Supplier Quality Manual

1.1 INSTRUCTIONS

The first three sections of this document provide an overview of Hibernicor, the key roles in the sourcing organization, and an overview of Hibernicor's expectations. The remaining sections provide more detailed expectations.

The manual aligns with the content of ISO13485 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes; however, it is not intended to take the place of the standard itself.

We recognize that Hibernicor has a wide variety of Suppliers and technologies; the expectations stated in this manual may apply in different ways, depending on the Product or Service supplied.

Please Note: Acceptance of a Hibernicor Purchase Order (PO) constitutes acknowledgement that the Supplier has read and understands the expectations of this Manual

Terms and definitions used in this manual are listed in **Appendix A.**

1.2 PURPOSE AND SCOPE

The purpose of this Supplier Quality Manual is to clearly communicate Hibernicor's expectations to all new and existing external suppliers. These quality expectations apply to the development, manufacture, and delivery of all products and services supplied to Hibernicor. Suppliers have a direct impact to Hibernicor delivering high-quality product to our customers. Therefore it is important to understand expectations, identify gaps and track progress to gap resolution. Hibernicor desires long-term partnerships with suppliers who strive to meet performance expectations and who comply with regulatory requirements.

Quality requirements and expectations may take the form of an agreement or specification. The expectations and guidance within this Manual are provided as a supplement, not as a replacement for or altering of the terms or conditions with pre-established contractual agreements, engineering drawings or specifications.

If conflicting interpretations of the standards arise, the following order of precedence applies unless otherwise noted contractually:

1. Contractual Agreements (Quality, Supply, etc.)
2. Specification Requirements
3. Hibernicor Purchase Orders
4. Supplier Quality Manual

1.3 CODE OF CONDUCT

Our relationships with Suppliers are based on lawful, efficient, and fair practices. Hibernicor expects our Suppliers and contractors to:

Abide by applicable laws, rules and regulations of the countries in which they operate

Uphold the human rights of workers and treat them with dignity and respect

Ensure a safe and healthy working environment

Practice social and environmental responsibility

Demonstrate the highest standards of business ethics

Hibernicor reserves the right to discontinue business relationships with Suppliers that fail to conduct business in a legal, responsible, and ethical manner.

1.4 HIBERNICOR MISSION

Hibernicor's mission is to be the standard of care for increasing the quality and quantity of donor hearts available for heart transplantation. The leadership and employees of Hibernicor are committed to fulfilling this mission and expect the same commitment from our Suppliers.

1.5 HIBERNICOR BUSINESS

Hibernicor develops solutions to improve the lives of organ transplantation recipients and patients. It has three main products:

Asporto – Hibernicor's signature product, Asporto is a heart transplant device designed to preserve the heart from organ procurement to cardiac transplantation.
Praesto – An electronic records system, Praesto is used by research laboratories during pre-clinical trials.
Reperio – This freeware allows organ transplantation centers, laboratories and surgeons to examine their organ transplants to improve donor-to-recipient organ matching.

2.1 HIBERNICOR SOURCING

Hibernicor understands our business segments are different in nature and in some cases have unique roles and responsibilities to support the functional areas of business, quality, and engineering; however, the main point of contact with our suppliers will be in commodity management. to develop a strong relationship with the Supplier, including, but not limited to, actions such as technology roadmap sharing, contractual relationship, quality, cost, delivery, and overall understanding of any Supplier related risk to Hibernicor.

2.2 SUPPLIER ORGANIZATION

Suppliers are responsible for ensuring that Products or Services meet established Hibernicor specifications and Quality Requirements. Audits, approvals or verification by Hibernicor of the Supplier's facility, quality system, process controls, acceptance activities, etc., does not absolve the Supplier of the responsibility to provide acceptable Products or Services.

3.1 QUALITY AGREEMENTS

In addition to the expectations contained in this Manual, Hibernicor will determine if a Quality Agreement is needed with our Suppliers. Quality Agreements outline the Supplier specific quality requirements and may be in the form of a

stand-alone Quality Agreement or as part of the Purchase Order and / or material specification. Once the need is determined, it is expected that the Supplier will work with Hibernicor to put this agreement in place.

3.2 NON-DISCLOSURE AGREEMENTS

Suppliers may be asked to sign a non-disclosure agreement, depending on the level of technology or information disclosed during the course of business. It is our policy to utilize a Hibernicor standard form that has been created for this purpose.

Information provided to Suppliers involving various trade secrets, designs, materials and other proprietary information of a secret and confidential nature may include, but are not limited to records, data, schedules, forecasts, formulae, processes, procedures, specifications, developments, designs, inventions, models, techniques, improvements or discoveries, patentable and otherwise.

It is Hibernicor's policy that Suppliers shall not use, transmit or disclose confidential information to any third party except in accordance with the terms of the non-disclosure or any other written agreement. Supplier shall not make any public announcement about or advertise the existence of this agreement, divulge its terms and conditions or any relationship with Hibernicor other than with prior written agreement of the other party. Suppliers shall agree not to display or use the Hibernicor logo, trade secrets, trademark, or Product(s) in any manner without prior written permission from their Hibernicor.

