Confluent Medical Technologies Quality Manual

1 Introduction to Confluent Medical Technologies

1.1 About Confluent Medical Technologies

Confluent Medical Technologies is a developer and manufacturer of components for both medical and commercial applications. Confluent Medical Technologies is also a manufacturer of medical devices. Confluent Medical Technologies' Headquarters is located in Fremont, California.

1.1.1 Confluent Medical Technologies consists of a number of previously independent organizations operating under one company name. These were Nitinol Devices and Components (NDC), Interface Catheter Solutions (ICS), End to End Medical (ETE) and Corpus Medical.

1.1.2 Some quality system elements are shared across organizations. Such sharing is defined in organization specific procedures. Refer to LST-03143 Confluent Medical Technologies Procedures to ISO 13485:2016.

1.2 Registrations

- ISO 13485: 2016 BSI # FM 703929, Confluent Fremont, CA, Confluent Laguna Niguel, CA, Confluent Campbell, CA, Confluent Warwick, RI, and Nitinol Devices & Components Costa Rica, S.R.L.
- US FDA Registration # 3007635982: Confluent, Fremont, CA
- US FDA Registration # 3009018440: Nitinol Devices & Components , Costa Rica, S.R.L, Coyol Free Zone B14, B15 and B25
- US FDA Registration # 3009650429: Confluent, , Campbell, CA
- State of California DHS # 51960: Confluent, Fremont, CA
- State of California DHS # 48859: Confluent, Laguna Niguel, CA
- State of California DHS # 55548: Confluent, Campbell, CA
- Canadian Medical Devices Registration – Licence # 814591

1.3 References

- ISO 13485: 2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- ISO 14971:2012, Medical Devices - Application of risk management to medical devices
- Title 21 CFR Part 820, Food and Drug Administration, "Quality System Regulation"
- Title 21 CFR Part 11, Food and Drug Administration, "Electronic Records; Electronic Signatures"
- CMDCAS Medical Device Regulations SOR/98-282 (Promulgated 1998. Latest Consolidated Version)

- Canadian Medical Device Regulation (CMDR)
- Medical Device Directives (MDD, 93/42/EEC, as amended)
- Japan's Pharmaceuticals and Medical Devices Agency (PMDA) Ministerial Ordinance #169
- Council Directive 93/42/EEC of 14 June 1993 (Consolidated 2007)
- Operating Procedures (OP's) established for the quality management system are located in Compliant Pro and accessible by company personnel.
- LST-03143 Confluent Medical Technologies Procedures to ISO 13485:2016

2 Scope

2.1 Application

2.1.1 Confluent Medical designs, develops and manufactures medical devices, medical device components, raw materials, (for both medical and non-medical uses) and provides analytical services/consulting. Finished medical devices are manufactured in an ISO class 8 cleanroom.

2.1.2 Confluent Medical has 5 locations of business; California (Fremont, Campbell and Laguna Niguel), Costa Rica, and Rhode Island (Warwick)

2.1.2.1 Fremont, Campbell and Laguna Niguel California perform all applications listed above. Currently there is no finished device manufacturing at the Fremont Site; therefore no ISO Class 8 cleanroom.

2.1.2.2 Costa Rica is a manufacturing site.

2.1.2.3 Warwick site designs, develops and manufactures textile and composite materials as components and assemblies.

2.1.3 Confluent Medical Technologies manages an inspection operation in Juarez Mexico, which is staffed by customer personnel in a customer owned building. This operation follows Confluent Medical Technologies procedures, but official registrations are maintained by the customer.

2.2 Exclusions - Design & Development Section is an exclusion for Juarez Site, for scope of Juarez is visual inspection to a customer component. For all other Sites, exclusions are none.

2.3 Non-Application – Refer to LST-03143 Confluent Medical Technologies Procedures to ISO 13485:2016

3 Quality System Overview

3.1 Confluent Medical Quality Policy (*translated in Spanish*)

(Política de Calidad de Confluent Medical)

Confluent Medical Technologies is focused on high quality products and satisfied customer-partners. This is accomplished by establishing a culture of teamwork, personal responsibility for work, creativity and integrity.

(Confluent Medical Technologies está enfocado en productos de alta calidad y clientes-socios satisfechos. Esto se logra estableciendo una cultura de trabajo en equipo, responsabilidad personal por el trabajo, creatividad e integridad).

Confluent Medical Technologies will achieve this commitment by:

(Confluent Medical Technologies alcanzará este compromiso mediante:)

- Continuously improving the effectiveness of our Quality Management System, our products and our services.

  (Mejoramiento continuo de la efectividad de nuestro Sistema de Calidad, nuestros productos y nuestros servicios.)

- Meeting regulatory requirements and satisfying the needs of our customers and partners.

  (Cumplimiento de requisitos regulatorios y satisfacer las necesidades de nuestros clientes y socios.)

- Striving to deliver high quality products with on-time delivery and superior services to achieve total customer satisfaction

  (Esfuerzo por entregar productos de alta calidad con entregas a tiempo y servicios superiores para alcanzar la satisfacción total del cliente.)

3.2 Confluent Quality Objectives

Confluent Medical Technologies considers the safety, efficacy and quality of our products to be of utmost importance. These high-level quality objectives are derived from the Quality Policy and are the foundation from which all quality goals and activities are developed. The Quality Objectives and goals or changes to them are generated during the Management Review meetings and recorded on management review meeting notes. In general, the Quality Objectives include Product Performance, Customer Communication (Complaints, returns, delivery performance), Supplier management, Training, and Corrective and Preventive Actions, and others. Specific objectives and measurement methods may vary by site, since each site has variations in the business focus and customer base.

3.3 Organizational Structures

The site-specific organizational structures are maintained as separate documents. Approved copies are maintained by the Quality Assurance departments for audit presentation. The organizational chart is established and maintained by the Human Resources department.

3.4 Quality System Effectiveness

Quality system effectiveness is documented and monitored through periodic review of the Quality Objectives. If Quality Objectives are not sufficiently achieved, action is taken and documented via the appropriate quality systems.

The QMS maintains its effectiveness by:

- Communicating to the organization the importance of meeting customer, statutory and regulatory requirements.
- Reviewing the quality policy for relevancy.
- Ensuring quality objectives are established.
- Conducting management reviews.
- Ensuring availability of resources.
  Ensuring customer expectations are determined, understood and translated into internal requirements.

3.5 Shared Quality System Elements/Documents

The Confluent Medical Technologies Quality Management System (QMS) shares resources across all sites in many cases, including elements involved in supplier management, document control, customer complaints, internal audits, purchasing, materials management, training and CAPA. While there may be local procedures describing the various interactions with these elements, testing and validation of such systems are considered to be applicable to all sites due to the nature of the systems.

Company level procedures are available for use at any site where system adoption has been completed and where an adoption and rollout has occurred. Documentation of the adoption may be through document change process or approved memorandum.

In many cases, manufacturing processes may have been validated at one site, or have instructions authored at the origin site. When moved to another site, the moving team will review the previous activity to determine its adequacy for the updated location and needs.

Many documents authored prior to the acquisition and merger of various partners will retain the original company logos until their next revision.

4 Quality Management System

4.1 General Requirements

The Confluent Medical Technologies Quality Management System is customized to the business needs of customers specific to each entity.

The Confluent Medical Technologies Quality Management System is established to implement the requirements of ISO 13485: 2016, US FDA 21 CFR Part 820 QSR (Quality System Regulation), Canadian Medical Device Regulation (CMDR) and other applicable regulatory requirements, and to establish policies and procedures that support the quality objectives of the company.

Confluent Medical Technologies as an organization shall:

- Determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization;
- Apply a risk based approach to the control of the appropriate process needed for the quality management system;
- Determine the sequence and interaction of these processes.

Confluent Medical Technologies uses risk-based approaches, which are included in specific procedures. Refer to LST-03143, Confluent Medical Technologies. Procedures to ISO 13485:2016, for the identified risk-based approach procedures for the quality management system.

