Optel

# Optel, Inc.

## Quality System Manual

1 January 2017

## Book 1 - Quality Manual & QMS Procedures

This manual is a preliminary draft
for review and comment only

# QUALITY SYSTEM MANUAL

## QUALITY SYSTEM PROCEDURES

# QUALITY SYSTEM OPERATIONAL PROCEDURES

## ELECTRONIC RECORDS/FORMS

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## 1.1 QUALITY POLICY

### The Optel Quality Policy

Optel, Inc.'s commitment to quality is:
1) to understand our Customer's expectations; and
2) to meet or exceed our commitment to those expectations by routinely quantitatively monitoring our processes, product attributes and quality system for the purpose of continuously improving our products, services and performance, thus enhancing customer satisfaction.

## 1.2 INTRODUCTION

1.2.1 Optel, Inc., A New York corporation, ("Optel" or the "Company") has developed and implemented this quality management system to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and to address customer satisfaction through the effective application of this quality system, including continuous improvement and the prevention of nonconformity..

1.2.2 This quality system complies with the requirements of the international standards ISO 13485:2012 and ISO 9000:2012. It also meets the requirements of the U.S. FDA as described in 21 CFR 820.

1.2.3 The manual is divided into eight sections modeled on the sectional organization of the ISO 13485:2012 standard. Sections are further divided into several subsections representing main quality system processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant operational procedures and other documents.

1.2.4 The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system.

1.2.5 Another purpose of this manual is to present the quality system to customers, suppliers, regulators and other external interested parties, and to inform them what specific controls are implemented at Optel to assure quality.

## 1.3 APPLICATION

1.3.1 1.3.1 The quality management system defined in this manual applies to the design, manufacture and distribution of commercial products, medical devices and veterinary products designed and manufactured by Optel, Inc. These products may include Optel's own products or products designed and manufactured for our customers.

## 1.4 EXCLUSIONS

1.4.1 The many of the products that are designed, manufactured and/or marketed by Optel are properly considered human medical devices, for which regulatory requirements vary considerably from country to country around the world. For example, in the United States (U.S.) the Food and Drug Administration (FDA) has regulatory

oversight for all human medical devices and dictates that companies producing human medical devices should "meet the performance standards." and must “assure that these devices are safe, effective and properly labeled."

Due to the requirements of the U.S. FDA and in a spirit of providing the highest quality products to its customers around the world, Optel has decided to follow, for all of the products that it designs, manufactures or markets, the established quality guidelines for medical devices set by the U.S. FDA under 21 CFR 820 and those of the International Standards Organization under ISO 13485. This quality system has been designed to meet the requirements of both 21CFR 820 and ISO 13485, and in addition, the requirements of ISO 9000:2012.

1.4.2 The quality management system shall be relevant to the nature of the Optel and its products, and to customer and regulatory requirements. For this reason, those requirements of ISO 13485, that do not apply are excluded from the scope of the quality system as long as the requirements of ISO 13485 are not superseded by 21 CFR 820 or ISO 9000:2012.

1.4.3 An ISO 13485:2012 requirement may be excluded only when the following three conditions are met:

- The requirement must be within ISO 13485 Clause 7, Product Realization;
- The exclusion may not affect Optel’s ability, nor absolve the Company from the responsibility, to provide product that meets specified requirements; and
- The exclusion may not affect Optel’s ability to carry out corrective action.

1.4.4 Processes which are applicable to the medical device(s), but which are performed by outside contractors, do not qualify for exclusion. They are accounted for in the quality system to ensure control over such outsourced processes.

1.4.5 The Quality Manager is responsible for identifying those requirements of ISO 13485 that do not apply to our organization or products, and to propose to the senior management that such requirements be excluded from the scope of the quality system.

1.4.5 Senior management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Operational Procedure QOP-56-01, Management Review).

1.4.7 Any exclusions taken are documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

CLAIMED EXCLUSIONS

I. None.

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## 2.1 REGULATORY REQUIREMENTS

2.1.1 ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes

2.1.2 Part 820 of Title 21 of the Code of Federal Regulations (CFR) - Quality System Regulation (QSR)
See: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=820
or the Electronic Code of Federal Regulations - e-CFR Title 21: Chapter I: Subchapter H: Part 820 for the most recent version of the regulation.

## 2.2 STANDARDS AND GUIDELINES

2.2.1 ISO 9001: 2012 Quality management systems – Requirements

2.2.2 ISO 14971:2007: Medical Devices – Application of Risk Management to Medical Devices

2.2.3 IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

2.2.4 IEC 62471:2006 Photobiological safety of lamps and lamp systems

2.2.5 EN 980:2008 Symbols for use in labeling of medical devices

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## DEFINITIONS

**3.1 ISO 13485 DEFINITIONS:**

3.1.1 **Active medical 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.

3.1.2 **Advisory notice:** notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what corrective or preventive action should be taken in:

- the use of a medical device,
- the modification of a medical device,
- the return of the medical device to the organization that supplied it, or
- the destruction of a medical device.

3.1.3 **Customer complaint:** written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

3.1.4 **Labeling:** written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

3.1.5 **Medical device:** any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

3.1.6 **Sterile medical device:** category of medical device intended to meet the requirements for sterility. Any device that is manufactured by Optel that is intended to be a sterile medical device under ISO 13485 must also comply with the requirements of the FDA's 21 CFR Part 820. as discussed in the FDA definitions that follow in section 3.

**3.2 FDA DEFINITIONS:**

3.2.1 **The Act:** The Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–394)). All definitions in section 201 of the act shall apply to the regulations in this part.

3.2.2 **Complaint:** Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

3.2.3 **Component:** Any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

3.2.4 **Control Number:** Any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.

3.2.5 **Design history file (DHF):** A compilation of records which describes the design history of a finished device.

3.2.6 **Design input:** The physical and performance requirements of a device that are used as a basis for device design

3.2.7 **Design output:** The results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

3.2.8 **Design review:** A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

3.2.9 **Design history record(DHR):** A compilation of records containing the production history of a finished device.

3.2.10 **Design master record(DMR):** A compilation of records containing the procedures and specifications for a finished device.

3.2.11 **Establish:** Define, document (in writing or electronically), and implement.

3.2.12 **Finished device:** Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

3.2.13 **Lot or batch:** One or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially
the same conditions and that are intended to have uniform characteristics and quality within specified limits.

3.2.14 **Management with executive responsibility:** Those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

3.2.15 **Manufacturer:** Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

3.2.16 **Manufacturing material:** Any material or substance used inor use to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

3.2.17 **Nonconformity:** The non-fulfillment of a specified requirement.

3.2.18 **Product:** Components, manufacturing materials, in- process devices, finished devices, and returned devices.

3.2.19 **Quality:** The totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

3.2.20 **Quality audit:** A systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these
procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

3.2.21 **Quality policy:** The overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

3.2.21 **Quality system:** the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

3.2.23 **Remanufacturer:** Any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

3.2.24 **Rework:** Action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

3.2.25 **Specification:** Any requirement with which a product, process, service, or other activity must conform.

3.2.26 **Validation:** Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
(i) *Process validation* - Establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.
(ii) *Design validation* - Establishing by objective evidence that device specifications conform with user needs and intended use(s).

3.2.276 **Veification:** Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

**3.3 ISO 9000:2000 DEFINITIONS:**

3.3.1 **Benchmarking:** A methodology that is used to search for best practices, and can be applied to strategies, policies, operations, processes, products, and organizational structures.

3.3.2 **Characteristic:** A distinctive feature or property of a thing and can be inherent or assigned. An inherent characteristic exists in a thing or is a permanent feature of it, while an assigned characteristic is a feature that is attributed or attached to it.

3.3.3 **Concession:** A special approval granted to release a nonconforming product for use or delivery,.usually for a limited time duration and for a limited quantity. Concessions should specify that the nonconforming characteristics may not exceed specified limits.

3.3.4 **Conformity:** To meet or comply with requirements. Requirements related to quality may include, but are not limited to, customer requirements, product requirements, management requirements, legal requirements, etc.

3.3.5 **Continuous Improvement**: A set of recurring activities that an organization carries out in order to enhance its ability to meet requirements.Improvements can be achieved by carrying out audits, self-assessments, management reviews,

and benchmarking, collecting data, analyzing information, setting objectives, and implementing corrective and preventive actions, among other methods and processes.

3.3.6 **Correction:** Any action taken to eliminate a nonconformity. As applied to products, corrections may include reworking, reprocessing or regrading products, assigning the product to a different use, or simply destroying the product.

3.3.7 **Customer:** Any natural person or legal entity which receives products or services from a process or supplier.. Customers can be either external or internal to an organization.

3.3.8 **Customer satisfaction:** A perception by a customer as to whether a supplier has met the necessary requirements. Satisfaction can range from high to low. For example, if a customer believes a supplier met their requirements, then the customer is likely to experience high satisfaction. Objective measures of customer satisfaction include return rates, complaint rates, customer surveys, customer focus groups and other similar methodologies.

3.3.9 **ISO Standards:** Agreements developed by the Technical Committees of the International Standards Organization and approved by its members following agreement on the proposed content of the standard. and prior to broad publication of the standard.

3.3.10 **Key Indicator:** Also known as a Key Performance Indicator ("KPI") - a metric or a measurement of a process or a characteristic. KPIs provide a measure of success or failure against previously established objectives and can be used to set measurable objectives, .evaluate progress, monitor trends, make improvements and support decision making.*KPIs* should be quantifiable and appropriate and should collect information that is useful to the organization and relevant to the needs and expectations of interested parties.KPIs may include metrics such as average revenue per customer, customer attrition rate, student failure rate, average, response time, average delivery time, employee retention rate, return on equity, lost time due to accidents, and energy costs per unit of production.

3.3.11 **Mission:** A mission statement expresses the purpose of a company or an organization and defines its reason for being (i.e., its raison d'être).

3.3.12 **Outsourced Processes or Products:** Any processes or products that are part of your organization's quality management system (QMS) but are performed by or procured from a party that is external to the organization. ISO 9001 requires that outsourced suppliers must be identified and controlled and that their processes and products must be effective.

3.3.13 **Preventative Actions:** Steps that are taken to remove causes of potential nonconformities or potential undesirable outcomes or situations.

3.3.14 **Product:** A product is the output of a process. Products can be tangible or intangible. ISO 9000 lists four generic product categories: services; software; hardware; and processed materials.

3.3.15 **Product inspection:** An activity that compares product characteristics with product requirements in order to evaluate conformity. Product inspections can use observation, measurement, testing and judgment to evaluate conformity.

3.3.16 **Quality Management System:** A set of interrelated or interacting processes and documents that organizations use to direct and control how quality policies are implemented and quality objectives are achieved. A process-based QMS uses a process approach to manage and control the implementation of its quality policy and achievement of its quality objectives.

3.3.18 **Quality Manual:** A set of documents and records that fully describe and record the actions of an organization's quality management system (QMS). It can be either paper based manual or an electronic manual.

