SWISS-TECH, LLC

Quality Management System Manual

ISO / AS

Quality Management System

Precision - Quality - Service

EXCEEDING ALL EXPECTATIONS

Since our inception in 1965, Swiss-Tech has supplied the medical, aerospace, hydraulic, electronic and other industries with exceptional quality components produced on Swiss-style screw machines.

Swiss-Tech has been able to invest in the latest technology, automation and an expansion of our state-of-the-art facility. Leading-edge technology, combined with a highly-skilled and dedicated workforce, and a carefully selected supplier base for special processes, enables us to provide complex, ready to use parts to our customers.

We believe in continuous improvement in products, processes and people. We consistently strive to exceed our customers expectations. To achieve these goals, we are guided by our mission statement:

Swiss-Tech is committed to delivering high-quality precision components that meet the need and expectations of our customers.
Swiss-Tech will continually strive to improve the quality of our delivered product as well as the processes we use to fulfill those obligations.
Swiss-Tech will ensure success through the adherence to an effective quality management system based on continual improvement and management commitment to achieve customer satisfaction.

Frank Meiland

President, Swiss-Tech, LLC

Swiss-Tech

Quality Management System Manual

Revision 20

Frank Meiland *March 10, 2016*
Frank Meiland, President

Scott Pacourek *March 10, 2016*
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Table of Contents

Contents **Page**

ISO / AS Quality Management System

1 Scope

Swiss-Tech is a job shop that manufactures Swiss Screw Machine Products. The design and control of those products are the exclusive purview of our customers. For this reason, Sections 7.3 Design and Development, and the Installation and Service activities provisions of Section 7.5.1.4 Production and Service Provision of the applicable ISO Standard(s), are excluded from Swiss-Tech's Quality Management System.

a) Swiss-Tech's Quality Management System is based on the requirements of ISO Standard(s) of current certification. The current certification(s) of Swiss-Tech's Quality Management System are the ISO 9001:2008, ISO13485:2003, and AS9100C Standard(s). All areas within the documentation of this Quality Management System where referenced as applicable ISO and / or AS9100 standards should be understood as meeting the requirements of the standard(s) explained in this paragraph.

1.1 General

Swiss-Tech's Quality Management System is based on the requirements of the applicable ISO and AS9100 standards which specifies the requirements that Swiss-Tech

a) will demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

1.2 Application

All requirements of the **applicable ISO and AS9100 standards**, except Sections 7.3 Design and Development, and the service provision of 7.5 Production and Services Provision, are applicable to Swiss-Tech's Quality Management System. Because of the nature of Swiss-Tech's business, any design related activities are limited to meeting the requirements of section 7.1 Planning of Product Realization. The exclusion of Sections 7.3 Design and Development, and the service provision from Section 7.5 Production and Service Provision, from Swiss-Tech's Quality Management System, does not affect Swiss-Tech's ability, or responsibility, to provide product that meets the customer's and applicable statutory and regulatory requirements.

2 Normative Reference

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, to Swiss-Tech's Quality Management System.

ISO 9000:2008, ISO 13485:2003, and AS 9100C all referenced as the applicable certified standard within this Quality management systems – Fundamentals and vocabulary

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in the applicable ISO standard apply.

Throughout the text of this QMS, wherever the term "product" occurs, it can also mean "service". In this context, service is defined as support for the product without liability to the design engineer or Swiss-Tech.

The following terms, used in this QMS are used to describe the supply chain and reflect the vocabulary used:

Supplier → organization (Swiss-Tech) → Customer

3.1 Risk

An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.

3.2 Special Requirements

Those requirements identified by the customer, or determined by Swiss-Tech, which have high risks to being achieved, thus requiring their inclusion in the risk management process. Factors used in the determination of special requirements include product or process complexity, past experience, and product or process maturity. Examples of special requirements include performance requirements imposed by the customer that are at the limit of the industry's capability, or requirements determined by Swiss-Tech to be at the limit of its technical or process capabilities. See 7.2.1 and 7.2.2 for requirements relating to the product.

3.3 Critical Items

Those items (e.g., functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product; including safety, performance, form, fit, function, producibility, service life, etc,; that require specific actions to ensure they are adequately managed. Examples of critical items include safety critical items, fracture critical items, mission critical items, key characteristics, etc.

3.4 Key Characteristics

An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life, or producibility, that requires specific actions for the purpose of controlling variation.

3.5 QMS

In this text, “QMS” may be used in place of Quality Management System.

4 Quality Management System

4.1 General Requirements

Swiss-Tech has established, documented, and implemented a quality management system. Swiss-Tech maintains this system and continually improves its effectiveness in accordance with the requirements of the applicable ISO and AS9100 standards and as outlined in SP-4.1-1, System Documentation. Swiss-Tech’s quality management system also addresses customer and applicable statutory and regulatory requirements as outlined in SP-7.1-1, Quality Planning system procedure. The needed processes and their interaction are shown in Appendix B – System Procedure Flowchart and in Appendix C – System Structure.

Swiss-Tech:

a) Determines the processes needed for the quality management system and their application throughout the organization (see 1.2),
b) determines the sequence and interaction of these processes,
c) determines criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitors, measures where applicable and analyzes these processes, and
f) implements actions necessary to achieve planned results and maintain the effectiveness through these processes, as outlined in SP-8.5.1-1, Continual Improvement Process.

Swiss-Tech manages these processes, in accordance with the requirements of the ISO International Standard.

Where Swiss-Tech chooses to outsource any process that affects product conformity to requirements, Swiss-Tech ensures control over such processes. Control of such outsourced processes is identified within the quality management system.

4.2 Documentation Requirements

4.2.1 General

The quality management system documentation includes

a) documented statements of a quality policy and quality objectives, stated in the Quality Management System Manual, and in SP-8.5.1-1, Continual Improvement,

b) a quality manual,
c) documented procedures and records required by the applicable ISO International Standard will be implemented and maintained, as per SP-4.2.1-1, System Procedures,
d) documents including records, determined by Swiss-Tech to be necessary to ensure the effective planning, operation and control of its processes.
e) records required by the International Standards of registration, per SP-4.2.4-1 Control of Records
f) any other documentation specified by national or regional regulations are requested of the customer through the Terms and Conditions of the sales order and documentation is controlled per SP-7.2.2-1, Quotes

Swiss-Tech has established and maintains a file that contains or identifies documents that define product specifications and quality management system requirements. These documents define the complete manufacturing process. Swiss-Tech ensures that all personnel have access to, and are aware of, relevant quality management system documentation and changes.

4.2.2 Quality Manual

Swiss-Tech established and maintains a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions 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 depicted in Appendix B – System Procedure Flowchart and in Appendix C – System Structure.

4.2.3 Control of Documents

Documents required by the quality management system are controlled according to:

Swiss-Tech's Quality Management System Manual,
SP-4.1-1, System Documentation,
SP-4.2.1-1, System Procedures,
SP-4.2.1-2, System Forms, and in,
SP-4.2.1-3, Work Instructions,
SP-4.2.3-1, Customer Drawings and Specifications,
SP-4.2.3-2, Control of Internal Drawings,
SP-4.2.3-3, Job Change Requests, and in, and
SP-4.2.3-4, Control of Industry Standards

Records are a special type of document and are controlled according to the requirements given in 4.2.4, and in SP-4.2.4-1, Control of Records.

