



Cutter Innovations

QUALITY SYSTEM MANUAL

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QUALITY POLICY STATEMENT

We, the management team of Cutter Innovations and all its employees, are committed to providing products and services that exceed our customers' expectations. By improving our manufacturing processes and driving a culture of quality from the top down, we will ensure that our customers enjoy a continuous high level of confidence in our relationship.

Top Level Quality Objectives

The following Top Level Metrics will be evaluated yearly and goals will be set accordingly using the Quality Objective Form (QM.FM1).

- On Time Delivery
- Customer Lot Acceptance
- Profit/Employee

MISSION STATEMENT

Cutter Innovations will provide responsive, transparent, and robust machining services that exceed our customers' expectations. Through our highly skilled individuals, focused approach, and commitment to quality, we will be able to bring value to our customers and share in their success.

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PURPOSE

This manual shall establish and define the fundamental elements of implementing a quality management system to ensure that products and services conform to specified requirements, regulatory requirements, and quality standards. Adhering to the Quality Policy Statement and focusing on the Quality Goals and Objectives, Cutter Innovations shall fulfill its mission as a custom contract manufacturer to the medical device industry.

SCOPE

Through this manual, Cutter Innovations has established a Quality Management System to comply with ISO 9001:2008, – Quality Management System Requirements.

Cutter Innovations shall strive to use the best practices, people, material, equipment and technology for servicing its customers.

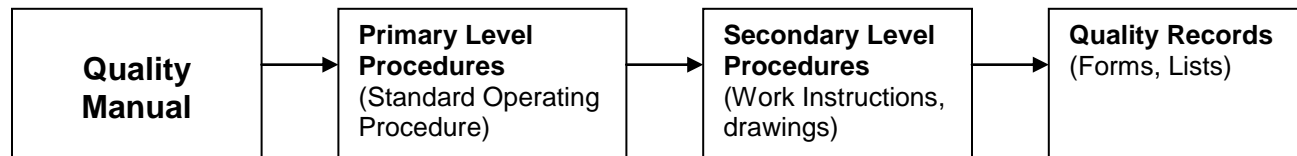
As a contract manufacturer, Cutter Innovations has adopted ISO 9001:2008 as the quality standard for ensuring those appropriate elements for meeting customer and regulatory requirements have been considered and implemented.

QUALITY SYSTEM PROCEDURES

Quality System Procedures have been established to implement the requirements of this Quality Manual. These procedures define Cutter Innovations' inter-departmental processes necessary to satisfy the expectations and requirements of our customers and regulatory requirements.

Quality System Procedures and other applicable quality records, shall be reviewed, approved and controlled through a defined process, represented by Cutter Innovations' management body, for ensuring that the requirements of this manual are met.