3.3.18 **Record:** A document that provides evidence activities have been performed or results have been achieved in the the past. For example, records can be used to show traceability requirements are being met, verification procedures are being performed, and that preventive and corrective actions are being carried out.

3.3.19 **Self Assessment:** A a comprehensive and systematic review of an organization's overall performance against its goals and objectives. Self assessments are used to achieve and sustain organizational success.

3.3.20 **Traceability:** The ability to identify and trace the history, distribution, location, and application of products, components, materials and.the calibration status of test instruments and reference standards. A traceability process records and follows the trail as products, parts, materials, etc. come from suppliers, are processed and ultimately distributed as end products.

3.3.21 **Work environment:** A term for working conditions which refers to all conditions and factors that influence work.In general, these include physical, social, psychological, and environmental conditions and factors. A work environment may include lighting, temperature, and noise factors, as well as the entire range of ergonomic influences. It also includes procedures such as supervisory practices as well as recognition programs, all of which influence work.

**3.4 OPTEL INC.'S INTERNAL DEFINITIONS:**

3.4.1

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## 4.1 GENERAL REQUIREMENTS

4.1.1 Quality system processes

4.1.1.1 The quality management system is designed as a system of interrelated processes. All main activities of the system are defined as Quality System Processes (QSPs) and are grouped into the following four categories (refer to the Quality System Process Map on next page):

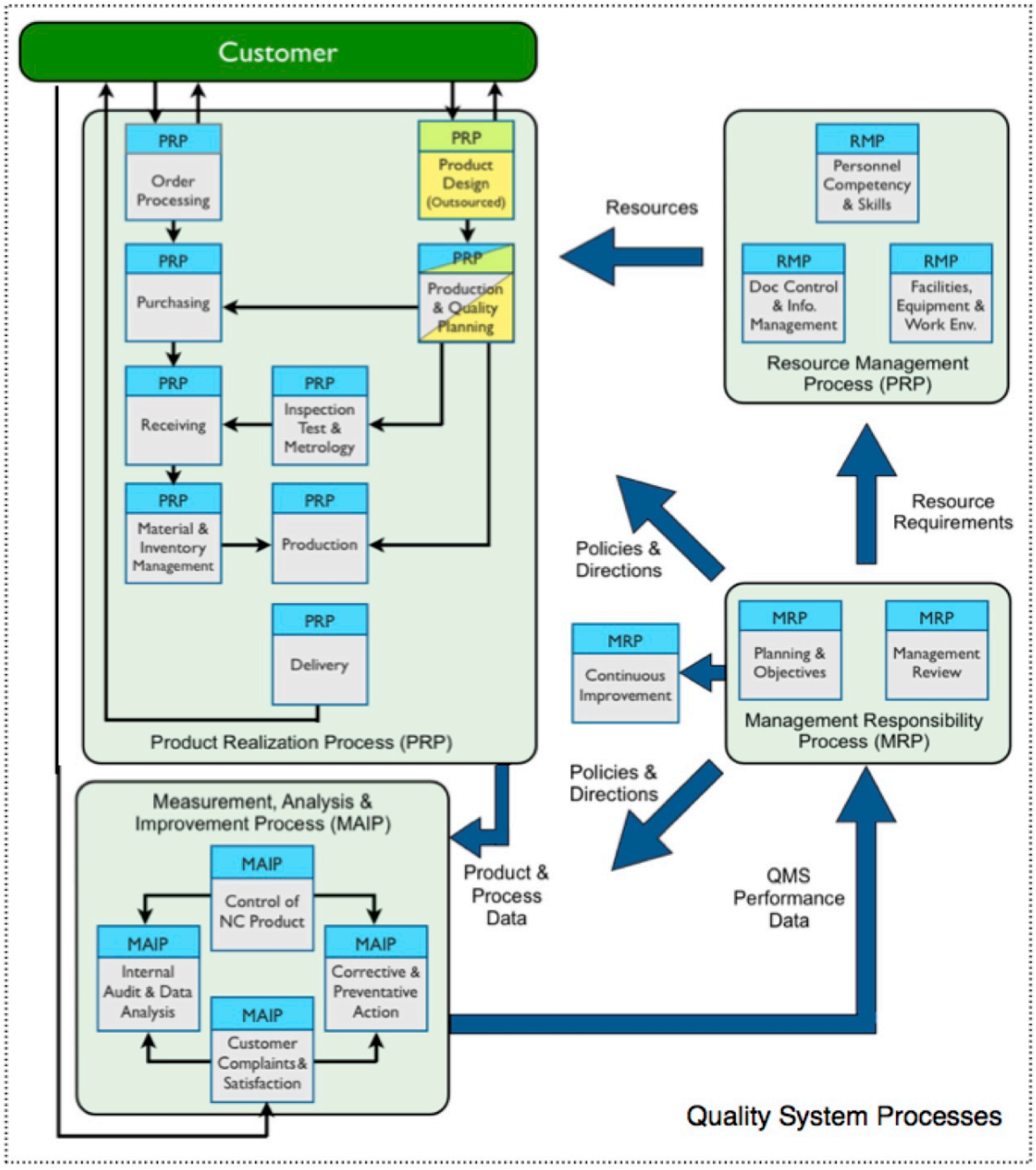
- Product Realization Processes (PRP);
- Measurement, Analysis and Improvement Processes (MAIP);
- Management Responsibility Processes (MRP); and
- Resource Management Processes (RMP).

Each of these processes is organized into a Plan-Do-Check-Act loop.

4.1.1.2 The sequence and interrelation between the four groups and individual QSPs are illustrated in the Processes Map diagram. Each QSP is further broken down into its sub-processes, as defined in the Process Map Matrix included after the diagram.

4.1.1.3 QSPs and their sub-processes are documented in this quality manual and in associated operational procedures and work instructions. This documentation defines the quality system processes and their sequence and interaction, and instructs on how to implement and apply them throughout the organization.

4.1.1.4 Quality system documentation also defines criteria and methods needed to ensure that the operation and control of quality system processes are effective. This includes assignment of responsibilities and allocation of resources for the process, instructions on how to carry out (or operate) the process, and definition of methods for monitoring and/or measuring the effectiveness of the process.




Quality System Process Map

PROCESS MAP MATRIX

| PRODUCT REALIZATION PROCESSES (PRPs) | |
|---|---|
| **Order Processing** | |
| **Purpose** | To determine customer product requirements and quantities, prepare quotations, and take orders from customers. |
| **Process Owner** | **Sales** |
| **Sub-Processes** | • Determine products required<br>• Determine customer requirements<br>• Evaluate capability and capacity to meet requirements<br>• Prepare quotations, bids and tenders<br>• Enter orders<br>• Receive, enter and process change orders<br>• Provide product information to customers |
| **Product Design**<br><br>***Product Design is performed by outsourced subcontractors to requirements set by Ovitz Corporation as indicated in yellow and lime on the Quality System Process Map illustrated above.*** | |
| **Production/Quality Planning** | |
| **Purpose** | To plan and develop processes for manufacturing and verification of product. |
| **Process Owner** | **Quality Manager** |
| **Sub-Processes** | • Determine quality objectives and requirements for products<br>• Develop, validate and document production processes (process flowcharts, process sheets, equipment setup instructions, tooling specifications, operator instructions, etc.)<br>• Establish product acceptance criteria and product verification requirements (measuring, inspections, tests, etc) |
| **Purchasing** | |
| **Purpose** | To select qualified vendors and to purchase from them materials, components, and services necessary for the manufacture and delivery of the product (for full scope of application refer to QOP-74-01, Purchasing). |
| **Process Owner** | **Purchasing** |
| **Sub-Processes** | • Evaluate and select suppliers and subcontractors<br>• Maintain a list of approved suppliers<br>• Prepare, review and issue purchasing documents<br>• Communicate with suppliers regarding their quality performance (notifications, requests for corrective actions, etc.) |
| **Receiving** | |
| **Purpose** | To receive purchased products, visually verify their conformity, and mark/label products with their identification and/or acceptance status, as applicable. |
| **Process Owner** | **Receiving** |

| | |
|---|---|
| **Sub-Processes** | • Receive purchased products<br>• Visually inspect incoming products<br>• Apply and/or record product identification and traceability of incoming products |
| **Material Inventory Management** | |
| **Purpose** | To receive, store and issue materials, components and parts to be incorporated into finished products. |
| **Process Owner** | **Production** |
| **Sub-Processes** | • Operating and maintaining storage areas<br>• Identifying and protecting product in storage<br>• Maintaining special storage conditions/environment<br>• Operating and maintaining the inventory management system |
| **Production** | |
| **Purpose** | To manufacture products conforming to applicable requirements. |
| **Process Owner** | **Production** |
| **Sub-Processes** | • Carry out manufacturing processes<br>• Ensure cleanliness of product and prevent contamination<br>• Maintain and record product identification and traceability<br>• Establish and maintain production records<br>• Train process operators and technicians (on-the-job)<br>• Maintain production equipment and tooling |
| **Delivery** | |
| **Purpose** | To deliver product to customers and distributors. |
| **Process Owner** | **Shipping** |
| **Sub-Processes** | • Process shipping orders<br>• Package and label product for shipping<br>• Dispatching or shipping product<br>• Establishing and maintaining shipping and distribution records |
| **Inspection, Test and Metrology** | |
| **Purpose** | To verify conformity of products and to identify, maintain and calibrate monitoring and measuring devices. |
| **Process Owner** | **Quality Manager** |
| **Sub-Processes** | • Monitor quality performance of suppliers<br>• Verify purchased product (QC inspection)<br>• Monitor, measure, and test products (in-process and final)<br>• Apply and maintain inspection status identification<br>• Release products<br>• Identify nonconforming products<br>• Select, calibrate and control the monitoring and measuring equipment |
| **MEASUREMENT AND IMPROVEMENT PROCESSES (MIPs)** | |
| **Control of Nonconforming Product** | |