Swiss-Tech has established the documented procedures that 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) to ensure that documents of external origin determined by Swiss-Tech to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Swiss-Tech 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 per the applicable procedure listed in 4.2.3.

Obsolete records are defined per the Records 5.0 in the applicable procedure per SP-4.2.4-1, Control of Records

This period will ensure 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 Swiss-Tech, which is a minimum of two years from the last shipment activity but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements which is supplied by the customer purchase order through requirements stated in the terms and conditions (4.2.1 f)

4.2.4 Control of Records

Records are established and controlled to provide evidence of conformity to requirements and of the effective operation of the quality management system will be controlled. Swiss-Tech has documented the following procedures to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records, both paper and electronic, are defined in the records' section of each System Procedure;

SP-4.2.1-1, System Procedure,
SP 4.2.1-2, System Forms,
SP 4.2.1-3, Work Instructions,
SP-4.2.4-1, Control of Records, and
SP-7.1-2, Customer's Special Documentation Requirements.

Additionally all records will remain legible, readily identifiable and retrievable.

Swiss-Tech retains records for a period of time at least equivalent to the lifetime of the medical device as defined per SP-4.2.4-1, Control of Records procedure. This will be a minimum of two years from the last shipment activity by Swiss-Tech or as specified by

relevant regulatory requirements, which is supplied by the customer purchase order through requirements stated in the terms and conditions (4.2.1 f)

The documented procedure SP-7.4.1-2, Control of Purchasing defines the method for controlling records that are created by and/or retained by suppliers.

5 Management Responsibility

5.1 Management Commitment

Swiss-Tech‘s top management provides evidence of its commitment to the development and implementation of the quality management system and continual improvement of its effectiveness by

a) Communicating to Swiss-Tech 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, and
e) ensuring the availability of resources.

5.2 Customer Focus

Swiss-Tech’s top management ensures that customer requirements are determined through the order review process, per SP-7.2.1-1, Order Entry, and are met [See 1.1 B) of QMSM] by using SP-7.2.3-1, Customer Satisfaction and SP-8.4-1, Data Analysis.

Swiss-Tech’s top management ensures that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved, as per SP-8.5.3-1, Preventative Action and SP-8.5.2-1, Corrective Action.

5.3 Quality Policy

Swiss-Tech‘s top management ensures that the quality policy

a) is appropriate to the purpose of Swiss-Tech,
b) includes and implements a commitment to comply with requirements and to continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood, meaning that the quality policy is comprehended and performed, within Swiss-Tech, and
e) is reviewed for continuing suitability.

5.3.1 Health and Safety Policy

It is the policy of this company that its operations shall be carried out with the greatest regard for the health and safety of all workers.

Management believes that safety and efficient production go hand-in-hand. Every effort will be made to prevent injury to our employees by taking all possible steps to improve working conditions and practices. In order to ensure the safety of our workers, the company has developed this health and safety policies and procedures that everyone must follow at all times. To enforce these procedures, management will make routine checks of the work site.

Swiss-Tech functions in full conformity with all safety laws, regulations, codes and standards applying to operations to ensure the safety and protection of all those working in our operations. All workers are also expected to comply with the law and company job requirements.

The Personal Protective Equipment required for all employees to wear while on the production floor is hearing protection (This is not a requirement for visitors), safety glasses or side shields, and non-slip oil resistant shoes or slip resistant overshoes for visitors and employees who do not have slip resistant shoes.

Our incident prevention program must have the co-operative efforts of both the workers and management in order to be successful. Everyone must help recognize and eliminate hazards as they are found. With the daily commitment and support of everybody, we can work together as a team to reduce job hazards and maintain an efficient and safe operation.

5.4 Planning

5.4.1 Quality Objectives

Swiss-Tech‘s top management ensures that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within Swiss-Tech. The quality objectives are measurable and consistent with the quality policy as outlined in SP-8.5.1-1, Continual Improvement.

5.4.2 Quality Management System Planning

Swiss-Tech’s top management ensures that

a) the planning of the quality management system is carried out in order to meet the requirements given in section 4.1, Quality Management System General Requirements, 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

Swiss-Tech's top management ensures that responsibilities and authorities are defined, and communicated within Swiss-Tech.

(See Appendix A, Swiss-Tech Organizational Chart)

Swiss-Tech's 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.

5.5.2 Management Representative.

Swiss-Tech's top management has appointed the Quality Assurance Manager who, irrespective of other responsibilities, has responsibility and authority that includes;

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to Swiss-Tech's top management on the performance of the quality management system and any need for improvement,
c) ensuring the promotion of awareness of regulatory and customer requirements throughout Swiss-Tech, and
d) the organizational freedom and unrestricted access to Swiss-Tech's top management, including liaison with external parties on matters relating to QMS, to resolve quality management issues.

5.5.3 Internal Communication

Swiss-Tech's top management ensures that appropriate communication processes are established within Swiss-Tech and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management Review

5.6.1 General

Swiss-Tech's top management reviews Swiss-Tech's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained (see 4.2.4) and as outlined in SP-5.6.1-1, Quality System Reviews.

5.6.2 Review Input

The input to management review includes information on

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system,
g) recommendations for improvement and
h) new or revised regulatory requirements

as outlined in SP-5.6.1-1, Quality System Reviews.

5.6.3 Review Output

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

a) improvement needed to maintain the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs,

as outlined in SP-5.6.1-1, Quality System Reviews.

Swiss-Tech records and maintains all results of management reviews.

6 Resource Management

6.1 Provision of Resources

Swiss-Tech determines and provides the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and
b) to meet regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

Personnel performing work affecting conformity to product requirements, directly or indirectly, is competent on the basis of appropriate education, training, skills and experience. Competence considerations include, but are not limited to: future demands, anticipated management and workforce succession needs, changes in the process and equipment, individual competency needs, and statutory and regulatory requirements, standards, directives, etc.

6.2.2 Competence, Training and Awareness

Swiss-Tech accomplishes competency, awareness and training, as outlined in SP-6.2.2-2 Training, in order to;

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,
b) where applicable provide training or take other actions to achieve the necessary competence,
c) evaluate the effectiveness of the actions taken,
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintain appropriate records of education, training, skills and experience, (see 4.2.4).

6.3 Infrastructure

Swiss-Tech determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) building, workspace, associated utilities, and preventive maintenance, outlined in SP-6.3-1, Preventive Maintenance,
b) process equipment, defined in SP-6.3-2, Control of Software and Hardware, and SP-6.3-3, CNC Machining Programs,
c) supporting services (such as transport, communication or information systems),
d) customer required contingency plans which will be provided to the customer upon request, and
e) pest control (such as insects or rodents) is provided on an as-needed basis in manufacturing and administrative areas

Swiss-Tech has established documented requirements for maintenance activities, including their frequency, when such activities or lack there of can effect product quality, per SP-6.3-1, Preventive Maintenance. Records are also maintained. (see 4.2.4)

6.4 Work Environment

Swiss-Tech determines and manages the work environment needed to achieve conformity to product requirements. Swiss-Tech complies with all Federal and State Health, Safety and Environmental regulations. The following requirements apply:

a) Establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1). Product is cleaned in accordance with section 7.5.1.2.1 b) therefore requirements contained in section 6.4 a) do not apply prior to the cleaning process
b) If work environment conditions can have an adverse effect on product quality,

establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1). Product is cleaned in accordance with section 7.5.1.2.1 b) therefore requirements contained in section 6.4 b) do not apply prior to the cleaning process

c) Ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person see 6.2.2 b) for details

d) If appropriate, special arrangements are established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel see 7.5.3) and work instruction SP 4.2.1-3.

