Title:	**Quality Manual**
Document type:	**Quality Manual**
Document ID:	**QM-1**
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Approval date:	2019-01-16
Effective date:	2019-01-16

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2. Scope

Leonhardt Launchpads is focused on developing products for our customers in the regenerative medtech space . Leonhardt Launchpad and it's Portfolio Companies are committed to compliance with applicable statutory and regulatory requirements while at the same time being focused on delivering value to our customers, shareholders and the broader medical community. The organization adheres to a strong set of values that provide direction and guide decisions.

This Quality Manual includes the minimum requirements of the Quality System. It is applicable to the global activities of Leonhardt Launchpads and its Portfolio Companies. This document is used to:

- Communicate the Quality vision, values, policies and objectives of the organization
- Demonstrate how the Quality System has been designed and implemented
- Demonstrate compliance with applicable standards and regulations
- Define the delegation of Quality System responsibility throughout the organization
- Establish Quality Management System scope including justifications for exclusion(s)

The responsibility for adherence and management of processes within the Quality System belongs to individual companies and sites as applicable according to this Quality Manual and is detailed further for each Portfolio Company through an approved Company Quality Plan (CQP). These responsibilities are described throughout this Quality Manual. Any exclusion shall be documented either within this Quality Manual or within company or site specific Quality System documents (e.g. Company Quality Plans).

3. Reference Documents

This Quality Manual describes the Quality System requirements including, but not limited to ISO 13485 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes and FDA CFR 820.

Additional requirements set forth by specific regional and/or national applicable regulatory/statutory requirements and standards can also be the basis for the quality system and are referenced in Company Quality Plans and Quality System documentation as appropriate.

The following support documents that supplement this Quality System Manual are listed below:

- Leonhardt Launchpad's Quality Policy (Section 6 of this Manual)
- Leonhardt Launchpad's Quality Objectives

- Portfolio Company Quality Plans (CQPs)

4. Terms and Definitions

Company Quality Plan (CQP) - High Level Quality, Project and Risk Management planning document created for specific Leonhardt Launchpads portfolio companies that governs the scope of quality activities for that company. By default, the CQP acts also as the Design and Development Plan for projects.

Company or Portfolio Company - Portfolio Company under the Leonhardt Launchpad umbrella

Parent Organization - Leonhardt Launchpads

Organization - Leonhardt Launchpads and it's Portfolio Companies

Management with Executive Responsibility - Management within Leonhardt Launchpads itself or management with assigned responsibility for applicable Portfolio Companies as applicable

5. Quality Management System

General Requirements

Quality Management System (QMS)

Management with Executive Responsibility (See Attachment A) shall establish, document, implement and maintain the Quality System.

The Quality System is continually assessed and improved in accordance with the requirements of applicable standards and regulations.

- Portfolio Companies will leverage the Quality System of Leonhardt Launchpads including Quality Processes, Procedures and Documentation
- Portfolio Companies will be responsible for defining the scope including personnel and quality system requirements for their organization through the creation of a Company Quality Plan (CQP)
- All project level requirements related to product in development are also defined and traced to the CQP, including but not limited to the design and development plan, risk management plan and manufacturing or prototype build considerations

QMS Processes

Management with Executive Responsibility shall:

- Determine processes needed for implementation and maintenance of a compliant Quality Management System
- Apply a risk-based approach to the control of QMS processes
- Determine the overall sequence and interaction of QMS processes

QMS Process Management

For each QMS Process, Management with Executive Responsibility shall :

- Determine criteria and methods necessary to ensure that both the operation and control of these processes are effective
- Ensure the availability of resources and information necessary to support the operation and monitoring of

these processes

- Implement actions necessary to achieve planned results and maintain effectiveness of these processes
- Monitor, measure and analyze these processes where applicable
- Establish and maintain records necessary to demonstrate conformance and compliance with applicable standards and regulatory requirements

QMS Process Changes

Management with Executive Responsibility shall manage all changes to the QMS by:

- Evaluating impact of changes on the QMS
- Evaluating impact of changes on the products manufactured under the QMS
- Controlling and documenting QMS changes

Outsourced Processes

When Leonhardt Launchpads or a Portfolio Company chooses to outsource any processes that affects product conformity to requirements, that entity shall monitor and ensure control over such processes. Control of outsourced processes is further defined within the Quality System processes and procedures.

- Leonhardt Launchpads and Portfolio Companies still retains responsibility of conformity for outsourced processes
- Process controls shall be proportionate to the risk involved
- External parties shall be evaluated to meet the needs of Leonhardt Launchpads and/or Portfolio Companies
- Written and Approved Quality Agreements or equivalent document shall be used as necessary based on risk

Software Considerations

Management with Executive Responsibility shall ensure processes are in place to validate computer software used in the QMS accordingly:

- Software applications shall be validated prior to initial use and , as appropriate, after changes to such software or its application
- Validation approach and activities using a risk-based approach proportionate to the risk associated with the use of the software
- Documenting and maintaining records associated with any validation activities

Documentation Requirements

Management with Executive Responsibility shall ensure that documentation requirements are fulfilled in accordance with applicable standards and regulations. The documentation shall include information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results. An outline of the QMS documentation structure is described below:

General

Quality System documentation is comprised of, but not limited to, the following key documents:

- Quality Policy and Quality Objectives
- Quality System Manual (this document)
- Documented policies and procedures
- Documents identified and established as necessary for the effective planning, operation and control of processes and product
- Device Master Records (DMRs)
- Quality Records (either hard copy or electronic versions are appropriate)

Quality Manual

Management with Executive Responsibility shall establish and maintain a Quality Systems Manual that includes:

- The scope of the QMS including justification for any exclusions
- Documented procedures or reference to them
- Interactions between processes of the QMS
- Structure of QMS Documentation

Device Master Record (DMR) or Product File

For each medical device Leonhardt Lauchpads or Portfolio Companies shall establish and maintain one or more files referencing documents that demonstrate conformity of the medical device product to any applicable standards and regulatory/statutory requirements.

