Terumo Medical Corporation

Supplier Quality Manual

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1. Corporate Value

In the world of medical devices and supplies, the cornerstones of excellence are dependability, predictability, and consistency. To ensure that every item we manufacture meets these criteria, Terumo Medical Corporation ("TMC") applies strict standards of quality control and assurance.

By developing innovative, high-quality medical products that the healthcare community can rely on, TMC realizes its goal of "Contributing to Society Through Healthcare."

Additional information about TMC can be found at http://www.terumomedical.com/.

2. Purpose

The TMC Supplier Quality Manual applies to Suppliers providing TMC with Products or Services that impact the TMC Quality Management System or TMC's medical device, referred to as "Supplier" throughout this document. This Supplier Quality Manual also applies to any new potential Suppliers being evaluated through TMC's supplier qualification process.

3. Definitions

1) "*Product*" means the Supplier's product sold (manufactured or distributed) to TMC pursuant to the Supply Agreement or TMC Purchase Order (if not covered by a Supply Agreement).
2) "*Service*" means the Supplier's service performed on TMC's medical device(s) pursuant to the Supply Agreement or TMC Purchase Order (if not covered by a Supply Agreement).
3) "*Sub-Tier Supplier*" means a vendor of Supplier of any contract services, material, component, or sub-assemblies incorporated into a Product.
4) "*Specifications*" means the specifications set forth in the part number and revision level controlled drawing and/or specification sheet for the applicable Product(s) that are referenced on the TMC Purchase Order at the time of issuance of such TMC Purchase Order, and all requirements of any applicable laws and governing regulations.
5) "*Supply Agreement*" means that certain agreement entered into by and between Supplier and TMC for the purchase and sale of the Products or Services.
6) *"Purchase Order"* means TMC's then current form of written commitment to purchase the Product(s) or Service(s).
7) "*Gage R&R*" studies measure the total repeatability and reproducibility of a gage system as a percentage of the total specification.
8) "*Measurement Systems Analysis*" (MSA) studies ensure the total system variation (including Gage R&R) of a measuring system as a percentage of the total part and process variation.

4. General Requirements

All Products and Services shall comply with TMC Specifications and requirements.

TMC has an expectation of ZERO DEFECTS on all Products and Services delivered from Supplier. In line with this ZERO DEFECTS goal, Supplier (including its Sub-Tier Suppliers) is required to:

1) Demonstrate compliance with any agreements, specifications, drawings, and applicable legal, regulatory, and statutory requirements.
2) Explicitly review and understand all requirements provided to Supplier concerning Products and Services. Ensure resources are available to participate in product quality planning, as requested.
3) Establish a change control system that reacts to changes in a timely and accurate fashion. In all cases, acquires written approval from TMC prior to implementing any change that is detailed in Section 8 (Change Management) of this document.
4) Measure own performance on all given and agreed Key Performance Indicators (KPIs) from TMC.
5) Possess expertise and resources to perform effective risk assessment for Products or Services.
6) Possess expertise and resources to perform effective root cause analysis, and to take corrective and preventive actions.
7) Notify TMC of any potential or actual non-conformance in Products or Services supplied to TMC in accordance with Section 7 (Nonconformances) of this document.
8) Ensure that all TMC, regulatory, and statutory requirements are flowed down to all Sub-Tier Suppliers. Supplier shall establish and maintain appropriate controls for Sub-Tier Suppliers, including periodically evaluating their performance.
9) Follow Good Documentation Practices (GDocP) when creating and maintaining records to ensure all information is legible, accurate, and performed by an authorized Associate.
10) Follow Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP), as applicable, in accordance with any appropriate legal, regulatory, or statutory requirements.

4.1. Quality Targets

Zero defects are the common expectation for all Suppliers.

In order to monitor the Supplier's efforts to reach Zero defects expectation, TMC may define specific targets to work towards these expectations.

4.2. Quality Improvement Plan (QIP)

At TMC's request, Supplier shall (within a commercially reasonable time) present a QIP to TMC that meets the targets and requirements stated in that QIP request. Once the QIP has been accepted by TMC, Supplier is responsible for implementing the QIP. The effectiveness of the implemented activities within the QIP shall be evaluated on regular basis by both Supplier and TMC. Failure to implement the QIP (or agreed activities from the QIP) may result in a change of Supplier's approval status.