| | |
|---|---|
| **Purpose** | To identify, control and disposition nonconforming products. |
| **Process Owners** | **Quality Manager** |
| **Sub-Processes and Procedures** | • Identify document and segregate (where applicable) nonconforming products<br>• Make nonconforming product disposition decisions<br>• Rework and verification of nonconforming products |
| **Internal Audits and Analysis of Data** | |
| **Purpose** | To verify conformity of the quality management system, and to evaluate its effectiveness and efficiency. |
| **Process Owners** | **Quality Manager** |
| **Sub-Processes and Procedures** | • Conduct internal audits of the quality system<br>• Analyze and evaluate results of internal, third-party and customer audits<br>• Collect and analyze quality performance data |
| **Corrective and Preventive Action** | |
| **Purpose** | To request, implement and follow up corrective and preventive (C&P) actions. |
| **Process Owners** | **Quality Manager** |
| **Sub-Processes and Procedures** | • Evaluate the need for corrective and preventive (C&P) actions<br>• Request and implement C&P actions<br>• Verify the implementation and effectiveness of C&P actions |
| **Customer Complaints & Satisfaction** | |
| **Purpose** | To process customer feedback and complaints and to measure customer satisfaction. |
| **Process Owners** | **Customer Service** |
| **Sub-Processes and Procedures** | • Receive and log customer feedback and complaints<br>• Process and respond to customer complaints<br>• Gather of information and data about customer satisfaction<br>• Analyze, report and present customer satisfaction information and data (preparing reports, plotting charts, holding meetings, etc) |
| **MANAGEMENT RESPONSIBILITY PROCESSES (MRPs)** | |
| **Planning and Objectives** | |
| **Purpose** | To define the quality policy and quality objectives, to plan the quality management system (QMS), and to implement management commitments. |
| **Process Owners** | **Management** |
| **Sub-Processes and Procedures** | • Establish the Quality Policy<br>• Establish and monitor quality objectives<br>• Plan the quality management system<br>• Define responsibilities and authorities<br>• Appoint Management Representative |
| **Management Review** | |
| **Purpose** | To review the suitability and effectiveness of the quality system; to consider changes to the quality system, quality policy and quality objectives; and to identify opportunities for improvement. |
| **Process Owners** | **Management** |

| | |
|---|---|
| **Sub-Processes and Procedures** | • Review, present, discuss and evaluate review input information<br>• Determine changes required (if any) for the quality policy, quality objectives and the quality management system<br>• Identifying opportunities for improvement and establishing quality objectives |
| **Continual Improvement** | |
| **Purpose** | To continually improve the quality management system, processes and products. |
| **Process Owners** | **Management** |
| **Sub-Processes and Procedures** | • Monitor performance of the quality management system<br>• Request and implement corrective and preventive actions<br>• Establish review and update the quality policy<br>• Establish, implement and monitor quality objectives<br>• Improve the Quality Management System |
| **RESOURCE MANAGEMENT PROCESSES (RMPs)** | |
| **Personnel Competence and Skills** | |
| **Purpose** | To define competency requirements, provide training, and ensure awareness about quality-related issues. |
| **Process Owners** | **Human Resources** |
| **Sub-Processes and Procedures** | • Determine competency requirements for jobs/positions affecting product quality<br>• Provide training and/or take other actions to satisfy competency requirements<br>• Evaluate the effectiveness of training<br>• Provide awareness programs to ensure employee motivation, empowerment, and knowledge of quality-related issues |
| **Document Control and Information Management** | |
| **Purpose** | To control documents related to products, manufacturing processes and the quality system; and to control quality records. |
| **Owners** | **Document Control** |
| **Sub-Processes and Procedures** | • Establish documents needed by the organization<br>• Review and approve documents<br>• Control document revisions and distribution (availability)<br>• Manage retention, storage, and disposition of records |
| **Facilities, Equipment and Work Environment** | |
| **Purpose** | To ensure appropriate and adequate facilities, production equipment and supporting services. |
| **Process Owners** | **Production** |
| **Sub-Processes and Procedures** | • Plant, facility and equipment planning<br>• Maintaining plant, facilities and manufacturing process equipment |

4.1.2 Resources and information

4.1.2.1 The Quality Manager is responsible for determining resource and information requirements necessary to support the operation and monitoring of quality system processes, and for communicating these requirements to the senior management. Senior management is responsible for ensuring the availability of necessary resources and information. ***QM Section 6.1 Provision of Resources*** explains in more detail how resource

requirements are identified and satisfied.

4.1.3 Monitoring and measurement

4.1.3.1 Performance of quality system processes is systematically monitored and measured. This is to ensure their effectiveness and identify opportunities for improvement.

4.1.3.2 Performance of quality system processes is monitored through internal quality audits (refer to ***QM Section 8.2*** and Operational Procedure ***QOP-82-02 Internal Quality Audits***). The overall performance of the quality system is monitored by measuring customer satisfaction (refer to ***QM Section 8.2*** and Operational Procedure ***QOP-82-01 Feedback and Customer Satisfaction***).

4.1.3.3 Quality system processes are reviewed and analyzed by the management review of the quality system (refer to ***QM Section 5.6*** and Operational Procedure ***QOP-56-01 Management Review***).

4.1.4 Continual improvement

4.1.4.1 Quality management system processes are regularly reviewed by senior management to identify any possible failures or breakdowns, as well as opportunities for improvement. Actions necessary to address actual or potential problems and to improve the quality system are implemented through corrective and preventive actions and through quality objectives.

4.1.4.2 ***QM Section 8.5*** and Operational Procedures ***QOP-56-01 Management Review*** and ***QOP-85-04 Corrective and Preventive Actions*** define how the quality management system itself ensures its own compliance and continual improvement.

4.1.5 Subcontracted processes

4.1.5.1 When processes that affect product conformity are subcontracted, special controls are implemented to ensure that these processes meet specified requirements. Such controls may include, as appropriate:

- Evaluation and pre-qualification of suppliers;
- Assessment of subcontractor's manufacturing processes and their quality system;
- Flow-down of customer (contract) requirements,
- Monitoring of supplier quality performance;
- Requirements for process control, inspection, testing or other records demonstrating product conformity; and
- Verification of the supplied product.

***QM Section 7.4*** and Operational Procedures ***QOP-74-01 Supplier Evaluation and Monitoring***, ***QOP-74-02 Purchasing***, and ***QOP-74-03 Verification of Purchased Product***, define these purchasing control processes.

4.1.5.2 Ensuring control over outsourced processes does not absolve Ovitz Corporation of the responsibility to conform to all customer and regulatory requirements.

4.2 DOCUMENTATION AND RECORDS

4.2.1 Documentation

4.2.1.1 Ovitz Corporation's quality system documentation comprises the following categories of documents:

- Quality system manual;
- Quality system operational procedures;
- Quality system forms;
- Work instructions;
- Device, labeling and packaging specifications;

- Manufacturing and servicing specifications;
- Quality assurance/control procedures and specifications; and
- Standards and codes.

These categories are further defined in Operational Procedure ***QOP-42-01 Control of Documents.***

4.2.2 Device Master Record

The Device Master Record (DMR) may be the actual engineering and production documents for a device organized and collected into one or more files or binders, or the DMR may be an index (a reference list) of all required documents, including their location. In this quality manual the DMR is an index, and there is a special operational procedure for establishing and maintaining DMRs.

4.2.2.1 Engineering, manufacturing and quality specifications, and other such documentation that define the medical device (or a family of similar devices) and the manner of production are organized into a Device Master Record (DMR). The DMR may be in the form of one or several files or binders with the actual documents, or in the form of an index referencing these documents and their revision status and location.

4.2.2.2 Operational Procedure ***QOP-42-02 Device Master Record*** defines the types of documents included in the record, and instructs how DMRs are established and maintained.

4.2.2.3 When a DMR document is withdrawn or superseded by a new revision, a copy of the obsolete document is retained for a period of time at least equivalent to the lifetime of the medical device, but not less than two years from the date of product release. If this document retention policy is in conflict with relevant regulatory requirements, the regulatory requirements shall take precedence.

4.2.3 Document control

4.2.3.1 Ovitz Corporation has a mix of paper and electronic documentation. It is the Company's goal to transition to an entirely electronic documentation system, as resources permit. As this transition progresses, new categories of documents will be transferred from paper to electronic document control system. Both systems are currently used, and are defined in Operational Procedure ***QOP-42-01 Control of Documents***.

4.2.3.2 The document control system defined in Operational Procedure ***QOP-42-01 Control of Documents*** ensures that:

- Documents are reviewed for adequacy and are approved prior to release;
- Documents are reviewed and updated as necessary, and revised documents are re-approved;
- Documents are identified, to include their current revision status and changes;
- Documents are distributed to, and are available at locations where they are used;
- Document distribution is controlled; and
- Obsolete documents are withdrawn from points of use, and/or are clearly identified to prevent their unintended use.

4.2.4 Control of records

Records and documents are different in some very important respects. Conceptually, the difference between a document and a record is that a document instructs or informs, while a record is a statement of actual facts or events. As an distinguishing example, records do not require to review or approved for issue, and should never be revised (revision of records would be falsification). The scope of records is to provide complete evidence of product and process conformity, and the conformity and effectiveness of the quality system.

4.2.4.1 Records are established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

4.2.4.2 Records are organized into the following five categories:

- Design History File (DHF),
- Device Master Record (DMR)
- Device History Record (DHR),
- Quality System Record (QSR), and
- Complaint Files

4.2.4.3 Operational Procedure QOP-42-03 Control of Records defines more specifically what records are maintained in each category and designates their storage locations and retention periods; and defines the process for ensuring that records are clearly identified, are stored in appropriate locations and conditions, are adequately protected, and are easily retrievable.

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## 5.1 MANAGEMENT COMMITMENT

5.1.2 Senior management is committed to communicate the importance of meeting customer as well as statutory and regulatory requirements. The Management Representative is responsible for implementing this commitment by promoting awareness of customer requirements throughout the organization. This responsibility of the Management Representative is defined in ***QM Section 5.5 Organization and Communication***.

5.1.3 Senior management defines the purpose and objectives for the quality management system. They are documented and communicated in the form of quality policy and quality objectives. Processes for establishing the quality policy and quality objectives are defined in this manual in ***QM Section 5.3 Quality Policy*** and ***Section 5.4 Quality System Planning***, and are further detailed in Operational Procedure ***QOP-56-01 Management Review***.

5.1.4 Senior management periodically reviews the quality management system to ensure its continuing suitability, adequacy, and effectiveness. The review evaluates current status and performance of the quality system and initiates actions to further improve the system. The process for conducting management reviews is defined in Operational Procedure ***QOP-56-01 Management Review***.

5.1.5 Senior management is committed to providing resources necessary for establishing, implementing, and improving the quality management system. ***QM Section 6.1 Provision of Resources*** defines processes for identifying resource requirements and allocation of resources for specific activities and projects.

## 5.2 CUSTOMER FOCUS

5.2.1 The principal objective of the quality management system is to focus our organization on the customer, and in particular, on customer satisfaction. The key to achieving high customer satisfaction is an accurate determination of customer requirements and an effective verification that the requirements are met.

5.2.2 Senior management ensures that customer requirements are determined and are well understood. This is done through the process of order and contract review, as defined in this manual in ***QM Section 7.2.1 Determination of Requirements Related to the Product*** and ***QM Section 7.2.2 Review of Requirements Related to the Product***, and in associated operational procedures.

5.2.3 Senior management ensures that customer requirements are met by inspecting and testing products at various stages of production and upon completion, as defined in this manual in ***QM Section 8.2.4 Monitoring and Measurement of Product***, and in associated operational procedures.

5.2.4 Senior management ensures that customer satisfaction is systematically monitored as a measure of performance in determining and meeting customer requirements. This process is defined in ***QM Section 8.2.1 Customer Satisfaction***, and in the associated operational procedure.