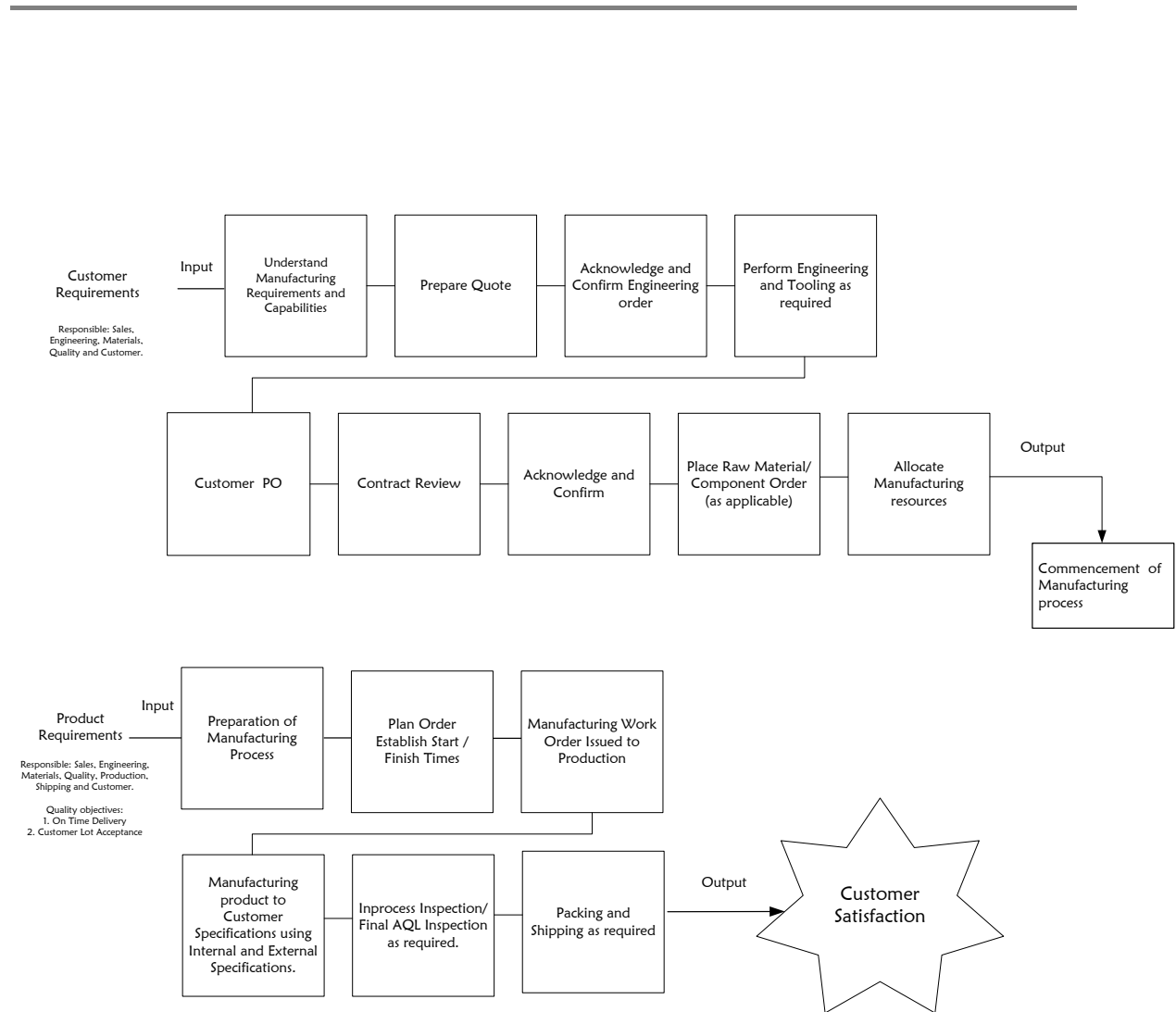
Approved documentation shall be structured as follows:



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QUALITY SYSTEM/BUSINESS PROCESSES

The following flow charts illustrate the interaction of business processes at Cutter Innovations that comprise the Quality System:





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QUALITY SYSTEM EXCLUSIONS

The core competency of Cutter Innovations is contract CNC machining and inspecting of components and sub assemblies. To this extent, some of the requirements for device manufacturing as defined in ISO 9001:2008 are not applicable. With regard to contract manufacturing, Cutter Innovations has implemented and adopted the appropriate requirements from ISO 9001:2008 to ensure conformance to product specification, compliance to applicable regulatory requirements and customer needs.

To the extent that Cutter Innovations does not design, develop, specify requirements for, determine the intended use of, distribute or service a finished device as an OEM, the following quality standard requirements have been excluded, in part or whole, from Cutter Innovations' Quality System program:

Quality System Element	ISO 9001:2008 reference	Justification
Design and Development	7.3	Design and development activities, as it applies to tool fabrication is specified, approved and controlled by the customer. This element does not apply.

THE FOLLOWING SECTIONS ARE NOT APPLICABLE TO THE QUALITY SYSTEM

Installation activities	7.5.1	Cutter Innovations does not distribute to the end user, or install any devices. This is the responsibility of the customer.
Servicing activities	7.5.1	Cutter Innovations does not service any devices. This is the responsibility of the customer



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QUALITY MANUAL CONTROL AND DISTRIBUTION

GENERAL

It shall be the policy of Cutter Innovations to not distribute controlled copies of this manual outside the business entity except for those organizations (e.g., ISO Registrar, Customers, etc.) requiring this control.

APPROVAL

Cutter Innovations' Quality Manual is a proprietary document controlled by Document Control and approved by the Management Representative and the President.