4.3. Communication

All formal communications must be in English, unless otherwise agreed with TMC. This shall apply to all documents sent by the Supplier to TMC. Supplier shall proactively and effectively involve the TMC Procurement Organization on all matters affecting TMC supply chain processes.

4.4. Record Retention

Supplier's records required by applicable International Organization for Standardization ("ISO") standards, laws, or governing regulations of applicable regulatory authorities shall be provided to TMC, upon request. This may include records such as design, production, inspection, and testing records and Quality Management System Records such as audits, nonconformances, and customer complaints.

These records shall be retained by Supplier for at least 15 years, after the last delivery of the relevant Product or Service to TMC. These records shall be legible, stored in an environment that prevents deterioration, and are accessible / available upon request. This requirement does not supersede any regulatory or statutory requirements for records retention. Any exceptions should be brought to the attention of TMC in writing, for prior written approval by TMC.

5. Supplier Qualification Requirements

Supplier qualification ensures that Supplier has a documented and effective system in place to produce Products and Services fulfilling all Specifications and requirements, and is capable in continuing to improve quality, delivery, and cost.

5.1. Quality Management System (QMS)

Supplier must maintain an effective documented QMS that communicates, identifies, coordinates, and controls all key activities necessary to design (if applicable), develop (if applicable), produce, deliver, and service Products and Services to TMC.

Supplier shall be certified/registered to at least one of the following applicable international quality management standards by a recognized, independent, and accredited third-party certification/registration body, based on the type of Product or Service provided:

Type of Supplier	**Standard**
Calibration Services and Laboratories	ISO 17025, Testing and Calibration Laboratories
Ethylene Oxide Sterilization Services	ISO 11135, Sterilization of Health Care Products – Ethylene Oxide
Radiation Sterilization Services	ISO 11137, Sterilization of Health Care products — Radiation
Supplier of Products with Animal Tissues and their Derivatives	ISO 22442, Medical Devices Utilizing Animal Tissues and their Derivatives
Supplier of Products that are considered Medical Devices	ISO 13485, Medical Devices
All Others	ISO 9001, Quality Management Systems

If Supplier does not hold a third-party certification, TMC may implement additional controls, as necessary, to verify conformance to TMC's expectations until the appropriate certification is achieved.

Note: Supplier to provide immediate notification to TMC if their registration expires and is expected to send an updated copy of the certificate each time it is renewed within two (2) weeks after having received it. The certificate is to be sent to the following TMC mailbox: TMC.SupplierQuality@terumomedical.com.

TMC reserves the right to access all TMC relevant certification/registration details of Supplier. In addition, TMC reserves the right to:

1) Conduct its own audit, at a mutually agreed upon time with Supplier;
2) Invite customers to participate in relevant audits with permission of the Supplier;
3) Disqualify, demote, adjust Supplier approval status, requiring requalification prior to resuming business and/or shipment with TMC;
4) Notify the third-party certification/registration body used by Supplier in case of the breach/misuse of its QMS.

5.2. Supplier Assessments – by TMC

TMC requires Suppliers providing Products or Services impacting TMC's QMS to be approved prior to the issuance of Purchase Orders or Supply Agreements. This includes an assessment of Supplier's QMS, which may include all locations that Products or Services are manufactured, serviced, or distributed to TMC.

The Supplier Assessment will include one or more of the following:

1) Questionnaire (Supplier self-assessment)
2) Remote Audit (also known as a Desktop or Documentation Audit)
3) On-Site Audit

Depending on the criticality and performance of Supplier, Supplier will be re-assessed at a frequency defined by TMC, or at any for-cause reason driven by poor quality of Product or Service.

When an on-site audit is required, Supplier (subject to any existing Nondisclosure or Confidentiality agreements between Supplier and TMC) shall provide TMC with such documentation, information and reasonable access to facilities and personnel as needed by TMC. This includes the right to audit Supplier and their respective operations during normal business hours.