For each quality management system process, Confluent Medical Technologies shall:

- Determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

- Ensure the availability of resources and information necessary to support the operation and monitoring of these processes;
- Implement actions necessary to achieved planned results and maintain the effectiveness of these processes;
- Monitor, measure as appropriate, and analyze these processes;
- Establish and maintain records needed to demonstrate conformance to OP-9016 Quality records and in compliance with applicable regulatory requirements.

Confluent Medical Technologies shall manage the quality management processes in accordance to ISO 13485:2016 and other applicable regulatory requirements. Changes to be made to processes shall be:

- Evaluated for their impact on the quality management system;
- Evaluated for their impact on the medical devices produced under the quality management system;
- Controlled in accordance with the requirements of ISO 13485:2016 and applicable regulatory requirements.

When Confluent Medical Technologies chooses to outsource any processes that affect product conformity to requirements, Confluent shall retain responsibility for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with Purchasing. The controls shall be documented in the written agreement of the Supplier Quality Agreement.

Confluent Medical Technologies documents procedures for the validation of computer software used in the Quality Management System. Such software shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.

In addition, the scope of the Confluent Medical Technologies Quality Management System covers production of standard product, provision of analytical/design services, new product design/development and all supporting activities.

The Management with Executive Responsibility approves initial release and changes to this document through the Engineering Change Order (ECO/ECR) process.

The processes needed for the management of the QMS consist of:

- Product Realization, where new product is developed based on customer needs and transferred to manufacturing,
- Delivery to customers, and

- Using customer feedback to make improvements to the Product Realization process. The customer feedback and communications processes include procedures to define the review of experience gained from devices in the post-production phase.

Management Review also ensures availability of adequate resources and technology to support the QMS.

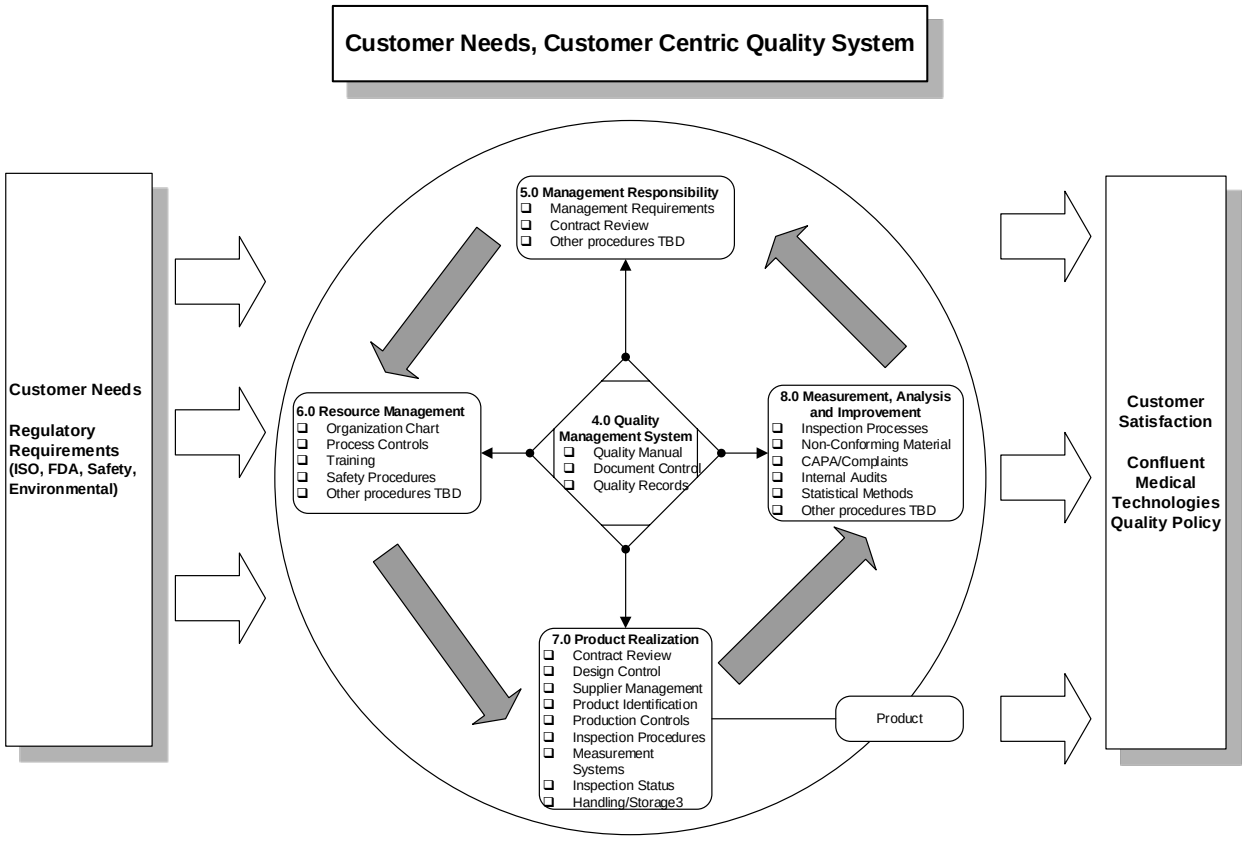
In addition, Internal Audits and Management Review processes are used to evaluate the effectiveness of quality system and drive improvement by monitoring and measuring the outcome of these processes.

The authority to perform the tasks identified in this document and other Quality System documents may not be delegated unless specifically stated otherwise. Such delegation is to be in writing, and the overall responsibility for proper performance of the task remains with the individual referred to in the documentation.

The responsibility for the Confluent Medical Technologies quality system has been assigned to Management with Executive Responsibility (MWER). The Vice-President of Quality Assurance and Regulatory Affairs has been designated by the Chief Executive Officer of Confluent Medical to be the Management Representative with full responsibility and authority for establishing and maintaining the quality system in accordance with Quality System requirements.

The responsibility for each site quality system has been further assigned to the site-head (Director or Manager) of Quality and/or Regulatory for the site, along with corresponding Management Representative Responsibilities.

The process depicted below provides an overview of the Confluent Medical Technologies Quality System model. The closed loop process ensures that Confluent Medical Technologies has not only established, but also improves processes and practices on a continuous basis.



4.2 Documentation Requirements

4.2.1 General

The Confluent Medical Technologies Quality Manual is the top-level document that describes the overall quality system in accordance with the stated quality policy and other documentation specified by applicable regulatory requirements.

Confluent Medical Technologies quality management system shall include:

- Documented statements of a quality policy and quality objectives;
- A quality manual;
- Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
- Other documentation specified by applicable regulatory requirements.

4.2.2 Quality Manual

Confluent Medical Technologies shall document a quality manual that includes:

- The scope of the quality management system, including details of and justification for any exclusion or non-application;
- The documented procedures for the quality management system, or reference to them;
- A description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

The Confluent Medical Technologies quality policy is stated in this Quality Manual. Top management identifies quality objectives that meet the requirements of the quality policy annually. The quality objectives are documented in the Management Review meeting minutes.

This Quality Manual outlines the structure of the documentation used in the quality management system with the quality policy and other top-level guidance (Level 1), and makes reference to Operating Procedures and Standard Operating Procedures for detailed procedures on the operation of the System (Level 2). Detailed procedures for manufacturing and supporting activities are found in Travelers, Work Instructions, and Inspection Plans, etc. (Level 3).

The Level 2 documents include:

- Confluent Medical Technologies Operating Procedures (OP)
- Site Standard Operating Procedures (SOP)
- Quality/Control Plans.

Quality Plans provide a summary of all quality activities in support of a product or product line. OPs/SOPs establish company-wide procedures and requirements. They are generally non-technical and may use a variety of formats. Each section of this quality manual is reflected in organization-specific applicable OPs/SOPs.

Level 3 documents include and are not limited to:

- Departmental Operating Procedures (DOP) describe the interdepartmental activities required to accomplish compliance with Quality System requirement(s).
- Travelers/Routers establish the process flow and processing instructions for items produced in the facility. Verification activities are included or incorporated as steps in the process flow defined by the traveler. Detailed instructions are normally incorporated in Work Instructions, which are referenced on the Traveler.

