Supplier Quality Agreement

Helmer Scientific Headquarters
14400 Bergen Boulevard, Noblesville, IN 46060

Introduction

Since 1977, Helmer Scientific has led the industry in the life science market by designing and manufacturing innovative products that support and aid our customers' efforts. Our mission and values form the foundation of our company. We continue to grow and provide quality products and service to the market we serve. To be an industry leader, every employee, customer, and supplier is integral to our organization's success and continuous growth.

Helmer Scientific is certified to ISO 13485: 2016 Quality Management System and is an FDA GMP compliant manufacturer of medical devices. We are committed to quality and continuous improvement, and we expect the same from all of our suppliers.

1.0 PURPOSE AND SCOPE

The Supplier Quality Agreement defines the expectations for all Helmer Scientific suppliers. The supplier agrees to meet or exceed the requirements and guidelines defined in this document. Throughout this document, the word “shall” or “must” indicates a requirement. The word “should” indicate a recommendation.

2.0 BUSINESS PARTNER CODE OF CONDUCT

The highest legal, moral, and ethical standards of honesty, integrity and fairness are to be practiced in the conduct of Helmer Scientific affairs. In order to meet this standard, Helmer Scientific expects each of its Business Partners to operate and act in full compliance with all applicable laws and regulations. Helmer Scientific expects that Business Partners will hold their suppliers and other third parties to the same standards.

3.0 SUPPLIER DIVERSITY

Helmer Scientific recognizes the value of diversity in its workforce and supply chain. Helmer Scientific seeks to utilize minority, women, and veteran-owned businesses when possible.

4.0 TERMS AND DEFINITIONS

Defect/ Non-Conformance	Non-fulfillment of a requirement related to an intended or specified use, including safety considerations and regulatory requirements. Non-conformance will be documented in the Helmer NPR (Non-conforming Product Report).
QMS	Quality Management System: A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management. It is based on the requirements detailed in ISO-9001:2008 with additional enhancements.
SCAR	Supplier Corrective Action Request: A formal request to take action to eliminate the cause(s) of an existing non-conformance or other undesirable situation in order to prevent recurrence.
Specifications	Documentation containing detailed descriptions of the form, fit, function and material requirements of the product to be provided by the supplier. Where this Agreement is accompanied by a Supply Agreement the definition in the Supply Agreement shall replace this definition
PPAP	Production Part Approval Process: Defines generic requirements for production part approval. The purpose of the PPAP is to determine that customer engineering design record and specification requirements are properly understood by the supplier.
Supply Agreement	Where applicable, means the Supply Agreement entered into between Helmer Scientific and Supplier, as amended and includes all schedules and exhibits thereto.

5.0 ASSOCIATED/REFERENCE DOCUMENT

The following documents are included in this agreement and can be found on the Helmer Scientific Website: https://www.helmerinc.com/supplier-resources

M2F010	Purchase Order Terms and Conditions
QSF031	Supplier Change Request
MSF013	Production Part Approval Process (PPAP)

Please note: the documents listed may be revised and therefore will take precedence over this original Supplier Quality Agreement.

6.0 GENERAL SUPPLIER REQUIREMENTS

6.1 The term supplier includes manufacturers, distributors, and consultants of products and services (together called "products" in this agreement). In the event of a conflict between the terms of this agreement and any buyer purchase order or other contract between the parties, unless the parties agree otherwise in writing, the various components of the agreements shall be given the following precedence:

1) Supply Agreement if any
2) Purchase order
3) Helmer Scientifics terms and conditions
4) Supplier Quality Agreement.

6.2 The supplier shall establish and maintain an effectively documented Quality Management System (QMS) that satisfies the requirements defined in section 7 of this agreement. Certification to an international quality management standard such as ISO9001 would address the majority of these requirements. Suppliers are strongly encouraged to seek such certification.

6.3 Helmer Scientific reserves the right to audit suppliers to verify conformance with the requirements of this agreement. Suppliers who have provided proof of quality system certification by a third party must notify Helmer Scientific within 30 calendar days if the certification has lapsed or has been revoked.

6.4 RISK ASSESSMENT AND CONTINGENCY PLANNING

6.4.1 The supplier shall conduct a risk assessment of their operations that support Helmer Scientific's production facilities, quality requirements, and delivery schedules.

