



Quality Manual

ISO-9001:2008

& ISO 13485: 2003

Swissline Precision Manufacturing, Inc.
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Approval: _____
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1 Table of Contents

1	TABLE OF CONTENTS	2
2	INTRODUCTION	3
3	COMPANY OVERVIEW	4
4	QUALITY MANAGEMENT SYSTEM	5
4.1	GENERAL REQUIREMENTS	5
4.2	DOCUMENTATION REQUIREMENTS	5
5	MANAGEMENT RESPONSIBILITY	6
5.1	MANAGEMENT COMMITMENT	6
5.2	CUSTOMER FOCUS	6
5.3	QUALITY POLICY	6
5.4	QUALITY PLANNING	7
5.5	RESPONSIBILITY, AUTHORITY AND COMMUNICATION	8
5.6	MANAGEMENT REVIEW	9
6	RESOURCE MANAGEMENT	9
6.1	PROVISION OF RESOURCES	9
6.2	HUMAN RESOURCES	9
6.3	INFRASTRUCTURE	9
6.4	WORK ENVIRONMENT	10
7	PRODUCT REALIZATION	10
7.1	PLANNING OF PRODUCT REALIZATION	10
7.2	CUSTOMER RELATED PROCESSES	11
7.3	DESIGN/DEVELOPMENT	11
7.4	PURCHASING	11
7.5	CONTROL OF PRODUCTION AND SERVICE PROVISION	12
8	MEASUREMENT, ANALYSIS AND IMPROVEMENT	14
8.1	GENERAL	14
8.2	MONITORING AND MEASUREMENT	15
8.3	CONTROL OF NONCONFORMING PRODUCT	16
8.4	ANALYSIS OF DATA	16
8.5	IMPROVEMENT	17



2 Introduction

The purpose of this Quality manual is to define the Quality System and policies of Swissline Precision Manufacturing, Inc. Swissline Precision Manufacturing, Inc. has developed and implemented an ISO 9001:2008 and ISO 13485:2003 quality management system to meet customer requirements, strive to exceed their expectations, and make Swissline Precision Manufacturing, Inc. a better company. The quality system complies with the ISO 9001:2008 and ISO 13485: 2003. It is applicable to all Swissline Precision Manufacturing, Inc. employees.

Swissline Precision Manufacturing, Inc.'s scope of registration is for:

Manufacture CNC precision machined components servicing the aerospace, medical, communication, technological and commercial industries.

In addition to the above scope, Swissline Precision adheres to customer specific and regulatory requirements including applicable sections of 21 CFR 820 Quality System Regulation (as required by contract). Swissline Precision does not distribute or commercialize finished medical devices and is not classed as the "Finished Device Manufacturer". Swissline Precision is a Subcontractor who manufactures to customers' specification requirements.

For ISO 9001, Design Control (7.3), Service provision (7.5.1) are not specified requirements of customer contracts and Swissline Precision Manufacturing, Inc does not perform any of these activities. Therefore, they are not included in the scope of registration for ISO 9001.

Design activities are not specified in customer contracts, therefore design control (ISO 13485 section 7.3) is excluded from the quality management system.

In addition to the design exclusion, the following activities are not applicable to the Swissline Precision ISO 13485 quality management system due to the nature of the medical devices and there are no specific requests for these activities in customer contracts. If they become applicable, then Swissline will determine, define and implement requirements in order to ensure controlled conditions.



ISO 13485 Section	Descriptions
7.5.1.2.2	Installation activities
7.5.1.2.3	Servicing activities
7.5.1.3	Particular requirements for sterile medical devices (control of production provision)
7.5.2.2	Particular requirements for sterile medical devices (Validation of processes)
7.5.3.2.2	Particular requirements for active implantable medical devices and implantable medical devices (Traceability)

This Quality Manual is divided into sections corresponding to the quality system requirements of the ISO 9001 and 13485 standards. Each section contains policies expressing Swissline Precision Manufacturing, Inc. intent to meet the principles of the applicable quality system element. Where a procedure exists defining the element in further detail, the section references the procedure/s that detail how the policy is implemented. These procedures will reference any pertinent instructions and forms required by the quality system.