7 Product Realization

7.1 Planning of Product Realization

Swiss-Tech 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, and is outlined in SP-7.1-1, Quality Planning. Swiss-Tech establishes documented requirements for risk management, and is outlined in SP-7.1-2 All records are controlled (see 4.2.4).

In planning product realization, Swiss-Tech determines the following, as appropriate:

a) the customer's quality objectives and requirements for the product utilizing SP-7.2.1-1; Order Entry;

b) the need to establish processes and documents, and to provide resources specific to the product as controlled through SP-4.2.3-1, Customer Drawings and Specifications, SP-4.2.3-2, Control of Internal Drawings, SP-7.5.3-1, Product Identification and Traceability, and SP-7.5.3-2, Material Identification and Traceability;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance using SP-7.1-2, Customers' Special-Documentation Requirements, and SP-8.2.4-4, Final Inspection;

d) records needed to provide evidence that the realization processes and resulting product meet requirements, as per section 4.2.4, Control of Records, of this Quality Management System;

e) configuration management appropriate to the product;

f) resources to support the use and maintenance of the product.

The output of this planning is in a form suitable for Swiss-Tech's method of operations.

7.1.1 Project Management

As appropriate to Swiss-Tech and the product, Swiss-Tech plans and manages product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints outlined in SP-7.1-1, Quality Planning.

7.1.2 Risk Management

Swiss-Tech has established, implemented, and maintains a process for managing risk to the achievement of applicable requirements, that includes as appropriate to Swiss-Tech and the product

a) assignment of responsibilities for risk management,
b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
c) identification, assessment and communication of risks throughout product realization,
d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
e) acceptance of risks remaining after implementation of mitigating actions.

Swiss-Tech manages this by using SP-7.1-1, Quality Planning, SP-7.1-2, Customer's Special Docs., and sections 1 and 5.5.1 of this QMSM.

7.1.3 Configuration Management

Swiss-Tech has established, implemented, and maintains a configuration management process that includes, as appropriate to the product

a) configuration management planning outlined in SP-7.1-1, Quality Planning, SP-7.1-2, Customer's Special Docs, and sections 1 and 5.1 of this QMSM,
b) configuration identification shown by 7.5.3 of this QMSM,
c) change control detailed by SP-4.2.3-3, Job Change Request,
d) configuration status accounting as per sections 8.2.4 and 8.2.3 of this QMSM, and
e) configuration audit outlined in section 4.2.4 of this QMSM and SP-8.2.2-1, Internal Audits.

7.1.4 Control of Work Transfers

Swiss-Tech has established, implemented, and maintains a process that plans and controls the temporary or permanent transfer of work (e.g., from one organization facility to another, from the organization to a supplier, from one supplier to another supplier) and verifies the conformity of the work to requirements, as outline in SP-4.2.3-4, Control of Industry Standards.

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

Swiss-Tech 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, where known,
c) statutory, regulatory, and special requirements applicable to the product, and
d) any additional requirements considered necessary by Swiss-Tech,

in accordance with SP-7.2.1-1, Order Entry.

7.2.2 Review of Requirements Related to the Product

Swiss-Tech reviews the requirements related to the product, utilizing SP-7.2.2-1, Quotations, SP-7.2.1-1, Order Entry, and SP-7.2.2-2, Scheduling. This review is conducted prior to Swiss-Tech'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) Swiss-Tech has the ability to meet the defined requirements,
d) special requirements of the product are determined, and
e) risks (e.g., new technology, short delivery time frame) have been identified (see 7.1.2).

Records of the results of the review and actions arising from the review are maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements are confirmed by Swiss-Tech before acceptance.

Where product requirements are changed, Swiss-Tech, using SP 7.2.1-1, Order Entry, ensures, that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer Communication

Swiss-Tech determines and implements effective arrangements for communicating with the customer in relation to

a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints, (see 8.2.1), and
d) advisory notices (see 8.5.1)

in accordance with SP-7.2.1-1, Order Entry, SP-7.2.2-2, Scheduling, and SP-7.2.3-1, Customer Satisfaction.

7.3 Design and Development

Swiss-Tech's customers have already established the product characteristics and specifications. Product is entirely produced in accordance with engineering drawings and specifications provided by the customer. The customer also has control of any future development or changes of the product characteristics. Swiss-Tech may need to adjust the product realization process for the final product to meet the customer's requirement and specification. This activity, when necessary, is planned and controlled via section 7.1, Planning of Product Realization, of our QMS, SP-7.2.1-1, Order Entry, and SP-4.2.3-2, Internal Drawings.

As a consequence of Swiss-Tech not planning and controlling the design and development of product, section 7.3, Design and Development, of the applicable ISO Standard is excluded from Swiss-Tech's QMS.

7.4 Purchasing

7.4.1 Purchasing Process

Swiss-Tech ensures that purchased product conforms to specified purchase requirements according to SP-7.4.1-2, Control of Purchasing. The type and extent of control applied to the supplier and purchase product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

Swiss-Tech is responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer in accordance with SP-7.4.1-2, Control of Purchasing and SP-7.5.4-1, Customer Supplied Material.

Swiss-Tech evaluates and selects suppliers based on their ability to supply product in accordance with Swiss-Tech's requirements, as outlined in SP-7.4.1-1, Supplier Evaluation. Criteria for selection, evaluation, and re-evaluation, are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained (see 4.2.4).

Swiss-Tech:

a) maintains a register of its suppliers, per SP-4.2.4-1, Control of Records that includes approval status (e.g., approved, conditional, disapproved) and the scope of the approval (e.g., product type, process family),
b) periodically review supplier performance; the results of these reviews are used as a basis for establishing the level of controls to be implemented,
c) define the necessary actions to take when dealing with suppliers that do not meet requirements,
d) ensure where required that both Swiss-Tech and all suppliers use customer-approved special process sources,

e) define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status, and
f) determine and manage the risk when selecting and using suppliers (see 7.1.2).

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements, as outlined in SP-7.2.1-1, Order Entry, and SP-7.4.1-1, Supplier Evaluation.
d) the identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data as outlined in SP-4.2.3-1, Customer Drawings and Specifications and SP-4.2.3-2, Control of Drawings,
e) requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by Swiss-Tech, and as applicable critical items including key characteristics outlined in SP-4.2.3-4, Control of Industry Standards,
f) requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection/verification, investigation or auditing,
g) requirements regarding the need for the supplier to
- notify Swiss-Tech of nonconforming product,
- obtain Swiss-Tech's approval for nonconforming product disposition,
- notify Swiss-Tech of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain Swiss-Tech's approval, and
- flow down to the supply chain the applicable requirements including customer requirements,
h) records retention requirements handled by SP-4.2.4-1, Control of Records, and
i) right of access by Swiss-Tech, their customers and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

Swiss-Tech ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability given in SP-7.5.3.2, Material ID and Traceability. Swiss-Tech maintains relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4)

7.4.3 Verification of Purchased Product

Swiss-Tech establishes and implements the inspection or other activities necessary for ensuring that purchased products meet specified purchase requirements, according to SP-8.2.4-1, Receiving Inspection. Swiss-Tech will not accept customer verification activities performed at any level of the supply chain as evidence of effective control of quality in place of their own.