6.4.2 The supplier shall prepare contingency plans to ensure continued operations for Helmer Scientific. The supplier shall communicate any critical risk scenario without a contingency plan that may result in a Major Disruption. The supplier shall provide the contingency plans to the buyer when requested.

6.5 ENVIRONMENTAL, HEALTH & SAFETY COMPLIANCE

6.5.1 Helmer Scientific is committed to sound Environmental, Health and Safety (EH&S) operating practices and encourages its suppliers to implement globally recognized Environmental, Health and Safety management systems. A robust EH&S program reduces operational impact on human health and the environment in a sustainable manner including:

- Decreased use of hazardous substances
- Reduced waste and emissions
- Improved energy and water conservation
- Greater reuse and recycling of materials
- Safe and healthy work environments that prevent accidents and injuries
- Continuous improvement in EH&S performance

6.5.2 At a minimum, the supplier shall work with Helmer Scientific to reduce the impact of packaging waste through:

- Reduction or elimination of unnecessary over packaging
- Implementation of returnable packaging
- Substitution of current packaging materials for recyclable materials

6.6 CLEANLINESS OF PREMISES

The supplier is strongly encouraged to adopt a cleanliness standard. The standard should include a process for establishing and maintaining a clean work environment. Helmer Scientific recommends the 5S program to establish the standard.

6.7 STATUTORY AND REGULATORY CONFORMITY

6.7.1 The supplier's product or service shall meet all statutory and regulatory requirements for the locations where it is manufactured and used. These requirements shall be properly documented, and records maintained.

6.7.2 Changes to certification status to specified standards and or directives e.g., Underwriters Laboratory (UL), European Union (CE mark), Canadian Standards (CSA) shall be immediately communicated to Helmer Scientific.

6.7.3 All items must be compliant with the current recast of the RoHS directive or have paperwork on file allowing exemption from the directive. RoHS compliance information or exemption status shall be provided to Helmer Scientific by the supplier within 72 hours of a request.

6.7.4 The supplier shall provide samples, testing, environmental and Material Safety Data Sheet (MSDS) information when requested.

6.7.5 The supplier will disclose to Helmer any materials of animal origin that are used as raw materials, or that come in direct contact with the Product. This includes, but is not limited to, raw materials, additives, excipients, lubricants, and packaging materials.

6.8 RETURN OF NONCONFORMING PRODUCT (HELMER REJECTED PRODUCT)

6.8.1 Helmer will perform an analysis of the nonconforming product to determine cause and disposition. In the event of a suspected or verified Nonconforming Material, a notification via email from the Helmer SQ (Supplier Quality) department will be sent to the supplier quality contact on file for your company/facility which will include a Helmer NPR (Nonconforming Product Report) number.

6.8.2 The Supplier has (10) business days from receipt of this notification to acknowledge the NPR, seek any additional information, and issue an RMA to Helmer. The RMA must include the NPR number(s) and the preferred disposition of the NCM: Return, Scrap, or Rework. Multiple NPR's can be included and referenced in a single RMA.

6.8.3 If the supplier wished to sort product the supplier may arrange for the sorting activity or request Helmer to perform the sort at $115/hr.

6.8.4 Disposition – RETURN (to supplier)

6.8.4.1 The Supplier RMA will include the preferred shipping method, contact info, any associated account information, and shipping address for the specific NPR(s). NCM intended to be Reworked or Scrapped at the supplier facility should still be dispositioned as "Return". The supplier is responsible for the cost and shipping arrangements of returned product.

6.8.4.2 No RMA material may be returned back to Helmer unless a new PO# has been provided by Helmer

6.8.5 Disposition - SCRAP

6.8.5.1 Any NPR that the supplier wishes Helmer to directly scrap onsite should be marked as Scrap. The NCM associated with the NPR will be disposed of by the Helmer SQ team.

6.8.6 Disposition - REWORK (at Helmer or local 3rd Party company):

6.8.6.1 The Supplier will coordinate with the Helmer SQ team on the agreed upon details and nature of the rework being performed on NCM associated with an NPR. The supplier can visit the Helmer facility to perform this rework, hire a 3rd party for rework onsite (offsite preferred), or enlist Helmer to rework if time sensitive (Helmer will invoice supplier at $115/hr. via our COPQ Invoice process).

6.8.7 If no acknowledgment is made by the Supplier to the Helmer SQ team within the allotted 10 business days from NPR notification, Helmer SQ will scrap the associated NCM on location and deduct the equal value credit from future remittance.

