Medical Device Quality Agreement Template

Prepared by

Dan O'Leary
Ombu Enterprises, LLC
3 Forest Ave.
Swanzey, NH 03446
www.OmbuEnterprises.com
603-209-0600

This document is intended to form the basis for a Supplier Agreement for a medical device manufacturer. The document should be tailored to the specific requirements based on the product or service procured, the capability of the customer, the capability of the supplier, and the regulatory framework applied to the medical device.

Contents

Medical Device Quality Agreement Template

Note: Forming the Base Supplier Agreement – This template contains many clauses that will not apply in a particular relationship between a manufacturer and a supplier. Remove these clauses to form the Base Supplier Agreement. Send the Base Control Plan to potential Suppliers as part of the evaluation.

Note: Forming the Final Supplier Agreement – After evaluation of the potential supplier you may need to include additional clauses to close the gap between Customer's requirements and the Supplier's capabilities.

1 Administrative Elements

1.1 Scope

This agreement defines the Quality Agreement between the parties identified below. It defines the commitment both parties make to ensure that their respective products and services satisfy the quality and regulatory requirements called out in this agreement. Both parties agree to cooperate in the success of this agreement.

This agreement does not define the forecasting, ordering, delivery, or pricing requirements for either party.

This agreement does not define the specifications for the products or services covered.

1.2 Parties to the Agreement

This Quality Agreement is executed between <Supplier Name> with business address at <address>, hereafter referred to as <Supplier> and <Customer Name> with business address at <address>, hereafter referred to as <Customer>. <Supplier> agrees to provide the goods or services defined below in full conformance with the requirements of this agreement.

Note: The Supplier Name and the Customer Name can be expanded to include further descriptive information about the company such as Company X, a contract manufacturer of medical devices duly organized and existing under the laws of <list appropriate jurisdiction>.

1.3 Definitions, Abbreviations, and Acronyms

The following terms are included in this agreement.

Accuracy – A statement of how close a measured value is to the actual (true) value. See also, precision.

Complaint – A written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

Concession – Permission to use or release material that does not conform to specified requirements. A concession is frequently called a Use-As-Is (UAI) disposition.

Corrective Action – Action to eliminate the cause of a detected nonconformity or other undesirable situation

Directed Procurement – A case in which the Customer directs the Supplier to obtain a good or service from a particular third party. In a directed procurement, the Customer is responsible for product qualification Supplier qualification, *etc*. The Supplier should track and report the third party's performance metrics to the Customer.

FIFO – First In, First Out

IM&TE – Inspection, measuring, and test equipment

Precision – A statement of the repeatability of a measure. See also, accuracy.

Product – Product is the output of a process and includes, but is not limited to, goods, services, software, documentation, and consulting.

Promptly – Unless specified otherwise, promptly means within ten working days.
QMS – Quality Management System

Repair – Action on nonconforming material to make it acceptable for the intended use

Rework – Action on nonconforming material to make it conform to the requirements

RMS – Risk Management System

Scrap – Action on nonconforming material to preclude its originally intended use

Supplier – The Supplier delivers product to the Customer. The term Supplier includes, but is not limited to, contractors, consultants, sister organizations, and parent organizations.

1.4 Referenced Documents

21 CFR Part 820 *Quality System Regulation*

GHTF/SG3/N15R8 *Implementation of risk management principles and activities within a Quality Management System*

GHTF/SG3/N17:2008 *Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers*

ISO 9001:2008 *Quality Management Systems – Requirements*

ISO 13485:2003 *Medical devices – Quality management systems – Requirements for regulatory purposes*

ISO 14971:2007 *Medical devices – Application of risk management to medical devices*

1.5 Products and Services Covered By This Agreement

This agreement pertains to the products listed in the table below.

Note: List the products that the Supplier provides to the Customer. The list should be specific, but should not include revision levels or other information at that specific level. For example, it would be better to say

Power Supply Part Number: A1234

rather than

Power Supply Part Number: A1234 Revision C

You probably do not want to reapprove the Supplier Agreement for every revision change in the product.

