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SCOPE

This procedure applies to the quality management system at Global Surgical Corporation

RESPONSIBILITIES

Top Management – Responsible for ensuring implementation and compliance to this policy

Quality Manager – Responsible for implementation and monitoring compliance of this policy

Departments – All the following departments are responsible for following the policy to include but are not limited to: QA, Engineering, Production, Tech Support and Customer Service

PROCEDURE

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 Section 4.0

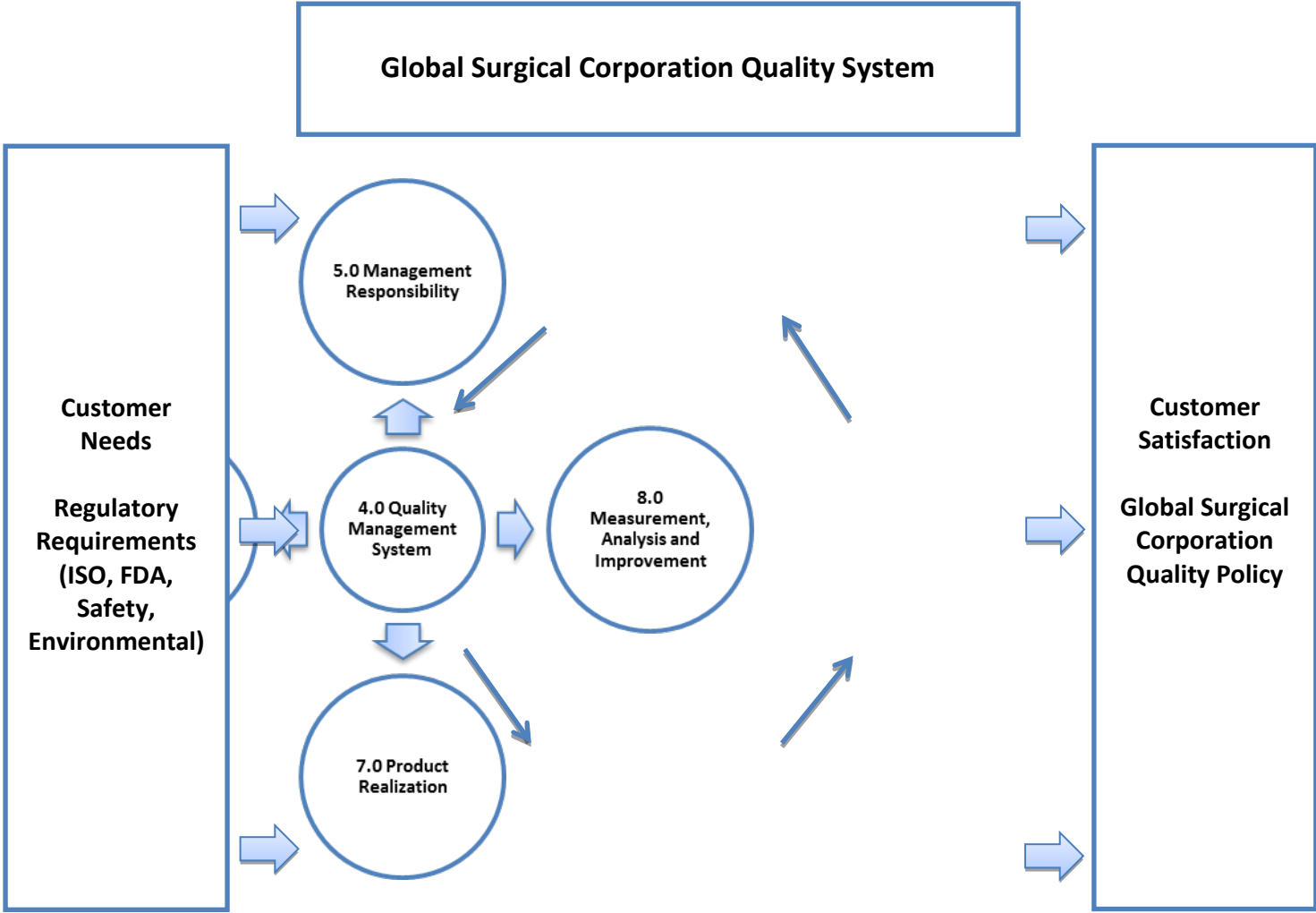
4.1 General Requirements


Global Surgical Corporation maintains an established, documented quality system to ensure that products conform to specified requirements. Global Surgical Corporation has prepared this manual to document the system in compliance with the requirements of ISO 13485, USFDA 21 CFR Part 820, Quality System Regulation and other standards.