3.3 DECLARATION OF RAW MATERIALS USED

Suppliers of components and finished devices are expected to have detailed information about the composition of the material on hand and make this available to Hibernicor upon request. This information, declaring the raw materials used to manufacture a product is required to fulfill Regulatory Body requirements for approval for use.

3.4 IMPORT COMPLIANCE

Suppliers who ship Product from outside the United States to a Hibernicor facility within the United States need to be aware of the following:

1. Hibernicor requires that, unless exempted by law, every article of foreign origin, or its container imported into the U.S. be marked in a conspicuous place as legibly and permanently as possible to indicate the English name of the country of origin to an ultimate purchaser in the U.S.

2. A commercial invoice signed by the seller, shipper or associated agent is required for Customs entry and is expected to be prepared in accordance with 19 CFR 141.86 of the customs regulations. Any inaccurate or misleading statement of fact in the commercial document may result in delays in release, detention of goods, increased review by import specialists or penalties against the importer.

3. Wood packaging material is closely regulated as it pertains to importation of goods into the U.S. The standard calls for wood packaging material to be either heat treated or fumigated with methyl bromide, in accordance with the Guidelines, and marked with an approved international mark certifying treatment.

3.6 BUSINESS CONTINUITY

Hibernicor expects its Suppliers to have a comprehensive crisis management approach to deal with potential disruptions. The approach is expected to include a plan of action, communication plans, escalation procedures, and roles and responsibilities. This plan is expected to address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain assessment of risk for equipment, material, supplied components and labor, etc. and be specific to Hibernicor Products and/or Services provided.

3.7 CHANGE MANAGEMENT

Change control is an essential element of ensuring we maintain the quality of our Products. We recognize that continuous improvement efforts may require changes to manage cost, quality, delivery and technology.

Through communication and collaboration we can ensure that these changes do not have unintended effects on our products, our operations and, more importantly, our customers and patients. Suppliers are responsible for notifying Hibernicor of changes made to materials, products or processes, including changes at their suppliers. Suppliers are expected to notify Hibernicor prior to implementing any change by submitting a written request.

3.8 SUB-TIER SUPPLIER CONTROL

Suppliers are expected to manage sub-tier suppliers with controls commensurate with risk. Suppliers are responsible to ensure that products manufactured utilize only authentic, conforming and specified material as stipulated in the specification.

Hibernicor's expectation is that the Supplier has in place formal purchasing and supplier control processes to manage sub- tiers. Suppliers are responsible for ensuring and controlling the quality of all components and raw materials that are purchased to manufacture product for Hibernicor. Where Hibernicor requires a supplier to engage with a specified sub-tier supplier, relationship management will be established between Hibernicor and the supplier.

Suppliers shall seek Hibernicor written approval prior to making any sub-tier supplier changes.

3.10 PROCESS CAPABILITY

Hibernicor expects suppliers to develop and maintain highly capable processes to produce quality products and services. Use of Statistical Process Control for special part and process characteristics is expected for all annotated, special, significant, or critical drawing characteristics. Data may be required with each shipment at the discretion of the receiving facility.

3.11 CONTROL PLANS

Hibernicor uses risk assessment to identify the need for control plans for purchased products. A control plan is a documented description of the systems for controlling part and process quality by addressing their key characteristics and engineering requirements. Each control plan describes the actions that are required at each phase of the process including receiving, in-process, outgoing, and periodic requirements.

Control Plan methodology is expected to be fully integrated into the Supplier's QMS. See **Appendix B** for a sample Control Plan template. Supplier Control Plans may be used in lieu of Hibernicor Control Plans as long as the content reflects the requirements as defined by Hibernicor to ensure ongoing process control.

3.12 COST OF POOR QUALITY

Hibernicor shall notify suppliers of nonconforming product. Hibernicor expects suppliers to replace nonconforming materials free of charge. Suppliers are expected to cover expenses (including freight and customs clearance, if any) incurred by Hibernicor in connection with (a) shipment of replacement Product to the same location and (b) shipment of the Nonconforming Product back to Supplier (if so requested by Supplier). In the event of a rejection of nonconforming Product, Suppliers are expected to ship replacement Product as soon as practical.

4.1 EXPECTATIONS

The Supplier's management is expected to establish, document, and implement an effective Quality Management System (QMS) to minimize nonconforming materials and maximize quality.

Suppliers that provide finished devices are expected to have a QMS in place that complies with the requirements of ISO9001, ISO13485, FDA 21 CFR Part 820 and/or other comparable standard or regulation. Suppliers that provide finished devices are also expected to complete FDA establishment registration and device listing requirements per FDA 21 CFR Part 807 as applicable.

