<company>

Quality Management System
Global Quality Manual

<header>

Approved by: _____
Date:

All matters referenced herein are from the authors' knowledge and related global web pages*

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a reference copy of this document may be viewed online: http://creative-logic-software.com/_wsn/page3.html#GQM

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Revision and Approval Record

Rev-Ver	DATE	REASON FOR CHANGE	AUTHOR(s)
0-A 0-B	Feb-09 Jun-09	Initial revision(s) of the document	Don Shave
1-0	Aug-09	Initial Release	Don Shave
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1 Overview

<company>, part of <corporation>, strives to observe key attributes of the relevant medical world more clearly, thereby helping its customers to better understand many attributes of disease, and how such diseases are diagnosed & treated to help allow individuals to live life to the fullest.

<corporation> is comprised of multiple businesses that address varying products and services provided by <company> to its customers. Refer to <company> Organizational Structure Diagram in Appendix A. The current details of the Quality Management System (QMS) of each <company>'s place of business (the "Site") are documented by Site Quality Plans (SQPs) at each <company> location. These details include location, the type of business, and the responsible Executive and Quality representatives.

Throughout this document, the term "**Quality Plan**" implies SQPs or Information Systems (IT) Quality Plans, as defined below:

> A **Site Quality Plan** (SQP) provides a cross reference between this Global Quality Manual, the <company> Global Quality Procedures, site-specific procedures and Work Instructions (WI), and relevant quality standards and regulations at the site, that together form a QMS for the site.

An **Information Systems Quality Plan** / **IT Quality Plan** are used to provide a cross-reference between this Global Quality Manual, the <company> Global Quality Procedures and Information System specific procedures and/or Work Instructions, and the appropriate quality standards and regulations at the site, that together define an IT QMS.

Such plans will provide a consistent approach to IT activities across multiple sites, eliminating the need for IT-specific standards, regulations, or procedures embedded in SQPs.

2 Global Quality Manual (GQM) Overview

2.1 Scope

This quality manual applies to all <company> businesses, functions and facilities worldwide.

The <company> business ranges from development of medical imaging devices to <specific items> and services. A wide range of relevant regulations, standards and other requirements or guidelines apply across <company>.

The QMS of <company> attempts to fully address the requirements of the applicable regulations described in Appendix B.

Periodic quality audits of <company>'s QMS in each of the sites help assure compliance to the relevant applicable regulations, standards and other requirements and guidelines. Audits will be conducted following approved procedures and the results will be documented and reviewed by management.

The structure of this document is derived from clauses of ISO13485/9001 as follows:

- Approvals are deployed as part of the cover sheet
- The Revision and Approval Record is deployed as Section 1
- Section 1, Scope and Section 2, Company information are deployed in Sections 2 & 3
- Section 3, Terms and definitions is deployed as Section 9
- All other ISO Clauses are aligned with numbered sections of this manual

2.2 Introduction

This manual describes a QMS that is applicable at all <company> sites in support of the <company> Quality Policy. It also delineates authorities, inter-relationships and responsibilities of personnel responsible for performing quality activities within the system.

The manual will provide policies for specific areas comprising the QMS to ensure compliance with applicable standards and regulations as identified in the SQP.

This manual can be used externally when required to introduce the <company> QMS to customers, or to other external organizations, or to individuals.

3 Quality Management System (QMS)

3.1 General Requirements

<company> has established, documented and implemented, and presently maintains, the effectiveness of a Quality Management System in accordance with the appropriate requirements of the following regulations, standards and directives and others, where applicable:

- EN ISO 13485:2003, Quality Management Systems – Medical Devices,
- 21 CFR Part 820, FDA's Quality System Regulation (QSR) for Medical Devices,
- 21 CFR Parts 210 and 211 FDA's current Good Manufacturing Practices (GMP) for Drugs,
- EU Directive 2003/94/EC, as detailed in Eudralex Vol 4, *Medicinal Products for Human and Veterinary Use*: Good manufacturing practice (GMP) Guidelines,
- ISO 9001:2000, Quality Management Systems, and
- Appendix B of this document, where applicable.

Appendix B describes the general applicability of these regulations, standards or directives to the various <company> businesses.

As part of <company>'s ongoing commitment to maintain its QMS across all of its businesses, <company>, in coordination with the various <company> businesses, will perform the following:

- periodically review & determine the sequence and interaction of these processes,
- ensure availability of resources/info necessary to support operation/monitoring of processes,
- evaluate operation/control of processes during management reviews and audits of the QMS.
- identify processes needed for the QMS and their application throughout the organization,
- implement actions necessary to achieve planned results, maintain and improve the effectiveness of these processes. and
- monitor, measure, and analyze these processes.

Should <company> choose to outsource any process that affects product conformity with specified requirements (e.g. regulations, standards or specifications), <company> will ensure the process is maintained in compliance with the applicable requirements of this GQM. Control of such outsourced processes is identified within the QMS of the appropriate <company> business.

