Creating a predictable supply through unwavering commitment to quality
WE WILL INNOVATE IN NEW WAYS AND COLLABORATE WITH NEW STAKEHOLDERS TO TAKE HEALTHCARE FURTHER, TOGETHER.
# TABLE OF CONTENTS

## 1.0 Introduction
1.1 How to Use This Manual
1.2 Purpose and Scope
1.3 Code of Conduct
1.4 Medtronic Mission
1.5 Medtronic Businesses
1.6 Supplier Diversity
1.7 Environmental/Social Obligations
1.8 Continuous Improvement

## 2.0 Key Roles and Responsibilities
2.1 Medtronic Sourcing
2.2 Supplier Organization

## 3.0 Overview of Supplier Expectations
3.1 Quality Agreements
3.2 Non-Disclosure Agreements
3.3 Environmental Compliance
3.4 Declaration of Raw Materials Used
3.5 Import Compliance
3.6 Business Continuity
3.7 Change Management
3.8 Sub-Tier Supplier Control
3.9 Measurement System Analysis (MSA)
3.10 Process Capability
3.11 Control Plans
3.12 Cost of Poor Quality (COPQ)

## 4.0 Quality Management System
4.1 Expectations
4.2 Documentation
4.3 Complaints and Adverse Events Reporting
4.4 Field Corrective Actions

## 5.0 Management Responsibilities
5.1 Management Commitment
5.2 Customer Focus
5.3 Quality Policy
5.4 Quality Planning
5.5 Responsibility, Authority and Communication
5.6 Management Review

## 6.0 Resource Management

## 7.0 Product Realization
7.1 Planning of Product Realization
7.2 Customer Expectations
7.3 Design and Development
7.4 Purchasing
7.5 Identification and Traceability

## 8.0 Control of Monitoring and Measuring Devices

## 9.0 Measurement, Analysis, and Improvement
9.1 General
9.2 Production and Process Control
9.3 Audits & Inspections
9.4 Monitoring and Measurement
9.5 Control of Nonconforming Product
9.6 Corrective and Preventive Action (CAPA) System

Appendix A: Acronyms
Appendix B: Terms and Definitions
Appendix C: Control Plan Template
Appendix D: Standards
FORWARD

An important building block for a successful Supplier-Customer partnership is communication. The manual provides an overview of Medtronic’s expectations to its Suppliers. Its purpose is to give our Suppliers and potential Suppliers the information required for securing business and maintaining a successful partnership.
INTRODUCTION

1.0

1.1 HOW TO USE THIS MANUAL

The first three sections of this document provide an overview of Medtronic, the key roles in the sourcing organization, and an overview of Medtronic’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 Medtronic 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.

Terms and definitions used in this Manual are listed in Appendix B.

Medtronic welcomes any questions regarding the content of the Supplier Quality Excellence Manual.

Please send feedback to: SQEM@medtronic.com
1.2 PURPOSE AND SCOPE

The purpose of this Supplier Quality Excellence Manual is to clearly communicate Medtronic’s Quality 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 Medtronic. Suppliers have a direct impact to Medtronic delivering high-quality Product to our customers. Therefore it is important to understand expectations, identify gaps and track progress to gap resolution. Medtronic establishes long-term partnerships with Suppliers who strive to meet performance expectations and 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 agreements, engineering drawings or specifications.

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

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

1.3 CODE OF CONDUCT

Our relationships with Suppliers are based on lawful, efficient, and fair practices. Medtronic 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
- Medtronic reserves the right to discontinue business relationships with Suppliers that fail to conduct business in a legal, responsible, and ethical manner.

Appendix D contains a list of regulations and standards that are applicable to Medtronic and may be applicable to our Suppliers also.