HISTORY / REVISION BLOCK

APPROVAL DATE	EFFECTIVE DATE	DESCRIPTION OF CHANGE	DCO #
7/11/12	7/26/12	Initial Release	001

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QUALITY SYSTEM PROCEDURE REFERENCE

Quality System Element	ISO 9001:2008	Primary Procedure Reference
Quality Management System	4.0	
General Requirements	4.1	QM-01
Documentation Requirements	4.2	
General	4.2.1	QS-04-01
Quality Manual	4.2.2	QS-04-01
Control of Documents	4.2.3	QS-04-01
Control of Quality Records	4.2.4	QS-04-06
Management Responsibility	5	
Management Commitment	5.1	QS-05-01
Customer Focus	5.2	QS-07-05
Quality Policy	5.3	QM-01
Planning	5.4	
Quality Objectives	5.4.1	QM.FM1
Quality Management System Planning	5.4.2	QS-05-01
Responsibility Authority and Communication	5.5	QS-05-01
Management Review	5.6	QS-05-02
Resource Management	6	
Provision of Resources	6.1	QS-05-02
Human Resources	6.2	
General	6.2.1	QM-01
Competence, Awareness, and Training	6.2.2	QS-06-01
Infrastructure	6.3	QS-08-06
Work Environment	6.4	QS-06-02
Product Realization	7	
Planning of product realization	7.1	QS-07-05
Customer Related Processes	7.2	
Determination of Requirements	7.2.1	QS-07-05
Review of Requirements Related to the Product	7.2.2	QS-07-05
Customer Communication	7.2.3	QS-07-05
Design and Development	7.3	QM-01
Purchasing	7.4	QS-07-06
Production (and Service Provision)	7.5	
Control of Production (and Service Provision)	7.5.1	QS-08-06
Validation of Processes for Production	7.5.2	QS-07-01

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Identification and Traceability	7.5.3	QS-08-04
Customer Property	7.5.4	QS-07-10
Preservation of Product	7.5.5	QS-07-11
Control of Monitoring and Measuring Devices	7.6	QS-07-12
Measurement Analysis and Improvement	8	
General	8.1	QM-01
Monitoring and Measurement	8.2	
Customer Satisfaction	8.2.1	QM-01
Internal Audit	8.2.2	QS-08-02
Monitoring and Measurement of Process	8.2.3	QM-01
Monitoring and Measurement of Product	8.2.4	QS-07-02
Control of Nonconforming Product	8.3	QS-08-05
Analysis of Data	8.4	QS-08-01
Improvement	8.5	
Continual Improvement	8.5.1	QM-01
Corrective Action	8.5.2	QS-08-03
Preventive Action	8.5.3	QS-08-03

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QUALITY SYSTEM REQUIREMENTS

4.0 Quality Management System

4.1 General Requirements

Cutter Innovations shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this Quality Manual.

Cutter Innovations' management shall:

- a) Identify the processes needed for the quality management system and their application throughout the organization,
- b) Determine the sequence and interaction of these processes,
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Measure, monitor and analyze these processes, and
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

Cutter Innovations' management team shall manage these using a Plan-Do-Check-Act approach in accordance with the requirements of this manual.