3 Company Overview

Swissline Precision Manufacturing, Inc. is a privately owned CNC Screw Machine company, servicing Aerospace, Medical, Communications, Technological and Commercial industries. We participate in "Dock to Stock" Certified Supplier programs with many of our customers and in 1999 Swissline was one of two Rhode Island companies awarded the Mass-Mutual Blue Chip Award recognizing innovation & growth in industry. Our formula for success is strong customer service relationships coupled with the latest CNC Technology in order to produce the highest quality products.



4 Quality Management System

4.1 General Requirements

The quality management system is the framework that allows Swissline to clearly define requirements, criteria and methods, thus providing our customers with confidence that the manufacture of products is performed in a well defined and controlled environment. The processes and their application to the quality system are determined and identified. The sequence of these processes and the interaction between them are determined. The interaction between the processes of the quality management system are defined in each quality system procedure and referenced documents.

Swissline ensures that the required resources are available, planned requirements are implemented and processes are monitored, measured and analyzed. Swissline also plans and implements continuous improvement activities, as applicable to maintain the effectiveness of the quality system.

Outsourced processes that affect product conformity are identified and controlled in accordance with the purchasing process.

Reference documents:

QSP-740: Purchasing and Supplier Management

Appendix 2: Swissline Precision Sequence and Interaction Key QMS Process

4.2 Documentation Requirements

Quality System documentation is developed to meet the requirements of ISO 9001 and ISO 13485. The quality system documents include:

- Quality manual
- Quality system procedures
- Work instruction documents
- External documents
- Product drawings
- Relevant process/system forms
- Any regulatory required documents
- Quality records

Quality system documents are controlled which includes review, approval, distribution, and change control. Quality system records are the documentation output of the quality system. These records are appropriately controlled and maintained.

Reference documents:

QSP-423: Document Control

QSP-424: Control of Quality Records



4.3 *Not Applicable*

5 Management Responsibility

5.1 *Management Commitment*

Swissline Precision Manufacturing, Inc. Top Management is responsible for establishing, implementing the quality management system and improving its effectiveness (ISO 9001) or maintaining its effectiveness (ISO 13485) specific responsibilities include: formulating the quality policy, establishing quality objectives, communicating to employees the importance of meeting requirements (customer, statutory and regulatory), defining the organizational structure, assigning authorities and responsibilities, appointing the management representative, periodically reviewing the quality system, and making available the resources and personnel necessary to maintain the system

5.2 *Customer Focus*

Swissline strives to identify current and future customer needs and to meet and exceed customer requirements.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer communication procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization (QSP-720).

5.3 *Quality Policy*

Swissline Precision Manufacturing, Inc Quality Policy Statement

We will sustain our Quality commitment by maintaining an effective Quality Management System and continuously improving our processes to satisfy our Internal and External customers

Each employee of Swissline Precision Manufacturing, Inc. shall:

- ◆ *Be responsible for his / her own quality.*
- ◆ *Satisfy the requirements of Internal and External customers.*
- ◆ *Achieve high work standards.*
- ◆ *Demonstrate full attention to work details.*



In pursuit of the quality policy, it is the intent of Swissline Precision to produce products that consistently meet and/or exceed our customers' expectations. The management of Swissline Precision is committed to this policy by developing and implementing a Quality Management system, making available the required resources, support, and training required to ensure the policy is understood by all employees, and implemented and maintained at all levels in the company. Swissline Precision Manufacturing, Inc. will periodically review the policy to determine its continuing suitability. The quality policy is the basis for determining specific quality objectives.

5.4 *Quality Planning*

5.4.1 *Quality Objectives*

Swissline Precision Manufacturing, Inc. Top Management ensures that relevant Quality Objectives are established at relevant functions of the company. The quality objectives defined will be measurable and consistent with the quality policy. The objectives, performance results, and any changes will be communicated to Swissline Precision Manufacturing, Inc. employees.

Reference documents:

QSP-500: Management Responsibility

5.4.2 *Quality Management System Planning*

Swissline Precision Manufacturing, Inc. Top Management defines the processes needed to meet the requirements and objectives of the quality system. Swissline Precision Manufacturing, Inc. ensures it has the required resources, personnel, documented processes, capabilities etc. in order to consistently meet the quality system requirements. Swissline Precision Manufacturing, Inc. management ensures that any planned changes do not adversely impact the integrity of the system.

