Quality Manual

APPROVALS:

Position	Name	Signed	Date
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Revision History

History			
Revision	**Changes**	**Approved By**	**Date Revised**
10	Original content from prior documentation systems	David McKeown	25-OCT-2021
11	Updated and added all content for QMS to match ISO 9001 requirements	John Beauchamp	16-JUN-2022
12	Updated Scope, Interaction of Operations flow diagram, and Section 8.3.	John Beauchamp	13Mar2023
13	Updated Section 8.3 for inclusion of design.	John Beauchamp	05Apr2023

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ABOUT US:

SAVILLEX has been manufacturing fluoropolymer products since 1976, supplying some of the world's largest companies and universities. Our main business groups consist of Labware, Packaging, ICP Sample Introduction Systems and Custom Services.

Throughout all our businesses, our goal remains the same: to apply our know-how in fluoropolymer molding and machining to develop the world's best fluoropolymer products – whatever the application. We manufacture the widest range of PFA labware, from vials and columns to pressure vessels and filter holders.

Check out our Savillex Profile: www.Savillex.com

QUALITY POLICY	Commitment to Quality We commit to continuously improve: Quality Value Safety Delivery relative to meeting the requirements of our: Employees Customers Suppliers Shareholders
PURPOSE	**The purpose of this quality manual is to clearly communicate Savillex's Quality information, and to serve as a framework or roadmap for i**mplementing and following a Quality Management System that meets the requirements of ISO in order to comply with customer requirements. **This manual is the responsibility of management, and thus conveys managerial commitment to quality and to the quality management system.**
MISSION	Savillex's quality mission is to deliver superior quality products and customer value through innovation, service, and manufacturing excellence.
SCOPE	Sales, design, production (including injection molding, secondary operations machining, welding, assembly), test requirements and verification of products.
EXCLUSIONS	None

Elements of the Quality Management System (QMS):

- The Key Business Processes (Sales, Order Entry, Job Creation, Purchasing, Receiving, Engineering, Operations, Packing & Shipping) are described and maintained in the S:\Quality\ISO Folder structure.
- The Quality Objectives are monitored and maintained within **QF-301, MANAGEMENT REVIEW RECORD FORM**.
- QMS documentation is stored within related folders in S:\Quality.
- QMS Records are detailed and retained in **QSR-100, MASTER DOCUMENT LIST WITH REVISION HISTORY**.
- Interested Parties are managed through Management Review.
- Supplier Management and Evaluation is maintained in S:\Quality\Suppliers of Pharma Products.
- Competence records of training, education, and experience are maintained department leadership except as required by OSHA or other government regulations.
- Calibration records are maintained in S:\Quality\Calibration\Calibration Forms.
- Equipment maintenance records are maintained in Equipment Maintenance Logbooks or hard files.
- Nonconforming and Corrective Action records are maintained in S:\Quality\MRB Folder or S:\Quality\Corrective Action.
- Internal Audits and Management Review Records are maintained in S:\Quality\Audits – internal bottle or S:\Quality\Audits – Internal Mfg.
- Improvement: SAVILLEX is committed to continually improving our processes and business performance to meet our customers' expectations.

QMS References and Definitions:

- SAVILLEX – SAVILLEX, LLC
- ISO 9001:2015 – American National Standard ASQ /ANSI/ISO 9001-2015, Quality Management Systems – Requirements.
- QMS – SAVILLEX ISO 9001:2015 Quality Management System.
- Customer Supplied Property – Any type of instrumentation, accessory, tooling, manual, or shipping container that belongs to the customer.
- Customer Supplied Material – Any type of information or raw material product supplied to be used in the manufacture, modification, or repair of customer owned property.
- Product – The end result of meeting all design requirements, contractual terms, and conditions.
- Document – written information used to describe how an activity is done.
- Record – captured evidence of an activity having been done.
- Quality Records – Documentation of those activities wherein records must be retained.
- RMA – Return Material Authorization form (Customer).
- Revision – print revision, print version, and form version.
- Customer / Part / Engineering files – electronic server files of customer documentation.
- Procedure – Internal Procedure maintained within the QMS
- Log – Log used within the QMS
- Form – Templates and forms used within the QMS
- KPI(s) – Key Process Indicator(s)
- KDI(s) – Key Decision Indicator(s)

- CA – Corrective Action. This form can be used both externally and internally through CA Forms
- NC – Non-Conformance
  - Rework: Efforts to bring nonconforming product into conformance through additional operations that do not alter the original design of the product.
  - Repair: Efforts to bring nonconforming product into conformance through additional operations that alter the original design of the product; this may be through the addition of material no specified in the original design, or through altering pre-existing design features.
  - Scrap: The discard of nonconforming product in lieu of reworks or repair
- Risk-Based Thinking Terminology
  - Risk – Negative effect of uncertainty
  - Opportunity – Positive effect of uncertainty
  - Uncertainty - A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

About the SAVILLEX Quality Manual:

This manual is prepared for the purpose of defining SAVILLEX's interpretation and application of the ISO 9001:2015 international standard, as well as to demonstrate how SAVILLEX complies with that standard.