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

- A general description of the medical device product, intended use and labeling (including instructions for use)
- Specifications of the medical device product
- Specifications or procedures for manufacturing, packaging, storing, handling or distribution of the medical device product
- Procedures for measuring and monitoring
- Requirements (where necessary) for installation of the medical device product
- Requirements (where necessary) for servicing the medical device product

Control of Documents

Management with Executive Responsibility shall ensure that procedures and documents required by the QMS are maintained and controlled. All QMS documents are controlled according to SOP-2, Control of Documentation procedure and defines the following:

- Initial review and approval of QMS documents for adequacy prior to use by the appropriate personnel. Approvals shall include the date and signature of the person approving the document

- Review and revising documents as necessary and ensuring proper approval of new revisions
- Ensuring that changes, history and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring proper levels of access control
- Identifying retention period of quality records
- Ensuring that documents of external origin are identified and their distribution controlled
- Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose
- Ensuring that changes to documents are reviewed and approved by appropriate personnel that has enough pertinent background information upon which to base its decision. Change records shall include a description of the change and when the change becomes effective
- Defining retention period for obsolete controlled documents. The retention period will ensure that documents to which medical device products have been manufactured and tested are available for at least the lifetime of the medical device product as defined by applicable standards and regulations. This retention period will not be less than the retention period of any resulting quality records created from the use of the document

Control of Quality Records

Quality records are maintained to provide evidence of conformity to requirements and the effective operation of the QMS. Management with Executive Responsibility shall ensure the following:

- Quality Records are established, identified and maintained to provide evidence of conformity to specified requirements and of the effective operation of the QMS
- Document procedure(s) to define the controls needed for identification, storage, security, integrity, retrieval, retention time and disposition of quality records
- Define and implement methods for protecting confidential health information contained in records in accordance with applicable regulatory requirements
- Ensure quality records remain legible, readily identifiable and retrievable along with changes to any records as well
- Electronic records and electronic signatures shall meet the requirements of applicable standards and regulations. Records in automated data processing systems shall be backed up on a periodic basis
- Records shall be retained for a period of time equivalent to the design and expected life of the product or the period required by applicable regulatory authorities, whichever is longer, but not less than a minimum of 2 years from the date of release for commercial distribution

6. Management Responsibility

Management Commitment

Management with Executive Responsibility is actively involved with implementing the Quality Management System. It has provided the vision and strategic direction and established a Quality Policy, Quality Objectives and Company Quality Plans (where applicable).

Management with Executive Responsibility has committed to the development and implementation of the Quality

Management System and to its maintenance and effectiveness by:

- Communicating to the organization the importance of meeting customer as well as applicable statutory and regulatory requirements
- Establishing and maintaining the Quality Policy
- Ensuring that Quality Objectives are established
- Ensuring that Company Quality Plans are established (where applicable)
- Conducting periodic Management Reviews
- Ensuring the availability of appropriate resources

Customer Focus

The organization strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations. Management with Executive Responsibility ensures that customer requirements are converted into internal requirements and communicated to the appropriate personnel within the organization.

Quality Policy

Management establishes and reviews quality objectives in support of the Quality Policy. Further, management reviews this Quality Policy periodically for its suitability and implements this policy throughout the organization by assuring associates are trained and understand the contents of this policy.

Management with Executive Responsibility has established a Quality Policy and adheres to this policy by:

- Designing, implementing and maintaining a Quality System that meets all required quality standards and is appropriate to the purpose of the organization
- Responding to customer needs and expectations
- Pursuing continuous improvement of our products, services and processes

Leonhardt Launchpads Quality Policy (and applicable to all Portfolio Companies)

We will provide superior quality of work in pursuit of our purpose to develop products that extend and improve quality of life for our customers. This will be accomplished by maintaining an effective quality system that complies with regulatory requirements that benefits our customers, associates and shareholders.

Planning

Quality Objectives

Management with Executive Responsibility shall establish Quality Objectives to support the organization ’s efforts in achieving the goals of the Quality Policy and are reviewed annually for suitability. Quality objectives shall be measurable and reviewed against performance goals during periodic management reviews.

QMS Planning

Management with Executive Responsibility shall ensure that planning of the Quality System is executed to meet the practices, resources and activities required by the Quality Manual (this document). Planning shall ensure that the Quality Objectives and integrity of the Quality System are maintained when changes are planned and implemented.

Quality System planning shall result in Company Quality Plans (where applicable) or equivalent documentation for new product development, product improvements and services which define quality practices, resources and activities relevant to medical device products that are designed and manufactured.

