	10.2 Nonconformity and corrective action	P113 Control of Nonconformances P115 Corrective Action
8.5.3 Preventive action	0.3.3 Risk-based thinking 6.1 Actions to address risks and opportunities 10.1 General 10.3 Continual improvement	P116 Preventive Action P117 Risk Management

Revision History		
Revision:	**Description:**	**Date:**
Rev. A	Added to QMS	07/07/2011
Rev. B	Updated ISO 13485 exclusions, updated quality docs	11/02/2011
Rev. C	Updated to reflect current quality documents	10/14/2016
Rev. D	Changed office manager to quality manager	11/14/2016
Rev. E	Updated to reflect current quality documents, update scope	10/12/2017
Rev. F	Updated new QMS documents	10/16/2017
Rev. G	Redone and simplified manual (Reducing 56 pgs to only 17 pgs)	11/16/2018
Rev. H	Added quality policy, interested parties table, referenced more docs	08/07/2020
Rev. I	Added history block	08/25/2020
Rev. J	Added Doc# and revision on footer and new procedure P129	09/01/2022
Rev. K	Clarified exclusions to state *ISO 13485:2016 only	09/05/2023
Rev. L	Added ISO 9001:2015 amendment to 4.1 Environmental Sustainability	10/03/2024

7. Processes and Their Interactions

Management	
➢ Management Review	➢ Internal Audit
➢ Quality Policy	➢ Corrective Action
➢ Goals & Objectives	➢ Risk Management
➢ Monitoring	➢ Strategic Planning



Resources & Support	
➢ Maintenance	➢ Training
➢ Calibration	➢ Documentation
	➢ Record Control