Reference documents:

All quality system procedures and related product documents



5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

The President and Vice President constitute Swissline Precision Top Management. Swissline has defined the responsibilities and authorities of personnel in Job Descriptions/Training Records. The relevant responsibility and authority is discussed with each employee at time of hire. As required, the management will review the responsibilities with the employee. The interrelationship of personnel who manage, perform, and verify work affecting quality is detailed in the Organizational Chart. Swissline Precision Top Management and their direct reports ensure that employees are aware of their job responsibilities and authorities and that they are following relevant procedures, instructions, specifications, etc. and that they are meeting requirements. Swissline Precision Top Management ensures that personnel who manage, perform and assess work affecting quality have the required authority and independence to perform such tasks without undue influences which might affect product quality.

Reference documents:

Appendix 1: Organizational Chart.

QSP-622: Competence, Awareness & Training

5.5.2 Management Representative

Swissline Precision Manufacturing, Inc. Top Management has appointed as the Management Representative the Quality Assurance Manager who has the authority and responsibility to ensure that: the quality management system processes are established and maintained, the performance of the quality system and improvements necessary are reported to top management, and awareness of customer requirements and regulatory requirements are promoted throughout the company and resolving matters pertaining to quality. In the absence of the Quality Assurance Manager, the President will assume the ISO Management Representative responsibilities. Swissline Precision Manufacturing, Inc. uses a Quality System Consultant to advise on Quality and Regulatory affairs.

5.5.3 Internal Communication

Swissline Precision Manufacturing, Inc. Top Management ensures that the necessary communication takes place between Swissline employees in order to meet quality system requirements. Pertinent job and quality information generally flows down to employees through department management either verbally or on the written documents. Meetings are held as necessary to review product/job requirements, communicate information and resolve quality issues. Swissline periodically provides feedback to employees on the effectiveness of the system.



5.6 Management Review

Swissline Precision Manufacturing, Inc. Top Management reviews the quality system at planned intervals. The reviews assess the effectiveness, adequacy and continuing suitability of the quality system. The review focuses on assessing Swissline Precision Manufacturing, Inc. performance against defined criteria and quality objectives and evaluating the effectiveness of the quality system. This will then determine whether improvements and changes needed to improve the effectiveness (ISO 9001) or maintain the effectiveness of the quality management system. Management Review Records are retained.

Reference Documents:

QSP-500: Management Responsibility

6 Resource Management

6.1 Provision of Resources

Swissline Precision Manufacturing, Inc. Top Management ensures the availability of resources necessary for the effective implementation of, and improvement of the quality system. These resources include adequate buildings, equipment, tools, people, and supporting services. These resources will allow Swissline Precision Manufacturing, Inc. to meet customer requirements, maintain (ISO 13485) and improve (ISO 9001) the Quality System effectiveness and help enhance customer satisfaction.

6.2 Human Resources

Employees are qualified on the basis of appropriate education, training, skills, and experience. Swissline Precision Manufacturing, Inc. determines the competency needs provides the necessary training to satisfy those needs. Training records are maintained.

Reference documents:

QSP-622: Competence, Awareness & Training

6.3 Infrastructure

Swissline Precision Manufacturing, Inc. Top Management determines and ensures that the infrastructure necessary for the realization of products is available and adequate to meet customer requirements and the objectives of the quality system. This infrastructure includes buildings, equipment, workspace, tools, information technology, and supporting services.

Reference Documents:

QSP-750: Product Realization

WI- 640 : Infrastructure and Work Environment



6.4 *Work Environment*

Swissline Precision Manufacturing, Inc. work areas will be organized in such a way that they are suitable to the needs of the product and are safe for work personnel. Efficient workflow, adequate work conditions, adequate lighting, proper maintenance of equipment, and suitable work areas ensure an adequate work environment to achieve product conformity and compliance with customer and regulatory requirements. Any specific work environment requirements (such as requirements for health, cleanliness and clothing; contamination control; environmental conditions control, etc.) required by contract are defined in manufacturing documents and implemented.