The sequence and interaction of processes needed for the quality management system are determined and documented along with criteria and methods needed to ensure that both operation and control of these processes are effective. This applies to internal as well as outsourced processing and services. The process depicted in Figure 1 provides an overview of the Global Surgical Quality Management System model. The closed loop process ensures that Global Surgical has not only established, but also maintains effectiveness of processes and practices on a continuous basis.

Global Surgical Corporation has made available resources and information necessary to support the operation and control of these processes. Systems are established for monitoring, measuring and analysis of Global's processes to assure planned results are achieved and to maintain the effectiveness of these processes.

Figure 1. Quality Management System Model



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4.2 Documentation

4.2.1 General

Global Surgical Corporation has prepared this Quality Policy Manual to document its quality system. Included are references to policies, objectives and procedures consistent with the requirements of the ISO 13485 Standard. Documents and records exist as appropriate to ensure effective planning, operation and control of Global's processes.

An outline of the structure of the documentation used by Global Surgical has been established. [21 CFR 820.20 (e)]

4.2.2 Quality Manual

The Global Surgical Corporation Quality Manual (this document) defines the policies, application, scope, exclusions and documentation of the quality management system.

4.2.3 Control of Documents

Procedures are established to control documents that make up the QMS. This process provides for the creation, identification, approval, distribution, revision, identification and disposal of such documents, and this process prevents the unintentional use of obsolete documents. Controls apply to internally generated documents as well as documents of external origin. The Quality Manager assumes responsibility for the document control activity.

4.2.4 Control of Records

Quality records are created and maintained as required to provide evidence of conformance to specified requirements and effective operation of the Global Quality System. Procedures provide for the identification, storage, protection, retrieval, retention and disposal of quality records. All records are retained for the expected life of the device or for two years – whichever is greater. [21 CFR 820.180(b)]

Device Master Records (DMRs) are prepared and approved for each type of device manufactured. DMRs include device specifications; production process specifications; quality assurance procedures and specifications; packaging and labeling specifications; and installation, maintenance and servicing procedures and methods. [21 CFR 820.181]

Device History Records (DHRs) are maintained to demonstrate that each medical device is manufactured in accordance with the DMR. DHRs include dates of manufacture; the quantity manufactured; the quantity released for distribution; acceptance records; labeling and any device identifications and control numbers used. [21 CFR 820.184]

Global Surgical maintains a quality system record which refers to the location of the procedures and documentation of activities that are not device specific but which are required by 21 CFR 820. [21 CFR 820.186]

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Procedures implementing this policy:

- SOP 4.2-01 Control of Documents - System
- SOP 4.2-02 Documentation Control - Product Specific
- SOP 4.2-04 Document Control – Engineering Change Orders (ECO)
- SOP 4.2-03 Control of Records

Date	Section	Description of Change
03/05/2015	All	Separated the QPM out into single section procedures. Revamped this section to include FDA and ISO 13485 requirements

		Quality Policy Manual	QPM – 5.0
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SCOPE

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PROCEDURE

MANAGEMENT RESPONSIBILITY – ISO 13485:2003 Section 5.0

5.1 *Management Commitment*

The Management of Global Surgical Corporation has authorized and approved this Quality Policy Manual as the guiding document for the quality management system. As part of its commitment, Management endorses and supports the Quality Policy Statement included in this manual for all employees and customers of Global Surgical Corporation. In addition, quality objectives are established and reviewed as part of strategic planning and the management review process.

Management communicates to the employees of Global Surgical Corporation the importance of meeting customer, statutory and regulatory requirements. Management understands the customers' requirements and provides the resources necessary to ensure compliance and to achieve ultimate customer satisfaction.

5.2 *Customer Focus*

The Management of Global Surgical Corporation ensures that customer requirements are determined and met through customer feedback, post-market surveillance, statutory and regulatory requirements, and evaluation of the organization's ability to meet customer needs.

5.3 *Quality Policy*

The quality policy is appropriate to the purpose of the organization, includes a commitment to comply with the requirements and to maintain the effectiveness of the quality management system, and provides a framework for establishing and reviewing quality objectives. Management ensures that the policy statement is communicated and understood by all employees. On a regular basis the policy is reviewed for continuing suitability. A signed copy is included in Appendix I of the manual as evidence of management's commitment to quality.