This manual presents "Notes" which are used to define how SAVILLEX has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015.

Where subordinate or supporting documentation is reference in this manual, these are indicated by **BOLD CAPITAL LETTERS**.

4. Context of the Organization

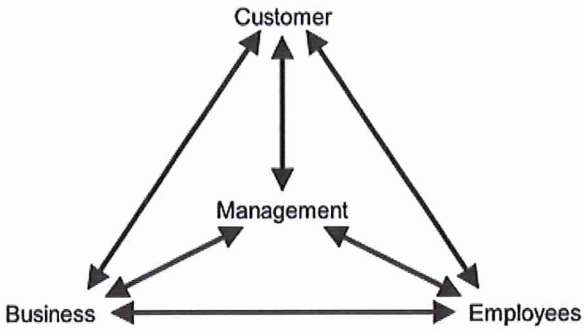
4.1. Understanding the Organization and Its Context

SAVILLEX has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of its business. This requires understanding internal and external issues that are of concern to SAVILLEX and its interested parties (per 4.2 below); the interested parties are identified per the **QF-301, MANAGEMENT REVIEW RECORD FORM**.

Such issues are monitored and updated as appropriate and discussed as part of management reviews.

4.2. Understanding the Needs and Expectations of Interested Parties

The issues determined per 4.1 above are identified through an analysis of risks facing SAVILLEX and its interested parties. "Interested parties" are those stakeholders who receive our products or services, or who may be impacted by them, or those parties who may otherwise have a significant interest in SAVILLEX. These parties are identified per **SOP-263, MANAGEMENT REVIEW**.



This information is then used by Top Management to determine the SAVILLEX's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.3. Determining the Scope of the Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, SAVILLEX has determined the scope of the management system as recorded above.

This scope applies to the locations listed on the cover of this Quality Manual. SAVILLEX claims exclusion of 8.3 Design and Development from the ISO 9001:2015 standard as Savillex does not currently develop new products for Savillex's own purpose. Savillex's product design and development is customer driven.

4.4. Quality Management System and Its Processes

4.4.1. Process Identification

SAVILLEX has adopted a process approach for its management system. By identifying top-level processes within SAVILLEX, and then managing each of these discretely, this reduces the potential for nonconforming products and services discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of top-level processes.

Note: not all activities are considered "processes" – the term "process" in this context indicates

the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to identified top-level processes.

The following top-level processes have been identified for SAVILLEX:

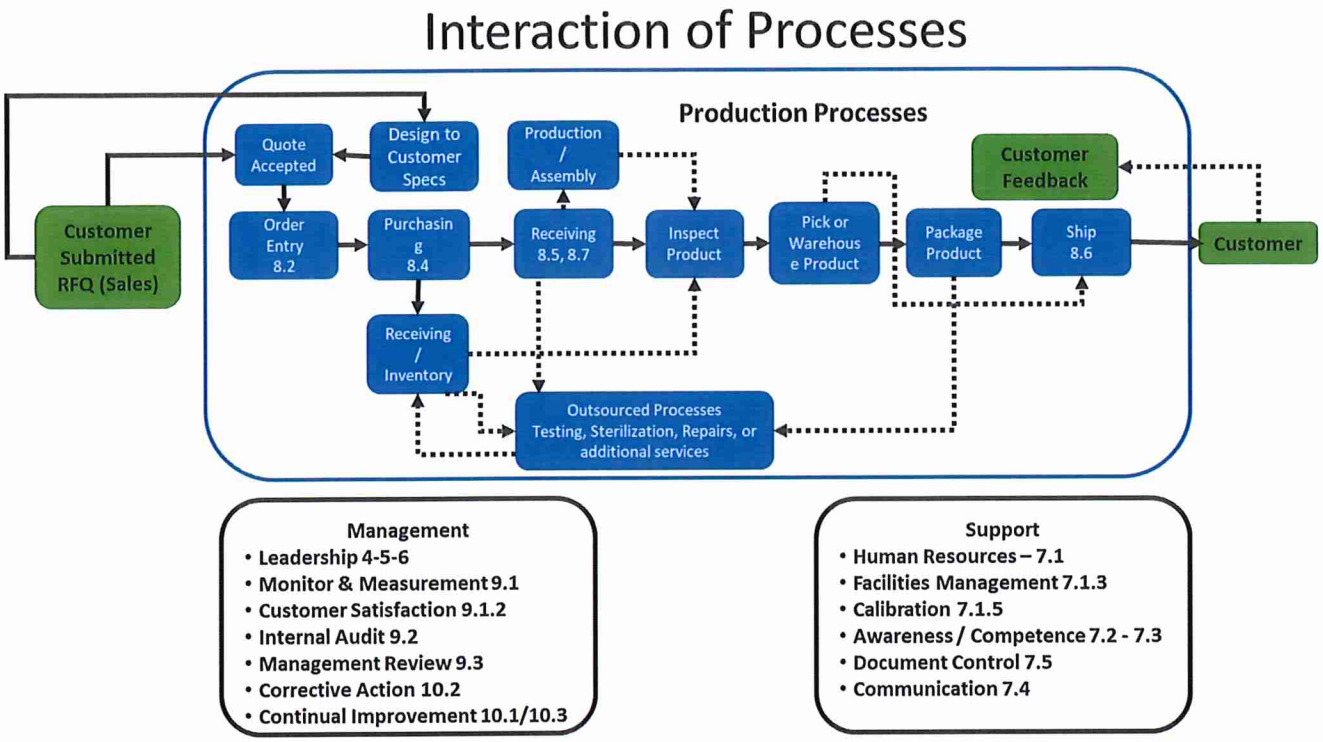
- Sales-Marketing-Quoting
- Order Entry
- Product Design/Engineering
- Job Creation
- Purchasing-Receiving-Outsourced Processes
- Manufacturing
- Packing & Shipping