1.4 MEDTRONIC MISSION

The Medtronic mission is very important to us as a company. First and foremost, our mission is to alleviate pain, restore health, and extend life. We at Medtronic are committed to fulfilling this mission and expect the same commitment from our Suppliers. Please take time to review and understand the Medtronic mission:

- To contribute to human welfare by application of biomedical engineering in the research, design, manufacture, and sale of instruments or applications that alleviate pain, restore health, and extend life.
- To direct our growth in the areas of biomedical engineering where we display maximum strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
- To strive without reserve for the greatest possible reliability and quality in our Products: to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity, and service.
- To make a fair profit on current operations to meet our obligations, sustain our growth, and reach our goals.
- To recognize the personal worth of employees by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company’s success.
- To maintain good citizenship as a company.

1.5 MEDTRONIC BUSINESSES

Medtronic understands that our four business groups are different in nature and may have unique Supplier quality requirements. However, the processes and tools depicted in this Manual represent the core Medtronic expectations.

For more information about Medtronic Products and the patients we serve, please visit http://www.medtronic.com.

Cardiac and Vascular Group

Cardiac Rhythm & Heart Failure Disease Management (CRHF): Our CRHF division develops, manufactures and markets Products for the diagnosis, treatment, and management of heart rhythm disorders and heart failure. Our Products include implantable devices, leads and delivery systems, Products for the treatment of atrial fibrillation (AF), Products designed to reduce surgical site infections, information systems for the management of patients with CRHF devices, and an integrated health solutions business.

Coronary & Structural Heart Disease Management (CSH): Our CSH division develops, manufactures and markets therapies to treat coronary artery disease (CAD), and heart valve disorders.
Our Surgical Innovations division develops, manufactures, and markets a comprehensive line of surgical medical devices for treating heart valve disease, peripheral vascular disease, and neuro-vascular disease. Our Cardiovascular disease solutions focus on the prevention and treatment of cardiovascular diseases, including acute coronary syndromes, chronic heart failure, and heart rhythm disorders. Our Peripheral Vascular Disease management solutions offer comprehensive treatment options for patients with peripheral artery disease, lower extremity ischemia, and chronic limb-threatening ischemia. Our Neurovascular disease solutions include technologies for treating stroke, carotid artery disease, and aneurysms. Our Cardiovascular disease solutions offer comprehensive treatment options for patients with heart failure, atrial fibrillation, and arrhythmia. Our Peripheral Vascular Disease management solutions provide comprehensive treatment options for patients with lower extremity ischemia and chronic limb-threatening ischemia. Our Neurovascular disease solutions offer comprehensive treatment options for patients with stroke, carotid artery disease, and aneurysms.
1.6 SUPPLIER DIVERSITY

A diverse base of high-quality Suppliers strengthens our ability to carry out our Mission to alleviate pain, restore health, and extend lives. A diverse supply chain, focused on the highest standards of quality, helps us connect with our patients, physicians, and communities as we work to improve lives.

Our United States Supplier Diversity program encompasses the following classifications.

- Small Business (SB)
- Small Disadvantaged Business (SDB)
- Woman-Owned Small Business (WOSB)
- Historically Underutilized Business Zone Small Business (HUBZone)
- Veteran-Owned Small Business (VOSB)
- Service-Disabled Veteran-Owned Small Business (SDVOSB)
- Minority Business Enterprise (MBE)
- Women Business Enterprise (WBE)

A Supplier may review requirements for each diversity category and register in the Medtronic Supplier Registration Portal by visiting www.medtronic.com/supplierdiversity.

1.7 ENVIRONMENTAL/SOCIAL OBLIGATIONS

At Medtronic, we expect that our Suppliers:

- Are aware of how their businesses and Products impact the environment
- Commit to continuous environmental, safety and health improvement
- Know and comply with federal, state and local regulatory requirements
- Notify us of any significant environmental compliance violations
- Comply with current global classifications of hazardous substances
- Supply composition information on parts/components as requested
- Be ISO 14001 certified or have a plan to become certified


1.7.1 Conflict Minerals

Medtronic expects Supplier to comply with the U.S. Securities and Exchange Commission (SEC) rules for reporting and disclosure requirements related to Conflict Minerals as part of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (“Dodd-Frank Act”). Medtronic supports the goals and objectives of Section 1502 of the Dodd-Frank Act that requires public companies to determine the sourcing of tin, tungsten, tantalum, and gold used in their Products and to file an annual report disclosing any such use. As part of our commitment to responsible sourcing and human welfare, Medtronic and our Supplier are expected to adopt a Conflict Minerals Policy.

