## Table of Contents

# 1. Introduction

Confluent Medical Technologies (Confluent) is a developer and manufacturer of medical devices and components for both medical and commercial applications.

Confluent's Headquarters is located in Scottsdale, Arizona. Confluent has 7 locations of business: California (Fremont and Laguna Niguel), Texas (Austin), Costa Rica (El Coyol, Alajuela), Rhode Island (Warwick), Maine (Windham) and Tennessee (Chattanooga).

# 2. Quality Policy

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 will achieve this commitment by:

- Continuously improving the effectiveness of our Quality Management System, our products and our services.
- Meeting regulatory requirements and satisfying the needs of our customers and partners.
- Striving to deliver high quality products with on-time delivery and superior services to achieve total customer satisfaction.

# 3. Scope

## 3.1 Applicable Regulations

The Confluent Quality Management System (QMS) is established to meet the following applicable regulations:

- ISO 13485: 2016
- ISO 14971:2019
- Title 21 CFR Part 820, Food and Drug Administration
- Title 21 CFR Part 11, Food and Drug Administration
- Medical Device Single Audit Program (MDSAP) - applicable regulatory requirements and medical device markets are: CMDR (Health Canada) and FDA 21 CFRs (USA).
- 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)
- Council Directive 93/42/EEC of 14 June 1993 (Consolidated 2007)
- European Medical Device Regulation (2017-745) (MDR)
- AS 9100 Rev. D

## 3.2 Scope of Activities

Confluent designs, develops and manufactures medical devices, medical device components, raw materials, (for both medical and non-medical uses) and provides analytical services/consulting.

| | |
|---|---|
| Fremont | Manufacturing site of materials, medical device components, and a design and development site. |
| Laguna Niguel | Manufacturing site of medical device components and sub-assemblies, and a design and development site. |
| Costa Rica | Manufacturing site of finished medical devices and medical device components. |
| Austin | Pilot manufacturing and a design and development site. |
| Chattanooga | Manufacturing site of medical device components. |
| Warwick | Manufacturing site of textile and composite materials for components and assemblies. |
| Windham | Manufacturing site of metal components and machining services. |
| India | Manufacturing site of materials. |
| Juarez, Mexico | Inspection operation staffed by customer personnel in a customer owned building. This operation follows Confluent procedures, but the customer maintains official registrations. |

Confluent recognizes that the administration of the QMS impacts the following interested parties:

- Customers – Require the provision of consistent high-quality products and services that are delivered on time, a stabile supply chain and a compliant QMS.
- Regulators – Require compliance with applicable regulations and standards, the continuous improvement of our QMS and that Confluent produces safe and effective products.
- Suppliers – Expect clearly defined requirements, a collaborative relationship and communication in regards to their performance.
- Employees – Expect the provision of necessary resources, training to perform their responsibilities adequately and a safe working environment.

## 3.3 Non-Applicable Sections

- Design & development (ISO 13485 7.3 and 21 CRF 820.30) is non-applicable for the Juarez, Costa Rica, Warwick, Windham and Chattanooga sites.
- Confluent does not provide installation as a contract manufacturer or as a legal manufacturer. Therefore, installation activities (ISO 13485 7.5.3 and 21 CFR 820.170) are non-applicable for all sites.

- Confluent does not provide servicing as a contract manufacturer or as a legal manufacturer. Therefore, servicing activities (ISO 13485 7.5.4 and 21 CFR 820.200) are non-applicable for all sites.
- In reference to MDSAP, applicable regulatory requirements/ medical device markets are: CMDR (Health Canada) and FDA 21 CFRs (USA). The following countries are excluded from MDSAP regulatory requirements: Australia (TGA), Japan (MHLW / PMDA) and Brazil (ANVISA).
- For more information on non-applications by site, refer to the site-specific QMS Traceability Matrix.

# 4. Definitions

- Complaint – Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, usability, safety, effectiveness or performance of a medical device after it has been released from Confluent's control or related to a service that affects the performance of such medical device.
- Device History Record (DHR) – A compilation of records containing the production history of a finished device.
- Device Master Record (DMR) – A compilation of records containing the procedures and specifications for a finished device.
- Manufacturer – Legal entity with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under the entity's name; whether or not such a medical device is design and/or manufactured by that entity itself or on its behalf by another entity.
- Medical Device – Instrument, apparatus, implement, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one of more of the specific medical purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
  - supporting or sustaining life;
  - control of conception;
  - disinfection of medical devices;
  - providing information by means of in vitro examination of specimens derived from the human body;
  - and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
- Nonconformity – The nonfulfillment of a specified requirement.
- Post Market Surveillance – Systematic process to collect and analyze experience gained from medical devices that have been placed on the market.