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process will have a **PROCESS DEFINITION** which defines:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives (KPI) related to that process

The sequence of interaction of these processes is illustrated here.



4.4.2. Process Controls & Objectives

Each process has at least one objective established for it; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

Throughout the year, metrics data is measured and gathered by process owners or other assigned delegates, to present the data to Top Management. The data is then analyzed by Top Management so that goals may be set, and adjustments made for the purpose of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable **PROCESS DEFINITIONS**.

Metrics, along with current standings and goals for each objective, are recorded in records of management review.

When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented for the identified

processes.

5. Leadership

5.1 Leadership & Commitment

5.1.1. General

Top Management of SAVILLEX provides evidence of its leadership and commitment to the development and implementation of the QMS and continually improving its effectiveness by:

- taking accountability for the effectiveness of the QMS;
- ensuring that the Quality Policy and objectives are established for the QMS and are compatible with the strategic direction and the context of the organization;
- ensuring the integration of the QMS requirements into the organization's other business processes, as deemed appropriate (see note);
- promoting awareness of the process approach;
- ensuring that the resources needed for the QMS are available;
- communicating the importance of an effective QMS and of conforming to the QMS requirements;
- ensuring that the QMS achieves its intended results;
- engaging, directing, and supporting persons to contribute to the effectiveness of the QMS;
- promoting continual improvement;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

5.1.2. Customer Focus

Top Management of SAVILLEX adopts a customer-first approach which ensures that customer needs and expectations are determined, converted into requirements, and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

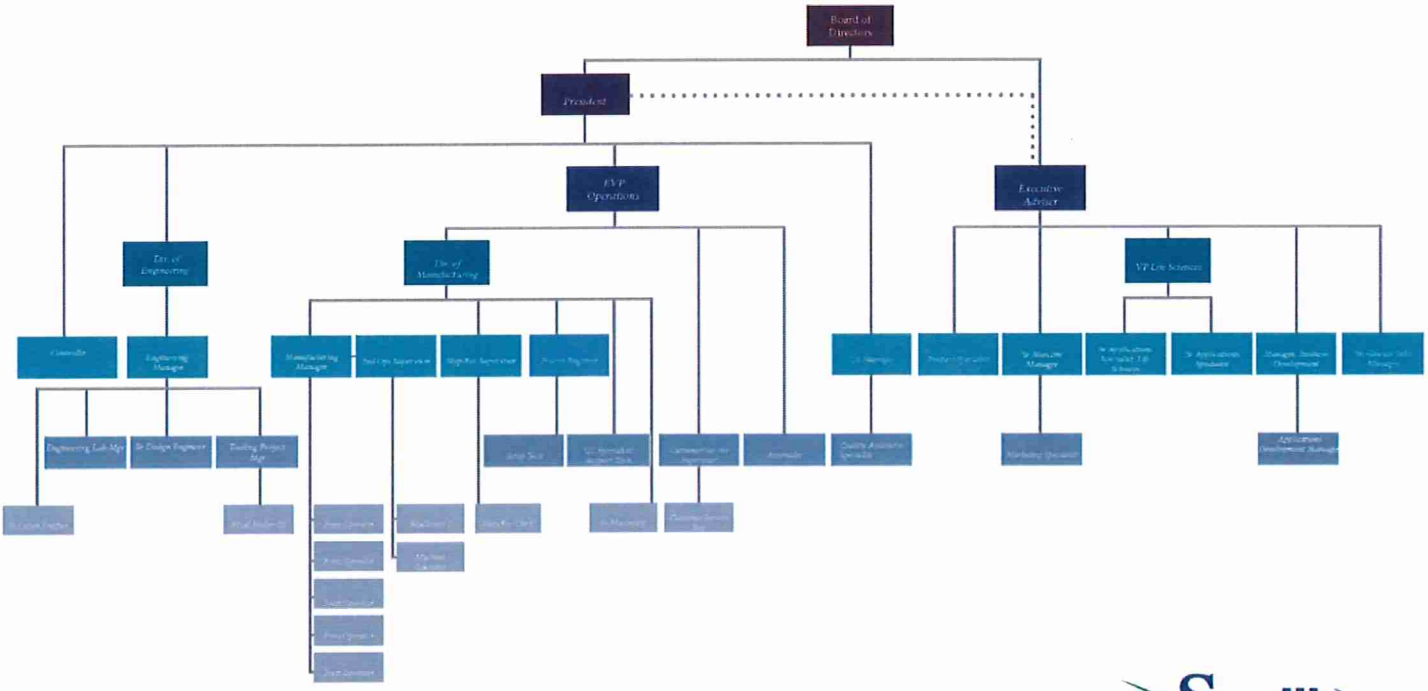
- customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- the focus on enhancing and improving customer satisfaction is maintained.