- Work Instructions (WI) provide detailed instructions that are too lengthy to be included on a traveler or other document. Work Instructions may also be created for detailed or step-by-step instructions for a process whose policies are described in an OP.
- Manufacturing Assembly Instructions (MAP) provide detailed work instructions primarily used by Production personnel that describe the procedure(s) used in the assembly process. Process Instructions (PI) provide detailed work instructions used for non-production/QC inspection applications, e.g. Preventative Maintenance.
- Inspection Plans (IP) identify specific inspections or tests to be performed, sampling plans, and the data or other records to be generated.
- Inspection Procedures provide detailed work instructions primarily used by Quality Assurance/Control personnel that describes the procedure(s) used during the inspection of materials, subassembly and finished devices to ascertain whether they conform to the respective specifications. Inspection procedures are documented in Work Instructions.
- Test Methods provide detailed instructions that define the procedure to conduct a specific test and/or operate specific test equipment, e.g. a Tensile tester. Test Methods are documented in Work Instructions.
- Inspection Data Sheets (DS) may be developed to record specific measurements or other quality data.
- Product drawings define company products, including dimensional, material, and functional characteristics.
- Tooling drawings define key tools, dies, and other production or test/inspection equipment.
- Product Specifications (PRD) may be created for products that are not suited for drawings.
- Purchase Specifications (PRS) define purchased items or material not appropriate for drawings.
- Workmanship Standards (WS) provide examples of qualitative references.
- Forms are used to define some activities, record inspection results, production data, or specific measurements.
- Run Sheets (RS) are used to record the master process and forming parameters for specific products.
- Lab Notebooks record design and development activities.
- Protocols and associated Reports define test and validation plans and their results.
- Approved Supplier List shows the suppliers that may be used to purchase inventory items and certain key manufacturing materials.

Included in Level 3 documentation are quality records that serve as evidence of the performance of all activities that impact product quality.

- Device Master Records (DMRs) containing product specifications, procedures for manufacture and inspections consist of the Level III documents records (drawings, work instructions, process instructions, inspection procedures, specifications, travelers, forms, etc.).

- Device History Records (DHR) or Lot History Records (LHR) also known as lot history folders, consist of process/manufacturing/inspection records for each lot.
- Design History File (DHF) contains design and development history for product, such as product requirements, design and development plan, FMEA/risk analysis, quality plan, design change records, validation documents etc.

Where Confluent Medical Technologies owns a specific design then a Device Master File (DMF) will be used. The DMF contains the Device Master Record (DMR) and the Design Dossier.

4.2.3 Medical Device File

When Confluent Medical Technologies is a Contract Manufacturer for and not the Legal Manufacturer of the Customer's medical device; then 4.2.3 Medical Device File requirements of ISO 13485:2016 does not apply and is considered a non-application. As the Contract Manufacturer, the customer documents (e.g. Device Master Record, Component Specification/Drawings) for the component supplied to Customer are retained in accordance to OP-9016, Quality Records.

When Fremont facility is the legal manufacturer and Costa Rica facility is the manufacturing site of a medical device, both facilities share the respective responsibilities. For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to the requirement of ISO 134845:2016 and compliance with applicable regulatory requirements.

The content of the file(s) shall include, but is not limited to:

- General description of the medical device, intended use/purpose, and labeling, including any instructions for use;
- Specifications for product;
- Specifications or procedures for manufacturing, packaging, storage, handling and distribution;
- Procedures for measuring and monitoring;
- As appropriate, requirements for installation;
- As appropriate, procedure for servicing.

4.2.4 Control of Documents

Documents that define products, processes, and the quality system are approved before controlled release and distribution. Documents are available for use in the locations required as well as electronically. Obsolete documents are removed when superseded. External documents such as industry or agency standards and customer drawings are controlled. Quality Assurance Document Control provides document control services; however, all employees are responsible for using correct documents, at the prescribed revision level, at all times.

Obsolete documents are retained for a period specified in the operating company's local procedure for Quality Records.

External documents are controlled and issued to ensure use of correct documents and current revisions. Such documents include external customer documents (such as drawings and specifications) and other external documents, such as industry standards.

4.2.4.1 Approval and issue

Controlled Documents are approved by the individuals assigned per local Document Control procedures, using local document control systems. The document control procedure is also available to approve changes in development items. Controlled copies are issued to the individuals or work areas that require them for day-to-day use. Uncontrolled reference copies may also be provided. Control status is indicated by the use of stamps with red ink on hard copies. Indexes are maintained. Documents are also maintained on-line as read only in the document control system.

4.2.4.2 Initial release and changes

Initial releases and changes are processed using the local document control processes. The changes are reviewed and approved per local Document Control procedures. Changes to associated documents are initiated as part of the document control approval cycle. A history of changes is maintained for approved documentation.

4.2.5 Control of Records

Quality records are created and maintained to provide documented evidence of the conformance of products and systems to specifications and process requirements. The records are identified, indexed, and stored to prevent deterioration and provide access in a reasonable period of time. Secrecy, Confidentiality, and Nondisclosure Agreements may govern customer access to records.

4.2.5.1 Identification of Quality Records

All documents that establish the history of the product and supporting systems are considered quality records. Exclusions include production or inspection tally sheets that are summarized on other records.

4.2.5.2 Filing and Storage

For product, quality records are filed with the Lot History File or Work Order File. System records are filed by in accordance with site-specific procedures.

4.2.5.3 Retention

Records on all media are retained that (1) are required by law; (2) necessary to support the orderly operation of the Company; or (3) provide the basis for recovery from a disaster. All other records will be destroyed. Retention guidelines are stated in local Quality Record procedure(s).

5 Management Responsibility

5.1 Management Commitment

The progress of the business and the effectiveness of the quality system are reviewed on a regular basis by Management with Executive Responsibility.

Management with executive responsibility (executive management) is responsible for establishing, implementing, and continuously improving the quality system.

Management is responsible for establishing the quality policy.

Personnel and other necessary resources are provided to accomplish the goals of the quality system.

There are several processes by which executive management communicates to the rest of the company regarding customer, regulatory and statutory requirements and the importance of meeting these requirements.

Informational meetings, plant meetings are conducted periodically.

Management Reviews, internal and external audits are conducted periodically to ensure that the Quality System is effective.

Management Review is the mechanism by which opportunities to improve are identified and resources are allocated to achieve those improvements. Quality objectives are defined at these reviews. Personnel and other necessary resources are provided to accomplish the goals of the quality system.

5.2 Customer Focus

In addition to communicating the importance of meeting customer requirements, top management ensures that customer requirements are determined, understood and met. Processes have been established to ensure device customer safety and efficacy.

Within the scope of the quality management system, contracts and agreements are defined and reviewed between Confluent Medical Technologies and its customers for work to be performed or product to be delivered. Requests for Quotations (RFQ) and Purchase Orders (PO) are reviewed to assure that requirements are defined and understood, and that Confluent Medical Technologies can meet the requirements.

The individual receiving the RFQ or PO (the Recipient) sponsors a Contract Review. Representatives of Sales/Customer Service, Operations (production), QA, and the Manufacturing Engineering participate in the Review, as necessary. Others may be included as needed.

The review assures that the customer's requirements are defined, documented, and understood and that they can be met. Reviews include as a minimum: specification requirements, documentation, manufacturability, price and delivery. Differences and/or specification conflicts are resolved before approving the Contract Review and accepting an order.

Initial reviews are approved by Managers, Directors, or higher levels in the organization. Repeat orders with previously reviewed requirements may be reviewed and approved by the Recipient. Results of the Contract Review are documented and maintained as records and are filed by Sales/Customer Service in the Customer Order File.

5.3 Confluent Medical Technologies Quality Policy

The Confluent Medical Technologies Quality Policy is defined in Section 3.1 of this Quality Manual. The quality policy is communicated and understood within Confluent Medical Technologies and is reviewed periodically by top management.