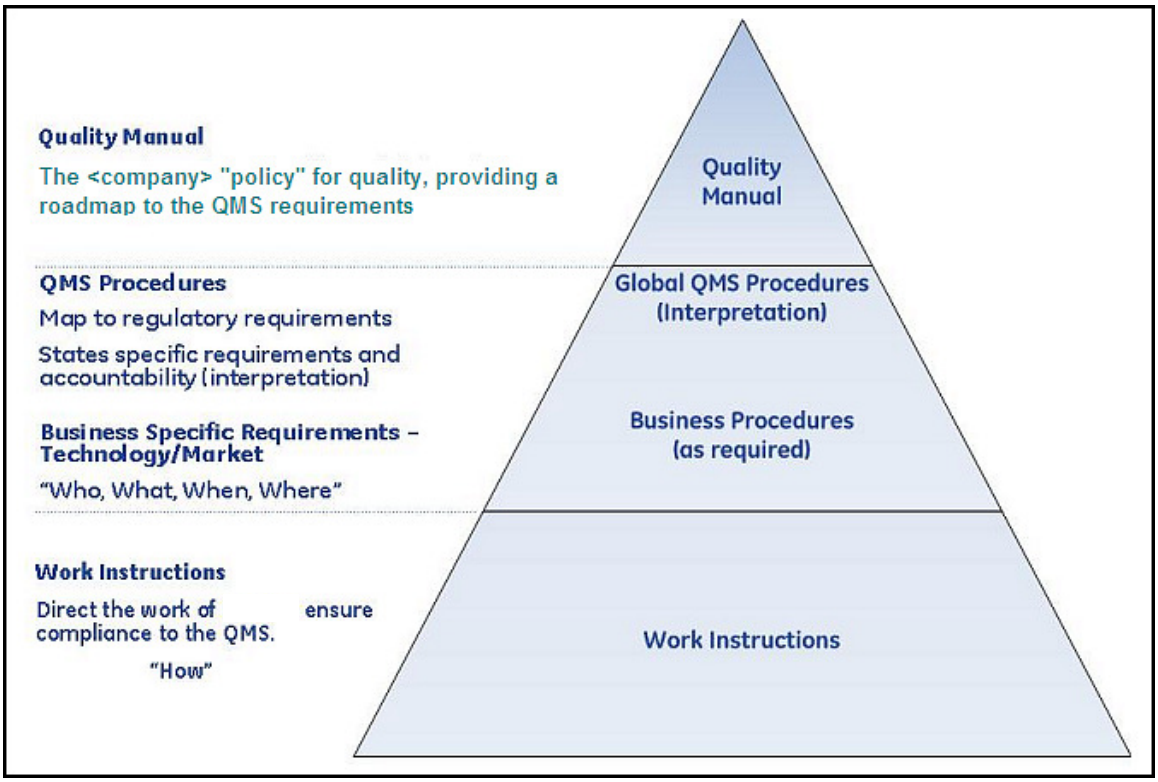
3.2 Documentation Requirements

3.2.1 General

A compliant QMS must include:

- Documented statements of a quality policy and quality objectives.
- A Global Quality Manual.
- <company> Global Quality Procedures (GQPs) defining the minimum acceptable level of quality compliance to identified standards and regulations.
- Business level procedures to address specific standards and regulations or technology and market considerations that require additional definition beyond the scope of the GQPs.
- Work Instructions to assure effective planning, operation, & control of processes, where needed
- Records required by the applicable standards or regulations.
- Any other documentation specified by international, national or regional regulations as applicable based on the Quality Plan.

<company>'s QMS documentation hierarchy is shown here as an example:



Both the Quality Policy and the GQM are the joint responsibility of the President and CEO of <company> and the <Chief Quality Officer> of <company>.

3.2.2 Global Quality Manual

The GQM contains statements of <company>'s general policies regarding its QMS. The GQM is supported by GQPs, Business Level Procedures, and Work Instructions (WI's) where applicable. The interpretation and application of this manual and the GQPs will be defined in the Quality Plans.

The scope of this GQM for <company> is defined by a <company> organizational structure diagram, shown in Appendix A. The interaction and applicability of key regulations, standards and guidelines to specific <company> businesses are listed in Appendix B. QMS key processes and their interactions with medical devices are illustrated in Appendix C.

3.2.3 Control of Documents

<company> establishes and maintains a process to control QMS documents according to the following:

- Written procedures that describe the document control process are controlled.
- Review and approval of documents for adequacy by authorized personnel prior to issuance.
- Review, update and re-approval of documents, as necessary.
- Identification of changes and current revision status of documents.

Controls are also provided to:

- Ensure that relevant WI's are available at locations where operations that impact the product or processes are performed,
- Prevent the unintended use of such documents that are invalid or obsolete,
- Confirm that such documents of external origin are identified and that their distribution is controlled, and
- Assure that such documents remain legible and readily identifiable.

3.2.4 Control of Records

<company> establishes and maintains a process to identify appropriate QMS records and provides evidence of conformity to regulatory requirements and company procedures when required. These records document and assist the effective operation of the QMS.

4 Management Responsibility

4.1 Management Commitment

<company> is committed to a strong QMS that complies with appropriate regulatory requirements and standards. This is achieved by providing an adequate organizational structure and the necessary resources to develop and implement quality planning and objectives.

Top management of each function or business ensures that this is done by:

- Establishing the appropriate responsibility, authority and interrelation of personnel who manage, perform and assess work affecting quality and provide the independence and authority necessary to perform these tasks.
- Communicating to the organization the importance of meeting customer, regulatory and statutory requirements concerning safety and performance of our products, by publication, implementation and distribution of the <company> Quality Policy.
- Ensuring that quality objectives are established in accordance with the <company> Quality Policy and with quality planning.

- Conducting management reviews to evaluate the effectiveness of implementation of the <company> Quality Policy.
- Ensuring the availability of adequate resources.
- Ensuring adequate personnel training and qualification.
- Ensuring timely closure of compliance issues.

4.2 Customer Focus

Management at <company> is responsible for confirming that customer requirements are determined and met via Marketing Research methodologies prior to product release and post-market surveillance methods.

4.3 Quality Policy

<company> will have a common Quality Policy across <company> that will be documented and communicated throughout the organization.

4.4 Planning

4.4.1 Quality Objectives

Annually, <company> Management sets Quality Objectives for the businesses that are measurable and consistent with the Quality Policy. The Management Review process monitors objective attainment. These objectives are shared within the organization across all businesses and functions.