Products Covered by This Agreement

Product Name	Supplier's Part Number	Customer's Part number

1.6 Site(s) Involved

The Supplier produces the product at any of the sites listed below. The Supplier ships the product to the Customer from any of the sites listed below.

Note: The table is not intended to show the relationship between the Supplier's production sites and Distribution sites. This could be a one-to-one, one-to-many, or many-to-one relationships. Entering a production site and a distribution site into the same row does not necessarily convey a connection.

Note: If the Supplier's Production Site or Distribution Site is outside the United States, then Customs consideration may apply.

Supplier Sites Involved in This Quality Agreement

Supplier Production Sites	Supplier Distribution Sites

The Customer receives the product at any of the sites listed below.

Customer Sites Involved in This Quality Agreement

Customer Receiving Sites

1.7 Quality Management Systems

1.7.1 Quality System Regulation

The Supplier and the Customer shall each maintain a Quality Management System (QMS) that conforms to the requirements of the FDA's Quality System Regulation (QSR) as stated in 21 CFR Part 820.

Should the Supplier determine that a requirement of 21 CFR Part 820 is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of making that determination. The list of agreed not appropriate or not applicable requirements is shown in Appendix 1.

1.7.2 ISO 13485:2003

The Supplier and Customer shall each maintain a Quality Management System (QMS) that conforms to the requirements of ISO 13485:2003.

The Supplier shall resister the QMS with a registrar acceptable to the Customer. The Supplier shall provide a copy of the registration certificate to the Customer.

Should the Supplier determine that a requirement of ISO 13485:2003 is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of making that determination. The list of agreed not appropriate or not applicable requirements is shown in Appendix 2.

1.7.3 ISO 9001:2008

The Supplier and Customer shall each maintain a Quality Management System (QMS) that conforms to the requirements of ISO 9001:2008.

The Supplier shall resister the QMS with a registrar acceptable to the Customer. The Supplier shall provide a copy of the registration certificate to the Customer.

Should the Supplier determine that a requirement of ISO 9001:2008 is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of making that determination. The list of agreed not appropriate or not applicable requirements is shown in Appendix 3.

1.7.4 ISO 14971:2007

The Supplier and the Customer shall each maintain a Risk Management System that conforms to the requirements of ISO 14971:2007. In addition, both the Supplier and the Customer shall integrate the Risk Management System (RMS) into the Quality Management System (QMS) employing the principles in GHTF/SG3/N15R8.

Should the Supplier determine that a requirement of ISO 14971:2007 is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of

making that determination. The list of agreed not appropriate or not applicable requirements is shown in Appendix 4.

1.7.5 Other Required Standards

The Supplier shall produce products in accordance with the requirements of the standards listed in the table below.

Should the Supplier determine that a requirement of a listed standard is not appropriate or not applicable to the product delivered, the Supplier shall notify the Customer within thirty days of making that determination. The list of agreed exclusions is also shown in the table below.

Standards That Specifically Apply To the Product Delivered By the Supplier

Standard	Title	Exclusions

1.8 Use of Third Parties

1.8.1 Directed Procurement

The Customer has qualified the Third Party Suppliers in the following table to provide the goods or services listed. For the purposes of this agreement, the Supplier does not have to qualify these Third Party Suppliers.

Note: Typical examples include an electrical transformer manufactured to your specifications which carries a UL mark or a previously validated sterilization process.

Third Party Suppliers – Directed Procurement

Supplier	Product or Service

When used on, applied to, or incorporated into the product provided to the Customer, the Supplier shall purchase the listed goods or services from the designated Third Party Supplier.

The Supplier shall provide the Customer with monthly performance reports on these Third Party Suppliers that includes the number of purchase order lines placed with the Third Party Supplier, the percentage of shipments received late, and the percentage of shipments rejected at receiving acceptance (21 CFR §820.80(b) or ISO 13485:2003 Clause 7.4.3).

1.8.2 Supplier Selected

If the Supplier uses a Third Party Supplier, other than directed procurement, to manufacture, package, label, test, or release product provided to the Customer, the role of the Third Party Supplier is identified in the table below.