Reference Documents:

QSP-750: Product Realization

WI- 640 : Infrastructure and Work Environment

7 *Product Realization*

7.1 *Planning of Product Realization*

Swissline Precision Manufacturing, Inc. plans and develops processes to meet product realization and contract requirements. Swissline Precision Manufacturing, Inc. documents the processes to the extent necessary to ensure the ability to consistency meet requirements. Swissline Precision Manufacturing, Inc. considers the following:

- Customer Product Requirements
- Specific product quality objectives and product quality requirements
- New resources, processes or documents necessary
- Criteria for product acceptance, inspection requirements, verification, validation and monitoring activities
- Records needed to prove processes and product meet requirements
- Risk management for the product/contract, as required

Reference documents:

Wi-710 Risk Management



7.2 *Customer Related Processes*

Swissline determines the customer product related requirements. All product quotes, contracts and orders are reviewed to assess if customer's requirements are adequately defined and understood, including any applicable statutory and regulatory requirements and any implied requirements. Swissline Precision Manufacturing, Inc. assesses the capacity and capability to meet requirements, and resolves any differences or issues from the quote/proposal phase. Change orders are reviewed, implemented and relevant personnel notified. Verbal orders are confirmed with the customer prior to acceptance. Swissline Precision Manufacturing, Inc. ensures that there are effective communication arrangements with our customers in relation to enquiries, requests, orders, feedback, complaints and Advisory notices, as applicable. Swissline Precision does not provide any specific post-delivery activities.

Reference documents:

QSP-720: Customer Related Processes
QSP-851 Customer Feedback & Communication

7.3 *Design/Development*

This clause is not applicable, as Swissline does not have a product development/design activity.

7.4 *Purchasing*

Swissline Precision Manufacturing, Inc. ensures that purchased products conforms to purchasing specifications. Criteria for selection, evaluation and re-evaluation of suppliers are defined. Records of supplier approval and performance are maintained. Purchasing documents clearly describe product/service ordered, including specific standards/quality clauses, as applicable. Purchasing documents are reviewed and approved prior to release. Where Swissline Precision Manufacturing, Inc. or our customer performs verification at the supplier premises, then the verification arrangements and release process is defined in the purchasing documents. Swissline Precision Manufacturing, Inc. performs receiving inspection to determine conformance to purchasing requirements. The level of inspection is dependent on the product and its impact on Swissline operations and finished product.

Reference Documents:

QSP-740: Purchasing and Supplier Management



7.5 Control of Production and Service provision

7.5.1 Control of Production and Service Processes

Production and Service processes are planned, documented as required, and carried out under controlled conditions. Swissline Precision Manufacturing, Inc. ensures that it understands the product specifications and determines the processes, and their sequence in order to produce product to specification. Swissline Precision Manufacturing, Inc. selects suitable process and measuring equipment. Personnel performing complex or critical operations are provided with instructions, drawings, and when applicable workmanship criteria. Production and process equipment is checked and maintained to ensure continuing process capability. Production areas are maintained in an orderly fashion to provide a suitable production and working environment. Inspections and tests are conducted at significant stages, including receiving, production, and prior to delivery of finished products. Records of manufacturing and inspections are maintained. Controlled conditions at Swissline Precision, include as appropriate:

- Specifications/Drawings-Product Specific documents defining characteristics and workmanship criteria
- Instructions/SOP's- Instruction type documents defining the manner of production
- Use of suitable manufacturing equipment in a suitable working environment
- Use of suitable measuring equipment, including inspection fixtures/tooling
- Measurement and monitoring of process and product characteristics
- Final product release and delivery activities
- Evidence of completion of required manufacturing and inspections, unless otherwise authorized and documented
- Control of manufacturing process and document changes
- Control of labeling and packaging operations
- Maintaining traceability to meet customer requirements

Manufacturing areas are maintained in an orderly fashion to provide a suitable manufacturing and working environment to ensure cleanliness of product and adequate contamination control. Manufacturing documentation is approved prior to use and changes are controlled to the levels required by contract. If any manufacturing work is subcontracted, then the necessary requirements and controls are defined in the Purchasing documents.