- Rework – Action taken on a nonconforming product so that is will fulfill the specified DMR requirements before it is released for distribution.
- Validation – Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

# 5. Quality System

## 5.1 General

The Confluent QMS is a series of integrated systems implemented to assure that all Confluent products are designed, manufactured, and distributed to meet customer expectations and pre-determined specifications, while at the same time complying with all appropriate regulatory requirements. The system consists of a formal organizational structure, which includes an independent Quality department to ensure that specified requirements are met, along with responsibilities, procedures, processes and resources required to implement effective quality management. This QMS provides a tool for the optimization and control of quality in relation to risk, cost and benefit. In addition, quality planning is included to preserve and improve the functioning and outputs of the QMS. Plans include product, process, and system improvements.

The scope of the Confluent QMS covers production of standard product, provision of analytical/design services, new product and process design/development and all supporting activities. Confluent uses risk-based approaches, which are included in specific procedures. The QMS may be customized to the business needs of customers.

Activities such as product development, process validation and change control generate quality plan/test protocols which define and document how quality requirements will be met. Customer complaints are investigated and, where appropriate, corrective action taken. Customer feedback is utilized to make improvements to the product realization processes. The customer feedback and communications processes include procedures to define the review of experience gained from devices in the post-production phase.

When Confluent chooses to outsource any processes that affect product conformity to requirements, Confluent retains responsibility for those outsourced processes. The controls implemented by Confluent are proportionate to the risk involved and the ability of the external party to meet Confluent's requirements. Those controls are documented in Quality Agreements.

Confluent documents procedures for the validation of computer software used in the QMS. Such software is 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 are proportionate to the risk associated with the use of the software.

## 5.2 QMS Documentation

### 5.2.1 Structure

The structure of the Quality System documentation is defined as follows:

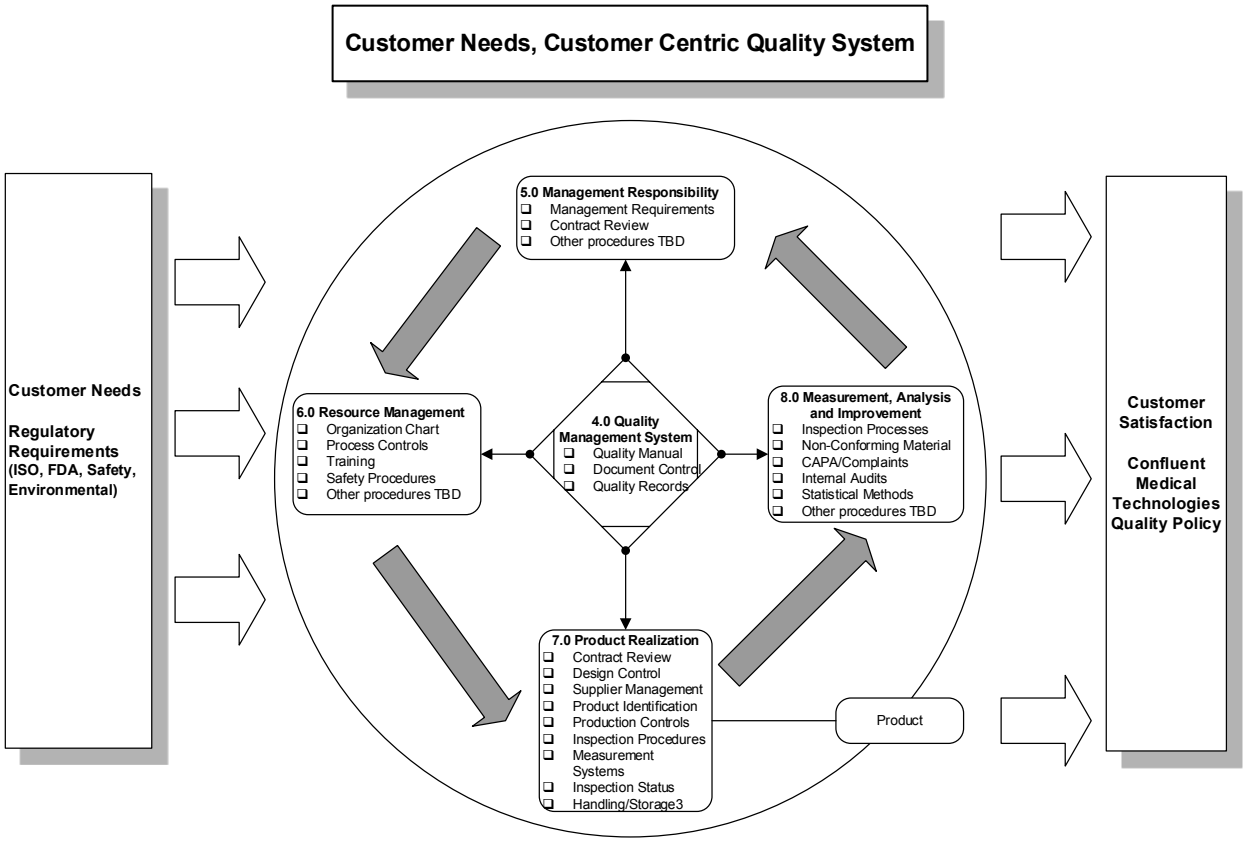
| LEVEL | DOCUMENTS |
|---|---|
| I | Quality Manual. |
| II | Operating Procedures (OPs). |
| III | Work Instructions, Travelers, Inspection Plans, etc. |
| IV | Quality Records. |