5.4 *Planning*

5.4.1 Quality Objectives

The Management of Global Surgical Corporation establishes measurable quality objectives that are consistent with the quality policy. When establishing quality objectives, product requirements, customer requirements and required resources needed to achieve the objectives are taken into consideration.

5.4.2 Quality Management System Planning

Quality planning is carried out at two levels:

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- Planning of the QMS, which takes place through management reviews and is part of the quality manager’s responsibilities. Quality objectives are set and reviewed during these reviews.
- Maintaining the integrity of the QMS when changes are planned and implemented. Integrity of the QMS is maintained when changes occur through control of documents, training of personnel, and monitoring of QMS performance.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

The Management of Global Surgical Corporation ensures that responsibilities and authorities are defined, documented and communicated within the organization.

The Responsibility Matrix (Table 1) summarizes the primary and contributing responsibilities of management personnel for the key elements of the QMS. [21 CFR 820.20(b)(1)]


The overall management structure of the organization, outlined in the organizational chart (Table 2), is supported by job descriptions and QMS documentation that outlines the responsibility, authority and interrelations of personnel who:

- Initiate action to prevent the occurrence of nonconformances
- Identify and record any quality concerns
- Initiate, recommend or provide solutions through designated channels
- Verify the implementation of corrective actions
- Control further processing or delivery of nonconforming product until the deficiency or condition has been corrected
- Audit and review quality systems to drive continuous improvement

[21 CFR 820.20(b)]

Table 1 - Responsibility Matrix

Responsibility	President	VP Operations	VP Engineering	VP Sales/ Marketing	VP Controller & HR	Quality Manager
P = Primary C = Contributing						
Management Review	P	C	C	C	C	C
Business Planning	P	C	C	C	C	
Customer Satisfaction	C	C	C	P	C	C
Documentation		C	P	C	C	P
Purchasing		P	C	C	C	C
Human Resources & Training		C	C	C	P	C
Facilities		P	C		C	C
Process Equipment		P	C		C	C
Product Design & Development		C	P	C	C	C
Product Validation		C	P	C		C
Customer Communication		C	C	P	C	C
Regulatory Compliance / FDA	C	C	P		C	C
Verification of Purchased Product		C	C			P
Identification and Traceability		P	C			C
Material Handling, Storage and Shipment		P	C	C	C	C
Control of Measuring Devices		C	C			P
Internal Audit	C	C	C	C	C	P
Verification of Process and Product		C	C			P
Analysis of Data		P	C	C	C	C
Control of Nonconforming Product		C	C			P
Corrective & Preventive Action	C	C	C	C	C	P

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5.5.2 Management Representative

Global Surgical Corporation has appointed the Quality Manager as Management Representative. The Management Representative has the responsibility and authority for ensuring the QMS is implemented, maintained and conforms to the applicable scope of the ISO 13485 Standard. The Management Representative reports to Executive Management on the performance of and improvements needed to the quality system and promotes an awareness of regulatory and customer requirements throughout the organization.

5.5.3 Internal Communication

Global Surgical Corporation ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS. This is established through quality steering team meetings, production meetings and management review.

5.6 *Management Review*

5.6.1 General

Top Management regularly reviews all elements of the Quality System in order to ensure the continued suitability, adequacy and effectiveness of the Quality System in meeting the requirements of ISO 13485 and Global Surgical’s Quality Policy and Quality Objectives. These reviews assess opportunities for improvement and the need for changes to the QMS. Records for management review are maintained.

5.6.2 Review Input

Management review inputs include where applicable:

- Results of internal audits
- Customer feedback
- Process performance and product conformity
- Status of corrective and preventive actions
- Follow-up actions from previous Management Reviews
- Changes that could affect the quality management system
- Review of risk management activities
- New or revised regulatory requirements
- Recommendations for improvement

5.6.3 Review Output

The resulting decisions and actions from the Management Reviews address improvements to the effectiveness of the system and its processes that could result in the addition of resources as needed to improve product relative to customer requirements.