Reference Documents:

QSP-750: Product Realization

QSP-740: Purchasing and Supplier Management

WI- 640 : Infrastructure and Work Environment



7.5.2 Validation of processes

Currently, Swissline does not perform any special processes. If a special process is identified, it will be controlled by a written instruction and validated. Additionally, the customer may identify processes that require validation as part of a process qualification requirement. If a special processes performed by outside sources must be documented by certification. Where required by contract, any software used to control production/process parameters will be validated. If validation is performed, validation records will be maintained. Validation shall confirm the ability of special processes to achieve planned results.

Reference Documents:

WI-752 Process Validation

7.5.3 Identification and Traceability

Materials, components, subassemblies, and products are suitably identified throughout the product realization process. This is achieved by a combination of labels, tags, marking, or reference to part/job paperwork. The identification of product status shall be maintained throughout production and storage, to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is shipped or used Traceability is controlled to the extent necessary, as required by Swissline Precision Manufacturing, Inc. and specific customer requirements.

Reference Documents:

QSP-750: Product Realization

QSP-753: Identification & Traceability

WI- 824 : Inspection Work Instruction

7.5.4 Customer Property

Swissline exercises care with customer property (including intellectual property) while under Swissline control. Customer provided product will be identified, verified, protected, stored and maintained appropriately. Customers may supply drawings, specifications, test documents, etc. during the contract review process. Lost, damaged, or otherwise unsuitable products/documents will be reported to the customer. The customer is responsible for providing acceptable product.

Reference Documents:

QSP-755: Material Control

QSP-423: Document Control



7.5.5 *Preservation of Product*

Swissline Precision Manufacturing, Inc. will safeguard and protect product during and between all processing steps including delivery. Preservation of product applies to finished product, components and constituent materials. Methods of identification, handling, packaging, storage and protection will be suitable to the product to prevent damage or deterioration. As applicable, part specifications or work instructions will define specific product/material preservation requirements.

Reference Documents:

QSP-755: Material Control

7.6 *Control of Monitoring and Measuring Devices*

Swissline Precision Manufacturing, Inc. determines inspections to be made and selects suitable measuring equipment to confirm product conformance to requirements. The measuring equipment used to confirm product to requirements will be of the required accuracy and appropriate for making the measurement. All instruments, tools, measuring equipment, and other devices used to verify the conformance of the product to the specification are identified, calibrated and suitably controlled. The equipment calibration will be traceable to National Standards or other Standards as required. If software is used for monitoring/measurement, then it will be validated prior to use and re-validated as appropriate. Calibration records are retained.

Reference Documents:

QSP-760: Control of Monitoring & Measuring Devices

8 *Measurement, Analysis and Improvement*

8.1 *General*

Swissline Precision Manufacturing, Inc. will plan and implement suitable monitoring, measurement, analysis and improvement processes. These will be performed to ensure product conformity, quality system conformity and continuous improvement in the effectiveness (ISO 9001) or maintain the effectiveness (ISO 13485) of the quality system. Where applicable, statistical techniques will be identified and implemented.

Reference Documents:

QSP-500: Management Responsibility

QSP-750: Product Realization



8.2 *Monitoring and Measurement*

8.2.1 *Customer Feedback*

Swissline Precision Manufacturing, Inc. will assess customer perception of Swissline Precision Manufacturing, Inc. product/service provided. The monitoring process includes data from customer complaints, returns and customer feedback. The Nonconformance control process is used to resolve complaints. Additionally, Swissline Precision Manufacturing, Inc. may decide to actively solicit customer satisfaction information from customers via surveys. Any customer satisfaction information obtained is reviewed by Quality Assurance then presented at Management Review meetings. The feedback methods will meet any applicable national or regional regulations. For ISO 13485, the feedback system will provide for early warning of quality problems and for input into the corrective and preventive action system.

Reference Documents:

QSP-500: Management Responsibility

QSP-830: Nonconformance Control

QSP-851: Customer Feedback and Communication

8.2.2 *Internal Audit*

Swissline Precision Manufacturing, Inc. will establish an internal audit program to determine if the quality system conforms to requirements and to determine whether it is effectively implemented and maintained. Audits are planned and carried out periodically by personnel independent of the activity being audited. Audit area management reviews the results of audits. Timely action is taken, where appropriate. Follow-up activities verify and record the implementation and effectiveness of the action taken. Audit results are reported at management review.