### 5.2.2 Quality Manual

This Quality Manual outlines the structure of the documentation used in the quality management system with a Quality Policy and other top-level guidance that is further defined and implemented through the next documentation level (Level II, Operating Procedures). Under the direction of Level II documentation, Level III documentation is developed and implemented. Level IV documentation contains the records of that implementation.

This Quality Manual must be approved by the Confluent Medical Technologies Chief Executive Officer and Senior Management.

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




Individual responsibility for quality system requirements is specified within each OP.

Top Management plans, resources and reviews the QMS to ensure the consistency of meeting customer requirements. Management Review also ensures availability of adequate resources and technology to support the QMS.

QMS 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.

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.

### 5.2.3 Medical Device File

When Confluent is a contract manufacturer for a customer and not the legal manufacturer of the customer's medical device, then portions of the Medical Device File requirements pertaining to Device Master Records and Quality System Records are followed. 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 with Confluent's procedures for Device Master Record, Quality System Record and Quality Records.

When Confluent is the legal manufacturer, for each medical device type or medical device family, Confluent will establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity to and compliance with applicable regulatory requirements.

### 5.2.4 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.

### 5.2.5 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. Retention periods for quality records are established and documented.

# 6. Management Responsibility

## 6.1 Management Commitment

Management is responsible for establishing and communicating the requirements of the quality system.

Top Management maintains its effectiveness of the QMS by:

- Communicating to the organization the importance of meeting customer, statutory and regulatory requirements.
- Establishing the quality policy and reviewing it 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.

## 6.2 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 QMS, contracts and agreements are defined and reviewed between Confluent 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 can meet the requirements.

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. Any changes to orders or contracts are documented and disseminated to the affected personnel to assure that customer expectations are met.

## 6.3 Quality Policy

The Confluent Medical Technologies Quality Policy is documented in Section 1 of this Quality Manual. The quality policy is communicated and understood within Confluent and is reviewed periodically by top management.

## 6.4 Quality Planning

### 6.4.1 Quality Objectives

Confluent considers the safety, efficacy and quality of our products to be of utmost importance. Quality objectives are derived from the Quality Policy and are the foundation from which all quality goals and activities are developed. The quality objectives are generated annually by Top Management and are reviewed at a minimum during Management Review meetings.

### 6.4.2 Quality Management System Planning

QMS planning is carried out by Top Management during Management Review meetings. When a change is made to the quality system as a result of an internal/external audit or management decision, it is reviewed for

effectiveness and appropriate justification and approvals are required to implement the change.