5.2. Policy

Top Management has developed the Quality Policy, defined above, that governs day-to-day operations to ensure overall products and services quality. The Quality Policy is released as a standalone document and is communicated and implemented throughout the organization.

5.3. Organizational Roles Responsibilities and Authorities

Top Management has assigned responsibilities and authorities for all relevant roles in SAVILLEX. These are communicated through the combination of the **ORGANIZATIONAL CHART** and **JOB DESCRIPTIONS**.



Quality Assurance: Verification that procedures are implemented and performed. Ensuring quality documentation is maintained and conducting audits. Establishing and maintaining an effectives QMS.
Operations Management: Creating procedures and work instructions (where needed) for the manufacturing processes. These processes/instructions will be carried out to ensure product quality and to satisfy customer requirements.
Engineering Management: Creating procedures and work instructions (where needed) for all Engineering and Design activities.
Sales Management: Creating procedures and work instructions (where needed) for all Sales and Contract Review activities.

Customer Service: Creating procedures and work instructions (where needed) for all customer service and support activities.

The QUALITY MANAGER has been assigned the role of Designated Management Representative when having a single point of contact to represent the SAVILLEX QMS is useful or required by customers or regulatory entities.

The Designated Management Representative shall also be responsible for:

- ensuring that the QMS conforms to the requirements of this International Standard;
- ensuring that established processes are delivering their intended outputs;
- reporting on the performance of the QMS and on opportunities for improvement to top management;
- ensuring the promotion of customer focus throughout the organization;
- ensuring that the integrity of the QMS is maintained when changes to the QMS are planned and implemented.
- Other duties of the Designated Management Representative may be defined herein or within other documented procedures.

6. Planning

6.1. Actions to Address Risks and Opportunities

Note: SAVILLEX views "uncertainty" as neutral but defines "risk" as a negative effect of uncertainty, and "opportunity" as a positive effect of uncertainty. SAVILLEX has elected to manage risks and opportunities separately, except where they may overlap. Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment, and recordkeeping will be performed to the level deemed appropriate for each circumstance or application.

SAVILLEX considers risks and opportunities when taking actions within the QMS, as well as when implementing or improving the QMS; likewise, these are considered relative to products and services. Risks and opportunities are identified as part of the **SOP-264, RISK MANAGEMENT** and **SOP-263, MANAGEMENT REVIEW** processes, as well as throughout all other activities of the QMS.

Risks are managed in accordance with **SOP-264, RISK MANAGEMENT**. This procedure defines how risks are managed to minimize their likelihood and impact. Opportunities are managed through **SOP-263, MANAGEMENT REVIEW**, which will determine how opportunities are managed to improve their likelihood and benefit.

6.2. Quality Objectives and Planning to Achieve Them

As part of the adoption of the process approach, SAVILLEX utilizes its process objectives, as discussed in 4.4 above, as the main quality objectives for the QMS. These include overall product-related quality objectives; additional product-related quality objectives may be defined in work

instructions or customer requirements.

