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Change Record

Rev	Date	Responsible Person	Description and Justification of Change
015	05/16/2018	Amine ElMaziati	• Removed "Reporting to Regulatory Authorities Clause 8.2.3" from Section 1.1 - Reduction in Scope and added section 8.2.3 Reporting to regulatory authorities to comply with the ISO 13485 requirement. • Added notes in section 7.2.1 & 7.2.2 to clarify that ISO13485:2016 Clauses 7.2.1 (d) and Clauses 7.2.2 (d) do not apply to PSS • Correct a typographical error in attachement-1 in which ISO13485:2003 was reference.
014	03/30/2018	Amine ElMaziati	Changes made to comply with the ISO 13485:2016. See history for Redline.
013	08/16/2017	Amine ElMaziati	Updated Section 1.0 Scope: 1. Update the ISO 11135 reference after the Dekra upgraded audit. 2. Added sections 1.1.5 to 1.1.10 to add the non-applicable articles from JMO 169 Removed Attachment 6 (Cross Reference Table of the differences between ISO 13485:2003 & JMO) to reflect the implementation of the new JMO revision.
001-012	Reference previous Revision History		

Distribution List

- Quality Systems Manual – Quality Assurance

Document Map

ATTACHMENTS:

INTRODUCTION TO

PARTER STERILIZATION SERVICES

QUALITY ASSURANCE POLICY MANUAL

The President of Operations and the Manager of Quality Assurance of Parter Sterilization Services (formerly defined as the Contract Sterilization of Parter Medical Products, Inc.) have endorsed and approved the Quality System described in this Quality Manual.

This Quality Manual hereby certifies that it meets the intent of International Standard ISO 13485:2016 (Medical Devices -- Quality Management Systems), QSR 21 CFR part 820 (Food and Drug Administration - Quality System Regulation) and the revisions thereto in effect on the date of their signatures.

The Quality Assurance Program of Parter Sterilization Services is described in the Quality Policies contained in this document. This manual defines senior management's quality assurance philosophy and operating policies. Responsibilities for their implementation and administration are defined. The Quality Policies provide general requirements to assure that acceptance criteria are met and consistent controls are exercised to maintain adherence to contractual and regulatory requirements.

In order to provide consistent quality service to our customers, Parter Sterilization Services operates from a standardized quality manual and quality system level procedures for controlling the technological process; and a standardized quality control level procedures and work instructions to meet the functional purpose of these requirements.

1.0 Scope (820.1)

Parter Sterilization Services, ("PSS"), hereafter referred to as "the organization", shall implement a quality management system that defines the quality system, its implementation for the processing services, and demonstrates the capability to consistently provide conforming products and services. The quality system's primary purpose is to achieve customer satisfaction through continual improvement and prevention of nonconformity.

This quality manual defines the quality management system and its implementation for processing services provided by the organization. This system is structured to comply with ISO 13485:2016, and 21 CFR part 820. Where other national standards or regulations (as they relate to EO sterilization processing) require adherence they shall be applied. This includes but is not limited to the current ISO 11135 and JMO 169.

* 1.1 Reduction in Scope

The following section is being excluded from the Quality Management System,

1.1.1 Section 7.3 Design and Development.
(21 CFR 820: section 820.30, Design Controls)

The following sections of EN ISO 13485:2016 as well as 21 CFR 820, are not applicable to the organization and are therefore not included in the scope of this quality manual.

1.1.2 Medical Device files, section 4.2.3.

1.1.3 Installation Activities, section 7.5.3 (installation of medical device). (21 CFR 820: section 820.170, Installation)

1.1.4 Servicing activities, section 7.5.4 , & Particular requirement for sterile medical devices, section 7.5.5 (21 CFR 820: section 820.200, servicing)

1.1.5 Particular Requirements for Active Implantable Medical Devices section 7.5.9.2.

The following sections of .IMO 169 are not applicable to the organization and are therefore not included in the scope of this quality manual

1.1.6 Reporting Adverse Events, etc., Article 69 Chapter 3

1.1.7 Relationship with Good Vigilance Practice (GVP), Article 70 Chapter 3

1.1.8 Domestic Quality Assurance Manager, Article 72 Chapter 3

1.1.9 Manufacturing Control and Quality Control of Biological Medical Devices, etc., Chapter 4 (Article 73 to Article 79

1.1.10 Manufacturing Control and Quality Control of Radioactive In Vitro Diagnostic Reagents. Chapter 5 (Article 80 and Article 81)

1.1.11 Application mutatis mutandis, etc. to Manufacturers, etc. Of Medical Devices, etc., Chapter 6 (Article 82 to Article 84)

The reduction in scope is reviewed annually during management review to determine the continued non applicability of any listed item.

2.0 Normative Reference

The organization's quality management system will comply with the most recent standards: ISO 13485, 21CFR part 820, ISO 11135.

21 CFR Part 820	United States Quality System Regulation
ISO 13485:2016	Medical Devices - Quality Management System - Requirements for Regulatory Purposes
Note:	A cross-reference table between the US Quality System Regulations and the International EN ISO 13485 Quality System Standard has been provided in Attachment 1 as a guide.
JMO 169	Japan Ministerial Ordinances 169

3.0 Terms and Definitions (820.3)

3.1 Active Device – Medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

3.2 Component – Raw material, substance, piece part, software, labeling or assembly which is intended to be included as part of the finished, packaged, and labeled medical device.

3.3 Contract – Agreed requirements between the organization and its customers, transmitted by any means.

3.4 Device Master Record (DM.R) – The compilation of records containing the procedures and specifications for a medical device.

3.5 Device History Record (DHR) – The compilation of records that contain the Production history of devices.

3.6 Established – Defined documented and implemented.

3.7 Labelling – Written, printed or graphic matter affixed to a medical device or any of its containers and wrappers or accompanying a medical device.

3.8 Medical Device – Any instrument, apparatus, implement, appliance, material, or other article, whether used alone or in combination intended by the manufacturer to be used for human beings for the purpose of:

3.9 Non-conformance – Failure to meet a specified requirement.

3.10 Product – The result of activities or process.

3.11 Quality Record – A record that provides objective evidence of compliance to specified requirements (financial records are excluded from this definition).

3.12 Quality System Record – A record that includes or refers to the location of procedures and documentation, which are not specific to a particular type of device.

3.13 Resources – Controls, equipment (manufacturing, inspection or test), fixtures, skills, processes, tooling, personnel, or documentation.

3.14 SOP – Standard Operating Procedures that define additional or unique Quality systems specific to the organization.

3.15 Verification – Confirmation by examination and objective evidence that specified requirements have been met.

3.16 Risk – Combination of the probability of occurrence of harm and the severity of that harm

3.17 Risk Management – systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

4.0 Quality Management System Requirements (820.5)

4.1 General Requirements

The organization has established a documented Quality Management System (QMS) as described in this manual and maintains its effectiveness in accordance with the requirements of the International Standard ISO 13485: 2016, 21 CFR, part 820, JMO 169 and assures compliance with applicable regulatory requirements. The content of this Quality Management System is documented and maintained under controlled conditions. Executive Management is responsible for ensuring the procedures and arrangements that are implemented according to the requirements of the above standards.