Responsibility, Authority and Communication

Responsibility and Authority

An organizational structure has been established to describe the interrelation of personnel within the organization. Job descriptions define the responsibilities and authorities of each position. Job descriptions and organizational structure are reviewed and approved by Management with Executive Responsibility for adequacy.

These documents are communicated and available to personnel to ensure they understand these responsibilities and authorities. Management with Executive Responsibility ensures that interrelations and overlapping responsibilities of all personnel who manage, perform and verify work affecting quality have sufficient independence and authority necessary to perform these tasks.

Management Representative

Management with Executive Responsibility is responsible for appointing the Management Representative. The Management Representative has the following responsibility and authority:

- Ensures processes needed for the QMS are established and implemented
- Reports to Management with Executive Responsibility on the performance of the QMS and any needs for improvement
- Promotes awareness of regulatory and customer requirements throughout the organization
- Acts as a liaison with external parties such as customers or auditors on matters relating to the QMS

Leonhardt Launchpads has appointed Jane Reedy as the Management Representative.

Internal Communications

Management with Executive Responsibility ensures communication throughout the organization regarding the effectiveness of the QMS. Examples of appropriate communication tools and/or methods are as follows:

- Email
- Reports
- Site Signage (e.g. Bulletin Boards, etc)
- Scorecards
- Meetings

Escalations

Management with Executive Responsibility shall ensure that procedures are established for communicating and escalating relevant information necessary to make timely, fact-based decisions regarding:

- Customer Impacts
- Patient/User Safety
- Adverse Event or trend
- Risk acceptability criteria that has been exceeded
- Quality/Regulatory/Compliance Management
- Unexpected quality issue or problem
- Failure to meet a QMS requirement

Management review

General

Management with Executive Responsibility reviews the QMS during periodic Management Reviews. These reviews assess the continuing QMS suitability, adequacy, and effectiveness. The reviews also identify opportunities for improvement and discuss any changes that are needed, including the Quality Policy and Quality Objectives. Records for Management Review are documented in the QMS in accordance with applicable retention requirements and include dates and results of these reviews.

Management Review Input

Inputs to Management Review shall include, but is not limited to:

- Feedback (including Customer)
- Complaint Handling (for Marketed Products where applicable)
- Reporting to applicable regulatory authorities
- Audits (internal and external)
- Monitoring and Measurement of Process performance
- Monitoring and Measurement of Product conformity
- Corrective and Preventive Action Status (CAPA)
- Follow-up actions from previous Management Reviews
- Changes that could affect the QMS
- Recommendations for improvement
- Applicable new or revised regulatory requirements or standards

Management Review Output

During Management Reviews, Management with Executive Responsibility will identify appropriate actions to be taken regarding the following:

- Improvements needed to maintain the effectiveness of the QMS and it’s processes

- Improvements of product related to customer requirements
- Changes needed to respond to applicable new or revised regulatory requirements
- Resource needs

Responsibilities for completing the required actions are assigned to members of the Management Review team as described within the Quality System procedures. Any decisions made during the review, assigned actions and their due dates are recorded.

7. Resource Management

Provision of resources

Management with Executive Responsibility shall determine and ensure that appropriate resources are available to implement and maintain the QMS and continually improve its effectiveness and enhance customer satisfaction while meeting regulatory and customer requirements

Human Resources

Management with Executive Responsibility is committed to supporting the Quality Policy, the QMS, Quality Objectives and planning through an effective organizational structure with adequately trained, qualified and competent staff (including Leonhardt Launchpad employees, Portfolio Company employees, advisors, temporary employees and/or consultants) by:

- Defining in Job Descriptions the necessary competence for personnel performing work affecting conformity to product requirements on the basis of appropriate education, training, skills and experience
- Providing training or other activities to achieve the necessary level of competency
- Evaluating effectiveness of training or activities taken. Methods used to assess effectiveness shall be proportional to the risk associated with the work related to such training or other activity.
- Ensuring that personnel are aware of relevant and important activities and how they contribute to the achievement of the Quality Objectives
- Ensuring that personnel are made aware of product, process and service defects that may occur from improper performance of their specific job
- Maintaining appropriate training, skills, experience and educations records

Each Portfolio Company or Portfolio Company site shall have a system for defining training requirements and documenting completion of training. Training records shall be maintained to demonstrate compliance to requirements.

The organization shall document and maintain organizational charts with sufficient detail to define the structure and interrelationships within the organization so as to facilitate understanding and communication of responsibilities.

Infrastructure

Management with Executive Responsibility shall determine, establish and maintain the infrastructure needed to achieve a safe work environment, conformity to product and servicing requirements, prevent product mix-up and ensure orderly handling of product.

Maintenance activities, including the interval of performing maintenance activities, shall be documented for any

activity that can affect product quality. Records of maintenance activities shall be maintained. Buildings, process equipment and supporting services such as transport, communication or informations systems shall be established and reviewed on a continual basis.

The infrastructure, work environment and contamination control requirements for organization facilities are primarily the following:

- Facility Management including buildings, utilities and maintenance
- Production, warehousing, working space and office areas
- IT systems
- Production and Test Equipment (including software)

Work Environment

Work Environment

Management with Executive Responsibility shall determine, manage and document the work environment necessary to achieve conformity to product requirements including, but not limited to:

- Requirements for health, cleanliness and clothing of personnel (if contact with the product or work environment could affect product quality)
- Appropriate training for those required to work temporarily under special environmental conditions and that personnel is competent or supervised by a competent person
- Data or data systems used to determine if the work environment is adequate

Contamination Control

Management with Executive Responsibility shall determine, manage and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel or product.