The quality objectives derived from the quality policy are reviewed annually and updated as needed by top management to maintain effectiveness of and compliance to the quality management system. (Section 3.2 of this Quality Manual)

5.4 Planning

5.4.1 Quality Objectives

The company management team is responsible for setting quality objectives and goals for the company. Functional Managers establish goals and objectives that are aligned with company goals for their departments.

5.4.2 Quality Management System Planning

The planning for Quality Management System is carried out by executive management during management review meetings. Quality objectives are set and reviewed during these meetings. When a change is made to the quality system as a result of an internal audit or management decision, it is reviewed for effectiveness and appropriate justification and approvals are required to implement the change.

5.5 Responsibility, authority and communication

The Company is organized as shown on the site organization charts. Approved organization charts are maintained by the Human Resources department and distributed upon need or as requested. Some individuals perform multiple roles; however, the roles and responsibilities relating to quality are clearly defined in later sections of the Quality Manual, job descriptions, or in other procedures. Independence and authority necessary to manage, perform, and assess tasks affecting quality are maintained by top management.

Job descriptions are assigned by department managers and are available in the manager's offices or maintained by Human Resources. Local supplementation by individual supervisors is permitted as required.

5.5.1 Responsibility and Authority

5.5.1.1 Executive Management

Establish and support the quality policy by providing the necessary resources.

Establish quality goals and objectives for the company.

5.5.1.2 Engineers

5.5.1.2.1 Process Engineers

Establish and document production processes that consistently meet product requirements.

Install and qualify/validate production processes.

Train, verify, and certify skills of operators on assigned processes.

Review and approve process and supporting documents for initial release and changes.

5.5.1.2.2 Product (Design) Engineers

Coordinate functional and other technical requirements with customers or design sponsor.

Design and initiate specification documentation for Confluent Medical Technologies designed products.

Review and approve product and supporting documents for initial release and changes.

Coordinate Design Control activities on assigned products.

Initiate travelers and other required documents for prototype or developmental products.

5.5.1.2.3 Manufacturing Engineers

Support ongoing manufacturing, through capability and quality improvement activities.

Initiate, review, and approve manufacturing and supporting documents.

Maintain validation status of processes in assigned areas.

5.5.1.3 Operations Vice-President/Director

Management of planning, throughput, production resources, process improvement activities for manufactured products and other requirements as necessary.

5.5.1.4 Value Stream Leader/Operations Leader

Maintain positive identification and traceability of product in the areas managed.

Manage production resources.

Monitor and control production processes.

Implement production documentation.

Assign trained/certified personnel to standard production processes.

Initiate production travelers for standard products.

Facilities Management for Confluent Medical Technologies building

Report utilities usage and cost to executive management

Manage Safety and Environmental compliance matters

5.5.1.5 Vice President, Quality Assurance and Regulatory Affairs

Management Representative for Confluent Medical Technology reports directly to the President of Confluent Medical Technology.

Coordinate and manage company quality assurance and regulatory issues.

Establish and maintain the quality management system.

Develop Quality Plans for principle products and product lines.

Develop Inspection Plans and supporting documents that specify inspection and test requirements and sampling levels.

Maintain positive control of nonconforming material and product.

Coordinate and carry out supplier quality assessments.

Maintain the calibration system.

Maintain the document control system.

Initiate and monitor corrective/preventive actions.

Review and analyze returned material.

Assess and improve measurement capability.

Coordinate internal audits and associated corrective actions.

Prepare certifications and other required quality documentation in support of shipping.

Qualify and approve personnel performing verification activities.

5.5.2 Management Representative

The Vice President of Quality Assurance and Regulatory Affairs, is the company's Management Representative. The Vice President of Quality Assurance and Regulatory Affairs has delegated the duties and responsibilities of the Management Representative to the Local Site Director or Manger of Quality Assurance.

The Management Representative is responsible for:

- Ensuring that processes needed for the quality management system are documented;
- Reporting to top management on the effectiveness of the quality management system and any need for improvement;
- Ensuring the promotion of awareness of applicable regulatory requirements and quality management requirements throughout the organization;
- Serving as the company's liaison with customers and other outside concerns on matters related to product quality and reliability.

5.5.3 Internal Communication

Management Indicators are established by Management with Executive Responsibility to provide visibility of key operations and performance. Indicators are added, deleted, and modified to suit current conditions and areas of emphasis. The indicators are generated periodically, distributed electronically and hard copies are also posted.

On a periodic basis, Management with Executive Responsibility will disseminate information regarding the state of the business.

5.6 Management Review

5.6.1 General

On a periodic basis, at least once a year, the Vice-President of Quality Assurance and Regulatory Affairs, or designee, will call a Management Review Meeting for Management with Executive Responsibility. Management Review covers site-specific performance and may be conducted as a consolidated review or site-specific reviews, at management discretion.

Management Review Meeting Minutes are prepared and circulated by the VP of Quality Assurance and Regulatory Affairs (or delegate) as required to provide pertinent information regarding quality of product and services or the effectiveness of the quality management system.

Management Indicators are established by Management with Executive Responsibility to provide visibility of key operations and performance. Indicators are added, deleted, and modified to suit current conditions and areas of emphasis. These indicators are reviewed as operations and quality metrics at varying times throughout the year.

5.6.2 Management Review Input

On a periodic basis, the VP of Quality Assurance and Regulatory Affairs, or designee will call a Management Review Meeting for the group of people identified

as Management with Executive Responsibility. Others may be invited to participate as required.

The agenda includes the topics such as Management Indicators, customer service and feedback, complaint handling, reporting to regulatory authorities, audit results monitoring and measurement of processes, monitoring and measurement of product, corrective and preventive action, follow-up actions from previous management reviews, changes that could affect the quality management system, recommendations for improvement, and applicable new or revised regulatory requirements. Other topics may be added as deemed appropriate.

5.6.3 Management Review Output

The VP of Quality Assurance and Regulatory Affairs or designee takes minutes of the meeting including a record of those attending, action items assigned, progress on ongoing actions, improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes, recommended improvements to product related to customer requirements, quality system and processes, resource needs, changes needed to respond to applicable new or revised regulatory requirements, and other pertinent summary information. A management review report is generated for each meeting and approved by Management with Executive Responsibility. Unless otherwise indicated, the report should include a statement to the effect that the Quality System is suitable and effective based on information reviewed and actions taken or assigned.

6 Resource Management

6.1 Provision of resources

6.1.1 General

Top Management determines and provides the resources necessary for the implementation, maintenance, and continual improvement of the entire quality system and to meet applicable regulatory and customer requirements. Top Management assigns appropriate resources to enhance customer satisfaction through meeting customer requirements.

6.1.2 Resource Determination

Top Management determines appropriate resource needs during periodic business reviews and during Management Review. Resource needs are established through consideration of customer satisfaction and quality management improvements. Top Management considers all resources necessary to accomplish these needs, including personnel, facilities, equipment and finances.

6.2 Human Resources

6.2.1 General

6.2.1.1 Qualification Documentation

Written job descriptions are in place for all activities affecting product quality to document the qualifications and duties of the positions determined to be necessary by Top Management.

6.2.1.2 Assignment of Resources

Resources are assigned based on experience, education, skills and training to appropriate tasks to meet established business and quality objectives.

6.2.2 Competence, Awareness and Training

6.2.2.1 Competence

Competency requirements are determined for each position through establishment of appropriate performance goals for the written job description. Performance monitoring and performance management are integrated into operations to ensure that assigned personnel are fulfilling requirements satisfactorily. In the case where personnel are not performing satisfactorily, performance management tools and appropriate training are used to correct unsatisfactory performance.

6.2.2.2 Awareness

The required training for each position includes training on the impact of their position on quality objectives and the quality management system.

6.2.2.3 Training

Training is conducted on a regular basis according to the requirements specified in the training procedures, this includes training to regulations, safety etc. New employees go through a series of training, so they have a thorough understanding of the company, product, customer and regulatory requirements.

Training needs are documented for each position via supervisor input and specific minimum requirements detailed in the training operating procedure. Completion of training requirements is verified prior to assignment to work. Training activities include a verification of training effectiveness and appropriate refresher training.