## 5.3 QUALITY POLICY

5.3.1 Quality policy is documented in this manual in ***QM Section 1.1 Quality Policy***.

5.3.2 Quality policy is established by the by the President. In formulating the quality policy, the President ensures that the policy is appropriate to the purpose of the Company, and includes a commitment to comply with the requirements and continually improve the effectiveness of the quality management system.

5.3.3 The quality policy provides a framework for establishing specific quality objectives, and provides direction for the continual improvement effort. The use of the quality policy in setting quality objectives is addressed in this

manual in ***QM Section 5.4.1 Quality Objectives*** and in Operational Procedure ***QOP-56-01 Management Review***. The use of the policy to facilitate continual improvement is explained in Operational Procedure ***QOP-85-01 Continual Improvement***.

T5.3.4 The quality policy is posted throughout the company, and its role is explained and discussed at the general orientation training provided to all employees. The quality policy is also communicated to customers, consumers and other interested parties. For this purpose, it is displayed in the reception area and posted on the company's website.

5.3.5 The quality policy is periodically reviewed within the framework of management reviews of the quality system. This is to ensure it's continual relevance and suitability. The process for reviewing the quality policy is defined in Operational Procedure ***QOP-56-01 Management Review***.

## 5.4 QUALITY SYSTEM PLANNING

5.4.1 Quality objectives

5.4.1.1 Quality objectives are established throughout the organization to implement the quality policy, to meet requirements for products and processes, and to improve quality system and quality performance.

5.4.1.2 Quality objectives are established at the management reviews of the quality system. Management reviews also initiate and monitor projects for achieving quality objectives. These processes for establishing, implementing and monitoring quality objectives are defined in Operational Procedure ***QOP-56-01 Management Review***.

5.4.1.3 Quality objectives define the direction and priorities for continual improvement. Use of quality objectives for facilitating continual improvement is explained in Operational Procedure ***QOP-85-01 Continual Improvement***.

5.4.2 Quality system planning

5.4.2.1 Quality system processes are planned to ensure that the system is appropriate for its intended purpose, and that it is effective and efficient. The purpose of the quality system is to:

- Achieve the quality policy;
- Ensure and demonstrate our ability to provide medical devices and related services that consistently meet customer requirements and applicable regulatory requirements;
- Ensure high level of customer satisfaction;
- Facilitate continual improvement; and
- Comply with requirements of ISO 13485 and ISO 9001standards, the FDA's 21 CFR 820 and other applicable regulatory requirements for quality management systems.

5.4.2.2 The output of quality system planning is documented in this quality manual, in associated operational procedures, and in other referenced documents. These documents identify and define all processes of the quality system (refer to ***QM Section 4.1 Quality System Processes***).

5.4.2.3 Changes to the quality system are planned within the framework of management reviews (refer to Operational Procedure ***QOP-56-01 Management Review***). These changes may be in response to changing circumstances, such as product, process, capacity, or other operational or organizational changes; or to improve the effectiveness and efficiency of the quality system.

5.4.3 Product realization and verification planning

5.4.3.1 Planning of product realization, verification, and validation processes is addressed in this manual in ***QM Section 7.1 Planning of Product Realization***.

## 5.5 ORGANIZATION AND COMMUNICATION

5.5.1 Responsibility and authority

5.5.1.1 Interrelation of all personnel who manage, perform and verify work affecting quality is identified in the ***Organizational Chart*** enclosed at the end of this Clause 5.5.1, and in operational procedures and other documents defining these activities. Senior management ensures that the personnel have sufficient independence and authority to perform these tasks, in particular, internal auditors and personnel responsible for monitoring experience from the post-production stage and reporting adverse events.

5.5.1.2 All departments and functions in the company are responsible for implementing, maintaining, and improving the quality system.

5.5.1.3 Authorities and responsibilities for specific processes of the quality management system are defined:

- Throughout this quality manual and in every operational procedure where the specific quality system process or activity is documented;
- In Quality System Process sheets in ***QM Section 4.1*** ( as Process Owners); and
- In job descriptions.

Job descriptions are necessary to satisfy requirements of ISO 13485 Clause 6.2.2. Competence, Awareness and Training.

5.5.1.4 Optel, Inc.'s Organization Chart

The chart on page 4 depicts the current Optel Organization Chart. The chart on page 5 is the Responsibilities and Authorities Matrix that relates the organizational titles of the various individuals in the current Optel organization to the functional titles defined in this Quality Manual and listed below.

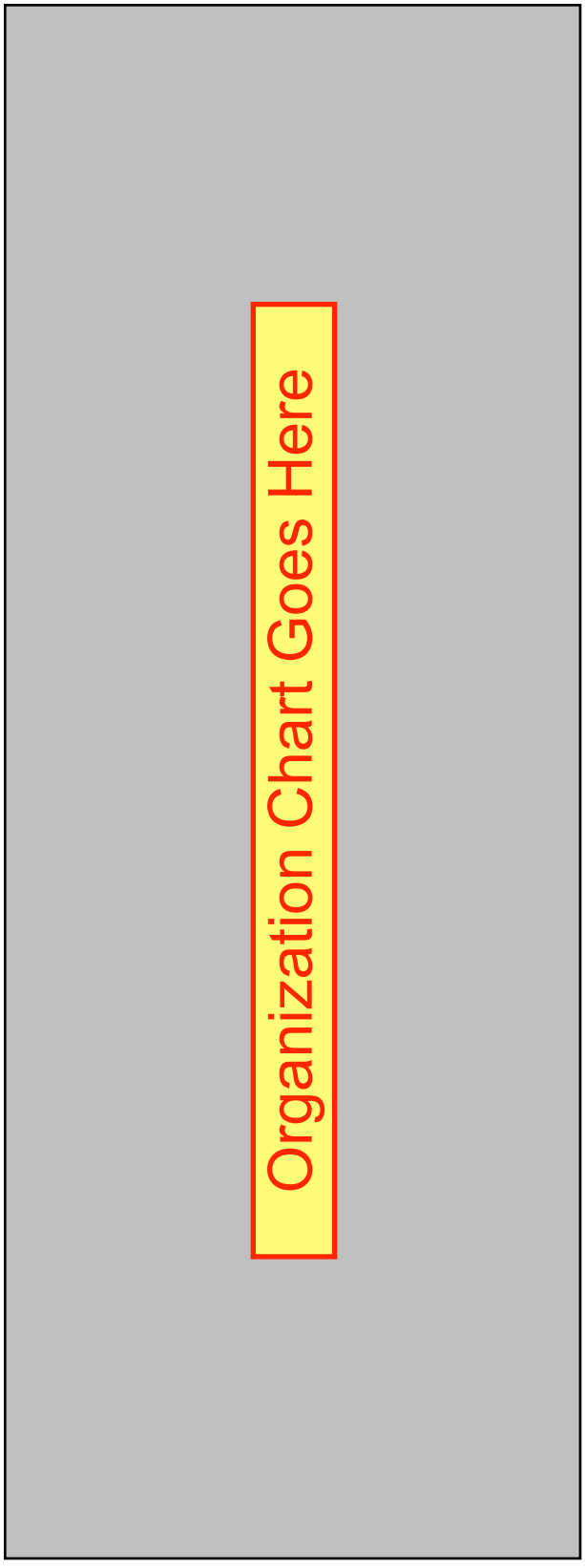
<Management Representative> (i.e., the Quality Manager)
<Sales>
<Customer Service>
<Engineering>
<Production>
<Production Engineering>
<Production Scheduling>
<Receiving>
<Shipping>
<Quality>
<Document Control>
<Human Resources>
<Accounting & Finance>

5.5.1.5 Responsibilities and Authorities Matrix

the Responsibilities and Authorities Matrix is found on page 5 of this section of the Quality Manual. In this documentation, specific responsibilities are assigned directly under the quality manual sections and in operational procedures where the pertinent activity is defined. For example, the Corrective and Preventive Action procedure defines who is authorized to request corrective actions, and who is responsible for implementing them. Responsibilities and authorities are also defined in job descriptions (refer to QM Section 6.2 and to operational procedure QOP-62-01).

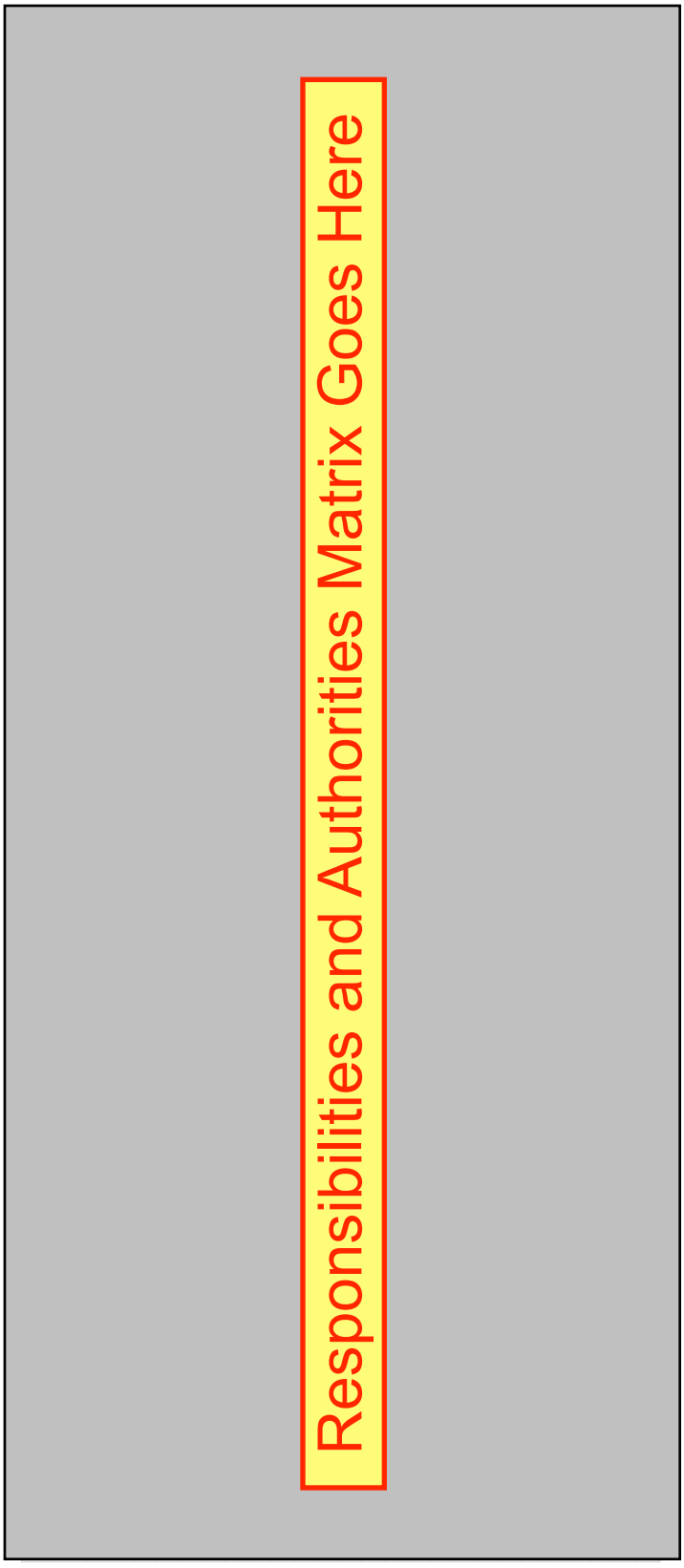
Note that the functional titles listed above in red bracketed (i.e., < >) text also appear in this same format throughout this Quality Manual and its associated Quality Operational Procedures (i.e., the QOPs). This format is used to clearly denote that the referenced title refers to a functional title of an individual within the context of Optel's Quality Management System. The Responsibilities and Authorities Matrix serves as a pointer from the functional title in the Quality Manual to the organizational title of a specific individual within in Optel's overall operational organization.