For sterile products, Management with Executive Responsibility shall determine, manage and document requirements for control of contamination with regards to microorganisms or particulates and maintain the required cleanliness during manufacture, assembly or packaging processes.

8. Product Realization

Product realization is achieved through effective planning to achieve product requirements and quality objectives. The product development process is a phase gate approach that drives lifecycle management including new product development and product change management.

Planning of Product Realization

Planning of Product Realization

Management with Executive Responsibility shall plan and develop processes necessary for product realization by establishing the following elements, as appropriate:

- Company Quality Plans and requirements for each product
- Establishing processes, documentation and resources (including infrastructure and work environment) to

support each product

- Establishing processes to ensure customer requirements are correctly translated into product specifications for design input
- Establishing processes to ensure product design is correctly translated into production specifications
- Verification, validation monitoring, measurement, inspection and test, handling, storage distribution and traceability activities specific to each product and criteria for product acceptance as applicable per regulations
- Documented requirements for risk management throughout product realization
- Records necessary to provide evidence that the realization process and resulting product requirements meet requirements

As an output to product realization, the organization shall maintain a Device Master Record (DMR) containing documents defining product specifications and quality system requirements for complete manufacturing of the product, or reference to documents containing the following information:

- Product or system specifications including relevant drawings, composition, formulation, component specifications and software specifications
- Production process specifications including equipment specifications, production methods, production procedures and production environment specifications
- Quality procedures and specifications including acceptance criteria and quality equipment that is used
- Packaging and labelling specifications including methods and processes used
- Installation, maintenance and servicing procedures and methods if applicable

The DMR must be reviewed, approved and controlled.

The organization shall perform risk management in accordance with applicable regulatory requirements for all products manufactured including service (where applicable) and distribution. The risk management program establishes processes for identifying hazards associated with its products, estimating and evaluating the associated risks, controlling those risks and monitoring the effectiveness of these controls.

Customer Related Processes

Determination of Requirements Related to Product

Management with Executive Responsibility shall ensure the consistency and conformance to customer requirements and expectations through a mutually beneficial relationship between the organization and the customer. The organization shall determine, review and communicate the requirements related to the product based on:

- Defined and documented customer-specific requirements, including delivery and post-delivery activities
- Requirements considered necessary for specified use or known and intended use but not stated by the customer
- Applicable regulatory and statutory requirements related to the product
- User training needed to ensure specified performance and safe use of the product
- Additional requirements where appropriate

Review of Requirements Related to Product

The organization will maintain records related to the above activities. Where no documented statements of requirements are provided by the customer, the organization shall confirm the requirements before acceptance. Where product requirements are changed, the organization shall ensure relevant documents are changed and that appropriate personnel are made away of the change(s).

Communication

In keeping with our commitment to customer satisfaction, the organization views effective customer communication as an essential element of customer satisfaction. Therefore, the organization shall communicate with customers with respect to:

- Product Information
- Inquiries, contracts or order handling (including amendments)
- Customer feedback, including customer complaints (See relevant Company Quality Plans for exclusion information regarding complaints)
- Advisory notices

The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

Design and Deployment

Design Control General

The organization shall ensure procedures are established and maintained to control the design and development of products, services and systems in order to ensure that specified design requirements are met.

Design Control and Development Planning (DDP)

The organization shall ensure procedures are established and maintained for plans that describe or reference the design and development activities for realization. These plans are part of the Company Quality Plan document. The plan shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process and should include:

- The design and development phases
- The review(s) needed at each design and development stage
- The verification, validation and design transfer activities that are appropriate at each design and development stage
- The responsibilities and authorities for design and development activities
- The methods to ensure traceability of design and development outputs to design and development inputs
- The resources needed, including necessary competence of personnel

As appropriate, the design and development planning documents shall be maintained and updated as the design and development evolves.

Design and Development Inputs

The organization shall ensure procedures are established and maintained defining and documenting design inputs relating to each product, service or system are appropriate and address the following:

- Functional, performance, usability and safety requirements, according to the intended use, including the needs of the customer and other stakeholders
- Applicable regulatory requirements and standards
- Applicable outputs of risk management
- Information derived from previous similar designs as appropriate
- Other requirements essential for the design and development of the product and processes

Inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated and not in conflict with each other.

Design and Development Outputs

The organization shall ensure procedures are established and maintained for defining and documenting design outputs and shall:

- Allow adequate evaluation of conformance to design input requirements
- Provide appropriate information for purchasing, production and service provision
- Contain or reference product acceptance criteria
- Specify those design outputs that are essential for the safe and proper functioning of the product, service and system.

Outputs of design and development shall be in a form suitable for verification against the design development inputs and shall be approved prior to release.

Design and Development Review

The organization shall ensure procedures are established and maintained to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the product, service or system development and shall:

- Evaluate the ability of results of design and development to meet requirements
- Identify and propose necessary actions
- Include representatives of functions concerned with the design and development stage being reviewed and include an independent reviewer(s) who does not have direct responsibility for the design stage being reviewed, as well as other specialist personnel as appropriate. Note: The independent reviewer, although independent, should still be knowledgeable in the technical aspects of the review material.