The training procedure ensures that personnel understand both the job function and the GMP requirements, including how the job relates to the overall quality system. In addition, personnel are trained to ensure that the consequences of improper performance are understood so that employees are aware of defects that they should look for and of the effect their actions can have on the safety and effectiveness of the device.

Training Records for both internal and external training are maintained. The Human Resources department maintains records of education, skills and experience in personnel files.

6.3 Infrastructure

Top Management establishes the facilities, workspace, hardware, equipment, software and supporting services necessary to achieve conformity of product. These requirements are monitored through various metrics to ensure adequacy and modified when appropriate to ensure conformity of product.

6.4 Work Environment and Contamination Control

6.4.1 Work Environment

Top management defines responsibilities, practices, and procedures for managing Environmental, (Industrial) Health, and Safety (EH&S) activities. The procedures

will provide direction and procedures for implementation of requirements established by governmental and other applicable regulatory agencies. Top management is responsible for establishing appropriate work methods, safety rules, protective equipment and ergonomics to ensure conforming product, and cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance. The adequacy of these controls is periodically assessed and corrective actions taken; as needed.

6.4.2 Contamination Control

Confluent Medical Technologies has procedures, such as such as gowning instructions, cleanroom transfer instructions, cleanroom monitoring instructions, and biological testing for specialized controlled environments to minimize contamination. In addition, these procedures control contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, Confluent Medical Technologies has cleanroom monitoring instructions and biological testing procedure for control of contamination with microorganisms or particulate matter with maintaining the required cleanliness during assembly or packaging processes.

7 Product Realization

7.1 Planning of product realization

Quality planning occurs throughout the product life cycle. Typical planning activities and the responsible people are defined in detailed Operating Procedures and Quality Plans and include:

- Review and documentation of customer requirements, including Design Inputs for new products.
- Identification and acquisition of necessary resources (equipment, personnel and associated skills, processes, controls, monitoring devices, inspection and test equipment, etc.).
- Identification of advanced measurement requirements that must be developed or acquired.
- Risk management throughout the product realization cycle.
- Identification of verification activities at appropriate steps in the process.
- Identification of Design Verification and Validation activities
- Establishment of workmanship standards.
- Identification of required records (including records of risk management activities).
- Identification of certification and test report requirements.

Inspection and testing is planned and conducted when purchased materials and components are received, at key stages of processing, and before release of product. Inspections are conducted according to approved plans. Qualified individuals from any organization may perform inspections and record results. Inspections may utilize data prepared by others to make decisions when specified in the Inspection Plan. Employees of QA/QC, or those

specifically delegated, must close out all Inspection Plans. Records are made of inspections specified in the Inspection Plan.

7.2 Customer related processes

7.2.1 Determination of requirements related to the product

Within the scope of the quality management system, contracts are defined as any agreement between Confluent Medical Technologies and a customer that defines work to be performed or product to be delivered. Requests for Quotations (RFQ) and Purchase Orders (PO) are reviewed to assure that requirements are defined and understood, and that Confluent Medical Technologies can meet the requirements.

For new product development design requirements or inputs are collected from many sources, including customers, suppliers, and professionals in the field of use, similar products, and others. The inputs are documented, subject to initial approval, and modifications are approved at later reviews as required.

7.2.2 Review of requirements related to the product

Contract review assures that the customer's requirements are defined, documented, and understood and that they can be met. Reviews include as a minimum: specification requirements, documentation, manufacturability, applicable regulatory requirements, price and delivery. Contract or order requests differences and/or specification conflicts are resolved before approving the Contract Review and accepting an order.

A Specification Review is conducted when a technical review of customer specifications is required.

Records of Contract Review and Spec reviews are maintained.

7.2.3 Customer communication

If customer requirements or specifications cannot be met, the information is communicated to the customer. Amendments to the contract may be made with the approval of the customer. Where no change agreements are in place, proper notification and authorization is required prior to implementation of improvements.

Where a component is included in a finished medical device sold by medical device companies, the company will respond to requests and inquiries in support of the complaint investigation led by the seller. Such requests are entered into the complaint system for tracking and into the Corrective and Preventive Action system if action is required.

The complaint handling procedure is also used to manage the resolution of complaints received on company products that are not finished medical devices.

7.3 Design and Development

As a developer and manufacturer of components for both medical and commercial applications (with the exception of Confluent Medical Technologies finished devices), Confluent Medical Technologies does not complete full design and development cycles for many new products. The designs typically originate at other sites or from the customer and the overall design control responsibility lies with them. However, within the scope of our involvement with the overall development project, Confluent Medical Technologies will adhere to design control procedures. Where Confluent Medical Technologies yields

to another site's design control procedures, a copy of the Design History File (DHF) index or table of contents will be maintained at Confluent Medical Technologies.

In the case of Confluent Medical Technologies finished devices (Confluent Medical Technologies sponsored design), Design Control procedures including Design Verification and Validation procedures are followed. Design Control activities are managed by the Fremont campus, while individual tasks may be executed at other sites depending on availability of resources.

The company Design Control/New Product Development procedures are intended to balance the freedom to innovate and the discipline required to consistently meet customer and regulatory requirements. Design activities before the formal documentation of Design Inputs are at the discretion of the engineer, and records are kept in laboratory notebooks. After the formal establishment of the Design Inputs, design activities are planned, controlled, and regularly reviewed/approved. The Design History File is maintained by the design team leader during the development process and then turned in to Document Control for archiving after the project is complete.

The procedures apply to design activities for which Confluent Medical Technologies is solely or partly responsible. For those design activities in which Confluent Medical Technologies is supporting other companies, the procedures of the sponsoring company may be used.

7.3.1 General

Confluent Medical Technologies has documented Design Control procedures for design and development.

7.3.2 Design and development planning

The product development team leader is responsible for documenting and updating the overall plan, which identifies activities, schedules, and responsibilities. The product development team leader coordinates organizational and technical interfaces, including information transfers and reviews.

7.3.3 Design and development inputs

Design inputs are collected from many sources, including customers, suppliers, professionals in the field of use, similar products, and others. The inputs are documented, subject to initial approval, and modifications are approved at later reviews as required.

Product requirements are defined, documented and approved. The requirements are generally maintained in the Design History File (DHF) during the development phase.

Risk Management: Design, application and manufacturing failures are considered via a controlled and approved process to minimize the potential impact to patients and users of the products manufactured by Confluent Medical Technology.

Overall strategic programs and tasks are developed to ensure this risk management occurs before, during and after launch. Data generated by these activities are reviewed to assess any needed changes to existing processes or designs.

7.3.4 Design and development outputs

Design outputs are documented and are compared to design inputs to assure that input requirements are met. Design outputs include, but are not limited to, design

and material specifications, testing and technical reports, drawings, work instructions and quality assurance procedures. Design outputs are reviewed and approved during design reviews that occur at various stages of the design effort, but particularly before sales release. Design output documentation is contained in the Device Master Record (DMR).

7.3.5 Design and development review

Design Reviews are held at key milestones. Individuals and management with responsibility for design activities participate and approve the results and plans. Minutes of the reviews are published, and identify all outstanding action items and who is responsible for resolving them. Initial and final reviews are required, but others may be scheduled as necessary, depending upon the scope of the project.

An initial review is done that formally establishes the basic concept feasibility, Design Inputs, and assigns resources.

An intermediate review may be done during product design and process development. The review confirms that design output meet design input requirements. For medical applications, a review is done prior to beginning human-use trials (first-in-man or clinical use). The review specifically focuses on confirmation of product safety.

A final review is done before product launch (sales release). The review confirms that Design Outputs meet Design Input requirements.

For Confluent Medical Technologies sponsored designs involving Confluent Medical Technologies controlled clinical studies, a Clinical Release Design Review is also required to assure the safety of the pre-production material for human use.

7.3.6 Design and development verification

Design verification is the confirmation that the design output is appropriate to produce a product that meets product specification requirements. Records of verifications performed are approved and maintained indicating the acceptability of inspection and test results.

7.3.7 Design and development validation

Design validation means establishing by objective evidence that device specifications conform with user needs and intended use. Records of design validations are approved and maintained indicating the acceptability of the studies.