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Procedures implementing this policy:

- SOP 5.4-01 Quality Planning
- SOP 5.6-01 Management Review
- SOP 8.2-01 Internal Audit
- SOP 8.5-01 Corrective and Preventive Action
- SOP 4.2-03 Control of Records

Date	Section	Description of Change
03/05/2015	All	Separated the QPM out into single section procedures. Revamped this section to include FDA and ISO 13485 requirements

		Quality Policy Manual		QPM – 6.0	
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Resource Management				Page 1 of 2	
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SCOPE

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Human Resources - Responsible for implementation and monitoring compliance of this policy

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PROCEDURE

RESOURCE MANAGEMENT PROCEDURE – ISO 13485:2003 Section 6.0

6.1 *Provision of Resources*

Global Surgical Corporation has determined resource requirements and is committed to providing the resources needed to implement and to maintain the effectiveness of the QMS in order to meet regulatory and customer requirements.

6.2 *Human Resources*

6.2.1 General

Personnel performing work affecting product quality are assigned to the described jobs in the organizational chart in accordance with the competencies (education, training, skills and experience) defined in job descriptions.


6.2.2 Competence, Awareness and Training

Personnel have the experience and/or are adequately trained to ensure that they are competent and capable of performing to expectations. Where training is necessary, the effectiveness of training is evaluated according to the training procedure. Personnel are made aware of the relevance and importance of their activities. Records reflecting education, training, skill level and experience of each employee are maintained.

6.3 *Infrastructure*

Global Surgical Corporation determines, provides and maintains the infrastructure necessary to achieve conformity to product requirements. The infrastructure includes:

- Buildings, workspace and associated utilities
- Process equipment, (including production equipment and software, reference standards used for calibration, etc.)
- Supporting services (such as computers, computer networks, lift trucks, etc.)

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All the requirements related to maintenance activities, inspections and adjustments are documented, and resulting records are maintained.

Global Surgical’s building is suitably designed and contains sufficient space for operation, prevention of mix-ups and orderly handling. Equipment used in the manufacturing process meets specification and is appropriately designed, constructed, placed and installed to facilitate maintenance, adjustment, cleaning and use. [21 CFR 820.70 (f) & (g)]

Global Surgical validates computer software utilized for production and for the quality system according to protocols for the computer software’s intended use. These validations activities and results are documented. [21 CFR 820.70 (i)]

6.4 Work Environment

Where work environment may affect the ability to achieve or conform to product quality requirements, adequate resources are provided to address such needs. The work environment requirements are documented in procedures [21 CFR 820.70(c)], monitored, inspected and controlled as applicable.

Work Environment requirements include:


- Health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the products.
- Environment conditions, including the use and removal of manufacturing material [21 CFR 820.70(h)], that can have an adverse effect on product quality where applicable.
- Providing special trainings for all personnel who are required to work temporarily under special environmental conditions.
- Special arrangements for the control of contaminated or potentially contaminated product to prevent contamination to other product, work environment and/or personnel where applicable.

Procedures and documents implementing this policy:

Job Descriptions

SOP 6.2-02 Training and Training Records

Date	Section	Description of Change
03/05/2015	All	Separated the QPM out into single section procedures. Revamped this section to include FDA and ISO 13485 requirements

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PROCEDURE

PRODUCT REALIZATION - ISO 13485:2003 Section 7.0

7.1 *Planning Product Realization*

Procedures for defining and documenting the quality requirements, process and controls for each product are maintained. Planning includes resource considerations as well as methods for verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance. Records are maintained as evidence of the planning process.

Statistical techniques and sampling plans procedures have been established to verify the acceptability of process capability and product characteristics. [21 CFR 820.250]


Global Surgical has established a multi-step process for risk management activities. These activities include risk acceptability which is determined by the probability of harm and the severity of harm associated with the device. The criteria for determining the acceptability is based upon federal regulations, applicable standards for the device, literature research, and market feedback. Market feedback includes but is not limited to complaints, general feedback and applicable medical device reportable incidents. These criteria ensure that any concerns surrounding the perceptions of the stakeholders and the generally accepted state of the art are considered. Risk management records are maintained.

7.2 *Customer Related Processes*

7.2.1 Determination of Requirements Related to the Product

Global Surgical Corporation determines the customer's product requirements. In addition to specified product requirements, consideration is given to customer requirements such as delivery and post-delivery activities, requirements that although are not stated are necessary for specified or intended use, statutory and regulatory requirements and any additional requirements that may be anticipated.