Records of the reviews including results, conclusions and necessary actions shall be documented and maintained.

Design and Development Verification

The organization shall ensure procedures are established and maintained for verifying the product, service or system design and shall:

- Confirm that the design and development outputs meets the design and development input requirements

- Ensure that verification plans are documented including methods, acceptance criteria and as appropriate, statistical techniques with rationale for any sample sizes chosen
- If the intended use of the product requires that the product be connected to, or have interface with other product(s), verification shall include confirmation that the design outputs meet design inputs when connected or interfaced

Records of the results and conclusions of verification and necessary actions shall be documented and maintained.

Design and Development Validation

The organization shall ensure procedures are established and maintained for validating the product, service or system design to ensure that the resulting product is capable of meeting the requirements of the specified application, user needs or intended use and shall:

- Ensure that validation plans are documented that include methods, acceptance criteria and as appropriate, statistical techniques with rational for any sample sizes chosen
- Ensure design validation shall be performed under defined operating conditions on initial production units, lots or batches, or their equivalents with the rationale for the choice of product used documented
- Include software validation and risk assessment, where appropriate
- Perform clinical evaluations or performance evaluations of the product in accordance with applicable regulatory requirements where applicable. Products used for clinical evaluation or performance evaluation are not considered to be released for use to the customer
- If the intended use of the product requires that the product be connected to, or have interface with other product(s), valuations shall include confirmation that the requirements for the specified application or intended use have been met when connected or interfaced
- Have completed validation activities prior to release for use to the customer

Records of the results and conclusions of validation and necessary actions shall be documented and maintained.

Design and Development Transfer

The organization shall ensure procedures are established and maintained to ensure successful transfer of design and development outputs to the production environment by ensuring:

- The product, service or system design and development outputs are verified as suitable for production before becoming final production specifications
- The production environment, facility and capabilities can meet product requirements

Records of design transfer activities shall be documented and maintained.

Design and Development Changes

The organization shall ensure procedures are established and maintained to control design and development changes by:

- Determining the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the product and its intended use
- Ensuring that the design and development changes are identified, reviewed, verified, validated (as appropriate) and approved prior to implementation

- Ensuring that review of design changes include evaluation of the effect of the change on the constituent parts and product in process or already delivered product

Records of design changes shall be documented and maintained.

Design and Development Records and Files

The organization shall ensure procedures are established and maintained for creating and maintaining a design and development file for each product, service or system. The file shall contain or reference the necessary information to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the design control section of this Quality Manual.

Purchasing

Purchasing Process

Management with Executive Responsibility shall establish a process for purchasing products, materials and services accordingly:

- Suppliers shall be selected, evaluated and approved for use on the basis of their ability to meet specified requirements.
- A list of Approved Suppliers shall be maintained
- Contracts with suppliers of goods and services shall be periodically reviewed to assure that compliance issues are handled appropriately
- Supplier should periodically be re-evaluated. The type and extend of control applied to suppliers shall be dependent upon the effect of the purchased product, service or material on the subsequent processing of or within the final product and proportionate to the risk associated with the product. Appropriate actions shall be taken to manage suppliers that fail to meet requirements or supplier performance levels established by Second Heart Assist, Inc.
- A supplier management program shall be established which includes criteria for selection, evaluation and re-evaluation of suppliers through a risk-based approach and provides for the verification of the adequacy of the suppliers quality program

Records regarding supplier management shall be documented and maintained.

Purchasing Information

Purchasing information shall describe or reference details on the product to be purchased accordingly:

- Purchasing information shall contain: Product specifications, requirements for approval of product, procedures, processes and equipment, requirements for qualification of personnel and quality system requirements.
- Purchasing documents shall contain information designating the product or services ordered
- Purchasing documents shall include, where possible, an agreement that the supplier agrees to notify Second Hearts Assist, Inc. of any changes to the product, service or material being purchased in order to determine if the changes could affect the quality of a finished product

Verification of Purchased Product

The organization shall establish inspection procedures for ensuring that purchased product meets specified purchasing requirements and shall include provisions for the following:

- Verification shall be based on supplier evaluation results and proportionate to the risks associated with the purchased product, services or material
- Received materials shall be verified against specified requirements
- Purchasing documents shall be reviewed against receiving documents and product specifications, where appropriate, to ensure compliance with specified requirements.
- For any product verified at the supplier location, the purchasing information shall contain the intended verification methods for product release.

Records pertaining to verification shall be documented and maintained.

Production and Service Provision

Management with Executive Responsibility shall establish procedures to ensure that production, installation and service processes conform to specified requirements as applicable.

Control of Production and Service Provision

The organization shall plan and execute production and service provisions under applicable controlled conditions to ensure that product conforms to specifications including, but not limited to:

- Availability of information that describes the characteristics of the product
- Availability of documented standard operating procedures, methods, work instructions and reference materials
- Qualification of infrastructure
- Availability and use of monitoring and measuring equipment
- Implementation of monitoring, measurement and control of process parameters and product characteristics during production
- Records of any sterilization process parameters for each batch of sterilized product
- Implementation of product release, delivery and post-delivery activities
- Implementation of defined operations for packaging and labelling

Where environmental conditions could reasonably be expected to have an adverse effect on product quality, procedures shall be established to adequately control these conditions. These control systems shall be periodically inspected to verify they are functioning properly. These activities shall be documented and reviewed. Requirements for health, cleanliness, personnel practices and personnel clothing shall be specified if contact between the personnel and product could reasonably be expected to have an adverse effect on product quality.