In selecting Third Parties Suppliers, the Supplier shall apply the requirements of 21 CFR §820.50 and ISO 13485:2003 Clause 7.4. In addition, the Supplier shall apply the principles in GHTF/SG3/N17:2008.

Third Party Suppliers

Supplier	Product or Service	QMS Applied

Note: If the Supplier considers the list of Third Party Suppliers as confidential, define the methods to protect the intellectual property. This could include non-disclosure agreements, confidentiality agreements, etc.

1.9 Term of Agreement

This Agreement shall become effective and binding upon the date of the final signature and shall remain in effect until 2 years after the last delivery of any product by the Supplier to the Customer, unless the Customer specifically requests an extension of the Agreement. Either party may terminate this Agreement by giving 6 months written notice to the other party.

1.10 Assignment

Neither party shall have the right to assign any or all of its rights or obligations under this agreement without the other party's prior written consent, which shall not unreasonably be withheld. The foregoing notwithstanding, prior written consent shall not be required in connection with a merger, consolidation, or a sale of all or substantially all of party's assets to a third party, except if such merger, consolidation or sale is with a competitor of the other party.

2 Compliance

2.1 Specifications

The Customer shall define the specifications for the product the Supplier provides. This could take many forms including drawings, reference to commercial specifications, identify of brand names, and standards. The specifications may be paper documents, electronic documents or other appropriate media.

The Supplier undertakes to deliver product in full conformance to the agreed specifications.

2.2 Specification Changes

Changes to specifications are made by mutual agreement between the Supplier and the Customer. In addition to agreement of the change, the Supplier and Customer will determine the effectivity date of the change.

When the specifications include references to brand names, the Supplier and Customer will mutually agree on the implementation of any changes made in the brand name product.

2.3 Activity by Regulators, Notified Bodies, or Certification Bodies

The Supplier shall promptly notify the Customer of any inspections, audits, formal visits, *etc*. of any regulator, notified body, or certification body acting in a formal capacity. In the US this includes, but is not limited to the Food and Drug Administration, the Environmental Protection

Agency, and the Occupational Safety and Health Administration. It also includes corresponding State Agencies.

Upon the Customer's request, the Supplier shall disclose the results of any inspections or audits and the associated cause and corrective action.

The Supplier shall promptly notify the Customer of any inspection or audit findings that impact the safety, effectiveness, conformity, or availability of product the Supplier provides to the Customer.

2.4 Third Party Quality Agreements

The Supplier shall have a Quality Agreement with Third Party Suppliers used for production, packaging, testing, processing, or release. Upon the Customer's request, the Supplier will provide a copy of the Quality Agreement.

3 Manufacturing, Packaging, and Labeling

3.1 Environmental Control

If environmental conditions could reasonably be expected to have an adverse effect on product quality, the Supplier shall establish and maintain procedures, including maintenance, adjustment, and inspection to adequately control these environmental conditions.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.2 Personnel

If contact between personnel and the product could reasonable be expected to have an adverse effect on product quality, the Supplier shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel to adequately control this contact.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.3 Equipment

The Supplier shall ensure that all equipment used in the manufacturing process for product is appropriately designed, constructed, placed, and installed.

The Supplier shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.4 Automated Processes

If the Supplier uses computers, software, or other automated methods as part of the production process, the Supplier shall validate the computer software for its intended use. The validation process shall create a validation protocol (describing the planned activities) and a validation report (documenting the outcome of the planned activities). All software changes shall be similarly validated prior to use.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.5 Inspection, measuring, and test equipment

The Supplier shall ensure that all inspection, measuring, and test equipment (IM&TE) used in the manufacturing process for product is suitable for its intended purposes and is capable of producing valid results. Suitability includes limits for accuracy and precision.

The Supplier shall establish and maintain schedules for the calibration, adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Calibration standards used for IM&TE shall be traceable to national or international standards.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.6 Process Validation

If the output of a Supplier's process is not fully verified by subsequent inspection or test, the Supplier shall validate the process with a high degree of assurance, typically demonstrating a $C_{pk} \geq 1.33$.