1.7.2 C-TPAT

Medtronic expects Suppliers to obtain certification with Customs-Trade Partnership Against Terrorism (C-TPAT): (i) obtain certification under the U.S. C-TPAT program and provide evidence of such certification to Medtronic; or (ii) demonstrate to Medtronic that it meets the criteria for such certification and has policies and procedures in place that meet C-TPAT requirements.

The U.S. Customs-Trade Partnership Against Terrorism 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. Further information can be found at www.cbp.gov.

1.8 CONTINUOUS IMPROVEMENT

Medtronic strives for reliability and quality in all of our Products. Medtronic recognizes that this cannot be done without the support of a strong supply base. To that end, Medtronic strives to achieve a world-class supply chain utilizing Lean Sigma methodologies that address the waste and variability in processes and supply chain systems. Lean Sigma combines Six Sigma with Lean Manufacturing methodologies.

Medtronic is dedicated to aligning its continuous improvement strategies with its supply base, namely through the following programs: Supplier Development, Supplier Owned Quality, and Supplier Lean Sigma Training.

1.8.1 Supplier Development

The Supplier Development program engages Suppliers to continuously improve process capability, reduce waste and variability, and other activities and projects. It utilizes tools such as Lean Six Sigma, Kaizen, Rapid Improvement Events, Value Stream Mapping, and training to perform gap analyses, reduce lead times and reduce defects. Medtronic trained engineers will partner with strategic Suppliers to drive process improvements throughout the value stream that they share.
Both Medtronic and our Suppliers can benefit from Supplier Development in the following ways:

- Improved quality and yield
- Supplier Owned Quality
- Improved production throughput
- Improved customer responsiveness (on-time delivery; lead time reduction)
- Cost reductions (inventory, overtime, labor and burden)
- Growth with less capital investment
- Opportunity to become a Medtronic Supplier Owned Quality participant

To achieve these mutual benefits, Medtronic partners with Suppliers on specific projects to implement process improvements that have positive outcomes for current and future Products.

### 1.8.2 Supplier Owned Quality

Supplier Owned Quality (SOQ) is a program developed by Medtronic to support the Supplier owning the Product quality of Products they deliver. Its aim is to avoid duplication or repeat inspection efforts within Medtronic. While Medtronic continues to own overall quality of our Product, our Suppliers are expected to own Product quality in all the Product (including their processes) that they provide. SOQ links the Supplier’s Product inspection data results to Medtronic, streamlining the acceptance process.

Select Suppliers benefit from engaging in Medtronic’s Supplier Owned Quality (SOQ) initiative by challenging themselves to meet increasing levels of supply maturity to ensure stable and predictable Products. The SOQ program has various maturity levels. Both the Supplier and Medtronic can monitor and act on performance trends to support improved Product outcomes.

Suppliers benefit from SOQ by receiving early feedback regarding Medtronic’s Product acceptance thus mitigating the risk of Product returns and the need to hold excessive inventory to support long acceptance lead times. Achieving the highest maturity levels with Statistical Process Control (SPC) reduces manufacturing variability and lowers scrap costs.

### 1.8.3 Supplier Lean Sigma Training

Medtronic offers Lean Sigma training for selected Suppliers. Through this program, participants learn the methodology in a formal classroom setting and learn to apply the knowledge and techniques to projects in their own organization.

Lean Sigma projects follow the Define, Measure, Analyze, Improve, and Control (DMAIC) roadmap, unifying Lean and Six Sigma toolsets to avoid non-value-add activities and reduce process variation.