All other Suppliers are expected to have a QMS in place that is aligned with or similar to ISO9001, ISO13485, FDA 21 CFR Part 820 or other comparable standard or regulation. For existing Suppliers that are not certified to ISO13485, it is preferred that those Suppliers have a plan in place to become certified and can demonstrate progress toward that plan. Any changes to the certifications or registrations status are expected to be communicated to Hibernicor in a timely manner.

The Supplier is expected to notify Hibernicor of a Regulatory inspection. The Supplier is expected to also provide timely notification to Hibernicor if it receives a 483, warning letter or finding from a Regulatory Agency.

New Quality System certification is expected to be provided where there are mergers, acquisitions, or affiliations associated with Suppliers. Suppliers are expected to forward evidence of their Quality System certification to Hibernicor upon request.

4.2 DOCUMENTATION

4.2.1 General

The Quality Management System documentation is expected to include, at a minimum:

1. Documented statements of a quality policy and quality objectives
2. Documented procedures as required by the Quality Management System
3. Documents needed by the organization to ensure the effective planning, operation and control of its processes
4. Records required by the Quality Management System

4.2.2 Control of Documents

Suppliers are expected to establish, maintain, and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System. Suppliers are expected to have a documented procedure for the control and distribution of drawings, documents and/or standards. Obsolete documents are expected to be destroyed or appropriately identified as such for limited distribution.

4.2.3 Control of Records

Records are expected to be stored in an environment that will prevent deterioration, damage, or loss, and are expected to be readily accessible to Hibernicor upon request. Suppliers will make available any and all quality Records, in a timely manner, upon request by Hibernicor or any regulatory body such as the FDA. Electronic record approvals and storage are expected to comply with 21 CFR Part 11 requirements. All quality Records are expected to be retained for a period of time equivalent to the design and expected life of the device.

4.3 COMPLAINTS AND ADVERSE EVENTS REPORTING

Hibernicor has the sole authority to correspond with all applicable regulatory authorities with respect to complaints about products. Hibernicor is responsible for complying with all regulatory requirements pertaining to the reporting of adverse events.

Specific requirements are defined in Quality Agreements, but in general Suppliers are expected to cooperate in dealing with customer and third party complaints and adverse events concerning the products and are expected to take action to promptly resolve such complaints and adverse events.

Suppliers are expected to:

1. Give prompt notice to Hibernicor by email or by telephone as soon as becoming aware of a product complaint or adverse event and provide written follow-up to Hibernicor.
2. Maintain a written record of all customer and third-party complaints and adverse events that relate to the Product(s), whether received orally or in writing;
3. Establish a tracking and traceability system for all product(s) so as to permit successful tracking in the event of a product recall.
4. Maintain complaint and adverse event records and files in accordance with Quality System requirements.

4.4 FIELD CORRECTIVE ACTIONS

If either party, in good faith, determines that a field corrective action or other action (e.g. Product Hold Order) involving a product should be considered, it will immediately notify the other party. Hibernicor will have the sole authority to determine whether any action such as a field corrective action or other action shall be undertaken where it owns the design and regulatory approval. Suppliers are expected to cooperate with Hibernicor to implement the action once the determination is made.

Supplier's senior management is expected to ensure an effective and continuously improving Quality System and maintain an organizational structure which ensures the Product is designed, developed and manufactured to Hibernicor requirements.

Senior management is expected to ensure that appropriate communication is established with Hibernicor regarding the effectiveness of and any changes in the Supplier's Quality Management System.

5.1 MANAGEMENT COMMITMENT

The supplier's leadership is expected to demonstrate a commitment to continuous improvement. Supplier senior management and leadership is expected to provide documented evidence of its commitment to the development and improvement of the Quality Management System by:

1. Communicating to the organization the importance of meeting customer as well as regulatory expectations and requirements
2. Establishing the quality policy and objectives
3. Conducting regularly scheduled management reviews on the effectiveness of the quality system and taking appropriate action when indicators are unfavorable
4. Ensuring the availability of necessary resources

5.2 CUSTOMER FOCUS

The supplier's senior management is expected to ensure that customer needs and expectations are identified, converted into requirements, and fulfilled with the aim of achieving customer satisfaction. Hibernicor expects that Suppliers conform to design and performance specifications. Suppliers are expected to meet requirements for reliability, delivery, cost management, and technical support.

5.3 QUALITY POLICY

The Supplier's senior management is expected to endorse a written quality policy that:

1. Is appropriate to the purpose of the organization
2. Includes a commitment to meeting customer requirements and to continuous improvement
3. Provides a framework for establishing and reviewing quality objectives

4. Is communicated and understood at all levels in the organization
5. Is reviewed for continued appropriateness

5.4 QUALITY PLANNING

The supplier's senior management is expected to ensure that measurable goals and objectives are established and consistent with the supplier's quality policy.

5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.1 Responsibility and Authority

A Quality Management System is expected to be implemented in order to provide confidence that the organization can satisfy the needs of its customers. The system is expected to be consistent with the supplier's size, culture, and products. Suppliers are expected to show evidence of a quality policy emphasizing continuous quality improvement driven by senior management. Management is expected to define specific quality indicators and goals, as well as have a system in place to track and monitor trends. Improvement activities are expected to be based around these trends.