## 6.5 Responsibility, Authority and Communication

### 6.5.1 Responsibility and Authority

The organization at Confluent is headed by the CEO who has the responsibility for interacting with the Quality Management Representative, and commitment to, the QMS. The implementation and maintenance of corporate policies, including quality-related objectives, is delegated through functional management to the individual employees. The Sr. Vice President of Quality Assurance and Regulatory Affairs is the designated Quality Management Representative, having authority and responsibility for ensuring that the QMS complies with applicable regulatory requirements, quality system standards, and this Quality Manual.

Product quality and service excellence are the collective responsibility of all Confluent employees. Management is responsible for providing quality planning, ongoing training and resources to ensure that the Confluent QMS, as outlined in this Quality Manual, is understood and followed. It is management's responsibility to assure that delegations of authority and responsibility are granted to qualified and competent individuals.

Organizational charts and descriptions of positional responsibilities and interrelations are maintained and controlled by the Human Resources department.

The responsibility and authority of Confluent employees who manage, perform, or verify work affecting the quality of products or services shall be recorded in the form of job descriptions, maintained in company files and listed in appropriate procedures. In addition, key personnel, as defined by the company, shall have assigned deputies to assume responsibilities in case of their absence.

The authority to perform the tasks and responsibilities identified in this document and other QMS documents may be delegated. 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.

### 6.5.2 Management Representative

The Management Representative for Confluent is the Sr. Vice President of Quality Assurance and Regulatory Affairs. S/he or his/her designee is responsible for continued monitoring of systems for compliance and effectiveness, and to routinely update Confluent Top Management on the progress, as well as. S/he has the delegated authority and responsibility for ensuring that QMS compliance requirements are implemented and

maintained, particularly with respect to the latest versions of regulatory requirements.

The Management Representative serves as Confluent's liaison to customers and other outside concerns on matters relating to product quality and reliability.

The responsibility for each site QMS 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.

#### 6.5.3 Internal Communication

Key Performance Indicators are established by Top Management 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, Top Management will disseminate information regarding the state of the business.

### 6.6 Management Review

On a periodic basis, but at least once per year, Management Review Meetings are held to ensure the continued suitability, adequacy and effectiveness of the QMS. These meetings may be conducted as a consolidated global review and/or as site-specific reviews, at the discretion of Top Management.

Records are maintained in the form of reports and/or minutes. Areas for improvement, changes needed to the QMS and resource needs are included as outputs.

## 7. Resource Management

### 7.1 Provision of Resources

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 (both internal and external). The term resources shall include human skills, utilities, workspace and equipment.

### 7.2 Human Resources

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.

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

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.

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

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 methods for verifying training effectiveness are proportionate to the risk associated with the work.

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 devices.

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

## 7.3 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.

## 7.4 Work Environment and Contamination Control

### 7.4.1 Work Environment

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

The procedures provide direction 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.

### 7.4.2 Contamination Control

Confluent has established documented procedures 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 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.

# 8. Product Realization

## 8.1 Planning of Product Realization

Quality planning occurs throughout the product lifecycle. Typical planning activities and the responsible people are defined in detailed OPs 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 are 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. Only qualified individuals may perform inspections and record results. Inspections may utilize data prepared by others to make decisions when specified in the Inspection Plan. Records are made of inspections specified in the Inspection Plan.

## 8.2 Customer-related Processes

### 8.2.1 Determination of requirements related to product

Within the scope of the QMS, contracts are defined as any agreement between Confluent 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 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.

### 8.2.2 Review of requirements related to 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 request 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 specification reviews are maintained.

### 8.2.3 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.

## 8.3 Design and Development

### 8.3.1 General

As a developer and manufacturer of components for both medical and commercial applications (with the exception of Confluent finished devices), Confluent does not complete full design and development cycles for many new products. The designs typically originate from customers and the overall design control responsibility lies with them. However, within the scope of our involvement with the overall development project, Confluent will adhere to design and development requirements as defined in our procedures.

In the case of Confluent finished devices (Confluent sponsored design), design and development activities are managed by a specific Confluent design and development site, while individual tasks may be executed at other Confluent sites depending on availability of resources.

Confluent's design and 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. Where Confluent yields to a customer's design and development procedures, a copy of the Design History File (DHF) index or table of contents will be maintained at Confluent.

### 8.3.2 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.

### 8.3.3 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 is incorporated as 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. 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.

### 8.3.4 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).

### 8.3.5 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 outputs 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 sponsored designs involving Confluent controlled clinical studies, a clinical release design review is also required to assure the safety of the pre-production material for human use.