4.4.2 Quality Management System Planning

<company> management ensures that the QMS planning is carried out in order to meet the requirements and quality objectives given in the GQM. The <company> Chief Quality Officer is responsible for the QMS integrity and will implement the appropriate planning, review and policy changes to maintain the system. Individual <company> sites and Information Systems (IT) operations are responsible for developing their own Quality Plans which reference this document, as required.

4.5 Responsibility, Authority, and Communication

4.5.1 Responsibility and Authority

The ultimate responsibility and authority for the application of this manual resides with the <company> President and CEO. The overall responsibility and authority is delegated by the <company> President & CEO to the Chief Quality Officer, who serves as <company>'s QMS management representative.

The management representative is responsible for: 1) ensuring that quality system requirements are effectively established and effectively maintained; and 2) reporting on the performance of the quality system to management with executive responsibility for review.

Each <company> employee is responsible for compliance to this manual.

<company>'s Chief Quality Officer has specific quality responsibilities, including:

- Defining measurable quality objectives,
- Communicating to employees the importance of meeting customer as well as statutory and regulatory requirements,
- Assigning a QMS representative in each of the <company> businesses
- Defining the quality and regulatory organizational structure,
- Assigning quality and regulatory authorities and responsibilities.
- Reviewing the QMS and determining suitability and adequacy of the system,
- Making available the resources and personnel necessary to effectively maintain the QMS.
- Monitoring effectiveness of the QMS
- Ensuring personnel, who manage, perform and verify work affecting quality, have defined organizational responsibilities and the independence and authority to perform these tasks.
- Implementing and enforcing GQPs, associated procedures and WI's, as appropriate.
- Ensuring that processes are in place to address compliance to manufacturing licenses, marketing authorizations and market regulatory requirements.
- Ensuring timely closure of compliance issues.

Responsibilities and authorities of personnel are documented via a job description or profile, an organization chart and/or yearly goals and objectives.

4.5.2 Management Representative

The <company> President and CEO appoints the Chief Quality Officer as the <company> Management representative.

The Chief Quality Officer appoints a Quality Representative for each <company> business. These representatives effectively act as the Management Representative for that business.

In addition, a Quality Representative will be designated at the site level and for Information Systems (IT) to provide local implementation of these responsibilities. These individuals, irrespective of other responsibilities also have the authority over and responsibility for the items listed below:

- ensuring processes addressing the QMS requirements are effectively established, implemented, and maintained in accordance with the GQPs and applicable regulations for the specific site/function.
- reporting to management on QMS performance and any need for improvement,
- ensuring the promotion of awareness of regulatory and customer requirements throughout the organization. and
- serving as <company>'s primary contact with external parties on matters relating to the companies QMS.

4.5.3 Internal Communication

At <company>, executive management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the QMS. The business Quality Representative is responsible for communications relating specifically to the QMS in each of the businesses. Site Quality Representatives report to the Quality Representative of their business. The business Quality Representatives each report to the Chief Quality Officer, ensuring communications cascade through the organization.

4.5.4 General

The Chief Quality Officer and the Business CEO review the organization's QMS according to established procedures to ensure its continuing suitability, adequacy, and effectiveness and to drive actions, where needed. Reviews are planned and conducted in accordance with a defined agenda and frequency stated in the QMS review procedure.

4.5.5 Management Review Inputs

Management Reviews performed at <company> are documented and include the dates and results of quality system reviews. A management review meeting agenda is prepared for each meeting that includes the following inputs:

- Audit results, both internal and external,
- Changes that could affect the QMS,
- Customer feedback,
- Follow-up actions from previous management reviews,
- New or revised industry or regulatory requirements
- Process and QMS performance and product conformity,
- Recommendations for improvement, and
- Status of preventive and corrective (CAPA) actions,
- Other items, as needed.

4.5.6 Management Review Outputs

QMS Reviews performed at <company> are documented and include appropriate review outputs. This is to include decisions and actions relating to the following:

- Improvement of product related to customer requirements,
- Improvements needed to maintain the effectiveness of the QMSs and their processes,
- Quality resource needs,
- Other outputs, as needed.

5 Resource Management

5.1 Provision of Resources

<company> determines and provides the resources needed to effectively implement the QMS, to maintain its effectiveness, and to meet regulatory and customer requirements, as is described below.

5.2 Human Resources

5.2.1 General

<company> confirms that personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience. <company> has processes for the hiring and training of all employees Responsibilities and authorities of personnel are documented via a job description/profile, organization charts or as goals and objectives.

5.2.2 Competence, Awareness and Training

<company> has established and maintained a process to determine the necessary competence and training required for personnel performing work affecting quality. Training requirements and results are documented.

Training is provided on an ongoing basis either as on-the-job training or via internal or external coursework.

Effectiveness of training is assessed by a written test, observation, question & answer or as deemed appropriate by the trainer on a case by case basis, in a manner consistent with the local site training procedure. Training ensures that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives. Records of completion of training are maintained for every employee.

5.3 Infrastructure

<company> has determined and provides and maintains the infrastructure needed to achieve conformity to product and QMS requirements. Infrastructure includes, as applicable,

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

This includes design and construction, lighting, ventilation, plumbing, waste management, sanitation and other items required by local regulation. <company> has established procedures that include requirements for maintenance activities, including their frequency, and when such activities or lack thereof can affect product quality. Records of such maintenance are maintained on site.
Where required for product protection <company> ensures such facilities are designed and maintained to control or minimize product contamination.

<company> complies with applicable global standards and national standards for each country.

5.4 Work Environment

<company> manages the work environment needed to achieve conformity to product and QMS requirements. Procedures are defined to address:

- Health, cleanliness, and clothing of personnel, if contact between personnel and the product or work environment could adversely affect the quality of the product.
- Contamination. <company> will establish and maintain facilities to control or minimize contaminants that have the potential to adversely affect product quality, such as dust, humidity, and insects.
- Training of temporary workers that work under special environmental conditions. <company> will establish and maintain procedures to specify the type of training or supervision required.
- Control of contaminated or potentially contaminated product to prevent contamination of other product, the work environment or of personnel.