5.5.2 Management Representative

The Supplier's senior management is expected to appoint member(s) of management who have responsibility and authority for the planning, execution, control, and improvement of quality-related activities.

5.5.3 Internal Communication

The organization is expected to ensure that communication takes place at all levels and to all functions regarding compliance to the Quality Management System and its effectiveness.

5.6 MANAGEMENT REVIEW

The Supplier's management is expected to evaluate the degree of compliance and effectiveness of the Quality Management System. Management Reviews will be held at set intervals with a pre-determined agenda that includes review of performance metrics and corrective action(s). A formal corrective action process is expected to address deficiencies within the Quality Management System. Action items are expected to be assigned and recorded in the minutes with follow-up in adjacent Management Reviews.

Suppliers are expected to provide the resources necessary to implement and maintain an effective Quality Management System and to continually improve its effectiveness. Employees of the Supplier are expected to be qualified for the job they perform through education, training, and/or work experience, and be knowledgeable of appropriate quality tools, defect awareness, and processes that affect the quality of Products and Services provided to Hibernicor. Suppliers are expected to maintain evidence of required and completed training. Suppliers are expected to maintain an appropriate work environment to prevent adverse effects on Product quality.

7.1 PLANNING OF PRODUCT REALIZATION

Suppliers are expected to evaluate and meet requirements for the Product or Service provided including:

Quality Requirements as specified by Hibernicor.

Statutory and regulatory requirements related to the product.

Supplier's own specifications and Quality Manual requirements.

Before committing to supply Product to Hibernicor, the supplier is expected to hold a Contract Review of the requirements related to the product or service, stated above, to ensure that product or service requirements are defined, order requirements are understood, and the Supplier has the ability to meet the defined requirements.

7.2 CUSTOMER EXPECTATIONS

7.2.1 Communication to Hibernicor

Suppliers are expected to identify and implement a communication plan with Hibernicor regarding Product information, contracts, order handling, and customer feedback and complaints. Suppliers are expected to provide prompt notification to Hibernicor of any Supplier Product recalls.

Suppliers are expected to provide Hibernicor the documents, paper or electronically, required to determine acceptance of Product during inspection, e.g. Certificate of Conformance, Certificate of Compliance, etc.

Suppliers are expected to have a process to identify and manage changes from their Suppliers in a timely manner. It is in both the Supplier's and Hibernicor's interest to review any potential changes as early in the process as possible.

7.2.2 Supplier's Obligations for Timely and Proper Notification of Change

7.2.2.1 Changes by Hibernicor

The Specifications may be revised by Hibernicor. Such revisions may require additional qualification. Hibernicor will notify Supplier of all relevant Specification revisions. The Supplier is expected to implement all revisions by agreed upon dates.

7.2.2.2 Changes by Supplier

Upon approval by Hibernicor of the initial design, any change(s) or deviation(s) considered by the Supplier are expected to be submitted via Hibernicor's Supplier Change Request System for review and approval prior to implementation. The information submitted is expected to include a complete description of the change and, working jointly with Hibernicor, Supplier shall determine the effect the change will have on all characteristics of the Product. Upon request, the Supplier is expected to submit samples of the proposed Product for evaluation and approval by Hibernicor.

7.2.2.3 Change/Approval

Hibernicor personnel shall review and approve changes that may affect the Product(s), including, without limitation:

Altering environment specs or conditions in areas used for Manufacturing, storage, or test (i.e. microbial/endotoxin/particulate monitor)

New or alternate Sub-Tier Suppliers

Change at a Sub-Tier Supplier

Change from manual to automated process

Control Plan changes or outgoing inspection plan changes

Changes to, or deviations from, Validated sterilization parameters

Equipment Qualification or Validation changes

New equipment introduction

Process deviation

Process changes

Product design changes

Product test changes

Product labeling or packaging changes

Product part number changes

Supplier Manufacturing site transfers

Supplier name or address changes

Materials and/or Component changes, including material composition changes

Specification changes (e.g. process, Product, test)

Any changes to use of materials of animal origin

Products reviewed by Supplier MRB for “Use As Is” disposition

7.3 DESIGN AND DEVELOPMENT

When responsible for Product Design, the Supplier is expected to establish and maintain design controls in accordance with 21 CFR Part 820 & ISO13485. Design Control elements include:

Design and Development Planning

Design Inputs

Design Outputs

Design Review

Design Verification

Design Validation

Design Transfer

Design Changes

Control of Design and Development Changes

Design History File (Applicable to OEM Suppliers Only)

7.4 PURCHASING

Suppliers are expected to establish and maintain controls on the purchase of Product or Services used in the manufacture of Product to ensure conformance to specified requirements. Purchasing Controls include evaluation and selection of Suppliers to pre-determined criteria, verification of purchased Products or Services, monitoring of Supplier performance (including Corrective and Preventative Actions) change control and documentation requirements.