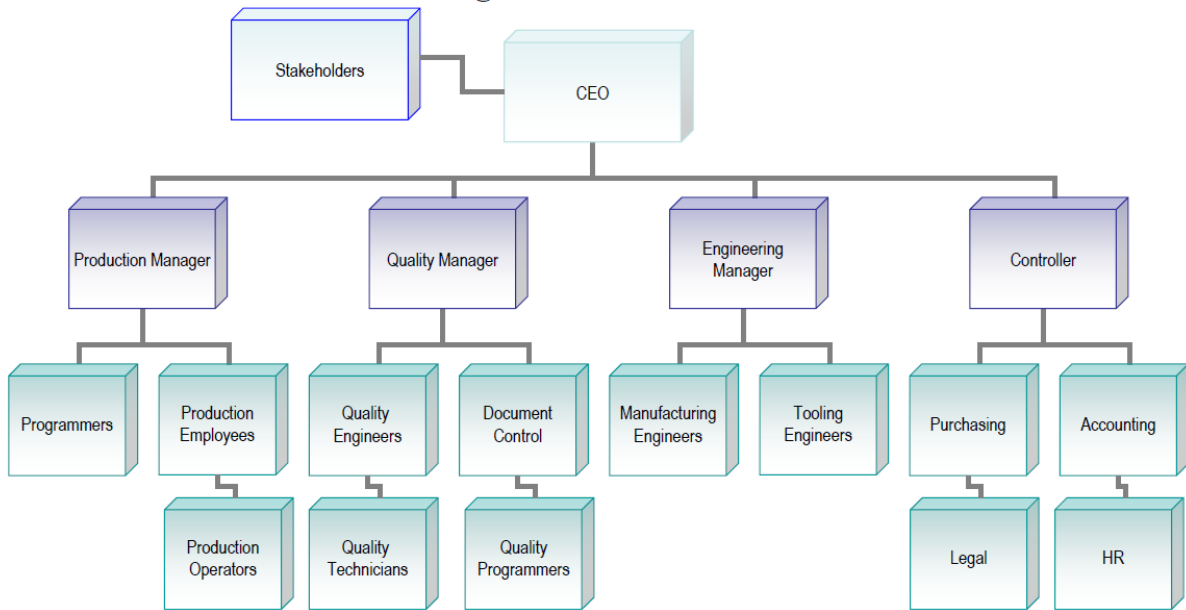
The organizational structure is depicted graphically in the following chart: (a more detailed organization chart is also maintained as a reference document)

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Organizational Chart



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4.2 Documentation Requirements

4.2.1 *General*

The quality management system documentation shall include:

- a) Documented statements of a quality policy and quality objectives,
- b) A quality manual,
- c) Documented procedures required by this manual,
- d) Documents needed by Cutter Innovations to ensure the effective planning, operation, and control of its processes,
- e) Quality records required by this manual (see 4.2.4), and
- f) Any documents specified by national or regional regulations.

Note 1: Where the term “documented procedure” appears within this manual, this means that the procedure is established, documented, implemented and maintained.

Note 2: The extent of the documented procedure can differ from one requirement to another due to:

- a) The Size of function and type of activities to be performed.
- b) The Complexity of processes and their interactions.
- c) The Competence of personnel.

Note 3: The documentation can be in any form or type of medium.

4.2.2 *Quality Manual*

Cutter Innovations has established this Quality Manual to include:

- a) The scope of the quality management system, including details of, and justification for, any exclusion.
- b) The documented procedures established for the quality management system, or reference to them.
- c) A description of the interaction between the processes of the quality management system.

4.2.3 *Control of Documents*

Documents required by the quality management system shall be controlled. Quality records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed:

- a) To approve documents for adequacy prior to issue.
- b) To review and update as necessary and re-approve documents.

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- c) To ensure that changes and the current revision status of documents are identified.
- d) To ensure that relevant versions of applicable documents are available at points of use.
- e) To ensure that documents remain legible and readily identifiable.
- f) To ensure that documents of external origin are identified and their distribution controlled.
- g) To prevent the unintended use of obsolete documents, and to apply a suitable identification to them if they are retained for any purpose.

Changes to documents shall be reviewed and approved by the original approving function which has access to pertinent information upon which to base a decision.

Documents pertaining to the manufacturing and testing of a medical device shall be retained in accordance with the retention policy of Cutter Innovations, but shall be no less than the lifetime of the medical device or the resulting record, as defined by the customer.

4.2.4 Control of Quality Records

Quality Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Quality records shall remain legible, readily identifiable and retrievable.

A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of quality records.

5.0 Management Responsibility

5.1 Management Commitment

Cutter Innovations' top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) Establishing the quality policy,
- c) Ensuring that quality objectives are established,
- d) Conducting management reviews, and
- e) Ensuring the availability of resources.

5.2 Customer Focus

Cutter Innovation's' top management shall ensure that customer requirements are determined, and fulfilled with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

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5.3 Quality Policy

Cutter Innovations' top management shall establish and maintain a quality policy that:

- a) Is appropriate to the purpose of the organization,
- b) Includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) Provides a framework for establishing and reviewing quality objectives,
- d) Is communicated and understood within the organization,
- e) Is reviewed for continuing suitability.