6 Product Realization

6.1 Planning of Product Realization

<company> has established and maintains processes to document the responsibilities for the planning of product realization and identification of assigned resources. The product realization procedures determine the following:

- Quality objectives and requirements for the product,
- Needed processes, documents, and resources specific to the product;
- Required specifications, verification, validation, monitoring, inspection, and test activities specific to the product,
- Criteria for product acceptance;
- Records needed to provide evidence that the realization processes and resulting product meet requirements.

Output planning is performed as outlined in processes and is part of the product realization process. In addition, documented requirements must be in place for risk management throughout product realization.

6.2 Customer-related Processes

6.2.1 Determination of Requirements Related to the Product

<company> determines the following:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities,
- Statutory and regulatory requirements related to the product, and
- Any additional requirements determined by <company>.

6.2.2 Review of Requirements Related to the Product

<company> establishes and maintains processes that define responsibility for accurately reviewing the requirements related to the product.

This review is conducted prior to a <company> commitment to supply a product to the customer (acceptance of contract or orders). Controls include a process to evaluate and confirm the following:

- Product requirements are defined and documented.
- Contract or order requirements differing from those previously expressed are resolved.
- <company> has the ability to meet those requirements.

The results and actions arising from the review are documented and maintained. Where a customer provides no documented statement of requirements, the customer requirements will be confirmed and documented prior to order acceptance.

Where product requirements are changed, a process must be in place to confirm that documents relevant to product requirements are amended and relevant personnel are made aware of the change.

6.2.3 Customer Communication

<company> has established and maintains processes used to communicate with customers. These processes address:

- Product information,
- Inquiries, contracts, order handling, including amendments,
- Customer feedback, including appropriate handling, reporting and investigation of customer complaints,
- Advisory notices (where applicable),
- Definition of responsibilities for communication with customers and regulators.

6.3 Design and Development

6.3.1 Design Planning

<company> has established and maintains a process that is described in procedures outlining the responsibility for design and development. The process requires that <company> plans and controls the design and development of the product. The process ensures that during the design and development planning, the following are addressed:

- Designation of the program manager, who:
  - Will manage interfaces between different groups involved in the design and development process.
  - Has the responsibility to ensure effective communication and clear assignment of responsibilities.
- Identification of responsibilities and authority for design and development,
- Identification of design and development stages and handoffs,
- Formal design review of design inputs, design verification, design transfer and validation, prior to the product release.

Design planning output is documented, approved and updated as appropriate throughout the design process. Design transfer activities during the design process are documented to ensure that all design outputs are verified as suitable for manufacturing before becoming final production specifications.

6.3.2 Design Inputs

<company> has a process which requires that design inputs are appropriate to address the intended use(s) of the device, including the needs of the user and patient. Design inputs include:

- Applicable statutory and regulatory requirements
- Contract requirements, if applicable
- Intended use and user needs (product usability)
- Other requirements essential for design and development
- Output(s) of risk management
- Product's functional, performance and safety requirements
- Where applicable, information derived from previous similar designs
- Review and approval of design input records

Design inputs must be adequate, complete, unambiguous, and not in conflict with each other. They must be reviewed and approved, and the approval must be documented.

6.3.3 Design Outputs

<company> has established a process to ensure design outputs are provided in a form that enables verification against the design inputs. Verifications are approved prior to release. Design outputs include:

- Traceability to the design inputs.
- Product acceptance criteria.
- Characteristics of the product that are essential for its safe and proper use.
- Information for purchasing, production and the provision of service.
- Review and approval of design output records.

The final design output is the verified and validated finished device, with labeling, packaging, and Device Master Record or Product Dossier. The Device Master Record includes purchasing specifications, manufacturing procedures, assembly drawings, software code, test procedures, service and installation manuals, and operator instructions.

6.3.4 Design Review

<company> has established and maintains a process that defines the appropriate stages for systematic reviews of design. These reviews are performed and documented in accordance with planned arrangements. The planned formal documented reviews and the stages at which they are required are described in the <company> Design Control procedure.

Design Reviews include:

- An evaluation of the design outputs to meet design inputs.
- Identification of potential problems and proposed necessary actions.

Reviewers include representatives of functions concerned with the design stage(s) being reviewed as well as identified independent reviewer not directly responsible for the product design. Records are maintained of the results of the reviews and any necessary actions.

6.3.5 Design Verification

<company> has established and maintains a design verification process which ensures that the design output meets the design input requirements. Design verification is accomplished by providing documented objective evidence that design outputs meet design input requirements. These activities are performed and documented by qualified personnel.

6.3.6 Design Validation

<company> has established and maintains a process which ensures that design validation is performed in accordance with an approved validation plan. The purpose of the validation is to confirm that the resulting product is capable of meeting the requirements for the specified application, including user needs and intended uses.

Validation is completed prior to the delivery or installation of the product.

> Note: If a medical device can only be validated following assembly and installation at point of use, delivery of validation units is not considered to be complete until the units have been validated and transferred formally to the customer. Validation plans that involve delivery of units to users shall be approved by the appropriate <company> or business regulatory function before shipment of the unit to ensure that the appropriate regulatory requirements are addressed.

Records of the results of validation and any necessary actions are maintained.

Design validation is performed under actual- or simulated-use conditions. These conditions are defined, documented and representative of the environment in which the product will be used.

Design validation demonstrates that:

- The design meets the device's intended use and the user needs defined in the design Inputs and the product specification.
- The user manual and operating instructions are validated.
- The device meets marketing requirements and claims.
- The device risk mitigation is effective.

<company> performs clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations or as deemed necessary by the product team.

> Note: Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery. External evaluation plans will be approved by the appropriate <company> or business regulatory function to ensure that applicable regulatory requirements are addressed.