The validation process shall create a validation protocol (describing the planned activities) and a validation report (documenting the outcome of the planned activities). All validated process changes shall be similarly validated prior to use.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

When the Supplier ships products produced using a validated process, the Supplier shall include process documentation showing the date the process was operated, the name of the operator, the identity of major equipment used, the identity and calibration recall date of the IM&TE used in the process, and the setting of each input process parameter.

3.7 Labeling Operations

The Supplier shall control all labeling and packaging operations to prevent labeling mix-ups.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

3.8 Packaging Operations

The Supplier will pack and package the product using the agreed methods or best practices to protect the product from deterioration or damage during processing, storage, handling, and shipment.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

4 Documentation and Records

4.1 Device History Record

The Supplier and Customer will agree on which party maintains selected portions of the Device History Record required by 21 CFR §820.181. This list also includes installation reports (21 CFR §820.170) and servicing reports (21 CFR §820.200). The responsibilities are defined in the following table.

Device History Record Responsibility

Record	Applicable	Supplier	Customer	Specific Records
Device specifications				
Production process specifications				
Quality assurance procedures and specifications				
Labeling specifications				
Packaging specifications				
Installation procedures and methods				
Installation records				
Maintenance procedures and methods				
Maintenance records				
Servicing procedures and methods				
Servicing records				

Upon the request of the Customer, the Supplier shall make all records available within two working days.

4.2 Record Retention

Records required by the agreed upon quality system will be maintained for a period of ____ years from _____ (specify).

5 Storage and Shipment

5.1 Storage

The Supplier shall establish and maintain procedures to control storage areas and stock rooms to prevent mix-ups, damage, deterioration, contamination, or other adverse effects.

The Supplier shall ensure that all products are stored to facilitate proper stock rotation and that product is retrieved from stock using First In, First Out (FIFO) methodology.

5.2 Shipment

The Supplier shall ship products to the Customer using agreed shipping methods to prevent the damage or deterioration of the product. The shipment methods are summarized in the table below, but may be augmented by specified requirements and standards.

Shipment Method Summary

Product	Packaging	Handling	Carrier	Reusable Container

Reusable containers are initially purchased by the Customer and provided to the Supplier as Customer owned material.

The Supplier will repair or replace damaged reusable containers as necessary to keep the circulating stock at the agreed level.

If the agreement is terminated, all reusable containers belong to the Customer.

6 Change Control

6.1 Change Requests

If the Supplier requests to change a document, specification, drawing, *etc*. under the Customer's control, the Supplier shall document the request including the specific change, the reason for the change, the benefit derived from approving the request, the loss incurred from disapproving the request, and the anticipated lead time before the change is reflected in the product.

The Customer shall promptly acknowledge receipt of each change request.

The Customer shall make a decision to accept or reject the change within thirty days of acknowledging receipt. For accepted changes, the Supplier and Customer will work together to develop a plan to implement the change.

6.2 Deviations

If the Supplier needs to deviate from a document, specification, drawing, *etc*. under the Customer's control, the Supplier shall document the deviation request including the specific deviation, the reason for the deviation, and the period (time, lots, *etc*.) the deviation will be in effect.

6.3 Other Changes

The Supplier shall promptly notify the Customer of changes, other than those documented above, in the product or service so the Customer may determine whether the changes may affect the quality of a finished device.

7 Non-Conformance, CAPA, and Complaints

7.1 Disposition of Non-conforming Material

The Supplier shall segregate, investigate, and disposition all nonconforming material. The Supplier is authorized to make rework and scrap dispositions without Customer Authorization. Concession or repair dispositions require the Customer's written authorization.

If the Supplier requests authorization for a repair or concession disposition, the Supplier shall document the disposition request including the inspection or test conducted, the actual results, and, if applicable, the proposed repair.

The Supplier shall update the production monitoring portion of the ISO 14971 Risk Management File to include information on the nonconformity.