7.3.8 Design and development transfer

Design transfer is the process of assuring that the design is correctly translated into production specifications. All specifications released to production are approved and under formal change control. Operators are trained. The Device Master Record (DMR) is complete. Processes are validated via equipment qualification (installation and operational qualification), process qualification and product performance qualification.

7.3.9 Control of design and development changes

Changes are evaluated as to the impact on the design's safety and efficacy as well as on regulatory strategy / issues. The appropriate verification / validation, review, and approval of the change is required before the implementation of the change. Design changes are documented and maintained in the Design History File.

7.3.10 Design and development files

A DHF is maintained for all designs, with all records necessary to demonstrate that the design was developed according to the design plan, to established procedures and to applicable regulatory requirements. Where Confluent Medical Technologies contributed design activities to the project, Confluent Medical Technologies will maintain a copy of the project Design History File index (table of contents) as well as copies of all design-related items generated by Confluent Medical Technologies. In projects where Confluent Medical Technologies did not participate in design activities, no DHF content will be retained.

7.4 Purchasing

Confluent Medical Technologies purchases supplies and subcontracted products/services from those that can satisfy quality, technical, and delivery requirements. Within the scope, suppliers and subcontractors are evaluated to determine their capability, and approved suppliers are used to purchase items and services. Purchasing documents clearly describe the product or service to be purchased, including quality requirements. Purchasing documents are reviewed and approved prior to release.

7.4.1 Purchasing process

The provisions of this section apply to materials, products, and services incorporated into Confluent Medical Technologies' products, typically referred to as inventory items. It also applies to value-added services, key manufacturing supplies, and services required by the quality management system. Common operating supplies and consumables use the same purchasing execution systems; however, controls are modified.

Suppliers are evaluated and approved based on their demonstrated or potential ability to meet quality, delivery, and price requirements. Evaluation and approval methods are defined. Suppliers are monitored to supplier performance to meet requirements of the purchased products. In addition, the results of the monitoring provide input into the supplier re-evaluation process and identify re-evaluation of specified suppliers per the Supplier Management procedure. Non-fulfillment of purchasing requirements are addressed with the supplier proportionate to the risk-associated with the purchased product and compliance with applicable regulatory requirements within the Supplier Management procedure.

Results of the evaluation aid in determining the approach to assuring the quality of a supplier's product; i.e., the level and intensity of inspection to be performed on receipt.

Approved Suppliers are documented in the purchasing system and the approved supplier list is managed in that system.

7.4.2 Purchasing information

Requirements for purchased products are defined in the Purchase Order (PO) and referenced documents. Referenced documents must include the Revision Level, if applicable. The reviewer/approver of the PO is responsible for reviewing the adequacy of the data, such as:

- description of item/material/service purchased
- quality or performance requirements
- certification and other documentation requirements

- indication of Company requirements, such as calibration, inspection, etc.
- use of approved suppliers

The reviewer/approver signs the Purchase Order indicating the accomplishment of the above review.

Reviewer/approver status is established.

Suppliers are requested to enter into an agreement to notify the company of any process or material changes that may affect the quality of the company's product.

7.4.3 Verification of purchased product

Within the scope, purchased product is inspected upon receipt to the extent necessary to verify conformance to requirements. The extent of verification activities are based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When Confluent Medical Technologies becomes aware of any changes to the purchased product, then it is necessary to determine whether the changes affect the product realization process or when Confluent Medical Technologies is the legal manufacturer to determine whether the changes affect the product realization of the medical device. Records of the inspection are kept.

Inspection and testing is planned and conducted when purchased materials and components are received. Inspections are conducted according to approved plans. Qualified individuals from any organization may perform inspections and record results. Inspections may utilize data prepared by others to make decisions when specified in the Inspection Plan. Qualified inspectors or those specifically delegated must close out all Inspection Plans. Records are made of inspections specified in the Inspection Plan.

For serious or repeated quality problems with a supplier, a Supplier Corrective Action Request (SCAR) is prepared and sent to the supplier for corrective action and response. Follow-ups are performed as required.

Verification at Subcontractor's Premises – When necessary or desirable to verify product at a subcontractor's facility, that requirement is cited in the Purchase Order.

Customer Verification of Subcontracted Product – Verification of subcontracted product by customers may be arranged on a case-by-case basis, and should be specified in the Purchase Order or contract.

7.5 Production and Service Provision

7.5.1 Control of production and service provision

Production operations that affect quality are planned and carried out under controlled conditions. Adequate processes and documented procedures are used. Work instructions are prepared to provide for uniform accomplishment of processes where the traveler cannot provide sufficient detail. Processing equipment is checked and maintained to provide consistent performance. Production areas are appropriately clean and suitable for the operation performed and the material processed.

Key processing equipment is evaluated prior to use / installation and/or during its lifetime to determine or change maintenance schedules. The engineer is responsible for identifying equipment to be included in the schedule, the frequency of

maintenance or verification, and the acceptable operating tolerances. The Operations (Production) Manager (or above) is responsible for execution of the schedule and any required actions, and the collection of records. Records indicate the action performed, the date performed, who performed it, and any actions taken. The schedule is maintained by the Operations (Production) Manager. When equipment which has missed a maintenance due date is used for production, a nonconformance is generated. The NCR includes an investigation of the reason(s) that the equipment has not been maintained and a disposition for use of the equipment and any material that was produced on the equipment after the due date.

The operations group is responsible for producing and maintaining demand schedules for the manufacturing areas. This is accomplished through the coordination of sales activities with material availability and manufacturing capabilities. A backlog of deliverable orders is generated and reviewed. As a result of these reviews, manufacturing and inspection activities are coordinated and performed.

The traveler is a controlled document that defines the source material(s), the sequence of operations, processing instructions, and verification steps.

Processing instructions are authored in accordance with local procedures. When processing instructions are lengthy (usually when they exceed three lines on a traveler), or an inspection/test procedure is complicated, a Work Instruction or Manufacturing Procedure is prepared and available at the work site. The traveler or Inspection Plan references the Work Instruction at the appropriate step.

Workmanship standards are created as retained samples, photographs, or written descriptions. The preferred sample is the "worst acceptable" or “limit” condition. Establishment of and changes to standards are performed as needed. The approval is on a tag or other document physically attached to the sample or via the document control process.

Inspection Plans are used to perform receiving, in-process and final inspections. Based on the result of the inspections, product is dispositioned.

The mode of delivery is as specified by the customer. Requirements are entered with the order and appear on the Packing Slip.

7.5.2 Cleanliness of product

Confluent Medical Technologies production varies in regards to needs for cleanliness and contamination controls. Product generally falls under one of two potential cleanliness needs.

- Product is delivered sterile and in its final packaging – in this case, Confluent Medical Technologies is fully responsible for determining and documenting the associated processes of cleaning and sterilization and validating such processes. Additionally, Confluent Medical Technologies is responsible for documenting the sterilization parameters for each production batch/lot.

- Product is delivered to the customer for additional processing or packaging in a “sufficiently clean” state to meet the customer’s needs – in this case, the

customer works with Confluent Medical Technologies to establish the proper process for cleanliness.

7.5.3 Installation Activities

Confluent Medical Technologies does not provide installation for the customers as a Contract Manufacturer and as a Legal Manufacturer; therefore Installation Activities is non-applicable for all sites.

7.5.4 Servicing Activities

Confluent Medical Technologies does not provide servicing for the customers as a Contract Manufacturer; therefore 7.5.4 Servicing Activities is non-applicable for all sites.

7.5.5 Particular Requirements for Sterile Medical Devices

Confluent Medical Technologies has sterilization processes that maintains records of the sterilization process parameters used for each sterilization batch. Each sterilization record(s) are traceable to each production batch of medical devices that Confluent Medical Technologies manufacture as a manufacturing site for required customers and as the Legal Manufacturer of a product device.

7.5.6 Validation of Processes for Production and Service Provision

Where characteristics cannot be checked after processing, processes are validated (qualified) and/or monitored to assure adequate results are obtained. Software that is used to make decisions in the manufacture or evaluation of product that directly affects product quality is validated. Software that is used to control manufacturing processes or perform calculations is verified to ensure it performs as intended.