5.4 Planning

5.4.1 *Quality Objectives*

Cutter Innovations' top management shall ensure that quality objectives, including those needed to meet requirements for product (see 7.1 a), are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 *Quality Management System Planning*

Cutter Innovations' top management shall ensure that:

- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
 - Quality planning will be conducted as part of the Management Review Meetings. Reference procedure QS-05-02.

5.5 Responsibility, Authority and Communication

5.5.1 *Responsibility and Authority*

Cutter Innovations' management team shall ensure that the responsibilities, authorities and their interrelation are defined and communicated within the organization. All personnel who manage perform and verify work-affecting quality shall have the independence and authority necessary to perform these tasks.

5.5.2 *Management Representative*

Cutter Innovations' top management has appointed a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

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- a) Ensuring that processes needed for the quality management system are established, implemented and maintained.
- b) Reporting to top management on the performance of the quality management system and any need for improvement.
- c) Ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.

5.5.3 Internal Communication

Cutter Innovations' management team shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. Internal communications will issued in the form of but not limited to monthly employee meetings, supervisory departmental meetings, internally issued memorandum, or bulletin boards.

5.6 Management Review

5.6.1 General

Cutter Innovations' top management shall review the organization's quality management system, at planned intervals to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review Input

The inputs to the management review shall include information on:

- a) Results of audits,
- b) Process performance and product conformance,
- c) Status of preventive and corrective actions,
- d) Follow-up actions from previous management reviews,
- e) Planned changes that could affect the quality management system,
- f) Recommendation for improvement, and
- g) New or revised regulatory requirements.

5.6.3 Review Output

The output from the management review shall include any decisions and actions related to:

- a) Improving and maintaining the effectiveness of the quality management system and its processes,
- b) Improving product related to customer requirements, and
- c) Resources needed.

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6.0 Resource Management

6.1 Provision of Resources

Cutter Innovations' management team shall determine and provide the resources needed:

- a) To implement and maintain the quality management system and continually improve and maintain its effectiveness.
- b) To enhance customer satisfaction by meeting customer requirements and meeting regulatory requirements.

6.2 Human Resources

6.2.1 *General*

Personnel performing work-affecting product quality shall be competent on the basis of applicable education, training, skills and experience.

6.2.2 *Competence, Awareness and Training*

Cutter Innovations shall:

- a) Determine the necessary competence for personnel performing work-affecting quality.
- b) Provide training or take other actions to satisfy these needs.
- c) Evaluate the effectiveness of the actions taken.
- d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- e) Maintain appropriate records of education, training skills and experience (see 4.2.4).

6.3 Infrastructure

Cutter Innovations shall also determine, provide and maintain the infrastructure needed to achieve the conformity to product requirements. Infrastructure includes, for example:

- a) Buildings, workspace and associated utilities.
- b) Process equipment, both hardware and software.
- c) Supporting services such as transport or communication.

Cutter Innovations shall establish documented requirements for maintaining activities, including the frequency, when such activities or lack thereof can affect product quality. Records of such activities shall be maintained.

6.4 Work Environment

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Cutter Innovations shall determine and manage the work environment needed to achieve conformity to product requirements.

Cutter Innovations shall implement the following:

- a) Establish documented requirements for health, cleanliness and clothing for personnel coming in contact with the product or process, where direct contact could adversely affect the quality of the product,
- b) Establish documented requirements, work instructions and system for monitoring, if the work environment can have an adverse effect on product quality,
- c) Appropriate training for those temporary employees required to work under special environmental conditions, and
- d) Appropriate arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the environment or personnel.

7.0 Product Realization

7.1 Planning Realization of Processes

Cutter Innovations shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirement of the other processes all through the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- a) Quality objectives and requirements for the product;
- b) The need to establish processes, documents and provide resources specific to the product;
- c) Verification and validation activities, and the criteria for acceptability;
- d) Records needed to provide evidence that the realization processes and resulting product fulfill requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

When deemed appropriate, risk assessment on the manufacturing process, which could adversely affect the quality of the product, shall be documented and reviewed.