Optel, Inc. Organization Chart




Approved by: Jay M. Eastman, CEO _____ Date _____

Optel, Inc. Responsibilities and Authorities Matrix



5.5.2 Management Representative

5.5.2.1 Optel appoints as the Management Representative its Quality Manager. The Management Representative has the authority and responsibility to:

- Ensure that the quality management system is implemented, maintained and continually improved;
- Promote awareness of regulatory and customer requirements throughout the organization;
- Report to the senior management on the efficiency and performance of the quality system; and
- Coordinate communication with external parties on matters relating to the quality system and ISO 13485 registration.

5.5.3 Internal communication

5.5.3.1 Internal communication regarding the quality system flows two ways:

The management communicates to the organization the quality policy and objectives; customer and regulatory requirements; product and process specifications; verification and validation requirements; and instructions on how to implement and use the quality system.

The organization communicates to the management information and data regarding quality performance, the effectiveness of the quality system, customer satisfaction, and opportunities for improvement.

5.5.3.2 The information is communicated through:

- Paper or electronic documents, such as manuals, procedures, instructions, drawings, specifications, quality records, reports, etc.;
- E-mails, memos, and meetings;
- Bulletin boards and the Company's website and newsletter;
- Training and awareness programs; and
- Employee suggestions, surveys and feedback.

Operational Procedures ***QOP-42-01 Control of Documents*** and ***QOP-62-01 Competence, Awareness and Training*** define processes for distributing documents and for providing training and awareness programs.

5.5.3.3 Management review meetings have a special role in ensuring proper communication between senior management and the organization. The meeting provides the framework for the organization to report on the status of quality-related issues and activities, and for the management to formulate and communicate policies and directives to change and/or improve the quality system. This process is defined in Operational Procedure ***QOP-56-01 Management Review***.

5.5.3.4 The Quality Manager has the overall responsibility for ensuring that all pertinent documents, reports and records are distributed to appropriate departments and functions, and that information and data about quality performance and the effectiveness of the quality system are reported to the senior management.

## 5.6 MANAGEMENT REVIEW

5.6.1 General

5.6.1.1 Management reviews of the quality management system are conducted at least twice a year. More frequent reviews are scheduled in periods when organizational, technological, product, or other changes require increased attention and input from senior management. The processes for initiating and conducting management reviews and for documenting their conclusions are defined in Operational Procedure ***QOP-56-01 Management Review***.

5.6.1.2 The purpose of management reviews is to:

- Evaluate the suitability, adequacy and effectiveness of the quality system;
- Consider changes to the quality management system and to the quality policy and quality objectives; and
- Identify opportunities for improvement of the quality system, processes and products.

5.6.1.3 Management reviews are chaired by the President and are attended by the Quality Manager <Quality>, <Sales>, <Customer Service>, <Engineering>, <Production Engineering>, <Purchasing>, <Production>, and <Human Resources>. The specific managers who must attend the management reviews are indicated in the .

5.6.2 Review input

5.6.2.1 Input into the management reviews consists of information and data related to quality performance of the organization. At a minimum, this includes:

- Results of audits,
- Customer feedback and complaints,
- Process performance and product conformity data,
- Status of preventive and corrective actions,
- Status of quality objectives,
- Changes that could affect the quality system,
- New or revised regulatory requirements,
- Follow-up actions from earlier management reviews, and
- Recommendations for improvement.

5.6.3 Review output

5.6.3.1 Management reviews are concluded with setting new quality objectives and initiating actions to improve the quality management system, processes, and products.

5.6.3.2 Results of management reviews are documented in minutes of the review meeting. The minutes include improvement actions, and assign responsibilities and allocate resources for implementation of these actions.

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## 6.1 PROVISION OF RESOURCES

6.1.1 Resources required for implementing, maintaining and improving the quality management system, and for addressing customer satisfaction, include personnel, infrastructure, work environment, process equipment, materials, information, and financial resources.

6.1.2 Determination of resource needs for specific activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

6.1.3 Depending on the type and nature of the operation or activity, resource requirements are defined in:

- Quality manual, operational procedures and work instructions (***QOP-42-01 Document Control***);
- Product and process drawings and specifications (***QOP-42-02 Device Master Record***);
- Production plans (***QOP-75-01 Production Work Order and History Record*** - This reference is specifically to the work order or traveler, where human/equipment/process resources are called out for every operation.);
- Job descriptions, competence matrixes, and training programs (***QOP-62-01 Competence, Awareness and Training***);
- Minutes of management reviews, quality objective records, and corrective and preventive action requests (***QOP-56-01 Management Review***, ***QOP 85-04 Corrective and Preventive Action***).

6.1.4 Top management has the responsibility and authority for provision of resources.

6.1.5 Management reviews of the quality system are the principal forum for determining resource requirements and providing resources for maintaining and improving the quality system, and for enhancing customer satisfaction. Operational Procedure ***QOP-56-01 Management Review*** defines this process.

## 6.2 HUMAN RESOURCES

### 6.2.1 GENERAL

6.2.1.1 Personnel performing work affecting product quality are competent. Competence is determined on the basis of appropriate education, training, skills and experience.

6.2.1.2 <Human Resources> department is responsible for training and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.

6.2.1.3 Departmental managers are responsible for identifying competency requirements and for providing training in their departments. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques, and other such skills as appropriate for particular positions and jobs.

### 6.2.2 COMPETENCE, AWARENESS AND TRAINING

6.2.2.1 Processes for ensuring adequate competency and awareness of personnel are defined in Operational Procedure ***QOP-62-01 Competence, Awareness and Training***. The procedure addresses issues related to:

- Determining competency requirements,
- Identifying training needs,

- Providing training,
- Evaluating the effectiveness of training,
- Ensuring quality awareness, and
- Maintaining training records.

## 6.3 INFRASTRUCTURE

### 6.3.1 BUILDINGS, WORKSPACE AND ASSOCIATED UTILITIES

6.3.1.1 Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained to achieve conformity to product requirements.

6.3.1.2 Departmental managers are responsible for identifying the need and requirements for new, and/or modification or repair of existing infrastructure and facilities in their departments. Requests for changes and/or expansions of facilities are submitted to the top management for review and approval.

6.3.1.3 Maintenance of buildings and facilities is performed by external contractors. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning. Repairs of buildings and other such facilities are contracted as needed. Purchasing is responsible for coordinating and managing maintenance contracts.

### 6.3.2 PROCESS EQUIPMENT

6.3.2.1 Procurement of new, and/or modification of existing process equipment (including hardware and software) are planned in conjunction with development of manufacturing processes, as defined in this manual in ***QM 7.1 Planning of Product Realization*** and Operational Procedure ***QOP-71-01 Production Planning and Risk Management***.

### 6.3.3 SUPPORTING SERVICES

6.3.3.1 Supporting services required by Optel include transportation, communication, and IT services:

- Transportation services are purchased from parcel delivery and courier services, and from trucking or other transportation companies or consolidators, as required. Transportation services are purchased in accordance with Operational Procedures ***QOP-74-01 Supplier Evaluation and Monitoring***, and ***QOP-74-02 Purchasing***.
- Communication services are provided by various telephone, wireless, and internet access companies. Purchasing is responsible for administrating and coordinating these contracts.
- IT systems are designed and implemented by external consultants, while the day-to-day operating of the systems is the responsibility of the < IT (Information Technology ) Manager>. The <IT Manager> is responsible for selecting IT consultants and for administrating IT contracts.

### 6.3.4 EQUIPMENT MAINTENANCE

6.3.5 Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment. Requirements for the maintenance of production equipment are specified in Operational Procedure ***QOP-63-01 Equipment Maintenance***.

## 6.4 WORK ENVIRONMENT

### 6.4.1 HUMAN FACTORS

6.4.1.1 <Human Resources> and departmental managers are responsible for ensuring suitable physical, social and psychological conditions in the workplace. This is to include such aspects as temperature, lighting, and

cleanliness; as well as language and interaction between employees.

6.4.1.2 <Production> and the Quality Manager are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures are defined and implemented for these operations.

6.4.1.3 Health and safety management system is independent from the quality management system. It is administrated by Human Resources and is documented in the Health and Safety (H&S) section of OPtel, Inc.'s Personnel Handbook.

### 6.4.2 WORK ENVIRONMENT IN PRODUCTION AND STORAGE AREAS

6.4.2.1 Work environment is properly controlled in areas where environmental conditions could have an adverse effect on product quality. Operational Procedure QOP-64-01 Production and Work Environment defines the management system for environmental control. The following aspects are controlled:

- **Health, cleanliness and clothing of personnel:** If contact between personnel and the product or work environment could adversely affect the quality of the product, requirements for health, cleanliness and clothing of personnel are established and documented;
- **Work environment conditions:** If work environment conditions can have an adverse effect on product quality, requirements for the work environment conditions and procedures to monitor and control the environment are defined and documented. Environmental control systems are periodically inspected to verify that the system, including necessary equipment is adequate and functioning properly;
- **Contaminated product:** If appropriate, special arrangements are established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product , the work environment or personnel.
- **Training:** Personnel who work under special environmental conditions are appropriately trained. Personnel who must work temporarily, or for any other reason enter environmentally controlled areas are also trained in appropriate procedures or are supervised by a trained person.

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## 7.1 PLANNING OF PRODUCT REALIZATION

### 7.1.1 PRODUCTION AND QUALITY PLANNING (DESIGN TRANSFER)

7.1.1.1 Production processes and product verification activities are planned. The planning includes the determination of:

- Requirements and quality objectives for products and processes;
- The need to develop production processes; establish process specifications, operator instructions and other such documentation; and provide training to process operators;
- Required product verification, inspection and test activities, and the criteria for product acceptance; and
- Records needed to provide evidence of product and process conformity.

7.1.1.2 Operational Procedure ***QOP-71-01 Production Planning*** assigns responsibilities and creates the framework for implementing the planning activities.