Lean Sigma training is another way by which Medtronic helps strategic Suppliers drive process improvements throughout the value stream that they share with us.

More information is available from the Medtronic Supply Chain Representative.

---

<table>
<thead>
<tr>
<th>INSPECTION</th>
<th>VISIBILITY</th>
<th>CONTROL</th>
<th>CAPABLE</th>
<th>PREDICTABLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier Owned Quality Level 1</td>
<td>Supplier Owned Quality Level 2</td>
<td>Supplier Owned Quality Level 3</td>
<td>Supplier Owned Quality Level 4</td>
<td>Supplier Owned Quality Level 5</td>
</tr>
<tr>
<td>Supplier is able to manufacture to requirements with acceptable quality, measurement, and data collection systems. <em>(Medtronic inspection remains)</em></td>
<td>Medtronic is accepting per supplier data and sufficient data has demonstrated ability to meet manufacturing specification limits.</td>
<td>Supplier has systems for defining control limits and is working to achieve sufficient stability to utilize SPC.</td>
<td>Supplier has systems for defining control limits and demonstrated an internal culture for stable and capable manufacturing responding to SPC signals.</td>
<td>Supplier demonstrates a continuous culture of manufacturing excellence by controlling inputs to ensure predictable outputs.</td>
</tr>
</tbody>
</table>

Figure 1: Maturity Model of SOQ
2.1 MEDTRONIC SOURCING

Medtronic 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 points of contact with our suppliers will be:

2.1.1 Global Commodity Management

Medtronic’s Global commodity representative is responsible for ensuring streamlined communications, facilitating access across the multiple business units and supporting the global strategy by driving cross business unit activities.

2.1.2 Business Unit Commodity Management

The Business Unit representative is the Supplier’s primary contact for business unit activities. The Business Unit representative is responsible for the 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 Medtronic.

2.2 SUPPLIER ORGANIZATION

Medtronic expects our Supplies to identify a designated contact within their organization to communicate with Medtronic for each function below:

2.2.1 Customer Representative

The customer representative is the primary contact within the Supplier’s organization for any key communications with Medtronic, including any quality, delivery, or commercial issue resolution.

2.2.2 Quality Management Representative

The Quality Management Representative within the Supplier’s organization is responsible for the implementation and maintenance of the Supplier’s Quality Management System such as defined by ISO 9001 and/or the ISO 13485 series of standards.
OVERVIEW OF SUPPLIER EXPECTATIONS

3.0

Suppliers are responsible for ensuring that Products or Services meet established Medtronic specifications and Quality Requirements. Audits, approvals or verification by Medtronic 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, nor will it preclude the subsequent rejection of unacceptable Product.

3.1 QUALITY AGREEMENTS

In addition to the expectations contained in this Manual, Medtronic 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 Medtronic 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 Medtronic 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 Medtronic’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 Medtronic other than with prior written agreement of the other party. Suppliers shall agree not to display or use the Medtronic logo, trade secrets, trademark, or Product(s) in any manner without prior written permission from their Medtronic Supply Chain Representative.

Medtronic values our relationships with our Suppliers and therefore would like to protect it through the use of this formal agreement.

3.3 ENVIRONMENTAL COMPLIANCE

Products & Services supplied to Medtronic are expected to meet the requirements of country, federal, state and local environmental regulations. The list below includes some of the regulations; however, compliance is not limited to these. Additional information may be required such as certification to any of the following or chemical composition of Products. Any suspicions that Products supplied to Medtronic are not compliant, are expected to be communicated to the appropriate buyer or supply chain representative immediately.