Hibernicor may choose to evaluate the Supplier’s sources to ensure the purchased Product or Service meets specified purchase agreements. In the event that, with Hibernicor’s knowledge and approval, Supplier subcontracts a portion of the manufacture and/or inspection of Products to sub-tier Suppliers, the expectations described in this manual are expected to be passed on to those Suppliers. Suppliers are expected to remain responsible for all acts or omissions of their sub-tier Suppliers.

7.5 IDENTIFICATION AND TRACEABILITY

7.5.1 Identification and Traceability

Suppliers are expected to establish and maintain a process for identifying and tracking Product during all stages of receipt, internal processing, test, storage, distribution, and shipment. Traceability to the lot / batch level is expected for but not limited to the following:

Materials

Process information

Shipments

7.5.2 Handling, Storage, Distribution, and Installation

Suppliers are expected to have systems in place to ensure that damage, deterioration, contamination or other adverse effects do not occur during the handling, storage and distribution of Product(s).

When a Product requires installation, Suppliers are expected to have adequate installation, inspection and testing instructions.

A Supplier is expected to establish and maintain documented procedures for the calibration, control, and maintenance of measuring, inspection, and test equipment used to ensure that Products and processes conform to applicable requirements. A Supplier is expected to calibrate these devices at consistent periodic intervals against applicable standards traceable to recognized national and/or international standards. If a Supplier finds that a gauge is not calibrated correctly or a gauge with expired calibration was used to verify parts for Hibernicor, the Supplier is expected to notify Hibernicor.

9.1 GENERAL

Suppliers are expected to use measurement, analysis, and improvement of performance metrics for Products delivered to Hibernicor. These performance metrics determine the current level of performance, drive continuous improvement activities, and monitor performance levels. Statistical tools are expected to be applied to measure the performance metrics for processes and Products and also supply chain performance. Suppliers are expected to define, plan, and implement measurements where processes affect the quality of Products or Services that Hibernicor receives.

9.2 PRODUCTION AND PROCESS CONTROL

Suppliers will have systems in place to define and maintain the manufacturing process and associated controls so that all Product conforms to their specifications, including, but not limited to:

- Approved and documented production processes, instructions, and methods that define and control the manner of production.
- Monitoring and control of process parameters and Product characteristics during production.
- Compliance with specified reference standards or codes
- Approval of processes and process equipment.
- Criteria for workmanship

Suppliers are expected to validate processes used for the manufacture of any Finished Product that cannot be fully verified by subsequent inspection and test (e.g. Sterilization), at a minimum (examples of Regulatory requirements can be found in FDA 21 CFR Part 820 Section 820.75 / ISO 13485:2003 Section 7.5.2). Guidance to performance process validation can be found in the publication ‘GHTF/ SG3/N99-10, Quality Management System – Process Validation Guidance’. Hibernicor would expect to review and approve validation plans and reports.

Suppliers are expected to identify, document and control key manufacturing process steps that affect Product performance.

9.3 AUDITS & INSPECTIONS

Hibernicor may choose to audit the Supplier or sub-tier Supplier’s manufacturing and Quality Systems. To ensure compliance to Quality Requirements, Hibernicor is expected to have access to observe and inspect Supplier’s:

Facility

Quality System

Processes

Suppliers are expected to provide a written response for all Hibernicor audit findings in a timely manner. Suppliers are expected to provide access to Regulatory Authorities for inspections or audit. Suppliers are expected to conduct internal audits to ensure compliance with its Quality System.

9.3.1 Unannounced Audits

Notified Bodies, which ensure the safety of medical devices sold in the European Union (EU) Member States, conduct unannounced audits of medical device manufacturers. Unannounced audits by a Notified Body (NB) may also be performed at Hibernicor's critical Contract Manufacturers or crucial Suppliers involved with producing Hibernicor Products sold in the EU.

9.4 MONITORING AND MEASUREMENT

9.4.1 Incoming Acceptance

Suppliers are expected to have procedures for acceptance of incoming product, including inspection, testing, and verification as conforming to Hibernicor specifications. Suppliers are expected to document acceptance or rejection of incoming Product.

9.4.2 In-Process Acceptance

Suppliers are expected to have in-process acceptance procedures to ensure that in-process Product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received.

9.4.3 Final Acceptance

Suppliers are expected to have procedures for final Product acceptance to ensure that each production unit, lot, or batch of finished Product meets Hibernicor's acceptance criteria. Finished Product shall be adequately controlled until released.

9.5 CONTROL OF NONCONFORMING PRODUCT

Suppliers are expected to establish and maintain procedures to control Product that does not conform to Hibernicor specifications. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of Nonconforming Product, including the need for an investigation, which shall be documented.

9.5.1 Production Defects

Production defects that exceed established process control/ action limits are expected to be investigated within Supplier's CAPA system. Production defects are expected to be recorded and analyzed for trends in order to identify need for further CAPA.