When changes are made to a process, revalidation may be required. Revalidation procedures are documented in accordance with local procedures.

Validated equipment shall be identified after validation is complete. Such equipment shall be operated by trained personnel only.

Sterilization processes are validated and records are kept of process settings for each batch/lot.

7.5.7 Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems

When Confluent Medical Technologies is the manufacturing site as a customer requirement to build product devices to final packaging assembly or is the Legal Manufacturer for a medical device there are documented procedures for the validation of processes for sterilization and sterile barrier systems within the quality management system.

7.5.8 Identification

Products are identified by description and the lot number.

The part and/or product description is assigned, and typically provides a description of the item and/or a link to the technical documentation. All product is identified to that description and a unique lot number through the use of tags or labels. Batches/partials may be assigned within a lot. Devices and components are serialized when necessary or appropriate.

Assigned descriptions are recorded in the company materials management system. Lot numbers are assigned by the materials management system for received and manufactured items. Production lots are made from the same source material lot(s) and the same setup. Batch numbers may be established within a production lot as required to expedite or facilitate processing. The Lot History File (Device History Record for finished devices) contains all pertinent records of lot, batch, and serial number assignment.

The status of product is clearly identified to assure that only product of known conforming quality is used, installed, or shipped. The status of product is identified by use of labels or tags, the completion status of travelers and quality plans, or its presence in a labeled location.

7.5.9 Traceability

7.5.9.1 General

Traceability from the lot number to precursor lot numbers and the source material is maintained.

7.5.9.2 Particular requirements for implantable medical devices

Non-application for all Confluent Medical Technologies Sites, for there are no implantable medical devices.

7.5.10 Customer property

Customer-supplied product is treated in the same manner as other received material or components. Verification is performed and traceability is maintained as required. Customer supplied product is clearly identified, handled and segregated in a manner that prevents damage and/or mix-ups.

Customer supplied material is labeled and entered into the inventory system indicating the ownership. Product provided for conversion (value-added processing) is maintained with the customer's identification until the conversion is complete.

Traceability is maintained to the material or product received from customers.

If there are discrepancies noted at any time, the customer is notified for disposition instructions.

7.5.11 Preservation of product

The company operates in a clean industrial environment or cleanroom as appropriate for the product being manufactured. Materials and products are managed to prevent damage and significant contamination during all stages of post-manufacturing.

Where special handling is required to prevent damage, precautions are taken on a case-by-case basis. Requirements are specified on specifications, travelers, packing slips, or other documents as appropriate.

Material and parts are stored in locations tracked by the company system. All material in storage is clearly identified as to description and inspection status.

Standard packaging procedures are described in Work Instructions or Travelers. Unique, customer-specific requirements are entered with the order and appear on the Packing Slip at time of shipment.

Generally, preservation, is not applicable or an issue due to the nature of the material.

7.6 Control of monitoring and measuring equipment

All inspection, measuring, and test equipment that affects product quality is controlled, calibrated, and maintained. Personally owned equipment within that scope is included. Calibration is traceable to the NIST or appropriate physical standard. All equipment is labeled as to its status in the calibration system. Equipment is selected to support the accuracy required by the product drawing or specification. Test equipment software is controlled.

Inspection, measuring, and test equipment is selected to provide the appropriate level of accuracy and precision required.

A master list is maintained in the company database of all equipment in the calibration system. Items excluded from the calibration system are recorded and a rationale for that exclusion is recorded. Items are labeled with the corresponding calibration status.

Items that require maintenance are listed on the Preventive Maintenance Database, which shows the identification, location, tasks to be performed, and the maintenance cycle. The database reflects the accomplishment of the maintenance; detailed records may be kept at the location of the maintained item.

Calibration services may be performed internally by controlled procedure or through outside services in compliance to Purchase Specifications.

8 Measurement, Analysis and Improvement

8.1 General

To ensure product conformity to specification, inspection and testing is planned and conducted when purchased materials and components are received, at key stages of processing, and before release of product. Inspections are conducted according to approved inspection plans. Records are made of inspections specified in the Inspection Plan.

Customer satisfaction is monitored and measured using several sources. The information from these sources is reviewed at the management review meetings.

Internal Audits are conducted to ensure conformity and effectiveness of the quality management system. The results of such audits are reviewed at the management review meetings.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems. Statistical Process Control (SPC) and Design of Experiment (DOE) techniques are applied where appropriate for measurement, analysis and improvement.

Statistically valid sampling plans are selected to assure the adequate control of quality. Statistically valid methods are used to determine sample sizes in the evaluation of processes and product characteristics.

8.2 Monitoring and measurement

8.2.1 Feedback

Customer satisfaction is monitored and measured primarily through customer complaints, returned goods and delivery information. The information from these

sources is reviewed at the management review meetings. Other indicators or sources for customer satisfaction used at Confluent Medical Technologies include sales volume tracking, customer audits, customer provided supplier ratings, etc.

8.2.1.1 Returned Goods

Customer satisfaction is also tracked through the number of returns from the customer. Returns to the company are authorized by a Return Authorization (RA) number. The percent returns and the dollar amount of returns vs. shipments are tracked and trended. Target goals have been set for both indicators. The reason for the return is also recorded. The data is reviewed at management review meetings and appropriate actions taken as necessary.

8.2.1.2 Delivery

The mode of delivery of product is specified by the customer. The delivery requirements are entered with the order and appear on the Packing Slip. Delivery information is tracked and trended. Target goals have been set.

Delivery indicators that are tracked and trended are % on-time delivery and average days late. The data is reviewed at management review meetings and appropriate actions taken as necessary.

8.2.1.3 Other Customer Satisfaction Indicators

Other indicators or sources used to monitor customer satisfaction are:

- Sales forecast and volume reviewed periodically to determine if sales plan is being met or if adjustments are necessary based on specific customer feedback.
- Customer Audits performed by some customers will be documented at the customer's discretion. These customer audit results are reviewed by management and retained.
- Customer supplier ratings provided by some customers

8.2.2 Complaint Handling

Procedures are established to manage the resolution of complaints received on all Confluent Medical Technologies products. Where a product is included in a finished medical device sold by medical device manufacturing companies, the company will respond to requests and inquiries in support of the complaint investigation led by the seller. Such requests are entered into the complaint system for tracking, and into the Corrective and Preventive Action system if action is required. A complaint may also be issued when a corrective action request is initiated by a customer.

US FDA Medical Device Reporting requirements are coordinated by the medical device manufacturer. EU Vigilance Reporting is coordinated by the medical device manufacturer.

Confluent Medical Technologies will notify the competent authorities immediately when becoming aware of any malfunction or deterioration of a device as well as inadequacy of Instructions for Use, which might lead to or led to death or serious deterioration of health.

Confluent Medical Technologies will notify the competent authorities immediately when becoming aware of any technical/medical reason leading to recall.

Customer complaints are examined for systemic issues during Management Review and when appropriate, Management issues Corrective Actions to address identified issues.

The overall complaint management system is managed by the Fremont site, with participation by other sites as needed. Field complaints, where patient impact may be reported are managed by the Fremont site.

8.2.3 Reporting to Regulatory Authorities

When Confluent Medical Technologies is the Legal Manufacturer for a medical device there are procedures within the quality management system when complaints meet specified reporting criteria of adverse events or issuance of advisory notices for providing notifications to the appropriate regulatory authorities in compliance to the applicable regulatory requirements.

8.2.4 Internal Audit

Audits of the quality system are performed on a scheduled basis to measure compliance to applicable standards and the effectiveness of the quality system. Qualified employees or outside consultants perform the audits. The auditor must have no direct responsibility for the area audited. Audit results are subject to Management Review.

8.2.4.1 Audit Schedules

All elements of the quality system are audited on an annual basis. A tolerance of plus or minus one calendar quarter is permitted.

8.2.4.2 Audit Plans

Checklists are created to allow systematic and efficient auditing. Known issues and the history of the area or element audited may be used to develop areas of concentration.