- Battery and Accumulator Directive 2006/66/EC
- Packaging Directives 94/62/EC, 2004/12/EC, COM Decision 97/129/EC
- REACH (Registration Evaluation Authorization and Restriction of Chemicals) Regulation 1907/2006/EC
- RoHS (Restriction of Hazardous Substances) EU 2003/95/EC and China

3.4 DECLARATION OF RAW MATERIALS USED

Suppliers of Components and Finished Devices are expected to have information about the composition (e.g. Trade or Chemical name, Color, Grade, etc.) on hand and make this available to Medtronic upon request. This detailed information, declaring the raw materials used to manufacture a Product is required to fulfill Regulatory Body requirements for approval for use. If Colorants are used, additional details (e.g. Color Description, Trade Name, etc.) for each ingredient or pigment used in the colorant formulation are expected to be known by the Supplier and made available as needed.
3.5 IMPORT COMPLIANCE

As Business becomes increasingly globalized, additional documentation and processes are required. Suppliers who ship Product from outside the United States to a Medtronic facility within the United States need to be aware of the following:

- Medtronic 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.
- 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.
- 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

Medtronic expects our Suppliers to complete a formal business Disaster Recovery Plan to ensure no interruption in supply to our patients is encountered. While contingency plans cannot be expected to cover all potential scenarios, we expect our Suppliers to maintain robust plans to facilitate rapid response and recovery in the event of disruptions.

Medtronic 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 Medtronic 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 and therapies, our operations and, more importantly, our customers and patients. Suppliers are responsible for notifying Medtronic of changes made to materials, Products or processes, including changes at their Suppliers.

Suppliers are expected to notify Medtronic prior to implementing any change by submitting a request through Medtronic’s Supplier Change Request System.

Please Note: Approval from Medtronic is required prior to implementing any changes. See section 7.2.3 for additional detail.

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 Product(s) manufactured utilize only authentic, conforming and specified material as stipulated in the specification.

Medtronic’s expectation is that the Supplier has in place formal Purchasing and Supplier control processes to manage sub-tiers. These controls are expected to include:

- Selection, evaluation and approval
- Product qualification
- Procurement
- Product acceptance
- Performance measurement and monitoring, including sub tier auditing programs
- Nonconforming Product and CAPA processes
- Change control

Suppliers are responsible for ensuring and controlling the quality of all components and raw materials that are purchased to manufacture Product for Medtronic.

Where Medtronic requires a Supplier to engage with a specified sub-tier Supplier, relationship management will be established between Medtronic and the Supplier.

Please Note: Prior to implementing sub-tier Supplier changes, Suppliers are expected to seek Medtronic approval (see section 7.2.3 for additional details).

3.9 MEASUREMENT SYSTEM ANALYSIS (MSA)

Medtronic expects Suppliers to develop and maintain capable, accurate and stable measurement methods and systems. Measurement System Analysis (MSA) is recommended in determining whether measurement or test equipment has sufficient accuracy, precision, or resolution to adequately provide information about process performance, or the effects of inherent or applied variation of the process under development. One recommended tool is Gage Repeatability and Reproducibility (Gage R&R or GR&R).
3.10 PROCESS CAPABILITY

Medtronic expects Suppliers to develop and maintain highly capable processes to produce quality Products and Services. Use of Statistical Process Control (SPC) for special part and process characteristics is recommended. SPC is expected for all annotated, special, significant, or critical drawing characteristics (unless otherwise specified). SPC data may be required with each shipment at the discretion of the receiving facility. Suppliers are expected to utilise indices such as $C_p / C_{pk} / P_p / P_{pk}$. Special characteristics will be defined in Medtronic specifications when applicable.

3.11 CONTROL PLANS

Each Medtronic business unit or geography 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 C for a sample Control Plan template. Supplier Control Plans may be used in lieu of Medtronic Control Plans as long as the content reflects the requirements as defined by Medtronic to ensure ongoing process control.

3.12 COST OF POOR QUALITY (COPQ)

Medtronic shall notify Suppliers of nonconforming Product. Medtronic expects Suppliers to replace nonconforming materials free of charge. Suppliers are expected to cover expenses (including freight and customs clearance, if any) incurred by Medtronic 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.
4.0 QUALITY MANAGEMENT SYSTEM

The Supplier’s management is expected to establish, document, and implement an effective Quality Management System (QMS).