The quality management system shall be implemented, maintained and improved by the organization. To implement the system the organization shall:

a) Identify the processes needed for the quality management system and their application throughout the organization (see Attachment 4);

b) Develop system level procedures that describe the activities required to implement the quality system;

c) Develop procedures that list the sequence and interactive nature of the process;

d) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.

e) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.

f) Measure, monitor, analyze processes, and implement actions necessary to achieve planned results and continual improvement.

g) Implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

h) Apply a risk based approach to the control of these processes.

i) Establish and maintain records to demonstrate conformance to the ISO 13485:2016, 21 CFR, part 820, and JMO 169

j) Any changes to these processes shall be evaluated for their impact on the quality management system, evaluated for their impact on the medical devices, and controlled in accordance with the ISO 13485:2016, 21 CFR, part 820, and JMO 169

4.2 Documentation Requirements

4.2.1 General

The organization establishes and maintains this Quality Manual to present the scope of the quality policy and quality objectives and to provide justifications for any exclusion to the International standard of ISO 13485: 2016 to which it is intended to comply with.

The Quality Assurance Manager (QA) has the responsibility for the control and distribution of this manual and for implementing approved changes and additions to any of the referenced documents in this Quality Systems Manual.

Quality management documentation shall include, at a minimum:

a) Documented statements of a quality policy and quality objectives.

b) A quality manual.

c) System procedures necessary to implement ISO 13485:2016 and 21 CFR Part 820, JMO 169.

d) Adequate work instructions and quality records to ensure effective operation and control of processes.

e) Documents needed by the organization to ensure the effective planning, operation and control of its processes.

f) Records required by International Standard.

g) Any other documents specified by national or regional regulations.

h) Where this standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.

i) The range and extent of quality system documentation shall be dependent on the size and type of processing in the facility; complexity and interaction of the processes; methods used, and the skills and training of personnel. These documents will define the complete sterilization process and its installation and servicing.

4.2.2 Quality Manual (820.20 e)

Procedures to control the development, release and revision of documents having an effect on quality are established. These include controls to prevent unexpected loss of electronic data or records essential to verifying product quality.

The Quality Manual shall contain:

a) The scope of the quality management system, including any exclusion;

b) The requirements and a description of the elements of the quality management system and their interaction;

c) Reference to the- procedures established to implement the quality system.

4.2.3 Control of Documents (820.40)

Documents and data having an effect on quality are reviewed and approved for adequacy by authorized personnel prior to issuance. Document control procedures define the process of revision control to preclude the use of invalid or obsolete documents.

a) Pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the Quality System are performed.

b) Current documents are identified and stamped Controlled Copy, (Blue Ink).

c) Invalid or obsolete documents are removed from use.

d) History/obsolete documents are identified and stamped Superseded (Red Ink).

e) Copied documents are identified and stamped Reference (Green Ink).

f) Records and documents shall be legible, readily identifiable, and retrievable and in the form of hard copy or electronic media; documents of external origin shall be identified and recorded.

g) A master list (e.g., index/date register) must identify the current revision level of documents to prevent the use of obsolete documents.

4.2.4 Control of Records (820.180)

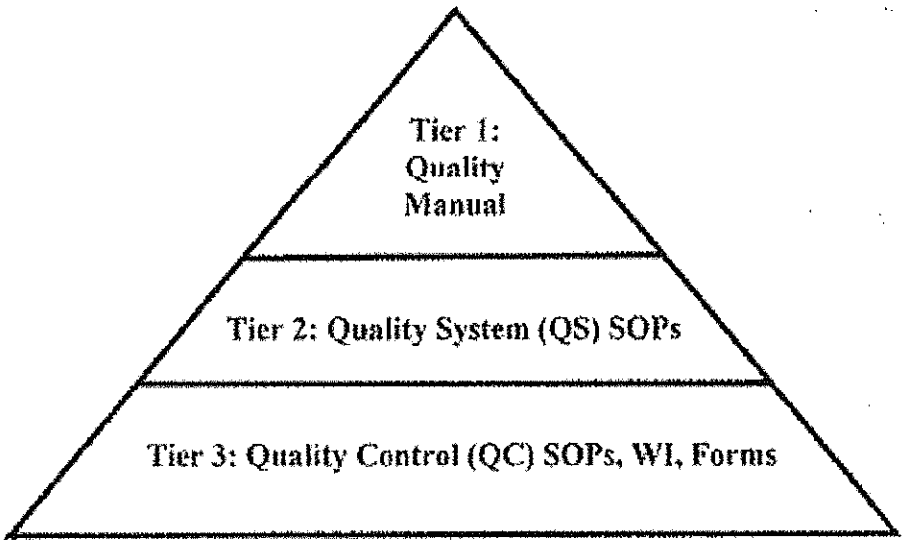
Procedures are established for the control of quality records, these controls include: identification, collection, indexing, access, filing, storage, maintenance and disposition.

Requirements for quality record type, development, legibility, handling, and retention times are defined.

Quality records are stored in a manner that prevents deterioration, damage or loss.

Quality record retention periods are defined not less than five years, unless the customer contractually requires a different retention period.

Quality System Records (820.186): QS-SOP's, QC-SOP's and work instructions define the record requirements and contents for the described operations and establishes the record storage location and function responsible for their maintenance. Refer to the master lists for both QC-SOP's, QS-SOP's and Controlled forms.



The organization has implemented a quality system consistent with regulatory requirements and its stated quality policy in the form of documented quality system and quality control standard operating procedures, associated working instructions ("WI") and forms, quality plans and documents.

A list of standard operating procedures related to the Quality System is provided as an attachment of the Quality Manual. The Quality Assurance Department maintains a complete listing of all documents.

Related Documents:

QS-SOP-030 Document and Data Control
QS-SOP-040 Document Numbering System
QS-SOP-050 Control and Change Process of Customer Specified Processing Parameters for Vacu-Gas Treatment
QS-SOP-060 Document Retention, Release and Distribution
QS-SOP-090 Product Identification and Traceability

5.0 Management Responsibility (820.20)

5.1 Management Commitment

The organization 's Executive Management is responsible for providing objective evidence for its commitment to the development and implementation and effectiveness of the quality management system and maintaining its effectiveness; reviewing the policy and objectives for continuing suitability by conducting Management reviews, communicating to the organization the importance of meeting customer as well as current and future statutory and regulatory requirements; ensuring the availability of resources and making sure that the quality policy is understood, implemented, and maintained at all level of the organization.

a) Creating and maintaining awareness of the importance to fulfill customer requirements, as well as regulatory and legal requirements, by ensuring policies for communication of customer requirements are established and implemented;

b) Establishing the quality policy, quality objectives and quality planning by developing, documenting, and ensuring communication of said policy, as well as achievement of objectives and plans;

c) Conducting management reviews at the senior management level and reviewing reports of management review submitted by facility personnel;

d) Ensuring the availability of resources.

5.2 Customer Focus

The organization's executive management is ultimately responsible for ensuring that customer requirements are identified and are consistently met.

a) Customer needs and expectations are determined and converted into requirements with the aim of achieving customer confidence by establishing policies for customer contracts and communication of contractual requirements to appropriate personnel throughout the process to ensure adherence;

b) Customer requirements are fully understood and met by establishing policies for the identification, review, and communication of the customer requirements.