6.8.8 Depending upon the nature of defect, an analysis report may be requested.

6.9 CONTINUOUS IMPROVEMENT

Suppliers are expected to demonstrate a commitment to continuous improvement in products and processes provided to Helmer Scientific. Suppliers are encouraged to develop processes designed to eliminate non-value-added activities and reduce costs.

6.10 SUPPLIER QUALIFICATION AND PERFORMANCE AND EVALUATION

6.10.1 Suppliers are expected to meet or exceed Helmer Scientific's requirements. As such, approved suppliers are qualified and monitored through qualitative evaluation and quantitative metrics. Examples of Quantitative Performance Metrics include quality, on-time delivery, responsiveness to SCARs and audit scores. Examples of Qualitative Evaluation include cost reduction, process/product improvement, innovation, responsiveness, business and financial strength, and value interactions.

6.10.2 Depending on their performance, suppliers will be placed in one of 3 status categories.

Approved – Scores indicate they have met and continue to meet requirements.

Probationary- Scores indicate performance is declining. Corrective action is underway. They may be placed on Purchasing Hold with this status.

Not Approved Supplier – Scores indicated the supplier has failed to meet requirements for an extended period of time and have not taken measures to correct performance.

6.10.3 Helmer Scientific may place a supplier on probationary or not approved status at any time for reasons such as, but not limited to, Issuance of a SCAR, Poor audit performance, Lack of Supplier response.

7.0 SUPPLIER QUALITY MANAGEMENT SYSTEM

7.1 CUSTOMER COMMUNICATION

The supplier is responsible for the validity and accuracy of the documents submitted electronically and must comply with all applicable legal requirements regarding electronic signatures. (Per FDA CFR Title 21, Part 11). All communications, both electronic and otherwise, with Helmer Scientific shall be in English.

7.2 DOCUMENT CONTROL

7.2.1 The supplier shall establish and maintain procedures to ensure that applicable documents related to the QMS, and Helmer Scientific design-owned documentation are updated, approved for use, available at points of use and controlled in a consistent manner.

7.2.3 The supplier's procedures shall include a master list of documents including the current revision level. The documents shall be maintained to prevent use of invalid or obsolete documents. The supplier shall maintain a record of each change implemented.

7.2.2 When the supplier has design responsibility, Helmer Scientific may request any documentation including drawings, engineering standards, and Specifications. The supplier shall notify Helmer Scientific of any changes in accordance with paragraph 7.14.5 of this agreement.

7.3 RECORDS

7.3.1 The supplier shall ensure that all records required by this agreement are legible, stored in an environment that prevents document deterioration and are readily accessible upon request.

7.3.2 The supplier's employees, contractors, and agents who create, receive, use, or manage these records are required to comply with the policies and procedures in accordance with customer, warranty, legal and regulatory requirements.

7.3.3 Helmer Scientific requires the supplier to maintain all records relating to products provided for the life of the product plus one (1) calendar year and any applicable contractual requirements, including but not limited to those for warranty and service, unless otherwise specified. The life of the product begins with product concept and extends until the end of active part production and service requirements.

7.4 TRAINING

The supplier shall provide appropriate training to ensure that employees are competent and qualified to produce quality products. The supplier shall review and document the required skills and competencies necessary for the production, inspection, handling, and delivery of products to Helmer Scientific. The supplier shall provide appropriate training to ensure that employees follow applicable procedures and instructions. The supplier shall maintain employee records of training.

7.5 SUB-SUPPLIER MANAGEMENT

7.5.1 The Supplier must maintain qualifications for subcontractors and the products purchased through them. It is the Suppliers' responsibility to ensure and control the quality of all components and raw materials that are purchased to manufacture components and parts for Helmer Scientific.

7.5.2 Suppliers will manage sub-tier Suppliers with controls commensurate with those that Helmer Scientific applies to direct Suppliers. Suppliers are responsible to ensure that product(s) manufactured utilize only authentic, conforming, and specified material requirements as stipulated in the Specifications. Prior to implementing changes, including changes requested by sub-tier Suppliers, Suppliers must notify Helmer Scientific according to section 7.14.5 of this agreement. Alternate components may be used at the supplier's discretion without Helmer approval if that component is an approved alternative part or is not specified on the BOM and is equivalent in specification to the original component (i.e., PCB C-type components).