4.1 EXPECTATIONS

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 Medtronic in a timely manner.

The Supplier is expected to notify Medtronic of a Regulatory inspection. The Supplier is expected to also provide timely notification to Medtronic 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 Medtronic upon request.

4.2 DOCUMENTATION

4.2.1 General

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

- Documented statements of a quality policy and quality objectives
- Documented procedures as required by the Quality Management System
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- 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 Medtronic upon request. Suppliers will make available any and all quality Records, in a timely manner, upon request by Medtronic 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

Medtronic has the sole authority to correspond with all applicable regulatory authorities with respect to complaints about the Product(s). Medtronic 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 Product(s) and are expected to take action to promptly resolve such complaints and adverse events. Suppliers are expected to:

- Give prompt notice to Medtronic by email or by telephone as soon as becoming aware of a Product complaint or adverse event and provide written follow-up to Medtronic.
- 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;
- Establish a tracking and traceability system for all Product(s) so as to permit successful tracking in the event of a Recall.
- 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(s) should be considered, it will immediately notify the other party. Medtronic 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 Medtronic to implement the action once the determination is made.

5.0 MANAGEMENT RESPONSIBILITIES

5.1 MANAGEMENT COMMITMENT

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

- Communicating to the organization the importance of meeting customer as well as regulatory expectations and requirements
- Establishing the quality policy and objectives
- Conducting regularly scheduled management reviews on the effectiveness of the quality system and taking appropriate action when indicators are unfavorable
- 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. Medtronic 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:

- Is appropriate to the purpose of the organization
- Includes a commitment to meeting customer requirements and to continuous improvement
- Provides a framework for establishing and reviewing quality objectives
- Is communicated and understood at all levels in the organization
- Is reviewed for continued appropriateness
5.4 QUALITY PLANNING

The Supplier’s senior management is expected to ensure that goals and objectives are established for the appropriate functions and levels. The goals and objectives are expected to be measurable 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.

6.0 RESOURCE MANAGEMENT

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 Medtronic. 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.
7.0 PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

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

- Quality Requirements specified by Medtronic.
- Statutory and regulatory requirements related to the Product.
- Supplier’s own specifications and Quality Manual requirements.

Before committing to supply Product to Medtronic, 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 Design for Reliability and Manufacturability (DRM)

DRM is a Medtronic program for achieving Product excellence through application of Lean Sigma practices, methods and tools to improve Product performance, reliability, manufacturability and costs. It is essential that we work together to understand requirements, apply design for manufacturability principles, and develop robust processes where capabilities are understood and effectively controlled. DRM elements include:

- Strategic Technology Planning
- Voice of the Customer (VOC)
- Concept Engineering
- Requirements Flow Down
- Robust Design
- Use Conditions
- Design for Manufacturing & Assembly (DFMA)
- Design for Reliability (DFR)
- Capability
- Control

7.2.2 Communication to Medtronic

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

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

7.2.3 Supplier’s Obligations for Timely and Proper Notification of Change

7.2.3.1 Changes by Medtronic

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

7.2.3.2 Changes by Supplier

Upon approval by Medtronic of the initial design, any change(s) or deviation(s) considered by the Supplier are expected to be submitted via Medtronic’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 Medtronic, 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 Medtronic.

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 Medtronic’s interest to review any potential changes as early in the process as possible.
7.2.3.3 Change/Approval
Medtronic 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 CAPA) change control and documentation requirements.
Medtronic may choose to evaluate the Supplier’s sources to ensure the purchased Product or Service meets specified purchase agreements. In the event that, with Medtronic’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.
CONTROL OF MONITORING AND MEASURING DEVICES

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 Medtronic, the Supplier is expected to notify Medtronic.