The process objectives have been developed in consideration that they are:

- consistent with the quality policy;
- measurable;
- consider applicable requirements;
- relevant to conformity of products and services and to enhancement of customer satisfaction;
- monitored;
- communicated;
- updated as appropriate.

Process quality objectives are defined in the minutes of management review per section 9.3 below.

The planning of process quality objectives is defined in section 4.4. above.

6.3. Planning of Changes

Changes to the quality management system and its processes are carried out in a planned manner per **SOP-262, CHANGE CONTROL**.

7. Support

7.1. Resources

7.1.1. General

SAVILLEX determines and provides the resources needed:

- to implement and maintain the QMS and continually improve its effectiveness
- to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are continuously assessed, and formally during management reviews.

7.1.2. People

Top Management ensures that it provides sufficient staffing for the effective operation of the

QMS, as well its identified processes.

7.1.3. Infrastructure

SAVILLEX determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- buildings, workspace, and associated facilities;
- process equipment, hardware, and software;
- supporting services such as transport;
- information and communication technology.

Equipment is validated per **EQUIPMENT QUALIFICATION DOCUMENTATION** and maintained per **SOP-180, MACHINE MAINTENANCE**.

7.1.4. Environment for the Operation of Processes

SAVILLEX provides a clean, safe, and well-lit working environment. Top Management of SAVILLEX manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in **SOP-236, PRODUCTION AND WORK ENVIRONMENTS** or subordinate procedures, work instructions, or job documentation. Where special work environments have been implemented, these shall also be maintained per 6.3 above.

Human factors are considered to the extent that they directly impact on the quality of products and services.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the QMS. Only work environment aspects which can directly affect process efficiency or product quality are managed through the management system.

7.1.5. Monitoring and Measuring Resources

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification; see **SOP-130, CALIBRATION PROGRAM PROCEDURE**.

Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, SAVILLEX determines which devices will be subject to calibration based on its processes, products, and services, or to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.

7.1.6. Organizational Knowledge

SAVILLEX also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

- internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
- external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained and made available to the extent necessary.

When addressing changing needs and trends, SAVILLEX shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.

7.2. Competence

Staff members performing work affecting product quality are competent based on appropriate education, training, skills, and experience. **PROCEDURES FOR TRAINING AND COMPETENCE** defines these activities in detail.

Note: The QMS does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.3. Awareness

Training and subsequent communication ensure that staff are aware of:

- the quality policy;
- relevant quality objectives;
- their contribution to the effectiveness of the management system, including the benefits of improved performance;
- the implications of not conforming with the management system requirements.

7.4. Communication

Top Management of SAVILLEX ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods include:

- informal discussions
- use of corrective and preventive action processes to report nonconformities or suggestions for improvement
- use of the results of data analysis

- meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS
- use of internal audit process results
- periodic SAVILLEX meetings with all employees
- internal emails
- memos to employees

SAVILLEX's "open door" policy allows any employee access to Top Management for discussions on improving the quality system, business, or products.

7.5. Documented Information

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information"; SAVILLEX does not use this term, but instead relies on the terms "document" and "record" to avoid confusion. In this context the terms are defined by SAVILLEX as provided above. Documents and records undergo different controls as defined herein.

Documents required for the QMS are controlled in accordance with **SOP-200, DOCUMENT CONTROL**. The purpose of document control is to ensure that staff have access to the latest, approved information, and to restrict the use of obsolete information. All documented procedures are established, documented, implemented, and maintained.

There are 5 levels of documentation utilized.
Level 1 – Quality Manual: This document.
Level 2 – SOP – Standard Operating Procedures: System and instructions for a specific business area. It may identify individual or departmental responsibility or identify other related documents that are required to ensure adequate records are retained.
Level 3 – WI – Work Instructions: Used where needed detail how particular tasks are performed where the absence of such instructions would adversely affect quality. System-generated travelers are an extended method of instruction for the manufacturing and assembly of products.
Level 4 – QF – Quality Forms: Used throughout manufacturing and inspection (hard and soft copies) to capture relevant process information and product knowledge.
Level 5 – CSP – Customer Specified Packaging: CSP Forms are used when customers have specific packaging requirements / requests.

CONTROL OF RECORDS PROCEDURES define the controls needed for the identification, storage, retrieval, protection, retention time, and disposition of quality records. The procedures also define the methods for controlling records that are created by suppliers.

These controls are applicable to those records which provide evidence of conformance to

requirements; this may be evidence of product or service requirements, contractual requirements, procedural requirements, or statutory/regulatory compliance. In addition, quality records include any records which provide evidence of the effective operation of the management system.

8. Operation

8.1. Operational Planning and Control

SAVILLEX plans and develops the processes needed for realization of its products and services. Planning of Product realization is consistent with the requirements of the other processes of the QMS. Such planning considers the information related to the context of the organization (see above), current resources and capabilities, as well as product or service requirements.