Design validations are performed on production or production equivalent units, lots, or batches of the finished device. If a production equivalent unit is utilized for design validation activities, a statement of product equivalence is completed and documented.

6.3.7 Design Changes

<company> has established and maintains a design change process that defines how changes are proposed, reviewed, approved, and incorporated into a product. Changes are modifications that affect the form, fit, function or compatibility of a part or assembly; modify software or firmware; or require change to the assembly or testing of the final product or its components. Design changes are performed following approved procedures and recorded.

6.3.8 Design Transfer

<company> has established and maintains a design transfer process that defines how to translate the device design into production. Design transfer includes activities that are performed on product to validate the production processes. Design transfer includes service activities required to demonstrate the product can be properly installed, maintained and repaired. Design transfer is performed following approved procedures and documented.

6.3.9 Design Records

<company> maintains a Design History File in accordance with approved procedures for each product development program. The Design History File contains records necessary to document that the design was developed in accordance with the approved Integrated Design Plan.

The following design control documents are included in the Design History File:

- Master index
- Integrated Design Plan and updates
- Design Inputs
- Formal Design Reviews
- Interim design outputs
- Design Verification
- Design Validation and Transfer
- Risk Management Summary
- Design changes

6.4 Purchasing

6.4.1 Purchasing Process

<company> has established and maintained documented processes to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.

<company> will evaluate and select suppliers based on their ability to supply product and services in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation have been established and will be maintained as appropriate.

Records of the results of evaluations and any necessary actions arising from the evaluation are maintained, following approved procedures

6.4.2 Purchasing Information

<company> will ensure the adequacy of specified purchase requirements prior to their communication to the supplier. To the extent required for traceability <company> maintains relevant purchasing information.

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

- Requirements, including quality requirements that must be met by suppliers, contractors, and consultants.
- Where possible, evaluation of potential supplies, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements, as appropriate.
- Requirements for approval of products, procedures, processes, and equipment.
- Where possible, requirements that suppliers, contractors, and consultants notify the appropriate <company> entity of changes in a product or service, as appropriate.
- Requirements for qualification of personnel.
- QMS requirements

6.4.3 Verification of Purchased Product

<company> has established and maintained approved procedures for the inspection and/or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where <company> or its customer intends to perform verification at the supplier's premises, <company> states the intended verification arrangements and method of product release in the purchasing information. Records of the verification are maintained.

6.5 Production and Service Provision

6.5.1 Control of Production and Service Provision

6.5.1.1 General Requirements

<company> has established and maintained processes that address production and service provision under controlled conditions. These include:

- The availability of information that describes the characteristics of the product.
- The availability of documented procedures, documented requirements, WI's, reference materials and reference measurement procedures as necessary to ensure product quality.
- The availability and use of suitable equipment and work environments.
- The availability and use of suitable monitoring and measuring devices.
- The implementation of suitable monitoring and measuring techniques.
- The implementation of release, delivery, and post-delivery activities.
- The implementation of labeling and packaging processes.

<company> provides traceability for each batch of medical devices to the extent specified in 8.5.3 and identifies the amount manufactured and amount approved for distribution. Batch records are verified, approved, and maintained in accordance with approved procedures. A batch is one or more medical devices traceable via a unique identifier.

6.5.1.2 Control of Production and Service Provision—Specific Requirements for Medical Devices:

Cleanliness of Product and Contamination Control

Where applicable <company> has established requirements for cleanliness of product if:

- Product is cleaned by <company> prior to sterilization and/or its use.
- Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use.
- Product is supplied to be used non-sterile and its cleanliness is of significance in use.
- Process agents are to be removed from product during manufacture.

Installation Activities

<company> develops, provides, and maintains procedures and documentation required to carry out installation and verification activities. <company> establishes acceptance criteria for verifying installation of products at the customer site. Records of installation and verification are documented and maintained as applicable, following approved procedures.

Servicing Activities

<company> will evaluate whether there is a need for servicing each product. Where servicing is a specified requirement, <company> establishes and maintains instructions and procedures for performing and verifying that the servicing meets the specified requirements.

When a report of service constitutes an allegation of a deficiency related to the quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution, the report is considered to be a complaint and is investigated per <company> complaint handling procedures. If the report involves a death, injury or hazard to safety, it is evaluated for reporting under Medical Device Reporting regulation 21CFR Part 803 or equivalent, as appropriate.

<company> allows servicing to be performed by third party service providers once they are approved under the supplier qualification program set forth by <company> procedures. <company> develops and provides documentation required to carry out service and verification activities. Records of service and verification are maintained, as applicable.

<company> analyzes service reports with appropriate statistical methodologies, and takes appropriate action based on the analyses.

6.5.1.3 Particular Requirements for Sterile Medical Devices

A GQP details <company>s Sterility Assurance procedure for a wide range of sterilization modalities, including control and monitoring of bioburden, control of raw materials and management of sterilization systems.

6.5.2 Validation of Processes for Production and Service Provision

6.5.2.1 General Requirements

<company> has established and maintains procedures to identify and validate software and processes for production or service provision that cannot be verified by monitoring and measurement techniques.

This includes software and processes where defects are discovered only after the product is in use, or after the service is delivered. Validations demonstrate the ability of these processes and software applications to achieve planned results. Validation planning will consider:

- Criteria for review and approval of such processes and software applications.
- Approval of processes and required equipment and qualification of personnel.
- Use of specific methods and procedures.
- Requirements for records that document the validation.
- Revalidation.

6.5.2.2 Particular Requirements for Sterile Medical Devices

<company> has established procedures for the validation of sterilization processes. Sterilization processes are validated prior to initial use. Validation and batch records are maintained.