5.3 Quality Policy (820.20 a)

"It is the policy of Parter Sterilization Services to meet the highest expectations of our customers and to provide exceptional customer support.

Parter Sterilization Services will continuously improve performance of the quality system as outlined in its Quality Manual.

Parter Sterilization Services is also committed to complying with all applicable standards and regulations.

Parter Sterilization Services will accomplish these objectives by creating a tradition of ownership and individual development within the workplace environment.

All the employees at Parter Sterilization Services are encouraged to report events that appear opposing to this quality policy with the management representative."

This quality Policy has been set by the Executive Management of PSS. The Quality Policy is explained and discussed at the training session given to all existing and new employees. This Quality Policy is also posted in conspicuous locations throughout the company.

The overall quality objectives for PSS are set by executive management who has a commitment to comply with requirements and to maintain the effectiveness of the quality management system. This commitment is communicated to each employee. Additionally, individual employee quality objectives are reviewed on an ongoing basis.

The quality policy is communicated throughout the organization and reviewed for continued suitability.

Organization Quality Mission:

a) Provide contract sterilization processing services that are consistently and reliably in compliance with the customer's specified parameters and instructions, *the company's* established system, and the industry's quality and regulatory;

b) Maintain a quality management system that provides the framework for achieving customer satisfaction, prevention of nonconformance, and continual improvement by applying a process-based approach throughout *the company.*

5.4 Planning (820.20 d)

5.4.1 Quality Objectives

Measurable quality objectives, consistent with the quality policy, are established at relevant functions and levels of the organization. Objectives are established to ensure the conformity to regulatory and customer requirements and are delivered to the customer in a timely manner.

a) The organization shall establish quality objectives at each relevant level and function within the organization.

b) The Quality Objectives shall be measurable and consistent with the quality policy and the commitment to continual improvement.

c) Quality objectives shall include those needed to meet requirements for services.

5.4.2 Quality Planning (820.20 d)

a) Senior management shall ensure that planning is carried out to achieve quality objectives, the quality system management requirements, and continual improvement of the quality management system.

- The necessity for documenting unique quality plans.
- Evaluation of the need for any new, unique, or additional resources.
- Assurance that the required services can be achieved with the existing resources.
- Assurance that current quality control test and inspection techniques and instrumentation are suitable.
- Identifying any measurement requirement that exceeds the organization's capability.
- Documentation of verification needs at defined stages.

b) Quality planning shall ensure that change is conducted in a manner that the integrity of the quality management system is maintained.

5.5 Responsibility, Authority, and Communication (820.20)

The administration of the quality management system shall be defined as described herein.

5.5.1 Responsibility and Authority (820.20 b)

a) Organization

The organizational charts, defined at the end of this section (Attachment A), define the reporting relationship of the various functions within the organization and business units.

The functional relationship of the various functions throughout the organization shall be developed and maintained. This shall indicate the title, authority and interaction of personnel, name of personnel are not required, and will be updated as needed listing a revision number and issue date.

b) Each member of the management is ultimately responsible for:

i. implementing and communicating the quality policy and requirements of the quality management system throughout their respective departments;

ii. assuring that requirements of the quality management system are available and followed by each employee;

iii. ensuring that employees are provided with the proper training to perform the duties required of their position;

iv. initiating action to prevent the occurrence of product nonconformance;

v. initiating and providing solutions through designated channels.

c) Specific responsibilities of managers are to be documented in applicable job descriptions.

d) Quality Assurance Manager Authority

<u>The Quality Assurance Manager is given the authority and responsibility to represent the facility on all quality matters pertinent to the Quality Management System as established through customer and regulatory requirements and company quality policies and procedures.</u>

5.5.2 Management Representative (820.20 b.3)

The Quality Assurance Manager is given the responsibility of Management Representative for the overall quality program at the Organization level for all business lines.

The Quality Assurance Manager has the authority and the responsibility for ensuring that the requirements of the quality system are implemented and communicated to all business units, reporting to senior management on the performance of the quality management system and any need for improvement, and ensuring the promotion and awareness of regulatory and customer requirements throughout the organization.

In addition the Quality Assurance Manager is given the authority and responsibility to,

a) maintain compliance to the requirements established in the quality management system.

b) quality system performance is evaluated and areas that need improvement are identified and reported to Senior management;

c) ensure awareness of regulatory and customer requirements.

5.5.3 Internal Communication

The management of the organization ensures that the necessary communication processes, which facilitate successful interrelationships, are established within the organization and that communication take place regarding the effectiveness of the QMS.

5.6 Management Review (820.20 c)

5.6.1 On an annual basis, senior management shall review and evaluate the suitability, adequacy, and effectiveness of the quality management system, policy, and objectives, including evaluating opportunities for improvements and the need for changes to said system.

5.6.2 The review input shall consist of evaluations of current performance and improvement opportunities related to findings from internal, regulatory, and customer audits, customer feedback, process performance and conformance, preventive and corrective actions, market strategies, and information on new or revised regulatory requirements, follow-up from earlier management reviews, and recommendations for improvement.

- Review of action items from last meeting.
- Results of internal and external audits.

- Customer Feedback
- Customer Complaint
- Process performance and product conformity.
  - Status of preventive and corrective actions (CAPA).
  - Trends of Nonconformance's and deviations.
- Changes that could affect the quality management system.
- Recommendation for improvement needed to maintain the effectiveness of the quality management system and its processes including resources, space and communication.
- New or revised regulatory requirements.
- A determination of whether the Quality Policy meets the company Goals and Objectives.

5.6.3 The output of management review shall include actions related to improvement of the quality management system and its processes, improvement toward meeting customer requirements, and any revised or new regulatory requirements, and resources needed to achieve improvement.

- Improvements need to maintain the effectiveness of the quality management system and its processes.
- Improvements of product release to customer requirements.
- Changes needed to satisfy the ISO 13485: 2016, ISO 11135, 21 CFR, part 820, & JMO 169
- Resources needed.

Related Documents:

QS-SOP-001 Quality Policy Statement
QS-SOP-003 Organizational Structure
QS-SOP-005 Quality Systems Program
QS-SOP-010 Management Review

6.0 Resource Management (820.20 b.2)

6.1 General Requirements

The organization shall determine and provide in a timely manner, the resources needed to establish, implement, maintain and improve the quality management system and meet customer requirements. Resource requirements are reviewed on an ongoing basis and as part of management review activities.

6.2 Human Resources (820.25)

6.2.1 Assignment of Personnel (820.25 a)

The organization's management ensures that sufficient personnel, with the necessary education, background, training, and experience are in place to perform activities required by the QMS and to meet regulatory and customer requirements.

6.2.2 Training, Awareness and Competency (820.25 b)

- The *organization's* Management determines the necessary competence for personnel performing work affecting product quality, and identifies needs for training or other appropriate intervention, to ensure that the desired performance is attained.
- As part of the *organization's* training program, personnel are made aware of the relevance and importance of their activities and how those activities contribute to the achievement of quality objectives. Personnel are also informed of device defects and errors that could result from the improper performance of their job responsibilities.
- Evaluation of effectiveness is conducted for training and other intervention activities, to improve both the `curriculum' and the effectiveness of what is provided.
- Records of employee education, training, skills and experience are maintained.