Such planning is accomplished through:

- Determining the requirements for the products and services;
- establishing criteria for the processes and the acceptance of products and services;
- determining the resources needed to achieve conformity to the product or service requirements;
- implementing control of the processes in accordance with the criteria;
- determining, maintaining, and retaining documents and records to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements.

Changes to operational processes are done in accordance with **PROCEDURES FOR CHANGE MANAGEMENT**.

Outsourced processes and how SAVILLEX controls them are defined in **PROCEDURES FOR OUTSOURCED PROCESSES**.

For some work, SAVILLEX plans and manages its provision of products and services in a structured and controlled manner; this is part of the Epicor ERP system. Such work includes scheduling tasks in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

8.2. Requirements for Products and Services

8.2.1. Customer Communication

SAVILLEX has implemented communication with customers in relation to:

- providing information relating to products and services;
- handling enquiries, contracts, orders, including changes;

- obtaining customer feedback relating to products and services, including customer complaints;
- handling or controlling customer property;
- establishing specific requirements for contingency actions, when relevant.

8.2.2. Determining the Requirements Related to Products and Services

During the intake of new business SAVILLEX captures:

- the requirements for the products and services, including any applicable statutory and regulatory requirements and other requirements deemed necessary by SAVILLEX
- requirements not stated by the customer but necessary for specified or intended use, where known

These activities are defined in **PROCEDURES FOR QUOTING AND ORDERS.**

8.2.3. Review of Requirements Related to Products and Services

Once requirements are captured, SAVILLEX reviews the requirements prior to its commitment to supply the product or service. This review ensures that:

- product requirements are defined
- contract or order requirements differing from those previously expressed are resolved
- the organization can meet the defined requirements, and/or the claims for the products and services it offers
- special requirements (see 8.5.1 below) can be met
- risks have been identified and considered

These activities are defined in **PROCEDURE FOR QUOTING AND ORDERS.**

8.2.4. Changes to Requirements for Products and Services

SAVILLEX updates all relevant requirements and documents when the requirements are changed and ensures that all appropriate staff are notified; see **PROCEDURES FOR CHANGE MANAGEMENT.**

8.3. Design and Development of Products and Services

For new designs and for significant design changes, SAVILLEX ensures the translation of customer needs and requirements into detailed design outputs. These address performance, reliability, maintainability, testability, and safety issues, as well as regulatory and statutory requirements.

New product designs are moved through a staged and gated process. The design team determines

which aspects of each stage are applicable for that particular product. The product development process is reviewed by a cross-functional team through 4 gated stages. Each stage covers important considerations:
1 – **CONCEPTUAL STAGE**: problem statement, customer needs/wants/feedback, product definition, product requirements and specs, competitive analysis marketing plan, R&D, technical feasibility, and product cost estimates.
2 – **DEVELOPMENT STAGE**: development plan with resources assigned, test plan developed, concepts, models and prototypes, product/process design, tooling, manufacturing methods, product refinement, initial testing results, and customer feedback (sampling only)
3 – **VALIDATION STAGE**: product performance, manufacturability, test plan completed, quality plan instituted, documentation completed, final product cost analysis, and field test results.
4 – **COMMERCIALIZATION STAGE**: MARCOM plan, model numbers entered, selling prices, discounts, etc., determined, literature, advertising, samples, training completed, inventory, product release, and market introduction

Amendment to a Design: When amendments to a design are necessary, an ECO process is followed with appropriate sign-offs prior to being implemented. Where change notifications are required, affected customers are notified.

This process ensures:

- Design planning is conducted
- Design inputs (requirements) are captured
- Design outputs are created under controlled conditions
- Design reviews, verification and validation are conducted
- Design changes are made in a controlled manner

These activities are further defined in **SOP-215, NEW PRODUCT QUALIFICATION**.

8.4. Control of Externally Provided Processes, Products and Services

SAVILLEX ensures that purchased product or services conform to specified purchase requirements.

SAVILLEX evaluates and selects suppliers based on their ability to supply products and services in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who do not provide conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in **SOP-216, PURCHASING, SOP-100, INSPECTION OF RAW MATERIAL**, and **QF-275, APPROVED PHARMA SUPPLIERS**.

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

To control its provision of products and services, SAVILLEX considers, as applicable, the following:

- the availability of documents or records that define the characteristics of the products and services as well as the results to be achieved through process control plans, records of inspection, and tests;
- the availability and use of suitable monitoring and measuring resources (Calibrated measurement tools);
- the implementation of monitoring and measurement activities, such as Part Acceptance Criteria, First Article Inspection (FAI), and In-Process Inspection;
- the use of suitable infrastructure and environment;
- the appointment of competent persons, including any required qualifications;
- the validation and revalidation of special processes if applicable (see below);
- the implementation of actions to prevent human error;
- the implementation of release, delivery, and post-delivery activities.