7.2.2 Review of Requirements Related to the Product

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Requirements related to the product are reviewed by appropriate personnel prior to commitment (acceptance of contracts / orders or changes) to supply a new or existing product to the customer. The review ensures that product requirements are defined, contract questions are resolved and that the organization has the ability to meet the defined requirements including delivery. Where the customer provides no documented statement of requirements, clarification issues must be confirmed during the review process. Relevant documents are amended to reflect product or contract changes and relevant personnel notified of such changes.

7.2.3 Customer Communication

Global Surgical Corporation has established an appropriate system by which the customer is notified or may inquire about product, contracts, changes, order status and advisory notices.

Global encourages customer feedback regarding product, service and complaints as a means of measuring customer satisfaction. Complaint files are maintained and procedures have been established for the receipt, review, and evaluation of complaints including those which are adverse events [21 CFR 820.198 & 21 CFR 803].

Procedures have been established for instances where device corrections and removals are necessary [21 CFR 806].

7.3 *Design and Development*

7.3.1 Design and Development Planning

Global Surgical has established documented design and development procedures for the planning and control of product.

During planning, the following are determined:

- The project stages
- Review, verification, validation and design transfer activities appropriate to each stage
- Responsibilities and authorities for design and development.


Planning output is documented, approved [21 CFR 820.30(b)] and updated as appropriate as the design and development progresses.

To ensure effective communication and clear assignment of responsibility, Global Surgical manages the interfaces between the different groups involved in design and development.

7.3.2 Design and Development Inputs

Design and development inputs are determined according to the design and development procedure. Records of these inputs are maintained. These inputs include:

- Functional, performance and safety requirements, according to the intended use
- Applicable statutory and regulatory requirements
- Applicable information derived from previous similar designs

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- Other requirements essential for design and development
- Output of risk management

All design inputs shall be reviewed and approved for adequacy according to the design and development procedure. Requirements are complete, unambiguous, and not in conflict with each other.

7.3.3 Design and Development Outputs

The outputs of design and development are provided in a form that enables verification against the design and development input, and the design outputs are approved prior to release. Records of design outputs are maintained.

Design and development outputs:

- Meet the input requirements for design and development
- Provide appropriate information for purchasing, production and service provision
- Contain products acceptance criteria
- Specify the characteristics of the product that are essential for safe and proper use

7.3.4 Design and Development Review

Reviews of design and development are conducted, in accordance with the nature of projects and planned arrangements, to:

- Evaluate the ability of the results of design and development to meet requirements
- Identify any problems and propose necessary actions

Participants in design and development review include representatives of functions concerned with the design and development stage being reviewed. Records of the results of the reviews are maintained.

7.3.5 Design and Development Verification


Verification of design and development is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results and approval of the verification are maintained.

7.3.6 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified intended use before product launch. Records of the results and approval of the validation are maintained.

7.3.7 Control of Design and Development Changes

All design and development changes are identified and analyzed according to the design and development procedure. The changes are reviewed, verified and validated as appropriate and approved prior to

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implementation. The review of design and development changes includes evaluation of the effect of the changes on products. Records of the review of changes are maintained.

7.3.8 Design Transfer

The design and development procedure defines the transfer of designs into production to ensure the device design is correctly translated [21 cfr 820.30 (h)].

7.3.9 Design History File

A design history file (DHF) is established and maintained for each type of device to demonstrate that the design meets the design and development procedure requirements [21 CFR 820.30 (j)].

7.4 Purchasing

7.4.1 Purchasing Process

Purchasing processes are controlled to ensure purchased product conforms to specified purchase requirements. This control is applied to purchased items, goods, equipment and services. The type and extent of control applied to the supplier and purchased item, etc. is dependent upon the effect of the purchased product on product quality.

Suppliers are evaluated and selected based on criteria defined in the supplier evaluation procedure. When feasible, purchasing will procure materials or services from established sources. Suppliers who do not continue to meet expectations may be removed from consideration of future purchases. Records of supplier evaluations are maintained.

7.4.2 Purchasing Information


Purchased materials, components and services required for the manufacture of products require written purchase orders, where applicable, that clearly describe or reference applicable requirements including approval of product, procedures, processes, equipment, personnel qualifications and quality management system requirements. Purchase orders are reviewed prior to release to the supplier to ensure the adequacy of the purchasing requirements.