Related Documents:

QS-SOP-290 Personnel Training

6.3 Infrastructure (Facilities) (820.70 f)

The organization shall determine and maintain the facilities needed to provide services that conform to customer requirements. The company shall provide and maintain the following:

6.3.1 Buildings, workspace and associated utilities to perform operations, prevent mix-ups and product damage.

6.3.2 Equipment used meets specified requirements and is designed and installed to facilitate maintenance, cleaning, and use. Maintenance schedules are established and maintenance activities are documented. Periodic inspections are performed to ensure that scheduled activities are being performed (both hardware and software).

6.3.3 Any support services required for the infrastructure at the organization shall be identified and implemented as needed.

6.3.4 Interrelations of personnel, who manage, perform and verify work affecting quality is defined in the organization chart.

6.4 Work environment (820.70 d)

The organization ensures that work environments are appropriate to achieve conformity to product requirements and to prevent contamination of product or equipment. Written procedures define the environmental control requirements, including the requirements for health, hygiene, and clothing at the organization. Personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised.

Written procedures are maintained that address prevention of contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality. Such procedures include the control of contaminated or potentially contaminated product.

a) adequate health, cleanliness, and safety practices;

b) work instructions;

c) adequate and comfortable working environment;

d) suitable equipment.

Related Documents:

QS-SOP-110	Preventive and Routine Maintenance
QS-SOP-120	Environmental Monitoring and Procedure for Employees or Worker's Safety
QS-SOP-130	Hazard Communication Program
QS-SOP-140	Sterilization Equipment and Process Change Control
QS-SOP-250	Handling, Storage, Packaging and Delivery

7.0 Product and/or Service Realization

7.1 Planning of Product Realization

The organization shall determine, plan and implement processes necessary to produce the required service. Planning of processes shall be consistent with the other requirements of the quality management system and shall be documented in a manner suitable for the operation. In planning the processes for realization of service, the following shall be determined, as appropriate:

a) Quality objective and requirements for the product;

b) The need to establish processes, documents, and provide resources to meet requirements;

c) Required verification, validation, monitoring, inspection, and test activities, and criteria for product acceptance (where applicable);

d) Records needed to provide evidence that the realization processes and resulting product fulfill requirements, and also providing evidence that the product and set-vices met the customer expectation in Device History Record (DHR). These records are retained for a minimum of fifteen (15) years.

Related Documents:

QS-SOP-005	Quality Systems Program
QS-SOP-020	Contract Review (Customer Requirement)
QS-SOP-060	Document Retention, Release and Distribution
QS-SOP-110	Preventive and Routine Maintenance Program
QS-SOP-130	Hazard Communication
QS-SOP-140	Sterilization Equipment and Process Change Control
QS-SOP-150	Installation, Qualification, Validation, Re-validation and Commissioning of Vacu-Gas Chambers
QS-SOP-155	Validation/Re-Validation of Incorporated Times in Sterilization Equipment
QS-SOP-160	Vacu-Gas Chamber's Microprocessor Validation and Qualification Software Challenge
QS-SOP-170	Installation, Qualification, Validation, Re-Validation and commissioning of Pre-Conditioning Room
QS-SOP-180	Installation, Qualification, Validation, Re-Validation and commissioning of Aeration Room
QS-SOP-190	Inspection and Testing
QS-SOP-320	Risk Assessment

7.2 Customer-Related Processes

* 7.2.1 Identification of Customer Requirements

The Organization shall establish a system to control activities associated with review of customer orders including the requirements for delivery and post-delivery activities.

When applicable, statutory and regulatory requirements related to the product and services shall be determined.

Each customer order or contract is reviewed to ensure that:

- All requirements are adequately defined and documented;
- *The organization* has the capability to meet these requirements;

Appropriate records of these contract review activities are maintained.

Documented procedures specify how amendments to an order are made. These procedures also indicate how amendments to orders are communicated to affected functions.

a) customer product or service requirements, including the requirements for delivery, and post-delivery activities;
b) requirements not specified by the customer but necessary for fitness of purpose;
c) regulatory and legal requirements.
d) any additional requirements determined by the organization.

Note: User training to customer product is not PSS responsibility and therefore is non-applicable.

* 7.2.2 **Review of Customer Requirements**

The contract review is performed and the requirements agreed upon. before the

acceptance of the contract to assure the facility's capability to meet the contractual requirements. The contract review shall assure that:

a) the requirements are clearly defined;
b) where the customer provides no written requirements, the requirements are confirmed before acceptance;
c) the requirements that differ from those previously expressed are resolved;
d) the requirement as defined and applicable per ISO 13485:2016, 21 CFR, part 820, and JMO 169 are met.
e) the organization has the ability to meet the defined requirements.

Records shall be maintained of contract review and subsequent amendments.

The method for amending contracts and communicating the amendment to appropriate personnel shall be defined and documented.

Note: User training to customer product is not PSS responsibility and therefore is non-applicable.

7.2.3 Customer Communication

A customer communication system shall be established with the aim of meeting the customer requirements. This system shall define the communication requirements relating to:

a) product and/or service information;

b) inquiry and order handling, including amendments to orders;

c) customer complaints and actions relating to nonconforming products or services;

d) customer feedback relating to performance of product or service.

Related Documents:

QS-SOP-020 Contract Review (Customer Requirement)
QS-SOP-230 Customer complaint Procedure
QS-SOP-240 Corrective and Preventive Action

7.3 Design and Development

"This element is excluded from the scope of the quality management system."

7.4 Purchasing (820.50)

7.4.1 Purchasing Process (820.50 a)

Methods, procedures and requirements shall be defined and implemented for purchase of supplies and services. The type and extent of control will be dependent upon the criticality of the purchased product or service. Suppliers and consultants providing supplies or services which are critical to the maintenance of the quality management system or process controls must be evaluated to ensure the vendors ability to provide the specified supply or service required. Evaluation and, reevaluation, and selection criteria shall be established in documented procedures. Records shall be maintained to demonstrate the method used to qualify critical suppliers.

7.4.2 Purchasing Information (820.50 b)

Records of purchasing activities are maintained as specified in purchasing procedures. Purchasing requirements are clearly defined and reviewed prior to use:

- A precise description, and/or identification of the service required, Methods, procedures and requirements shall be developed for the purchase of supplies or services and clearly communicated, defined, and understood by the vendors through the use of contracts, specifications, drawings or purchase orders

- Drawing, specification, particular process, handling or inspection requirements, technical data, test, quality standard or qualification requirements necessary for the sub-contractor to supply the components or service, Purchasing documents shall include appropriate information to provide adequate qualification and approval of purchased products and services. Where appropriate, requirements for approval or qualification of product, procedures, processes, equipment, personnel, and quality management system will be defined
- An agreement that sub-contractors shall notify the organization of changes in the components or service that may impact the quality
- Purchasing documents are reviewed for accuracy and completeness prior to release by authorized individuals.

7.4.3 Verification of Purchased Product/Service

The organization shall define and establish methods for the verification of purchased services and/or supplies for conformance to the specified requirements. The control of nonconforming materials or suppliers shall be documented in system level procedures. Where the customer proposes that verification activities be performed at the supplier's premises, the verification requirements shall be specified in the purchasing documents.