For all Supplier Assessment types, it is expected that Supplier will complete the assessment requirements within the time period defined by TMC, unless otherwise agreed to in writing by both parties.

Supplier shall promptly take action as required by TMC to correct any deficiencies within thirty (30) days of the request (or any alternate time period to which TMC agrees).

5.3. Supplier Assessments – by Regulatory Authorities

Supplier will assist as needed in supporting TMC audits by notified bodies or regulatory authorities (whether announced or unannounced). Supplier shall provide representatives of regulatory authorities and notified bodies with such documentation, information and reasonable access to facilities and personnel as needed by regulatory authorities and notified bodies. This includes copies of all requested documentation related to Product design, manufacturing processes, material/device history records, Specifications, Sub-Tier Suppliers, proof of manufacturability (including packaging and labeling), regulatory approvals, regulatory, notified body, or ISO audits/inspections, and other communications with regulatory or ISO authorities that may be generally or specifically related to Product.

Supplier shall immediately notify TMC in writing as soon as Supplier becomes aware of any findings issued by any regulatory authorities and/or notified bodies that would in any way impact Product. Supplier shall promptly take action to correct any of those deficiencies within a time period agreed upon with TMC in writing.

6. Material Qualification Requirements *(Only applicable to Product Suppliers)*

The purpose of this section is to define general guidelines of approving Product for use in TMC's medical device. Product supplied to TMC must be approved prior to use. This includes all new Product to TMC, as well as changes to existing Product. This process is referred to as "Material Qualification."

Material Qualification ensures that Supplier has the capability to consistently provide Product that conforms to all Specifications. Material Qualification will take place before start of serial production, shall be scheduled and executed in accordance with a date/timeline, agreed to with TMC in writing.

TMC reserves the right to determine if any or all the Material Qualification requirements are to be reviewed on-site at Supplier's facility.

After Material Qualification approval, Supplier shall not make any changes to Product or process, without prior approval from TMC. In case of a need for change, Supplier shall refer to the required change request process as stated in Section 8 (Change Management) of this Supplier Quality Manual.

For Product distributed to TMC, Material Qualification may be completely or partially performed with the manufacturer of the Product. This will be agreed upon in advance between TMC and Supplier.

TMC will outline the requirements for Material Qualification on a formal request to Supplier. Dependent on the degree of risk of the Product to TMC's medical device, one or more of the following may apply:

6.1. First Article Inspection

A First Article Inspection will be performed in order to verify that Supplier is able to meet all Specifications outlined by TMC, not only those that are routinely inspected. Measurement values will be recorded and reported to TMC.

6.2. Critical to Quality Characteristics (CtQ)

A Critical to Quality (CtQ) characteristic is any feature of a material, process, part, assembly, or test that has a significant influence on Product safety, efficacy, fit, form, function or any other expected deliverable, as specified by TMC. TMC will select and identify the CtQ characteristics, which Supplier is required to control. CtQ characteristics will be communicated through:

1) Notations and/or symbols documented on TMC engineering drawings or Specifications.
2) Material Qualification request to Supplier.

Note: CtQ characteristics shall also include any relevant regulatory and statutory requirements in addition to those defined by TMC. These items will be identified by TMC as outlined above.

It is the responsibility of Supplier to include all CtQ characteristics and special process characteristics (as defined by Supplier) in their Control Plan and Process Validation.

6.3. Process Validation

At minimum, for all CtQ characteristics, an acceptable level of process capability and performance shall be determined prior to production in order to prove that Supplier's process consistently produces conforming Product when operating within specified limits.

As requested by TMC and agreed upon with Supplier, Process Validation shall be performed. This may include: An Installation Qualification (IQ) to show that equipment was installed and operates correctly, an Operational Qualification (OQ) to challenge the process limits, and a Performance Qualification (PQ) to demonstrate performance at nominal settings over a defined number of lots while introducing variation in other areas such as materials, personnel, and time.

The number of samples and acceptance criteria for Process Validation will be agreed upon with TMC in writing. Acceptable process capability levels (Ppk and Pp) may be determined by TMC based on the risk of Product on TMC's medical device.