### 8.3.6 Design and development verification

In design verification, Confluent confirms 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.

### 8.3.7 Design and development validation

In design validation, Confluent establishes 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.

### 8.3.8 Design and development transfer

In design transfer, Confluent ensures 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.

### 8.3.9 Design and development changes

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

### 8.3.10 Design and development files

A design history file (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 contributed design activities to the project, Confluent will maintain a copy of the project DHF index (table of contents) as well as copies of all design-related items generated by Confluent.

## 8.4 Purchasing

### 8.4.1 Purchasing process

Confluent 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.

Suppliers are evaluated and approved based on their demonstrated or potential ability to meet quality, delivery, and price requirements, as well as the risk associated with the medical device. Evaluation and approval methods are defined. Suppliers are monitored for 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. 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.

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 an approved supplier list is maintained.

### 8.4.2 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 in the PO.

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.

### 8.4.3 Verification of purchased product

Purchased product is inspected upon receipt to the extent necessary to verify conformance to requirements. The extent of verification activities is based on the supplier evaluation results and proportionate to the risks associated with the purchased product.

When Confluent becomes aware of any changes to the purchased product, a determination is made whether or not the changes affect the product

realization process. When Confluent is the legal manufacturer, a determination is made whether or not the changes affect the product realization of the medical device.

Inspection and testing are 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.

When necessary or desirable to verify product at a subcontractor's facility, that requirement is cited in the purchase order.

Verification of subcontracted product by customers may be arranged on a case-by-case basis, and is specified in the purchase order or contract.

## 8.5 Production and Service Provision

### 8.5.1 Control of production and service provision

Production operations that affect quality are planned and carried out under controlled conditions in the specified manner and sequence. Manufacturing processes are identified, planned, and controlled to repeatedly produce the same high-quality product. Travelers are created to define the source material(s), the sequence of operations, processing instructions, and verification steps. Work instructions are prepared to provide for uniform accomplishment of processes where the traveler cannot provide sufficient detail. Where applicable, the traveler or inspection plan references the work instruction at the appropriate step.

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.

Production areas are maintained to provide a suitable environment for the processes being performed. Work areas are spatially segregated to avoid mix-ups and overcrowding. Lot segregation is practiced for every operation.

Demand schedules are generated and maintained 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.

Workmanship standards may be 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.

Labeling is adequate to withstand the conditions during handling, storage, packaging and shipment. Confluent reviews and approves all labeling prior to implementation. Documented procedures provide guidance to prevent labeling mix-ups during storage, labeling and packaging operations.

Packaging and labeling operations are performed in accordance with documented procedures.

The mode of delivery is as specified by the customer and requirements are entered with the order.

### 8.5.2 Cleanliness of product

Confluent 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 is responsible for determining and documenting the associated processes of cleaning and sterilization and validating such processes.
- 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 to establish the proper process for cleanliness.

Requirements for the health, cleanliness, and clothing of personnel are established, documented, and maintained. Housekeeping and hygiene guidelines are also highlighted, along with the importance of protecting product and raw materials from contamination.

Environmental requirements are established and documented for all manufacturing, storage, and laboratory space where control and monitoring of environmental conditions is necessary to assure product quality.

In addition, documented procedures are maintained for cleaning the product, as well as cleaning methods and schedules for manufacturing areas.

### 8.5.3 Installation activities

Confluent does not provide installation as a contract manufacturer or as a legal manufacturer.

### 8.5.4 Servicing activities

Confluent does not provide servicing as a contract manufacturer or as a legal manufacturer.

### 8.5.5 Particular requirements for sterile medical devices

Confluent has procedures to maintain records of the sterilization process parameters used for each sterilization batch. Sterilization records are traceable to each batch of sterile medical devices that Confluent produces.

### 8.5.6 Validation of processes for production and service provision

Where results of a process cannot be fully verified through subsequent inspection and/or testing, processes are validated and/or monitored to assure adequate results are obtained. Processes are controlled to assure specified requirements are met. Control is implemented through the use of validations, continuous monitoring, documented procedures, and recorded results.

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

Records of process validation, operating procedures, equipment maintenance, and personnel training are maintained.

Software that is used to make decisions in the manufacture or evaluation of product that directly affects product quality is validated. This validation is proportionate to the risk associated with the software use. Software that is used to control manufacturing processes or perform calculations is verified to ensure it performs as intended.