Related Documents:

QS-SOP-070 Purchase Order Guideline
QS-SOP-080 Supplier Qualification Program
QS-SOP-190 Inspection and Testing
QS-SOP-220 Control of Non-Conforming Material or Process
QC-SOP-070 Receiving, Handling and Shipping of EO/CO2 Inspection and Testing
QC-SOP-080 Receiving Inspection

7.5 Production and Service Provision

7.5.1 Control of Production (Operations)

Manufacturing processes affecting quality are developed, implemented, controlled and monitored according to documented specifications and procedures. Processes are carried out under the following controlled conditions:

- Documentation that defines requirements for components, processes, work instructions, inspection, test and product release
- The use of suitable equipment, which is approved prior to manufacturing salable product
- The use of personnel trained or qualified for the task they undertake, provided with any criteria for workmanship needed to meet specified requirements

- Monitoring and control of process parameters and product characteristics through inspection, test and verification activities to assure conformance to specified requirements, standards or codes
- Requirements for maintenance of equipment
- The qualification and validation of specified processes
- Maintenance of appropriate records to verify conformance to specified requirements
- Control of production or process changes requiring verification or validation prior to use and validation of software controlled automated processes or equipment where conformance to specifications cannot be subsequently verified by inspection or test
- Validation of computers or automated data processing systems that are used as part of production or the quality system.

7.5.2 Validation of Processes (820.75)

a) Where the results of a process cannot be fully verified by inspection and test, the process shall be validated to demonstrate effectiveness and acceptability.

b) Procedures shall be established for validation to define and address:

i. the processes to be qualified prior to use;

ii. the use of qualified equipment and/or personnel;

iii. the specific procedures and necessary documents;

iv. re-validation requirements;

v. requirements for records.

7.5.3 Identification and Traceability (820.60, 820.65, 820.86)

Procedures are established for the identification of components and product during all stages of receipt, production and delivery. Unique lot numbers are assigned to all material and component. Nonconforming product /components are clearly identified and documented. Procedures are established to assure the integrity and traceability are maintained.

The inspection and test status of product /components is identified according to documented procedures, including identification of nonconforming product. Acceptance activities for receipt, in-process, and finished process acceptance are documented. Acceptance records include: the activity performed; the date; the

results; the signature of the individual(s) conducting the activities; and, the equipment used. Acceptance records are maintained as part of the DHR.

7.5.4 Customer Property

Customer property shall be identified, verified, stored, processed, and maintained in a manner to prevent loss, mix-up, or damage. Any customer property that is identified as being lost, damaged, or otherwise unsuitable for use shall be recorded and reported to the customer. Customer property in. the form of confidential information will remain confidential.

7.5.5 Preservation of Product (Handling, packaging, storage, preservation and delivery) (820.140, 820.150, 820.160)

Procedures are established for handling, storage, packaging, preservation and delivery of product.

Methods of handling are provided to prevent damage or deterioration. These include; documented procedures that define requirements through all stages of processing and packaging, labeling and the use of appropriate environmental controls for medical devices.

Designated areas are assigned for storage of materials, components and product. Methods are established to control receipt and dispatch. The condition of product in stock is assessed at intervals appropriate to its storage requirements.

Controls are established for the preservation and segregation of product, including requirements for traceability and environmental conditions in manufacturing, packing, and warehouse locations.

Related Documents:

QS-SOP-030	Document and Data Control
QS-SOP-040	Document Numbering System
QS-SOP-060	Document Retention, Release and Distribution
QS-SOP-090	Product Identification and Traceability
QS-SOP-110	Preventive and Routine Maintenance
QS-SOP-140	Sterilization Equipment Change Control
QS-SOP-150	Installation, Qualification, Validation, Re-validation and Commissioning of Vacu-Gas Chambers
QS-SOP-155	Validation/Re-Validation of Incorporated Times in Sterilization Equipment
QS-SOP-160	Vac-Gas Chamber's Microprocessor Validation and Qualification Software Challenge
QS-SOP-170	Installation, Qualification, Validation, Re-Validation and commissioning of Pre-Conditioning Room
QS-SOP-180	Installation, Qualification, Validation, Re-Validation and commissioning of Aeration Room
QS-SOP-190	Inspection and Testing
QS-SOP-200	Calibration
QS-SOP-220	Control of Non-Conforming Material or Process
QS-SOP-250	Handling, Storage, Packaging and Delivery

7.6 Control of Measurement and Monitoring Devices; Inspection, Measuring, and Test Equipment (820.72 a, b)

The organization shall control, calibrate, and maintain measurement and monitoring equipment (device) used to demonstrate the conformance of the processes to specified requirements.

The organization shall:

a) identify the measurements to be made, the accuracy required, and selection of the appropriate device, based upon the specified criteria;

b) identify, calibrate, maintain, and adjust all inspection, measuring and test equipment, and devices that can affect process quality at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to nationally recognized standard, where no such standards exist, the basis used for calibration must be documented;

c) establish, document, and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria, and the action to be taken when results are unsatisfactory;

d) ensure devices are capable of and used in a manner that measurement uncertainty, including accuracy and precision, is known and consistent with the required measurement capability;

e) identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status;

f) record and maintain calibration activities as quality records;

g) evaluate and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration and take appropriate action where necessary;

h) ensure that the environmental conditions are suitable for calibrations, measurements, and tests being performed;

i) ensure that the handling, preservation, and storage of the devices are such that the devices are protected from damage and deterioration;

j) safeguard the devices from adjustments which would invalidate the calibration setting;

k) validate test hardware or test software used to verify the acceptability of processes.

Related Documents:

QS-SOP-110	Preventive and Routine Maintenance
QS-SOP-155	Validation/Re-Validation of Incorporated Times in Sterilization Equipment
QS-SOP-160	Vac-Gas Chamber's Microprocessor Validation and Qualification Software Challenge
QS-SOP-200	Calibration

8.0 Measurement, Analysis, and Improvement (820.198, 820.22)

8.1 General

Monitoring, measurement, analysis and improvement processes are planned and implemented to demonstrate product conformity, to ensure conformity of the QMS, and to maintain the effectiveness of the QMS. This includes the application of appropriate methods, including statistical techniques.

a) demonstrate conformity of the product and compliance with customer's requirements;

b) ensure conformity of the quality management system;

c) continually improve the effectiveness of the quality management system.

The organization shall identify and use the appropriate statistical techniques.

Related Documents:

QS-SOP-010 Management Review
QS-SOP-310 Statistical Technique

8.2 Measurement and Monitoring

8.2.1 Measurement and Monitoring of Customer Satisfaction

The organization shall monitor information relating to customer perception as to whether the organization has fulfilled customer requirements. The methods used to measure this information shall be planned.

8.2.2 Complaint (820.198)

The organization shall document procedures for timely complaint handling in accordance with applicable regulatory requirements. These procedures shall include at a minimum requirements and responsibilities for:

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

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

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

Related Documents:

QS-SOP-230 Customer Complaint Procedure
QS-SOP-310 Statistical Technique

* 8.2.3 **Reporting to regulatory authorities**

The organization shall notify the applicable regulatory authorities for any major changes to the QMS or the name and address of the organization. The notification and change shall be discussed during the management review.