9.5.2 Escapes

Suppliers are expected to have control systems in place to prevent Nonconforming Product from being integrated with conforming Product. In the event these systems fail, Suppliers are expected to immediately notify Hibernicor by telephone and email of escapes of Nonconforming Product, to allow Hibernicor to investigate and take containment action. Suppliers are expected to fully cooperate in any investigation of containment action.

9.5.3 Disposition of Nonconforming Product

Suppliers are expected to have procedures covering disposition of Nonconforming Product, including review and documentation of decisions. Procedures for rework, retest and re-evaluation of Nonconforming Product are expected to be agreed with Hibernicor.

Suppliers are expected to document rework activities in the Device History Record (DHR) or equivalent and submit rework report to Hibernicor, upon request.

9.6 CORRECTIVE AND PREVENTIVE ACTION (CAPA) SYSTEM

Suppliers are expected to establish and maintain a CAPA system. The CAPA system is expected to include, at a minimum, the following requirements:

- Analysis of sources of quality data (e.g., Manufacturing processes, production defects , Product disposition records, quality audit records and reports, complaints, escapes, adverse events, environmental monitoring, Supplier Corrective Action Preventive Action (SCAPA), returned Product or

similar Product) using statistical methods and trending where applicable, to identify existing and potential causes of Nonconforming Product or other quality problems.

- Investigations to identify the root causes of nonconformances.
- Identification of the actions needed to correct nonconformances and to prevent their recurrence.
- Verification or validation of corrective and preventive actions to assure their effectiveness and to confirm that Product is not adversely affected by the action(s) taken.
- Dissemination of information concerning quality problems or nonconforming Product to personnel responsible for assuring Product quality.
- Management review of identified quality problems and associated CAPA activities.
- Documentation of CAPA activities and results.

Abbreviations

CAPA	Corrective and Preventive Action
CFR	Code of Federal Regulations
COPQ	Cost of Poor Quality
DHF	Design History File
DHR	Device History Record
DRM	Design for Reliability and Manufacturability
EU	European Union
FDA	Food and Drug Administration
FMEA	Failure Mode and Effect Analysis (dFMEA & pFMEA)
ISO	International Standard Organization
MSA	Measurement System Analysis
NB	Notified Body
OEM	Original Equipment Manufacturer
PHO	Product Hold Order
PO	Purchase Order
QMS	Quality Management System
SCAPA	Supplier Corrective and Preventive Action
SPC	Statistical Process Control
SOQ	Supplier Owned Quality
UAA	Unannounced Audit

Appendix A

Business Continuity Management: A holistic management process that identifies potential impacts that threaten an organization and provides a framework for building resilience with the capability for an effective response that safeguards the interests of its key stakeholders, reputation, brand and value creating activities

Certificate of Conformance (COC): A document, signed by an authorized representative of Supplier, attesting that a particular Product is manufactured or serviced in accordance with applicable Quality Management System requirements, specifications or the Quality Agreement. This may also be referred to as a Certification of Compliance.

Commercial Invoices: The document prepared by the seller which contains the description, value and country of origin of the merchandise being imported into the U.S. It also contains the terms of sale (FOB, CIF, C & F and CFR), the Harmonized Tariff Schedule (HTS) Code and the FDA Product code if applicable.

Component: Any raw material, substance, piece, part, software, firmware, labeling or assembly which is intended to be included as part of the finished, packaged, and labeled device.

Conflict minerals: Minerals mined in conditions of armed conflict and human rights abuses, and which are sold or traded by armed groups.

Contract Manufacturer: A contractor that manufactures Finished Devices distributed by Hibernicor; Hibernicor maintains control/approval of the Specifications. The finished Product may be supplied to Hibernicor for final packaging and labeling or be labeled by the contractor with the Hibernicor name and brand. Contract manufacturing may include sterilization, packaging, labeling, or servicing activities.

Control Plan: A document that identifies key Manufacturing process steps, critical inputs to and critical variables of such steps, and that defines process monitoring control strategies and tools.

Corrective and Preventive Action (CAPA): A corrective action and preventive action system for identifying and preventing or eliminating the cause of an existing or potential nonconformity, defect, or other undesirable situation in order to prevent occurrence or recurrence.

Country of Origin: The country of manufacture, production or growth of any article of foreign origin entering the U.S. Any additional work done, or material added, in another country may change the country of origin. To determine if the change to the article is significant enough to effect a change in country of origin, refer to www.cbp.gov.

C_p: A capability index for a stable process that compares the process capability to the maximum allowable variation as indicated by the tolerance.

C_{pk}: A capability index for a stable process that takes process location as well as capability into account.

Critical Component: A component of a finished device, which if fails could result in a hazard to a patient and/or user and/or is identified in the Product development process as being part of a critical feature or function of the device.

Critical Feature: The process specified by Hibernicor for identifying features requiring control.

Customer: Hibernicor or the customers of Hibernicor.

C-TPAT: The U.S. Customs-Trade Partnership Against Terrorism (C-TPAT) seeks to safeguard the world's vibrant trade industry from terrorists, maintaining the economic health of the U.S. and its neighbors. The partnership develops and adopts measures that add security but do not have a chilling effect on trade.