6.5.3 Identification and Traceability

6.5.3.1 Identification

<company> has established and maintains a process to control how products are identified. This includes appropriate identification and, as appropriate, isolation of returned product to prevent it being confused with conforming product.

6.5.3.2 Traceability

General

<company> has established and maintains a process to define traceability requirements, the extent of traceability within a product, and the records required to account for product. At defined points where traceability is a requirement, <company> provides necessary controls to make the product uniquely traceable, and to create a record of the product.

Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices

In defining the records required for traceability, <company> includes records of components, materials and work environment conditions that could cause a medical device to not satisfy its specified

requirements. <company> requires that its agents or distributors maintain records of the distribution of medical devices so as to allow traceability. These records are available for inspection and include the name and address of the shipping package consignee.

6.5.3.3 Status Identification

<company> has established and maintains processes to identify product status with respect to monitoring and measurement requirements. The identification of product status is maintained throughout production, storage, installation, and servicing of the product to confirm that only product that has passed the required inspections and tests (or has been released under an authorized deviation) is shipped, used, or installed.

6.5.4 Customer Property

It is <company>'s policy to exercise care with customer property while it is under <company> organization's control or is being used by the <company> organization. <company> will identify, verify, protect, and safeguard customer property provided for use or incorporation into the product.

If customer property is lost, damaged, or otherwise found to be unsuitable for use, this will be reported to the customer and records maintained. Customer property can include intellectual property or confidential health information. The confidentiality of individual patient records is preserved.

<company>'s policy is to treat a customer's intellectual property or confidential health information as customer property. Intellectual property is handled through the <company>'s Legal organization. Health information is handled confidentially throughout the <company> organization, and in a manner that complies with applicable privacy regulations.

6.5.5 Preservation of Product

<company> has established and maintains processes for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage, & protection. Preservation also applies to constituent parts of a product.

<company> has also established and maintains procedures or WI's for the control of product with a limited shelf-life or which requires special storage conditions, as applicable. Any special storage conditions are to be controlled and recorded.

6.6 Control of Monitoring and Measuring Devices

<company> determines any monitoring and measurement that is to be undertaken and identifies the monitoring and measuring devices needed to provide evidence of conformity of product to pre-determined requirements.

<company> has established and maintains processes to confirm that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements in accordance with approved procedures. Valid results are to be confirmed with measuring equipment that is:

- Calibrated or verified at specified intervals, or prior to use as appropriate, against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification will be recorded;
- Adjusted or re-adjusted as necessary;
- Identified to enable the calibration status to be determined;
- Safeguarded from adjustments that would invalidate the measurement result;
- Protected from damage and deterioration during handling, maintenance and storage.

If and when equipment is found to not conform to requirements, <company> will assess and record the validity of the previous measuring results. <company> will take appropriate action in regards to the equipment and any product affected. Records of the results of calibration and verification activities will be maintained.

When software is used in the monitoring and measurement of specified requirements, the ability of the software to satisfy the intended application will be validated. The validation is to be undertaken prior to initial use and reconfirmed as necessary.

7 Measurement, Analysis and Improvement

7.1 General

<company> has planned and implemented the monitoring, measurement, analysis, and improvement processes needed:

- To demonstrate conformity of the product,
- To ensure conformity of the QMS, and
- To maintain the effectiveness of the QMS.

This plan includes determination of applicable methods, including statistical techniques, and the extent of their use.

<company> has established documented procedures for implementation and control of the application of statistical techniques and their results recorded.

7.2 Monitoring and Measurement

7.2.1 Feedback

As part of the Management Review, <company> monitors information to evaluate the ability of the organization to meet customer requirements and regulatory compliance. Management Review is a feedback system to address quality problems and to provide input to the corrective and preventive (CAPA) action processes. <company> uses customer feedback and complaints from the postproduction phase as one of the inputs to CAPA processes and new product design programs.

7.2.2 Internal audit

<company> conducts internal audits to evaluate that the organization:

- Conforms to internal procedures, to the requirements of the applicable regulations and to the QMS requirements established by <company>, and
- Has been effectively implemented and maintained.

The audit criteria, scope, frequency, and methods are defined and documented. Internal audit activities are summarized and presented at each Quality Management Review

<company> has a procedure to define the responsibilities and requirements for planning and conducting audits, reporting results, and maintaining audit records.

The management responsible for the area being audited ensures that corrective and preventive (CAPA) actions are taken to address detected nonconformities and their causes.

7.2.3 Monitoring And Measurement Of Processes

<company> applies suitable methods for monitoring and, where applicable, measurement of QMS processes. These methods demonstrate the ability of the processes to create product that meets specification in accordance with <company> procedures and applicable regulations. When specifications are not met or procedures or process or regulatory requirements are not followed, a Corrective & Preventive (CAPA) process is used to assess the need for action.

7.2.4 Monitoring And Measurement Of Product (Inspection And Test)

<company> monitors and measures the characteristics of the product to verify that product requirements are met. These measurements are carried out at defined stages of the product realization process in order to demonstrate the product meets specifications in accordance with <company> procedures and applicable regulations. Release of product that meets specification will be documented and will contain the name(s) of the person(s) authorizing release.

7.3 Control Of Nonconforming Product

<company> has established and maintains procedures to ensure product that which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

<company> takes one or more of the following actions to disposition nonconforming product:

- Rejection of the nonconforming product
- Taking action to address the detected nonconformity;
- Authorizing its use, release, or acceptance of the nonconforming product if a thorough investigation supports such disposition, including documented rationale and approval.

<company> will ensure that nonconforming product is accepted by deviation only if regulatory requirements are met after completion of investigation with documented rational and approval. Records of the investigation and the identity of the person(s) authorizing the deviation will be maintained.

7.4 Analysis of Data

<company> has established and maintains processes to determine, collect, and analyze data to evaluate the suitability and effectiveness of the QMS following approved procedures. The analysis of data provides information relating to:

- Feedback
- Conformity to product requirements
- Characteristics and trends of processes and products.
- Suppliers.