8.2.4 **Internal Audit (820.22)**

The organization shall perform internal quality assessments to assure effective implementation and compliance to the quality management system, regulations, and international standards, and the methods used to measure and monitor the quality management system. Audits shall be scheduled at planned intervals, on the basis of the status and importance of the area, and results of previous audits. Audits shall be conducted by qualified individuals that do not have direct responsibility for the location being audited. The organization shall have a system level procedure for internal audits that includes:

a) audit scope, methodology and frequency;

b) responsibilities and requirements for conducting audits, recording and reporting results to management;

c) timely corrective action on deficiencies found during the audit;

d) follow-up actions to verify the implementation of corrective action, and reporting the verification results.

Related Documents:

QS-SOP-280 Internal Quality Audit

8.2.5 **Measurement and Monitoring of Process, Process Control (820.70)**

The organization shall define and document methods for measurement and monitoring of processes necessary to ensure requirements are achieved and to demonstrate the process's continued ability to satisfy its intended purpose. Results shall be used to maintain and improve these processes.

The process will be implemented, measured and monitored for a state of control through the following:

a) documented procedures and work instructions;

b) approval of processes and process equipment;

c) suitable equipment, designed in a manner to perform maintenance, adjustments, and cleaning;

d) work performed by trained personnel and applicable criteria for workmanship defined;

e) compliance with applicable national reference standards/codes, regulations, documented procedures and quality plans;

f) monitoring, control, and inspection of the process through routine process data review and testing;

g) suitable environment, facilities, and environmentally controlled conditions to perform quality operations;

h) adequate buildings of suitable design and sufficient space to perform necessary operations;

i) ensure process integrity, prevent mix-ups, and preserve product condition;

j) preventive maintenance and inspection of equipment;

k) automated data processing systems and software. and any changes to said systems or software, used for production or quality system management, are validated for intended use;

l) compliance to all quality management system and safety requirements;

m) adequate health, cleanliness, and personnel practices.

n) internal audits

o) All process inspections and testing shall be documented and retained as quality records.

8.2.6 Measurement and Monitoring of Product and/or Service (820.80)

Procedures shall be established for receiving, in process, and final inspection activities to assure that purchased supplies and services supplied to customers conform to specified acceptance criteria.

Evidence of conformity to acceptance criteria shall be documented and records shall indicate the authority responsible for the release of the product or service. Product release shall not proceed until all the specified activities have been satisfactorily completed, unless otherwise approved by the customer.

Related Documents:

QS-SOP-190 Inspection and Testing
QS-SOP-220 Control of Non-conforming Material or Process
QC-SOP-080 Receiving Inspection

8.3 Control of Nonconformity (820.90)

8.3.1 Nonconformity Control

The organization shall establish and maintain procedures to assure that product that does not conform to specified requirements is controlled to prevent unintended use or delivery. The procedures shall also define the responsibility and authority in dealing with nonconforming product.

Controls shall be documented in established procedures to provide for the identification, documentation, evaluation, segregation and disposition of nonconforming product.

8.3.2 Nonconformity review and disposition

Nonconformities shall be reviewed and action taken in accordance with documented procedures.

These nonconformities shall be handled in one or more of the following ways:

a) corrected or adjusted to conform to requirements, or

b) accepted under concession, with or without correction or adjustment, or

c) re-assigned for alternative valid application, or

d) rejected as unsuitable.

Note: Re-work to customer product is not PSS responsibility and therefore is non-applicable.

Corrections or adjustments of nonconforming product and/or service must be performed in accordance with written procedures and customer requirements.

Records of nonconformities and subsequent actions taken, including concessions obtained, shall be maintained. When nonconforming product is detected after delivery or use has started, *the organization* shall take action appropriate to the effects, or potential effects, of the nonconformity.

Related Documents:

QS-SOP-220 Control of Non-conforming Material or Process
QS-SOP-240 Corrective and Preventive Action

8.4 Analysis of Data for Improvement

The organization shall establish and implement methods for the analysis of data in order to determine the effectiveness of the quality management system and identify areas of improvement. Applicable system level procedures shall identify the appropriate data for analysis from the quality records to evaluate quality performance trends. Results of said data analysis shall be submitted as input to management review.

The data shall be analyzed to provide information regarding:

a) customer satisfaction through service quality trends regarding conformance to customer requirements;
b) conformance to product requirements;
c) process operation trends of performance to specifications;
d) preventive actions;
e) supplier performance;
f) audits.

Related Documents

QS-SOP-010 Management Review
QS-SOP-080 Supplier Qualification Program
QS-SOP-220 Control of Non-conforming Material or Process
QS-SOP-230 Customer Complaint Procedure
QS-SOP-240 Corrective and Preventive Action
QS-SOP-280 Internal Quality Audit

8.5 Improvement (820.100)

8.5.1 Planning and Continual Improvement

The organization continuously improves the effectiveness of the QMS through the use of the quality policy, quality objectives, internal audits, analysis of data, corrective and preventive actions, and management review. Continual improvement of the quality management system will be promoted by:

a) the quality policy, objectives, internal audit results, analysis of data, corrective and preventive action;
b) and management review.

Related Documents:

QS-SOP-010 Management Review
QS-SOP-240 Corrective and Preventive Action
QS-SOP-280 Internal Quality Audits
QS-SOP-310 Statistical Techniques

8.5.2 Corrective Action

Procedures are established for implementing corrective actions. Any actions taken to eliminate the causes of actual nonconformities are appropriate to the level of risk and magnitude of the problems. Changes resulting from any corrective actions are documented according to document change control requirements. Procedures for corrective action include the following elements:

- Fully documenting and maintaining records of all customer complaints and reports of product nonconformance to assure effective handling, including documentation of corrective actions or justification for determining that no corrective action is needed
- Investigation into the cause of any nonconformities affecting the product, process and quality system and documenting the results of the investigation
- Determination of the corrective actions needed to prevent recurrence of any nonconformance
- The application of controls to assure the implementation of effective corrective action

  a) identification of nonconformities (including customer complaints);

  b) determination of the causes of nonconformities;

  c) evaluation of the need for actions to ensure that nonconformities do not recur;

  d) implementation of actions determined necessary to ensure that nonconformities do not recur; recording the results of actions taken;

  f) ensuring that corrective actions taken are effective and recorded.

Related Documents:

QS-SOP-240 Corrective and Preventive Action

8.5.3 Preventive Action

Measures are identified which constitute a system providing early warning of quality problems to allow preventive actions to be implemented. Procedures, established for implementing preventative actions, include the following elements:

- The use of appropriate sources of information to eliminate the cause of potential nonconformities
- Documentation of steps taken as preventive action, including analysis, initiation and application of controls to assure the steps taken are effective
- Inclusion of preventive actions as part of management review activities

Related Documents:

QS-SOP-240 Corrective and Preventive Action

9. Attachments

Attachment 1 - Cross Reference Table: EN ISO 13485:2016 and CFR Part 820

Attachment 2 - Quality System SOP List (Tier 2)

Attachment 3 - Quality Control Procedures List (Tier 3)