Where purchased product is released for production use pending completion of all required verification activities, it will be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where Swiss-Tech delegates verification activities to the supplier, the requirements for delegation will be defined and a register of delegations maintained (see 4.2.4).

Where Swiss-Tech or its customer intends to perform verification at the supplier's premises, Swiss-Tech states the intended verification arrangements and method of product release in the purchasing information, per SP-7.4.1-2, Control of Purchasing Records of verification are maintained. (see 4.2.4)

7.5 Production and Service Provision

7.5.1 Control of production and service provision

7.5.1 General requirements

Swiss-Tech plans and carries out production under controlled conditions. Controlled conditions include, as applicable;

a) the availability of information that describes the characteristics of the product, per SP-4.2.3-1, Customer Drawings, SP-4.2.3-2, Control of Internal Drawings, and SP-4.2.3-4, Control of Industry Standards.
b) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary and outlined in SP-7.5.1-1, Machining Work Instructions, and SP-4.2.1-3, Work Instructions.
c) the use of suitable equipment, according to SP-6.3-3, CNC Machining Programs, SP-6.3-1, Preventive Maintenance, and SP-7.5.1-2, Control of Tooling,
d) the availability and use of monitoring and measuring equipment, as outlined in SP-7.5.1-3, Calibration,
e) the implementation of monitoring and measurement according to SP-8.2.4-3, In-Process Inspection,
f) the implementation of product release, delivery and post-delivery activities, as found in SP-7.2.1-1, Order Entry and SP-7.5.1-4, Handling, Storage, Packing, Preservation and Shipping,
g) accountability for all product during production (e.g., parts quantities, split orders, nonconforming products) shown in SP-7.5.3-1, Product ID and Traceability,
h) Evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized outlined in

SP-8.2.4-3, In-Process Inspection, SP-8.2.4-4 Final Inspection, and SP-8.2.4-2, First Article Inspection,

i) Provision for the prevention, detection, and removal of foreign objects according to SP-7.1-1, Quality Planning SP-8.5.3-1, Preventative Action,

j) Monitoring and control of utilities and supplies as per SP-6.3-1, Preventive Maintenance and SP-7.4.1-2, Control of Purchasing, to the extent they affect conformity to product requirements,

k) Criteria for workmanship, specified in the clearest practical way (e.g., written standards, representative samples, illustrations) outlined in SP-4.2.1-3, Work Instructions, SP.7.1-1 Quality Planning procedure and

l) the implementation of defined operations for labeling and packaging.

Planning considers, as appropriate

- establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
- designing, manufacturing and using tooling to measure variable data,
- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and
- special processes (see 7.5.2).

Swiss-Tech establishes and maintains a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution.

The batch records are verified and approved.

7.5.1.1 Production Process Verification

Swiss-Tech conducts first article inspection according to SP-8.2.4-2, First Article Inspection, by using a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. Swiss-Tech repeats this process when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

7.5.1.2 Control of production and service provision-Specific requirements

Personnel authorized to approve changes to production processes will be identified. See SP-8.5.1-1, Continual Improvement.

Swiss-Tech will control and document all changes affecting processes, production, production equipment, tools or software programs, per SP-4.2.4-1, Control of Records and SP-6.3-2, Control of Software and Hardware.

The results of changes to production processes will be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity defined by SP-4.2.3-4, Control of Industry Standards.

7.5.1.2.1 Cleanliness of product and contamination control

Swiss-Tech establishes documented requirements for cleanliness of product if

a) product is cleaned by Swiss-Tech prior to sterilization and/or its use, or
b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or
c) product is supplied to be used non-sterile and its cleanliness is of significance in use, or
d) 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 a) and 6.4 b) do not apply prior to the cleaning process.

As a consequence of Swiss-Tech not installing and servicing activities or sterilizing medical devices, sections 7.5.1.2.2 and 7.5.1.2.3 of section 7.5 Production and service provision, of the applicable ISO Standard is excluded from Swiss-Tech's QMS.

7.5.1.3 Control of Production Equipment, Tools and Software Programs

Production equipment, tools and software programs used to automate and control/monitor product realization processes, will be validated prior to release for production and will be maintained defined by SP-6.3-2, Control of Software and Hardware and SP-7.5.1-3, Calibration.

Storage requirements, including periodic preservation/condition checks, will be defined for production equipment or tooling in storage.

7.5.2 Validation of Processes for Production and service provision

7.5.2.1 General requirements

Swiss-Tech validates any processes, including special processes, for production where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use.

Validation demonstrates the ability of these processes to achieve planned results.

Swiss-Tech establishes arrangements for these processes including, as applicable;

a) defined criteria for review and approval of the processes in SP 7.5.2-1, Process Validation, SP-7.1-1, Quality Planning and SP-7.1-2, Customers' Special-Documentation Requirements,

b) approval of equipment and qualification of personnel according to SP-6.2.2-2, Training.
c) use of specific methods and procedures, including SP-7.2.3-1, Customer Satisfaction.
d) requirements for records, (see 4.2.4) and
e) revalidation including the use of SP-8.2.4-4, Final Inspection.

Swiss-Tech establishes documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements, SP-6.3-2 Control of Software and Hardware.

Such software applications are validated prior to initial use.

Records of validation are maintained (see 4.2.4).

7.5.2.2 Particular requirements for sterile medical devices

As a consequence of Swiss-Tech not sterilizing medical devices, section 7.5.2.2, of section 7.5.2 Validation of processes for production and service provision, of the applicable ISO Standard is excluded from Swiss-Tech's QMS.

Swiss-Tech validates software and hardware as appropriate per documented procedure SP-6.3-2, Control of Software and Hardware. Records of validation are maintained (see 4.2.4)

7.5.3 Identification and Traceability

Swiss-Tech identifies the product by suitable means throughout product realization.

Swiss-Tech maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

Swiss-Tech identifies the product status with respect to monitoring and measurement requirements throughout product realization, using SP-8.2.4-2, First Article Inspection, SP-8.2.4-3, In-Process Inspection, and SP-8.2.4-4, Final Inspection.

When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), Swiss-Tech will establish appropriate controls for the media.

Where traceability is a requirement, Swiss-Tech controls the unique identification of material and product and maintain records (see 4.2.4) using SP-7.5.3-1, Product Identification and Traceability, SP-7.5.3-2, Material Identification and Traceability, and in SP 8.2.4-1, Receiving Inspection.

Swiss-Tech includes records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.

Swiss-Tech requires that its agents or distributors maintain records of the distribution of medical devices to allow traceability and those records are available for inspection

Records of the name and address of the shipping package consignee are maintained (see 4.2.4).