7.4.3 Verification of Purchased Product

Global Surgical Corporation ensures that purchased material has been inspected or otherwise verified as conforming to requirements. Records of such activities are maintained. One or more of the following methods may be used to evaluate product prior to release:

- Incoming inspection and lot release
- Receipt of statistical test data from the supplier
- Part evaluation by accredited test labs
- Supplier warrants for certification
- Functional acceptance of assembled components

Where product verification is performed at the supplier's facility, the intended verification arrangements and method of product release is clearly specified in the purchasing information. Records of product verification are maintained.

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7.5 Production and Service

7.5.1 *Control of Production and Service Provision*

7.5.1.1 General Requirements

Global Surgical Corporation ensures that production processes are planned, documented and performed under controlled conditions as applicable. These controls may include:

- The availability of product specifications
- Use of documented procedures, work instructions and reference standards for operations where the absence of such documents could adversely affect product quality.
- Selection, use and maintenance of suitable production equipment and working environment
- Monitoring of designated process parameters and product characteristics including compliance with all customer requirements.
- Measuring product characteristics.
- Implementation of release, delivery and post-delivery activities
- Implementation of defined activities for labeling and packaging.

Labeling activities at Global Surgical are documented in a procedure.[21 CFR 820.120]

7.5.1.2 Control of production and service provision – specific requirements

7.5.1.2.1 Cleanliness of product and contamination control

Global Surgical’s manufactured products are non-critical devices which are supplied non-sterile. Work environment requirements are monitored and controlled to ensure product quality and cleanliness.

7.5.1.2.2 Installation Activities


Global Surgical representatives or Global Surgical’s authorized service technicians install and verify the installation of the applicable medical devices according to documented requirements. If the customer requirements include installation by someone other than Global Surgical representatives or Global Surgical’s authorized service technicians, installation instructions are supplied to the customer. Records of the installation and verification performed by Global Surgical or Global Surgical’s authorized service technician are maintained.

7.5.1.2.3 Servicing Activities

Global Surgical services applicable medical devices according to documented requirements and procedures.[21 CFR 820.200] Records of the servicing activities and verification of servicing activities performed by Global Surgical are maintained.

7.5.2 Validation of Processes for Production and Service Provision

7.5.2.1 *General Requirements*

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Global Surgical validates applicable processes for production and service provision where the resulting output cannot be verified by subsequent monitoring and measurement. In order to demonstrate the ability of these processes to achieve planned results, the following items are considered in preparing validations:

- Defined review and approval of processes
- Approval of processes and equipment with first piece sign-off requirements
- Use of physical samples and written standards to define workmanship and inspection criteria
- Suitable maintenance activities to maintain and improve process capabilities
- Qualification of personnel
- Requirements for maintaining quality records
- Revalidation

Documented procedures are established for process validations performed at Global Surgical. [21 CFR 820.75]

Global Surgical has documented procedures for validation of software that is used for production and service provision when such software affects the ability of the product to conform to specified requirements.

Records of validation are maintained.

7.5.3 Identification and Traceability

7.5.3.1 Identification

Documented procedures exist to ensure product is suitably identified throughout the production process including inspection status relative to verification requirements. Any product returned to Global Surgical is identified and distinguished from conforming product.

7.5.3.2 Traceability

7.5.3.2.1 General


Where traceability is a requirement, adequate controls and unique identification are in place. Documented procedures [21 CFR 820.65] and records maintained as applicable.

7.5.3.3 Status Identification

Status of product is maintained throughout product realization, storage, installation, servicing and recall of the product.

7.5.4 Customer Property

In the event customer owned property is used or is under Global Surgical’s control, adequate measures are in place to ensure it is properly identified, handled, maintained and protected. Product that is damaged, lost or otherwise unsuitable for use is reported to the customer and records are maintained.

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7.5.5 Preservation of Property

Global Surgical maintains documented procedures and/or documented work instructions to ensure product is handled, packaged, stored and protected during internal processing and during delivery to the intended destination. Additionally these procedures and/or work instructions include the control of product with a limited shelf-life and product that requires special storage conditions. Applicable special storage conditions are controlled and recorded accordingly.

7.6 Control of Monitoring and Measuring Devices

Global Surgical Corporation maintains documented procedures for the control, calibration and maintenance of monitoring, measuring and test equipment. The accuracy of measurement equipment is assessed and compared to measurement requirements.