7.5.3 Helmer Scientific shall be permitted to conduct an audit of the sub-supplier facility. The scope of each audit will be at the sole discretion of Helmer Scientific. Helmer Scientific shall notify the supplier of the planned date of the audit. The supplier must notify the sub-supplier of this requirement. Any verification performed by Helmer Scientific does not relieve the supplier of the responsibility to provide quality products.

7.6 INCOMING INSPECTION

7.6.1 The supplier shall implement a process to ensure the quality of incoming deliverables meets Helmer Scientific's requirements. The process should incorporate standard methods including:

- ❖ Statistical data evaluation from the sub-supplier
- ❖ Performance-based receiving inspection
- ❖ Testing based on approved sampling plans
- ❖ Supplier audits or assessments coupled with records of acceptable delivered product quality.
- ❖ Part evaluation by an approved laboratory
- ❖ Certificate of analysis or conformity

7.6.2 All non-conforming material resulting from this process shall be identified and quarantined. The supplier and sub-supplier shall have a process to disposition non-conforming product.

7.7 QUALITY PLANNING

7.7.1 The supplier shall develop the processes required for the quality planning of product. In the planning of product, the supplier shall work with Helmer Scientific to:

- ❖ Develop quality objectives and requirements for the product
- ❖ Establish processes, documents, and provide resources
- ❖ Determine required verification, validation, monitoring, inspection and test activities and the criteria for acceptance
- ❖ Define records required to provide evidence of product conformity

7.7.2 The supplier shall implement a framework that ensures robust product and process development capabilities. The process should be implemented from initial product concept and continue through the production launch phase of the project.

7.7.3 The supplier shall evaluate and mitigate quality risks utilizing FMEA or equivalent risk analysis methodology.

7.8 PRODUCT DESIGN AND DEVELOPMENT

7.8.1 When design responsible, the supplier shall complete the initial product design and maintain a record of all changes for each product. Helmer Scientific shall be notified of all changes impacting product form, fit, function or potential influence on user experience. All changes shall be reviewed, verified, and validated, prior to the implementation and acceptance by Helmer Scientific.

7.8.2 The supplier shall verify that the product meets the requirements established during the planning activities. The supplier may be required to participate in design reviews with the Helmer Scientific project team.

7.9 PROCESS VALIDATION

7.9.1 Processes outputs that cannot be fully verified by subsequent measurement or other means of verification shall be validated to ensure they will consistently meet the design requirements.

7.9.2 The validation shall be performed according to an approved validation plan. Helmer Scientific reserves the right to review and approve the validation plan.

7.9.3 Production intent materials, tooling, processes, and sub-suppliers should be used to produce products for validation testing. Helmer Scientific may require product for testing requirements.

7.10 HELMER SCIENTIFIC DESIGNATED SPECIAL CHARACTERISTICS

7.10.1 Helmer Scientific drawings and Specifications may designate product features as Special Characteristics, Critical-to-Quality or other designations. These features will be designated by a K (Key Characteristic - important for fit, form, function and or customer satisfaction) or C (Critical Characteristic - Safety or Performance related to intended use of device).

7.10.2 The supplier shall ensure process capability for all designated special characteristics. Helmer Scientific reserves the right to review and approve process control plans.

7.11 INSPECTION, MEASURING AND TEST EQUIPMENT

7.11.1 The supplier shall ensure all inspection, measuring and testing equipment is qualified at defined frequencies. Records shall be maintained for all gauges, measuring, and testing equipment including:

- ❖ Equipment identification and calibration standard
- ❖ Any out-of-specification readings
- ❖ Impact assessment for out-of-specification condition
- ❖ Statements of conformity after calibration or verification

7.11.2 The supplier shall notify Helmer Scientific of potential suspect product when an out-of-calibration condition is detected after production launch. The supplier shall take appropriate actions to prevent further use of discrepant product at Helmer Scientific. All suspect products at the supplier must be identified and quarantined. Refer to section 7.18 Non-Conforming Product for additional information.

7.11.3 Computer software and its application shall be verified and documented on a regular basis when used for monitoring or measuring product conformity.

7.12 PRODUCTION PART APPROVAL PROCESS

7.12.1 The supplier shall demonstrate that the manufacturing processes have the potential to produce product consistently meeting these requirements. Helmer will identify the PPAP submission level based on the part criticality and function. *An example would be an "Off-the-shelf" item part with no critical features will only require a level one PPAP cover page submission.*

7.12.2 Helmer Scientific requires PPAP submissions for approval of new or revised product. If required, the supplier shall not ship any production product until signed approval is received from Helmer Scientific per agreed method or documentation.