Records of the results of the analysis of data are maintained.

7.5 Improvement

<company> identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the QMS through the use of the <company> Quality Policy, quality objectives, audit results, analysis of data, corrective and preventive actions (CAPA), and management review. Proposed changes are assessed for regulatory implications.

<company> has established and maintains processes for the issue and implementation of recalls and/or advisory notices (where applicable). These procedures may be implemented at any time.
Records of customer complaint investigations are maintained. If investigation determines that the activities outside of <company> may have contributed to the customer complaint, relevant information is exchanged between the organizations involved.

Processes must be in place and are maintained for reporting to regulatory agencies that require notification of adverse events that meet specified reporting criteria; <company> has established processes for such notifications to regulatory authorities and any appropriate follow-up.

7.5.1 Corrective action

<company> takes appropriate action to address the cause of nonconformities in order to reduce likelihood of recurrence.

<company> has a process for corrective action which defines requirements for:

- Reviewing nonconformities.
- Determining the causes of nonconformities.
- Evaluating the need for action to reduce likelihood of occurrence that nonconformities recur.
- Determining and implementing action needed
- Recording of the results of any investigation and of any action taken.
- Reviewing corrective action taken and its effectiveness.

7.5.2 Preventive Action

<company> has established and maintains procedures to assure that causes of potential nonconformities are addressed in order to reduce the likelihood of their occurrence.

<company> has a process for preventive action which defines requirements for:

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

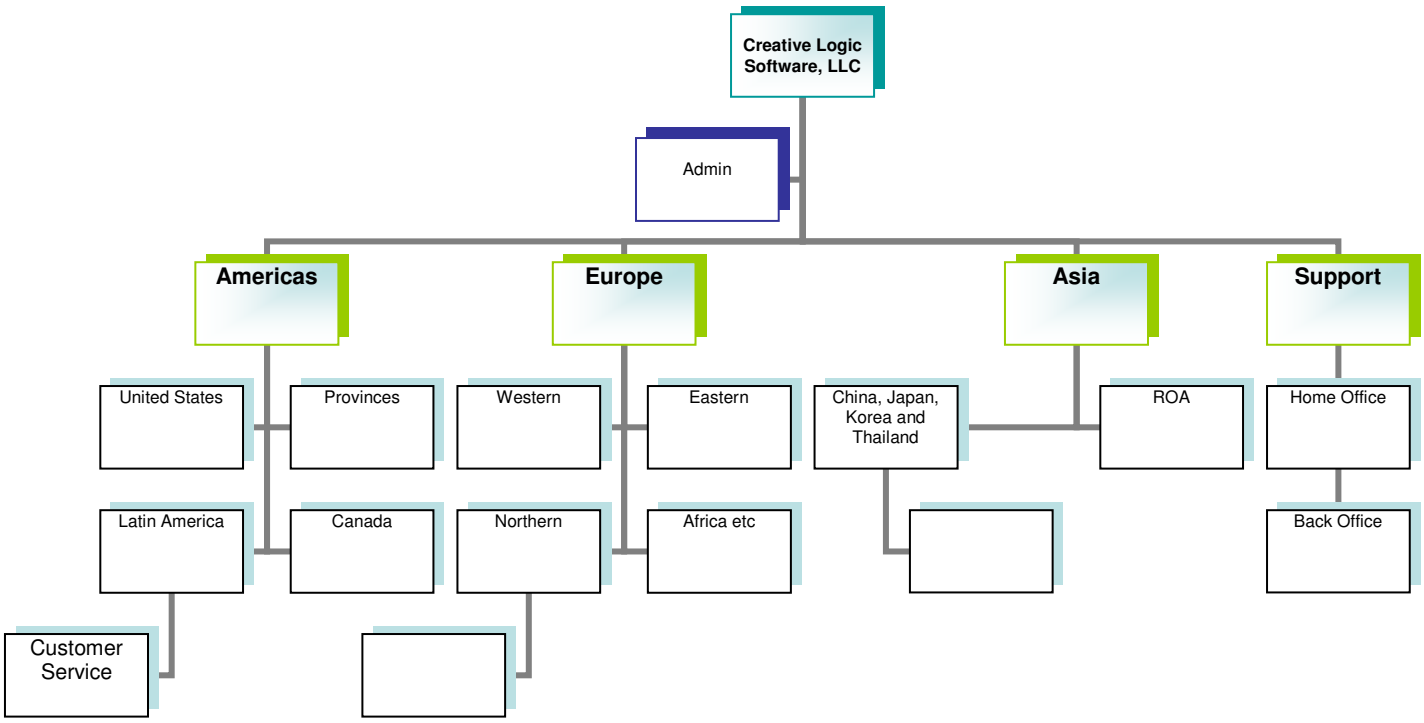
8 Terms and Definitions

The following table defines acronyms and terms used in this document.

Term or Acronym	Definition
CAPA	Corrective and Preventive Actions
CFR	Code of Federal Regulations
EU	European Union
FDA	United States Food & Drug Administration
GQM	Global Quality Manual
GMP	Good Manufacturing Practices
ISO	International Standards Organization
QMS	Quality Management System
QSR	Quality System Regulation
SQP	Site Quality Plan
WI	Work Instruction (details on how a process is to be deployed)

APPENDICES

Appendix A: Sample Organizational Structure Diagram



Appendix B: Applicable Regulations

A sample summary of certain Applicable Regulations & Standards is listed here for reference:

- ISO13485:2003 Medical Devices requirements & ISO9001 Quality Management Systems requirements
- FDA 21CFR Part 820 (Quality System Regulations), 210 and 211
- Canadian Medical Devices Regulations and amendments (CMDR) SOP 98-282 (with amendments),
- EC Directive 93/42/EEC MDD
- Japanese Pharmaceutical Affairs Law & MHLW Ministerial Ordinance No.169 "Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostics Reagents", 2004
- European, United States and Japanese Pharmacopoeia
- 2003/94/EU Principles and guidelines for good manufacturing practice for medicinal products for human use

International sites that are part of <company> are responsible for listing additional applicable regulations, standards and other requirements and guidelines in the Site Quality Plans.