8.2.4.3 Audit Results

Each audit generates a report and requests for corrective action, if necessary. Audit corrective actions are logged and managed according to the Corrective and Preventive Action system; however, the records of the Internal Audits are considered company-confidential.

8.2.4.4 Follow-up

Where corrective action is required, it is verified by the original auditor or another qualified individual. The adequacy of follow-up is audited during subsequent audits and/or during the annual audit of the internal audit system. Records of the follow-up are kept.

8.2.5 Monitoring and Measurement of Processes

The key quality management system processes at Confluent Medical Technologies have been identified as:

- Supplier Management
- Process Control

- Handling, Storage, Packaging and Delivery
- Resources (Personnel, Facilities, Equipment)
- Document Control
- Regulatory Requirements

The following methods are in place to measure and monitor the above processes:

- Internal Quality Audits
- Other internal audits (workstation practices audit, line clearance audits, etc.)
- Customer Satisfaction (Complaints, Delivery and Returns)
- Product Acceptance/ non-conformance
- Management Review process

The intended purposes of the above key processes are quantified by output of the processes, such as conformance to product specifications, yields, etc.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems. Statistical Process Control (SPC) and Design of Experiment (DOE) techniques are applied where appropriate.

Statistically valid sampling plans are selected to assure the adequate control of quality. Statistically valid methods are used to determine sample sizes in the evaluation of processes and product characteristics.

Procedures are developed and used to assure uniform application of the techniques selected.

Processes are evaluated to determine the statistical capability, and improvements and/or the application of SPC may be utilized to provide capable processes. DOE techniques may be applied to optimize processes and to improve them where capability does not meet requirements. Sampling plans are selected according to results of risk analysis or past performance and other analyses of product and process. Sampling plans are reviewed as needed, based upon frequency of nonconformances and other feedback information to assure their adequacy.

8.2.6 Monitoring and Measurement of Product

8.2.6.1 Receiving Inspection

Material intended for use in final product (inventory item) is subject to inspection according to an Inspection Plan. Urgently required material may be pre-released to production. In that case, the traveler for the job is annotated "PRE-RELEASED MATERIAL" or similar, and the acceptability of the material is verified before the traveler is completed and the product is released.

8.2.6.2 In-process Inspection

In-process inspections are performed as required at specified points on the Traveler or as required by a Work Instruction. These may be performed by qualified production or inspection personnel. Records are maintained.

8.2.6.3 Final Inspection

Final inspections are performed to confirm that all production operations are complete and that product meets requirements. The final inspections

are performed before the product is shipped or placed in finished goods inventory. Verification of the acceptability of pre-released material is performed before final acceptance. Quality Assurance personnel, or others specifically delegated, must close out the inspection by signing the Inspection Plan indicating the inspection is complete and all required actions accomplished.

8.2.6.4 First Article Inspection

First Article Inspections are performed at the discretion of the Production Manager unless the Traveler or other specifying document specifically requires the performance of the First Article.

8.2.6.5 Inspection and Test Records

Records are made of inspections specified in the Inspection Plan including the identity of personnel performing any inspections or testing.

8.3 Control of nonconforming product

To prevent unintended use or installation, nonconforming product is clearly identified by labeling of the product and/or its placement in an area specifically reserved for nonconforming material. Material which is suspected or known not to conform to the specification is identified and segregated from acceptable material, to prevent commingling and further use until disposition is determined

Responsibility for dispositioning is defined. Use-As-Is dispositions for specified requirements require the approval of the customer and the VP QA/RA. Use-As-Is dispositions typically require the establishment or revision of specifications, workmanship standards, or other requirements documents.

8.3.1 General

"REJECTED" or "SCRAP" labels/tags are used to identify nonconforming material. That material is labeled and/or placed in a location reserved for nonconforming or suspect material. "HOLD" or "QC HOLD" labels are used for material that has been found to be discrepant during inspections but not yet dispositioned.

8.3.2 Actions in response to nonconforming product detected before delivery

Nonconforming product detected before delivery shall follow in accordance to the nonconforming material process.

8.3.3 Actions in response to nonconforming product detected after delivery

Actions in response to nonconforming product detected after delivery shall follow in accordance to the nonconforming material process.

8.3.4 Rework

After completion of rework that takes the non-conforming product or critical component through a non-standard process, the product or critical component must be verified (i.e. re-tested, re-inspected and re-evaluated) to ensure that it meets the applicable criteria and regulatory requirements. In addition, a determination of any adverse effects from the rework upon the product or critical component, must be documented on the DHR (Batch Record).

8.3.5 Physical Controls

"REJECTED" or "SCRAP" labels/tags are used to identify nonconforming material. That material is labeled and/or placed in a location reserved for nonconforming or suspect material. "HOLD" or "QC HOLD" labels are used for material that has been found to be discrepant during inspections but not yet dispositioned.

8.3.6 Review and Disposition

Nonconforming material is documented on a Nonconformance Report (NCR). Each document requires review, evaluation, and disposition. Where Work Instructions contain specific nonconformance identification and disposition actions, the material may be rejected, properly identified (labeled "REJECTED") and accounted for on the Traveler by the operator without further approvals.

8.3.7 Waivers and Deviations

Where nonconforming material is to be offered to a customer, a waiver or deviation (customer concession) must be obtained from the customer's authorized representative prior to shipment. Where a written confirmation is unavailable, the documentation must show the name of the customer representative granting the verbal waiver, and the dated signature of the company representative documenting the verbal communication. All waivers and deviations are limited by time, quantity, or lot number.

8.3.8 Referral for Corrective and Preventive Action

Some nonconformances may dictate the generation of a formal Corrective Action Request. Corrective and preventive actions process is described in accordance with local procedures.

8.4 Analysis of Data

Confluent Medical Technologies has determined the appropriate data to be collected to demonstrate the suitability and effectiveness of the quality management system and determine where improvement is needed. This data consists of Internal Audits results, Customer Satisfaction information (customer complaints, on time delivery, and returns), Non-conformance and product yields.

The monitoring and measurement methods for key processes are the input to Management Review. The continuing suitability of these processes are confirmed at the Management Review meetings and documented in the meeting notes.

The data analysis and review may also result in generating and corrective and preventive actions, identification of improvements, supplier information, trends and determining the suitability and effectiveness of the QMS based on Quality policies and objectives.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems. Statistical Process Control (SPC) and Design of Experiment (DOE) techniques are applied where appropriate.

Statistically valid sampling plans are selected to assure the adequate control of quality. Statistically valid methods are used to determine sample sizes in the evaluation of processes and product characteristics.

8.5 Improvement

8.5.1 General

Management with executive responsibility (executive management) is responsible for establishing, implementing, and continuously improving the quality system.

Executive management, and others as required, formally reviews the quality system for compliance and effectiveness at least annually. Results and actions taken are documented.

Advisory notices and regulatory notification are executed in accordance with MEDDEV 2.12/1 only for devices where Confluent Medical Technologies holds the reporting responsibility in accordance with an approved quality agreement.

Customer complaints are recorded and investigated. If a corrective action/preventive action is not issued for a device complaint, the reason should be recorded. Results of all investigations must be documented.

8.5.2 Corrective Action

Corrective action is recognized as a key element in the continued improvement in quality Corrective Actions are taken to eliminate the causes of an existing nonconformance, defect, or other undesirable situation in order to prevent recurrence. Corrective actions are put into place once something has been identified as having gone wrong. Corrective action definition and details are documented in local procedures. The management team assures adequate resources are available to identify and implement corrective and preventive actions.

8.5.3 Preventive Action

Preventative action is recognized as a key element in the continued improvement in quality. Preventive Actions are taken to eliminate the cause of a potential nonconformance, defect, or undesirable situation to prevent occurrence. The degree of preventative action taken should be dependent upon and related to the risk, size, and nature of the problem and its effect(s) on product quality. Preventive actions are more proactive and are put in place once something has been identified as having the possibility of going wrong. Preventive action definition and details are documented in local procedures. The management team assures adequate resources are available to identify and implement preventive actions. .

APPENDIX A: Table of Contents