7.2 Customer-Related Processes

7.2.1 *Determination of Requirements Related to the Product*

Cutter Innovations shall determine:

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- a) Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- b) Requirements not stated by the customer but necessary for specified use or known and intended use,
- c) Statutory and regulatory requirements to the product, and
- d) Any additional requirements determined by the organization.

7.2.2 *Review of Requirements Related to the Product*

Cutter Innovations shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of changes to contracts or orders) and shall ensure that:

- a) Product requirements are defined and documented,
- b) Contract or order requirements differing from those previously expressed are resolved, and
- c) The organization has the ability to meet defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed before acceptance. Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 *Customer Communication*

Cutter Innovations shall determine and implement effective arrangements for communicating with customers in relation to:

- a) Product information,
- b) Inquiries, contracts or order handling, including amendments,
- c) Customer feedback, including customer complaints, and
- d) Advisory notices

7.3 Design and Development

As a contract manufacturer, the requirements for Design and Development activities as described in ISO 9001:2008, are not applicable to Cutter Innovations' manufacturing process. See Quality System Element Exclusions for more detail (page 7).



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As a contract manufacturer, Cutter Innovations does not design or develop any devices for its own intended use. All manufacturing requirements, part specifications, intended use of the device and device labeling is specified and documented by the customer.

Whereby Cutter Innovations has been contracted to manage design and development activities for a finished device, a formal Design Control program shall be established and implemented by Cutter Innovations to ensure that regulatory, quality standard and customer requirements are met.

7.4 Purchasing

7.4.1 *Purchasing Process*

Cutter Innovations shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

Cutter Innovations shall evaluate and select suppliers based on their ability to supply product in accordance with the organization requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 *Purchasing Information*

Purchasing information shall describe the product to be purchased, including where appropriate:

- a) Requirements for approval of product, procedures, processes and equipment,
- b) Requirements for qualification of personnel, and
- c) Quality management system requirements.

Cutter Innovations shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier. To the extent required for traceability, relevant purchasing information, i.e. documents and records shall be maintained.

7.4.3 *Verification of Purchased Products*

Cutter Innovations shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where Cutter Innovations or its customer intends to perform verification at the supplier's premises, they shall state the intended verification arrangements and the method of product release in the purchasing information. Verification records shall be maintained.

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7.5 Production

7.5.1 *Control of Production*

Cutter Innovations shall plan and carry out production under controlled conditions. Controlled conditions shall include, as applicable:

- a) The availability of information that describes the characteristics of the product,
- b) The availability of documented procedures, requirements, work instructions, and reference material as necessary,
- c) The use of suitable equipment,
- d) The availability and use of monitoring and measurement devices,
- e) The implementation of release, delivery and post delivery activities, and
- f) The implementation of defined operations for labeling and packaging.

Cutter Innovations shall maintain a record for each lot of devices that provides the traceability to the extent specified. The Device History Record shall identify the amount manufactured, and amount approved for distribution. The Device History Records shall be verified and approved.

7.5.2 *Validation of processes for Production*

Cutter Innovations shall validate any processes for production where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Validation shall demonstrate the ability of these processes to achieve planned results.

Cutter Innovations shall establish arrangements for these processes including, as applicable

- a) Defined criteria for review and approval of the processes.
- b) Approval of equipment and qualification of personnel.
- c) Use of specific methods and procedures.
- d) Requirement for records (see 4.2.4).
- e) Revalidation.

Where computer software is applicable to the manufacturing process, whereby the software may have an adverse affect on the quality of the product, validation of the computer software shall be conducted and documented.

7.5.3 *Identification and Traceability*

Where appropriate, Cutter Innovations shall identify the product by suitable means throughout product realization. Such means for product identification shall be documented in a procedure. Cutter Innovations shall establish documented procedures to ensure that devices returned from the customer is identified and distinguished from confirming product. Documented procedures for

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traceability shall be established. Such procedures shall define the extent of product traceability and the records required.

Where traceability is a requirement, Cutter Innovations shall control and record the unique identification of the product (see 4.2.4).

7.5.3.3 *Status Identification*

Cutter Innovations shall identify the product status with respect to monitoring and measurement requirements. The identification of product status shall be maintained throughout production, storage and distribution to ensure that only product that has passed the required inspection and tests is dispatched, used or installed.