Design and Development: Activities conducted pursuant to applicable Quality Management System requirements, including FDA's Quality System Requirements, ISO 13485, or both, to design and develop the Product for manufacture.

Design History File (DHF): A compilation of records which describes the design history of a finished device.

Design Input: The physical and performance requirements of a device that are used as a basis for device design.

Design Output: The results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the Device Master Record (DMR). The total finished Design Output consists of the device, its packaging and labeling, and the DMR.

Design Review: A documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Design Validation: Establishing by objective evidence that the device specifications conform with user needs and intended use(s).

Design Verification: Confirmation by examination and provision of objective evidence that specified design requirements have been fulfilled.

Device History Record (DHR): A compilation of records containing the production history of a finished device.

Device Master Record (DMR): A compilation of records containing the procedures and specifications for a finished device.

Disaster Recovery Plan: A documented process or set of procedures to protect and recover a business in the event of a disaster.

Field Corrective Action: Any recall, market withdrawal, stock recovery, safety alert, correction, removal, or field action.

Finished Device: Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Gage Repeatability and Reproducibility (GR&R or GRR): Statistical measure to analyze how much variation exists in a gauge, measurement or test equipment.

Lot or Batch: One or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Manual: This quality manual and its appendices.

Manufacturing Material: Any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a by-product constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

Hibernicor Contract/Agreement: Hibernicor documents including purchase orders, purchasing terms and conditions, engineering drawings, specification requirements, and contracts (quality, supply, development, etc.).

Nonconforming Product: Product or material that does not meet specified requirements, such as:

- Material built to an incorrect configuration
- Material built with non-validated process parameters or material processes outside of approved parameters
- Material built with unapproved components, counterfeit components, or components not meeting Specification

Notified Body (NB): Independent public or third-party organizations or companies designated by European Union (EU) Member States to carry out control of manufacturing of medium and high risk medical devices put on the EU market. Their role is to ensure the safety of medical devices sold in EU Member States.

OEM Supplier: Supplier that manufactures Medical Finished Devices used and/or sold by Hibernicor, in which the Supplier holds legal title, design, manufacturing, and regulatory responsibility. Supplier Owned Quality: Term used to describe the various levels of maturity of our Suppliers Quality Management system to conduct inspections, monitor and act on performance trends and ensure stable and predictable Product performance.

P_p: A performance index that compares the process performance to the maximum allowable variation as indicated by the tolerance.

P_{pk}: A performance index that takes process location as well as the performance into account.

Product: Components, manufacturing materials, in- process devices, finished devices, and returned devices.

Product Hold Order (PHO): The activity that prevents known and potential nonconforming Product within direct and/or indirect Hibernicor control from forward movement.

Qualification: Activity and analysis performed to demonstrate adherence to predetermined criteria. Qualification for a Product means Product testing or inspection conducted according to an approved and controlled protocol to ensure the Product meets Specifications.

Quality System or Quality Management System: The regulatory requirements for the methods used in, and the facilities and controls used for, the design, manufacture, packing, labeling, storage, installation, and servicing of Finished Devices, as codified in 21 CFR Part 820 or embodied in ISO 13485/ISO 9001.

Records: Written or electronic accounts, notes, data, record of, and information and results obtained from performance of services of all work done under the Quality Management System, this Manual, or Quality Agreement.

Specification: Any requirement with which a Product, process, Service, or other activity must conform.

Supplier: A provider of Products or Services to Hibernicor.

Statistical Process Control (SPC): Application of statistical methods such as control charts to analyze a process and determine appropriate actions to take to achieve and improve statistical capability.

Supplier Owned Quality: Supplier owns Product quality including inspection and release activities