Measuring and testing equipment and comparative references (gages and templates) used for verification of products and for controlling production processes are regularly calibrated against standards traceable to national or international measurement standards and labeled with calibration stickers that enable the calibration status to be determined. Equipment used for purposes other than verification of products or control of production processes is exempt from calibration. Competent outside service providers will perform calibration services that exceed Global Surgical’s internal calibration capability.


Product that has been previously produced by a measuring device found to be out of calibration is assessed to verify that it meets requirements.

A master list of measuring and testing equipment showing gage status, calibration frequency and location is maintained. The calibration program includes both personal and company provided gages and measurement equipment.

Procedures implementing this policy:

- SOP 7.3-01 Design and Development
- SOP 7.4-01 Purchasing
- SOP 7.4-03 Verification of Purchased Product
- SOP 7.5-02 Identification and Traceability
- SOP 7.6-01 Control of Monitoring and Measuring Devices
- SOP 7.2-02 Sales Order Process

Date	Section	Description of Change
03/05/2015	All	Separated the QPM out into single section procedures. Revamped this section to include FDA and ISO 13485 requirements

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Approved by: Larry Mattson		Date: 3/6/2015	

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PROCEDURE

MEASUREMENT, ANALYSIS AND IMPROVEMENT - ISO 13485:2003 Section 8.0

8.1 *General*

Global Surgical Corporation has identified key performance areas that reflect the effectiveness of the quality management system and production processes. Systems have been developed to monitor, measure and record the results to demonstrate conformity of the product, to ensure conformity of the quality management system (QMS) and to maintain the effectiveness of the QMS. Analysis of the data enables management to make sound decisions regarding performance and continual improvement opportunities.

Where statistical tools may be appropriately used, employees responsible for analyzing, interpreting and acting on statistical data are trained in basic understanding of statistical concepts such as variation, process control, process capability and the impact of over-adjustment.

8.2 *Monitoring and Measurement*

8.2.1 Feedback –


Global Surgical Corporation maintains documented procedures and records for customer feedback to ensure customer requirements are met. Through the customer feedback system, potential quality issues are identified and inputted into the corrective and preventive action system as applicable. Results are compiled and reported to management at monthly and management review meetings.

Customer feedback may include customer complaints, general customer feedback and any post-production feedback such as customer surveys.

8.2.2 Internal Audit –

Global Surgical Corporation plans and conducts internal quality audits in accordance with documented procedures as one measure to determine if the QMS is effectively implemented and maintained. These audits cover the requirements of 21 CFR 820 as well as company policies and procedures. Internal audits are conducted by impartial and objective trained auditors and are performed based on an audit schedule that considers the risk and performance of the processes being audited as well as the results of previous audits.

The procedure documents the responsibilities and requirements for planning and conducting internal audits to include audit criteria, scope, frequency and method. It also documents the format for reporting results and record maintenance requirements.

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The Quality Assurance Manager determines whether or not the non-conformances documented in the audit report require a corrective action. Corrective Actions are handled according to the corrective action process. Follow-up activities are performed to verify implementation of the actions taken and to report the verification results.

8.2.3 Monitoring and Measurement of Processes –

QMS processes are monitored and measured, where applicable, through suitable methods. These methods demonstrate the ability of the QMS processes to achieve planned results. When planned results are not achieved, correction and corrective actions are taken as defined in the corrective and preventive action procedure.

8.2.4 Monitoring and Measurement of Product –

8.2.4.1 General Requirements

Global Surgical monitors and measures product to verify that all product requirements have been met according to planned arrangements and documented procedures. These acceptance activities include receiving, in-process and final acceptance [21 CFR 820.80]. Where applicable, statistical techniques and sampling plans procedures have been established to verify the acceptability of process capability and product characteristics. [21 CFR 820.250].

Product is not allowed to proceed to subsequent operations unless it has been properly verified and identified as meeting acceptance criteria. Evidence of conformity with the acceptance criteria and record of the personnel authorizing the product release are maintained. Product is not released for shipment until all planned requirements have been satisfactorily completed or unless approved by a relevant authority.

The acceptance status of product is identified throughout manufacturing, packaging, labeling, installation and servicing of the product to ensure that only product which has passed the required acceptance activities is distributed, used or installed [21 CFR 820.86].