The identification of product status is maintained throughout production, storage, installation and servicing of the 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

Swiss-Tech has established a documented procedure per SP-8.3-1, Control of Nonconforming Materials, to ensure that materials returned from the customer are identified and distinguished from conforming product (see 6.4d).

7.5.4 Customer Property

Swiss-Tech exercises care with customer property, including intellectual property, while it is under Swiss-Tech's control or being used by Swiss-Tech. Swiss-Tech identifies, verifies, protects and safeguards customer property provided for use, or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, Swiss-Tech will report this to the customer and maintain records (see 4.2.4) as outlined in SP-7.5.4-1, Customer Supplied Materials, and in SP 8.2.4-1, Receiving Inspection.

7.5.5 Preservation of Product

Swiss-Tech has established documented procedures or work instructions for preserving the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product, as outlined in SP-7.5.1-4, Handling, Storage, Packaging, Preservation, and Shipping.

Preservation of products also includes, where applicable in accordance with product specifications and applicable statutory and regulatory requirements, provisions for

a) cleaning,
b) prevention, detection and removal of foreign objects,
c) special handling for sensitive products,
d) marking and labeling including safety warnings,
e) shelf life control and stock rotation, and
f) special handling for hazardous materials.

Swiss-Tech establishes documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions.

Such special storage conditions are controlled and recorded (see 4.2.4).

7.6 Control of Monitoring and Measuring Equipment

Swiss-Tech determines the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determine requirements, as outlined in SP-7.5.1-3, Calibration.

Swiss-Tech maintains a register of the monitoring and measuring equipment, which includes, but is not limited to: test hardware, test software, automated test equipment (ATE), plotters, and customer supplied equipment, and defines the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency checks, check method and acceptance criteria, as shown in SP-7.5.1-3, Calibration.

Swiss-Tech has established documented procedures 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.

Swiss-Tech ensures that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out, as per SP-7.5.1-3, Calibration.

Where necessary to ensure valid results, measuring equipment is

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification is recorded; (see 4.2.4)
b) adjusted or re-adjusted as necessary;
c) have identification in order to determine its calibration status;
d) safeguarded from adjustments that would invalidate the measurement result;
e) protected from damage and deterioration during handling, maintenance and storage.

Swiss-Tech has established, implemented, and maintains a process for the recall of monitoring and measuring equipment requiring calibration or verification, as defined by SP-7.5.1-3, Calibration.

In addition, Swiss-Tech assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. Swiss-Tech takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application, as regulated by SP-6.3-2, Control of Software and Hardware, is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

8 Measurement, Analysis and Improvement

8.1 General

Swiss-Tech plans and implements the monitoring, measurement, analysis and improvement processes needed

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

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

Statistical techniques can be used to support

- design verification (e.g., reliability, maintainability, safety),
- process control,
    - selection and inspection of key characteristics,
    - process capability measurements,
    - statistical process control,
    - design of experiment,
- inspection, and
- failure mode, effect and criticality analysis.

8.2 Monitoring and Measurement

8.2.1 Feedback

As one of the measurements of the performance of the quality management system, Swiss-Tech monitors information relating to whether Swiss-Tech has met customer requirements. The methods for obtaining and using this information are outlined in SP 7.2.3-1, Customer Satisfaction.

Information to be monitored and used for the evaluation of customer satisfaction includes, but is not limited to, product conformity, on-time delivery performance, customer complaints and corrective action requests. Swiss-Tech has developed and implemented plans for customer satisfaction improvement that addresses deficiencies identified by these evaluations, and assess the effectiveness of the results, defined in SP 7.2.3-1, Customer Satisfaction.

Swiss-Tech has established a documented procedure for a feedback system (see 7.2.3c) to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3)

If national or regional regulations require Swiss-Tech to gain experience from the post-production phase, the review of this experience will form part of the feedback system. (see 8.5.1)

8.2.2 Internal Audit

Swiss-Tech conducts internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements, including customer contractual requirements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by Swiss-Tech, and is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. The selection of auditors and conduct of audits ensures objectively and impartiality of the audit process. Auditors do not audit their own work.

A documented procedure has been established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting audit results.

Records of the audits and their results will be maintained and is defined in SP 8.2.2-1, Internal Audits. (See 4.2.4)

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 (see 8.5.2).

8.2.3 Monitoring and Measurement of Processes

Swiss-Tech applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes as outlined in SP-8.2.2-1, Internal Audits and SP-8.2.3-1, Process Measurements/Statistics. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and preventive action is taken as appropriate, per SP-8.5.2-1, Corrective Action, and SP-8.5.3-1, Preventive Action.

In the event of process nonconformity, Swiss-Tech will

a) take appropriate action to correct the nonconforming process,
b) evaluate whether the process nonconformity has resulted in product nonconformity,
c) determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
d) identify and control any nonconforming product (see 8.3)

in accordance with SP-8.3-1, Control of Nonconforming Material.

8.2.4 Monitoring and Measurement of Product

Swiss-Tech monitors and measures the characteristics of the product to verify that product requirements have been met according to SP-8.2.4-1, Receiving Inspection, SP-8.2.4-2, First Article Inspection, SP-8.2.4-3, In-Process Inspection, SP-8.2.4-4, Final Inspection, and SP-8.2.3-1, Process Measurements/Statistics, and SP-7.1-2, Customers' Special-Documentation Requirements. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements, and documented procedures (see 7.5.1.1) Evidence of conformity with the acceptance criteria will be maintained.

Measurement requirements for product acceptance is documented and includes

a) criteria for acceptance and/or rejection,
b) where in the sequence measurement and testing operations are to be performed,
c) required records of the measurement results (at a minimum, indication of acceptance or rejection), and
d) any specific measurement instruments required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified Swiss-Tech ensures they are controlled and monitored in accordance with the established processes.

When Swiss-Tech uses sampling inspection as a means of product acceptance, the sampling plan will be justified on the basis of recognized statistical principles an appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability) outlined in SP-8.2.3-1, Process Measurement Statistics.

Where product is released for production use pending completion of all required measurement and monitoring activities, it will be identified and recorded to allow recall and replacement if it is a subsequently found that the product does not meet requirements..

Records indicate the person(s) authorizing release of product for delivery to the customer. (See 4.2.4).

Where required to demonstrate product qualification, Swiss-Tech ensures that records provide evidence that the product meets the defined requirements in accordance with SP-4.2.4-1, Control of Records.

The release of product will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer. (See 7.1)

Swiss-Tech ensures that all documents required to accompany the product are present at delivery, per SP-7.5.1-4 Handling, Packing, and Shipping.

Swiss-Tech will record (see 4.2.4) the identity of personnel performing any inspection or testing.

8.3 Control of Nonconforming Product & Material

Swiss-Tech ensures that product and material that does not conform to relevant requirements is identified and controlled to prevent its unintended use or delivery. Swiss-Tech uses the procedure SP 8.3-1, Control of Nonconforming Materials and SP 7.2.3-1, Customer Satisfaction, to define the controls and related responsibilities and authorities for dealing with nonconforming product, including nonconforming product returned by a customer

Swiss-Tech's documented procedure defines the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

Where applicable, Swiss-Tech deals with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;
b) by authorizing its use, release or acceptance under concession;
c) by taking action to preclude its original intended use or application.
d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started
- Swiss-Tech's nonconforming product control process will provide for timely reporting of delivered nonconforming product;
e) by taking actions necessary to contain the effect of the nonconformity on other processes or products, outlined in SP-8.5.2-1, Corrective Action.