Validation or “Validate”: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

Appendix B

CONTROL PLAN CONTENT	CONTENT DESCRIPTION
Control Plan Number:	Enter the control plan document number used for tracking, if applicable.
Control Plan Type: (pre-production or production)	Indicate the appropriate category. - Pre-Production: A description of the dimensional measurements, material and performance tests that will occur prior to normal production. - Production: A comprehensive documentation of Product/process characteristics, process controls, tests, and measurement systems occurring during normal production.
Control Plan Original Date:	Enter the date that the original control plan was compiled.
Part Number & latest revision level:	Enter the number of the system, subsystem or component being controlled. When applicable, enter the latest engineering change level and/or issue date from the drawing specification.
Part/Process/Project Name & Description:	All steps in the manufacturing of a system, subsystem, or Product are described in a process flow diagram. Identify the Product/process/project name that best describes the activity being addressed.
Control Plan Revised Date:	Enter the date of the latest Control Plan updates.
Customer Purchasing Contact/ Address/ Phone: Hibernicor Plant Location	Enter the name and telephone number of the primary customer contact responsible for the control plan. Enter name of the customer facility receiving the Supplier Product or Service.
Customer Quality Contact/Phone:	Enter the name and telephone number of the primary customer Quality contact responsible for the Control Plan.
Customer Team member:	Enter the name and telephone number of the primary customer team member responsible for the Control Plan.
Customer Approval/Date:	Obtain the responsible customer quality representative approval (if required).
Supplier Purchasing Contact/ Address/ Phone: Supplier Plant Location:	Enter the name and telephone number of the primary Supplier purchasing contact responsible for the control plan. Enter name of the Supplier manufacturing plant where the Product is produced and where the control plan will be executed.
Supplier Quality Contact/Phone:	Enter the name and telephone number of the primary Supplier quality contact responsible for the Control Plan.
Supplier Team Member:	Enter the name and telephone number of the primary Supplier Team member responsible for the Control Plan.
Supplier Approval/Date:	Obtain the responsible Supplier manufacturing plant approval (if required).
Product/Process Number:	This item number is usually referenced from the Process Flow Chart. If multiple part numbers exist (assembly), list the individual part numbers and their processes accordingly.
Process Name/Operation Description:	All steps in the manufacturing of a system, subsystem, or Product are described in a process flow diagram. Identify the process/operating name from the flow diagram that best describes the activity being addressed.
Machine Device. Jig Tools for Mfg:	For each operation that is described, identify the processing equipment, e.g. machine, device, jig, or other tools for manufacturing, as appropriate.
Characteristics:	Definition: A distinguishing feature, dimension or property of a process or its output (Product) on which variable or attribute data can be collected. Use visual aids where applicable.
Number	Enter a cross reference number from all applicable documents such as, but not limited to, process flow diagram, numbered blueprint,

	FMEA's and sketches (computer generated or otherwise), if required.
Product	Product Characteristics are the features or properties of a Product that are described on drawings or other primary engineering information. The Core Team should identify the Special Product Characteristics that are a compilation of important Product Characteristics from all sources. All Special Characteristics need to be listed on the Control Plan. In addition, the manufacturer may list other Product Characteristics for which process controls are routinely tracked during normal operations.
Process	Process Characteristics are the process variables (input variables) that have a cause and effect relationship with the identified Product Characteristic. A Process Characteristic can only be measured at the time it occurs. The Core Team should identify Process Characteristics for which variation should be controlled to minimize Product variation. There could be one or more Process Characteristics listed for each Product Characteristic. In some processes one Process Characteristic may affect several Product Characteristics.
Special Char. Class.	Use the appropriate classification as required by the customer, to designate the type of special characteristic or this field can be left blank for other undesignated characteristics. Customers may use unique symbols to identify important characteristics, such as those that affect customer safety, compliance with regulations, function, fit or appearance. These characteristics are variously termed, "Annotated", "Critical", "Key", "Safety", or "Significant."
Spec/Work Instruction # and Revision	Enter the number and revision level of the specification referenced.
Methods:	Definition: A systematic plan using procedures and other tools to control a process.
Product/Process Specification Tolerance	Specifications/tolerance may be obtained from various engineering documents, such as, but not limited to, drawings, design reviews, material standard, computer-aided design data, manufacturing, and/or assembly requirements.
Evaluation Measurement Technique	This column identifies the measurement system being used. This could include gages, fixtures, tools and/or test equipment required to measure the Product/process/manufacturing equipment. An analysis of the linearity, reproducibility, repeatability, stability and accuracy of the measurement systems should be done prior to relying on a measurement system and improvements made accordingly.
Sample Size	When sampling is required, list the corresponding sample size.
Sampling Freq.	When sampling is required, list the corresponding frequency.
Control Method	This column contains a brief description of how the operation will be controlled, including procedure numbers where applicable. The control method utilized should be based on effective analysis of the process. The control method is determined by the type of process that exists. Operations may be controlled by, but are not limited to, Statistical Process Control, inspection, attribute data, mistake-proofing, (automated/non-automated), and sampling plans. The Control Plan descriptions should reflect the planning and strategy being implemented in the manufacturing process. If elaborate control procedures are used, the plan will typically reference the procedure document by a specific identification name and/or number. The method of control should be continually evaluated for effectiveness of process control. For example, significant changes in the process and process capability should lead

	to an evaluation of the control method.
Responsible Position	Person responsible for ensuring the control methods are employed.
Reaction Plan	The reaction plan specifies the corrective actions necessary to avoid producing non-conforming Products or operating out of control. The actions should normally be the responsibility of the people closest to the process, the operator, job setter or supervisor, and be clearly designated in the Control Plan. Provisions should be made for documenting corrective actions. In all cases, suspect and nonconforming Products need to be clearly identified, quarantined and disposition made by the responsible person designated in the reaction plan. This column may also refer to a specific reaction plan number and identify the person responsible for the reaction plan.
Revision #	The revision number of the Control Plan
Document Change # (ECO or DCR #)	The change control identifier supporting the change, if applicable.
Revision Date	Enter the documentation supporting the referenced change, if applicable.
Description of change	Enter a description of the change.