7.1.1.3 Results of production and quality planning are documented in the Work Order (i.e. a job traveler), as documented in Operational Procedure ***QOP-75-01 Production Work Order and History Record***.

### 7.1.2 RISK MANAGEMENT

7.1.2.1 Risk analysis studies are conducted for key manufacturing and other product realization processes. This is to identify high risk activities and to focus the quality system controls on these areas, and thus reduce the risk.

7.1.2.2 Operational Procedure ***QOP-71-02 Process Risk Management*** assigns responsibilities and creates the framework for conducting risk analysis studies and risk management.

## 7.2 CUSTOMER-RELATED PROCESSES

### 7.2.1 DETERMINATION OF REQUIREMENTS RELATED TO THE PRODUCT

7.2.1.1 Product requirements are determined, to include:

- Requirements specified by the customer;
- Requirements not stated by the customer, but necessary for intended use;
- Statutory and regulatory requirements;
- Any additional requirements determined by Optel.

7.2.1.2 Operational Procedure ***QOP-72-01 Order Processing and Review*** explains how product requirements are determined.

### 7.2.2 REVIEW OF REQUIREMENTS RELATED TO THE PRODUCT

7.2.2.1 Prior to the commitment to supply a product to the customer, orders are reviewed to ensure that:

- Product requirements are defined;
- Any ambiguities and conflicts in contract or order requirements are resolved; and
- Optel is able to meet customer requirements.

Records of the results of the review and any associated actions are maintained.

7.2.2.2 When the customer provides no documented statement of requirements (as with verbal orders), the customer requirements are confirmed before acceptance.

7.2.2.3 Change orders and amendments are processed and reviewed using the same procedures that apply to the processing of initial orders. Change orders are communicated to all functions within the organization that may be affected by the change of customer requirements.

7.2.2.4 Processes for handling and reviewing orders and change orders are defined in Operational Procedure ***QOP-72-01 Order Processing and Review***.

**7.2.3 CUSTOMER COMMUNICATION**

7.2.3.1 The <Marketing> department is responsible for developing and controlling the company's brochures, catalogs, website and other forms of promotional and product information material. These materials are based on technical specifications developed by <Design Engineering>. Only designated personnel from <Marketing>, <Sales>, <Customer Service> and <Design Engineering> are authorized to communicate with customers regarding product information. The <Customer Service Manager> is responsible for designating this personnel, and for supporting them with training and current product information.

7.2.3.2 Arrangements for communicating with customers regarding enquiries and order handling are defined in Operational Procedure ***QOP-72-01 Order Processing and Review***.

7.2.3.3 Arrangements for communicating with customers regarding customer feedback and complaints are defined in Operational Procedures ***QOP-82-01 Feedback and Customer Satisfaction*** and ***QOP-85-03 Customer Complaints***.

## 7.3 DESIGN AND DEVELOPMENT

### 7.3.1 General

7.3.1.1 Optel designs its portions of its own standard catalog products as well as customer-specified products and modifications. <Design Engineering> is responsible these portions of of design. The quality control system for design is defined in Operational Procedure QOP-73-01 Design Control.

### 7.3.2 Design planning

7.3.2.1 The <Chief Engineer> is responsible for the planning of design projects, including the identification of design, review, verification and validation activities; scheduling the project; assignment of qualified personnel; and control of organizational and technical interfaces. The design project plan is documented in Form QF-73-01-1, Design Project Plan.

### 7.3.3 Design inputs

7.3.3.1 Design input requirements are developed by <Design Engineering> from product concepts, such as product briefs, sketches, models, rough prototypes, etc. Design inputs are reviewed and approved before they are used in design.

### 7.3.4 Design outputs

7.3.4.1 Device design output consists of documents, samples, models, math data, software, etc., that specify the device and its manufacturing, packaging, labeling, installation and servicing; as well as product acceptance criteria.

7.3.4.2 Where required, design output documents include Design Risk Analysis. Risk analysis studies are conducted in accordance with Operational Procedure QOP-73-02 Design Risk Management.

7.3.4.3 Design output documents are checked and approved before they are released for production. Design output documents are organized in a Device Master Record (DMR), and are maintained and controlled in accordance with Operational Procedures QOP-42-01 Document Control and QOP-42-02 Device Master Record.

**7.3.5 Design reviews**

7.3.5.1 Design reviews are carried out at appropriate stages in accordance with the design project plan. The purpose of the design reviews is to evaluate the ability of the design to meet design input requirements, and to identify any problems and propose necessary actions.

7.3.5.2 Participants in design reviews include representatives of functions concerned with the design stage being reviewed, as well as other specialist personnel.

**7.3.6 Design verification and validation**

7.3.6.1 Device designs are verified and validated in accordance with planned arrangements (design project plan). The purpose is to ensure that the design outputs have met the design input requirements, and that the resulting device is capable of meeting the requirements for specified application or intended use.

7.3.6.2 Device validation is completed prior to the delivery of the device.

7.3.6.3 Records of the results of device design verification and validation, and any necessary actions, are maintained.

**7.3.7 Design changes**

7.3.7.1 Design changes are initiated, processed and controlled using the Engineering Change Request (ECR) system defined in Operational Procedure QOP-73-03 Control of Design and Process Changes. Design changes are reviewed, verified and validated as appropriate, and approved before implementation.

## 7.4 PURCHASING

**7.4.1 Supplier Evaluation and Monitoring**

7.4.1.1 Optel evaluates its suppliers and purchases only from those who can satisfy quality requirements. <Purchasing> and the Quality Manager conduct supplier evaluations and audits as required for each supplier. Suppliers who meet requirements are entered on the Approved Supplier List.

7.4.1.2 The Quality Manager continually monitors supplier quality performance. Suppliers showing inadequate performance are requested to implement corrective actions. If the corrective actions are not implemented and/ or are not effective, the supplier is removed from the Approved Supplier List. The processes for evaluating and monitoring suppliers are defined in Operational Procedure ***QOP-74-01 Supplier Evaluation and Monitoring***.

**7.4.3 APPROVED SUPPLIER LIST**

7.4.3.1 Purchasing maintains an Approved Supplier List. Orders for materials, components and subcontracted services may only be placed with vendors that are on the list.

**7.4.4 PURCHASING INFORMATION**

7.4.4.1 Purchasing documents are prepared by the Purchasing department. The documents clearly and completely describe ordered products, including precise product identification and quality requirements. Purchasing documents are reviewed and approved prior to release. The processes for the preparation, review and approval of purchasing documents are defined in Operational Procedure ***QOP-74-02 Purchasing***.

**7.4.5 VERIFICATION OF PURCHASED PRODUCT**

7.4.5.1 Purchased products are verified prior to use in production and/or dispatch to customers. The Quality Manager is responsible for selecting appropriate methods for purchased product verification and acceptance. Operational Procedure ***QOP-74-03 Verification of Purchased Product*** defines the processes for verifying, identifying and releasing purchased products.

7.4.5.2 When verification of purchased product is to be performed at supplier's premises, purchasing documents

specify the intended verification arrangements and method of product release.

## 7.5 PRODUCTION AND SERVICE PROVISION

### 7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

#### 7.5.1.1 GENERAL REQUIREMENTS

Device manufacturing and provision of associated services are carried out under controlled conditions. The controlled conditions include the control of, as applicable:

- **Product and process information and work instructions:** Information and instructions specifying product characteristics and manufacturing processes are communicated to process operators in the form of work orders, drawings, specifications, samples, work instructions, and product-specific templates and tooling. This information is developed in the phase of product design (per Operational Procedure ***QOP-73-01 Design Control***) and in the phase of production and quality planning (per Operational Procedure ***QOP-71-01 Production Planning***). The resulting documents are controlled in accordance with Operational Procedures ***QOP-42-01 Control of Documents***, ***QOP-42-02 Device Master Record***, and ***QOP-75-01 Production Work Order and History Record***.
- **Process equipment:** Process equipment, machines, hardware, and software are selected on the basis of their ability to consistently produce products and provide services that meet specified requirements. Selection and maintenance of process equipments are addressed in Operational Procedures ***QOP-71-01 Production Planning*** and ***QOP-63-01 Equipment Maintenance***.
- **Monitoring and measuring devices:** Requirements for measuring and monitoring devices are determined in accordance with product and process monitoring and measurement programs defined in product realization planning (refer to ***QOP-71-01 Production Planning***). The system for managing and controlling measuring and monitoring devices is defined in Operational Procedure ***QOP-76-01 Measuring and Monitoring Equipment***.
- **Monitoring and measurement activities:** Monitoring and measurement of product is implemented through the program of receiving, in-process and final inspections, as defined in Operational Procedures ***QOP-74-03 Verification of Purchased Product***, ***QOP-82-03 In-process Inspections***, and ***QOP-82-04 Final Acceptance Inspection***. The program for monitoring and measurement of production processes is developed and implemented in accordance with Operational Procedures ***QOP-71-01 Production Planning***, ***QOP-75-03 Validation of Processes and Software***, and ***QOP-82-03 In-process Inspections***.
- **Product release and delivery:** Products are released for delivery only after all specified production activities have been satisfactorily completed and conformity of the product and of the associated Device History Record have been verified. Operational Procedure ***QOP-82-04 Final Acceptance Inspection*** defines the system for finished product verification and release. Activities related to product shipping and delivery are defined in Operational Procedure ***QOP-75-07 Storage and Delivery***.
- **Installation and Servicing:** The some of the products sold by Optel may require provision of installation services by the Company. Device servicing specifications and instructions are developed as part of the device design project, subject to all applicable controls specified in Operational Procedure ***QOP-73-01 Design Control***. The system for controlling installation and servicing operations is defined in Operational Procedure ***QOP-75-04 Installation and Servicing***.
- **Labeling and packaging:** Labeling and packaging are considered to be a part of the device itself, and thus all components, processes and activities related to labeling and packaging must meet the same requirements that apply to the design and manufacturing of the device. Application of quality system controls to labeling and packaging are explained in Operational Procedure ***QOP-75-06 Labeling and Packaging***.

#### 7.5.1.2 CLEANLINESS OF PRODUCT AND CONTAMINATION CONTROL

7.5.1.2.1 Documented requirements for cleanliness of product are established when product cleanliness is of significance, and when the product is to be cleaned for any reason and at any time prior to use. Operational

Procedure ***QOP-75-02 Cleanliness and Contamination of Product*** sets more detailed criteria for when requirements for cleanliness of product need to be established, who is responsible for defining these requirements, and how cleaning processes are developed, validated and implemented.

7.5.1.2.2 Devices that may have been biologically contaminated are labeled BIO HAZARD and are immediately moved to a special decontamination area. More detailed instructions on how to identify, handle, segregate and decontaminate these devices are included in Operational Procedure ***QOP-75-02 Cleanliness and Contamination of Product*** and in applicable work instructions.

7.5.1.2.3 For other types of contaminants that do not create a bio hazard, products that are suspected of being contaminated are handled, identified and processed in accordance with Operational Procedure ***QOP-83-01, Control of Nonconforming Product***.