7.5.4 *Customer Property*

Cutter Innovations shall exercise care with customer property while it is under the organization's control or being used by the organization. Cutter Innovations shall identify, verify, protect and safeguard customer property (including intellectual property) provided for use or incorporation into the product.

If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

7.5.5 *Preservation of Product*

Cutter Innovations shall establish documented procedure for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

Whereby limited shelf-life or special storage conditions are required, documented procedures shall be established. Such special storage conditions shall be controlled and recorded.

7.6 Control of Monitoring and Measuring Devices

Cutter Innovations shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

Cutter Innovations shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall:

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- a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
- b) Be adjusted or re-adjusted as necessary;
- c) Be identified to enable the calibration status to be determined;
- d) Be safeguarded from adjustments that would invalidate the measurement result;
- e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, Cutter Innovations shall assess and record the validity of previous measuring results when the equipment is found not to conform to requirements. Cutter Innovations shall take appropriate action on equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8.0 Measurement, Analysis and Improvement

8.1 General

Cutter Innovations shall plan and implement monitoring, measurement, analysis and improvement processes needed:

- a) To demonstrate conformity of the product,
- b) To ensure conformity of the quality management system, and
- c) To continually improve and maintain the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 *Customer Satisfaction*

As one of the measurements of the performance of the quality management system, the Cutter Innovations management team shall monitor information relating to customer perception as to whether the organization has fulfilled customer requirements. The methods for obtaining and using this information shall be determined.

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A documented procedure for a feedback system (Customer Complaints) to provide early warning of quality problems and for input into the corrective and preventive action processes shall be established.

8.2.2 *Internal Audit*

Cutter Innovations shall conduct internal audits at planned intervals to determine whether the quality management system:

- a) Conforms to planned arrangements (see 7.1) to the requirements of this manual and to the quality management system requirements established by Cutter Innovations.
- b) Is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as results of previous audits. The audit criteria, scope, frequency and methods shall be defined.

Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Cutter Innovations may use qualified outside consultants to perform required internal audits if necessary.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

8.2.3 *Monitoring and Measurement of Processes*

Cutter Innovations shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.

These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, appropriate correction and/or corrective action shall be taken to ensure conformity of the product.

8.2.4 *Monitoring and Measurement of Product*

Cutter Innovations shall monitor and measure the characteristics of the product to verify that product requirements are fulfilled. This shall be carried out at appropriate stages of the product realization process in accordance with planned arrangements (see 7.1).

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Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4). Product release shall not proceed until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

8.3 Control of Nonconforming Product

Cutter Innovations shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

Cutter Innovations deals with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity.
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.
- c) By taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4). When nonconforming product is corrected, it shall be subject to re-evaluation to demonstrate conformity to the requirements. Per Cutter Innovations' MRB process, when nonconforming product is detected after delivery or use has started, Cutter Innovations shall take action appropriate to the effects, or potential effects of the nonconformity.

Where product requires rework, the rework instructions shall be documented, reviewed and approved by the same approval process as the original work instructions. Prior to approval, a determination of any adverse effects of the rework upon product shall be made and documented.

8.4 Analysis of Data

Cutter Innovations' management team shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This includes data generated by monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

- a) Customer satisfaction / feedback (see 8.2.1),
- b) Conformance to product requirements (see 7.2.1),
- c) Characteristics and trends of processes and products including opportunities for preventive action.
- d) Supplier quality.

Records of the results of the analysis of data shall be maintained.

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8.5 Improvement

8.5.1 *Continual Improvement*

Cutter Innovations shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

Records of all customer complaint investigations shall be maintained. If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved.

If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized and recorded

8.5.2 *Corrective Action*

Cutter Innovations shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the cause of nonconformities,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing action needed,
- e) Records of the results of the investigation and action taken (see 4.2.4), and
- f) Reviewing corrective action taken and its effectiveness.

8.5.3 *Preventive Action*

Cutter Innovations shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Recording the results of any investigation and action taken (see 4.2.4), and
- e) Reviewing preventive action taken and its effectiveness.



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8.5.4 *Advisory Notices*

Cutter Innovations is not responsible for the creation or distribution of advisory notices to product end users. It is the responsibility of Cutter Innovations' customers to initiate these types of advisories.