Product used for evaluation shall be consecutively produced and randomly sampled in the production run. The samples shall be collected in production, when the process is stable (i.e., when no adjustments are being performed) during the production run. No adjustments or maintenance to the process is allowed during the production run. Results shall include appropriate references to the equipment and procedures used for measurement, if applicable.

If the required acceptance criteria are not met prior to the first build of serial production, additional controls may be stipulated by TMC until acceptance criteria are met.

6.4. Measurement System Analysis (MSA)

Supplier must implement test methods that are properly qualified to ensure accurate and repeatable results. Supplier will provide TMC with a description of the measurement equipment and test method utilized, with evidence of calibration at defined intervals against measurement standards traceable to international or national measurements standards. A Gage Repeatability and Reproducibility (Gage R&R) or Measurement System Analysis (MSA) may be required.

TMC requires Gage R&R and MSA for all variable gages that are used to monitor CtQ characteristics, when specified by TMC. TMC may request Supplier to participate in a correlation study to compare Supplier measurement results against results obtained by TMC gages and methods. Acceptance criteria for Gage R&R and MSA studies will be communicated by TMC and agreed upon with Supplier in writing.

Where possible, variable test methods and gages should be used over attribute test methods and gages. Attribute gages that are used to monitor CtQ characteristics must also undergo applicable gage studies. The method used shall be formally agreed upon in advance in writing between TMC and Supplier.

If the gage system fails, Supplier shall take corrective action to make the gage measurements repeatable and reproducible. A gage shall be proven repeatable and reproducible before it can be used in a capability study or to be used to accept or reject Products.

TMC reserves the right to specify the MSA study and methodology, and Supplier shall comply with and fulfill all TMC requirements.

6.5. Control Plan

Supplier shall prepare a Control Plan for their complete process, including but not limited to receiving, in-process, lot release testing and shipment. This Control Plan shall detail the control and inspection activities that have been implemented to ensure conformity to Specifications.

The Control Plan is a living document and shall be revised as changes are made to Product, process and when quality issues are found. Control Plans shall be reviewed and updated, as necessary, as part of the nonconformance process defined in Section 7 (Nonconformances) of this document.

6.6. Inspection/Lot Acceptance

Inspection/Lot Acceptance criteria must be established by Supplier in order to define the requirements for release of Product. This includes acceptance criteria, sample size, and sample frequency for incoming, in-process, and final acceptance testing.

At a minimum, TMC will assess if all CtQ characteristics are inspected as part of normal lot acceptance testing. Supplier is responsible for verifying quality for all items delivered to TMC. When Supplier chooses to implement sampling plans for the acceptance of materials, the sampling plans shall have a statistical rationale.

7. Nonconformances

7.1. Identification and Containment

If a nonconformance affecting Product or Service is identified after providing Product or Service to TMC, Supplier shall immediately notify TMC. If a nonconformance is identified by TMC, TMC will notify Supplier.

For Product Suppliers, nonconforming Product shall be segregated and quarantined to prevent the inadvertent release of nonconforming Product to TMC or its customer. As part of the full scope of the Supplier's containment, all material (including in-house, in-transit, and previously shipped) shall be considered.

7.2. Request for Supplier Waiver

If Supplier requires a deviation to established processes or wishes to request authorization from TMC to provide Products or Services that do not meet Specifications (*"Supplier Waiver"*), Supplier can request such by initiating a Supplier Waiver request. This Supplier Waiver request will contain a detailed description and justification, including summary of any testing or evaluation performed as applicable.

Supplier shall not provide any Product or Service related to Supplier Waiver to TMC without prior written approval by TMC.

TMC's Supplier Waiver Request form shall be used (Reference Section 13: Templates) and sent to the following TMC mailbox: TMCSupplierChangeNotification@terumomedical.com.