**7.5.1.3 INSTALLATION**

With regard to installation, for products manufactured by Optel are three possibilities which can occur : 1) Products of a type that does not require installation, in which case an installation procedure is not applicable; 2) Products that are manufactured by Optel and sold to its own direct end user customers for which installation is performed by Optel or Optel's agent prior to "delivery"; or 3) Products sold to Optel corporate customers that in turn add value to the product and subsequently sell the product to their agents or end user customers. For these latter two cases Operational Procedure QOP-75-04 applies.

7.5.1.3.1 Product installation instructions are developed as part of the product design project, subject to all applicable controls specified in Operational Procedure ***QOP-73-01 Design Control***, and are published in a booklet enclosed with the product.

7.5.1.3.2 Development, validation and control of installation instructions are addressed in Operational Procedure ***QOP-75-04 Installation and Servicing***.

**7.5.1.4 SERVICING**

7.5.1.4.1 The system for providing device servicing is defined in Operational Procedure ***QOP-75-04 Servicing***.

7.5.1.4.2 Where applicable, quality system requirements for controlling the design and manufacture of new products are also applied to servicing activities. Particularly, those pertaining to product and process specifications and instructions (***QOP-71-01 Production Planning***), training of personnel (***QOP-62-01 Competence, Awareness and Training***), performing and controlling realization processes (***QOP-75-03 Validation of Processes and Software***), verification and acceptance activities (***QOP-76-01 Measuring and Monitoring Equipment*** and ***QOP-82-04 Final Acceptance Inspection***), and maintenance of records (***QOP-42-03 Control of Records***).

7.5.1.4.3 Servicing is concluded by verifying that the servicing meets specified requirements. Checklists, inspection instructions and test procedures, as applicable, are documented and the servicing personnel are trained in their use (refer to Operational Procedure ***QOP-75-04 Installation and Servicing***).

7.5.1.4.4 Servicing diagnosis, repairs and verification results are recorded in the Service Report. At a minimum, the report includes:

- The name of the product serviced,
- Product serial or batch number,
- The date of service,
- The technician servicing the device,
- The service performed, and
- The test and inspection data.

A model of the report is documented in Quality System Form ***QF-75-04-1 Service Report***, and its use is explained in Operational Procedure ***QOP-75-04 Installation and Servicing***.

7.5.1.4.5 Service reports are analyzed with appropriate statistical methodology to identify any systematic failures and

quality problems that need to be addressed with corrective or preventive actions. Operational Procedure ***QOP-75-04 Installation and Servicing*** instructs in more detail how the analysis is carried out and used.

7.5.1.4.6 Service requests associated with any allegation of serious injury or death are automatically considered as complaints, and are recorded and investigated, in accordance with Operational Procedure ***QOP-85-03 Customer Complaints***, to determine whether the complaint represents an event which must be reported to the FDA.

**7.5.2 VALIDATION OF PROCESSES FOR PRODUCTION AND SERVICE PROVISION**

7.5.2.1 Special processes are those processes where the resulting output cannot be verified by subsequent measurement or monitoring.examples of special processes include: joining of materials by welding, soldering or gluing; molding and casing of metals, plastics or cements; coating with paints, epoxy, or other materials; heat, radiation or chemical treatment of materials; etc. <Production Engineering> and the Quality Manager are responsible for identifying, validating and documenting special processes, as defined in Operational Procedure ***QOP-75-03 Validation of Processes and Software***.

7.5.2.3 Computer software that controls production process, and where malfunctioning of the software could result in product nonconformity, is validated prior to initial use. This applies also to software that is used in QC inspection equipment (or otherwise in monitoring and measurement of specified requirements). The control system for software validation is defined in Operational Procedure ***QOP-75-03 Validation of Processes and Software***.

**7.5.3 IDENTIFICATION AND TRACEABILITY**

7.5.3.1 **Identification:** Materials, components and finished devices are identified throughout all stages of product realization and when in storage. The system and methods for identifying products are explained in Operational Procedure ***QOP-75-05 Product Identification and Traceability***. Additional relevant procedures are ***QOP-75-01 Production Work Order and History Record***; and ***QOP-75-06 Labeling and Packaging***.

7.5.3.2 **Traceability:** Traceability is maintained when required by applicable laws and regulations, or when specified internally to facilitate corrective actions. Traceability is based on identifying the finished devices, or batches, with unique control numbers. Activities related to maintaining and recording traceability are addressed in Operational Procedures ***QOP-75-05 Product Identification and Traceability***, and ***QOP-75-01 Production Work Order and History Record***.

7.5.3.3 **Acceptance status:** Throughout product realization, and when in storage, products are identified with respect to their acceptance status, e.g., to indicate whether they have passed or failed the specified inspections and/or tests. This is to prevent nonconforming product from being used or dispatched. General requirements for acceptance status identification are defined in Operational Procedure ***QOP-75-05 Product Identification and Traceability***. Specific identification methods are defined in Operational Procedures ***QOP-74-03 Verification of Purchased Product***, ***QOP-82-03 In-process Inspections***, ***QOP-82-04 Final Inspection***, and ***QOP-83-01 Control of Nonconforming Product***.

**7.5.4 CUSTOMER PROPERTY**

7.5.4.1 Customer-supplied products are received and inspected following the same procedure that applies to the purchased products, i.e., Operational Procedure ***QOP-74-03 Verification of Purchased Product***. In the event the supplied products fail receiving inspection, or are not suitable for any other reason, the customer is contacted.

7.5.4.2 Marking, storage, handling, and preservation of customer supplied products follow the same procedures that apply to the purchased products. The applicable Operational Procedures are ***QOP-75-05 Product Identification and Traceability*** and ***QOP-75-07 Storage and Distribution***.

7.5.4.3 Customer-owned tooling, gauges and returnable packaging are permanently marked so that ownership of each item is visually apparent.

7.5.4.4 Customer's software, documents, and other intellectual property are protected to the same extent as would

internal Dairy Quality's documents of similar content, unless there are contractual requirements for special measures to protect customer's intellectual property.

7.5.4.5 When specified in a contract, special handling instructions from customers will take precedent over the company's standard procedures.

7.5.4.6 Customers are immediately informed in the event of loss, damage, deterioration, or unsuitability of their products.

**7.5.5 PRESERVATION OF PRODUCT**

7.5.5.1 **Handling and preservation:** Production is responsible for product handling and preservation; and in particular for ensuring that containers holding products are suitable and are in good condition, that equipment used for internal transportation of products is well maintained and is properly operated, and that products are adequately protected during production and storage. Operational Procedures ***QOP-75-02 Cleanliness and Contamination of Product*** and ***QOP-75-07 Storage and Distribution***, define how these policies are implemented.

7.5.5.2 **Storage:** Stockrooms and storage, staging, and holding areas are controlled by the department that brings in new stock or uses the area. Storage areas are appropriate to ensure adequate preservation and protection of product. Procedures and/or work instructions are established for control of product with limited shelf-life or requiring special storage conditions. Operational Procedure ***QOP-75-07 Storage and Distribution*** defines the processes for operating and maintaining the storage areas.

7.5.5.3 **Packaging, labeling and shipping:** Primary packaging are boxes, bags or other packaging in which products are presented to the customers and patients. Secondary packaging are cardboard boxes, crates, or other additional packaging intended to contain and protect products for shipping and transportation. Primary packaging and labeling are considered to be production processes and are controlled as defined in Operational Procedure ***QOP-75-06 Labeling and Packaging***.

## 7.6 CONTROL OF MONITORING AND MEASURING DEVICES

**7.6.1 GENERAL**

7.6.1.1 Appropriate measuring and monitoring devices are selected to ensure that measurement capability is consistent with the measurement requirements. Devices used for ensuring and verifying product conformity are calibrated. Operational Procedure ***QOP-76-01 Measuring and Monitoring Equipment*** defines the calibration and control system.

**7.6.2 MEASURING AND MONITORING DEVICES CALIBRATION AND MAINTENANCE**

7.6.2.1 The scope of the calibration control system extends to the measuring and test equipment, comparative reference hardware (such as gauges and templates), and test software used for:

- Setup and monitoring of production processes;
- Monitoring of environmental conditions;
- Verification of product conformity; and
- Operations where defined accuracy of a measurement is required to assure product conformity.

7.6.2.2 The Quality Manager is responsible for calibrating and maintaining measuring and monitoring devices. All active devices are inventoried in a controlled list, indicating their calibration status and location.

7.6.2.3 Measuring devices are checked, adjusted and re-adjusted as necessary; and are calibrated at specified intervals (or prior to use) against measurement standards traceable to international or national measurement standards.

7.6.2.4 Calibration is recorded in a calibration certificate and the calibrated devices are labeled with a calibration sticker to identify their calibration status.

7.6.2.5 Measuring and monitoring devices are safeguarded from adjustments that would invalidate the measurement

result.

7.6.2.6 Measuring and monitoring devices are protected from damage and deterioration during handling, maintenance and storage.

**7.6.3 VALIDITY OF MEASUREMENTS MADE WITH NONCONFORMING DEVICES**

7.6.3.1 When measuring equipment is found not to conform to requirements, previous measuring results are reassessed, and appropriate action is taken on the equipment and any product affected.

**7.6.4 VALIDATION OF SOFTWARE**

7.6.4.1 In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

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## 8.1 GENERAL

### 8.1.1 PLANNING

8.1.1.1 Measurement and monitoring activities to ensure and verify product conformity are defined in engineering specifications and drawings, production work orders, inspection and testing procedures, and process control procedures. These activities are further defined in Operational Procedures ***QOP-74-03 Verification of Purchased Product***, and ***QOP-82-04 Final Inspection***.

8.1.1.2 The conformity and effectiveness of the quality system are monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to the top management and are used to identify opportunities for improvement. Activities related to internal audits and to measuring customer satisfaction and quality performance are defined in Operational Procedures ***QOP-82-02 Internal Quality Audits*** and ***QOP-82-01 Feedback and Customer Satisfaction***.

### 8.1.2 STATISTICAL TECHNIQUES

8.1.2.1 As applicable, statistical techniques may be applied to the following types of activitie s:

- Control of process stability and performance (SPC on data from suppliers);
- Establishment of sampling plans for inspections and testing;
- Evaluation of measurement systems; and
- Analysis of quality performance and other company-level data.

8.1.2.3 Departmental managers are responsible for identifying the need for using statistical techniques in their departments and in other activities for which they are responsible. the Quality Manager may be called upon to assist other departments in selecting and documenting specific techniques.

### 8.1.3 SAMPLING PLANS

8.1.3.1 Sampling plans for inspections, testing and other product and process acceptance activities are documented. Sampling plans are reviewed and approved by the Quality Manager to ensure that they are based on valid statistical rationale and are appropriate.