Reference Documents:

QSP-822: Internal Audit

8.2.3 *Monitoring and measurement of processes*

Swissline Precision Manufacturing, Inc. applies suitable methods for monitoring the Quality System. These include the internal audit, corrective action, preventive action, management review and data analysis processes. The Management review will identify any other monitoring and/or measurement processes determined necessary. Such monitoring processes will be implemented accordingly. When planned results are not achieved, then appropriate correction will be taken. If required corrective action will be taken.



Reference Documents:

QSP-500: Management Responsibility
QSP-822: Internal Audit
QSP-850: Corrective & Preventive Action

8.2.4 *Monitoring and Measurement of Product*

Swissline Precision Manufacturing, Inc. monitors and measures product to ensure conformity with requirements in accordance with a defined plan. This includes all monitoring and measurement activities associated with materials, components, assemblies, and product from receipt to product delivery. Inspection Records are retained which show that product requirements have been met, the required inspections have been completed, and identifies the inspection authority responsible for release of the product. Where required, these records will show actual inspection results data. Final product release or delivery will not take place until all required activities and inspections have been performed to requirements.

Reference Documents:

QSP-750: Product Realization
WI -824: Inspection Work Instruction

8.3 *Control of Nonconforming Product*

Swissline Precision Manufacturing, Inc. will control nonconforming product detected before and after delivery/use has started. Swissline Precision Manufacturing, Inc. personnel are encouraged to be vigilant in identifying nonconforming product. Nonconforming product is reviewed and dispositioned in an appropriate manner. Swissline Precision adheres to any required customer or regulatory requirements for disposition and reporting. Records of nonconforming products and their dispositions are retained.

Reference documents:

QSP-830: Nonconformance Control

8.4 *Analysis of Data*

Swissline Precision Manufacturing, Inc. will review and analyze data to demonstrate the effectiveness of the quality system and to evaluate improvement opportunities (ISO 9001). For the ISO 13485 the data analysis will evaluate if improvement of the effectiveness of the quality management system can be made. The data reviewed will include: customer satisfaction, product conformity, product and process trends, preventive action opportunities, and supplier performance information. The analysis and results will be presented to management review for evaluation.

Reference documents:



QSP-500: Management Responsibility
QSP-830: Nonconformance Control
QSP-850: Corrective & Preventive Action

8.5 *Improvement*

8.5.1 *General*

Swissline Precision Manufacturing, Inc. identifies and implements any changes necessary to maintain the continued suitability and improve the effectiveness of the quality system (ISO 9001) and to maintain the continued suitability and effectiveness of the quality management system (ISO 13485). Swissline Precision Manufacturing, Inc. will primarily use quality policy, quality objectives the feedback measures of corrective and preventive action, audit results, management review, and the analysis of the data to identify to improvement activities. Swissline Precision Manufacturing, Inc. will also use the quality policy and quality objectives as source of improvement. Swissline Precision Manufacturing has procedures and systems in place to manage customer feedback, coordinating with affected/responsible organizations, and for compliance with applicable regulatory requirements including complaints, advisory notices, and adverse events. These procedures shall be capable of being implemented at any time. Records of improvements are maintained.

Reference documents:

QSP-500: Management Responsibility
QSP – 830 Non Conformance Control
QSP-851: Customer Feedback and Communication

8.5.2 *Corrective Action*

Swissline takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure (QP-850) defines requirements for

- Reviewing nonconformities (including customer complaints),
- Determining the causes of nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur,
- Determining and implementing action needed,
- Records of the results of action taken (see 4.2.4), and
- Reviewing corrective action taken.
- Determining and implementing the action needed, including, if appropriate, updating documentation



Reference documents:

QSP-850: Corrective & Preventive Action

8.5.3 *Preventive Action*

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

A documented procedure (QP-850) defines requirements for:

- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken
- Reviewing preventive action taken
- Reviewing preventive action taken and its effectiveness

Reference documents:

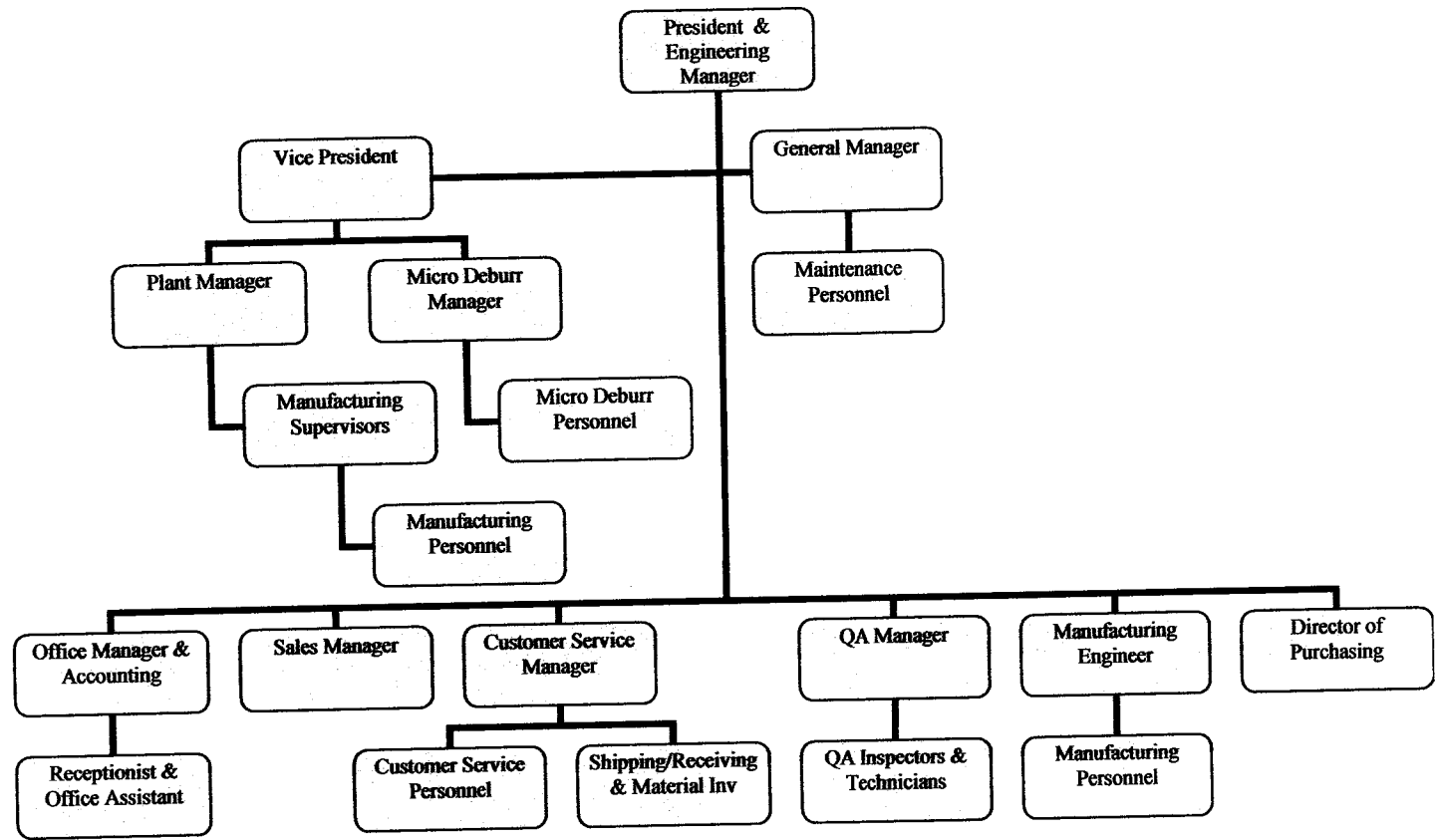
QSP-500: Management Responsibility

QSP-850: Corrective & Preventive Action



SWISSLINE PRECISION ORGANIZATIONAL CHART

Appendix 1-1





Swissline Precision Mfg. Sequence and Interaction of Key QMS

Appendix 2-2