Where special requirements, key characteristics and/or critical items are identified or deemed appropriate, the processes will be planned and controlled to manage these aspects.

Where appropriate, special statistical techniques may be used to control or monitor operational processes. In such cases, the techniques selected shall be based on known standards or otherwise justified as statistically valid. This includes sampling plans when sampling is used for inspection, testing, or other purposes.

At this time, SAVILLEX does not utilize any in-house "special processes" where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to outside suppliers and controlled per **PROCEDURES FOR OUTSOURCED PROCESSES**.

8.5.2. Control of Equipment, Tools, and Software Programs

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes are validated prior to final release for production and are be maintained. Special storage requirements, if applicable, are defined for production equipment or tooling including any necessary periodic preservation or condition checks. This is further defined in

equipment specific **PROCEDURES FOR EQUIPMENT VALIDATION (IQ, OQ, PQ)**.

Validation and Control of Special Processes

At this time, SAVILLEX does not utilize any in-house "special processes" where the result of the process cannot be verified by subsequent monitoring or measurement. Any such special processes are sent to outside suppliers and controlled per **PROCEDURES FOR OUTSOURCED PROCESSES**.

8.5.3. Production Process Verification

Product or service processes in use as of 01Jun2022 are approved based on previous experience.

New product or service processes are validated prior to use or implementation. This may include running test product through the new process or equipment, or by performing a First Article Inspection on a part produced by the process, tooling, or equipment. First Article is discussed further in section 8.6.3 below.

8.5.4. Identification and Traceability

Where appropriate, SAVILLEX identifies its product or service or other critical process outputs by suitable means. Such identification includes the status of the product or service with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all product or service shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, SAVILLEX controls and records the unique identification of the product or service. This shall include, as appropriate:

- product identification to be maintained throughout the product life
- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch to the destination (e.g., delivery, scrap)
- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly
- for a product, a sequential record of its production

SOP-219, LOT NUMBERING FOR BOTTLED PRODUCT defines these methods in detail.

8.5.5. Property Belonging to Customers or External Providers

SAVILLEX exercises care with customer or supplier property while it is under the organization's

control or being used by the organization. Upon receipt, such property is identified, verified, protected, and safeguarded. If any such property is lost, damaged, or otherwise found to be unsuitable for use, this is reported to the customer or supplier and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage, or inappropriate use.

Customer-related instructions include drawings, material lists, special inspections, testing, processing, and packaging instructions, etc., which translate the specific requirements of a contract into working documents.

SAVILLEX has established and **maintains documents for mold inventory** for our process verification, storage, and maintenance of customer-supplied tools/molds. SAVILLEX will notify the customer of any tools/molds that are damaged, lost, or otherwise unsuitable for use.

This activity is controlled by the Engineering Tooling Department.

8.5.6. Preservation

SAVILLEX preserves conformity of product during internal processing and delivery to the intended destination. This preservation includes cleaning, special handling for sensitive products, marking and labeling including safety warnings, shelf-life control and stock rotation, and special handling for hazardous materials. Preservation also applies to the constituent parts of a product.

PROCEDUREs FOR PRODUCT PRESERVATION define the methods for preservation of products.

8.5.7. Post-Delivery Activities

As applicable, SAVILLEX conducts the following activities which are considered "post-delivery activities":

- Customer Complaint handling
- Customer Change Control Notification
- Product Recall

Post-delivery activities are conducted in compliance with the management system defined herein. In determining the extent of post-delivery activities that are required, SAVILLEX considers:

- statutory and regulatory requirements;
- the potential undesired consequences associated with its of products and services;
- the nature, use and intended lifetime of its of products and services;
- customer requirements;

- customer feedback.

When problems are detected after delivery, SAVILLEX takes appropriate action including investigation and reporting; see section 10.2.

8.5.8. Control of Changes

SAVILLEX reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements.

Process change management is defined in **SOP-262, CHANGE CONTROL**.

Documents are changed in accordance with **SOP-200, DOCUMENT CONTROL**.

8.6. Release of Products and Services

Products and services undergo inspection and/or testing to ensure they meet all requirements at critical stages throughout the various processes, and then prior to final delivery.

Measurement requirements are documented; this documentation is part of the order documentation, and includes:

- criteria for acceptance and / or rejection,
- where in the sequence measurement and testing operations are performed,
- a record of the measurement results, and
- type of measurement instruments required, and any specific instructions associated with their use

Test records will show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product or service qualification SAVILLEX will ensure that records provide evidence that the product or service meets the defined requirements.