### 8.5.7 Particular requirements for validation of processes for sterilization and sterile barrier systems

When Confluent builds product to the final packaging assembly, or is the legal manufacturer for a medical device, processes for sterilization and sterile barrier systems are validated and records are kept of process settings for each batch/lot.

When changes are made to a sterilization or sterile barrier packaging process, revalidation may be required. Revalidation protocols are documented in accordance with Confluent validation procedures.

Records of process validation, operating procedures, equipment maintenance, and personnel training are maintained.

### 8.5.8 Identification

Products are identified by description, lot number and status. 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 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.

Procedures defining traceability requirements are established and documented. Components, in-process materials and products are identified with status and traceability information as laid out in these procedures. Product is appropriately identified throughout all stages of production and distribution. The extent of the measures employed is determined by the criticality of the component.

Collectively, the work order package used to make a product serves as the Device History Record (DHR) for that product. Throughout the manufacturing cycle, the work order package is either with the material, or is readily available so that the status of the material may be determined. This identification provides traceability and facilitates problem solving.

A unique lot or serial number is also included as part of the labeling for each lot of finished product. Labels are stored in restricted areas. Excess labeling materials are destroyed or returned to stock. Nonconforming products or materials are segregated and maintained in a designated Quarantine area until final disposition, as determined by the NCR process.

### 8.5.9 Traceability

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

For implantable medical devices, Confluent maintains records of components, materials and work environment conditions. As a contract manufacturer, Confluent also maintains consignee distribution records for shipments of implantable devices to our customers.

### 8.5.10 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.

### 8.5.11 Preservation of product

Confluent operates in a clean industrial environment or cleanroom as appropriate for the product being manufactured. Materials and products are managed to prevent damage, deterioration and contamination during all stages of processing, storage, handling and shipment.

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.

Product packaging and labeling are designed and constructed to prevent product damage under normal conditions, and to attempt to show adulteration during processing, storage, handling and distribution. All final product packaging configurations are qualified prior to being marketed. The effects of handling, transport and storage are assessed as part of this qualification.

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.

## 8.6 Control of Monitoring and Measuring Equipment

All inspection, measuring, and test equipment that affects product quality is controlled, calibrated, and maintained. Calibration is traceable to the (National Institute of Standards and Technology (NIST) or appropriate physical standard. All equipment is labeled as to its status in the calibration system. Equipment is

selected to support the accuracy and precision required by the product drawing or specification. Test equipment software is controlled, including validation prior to use and revalidation after changes as determined appropriate. This validation is proportionate to the risk associated with the software use.

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.

Calibration services may be performed internally by controlled procedure or through qualified outside service providers.

Records are maintained of the calibration date, procedures used, calibrator, and next calibration due date. Out of tolerance equipment requires documented disposition of any materials, components, or product processed with the non-conforming equipment.

# 9. Measurement, Analysis and Improvement

## 9.1 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 multiple sources. The information from these sources is reviewed in Management Review.

Internal Audits are conducted to ensure conformity and effectiveness of the quality management system. The results of such audits are reviewed in Management Review.

Statistical techniques are used to define process parameters, optimize product performance, and to identify root causes of problems.

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

## 9.2 Monitoring and Measurement

### 9.2.1 Feedback

Customer satisfaction is monitored and measured primarily through customer complaints, returned goods and delivery information. The information from these sources is reviewed in Management Review and is an input into product and process risk management. Other indicators or sources for customer satisfaction used at Confluent Medical Technologies

include sales volume tracking, customer audits and customer provided supplier ratings.

### 9.2.2 Complaint handling

Processes are established to manage the receipt, processing and resolution of complaints received on all Confluent 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.

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

Complaint records, including any investigation reports, are maintained by the Quality Assurance department.

### 9.2.3 Reporting to regulatory authorities

When Confluent is the contract manufacturer for a medical device, reporting requirements are coordinated by the medical device legal manufacturer.

When Confluent is the legal manufacturer for a medical device and complaints meet specified reporting criteria of adverse events or issuance of advisory notices, Confluent provides notifications to the appropriate regulatory authorities in compliance to the applicable regulatory requirements.

Confluent will notify the required regulatory agencies and competent authorities immediately per their notification requirements, 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 will notify the required regulatory agencies and competent authorities immediately per their notification requirements, when becoming aware of any technical/medical reason leading to recall or field corrective action.