8.1.3.2 Sampling plans are issued and controlled as work instructions, in accordance with Operational Procedure ***QOP-42-01 Control of Documents***. They are either included with the inspection/testing instructions to which they pertain, or are issued as independent documents.

8.1.3.3 Sampling plans are reviewed and re-evaluated whenever there is a significant change in reject rates (identified nonconformities) at a given inspection point, and when a nonconforming product is shipped, or otherwise identified after it has passed its acceptance inspection. Reevaluation of a sampling plan is carried out within the framework of the pertinent corrective action (refer to Operational Procedure ***QOP-85-04 Corrective and Preventive Action***) and the plan is revised and reissued in accordance with Operational Procedure ***QOP-42-01 Control of Documents***.

## 8.2 MONITORING AND MEASUREMENT

### 8.2.1 POST-PRODUCTION FEEDBACK AND CUSTOMER SATISFACTION

8.2.1.1 The post-production feedback system provides early warning of quality problems and input into the corrective and preventive action processes. The following sources of information are used:

- Customer, user and patient complaints;
- Defective or otherwise nonconforming product returned by customers;
- Servicing records;
- Monitoring orders for consumable components; and
- Reviews and articles in trade and professional publications.

8.2.1.2 Operational Procedure ***QOP-82-01 Feedback and Customer Satisfaction*** defines the responsibilities and methods for collecting the post-production feedback information.

8.2.1.3 <Marketing> is responsible for developing suitable indicators of customer satisfaction, and for defining methods for collecting and analyzing the pertinent information.

8.2.1.4 Information and data pertaining to customer satisfaction are collected from several sources, including:

- Customer complaints and other feedback,
- Customer satisfaction surveys,
- Product returns and warranty claims, and
- Repeat customer rates.

8.2.1.5 Operational Procedures ***QOP-82-01 Feedback and Customer Satisfaction*** and ***QOP-85-03 Customer Complaints***, define the system for collecting and analyzing customer satisfaction information.

8.2.1.6 Customer satisfaction is used as one of the measurements of the performance of the quality management system. For this purpose, customer satisfaction information is reported to, and evaluated by the management review of the quality system, as defined in Operational Procedure ***QOP-56-01 Management Review***.

**8.2.2 INTERNAL AUDIT**

8.2.2.1 The Quality Manager is responsible for conducting internal audits of the quality management system to determine whether the quality system:

- Conforms to quality plans, to management system requirements as defined in this quality manual and operational procedures, and to the requirements of the ISO 13485 and ISO 9001 standards and other regulatory requirements including the FEA's 21 CFR 820,
- Is effectively implemented and maintained.

8.2.2.2 Internal audits are conducted in accordance with a planned program, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of the previous audits.

8.2.2.3 Appropriate corrective actions are taken by management personnel responsible for the areas where nonconforming processes and/or practices are identified by the audit. Auditors follow up to ensure that the actions taken are fully implemented and are effective.

8.2.2.4 Operational Procedure ***QOP-82-02 Internal Quality Audits*** defines the processes for planning, conducting and reporting internal audits, as well as taking corrective actions ad follow-ups.

**8.2.3 MONITORING AND MEASUREMENT OF PROCESSES**

8.2.3.1 Quality management system processes are monitored by a variety of approaches and techniques, as appropriate for a particular process and its importance. These include:

- Conducting internal audits of the quality system (***QOP-82-02 Internal Quality Audits***);
- Monitoring trends in corrective and preventive action requests (***QOP-85-04 Corrective and Preventive Actions***);
- Measuring product conformity and monitoring other quality performance data and trends (***QOP-74-03, Verification of Purchased product***, ***QOP-82-03 In-process Inspections***, and ***QOP-82-04 Final Acceptance Inspection***); and

- Measuring and monitoring customer satisfaction (***QOP-82-01 Feedback and Customer Satisfaction***).

8.2.3.2 When a quality system process does not conform to requirements, the Quality Manager initiates a corrective action request to address the problem. The process for requesting and implementing corrective actions is defined in Operational Procedure ***QOP-85-04 Corrective and Preventive Action***.

### 8.2.4 Monitoring and Measurement of Product

8.2.4.1 The monitoring and measurement program for products is defined in drawings and specifications, production work orders, purchasing documents, and in inspection and testing procedures. Documents defining the inspection and testing program are collectively referred to as control plans.

8.2.4.2 **Verification of purchased product:** All purchased products are subjected to a visual inspection by the receiving clerk. Some designated products are also subjected to a more detailed and technical QC inspection. Processes for performing these inspections are defined in Operational Procedure ***QOP-74-03 Verification of Purchased Product***.

8.2.4.3 **In-process inspections:** In-process inspections are in the form of first article inspections, operator and QC inspections, continuous product verification by automated inspection equipment, and statistical process control (SPC). The focus is on defect prevention rather than detection. Systems for performing in-process inspections are defined in Operational Procedures ***QOP-82-03 In-process Inspections*** and ***QOP-82-03 Statistical Process Control***.

8.2.4.4 **Final acceptance inspection:** Finished products are subjected to the final QC inspection. First, inspectors verify that all specified receiving and in-process inspections have been carried out satisfactorily. Then they perform the remaining inspections and tests necessary to complete the evidence of product conformity. Only devices that pass the final inspection can be distributed. Operational Procedure ***QOP-82-04 Final Acceptance Inspection*** defines these activities.

8.2.4.5 Results of inspections and tests are recorded. Instructions for establishing records for specific types of inspections are defined in inspection procedures and work instructions. Filing and maintenance of inspection records are regulated by Operational Procedures ***QOP-75-01 Production Work Order and History Record*** and ***QOP-42-03 Control of Records***.

8.2.4.6 Devices are released for distribution only after all specified activities have been satisfactorily completed and conformity of the product has been verified. Only personnel performing final product inspections and tests have the authority to release products. The identity of the person authorizing product release is recorded. Operational Procedure ***QOP-82-05 Final Acceptance Inspection*** defines specific methods for product release.

## 8.3 Control of Nonconforming Product

### 8.3.1 Identification and Documentation

8.3.1.1 Nonconforming products are documented in the Product Nonconformity Report (PNR). The report describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.). The use of the PNR and its processing are explained in Operational Procedure ***QOP-83-01 Control of Nonconforming Product***.

8.3.1.2 When nonconforming product is detected after delivery or use has started, the effects, or potential effects of the nonconformity are evaluated by the Quality Manager, and appropriate action is taken.

8.3.1.3 To prevent nonconforming products from being used or shipped, the products are marked with a REJECTED label or tag, and are segregated.

### 8.3.2 Nonconformity Review and Disposition

8.3.2.1 The Quality Manager is responsible for reviewing nonconformities and deciding on the disposition of nonconforming products. In simple and routine cases this responsibility is delegated to production supervisors.

8.3.2.2 The disposition decision may be to rework, accept as-is, or scrap.

8.3.2.3 Processes for reviewing product nonconformities, for making disposition decisions, and for recording these activities are provided in Operational Procedure ***QOP-83-01 Control of Nonconforming Product***.

**8.3.3 REWORKING PRODUCTS**

8.3.3.1 Rework operations are documented in written rework instructions that undergo the same authorization and approval as the original work instructions, as required in Operational Procedure ***QOP-83-01 Control of Nonconforming Product***. Reworked products are re-inspected to demonstrate conformity to original requirements. These verification activities are carried out in accordance with applicable inspection instructions and procedures (refer to Operational Procedures ***QOP-82-03 In-process Inspections*** and ***QOP-82-04 Final Acceptance Inspection***).

## 8.4 ANALYSIS OF DATA

**8.4.1 GENERAL**

8.4.1.1 The Quality Manager coordinates the collection and analysis of appropriate data to demonstrate the suitability and effectiveness of the quality management system, and to identify opportunities for improvement.

8.4.1.2 Operational Procedure ***QOP-84-01 Analysis of Data*** defines the processes for collecting, analyzing and using the quality performance data.

**8.4.2 SCOPE**

8.4.2.1 The quality performance data focuses on providing information relating to:

- Customer feedback,
- Conformity to product requirements,
- Characteristics of processes and products, and
- Supplier quality performance.

A complete list of specific categories of collected data is included in Operational Procedure ***QOP-84-01 Analysis of Data***.

## 8.5 IMPROVEMENT

**8.5.1 GENERAL**

**8.5.1.1 CONTINUOUS IMPROVEMENT**

8.5.1.1.1 Optel continually improves the effectiveness of its quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. Operational Procedure ***QOP-85-01 Continuous Improvement*** defines this process.

8.5.1.1.2 Internal audit results and quality performance data are analyzed by management review to assess the effectiveness of the quality system and current organizational performance. Opportunities and priorities for improvement are identified by comparing present quality performance to goals and aspirations defined in the quality policy. This process is defined in Operational Procedure ***QOP-56-01 Management Review***.

8.5.1.1.3 Improvement projects are defined either as corrective and preventive actions or as quality objectives. These processes are defined in Operational Procedures ***QOP-85-04 Corrective and Preventive Actions***, and ***QOP-56-01 Management Review***, respectively.

**8.5.1.2 DEVICE RECALL AND ADVISORY NOTICES**

8.5.1.2.1 The recall committee, including at least the President, and the Quality Manager, is responsible for decisions regarding device recalls and issuing of advisory notices. In an emergency, and when there is no time to assemble the full committee, either the President or the Quality Manager alone is authorized to initiate a recall.

8.5.1.2.2 Planning of the recall, receipt of the recalled devices, communication with regulatory authorities, and other activities related to recall and to issuing of advisory notices are defined in Operational Procedure ***QOP-85-02 Device Recall and Advisory Notices***.

**8.5.1.3 CUSTOMER COMPLAINTS**

8.5.1.3.1 Customer complaints that allege deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a distributed device are logged and documented.

8.5.1.3.2 Complaints that involve a possible failure of a device, labeling, or packaging to meet any of its specifications, and/or complaints representing an event which must be reported to regulatory authorities are always investigated, and the results of the investigation are documented.

8.5.1.3.3 The system for receiving, logging, investigating and responding to customer complaints is defined in Operational Procedure ***QOP-85-03 Customer Complaints***.

**8.5.2 CORRECTIVE AND PREVENTIVE ACTION**

8.5.2.1 Corrective actions are taken to eliminate causes of actual nonconformities in order to prevent their recurrence.

8.5.2.2 Preventive actions are implemented to eliminate causes of potential nonconformities in order to prevent their occurrence.

8.5.2.3 The process for taking corrective and preventive actions includes requirements for:

- Reviewing nonconformities and potential nonconformities,
- Determining causes for actual and potential nonconformities,
- Evaluating the need for action to ensure that nonconformities do not recur and that potential nonconformities are prevented,
- Determining and implementing actions needed, including, if appropriate, updating documentation,
- Recording the results of any investigations and of actions taken, and
- Reviewing the corrective or preventive action taken and its effectiveness.

This process is defined in Operational Procedure QOP-85-04 Corrective and Preventive Action.