Similarly, Information Systems (IT) is responsible for listing additional applicable regulations, standards and other requirements and guidelines in the Information Systems (IT) Quality Plans.

A matrix of the example QMS is mapped to certain Regulations & Standards below; section numbering is aligned with clauses of ISO13485/9001

Quality Manual: Section 4.0, Quality Management System

Quality System Element	FDA 21CFR Part 820	FDA 21CFR 210 & 211	ISO 13485 & ISO 9001	EU Directive 2003/94/EC as detailed in Eudralex Vol 4 (GMPs)	MHLW Ordinance No. 169
Quality System	820.5, 820.20		4.1, 4.2.1, 4.2.2	Chapter 1	Article 5
Document Controls	820.40	211.180	4.2.3	Chapter 4	Article 6, 7, 8
Control of Quality Records	820.180, 820.181, 820.184, 820.186, 820.198	211.100, 211.182, 211.184, 211.186, 211.188, 211.192, 211.194, 211.196, 211.198	4.2.4	Chapters 4,6	Article 9

Quality Manual: Section 5.0, Management Responsibility

Quality System Element	FDA 21CFR Part 820	FDA 21CFR 210 & 211	ISO 13485 & ISO 9001	EU Directive 2003/94/EC as detailed in Eudralex Vol 4 (GMPs)	MHLW Ordinance No. 169
Management Commitment	820.20		5.1	Chapters 1, 2	Article 10
Customer Focus			5.2	Chapter 8	Article 11
Quality Policy	820.20		5.3		Article 12, 13
Quality Planning	820.20, 820.5		5.4	Chapter 1	Article 14
Responsibility, authority and communication	820.20	211.22	5.5	Chapter 2	Article 15
Management Review	820.20		5.6		Article 16

Quality Manual: Section 6.0, Resource Management

Quality System Element	FDA 21CFR Part 820	FDA 21CFR 210 & 211	ISO 13485 & ISO 9001	EU Directive 2003/94/EC as detailed in Eudralex Vol 4 (GMPs)	MHLW Ordinance No. 169
Resources	820.20		6.1	Chapter 2	Article 21
Personnel, Competence, Awareness and Training	820.25	211.22 211.25 211.28	6.2	Chapter 2	Article 22, 23
Infrastructure	820.70	211.42 211.44 211.46 211.48 211.50 211.52 211.56 211.58	6.3	Chapter 3	Article 24
Work Environment	820.70	211.42 211.44 211.46 211.48 211.50 211.52 211.56 211.58	6.4	Chapter 3	Article 25

Quality Manual: Section 7.0, Product realization

Quality System Element	FDA 21CFR Part 820	FDA 21CFR 210 & 211	ISO 13485 & ISO 9001	EU Directive 2003/94/EC as detailed in Eudralex Vol 4 (GMPs)	MHLW Ordinance No. 169
Planning of product realization and Risk Management	820.30		7.1		Article 26
Customer-related processes	820.30		7.2	Chapter 8	Article 27, 28, 29
Design and development	820.30		7.3	Chapter 1	Article 30, 31, 32, 33, 34, 35, 36
Purchasing	820.50, 820.80		7.4	Chapter 1	Article 37, 38, 39
Production and Service Provisions: Production and Process Controls ID and Traceability Inspection and Testing Service and Install	820.70, 820.75, 820.60, 820.65, 820.80, 820.86, 820.170, 820.200	211.80, 211.82, 211.86, 211.87, 211.100, 211.101, 211.111, 211.113, 211.115, 211.160	7.5	Chapter 1	Article 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50
Customer Property	N/A		7.5.4		Article 51

Quality System Element	FDA 21CFR Part 820	FDA 21CFR 210 & 211	ISO 13485 & ISO 9001	EU Directive 2003/94/EC as detailed in Eudralex Vol 4 (GMPs)	MHLW Ordinance No. 169
Handling, Storage, Packaging, Labeling, Preservation and Delivery of product	820.120, 820.130, 820.140, 820.150, 820.160	211.122, 211.125, 211.130, 211.132, 211.134, 211.137, 211.142, 211.150	7.5.5	Chapter 1	Article 52
Control of monitoring and measuring devices	820.72	211.68	7.6		Article 53

Quality Manual: Section 8.0, Measurement, Analysis and Improvement

Quality System Element	FDA 21CFR 820	FDA 21CFR 210 & 211	ISO13485 (2003) & ISO 9001 (2000)	EU Directive 2003/94/EC as detailed in Eudralex Vol 4 (GMPs)	MHLW Ordinance No. 169
General	820.250		8.1		Article 54
Feedback	820.100		8.2.1		Article 54, 55
Internal Auditing	820.22		8.2.2	Chapter 9	Article 56
Monitoring and measurement of processes	820.22	211.105, 211.110	8.2.3		Article 57
Monitoring and measurement of product (Inspection and Testing)	820.70, 820.250, 820.80	211.22, 211.80, 211.82, 211.110	8.2.4	Chapter 6	Article 58, 59
Control of nonconforming product	820.90	211.82, 211.87, 211.89, 211.198, 211.208	8.3	Chapters 1,6	Article 60
Analysis of data	820.250	211.103, 211.160	8.4		Article 61
Improvement	820.20, 820.100		8.5		Article 62, 63, 64

Appendix C: Product Life-cycle Model

A model is provided here, illustrating the approximate interactions of the processes in a Quality Management System for medical devices.