Management with Executive Responsibility shall ensure:

- All personnel who are required to work under special environmental conditions for any period of time shall be appropriately trained or supervised by a trained person
- Procedures are established to prevent contamination of equipment or product by any substance that could reasonably be expected to have an adverse effect on product quality

- Buildings used in the manufacture of product shall be of suitable design and contain sufficient space to prevent mix-ups and to assure orderly handling
- Criteria for workmanship are expressed in documented standards or by approved samples
- Equipment used in manufacturing processes must meet specified requirements and be appropriately constructed, designed and installed to facilitate maintenance, adjustment, cleaning and use
- Procedures for maintenance activities shall be established and maintained. Maintenance schedules including the date and individual(s) performing the work shall be documented. Inspections shall be performed to assure adherence to maintenance schedules. Records of these inspections shall be documented.
- Allowable equipment adjustments shall be visibly posted on or near any equipment that requires periodic adjustments, or readily available to personnel performing these adjustments
- Procedures shall be implemented for the use and removal of manufacturing material where it would reasonably be expected to have an adverse effect on product quality. The removal of manufacturing material shall be documented

Management with Executive Responsibility shall ensure procedures are established and maintained for identifying product during all stages of receipt, production, distribution and installation in order to prevent mix-ups. These procedures shall ensure:

- Labels are printed and applied so as to remain legible and affixed during processing, handling, distribution and where appropriate, use. A designated individual(s) shall inspect labelling prior to use to ensure accuracy of required information. The release of labelling shall be documented in a Device History Record (DHR), lot/batch records or equivalent
- Labels shall be stored and applied in a manner that prevents mix-ups.
- Labelling used in manufacturing process on product shall be documented in the DHR, lot/batch record or equivalent
- Products shall be packaged and placed in shipping containers designed and constructed to protect the product from alteration or damage during customary conditions of processing, storage, handling and distribution
- Storage areas and stock rooms shall be controlled to prevent mix-ups, damage, deterioration, contamination or other adverse effects and to ensure that obsolete, rejected or deteriorated product is not used or distributed. The receipt and dispatch of material and product from storage and stock rooms shall be controlled

DHRs, lot/batch records or equivalent documentation to demonstrate the product has been manufactured in accordance with requirements shall include or refer to the location of the following minimum information:

- Date(s) of Manufacture
- Quantity Manufactured
- Quantity Released
- Acceptance Records which demonstrate the product has been manufactured in accordance with the DMR or equivalent master specification files
- Primary identification label and labeling used for each production unit
- Any product identification and control numbers used

Cleanliness of Product

Management with Executive Responsibility shall establish requirements to ensure cleanliness of product if any of the following conditions exist:

- Product is cleaned prior to sterilization or use
- Product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or use
- Product can't be cleaned prior to sterilization or use and its cleanliness is of significance for proper use
- Product is supplied to be used non-sterile and its cleanliness is of significance for proper use
- Process agents are to be removed from product during manufacturing

Installation Activities

If installation of product is a specified requirement, Management with Executive Responsibility shall establish procedures to ensure requirements for product installation and acceptance criteria for verification of installation.

If the customer requirements allow installation of the product to be performed by an external party other than Second Heart Assist, Inc. then documented requirements for product installation and verification of installation shall be provided.

Records of product installation and verification of installation performed by Second Heart Assist, Inc. shall be documented and maintained.

Servicing Activities

If servicing of product is a specified requirement, Management with Executive Responsibility shall establish procedures for performing servicing activities and verifying that product requirements are met

The organization shall analyze records of servicing activities to assess if the service issue needs to be categorized and managed as a complaint or is a source of input to the improvement process.

Records of any service activity shall be documented and maintained.

Particular Requirements for Sterile Product

The organization shall maintain records of sterilization process parameters used for each sterilization batch. Sterilization record shall be traceable to each production batch, lot or unit of the product.

Validation of Processes for Production and Service Provisions

Management with Executive Responsibility shall establish procedures for validation of any processes for production and service provisions where the resulting output can't be or is not fully verified by subsequent inspection and test. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. This also includes any processes that include the application of computer software.

Any validation process should be executed with a high degree of assurance and approved according to established procedures.

Records of process validation activities, including results and conclusions of the validation, shall be documented and maintained.

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

As applicable, the organization shall establish procedures for the validation of processes for sterilization and sterile barrier systems. These processes shall be validated prior to implementation and/or following any product or process changes, as determined appropriate based on the risk associated with a single change or series of changes taking place over time.

Records of sterilization process validation activities, including results and conclusions of the validation, shall be documented and maintained.

Identification

Management with Executive Responsibility shall ensure procedures are established and maintained for final product identification and identification throughout manufacturing processes. Identification should include:

- Identifying product during all stages of receipt, production, distribution and installation, including product acceptance status
- Unique identification of the product documented and traceable to a DHR, lot/batch record or equivalent.
- As required by any applicable regulatory requirements regarding unique device identification
- Documented procedures to ensure products returned to Second Heart Assist, Inc. are identified and distinguished separately at all times from conforming product

Traceability

When traceability is a specified requirement, Management with Executive Responsibility shall ensure procedures are established and maintained that define the extent of traceability required in accordance with applicable regulatory requirements and to facilitate any corrective action. This traceability shall be documented in the DHR, lot/batch record or equivalent record.