Attachment 4 - Interaction of Quality System Process

Attachment 5 - Process Map

Attachment A - Organization Chart

Attachment 1

Cross Reference Table: ISO 13485:2016and 21 CFR, Part 820

ISO 13485:2016	21 CFR, Part 820
4 Quality management system (QMS)	820.5 Quality system
4.1 General requirements	
4.2 Documentation requirements	
4.2.1 General	
4.2.2 Quality manual	
4.2.3 Medical Device File	820.120 Device Labelling 820.130 Device packaging 820.140 Handling 820.150 Storage 820.160 Distribution 820.170 Installation 820.180 Records 820.181 Device Master Record 820.200 Servicing
4.2.4 Control of documents	820.40 Document controls
4.2.5 Control of records	820.180 General requirements
	820.181 Device master record
	820.184 Device history record
	820.186 Quality system record
5 Management responsibility	820.20 Management responsibility
5.1 Management commitment	
5.2 Customer focus	
5.3 Quality policy	820.20 Management responsibility
5.4 Planning	
5.4.1 Quality Objectives	
5.4.2 QMS planning	820.5 Quality system
5.5 Responsibility, authority and communication	820.20 Management responsibility
5.5.1 Responsibility and authority	
5.5.2 Management representative	
5.5.3 Internal Communication	
5.6 Management Review	
5.6.1 General	
5.6.2 Review input	
5.6.3 Review output	
6 Resource management	
6.1 Provision of resources	
6.2 Human resources	
6.2.1 General	
6.2.2 Competence, awareness and training	
6.3 Infrastructure	820.70 Production and process control
6.4 Work environment	
7 Product realization	820.5 Quality system
7.1 Planning of product realization	
7.2 Customer-related processes	
7.2.1 Determination of requirements related to the product	
7.2.2 Review of requirements related to the product	
7.2.3 Customer communication	
7.3 Design and development	820.30 Design controls
7.3.1 General	
7.3.2 Design and development planning	
7.3.3 Design and development inputs	
7.3.4 Design and development Outputs	
7.3.5 Design and development review	
7.3.6 Design and development verification	
7.3.7 Design and development validation	

ISO 13485:2016			21 CFR, Part 820
	7.3.8	Design and Development Transfer	
	7.3.9	Control of design and development changes	
	7.3.10	Design and development files	
7.4	Purchasing		820.50 Purchasing controls
	7.4.1	Purchasing .process	
	7.4.2	Purchasing information	
	7.4.3	Verification of purchased product	820.80 Receiving, in-process and finished product acceptance
7.5	Production and service provision		820.70 Production and process controls
	7.5.1	Control of production and service provision	
	7.5.2	Cleanliness of Product	
	7.5.3	Installation Activities	820.170 Installation
	7.5.4	Servicing	820.200 Servicing
	7.5.5	Particular Requirements for Sterile Medical Devices	Not Specified
	7.5.6	Validation of Processes for Production and Service Provision	820.75 Process validation
	7.5.7	Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems	Not Specified
	7.5.8	Identification	820.60 Identification
	7.5.9	Traceability	820.65 Traceability
	7.5.10	Customer Property	Not Specified
	7.5.11	Preservation of Product	820.120 Device labelling 820.130 Device packaging 820.140 Handling 820.150 Storage 820.160 Distribution
7.6	Control of monitoring and measuring devices		820.72 Inspection, measuring, and test equipment
8	Measurement, analysis and improvement		
8.1	General		820.250 Statistical techniques
8.2	Monitoring and measurement		820.198 Complaint files 820.22 Quality Audit
8.3	Control of Nonconforming Product		820.90 Nonconformity Review and Disposition
8.4	Analysis of Data		820.250 Statistical Techniques
8.5	Improvement		820.100 Corrective and Preventative Action

Attachment 2

Quality System SOP List (Tier 2)

SOP Number	SOP Title
QS-SOP-001	Quality Policy Statement
QS-SOP-003	Organizational Structure
QS-SOP-005	Quality Systems Program
QS-SOP-010	Management Review
QS-SOP-020	Contract Review
QS-SOP-030	Document And Data Control
QS-SOP-040	Document Numbering System
QS-SOP-050	Control And Change Process Of Customers' Specified Processing Parameters for Vacu-Gas treatment
QS-SOP-060	Document Retention. Release And Distribution
QS-SOP-070	Purchase Order Guideline
QS-SOP-080	Supplier Qualification Program
QS-SOP-090	Product Identification And Traceability
QS-SOP-I 10	Preventive And Routine Maintenance
QS-SOP-120	Environmental Monitoring And Procedure For Employees Or Workers' Safety
QS-SOP-130	Hazard Communication Program
QS-SOP-140	Sterilization Equipment Change Control
QS-SOP-150	Installation, Qualification, Validation, Re-Validation And Commissioning Of Vacu-Gas Chambers
QS-SOP-155	Validation/Re-Validation of Incorporated Timers in Sterilization Equipment
QS-SOP-160	Vacu-Gas Chamber's Microprocessor Validation And Qualification - Software Challenge
QS-SOP-170	Installation, Qualification, Validation, Re-Validation And Commissioning Of Pre-Conditioning Room
QS-SOP-IS0	Installation, Qualification, Validation, Re-Validation And Commissioning Of Aeration Room
QS-SOP-190	Inspection And Testing
QS-SOP-200	Calibration
QS-SOP-220	Control Of Non-Conforming Material Or Process
QS-SOP-230	Customer Complaint Procedure
QS-SOP-240	Corrective And Preventive Action
QS-SOP-250	Handling, Storage, Packaging And Delivery
QS-SOP-280	Internal Quality Audits
QS-SOP-290	Personnel Training
QS-SOP-310	Statistical Techniques
QS-SOP-320	Rish Assessment
QS-SOP-410	Scheduled Tasks