7.3. Disposition of Nonconformance

Any affected Product from the nonconformance shall be dispositioned using one or more of the following actions, after written agreement with TMC:

1) Return of Product to Supplier, with the condition of:
    a) Complete replacement or credit of Product (returned Product will not be re-sent to TMC);
    b) 100% sorting of Product (Nonconforming quantity separated from conforming quantity. Only conforming quantity may be re-sent to TMC);
    c) Rework of Product.
2) Third-party sorting of Product organized at any location specified by TMC;
3) Supplier sorting of Product at TMC site;
4) Scrap of Product;
5) Accepted for use by concession.

After completing sorting or reworking dispositions, Product must be verified that it meets Specifications prior to release to TMC. Verification plan must be approved by TMC in writing prior to any re-shipment.

7.4. Corrective and Preventive Actions

When a nonconformance is discovered and Supplier is deemed to be at fault, TMC will issue a Supplier Corrective Action Request (SCAR) to Supplier. Supplier shall submit a formal written corrective and preventive action report, to address the specific defects identified.

Supplier shall implement all needed containment actions and submit to TMC in writing within 3 working days (starting from Supplier´s receipt of the SCAR or alternate period to which TMC agrees in writing). If TMC disagrees with Supplier's containment action, Supplier must respond (with a revised containment action) within 3 working days (starting from Supplier's receipt of TMC's notice).

Failure investigation leading to the root cause determination and a plan for corrective action shall be completed within 30 days or alternative timeframe agreed upon in advance and in writing with TMC. Supplier shall consider both why the specific nonconforming condition occurred and why it was not detected by its own quality controls. Supplier shall provide evidence of the root cause investigation and analysis including the methods and results of the root cause analysis. This includes tools used during the root cause analysis, which may include 5-Why, Fishbone, Fault Tree Analysis, Process Map, or Brainstorm.

Corrective action objective evidence will be provided in accordance with the due dates set by Supplier in the corrective action plan. TMC will review the objective evidence and develop a plan for verification of its effectiveness.

Involvement of TMC in the approval of the SCAR does not change the fact that Supplier remains responsible for the nonconformance, including any nonconformances resulting from the implementation of the containment, correction, and corrective actions. Until the SCAR has been verified and closed by TMC, Supplier shall adopt all measures to safeguard the interest of TMC (and TMC's customers).

8. Change Management

8.1. Document Control

Supplier shall have a process to control revisions and to ensure the correct revision of any procedures, specifications, drawings, artworks, forms, or other documentation is utilized at all times. Supplier shall have a process to obsolete previous revisions of all previously mentioned documentation.

8.2. Change Control / Notification

Supplier shall not make any temporary or permanent changes to any of the following (collectively "Changes") without prior written notification and agreement with TMC. Any Change is subject to sole and final written approval from TMC. Supplier's prior written notice of a proposed Change to TMC shall include the details regarding such proposed Change, samples of any affected Product, and any other appropriate information requested by TMC.

Such notification shall be submitted to TMC twelve (12) months in advance or as otherwise agreed in writing with TMC. Supplier shall follow this requirement across its entire supply chain, which includes its Sub-Tier Suppliers. Notwithstanding the foregoing, if events requiring such Change are beyond the reasonable control of Supplier, Supplier shall promptly notify TMC in writing after becoming aware of such events.

Changes include, but are not limited to:

1) Any change affecting established Specifications or agreements for the Product or Service;
2) Product design change, which includes the Product's labeling/packaging;
3) Any safety, efficacy, form, fit, function, material, or material composition change in Product or Service;
4) Change to regulatory, statutory, legal, or QMS status;
5) Company name change;
6) Any Sub-Tier Supplier change;
7) Any process change (which includes testing and inspection), including:
    a) Change of process parameters outside of previously approved operating parameters;
    b) Moving production & laboratory equipment internally within the facility or to other facilities/locations;
    c) Change in manufacturing or service site location/address;
    d) Change of Product storage location (e.g., warehousing change);
    e) Change of inspection or testing methods outside of previously approved operating parameters;
    f) Change in production or laboratory materials (e.g., chemicals, reagents, cleaning agent);
    g) New/replacement equipment or tooling (excluding like-for-like replacement);
    h) New/replacement molds.