Particular Requirements for Implantable Products

For implantable devices, the following apply:

- Traceability records of components, materials and conditions for the work environment to manufacture product if any of these could cause the product to not satisfy its specified safety and performance requirements
- Maintaining distribution records of finished products including the name and address of initial consignee, quantity of products shipped, date shipped and the batch records or other unique traceability number that is utilized
- Assurance that suppliers of distributions services or distributers maintain these records and that records are available for inspection
- Assurance that all distribution records including the name and address of final consignee is maintained

Customer Property

Management with Executive Responsibility shall ensure that customer-supplied property will be identified and handled under the same quality system requirements as other materials while it is under organizational control or being used by the organization. It is the responsibility of the organization to notify the customer of loss, damage or unsuitability for use and report this to the customer. Records of these activities shall be documented and

maintained.

Preservation of Product

Management with Executive Responsibility shall establish procedures for preserving the product and its constituents during processing, storage, handling and distribution to the intended destination in order to maintain conformity to requirements. These procedures shall include requirements for protecting the product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage and handling by:

- Designing and constructing suitable packaging and shipping containers
- Documenting requirements for special conditions needed if packaging alone can ’t provide preservation
- Requirements for identification, handling, packaging, storage and protection including control of product with limited shelf-life or those requiring special storage conditions
- Storage of products with specific temperature requirements under conditions that are controlled and documented

Control of Monitoring and Measuring Devices

Management with Executive Responsibility shall establish procedures and processes to ensure control and extent of inspection, monitoring, measuring and test equipment used to demonstrate product conformance to requirements. Measurement and test equipment, including automated or electronic equipment shall be:

- Suitable for its intended purpose and capable of producing valid results, including accuracy and precision requirements
- Calibrated or verified at specified intervals and prior to use against measurement standards traceable to international or national measurement standards. When no such standards exists, the basis used shall be recorded
- Adjusted or readjusted as necessary, inspected, checked, maintained and recorded
- Identified and calibration status identified
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during use, maintenance and storage

The organization shall perform calibration in accordance with documented procedures. When calibrations do not conform to requirements, action shall be taken with regards to the equipment and any product affected.
Calibration records and verification shall be documented and maintained and include:

- Equipment Identification
- Calibration Date(s)
- Person performing the calibration
- Result of the Calibration and next Calibration due date
- Previous measurement results

Calibration status/information shall be displayed on or next to the equipment or shall be readily available to personnel using the equipment or responsible for calibrating the equipment.

The organization shall document validation of computer software used for monitoring and measurement activities

where applicable. Validation should be completed prior to initial use and, as appropriate, after changes to the software or application. Specific approach and activities shall be proportionate to the risk associated with the use of the software and any effect on conformity of the product.

9. Measurement Analysis and Improvement

Management with Executive Responsibility shall ensure continual improvement in the effectiveness of the quality system through Management Review (measurement and analysis), audits and CAPA

General

Management with Executive Responsibility shall establish procedures to plan and implement the monitoring, measurement, analysis and improvement processes needed to:

- Demonstrate conformity to the product requirements
- Ensure conformity of the Quality System
- Maintain effectiveness of the Quality System
- Maintain continuity of improvement

Monitoring and Measurement

Monitoring and measurements shall be conducted to ensure customer satisfaction and product specification compliance as noted in the following sections.

Feedback and Customer Satisfaction

Management with Executive Responsibility shall establish procedures for the feedback process and shall gather and monitor information on whether Second Heart Assist, Inc. has met customer requirements through activities such as, but not limited to:

- Analyzing production and post-production data
- Analyzing data and information collected from customer focus groups
- Analyzing data from customer complaint systems
- Analyzing data from Sales and Marketing
- Analyzing data and information from Service team
- Conducting Post-Market surveillance

Data and information gathered here shall be used as a potential input into the risk management process for monitoring and maintaining product requirements including product realization and improvement processes.

Complaint Handling

Management with Executive Responsibility shall establish procedures for receiving, reviewing and evaluating complaints to ensure timely complaint handling in accordance with applicable regulatory requirements. Procedures shall include at a minimum, requirements and responsibilities for:

- Uniform and timely processing of complaints
- Receiving and recording information

- Evaluating if feedback constitutes a complaint
- Investigating complaints to ensure investigation meets regulatory requirements, or if an investigation is warranted. If it is determined an investigation is warranted, then the investigation documentation should include the name of the product, date the complaint was received, product batch or lot numbers, name and address of the complainant, details around the nature of the complaint, dates and results of the investigation, corrective action taken and any reply to the complaint
- Justification for complaints determined not to need investigation
- Determining the need to report information to the appropriate regulatory authorities such as whether the complain represents a reportable adverse event and if so, then reporting of these adverse events in compliance with timelines established by applicable regulatory requirements
- Handling of complaint related product

If an investigation determines that activities outside of the organization's entities contributed to the complaint, relevant information shall be exchanged between the organization and the external parties involved.

Reporting to Regulatory Authorities

Management with Executive Responsibility shall establish procedures for providing notification to appropriate regulatory authorities for complaints that meet specified reporting requirements of adverse events.