Dispositions of use-as-is or repair will only be used after MRB approval as stated in SP-8.3-1, Control of Nonconforming Materials.

Swiss-Tech will not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositioned for scrap will be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Swiss-Tech ensures that nonconforming product is accepted by concession only if regulatory requirements are met.

Records of the identity of the person(s) authorizing the concession are maintained (see 4.2.4).

When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (see 4.2.4).

Records of the nature of the nonconformities and any subsequent actions taken, including concessions obtained will be maintained. (see 4.2.4)

If product needs to be reworked (one or more times), Swiss-Tech documents the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction.
Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product is made and documented (see 4.2.3 and 7.5.1).

8.4 Analysis of Data

Swiss-Tech has established documented procedures to determine, collects, and analyzes appropriate data, per SP-8.4-1, Data Analysis, to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

a) feedback (see 8.2.1),
b) conformity to product requirements, (see 8.2.4)
c) characteristics and trends of processes and products including opportunities for preventive action, (see 8.2.3 and 8.2.4) and
d) suppliers.

Records of the results of the analysis of the data will be maintained (see 4.2.4)

8.5 Improvement

8.5.1 General

Swiss-Tech identifies and implements any changes necessary to ensure and maintain the continued suitability and the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review according to SP 8.5.1-1, Continual Improvement.

Swiss-Tech has established documented procedures for the issue and implementation of advisory notices. These procedures are capable of being implemented at any time.

Records of all customer complaint investigations are maintained (4.2.4).If investigation determines that the activities outside of Swiss-Tech contributed to the customer complaint, relevant information will be exchanged between the organizations involved.

If any customer complaint is not followed by corrective and/or preventive action, the reason will be authorized (see 5.5.1) and recorded. (see4.2.4)
If national or regional regulations require notification of adverse events that meet specified reporting criteria, Swiss-Tech has established documented procedures to such notification to regulatory authorities.

Swiss-Tech monitors the implementation of improvement activities and evaluate the effectiveness of the results.

8.5.2 Corrective Action

Swiss-Tech takes action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

SP-8.5.2-1, Corrective Action, defines requirements for

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2),
e) recording of the results of any investigation and of action taken, (see 4.2.4) and
f) reviewing the effectiveness of the corrective action taken and its effectiveness
g) flowing down corrective action requirements to a supplier when it is determined that the supplier is responsible for the nonconformity,
h) specific actions where timely and/or effective corrective actions are not achieved, and
i) determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required.

8.5.3 Preventive Action

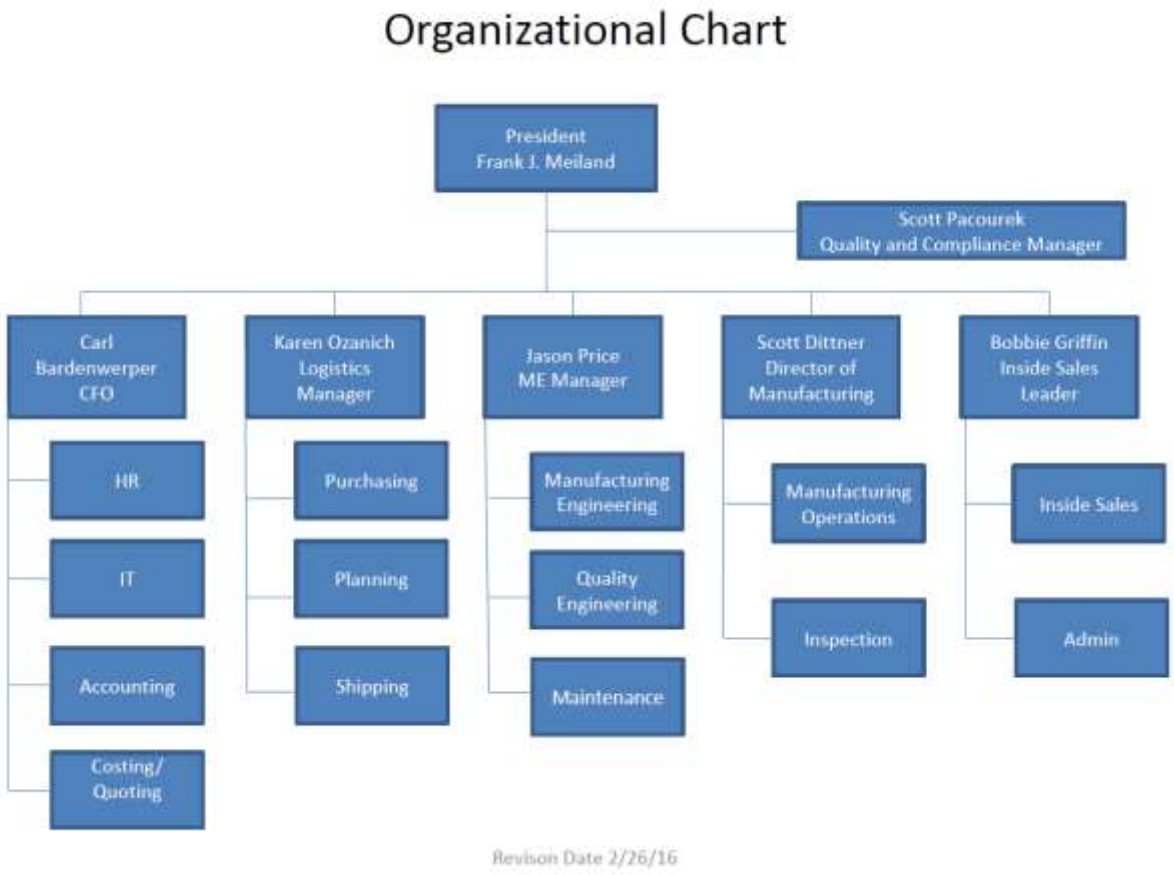
Swiss-Tech determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions, such as risk management, error proofing, failure mode, effect analysis (FMEA) and information on product problems reported by external sources, are appropriate to the effects of the potential problems.