MEASUREMENT, ANALYSIS, AND IMPROVEMENT

9.0

9.1 GENERAL

Suppliers are expected to use measurement, analysis, and improvement of performance metrics for Products delivered to Medtronic. 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 Medtronic 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’. Medtronic 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

Medtronic may choose to audit the Supplier or sub-tier Supplier’s manufacturing and Quality Systems. To ensure compliance to Quality Requirements, Medtronic 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 Medtronic 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 (UAA)
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 Medtronic’s critical Contract Manufacturers or crucial Suppliers involved with producing Medtronic 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 Medtronic 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 Medtronic’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 Medtronic 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 Medtronic by telephone and email of escapes of Nonconforming Product, to allow Medtronic 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 Medtronic.

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

Please Note: Acceptance of a Medtronic Purchase Order (PO) constitutes acknowledgement that the Supplier has read and understands the expectations of this Manual.
## APPENDIX A: ACRONYMS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPA</td>
<td>Corrective and Preventive Action</td>
</tr>
<tr>
<td>CFR</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>COPQ</td>
<td>Cost of Poor Quality</td>
</tr>
<tr>
<td>DHF</td>
<td>Design History File</td>
</tr>
<tr>
<td>DHR</td>
<td>Device History Record</td>
</tr>
<tr>
<td>DRM</td>
<td>Design for Reliability and Manufacturability</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FMEA</td>
<td>Failure Mode and Effect Analysis (dFMEA &amp; pFMEA)</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standard Organization</td>
</tr>
<tr>
<td>MSA</td>
<td>Measurement System Analysis</td>
</tr>
<tr>
<td>NB</td>
<td>Notified Body</td>
</tr>
<tr>
<td>OEM</td>
<td>Original Equipment Manufacturer</td>
</tr>
<tr>
<td>PHO</td>
<td>Product Hold Order</td>
</tr>
<tr>
<td>PO</td>
<td>Purchase Order</td>
</tr>
<tr>
<td>QMS</td>
<td>Quality Management System</td>
</tr>
<tr>
<td>SCAPA</td>
<td>Supplier Corrective and Preventive Action</td>
</tr>
<tr>
<td>SPC</td>
<td>Statistical Process Control</td>
</tr>
<tr>
<td>SOQ</td>
<td>Supplier Owned Quality</td>
</tr>
<tr>
<td>UAA</td>
<td>Unannounced Audit</td>
</tr>
</tbody>
</table>
APPENDIX B: TERMS AND DEFINITIONS

**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 Medtronic. Medtronic maintains control/approval of the Specifications. The finished Product may be supplied to Medtronic for final packaging and labeling or be labeled by the contractor with the Medtronic 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 Medtronic for identifying features requiring control.

**Customer**: Medtronic or the customers of Medtronic.

**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.

Medtronic Contract/Agreement: Medtronic 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 Medtronic, 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 Hold Order (PHO): The activity that prevents known and potential nonconforming Product within direct and/or indirect Medtronic 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 Medtronic.

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 C: CONTROL PLAN TEMPLATE

### CONTROL PLAN

<table>
<thead>
<tr>
<th>Part/Process/Project Name or Description</th>
<th>Control Plan Type:</th>
<th>Control Plan Number:</th>
<th>Original Date:</th>
<th>Revised Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Customer Purchasing Contact/Address/Phone</td>
<td>Pre-Production</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer Quality Contact/Phone:</td>
<td>Production</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier Purchasing Contact/Address/Phone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier Quality Contact/Phone:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Part/Process/Project Specification

<table>
<thead>
<tr>
<th>Part/Process/Project Number</th>
<th>Process/Operation Description</th>
<th>Machine/Device/Jig/Tools for Mfg</th>
<th>Characteristics</th>
<th>Special Char. Class</th>
<th>Spec/Work Instruction #/Revision</th>
<th>Control Method</th>
<th>Responsible Party</th>
<th>Reaction Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### CONTROL PLAN CHANGE LOG