Internal Audit

Management with Executive Responsibility shall establish procedures to ensure that internal quality audits are conducted periodically at specified intervals to demonstrate that the Quality System conforms to applicable regulatory requirements, quality system requirements established by the organization and that the quality system is effectively implemented and maintained.

Documented procedures shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results to all appropriate levels of the organization. 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.

Management is responsible for the area being audited to ensure that any necessary corrective action are taken without delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and reporting of verification results.

Monitoring and Measurement of Processes

Management with Executive Responsibility shall establish procedures to ensure suitable methods for monitoring and measurement of the Quality System processes are applied to demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken as appropriate.

Monitoring and Measurement of Product

Product requirement shall be fulfilled through monitoring and measuring characteristics of the product at applicable stages of the product realization process in accordance with planned and documented procedures.

Evidence of conformity with acceptance criteria shall be maintained as follows:

- Incoming, in-process and final product shall be inspected and tested, as appropriate, to documented procedures to ensure conformance to specified requirements
- Records of these activities shall be maintained in the Device History Record (DHR), batch/lot record or equivalent and indicate persons authorizing release of the product (including their signatures), acceptance activities performed, date of activities performed, results of activities and any test equipment used to perform measurement activities
- Release of product and delivery to the customer shall not proceed until planned arrangements have been satisfactorily completed, unless otherwise approved by relevant authority and where applicable, by the customer
- For implantable medical devices, the identity of personnel performing any inspection or testing shall be recorded

Control of Nonconforming Product

General

Management with Executive Responsibility shall establish procedures to control product that does not conform to specified requirements and shall address:

- Provisions to identify and control nonconforming product to prevent its unintentional use or delivery
- Controls and related responsibilities and authorities for identification, documentation, segregation, evaluation and disposition of nonconforming product
- Evaluations of nonconformities shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity

Actions in Response to Nonconforming Product Detected Before Delivery

When nonconforming product is detected before delivery the procedure shall address the following:

- Action to eliminate the detected nonconformity (e.g. Rework)
- Action to remove it from use (e.g. Scrap)
- Authorizing product use, release or acceptance under concession only if justification is provided, approval and identity of the person(s) approving the concession and all applicable regulatory requirements have been met

Records of activities related to nonconforming product shall be documented and maintained.

Actions in Response to Nonconforming Product Detected After Delivery

When nonconforming product is detected after delivery or use has started the procedures shall address the following:

- Action appropriate to the effects or potential effects of the nonconformity
- Issuance of advisory notices in accordance with applicable regulatory requirements
- Ensuring implementation of recalls and field corrective actions when necessary to correct product issues after the product is no longer in the company’s possession

Records of actions related to nonconforming product shall be documented and maintained.

Rework

Procedures shall be established for rework of product, including retesting, to ensure that product meets its approved specifications. Rework instructions shall be authorized and approved in a manner consistent with the original work instruction. When nonconforming product is corrected/reworked, it shall be subject to re-verification to demonstrate conformity to original requirements. Prior to authorization and approval, a determination of any adverse effects of the rework to the product shall be made and documented.

Records of actions related to rework shall be documented and maintained.

Analysis of Data

Management with Executive Responsibility shall establish procedures to ensure that the data generated as a result of monitoring and measurement, and from other relevant sources as identified below, shall be analyzed to demonstrate the suitability, adequacy, effectiveness and continual improvement of the Quality System and shall be evaluated as part of risk management and included in Management Review.

Examples of potential relevant sources:

- Customer Feedback
- Conformance to Product Requirements
- Characteristics and trends of products and processes
- Suppliers
- CAPA
- Audits
- Service Reports
- Other sources of quality data using statistical techniques

Improvement

General

Management with Executive Responsibility shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the Quality System including product safety and performance through the use of the Quality Policy, Quality Objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and Management Review.

Corrective Action (CAPA)

Management with Executive Responsibility shall establish procedures that ensure suitable corrective actions are implemented to prevent recurrence of quality issues. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformance encountered. Procedures shall provide requirements for:

- Reviewing existing nonconformities (including complaints)
- Identifying existing causes of quality issues by analyzing quality data
- Investigating root cause of nonconformities relating to product, processes or quality system where the

degree of investigation is proportionate to the significance of risk regarding the quality issue

- Determining actions needed to correct existing issues and ensure nonconformities do no occur
- Planning and documenting actions needed and implementing this actions
- Applying a risk-based approach to determine when a quality issue or trend should result in a formal CAPA

Preventive Action (CAPA)

Management with Executive Responsibility shall establish procedures to determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the potential problems. Procedures shall provide requirements for:

- Identifying causes of potential quality issues or nonconformities by analyzing quality data
- Applying a risk-based approach to determine when a potential quality issue or trend should results in a preventive action
- Evaluating and determining actions needed to prevent occurrence of potential quality issues or nonconformance
- Verifying and/or validating preventive actions taken to ensure action does not adversely affect product requirements, safety performance or regulatory requirements and that the action is effective
- Implementing and recording changes
- Disseminating information related to the preventive action to those directly responsible, at Management Review and to other affected areas of interest
- Records to document activities of preventive action

10. Attachments

1. Attachment A - Leonhardt Launchpads Management with Executive Responsibility 1 (1).docx