When key characteristics have been identified, they are monitored and controlled as required.

Product is not used until it has been inspected or otherwise verified as conforming to specified requirements, except when released under positive-recall procedures pending completion of all required measurement and monitoring activities.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of products and services.

8.6.1 Receiving Inspection and Testing

Incoming raw materials, processed products or other critical received goods undergo inspection and/or testing at receiving, prior to entry into the production processes. These activities are defined in **SOP-100, INSPECTION OF RAW MATERIALS**.

8.6.2. In-Process Inspection and Testing

At defined stages throughout production and service process, inspections and/or tests are conducted to ensure the products and services satisfy the requirements for that process or activity, prior to being released to the next process or activity. This is defined in **PROCESS DEFINITIONS** and/or job documentation specific to each job.

8.6.3. First Article Inspection

First Article Inspections shall be performed at the discretion of Quality and/or when required by customer or contract requirements.

Such First Article Inspections are a complete inspection of a completed part, of all dimensions and criteria, to validate the production processes and equipment. The product used shall be a representative item from the first production run 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. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

SAVILLEX uses forms and/or computer software to satisfy first article requirements; where the customer dictates a format for First Article reporting, these formats will be used instead.

8.6.4. Final Inspection and Testing

Final acceptance criteria for products and services are defined in appropriate subordinate documentation. Reviews, inspections, and tests are conducted at appropriate stages to verify that the product and service requirements have been met. This is done before products and services are released or services are delivered.

Each process utilizes different methods for measuring and releasing products and services. These methods are defined in **PROCESS DEFINITIONS**.

8.7. Control of Nonconforming Outputs

SAVILLEX ensures that products and services or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The controls for such nonconformances are defined in **SOP-210, CONTROL OF NON-CONFORMING PRODUCT**.

9. Performance Evaluation

9.1. Monitoring, Measurement, Analysis and Evaluation

9.1.1. General

SAVILLEX has determined which aspects of its quality management system must be monitored and measured, as well as the methods to utilize and records to maintain, within this **QUALITY MANUAL** and subordinate documentation.

Monitoring and measurement of the processes, as defined in 4.4 above, ensure that Top Management evaluates the performance and effectiveness of the quality management system itself.

9.1.2. Customer Satisfaction

As one of the measurements of the performance of the management system, SAVILLEX monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information include:

- recording customer complaints
- product rejections or returns
- repeat orders for product
- changing volume of orders for product
- trends in on-time delivery
- obtain customer scorecards from certain customers
- submittal of customer satisfaction surveys

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations and assess the effectiveness of the results.

9.1.3. Analysis and Evaluation

SAVILLEX analyzes and evaluates the data and information arising from monitoring and measurement to evaluate:

- conformity of products and services;
- the degree of customer satisfaction;
- the performance and effectiveness of the quality management system;
- if planning has been implemented effectively;
- the effectiveness of actions taken to address risks and opportunities;
- the performance of external providers;
- the need for improvements to the quality management system.

Statistical techniques used may be defined in appropriate documented procedures; in all cases, the methods are based on established standards or are otherwise determined to be statistically valid.

9.2. Internal Audit

SAVILLEX conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in **SOP-246, INTERNAL AUDIT PROCESS FOR MANUFACTURING**.

9.3. Management Review

Top Management reviews the management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. The review includes assessing opportunities for improvement, and the need for changes to the management system, including the Quality Policy and quality objectives.

Management review frequency, agenda (inputs), outputs, required members, actions taken, and other review requirements are defined in **SOP-263, MANAGEMENT REVIEW**.

Records from management reviews are maintained.

10. Improvement

10.1. General

SAVILLEX uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible.

Improvement shall be driven by an analysis of data related to:

- conformity of products and services;
- the degree of customer satisfaction;
- the performance and effectiveness of the management system;
- the effectiveness of planning;
- the effectiveness of actions taken to address risks and opportunities;
- the performance of external providers;
- other improvements to the management system.

10.2. Nonconformity and Corrective Action

SAVILLEX takes corrective action to eliminate the cause of nonconformity to prevent recurrence. Likewise, the Savillex takes preventive action to eliminate the causes of potential nonconformities to prevent their occurrence.

These activities are done using the formal **CAPA SYSTEM** and are defined in **SOP-211, CORRECTIVE AND PREVENTIVE ACTION**.

10.3. Continual Improvement

Through the process effectiveness reviews, done as part of Management Review, SAVILLEX works to continually improve the suitability, adequacy, and effectiveness of the quality management system. This includes seeking opportunities for improvement.

These activities are done using the formal **SOP-263, MANAGEMENT REVIEW** and are defined in **SOP-265, CONTINUOUS IMPROVEMENT**.