8.3 Control of Nonconforming Product

Product that does not meet specified requirements is controlled to prevent its unintended use or delivery. In accordance with documented procedures, nonconforming product and material are tagged and held pending investigation, documentation and disposition by personnel authorized to make such determinations. Procedures provide for the notification of all functions concerned, including affected customers as deemed appropriate. Records of nonconformities and actions taken are maintained.

Nonconforming product is reviewed by appropriate management authorities for disposition and corrective action. Procedures provide for the disposition of nonconforming product as follows:

- Rework – Product is reworked to meet the specified requirements. All products subjected to rework are re-inspected in accordance with specifications or test instructions. Rework activities should be performed in designated work areas isolated from normal production activities when feasible and in accordance with documented rework instructions. Any potential adverse effects of the rework upon the product are documented accordingly.
- Use As Is - Customer and/or management acceptance of product by concession provided regulatory requirements are met. Records of the concession and the identity of the person authorizing the concession are maintained.
- Reject and scrap – Action is taken to remove and dispose of the product as appropriate.

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Where nonconformances are detected subsequent to delivery, appropriate containment action will be taken based on the effects or potential impact of the nonconformity.

8.4 Analysis of Data

Global Surgical maintains documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS, and to evaluate if improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring and measurement and other relevant sources. This analysis of data provides information relating to:

- Customer feedback
- Product performance conformance to product requirements
- Characteristics and trends of processes and products including opportunities for preventive action
- Delivery performance
- Supplier performance

Records of data analysis are maintained accordingly.

8.5 Improvement

8.5.1 General

Global Surgical maintains the suitability and effectiveness of the QMS through the use of quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Additionally, the procedures that document the requirements for adverse events and advisory notices are established, and the records of customer complaint investigations are maintained. If the complaint investigation determines that activities outside Global Surgical contributed to the complaint, Global Surgical communicates with the other organization as necessary. In the event that a customer complaint is not followed by a corrective or preventive action, the rationale and authorization surrounding this decision is recorded.

8.5.2 Corrective Action

Global Surgical maintains documented procedures to ensure the corrective action process has been implemented. The purpose of this process is to eliminate the cause of nonconformities in order to prevent reoccurrence. Determining and implementing a corrective action includes the following stages:

- Reviewing nonconformities (including customer complaints)
- Determining the root cause of the nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur
- Determining and implementing action needed
- Recording the results of the actions taken
- Reviewing the corrective action taken and its effectiveness

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8.5.3 Preventive Action


Global Surgical maintains documented procedures to ensure the preventive action process has been implemented. The purpose of this process is to eliminate the causes of potential nonconformities in order to prevent occurrence. Determining and implementing a preventive action includes the following stages:

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

Procedures implementing this policy:

- SOP 8.2-01 Internal Audit
- SOP 8.2-04 Complaint Reporting
- SOP 8.2-05 Measurement of Processes and Product
- SOP 8.2-06 Recall and Market Withdrawal
- SOP 8.3-01 Control of Nonconforming Product
- SOP 8.5-01 Corrective and Preventive Action

Date	Section	Description of Change
03/05/2015	All	Separated the QPM out into single section procedures. Revamped this section to include FDA and ISO 13485 requirements

		Quality Policy Manual	QPM - Reg
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Approved by: Larry Mattson		Date: 3/6/2015	

SCOPE

This procedure applies to the quality management system at Global Surgical Corporation as it pertains to regulations

RESPONSIBILITIES

Top Management – Responsible for ensuring implementation and compliance to this policy

Regulatory Engineer –Responsible for implementation and monitoring compliance of this policy

PROCEDURE - Regulatory

Global Surgical acknowledges that regulatory requirements are ever changing and has dedicated resources to monitor and implement regulatory changes as applicable. These requirements are dependent on what markets Global Surgical’s products are sold, the intended use and design of products and any customer specific requirements.

New/revised regulations are discussed and documented in the management reviews as Section 5.6 of QPM-5.0 Management Review describes.

Procedures implementing this policy:

- SOP 7.3-02 Technical Files
- SOP 7.3-03 Declaration of Conformity
- SOP 7.3-04 Clinical Evaluations
- SOP 8.2-06 Recall and Market Withdrawal
- SOP 8.2-07 Medical Device Report Handling - FDA
- SOP 8.2-08 Medical Device Report Handling - Health Canada
- SOP 8.2-09 Medical Device Report Handling - European Union

Date	Section	Description of Change
03/05/2015	All	Separated the QPM out into single section procedures. Added a Regulatory section.