7.2 Corrective Action

7.2.1 Supplier Initiated Corrective Action

The Supplier shall initiate corrective action for all detected nonconforming material regardless of disposition. Corrective Action shall include the following steps.

1. Determining the cause(s) of nonconformity
2. Evaluate the need for action to ensure the nonconformity doesn't recur
3. Determine the action needed to prevent recurrence
4. Implement the action needed to prevent recurrence
5. Review the effectiveness of the corrective action

The Supplier shall keep records of these activities and make them available to the Customer upon request.

7.2.2 Customer Initiated Corrective Action

The Customer may initiate corrective action for the Supplier when the Customer identifies a nonconformity after receipt of the Supplier's product.

The Supplier shall initiate corrective action upon receipt of the Customer's initiation. The Supplier's Corrective Action shall include the following steps.

1. Determining the cause(s) of nonconformity
2. Evaluate the need for action to ensure the nonconformity doesn't recur
3. Determine the action needed to prevent recurrence
4. Implement the action needed to prevent recurrence
5. Review the effectiveness of the corrective action

The Supplier shall report the results of the corrective action to the Customer within 15 working days of initiation. When the Corrective Action is not completed within 15 working days, the Supplier shall provide a status report every 5 working days until the corrective action is completed.

The Supplier shall keep records of these activities and make them available to the Customer upon request.

7.3 Complaints

7.3.1 Supplier Received Complaints

If the Supplier receives a compliant related to the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.

The Customer will enter the complaint into the Customer's Complaint Management System (21 CFR §820.198) and review and evaluate the complaint to determine whether an investigation is necessary. The Customer will notify the Supplier of the decision to investigate or not.

If the Customer requires the Supplier's assistance in the investigation, the Customer will follow the Customer Initiated Corrective Action described above.

7.3.2 Customer Received Complaints

If the Customer receives a complaint related to the product the Customer supplies, the Customer will enter the complaint into the Customer's Complaint Management System (21 CFR §820.198) and review and evaluate the complaint to determine whether an investigation is necessary.

If the Customer requires the Supplier's assistance in the investigation, the Customer will follow the Customer Initiated Corrective Action described above.

7.4 Medical Device Reports

If the Supplier files a Medical Device Report for the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.

The Supplier and the Customer shall cooperate in the exchange of information required to effectively manage the Supplier's medical device report in the Customer's Medical Device Event files.

7.5 Corrections and Removals

If the Supplier files a Corrections or Removals for the product, or any similar product, the Supplier provides to the Customer, the Supplier shall promptly notify the Customer.

The Supplier and the Customer shall cooperate in the exchange of information required to effectively manage the Supplier's Correction or Removal Report in the Customer's Corrections and Removals Records.

8 Audits

8.1 Customer Audits of Supplier Facilities

The Supplier shall allow the Customer, or its authorized representative, to perform audits of the Supplier's facilities, systems, documentation, and other requirements related to this agreement.

Audits shall be conducted at mutually agreed dates and times.

The Supplier and Customer will agree upon methods to protect intellectual property such as confidentially agreements, non-disclosure agreements, *etc*.

8.2 Customer Audit Findings

When conducting audits at the Supplier's location, the Customer will issue an Audit Report within five working days of the audit's conclusion.

The Supplier shall issue a plan to determine the correction, cause, and corrective action for each finding within thirty days of the Audit Report's issue date.

8.3 Auditing Third Party Suppliers

The Supplier shall allow the Customer, or its authorized representative, to perform audits of the Third Party Supplier's facilities, systems, documentation, and other requirements related to this agreement.

Audits shall be conducted at mutually agreed dates and times.

The Supplier, Customer, and Third Party Supplier will agree upon methods to protect intellectual property such as confidentially agreements, non-disclosure agreements, *etc*.

Annex 1
The list of agreed not appropriate or not applicable requirements from 21 CFR Part 820

Annex 2
The list of agreed not appropriate or not applicable requirements from ISO 13485:2003

Annex 3
The list of agreed not appropriate or not applicable requirements from ISO 9001:2008

Annex 4
The list of agreed not appropriate or not applicable requirements from ISO 14971:2007