<table>
<thead>
<tr>
<th>Revision #</th>
<th>Document Change No.</th>
<th>Revision Date</th>
<th>Description of Change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONTROL PLAN CONTENT</strong></td>
<td><strong>CONTENT DESCRIPTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Plan Number:</td>
<td>Enter the control plan document number used for tracking, if applicable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Plan Type:</td>
<td>Indicate the appropriate category.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(pre-production or production)</td>
<td>- Pre-Production: A description of the dimensional measurements, material and performance tests that will occur prior to normal production.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Production: A comprehensive documentation of Product/process characteristics, process controls, tests, and measurement systems occurring during normal production.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Plan Original Date:</td>
<td>Enter the date that the original control plan was compiled.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part Number &amp; latest revision level:</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part/Process/Project Name &amp; Description:</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Plan Revised Date:</td>
<td>Enter the date of the latest Control Plan updates.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer Purchasing Contact/ Address/ Phone: Medtronic Plant Location</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer Quality Contact/Phone:</td>
<td>Enter the name and telephone number of the primary customer Quality contact responsible for the Control Plan.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer Team member:</td>
<td>Enter the name and telephone number of the primary customer team member responsible for the Control Plan.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Customer Approval/Date:</td>
<td>Obtain the responsible customer quality representative approval (if required).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier Purchasing Contact/ Address/ Phone: Supplier Plant Location:</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier Quality Contact/Phone:</td>
<td>Enter the name and telephone number of the primary Supplier quality contact responsible for the Control Plan.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier Team Member:</td>
<td>Enter the name and telephone number of the primary Supplier Team member responsible for the Control Plan.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supplier Approval/Date:</td>
<td>Obtain the responsible Supplier manufacturing plant approval (if required).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product/Process Number:</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process Name/Operation Description:</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Machine Device, Jig Tools for Mfg:</td>
<td>For each operation that is described, identify the processing equipment, e.g. machine, device, jig, or other tools for manufacturing, as appropriate.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Characteristics:</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONTROL PLAN CONTENT</td>
<td>CONTENT DESCRIPTION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>---------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Process</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special Char. Class.</td>
<td>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.”</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spec/Work Instruction # and Revision</td>
<td>Enter the number and revision level of the specification referenced.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methods</td>
<td>Definition: A systematic plan using procedures and other tools to control a process.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product/Process Specification Tolerance</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaluation Measurement Technique</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample Size</td>
<td>When sampling is required, list the corresponding sample size.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sampling Freq.</td>
<td>When sampling is required, list the corresponding frequency.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control Method</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Responsible Position</td>
<td>Person responsible for ensuring the control methods are employed.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reaction Plan</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>REACTION PLAN</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision #</td>
<td>The revision number of the Control Plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document Change # (ECO or DCR #)</td>
<td>The change control identifier supporting the change, if applicable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision Date</td>
<td>Enter the documentation supporting the referenced change, if applicable.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of change</td>
<td>Enter a description of the change.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX D: STANDARDS

- Annex II AIMDD 90/385/EEC - Active Implantable Devices
- Annex II MDD 93/42/EEC - Medical Devices
- Australia - Therapeutics Goods (Medical Devices) Regulations 2002
- Brazil RDC16/2013 – GMP Requirements for Medical Devices and IVDs
- FDA 21 CFR Part 210 - Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- FDA 21 CFR Part 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals
- FDA 21 CFR Part 312 - Investigational New Drug Application
- FDA 21 CFR Part 807 - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
- FDA 21 CFR Part 820 - Quality System Regulation
- CMDR, SOR/98-282 – Canada Medical Devices Regulations
- KGMP 2008-11 - Korea Good Manufacturing Practice (KGMP)
- MHLW GMP Ordinance #169 – Japan Quality Management System Compliance
- Battery and Accumulator Directive 2006/66/EC
- REACH (Registration Evaluation Authorization and Restriction of Chemicals) Regulation 1907/2006/EC
- RoHS (Restriction of Hazardous Substances) EU 2003/95/EC and China