### 9.2.4 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.

### 9.2.5 Monitoring and measurement of processes

Confluent utilizes the following methods to measure and monitor the ability of QMS processes to achieve planned results:

- Internal quality audits
- Other internal audits (manufacturing line audits, etc.)
- Customer Satisfaction (Complaints, Delivery and Returns)
- Product Acceptance/Nonconformances
- Management Review

When planned results are not achieved, corrective and preventive action is taken, as appropriate.

### 9.2.6 Monitoring and measurement of product

Material intended for use in final product (inventory item) is subject to receiving inspection according to an inspection plan. Where specified, Certificates of Compliance and/or Certificates of Analysis may be required from the vendor. Urgently required material may be pre-released to production. In that case, the traveler for the job is annotated as necessary to denote that status, and the acceptability of the material is verified before the traveler is completed and the product is released.

In-process inspections are performed as required at specified points as designated on the traveler or as required by a work instruction. These may be performed by qualified production or inspection personnel.

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 are required to perform authorization of final release.

First Article Inspections are performed at the discretion of Operations unless the traveler or other specifying document specifically requires the performance of a First Article Inspection.

Inspection and test status of product is maintained throughout the manufacturing process to ensure that only product which has passed the required inspections and tests is released to finished goods inventory and dispatched to the customer. Responsibility and authority for release of conforming product is defined and documented.

Product is identified with the inspection and test status using several methods, depending on the stage of manufacture, in accordance with

documented procedures. The product may be identified with labeling, stored in a designated area, or accompanied by documentation that provides the status.

Inspection and test records are established and maintained to provide evidence that defined acceptance criteria have been met. These records include the identity of the personnel performing the inspections, and are maintained in accordance with the defined records retention schedule.

## 9.3 Control of Nonconforming Product

### 9.3.1 General

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.

### 9.3.2 Actions in response to nonconforming product detected before delivery

Nonconforming product is reviewed by designated individuals in accordance with documented procedures to confirm the discrepancy and determine the cause. Responsibility and authority for disposition of nonconforming product is defined in standard operating procedures. Disposition of discrepant material is made and documented, including correction and where determined to be applicable, corrective action and steps to prevent recurrence.

Documented procedures specify the required approval for Use-As-Is dispositions, which also typically require the establishment or revision of specifications, workmanship standards, or other requirements documents.

### 9.3.3 Actions in response to nonconforming product detected after delivery

Nonconforming product that is determined to have been distributed will be evaluated for action appropriate to the effects or potential effects of the nonconformity.

Documented procedures specify the requirements for actions taken in the event it is determined that an advisory notice, product recall (removal or correction), market withdrawal, or stock recovery is required.

### 9.3.4 Rework

Product requiring rework is clearly identified and segregated. Rework is performed according to documented, approved rework procedures. A

verification is then performed to ensure that the reworked products or components meet applicable criteria and regulatory requirements, and that there were no adverse effects on the product as a result of the rework. Records of rework are maintained.

## 9.4 Analysis of Data

Confluent 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 includes internal audit results, supplier audit results and scorecards, customer feedback, post market surveillance data, nonconformance reports and product yields.

The monitoring and measurement methods for key processes are an input to Management Review. The continuing suitability of these processes, our objectives and quality policy are confirmed 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. Procedures are established to assure uniform application of the techniques selected.

Statistically valid and risk-based 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. Sampling plans are reviewed as needed, based upon frequency of nonconformances, results of risk analysis and other feedback information to assure their adequacy.

## 9.5 Improvement

### 9.5.1 General

Top management is responsible for identifying and implementing any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the QMS and medical device safety and performance.

Top management team assures adequate resources are available to identify nonconformities and potential nonconformities, to implement corrective and preventive actions and to verify those actions are effective.

Records of investigations and actions taken are maintained.

### 9.5.2 Corrective action

Confluent has established procedures detailing the requirements for corrective action to address the causes of nonconformities to prevent their recurrence.

Corrective actions are taken without undue delay and are proportionate to the risk associated with the nonconformities.

### 9.5.3 Preventive action

Confluent has established procedures detailing the requirements for preventive action to address the causes of potential nonconformities to prevent their occurrence.

Preventive actions are proportionate to the risk associated with the potential nonconformities.