SP-8.5.3-1, Preventive Actions, defines the requirement for

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) recording of the results of any investigation and of action taken (see 4.2.4), and

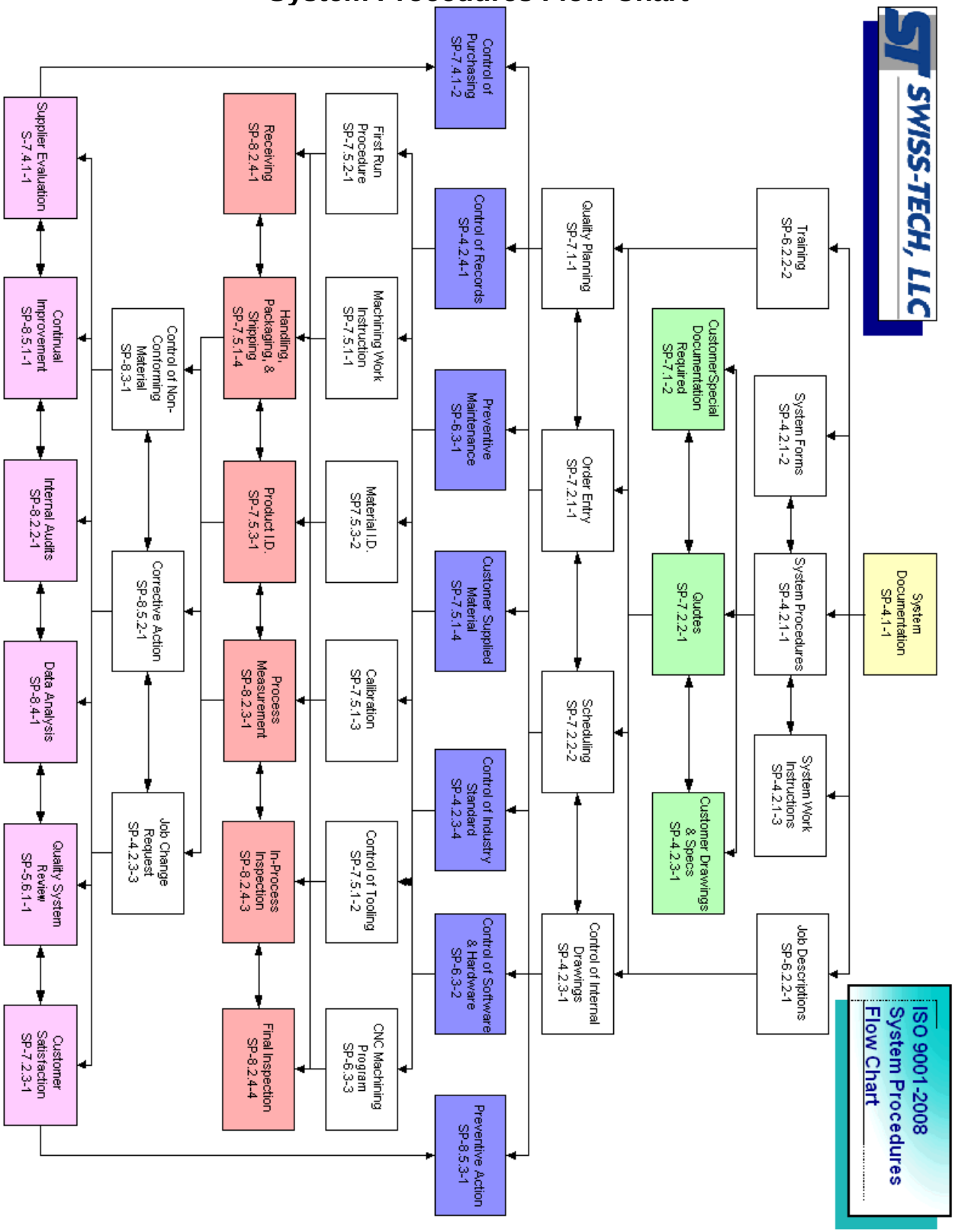
e) reviewing preventive action taken and its effectiveness.