Supplier's noncompliance with the above requirements is considered a material breach of this Supplier Quality Manual and the Supply Agreement or comparable purchasing agreement between Supplier and TMC. For any Product Change, TMC reserves the right to requalify Product with an appropriate Material Qualification.

For all Change requests, temporary as well as permanent, Supplier shall provide notification to TMC to the following TMC mailbox and complete TMC's Supplier Change Notification form when requested by TMC: TMCSupplierChangeNotification@terumomedical.com.

9. Identification and Traceability *(Only applicable to Product Suppliers)*

9.1. Raw Material Lot Control

Supplier shall maintain appropriate material traceability throughout the supply chain, including maintaining appropriate Certificate of Conformance/Certificate of Analysis from Sub-Tier Suppliers.

When Supplier elects to utilize more than one lot of raw material to manufacture Product, Supplier shall have documentation and traceability to each raw material certification and identification of each lot.

Supplier will establish procedures which allow for the identification of materials at all stages, including receiving, in-process, and product release. Additionally, Supplier will establish procedures which allow for the identification of the status of materials, including accepted, nonconforming, or rejected.

When requested, Supplier will provide TMC the manufacturing and quality documentation (such as batch records, Device History Record) or information on materials utilized in the production of Product.

9.2. Labeling

Product must include adequate labeling for identification in order to prevent mix-ups or use of expired material. Labeling requirements will be outlined in Specifications.

9.3. Certificate of Conformance (COC) / Certificate of Analysis (COA)

Supplier shall provide a COC or COA pertaining to each supplied lot as outlined in Specifications. When required by TMC, Supplier may need to provide additional data or certification to satisfy any applicable standards or regulatory requirements.

10. Materials of Concern Compliance *(Only applicable to Product Suppliers)*

Global environmental regulations and customer requests pertaining to the materials used in TMC's medical devices are increasing and evolving, which requires TMC to effectively gather and store information about the composition of Products from Suppliers.

Materials of Concern encompass regulations or requests including, but not limited to:

1) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
2) CA Proposition 65
3) Conflict Minerals
4) Latex
5) Materials with Animal Origin
6) Polyvinyl Chloride (PVC)
7) Bisphenol A (BPA)
8) Phthalates
9) Heavy Metals
10) Recyclable Content

In order to comply with regulations for specific sales geographies, Supplier must communicate the composition of any Product provided to TMC upon request. TMC utilizes an industry leading web-based data collection vendor to send questionnaires on behalf of TMC. This includes a user-friendly portal where Supplier will submit declarations and/or submit responses for each part supplied. Supplier will receive one or more requests per year, depending on changes made to regulations affecting the Products supplied to TMC. Supplier is responsible for understanding the composition of the Product supplied to TMC in order to complete the information requested by TMC.

11. Risk Management / Business Continuity Planning

Supplier shall identify and prioritize risks affecting delivery of Products or Services to TMC. Supplier shall, upon request, provide TMC with proper contingency plans for the highest ranked risks to ensure un-interruption of delivery.

Supplier shall have a business continuity plan that would allow for the secure and confidential storage and recovery of engineering drawings, electronic media, contracts, and production tooling in the event of damage or loss. This plan should also contain contingency plans to satisfy requirements in the event of significant equipment failure, facility interruptions and returns.

12. Supplier's Liability

In addition to Supplier's obligations defined within this Supplier Quality Manual, Supplier is liable according to the terms and conditions of any existing Supply Agreement or other comparable agreement defining the purchasing of the Products or Services between TMC and Supplier. Supplier remains liable for cost of poor quality relating to nonconformances, according to this Supplier Quality Manual and any Supply Agreement or other comparable agreement defining the purchasing of the Products or Services between TMC and Supplier.

13. Templates

The following are forms referenced in this Supplier Quality Manual:

1) Supplier Change Notification Form
2) Supplier Waiver Request Form

To obtain blank forms or for assistance in completing forms, Supplier should contact the following TMC Supplier Quality mailbox: TMC.SupplierQuality@terumomedical.com. The current revisions of this Supplier Quality Manual and the forms listed above can be found on the TMC Website: https://www.terumomedical.com/support/supplier-information.html.