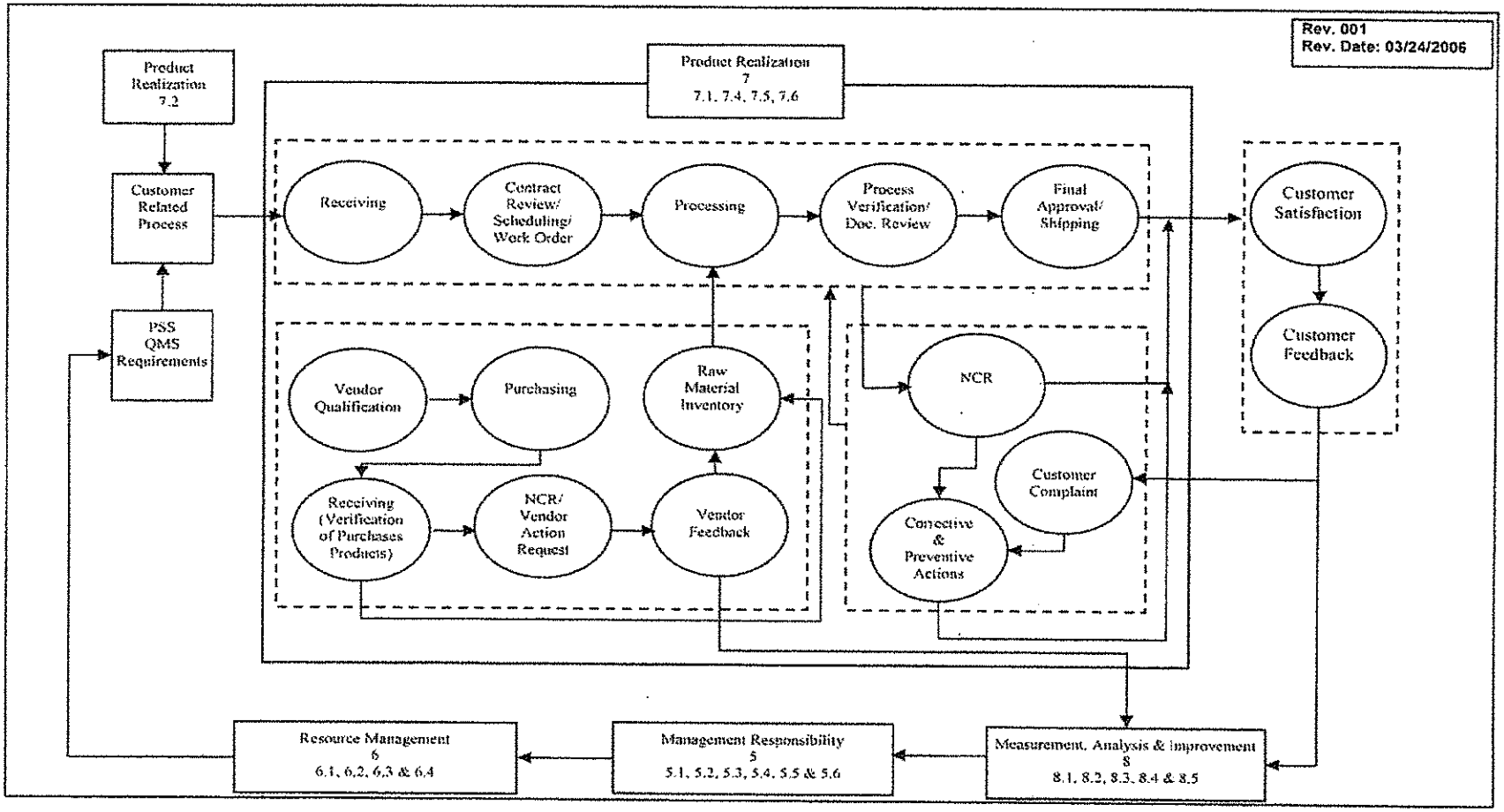
Attachment 3

Quality Control Procedures List (Tier 3)

SOP Number	SOP TITLE
QC-SOP-005	Limited Access to Premises
QC-SOP-010	Plant Layout And Material Flow
QC-SOP-020	Pre-Conditioning Room Parameters
QC-SOP-030	Aeration Room Parameters
QC-SOP-040	Loading and Unloading the Vacu-Gas Chambers
QC-SOP-045	Respiratory Mask
QC-SOP-050	Checklist and Instructions For Starting a Sterilizer Operated And Controlled by Microprocessor
QC-SOP-060	Instruction For Connection And Disconnection Of Compressed Gas Cylinders
QC-SOP-070	Receiving, Handling And Shipping of FO/CO2 Product
QC-SOP-080	Receiving Inspection
QC-SOP-090	Procedure For Vacu-Gas Treatment of Customer's Product
QC-SOP-100	Power Failure And Related Corrective Actions
QC-SOP-110	Water Softener System
QC-SOP-120	Pest Control Procedure And Schedule
QC-SOP-130	Computer System Data
QC-SOP-140	Operational Check of EO Monitor
QC-SOP-150	Calibration of the Ethylene-Oxide Monitor

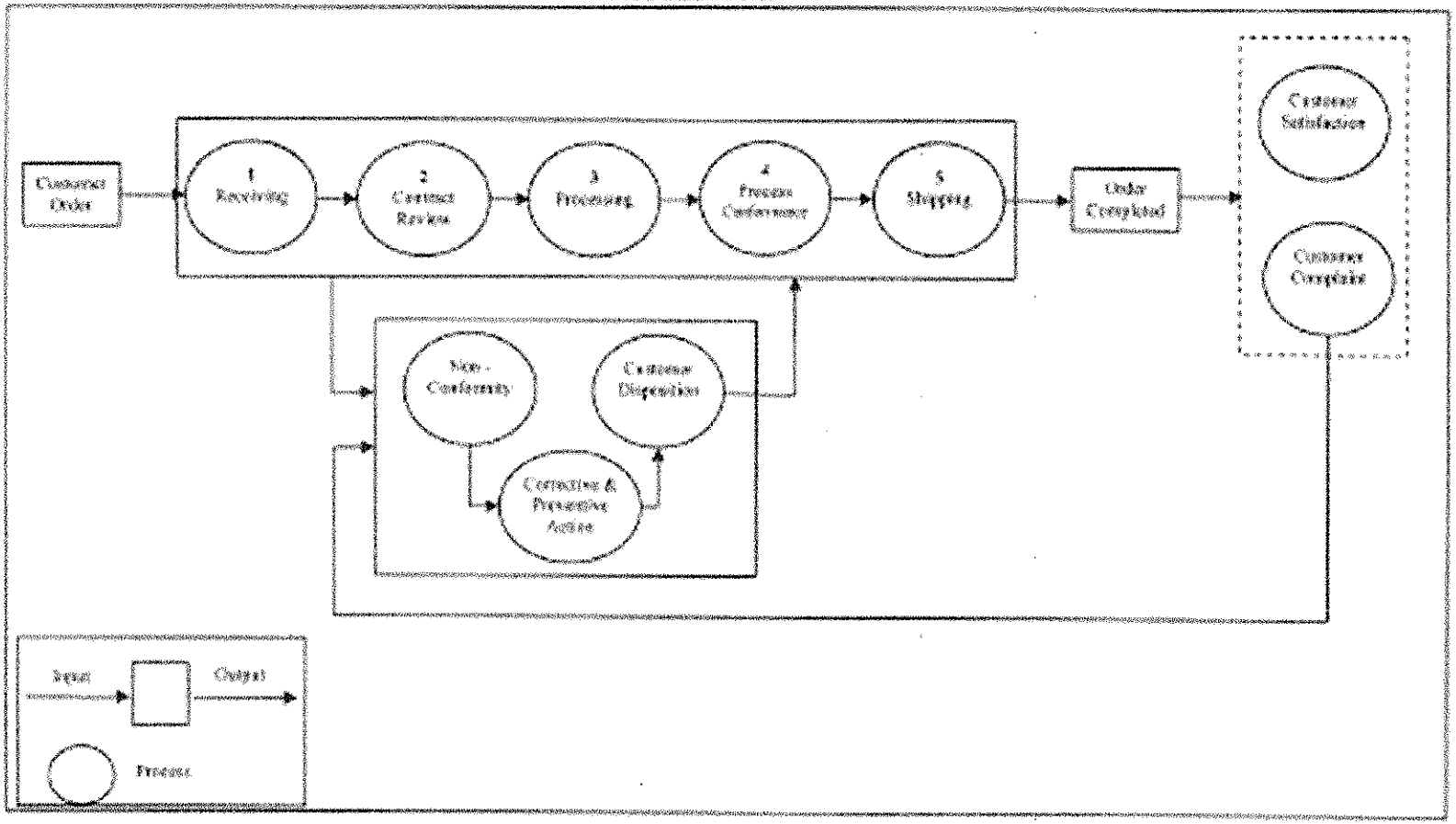
Attachment 4

Interaction of Quality System Process



Attachment 5

PARTER STERILIZATION SERVICES
PROCESS MAP



Attachment A

PARTER STERILIZATION SERVICES

Organization Chart