Appendix A
Organizational Chart



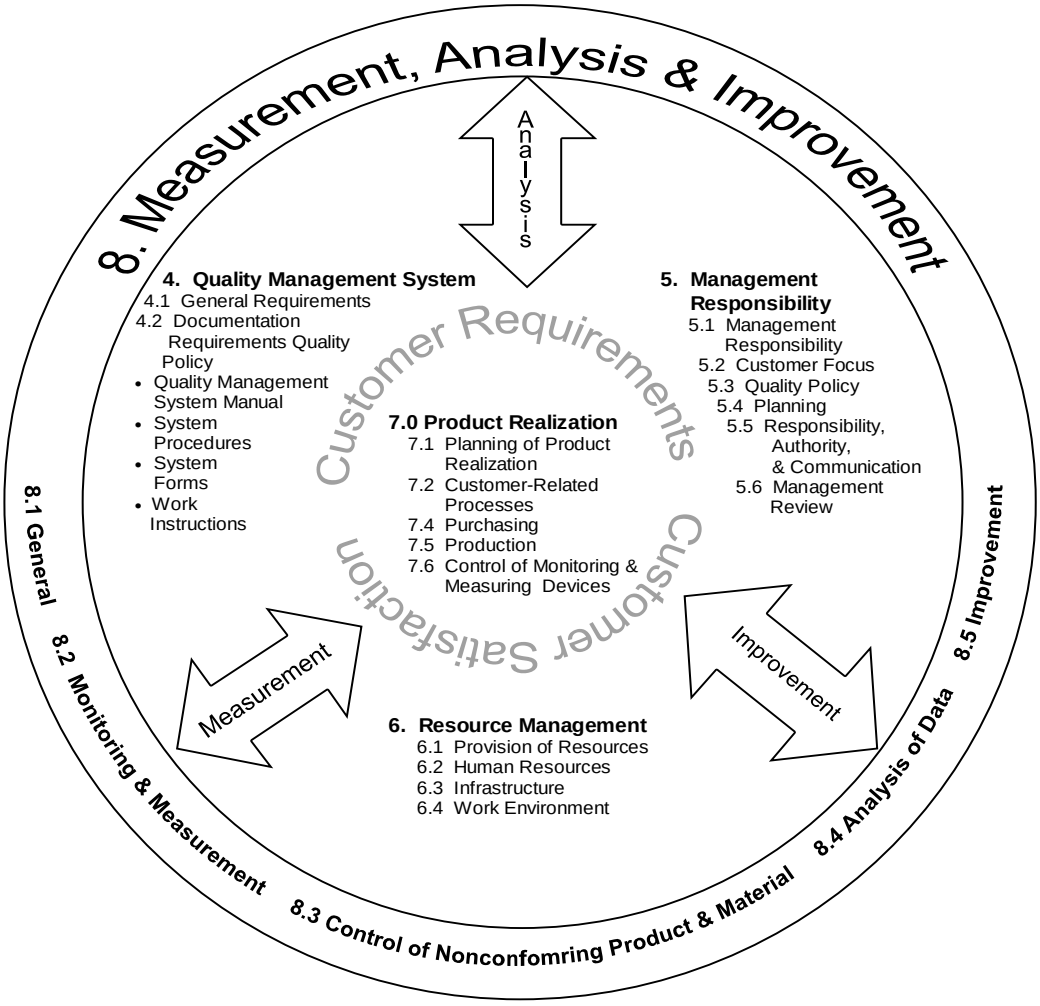
Appendix B

System Procedures Flow Chart



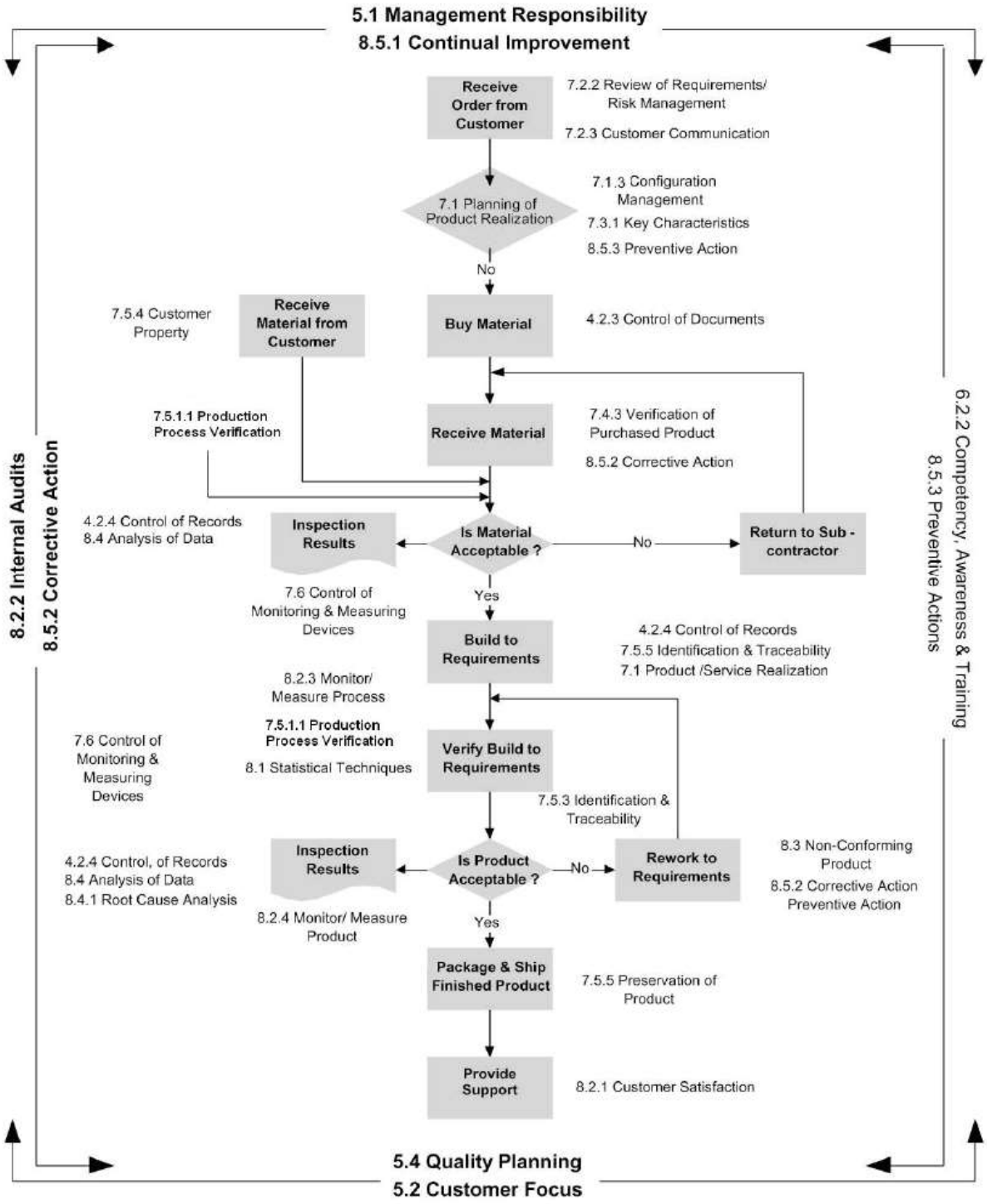
Appendix C
System Structure

Depiction of the interaction between the processes of Swiss-Tech's Quality Management System

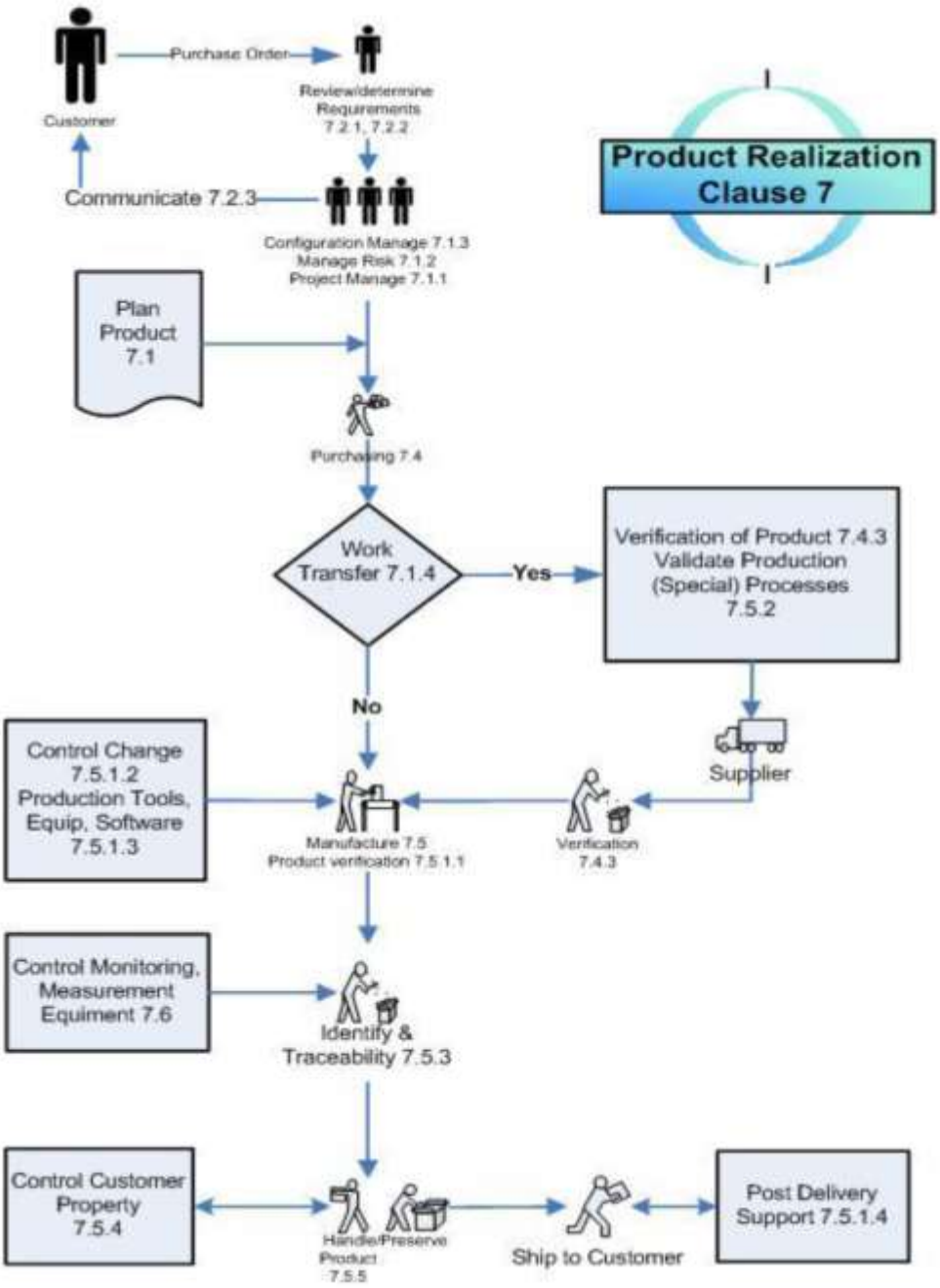


Appendix D

AS9100 QMS System Diagram



Product Realization Appendix E



Interaction of Processes Appendix F