7.12.3 Helmer Scientific shall determine the PPAP level required. The Helmer Scientific PPAP owner shall work with the supplier to define the PPAP submission supporting data and the PPAP production run quantity. For product deemed critical to equipment function, a level 3 PPAP may be requested with a minimum; BOM verification, Dimensional Report, RoHS, and FMEA & Control Plan.

7.12.4 Helmer Scientific will provide a status of:

- ❖ Approved – the product or service meets all requirements, and the supplier is authorized to deliver production quantities.
- ❖ Rejected – the product or service fails to meet the requirements and the Supplier is not authorized to deliver the product or service. After implementing the corrective actions identified, the supplier must re-submit the PPAP to Helmer Scientific for approval.
- ❖ Interim Approval – the product or service may be delivered for a specific time or quality while the supplier implements the required corrective actions. The supplier must re-submit the PPAP to Helmer Scientific for approval.

7.13 PRODUCTION MONITORING

7.13.1 If Helmer defines critical characteristics (identified as ◇K or ◇C dimensions) or a critical performance characteristic, the supplier's control plan shall identify all Helmer Scientific requirements and the method of inspection and when applicable functional verification to be performed. Helmer Scientific may specify certain criteria for inspection methods and functional verification.

7.13.2 The control plan shall establish the method and frequency of monitoring and measuring the product and processes to ensure conformity to Helmer Scientific requirements.

7.13.3 The supplier shall establish procedures to control non-conforming product or service. The non-conforming product shall not be released or delivered unless approved by the supplier's authorized representative and, when applicable, Helmer Scientific. Refer to section 7.14.5 Deviation Request for additional information.

7.14 CHANGE CONTROL

7.14.1 After product approval, the supplier shall control all changes to Helmer Scientific products. The supplier's QMS shall include procedures to manage all changes to engineering documents, manufacturing equipment and tooling, test and measurement equipment and all materials used in the process. Changes shall be submitted using Helmer form QSF031.

7.14.2 Changes to products designed by and or customized for Helmer Scientific must be approved by Helmer Scientific prior to implementation. See paragraph 7.14.5 for the Engineering Change and Deviation Request process. Some examples requiring notification and when applicable PPAP re-submission:

- ❖ Drawing or specification change
- ❖ Material change or new material supplier
- ❖ Special process change including heat treatment, plating, coating, etc.
- ❖ New or modified production tooling

- ❖ Re-locating equipment within a site
- ❖ Manufacturing location change
- ❖ New sub-supplier or sub-supplier process change

7.14.3 The acceptance criteria for a planned change shall be agreed upon by Helmer Scientific and the supplier prior to implementation. The process for accepting a change may require substantial time to complete all tasks identified. Refer to section 7.12 Production Part Approval Process for additional information. In the event of an unauthorized change, the supplier must notify Helmer Scientific within 24 hours of detecting the change. The supplier may be placed on Purchase Hold if the proper notifications and processes are not followed.

7.14.4 The supplier shall not implement a Helmer requested change until issued a formally revised drawing and Purchase Order (if applicable) from the Helmer Scientific Purchasing Department.

7.14.5 **Supplier Requested Changes and Deviations**

a) To request approval for changes or temporary deviations the Supplier shall complete a Supplier Engineering Change/Deviation Request form QSF031 and submit to the Helmer Scientific Purchasing Department.

b) The supplier shall provide samples, when requested, to evaluate impact of the change in both the design and in use at the Helmer Scientific facility. Any costs associated with testing, evaluating, or accommodating the change or deviation is the supplier's responsibility.

c) Excessive requests for deviation may be an indication that the supplier's QMS may not be performing as expected and may result in a Supplier Corrective Action Request (SCAR).

7.15 PREVENTIVE MAINTENANCE

7.15.1 The supplier shall plan and operate a comprehensive maintenance system for the production equipment used to support product build. The maintenance system, at a minimum, shall include a planned maintenance activity and maintenance history

7.15.2 The supplier shall immediately notify Helmer Scientific if any equipment or tooling owned by Helmer Scientific is found to be defective or unsuitable for production. All tool modifications and design changes shall be recorded and maintained. Records of all repair or replacements actions must be submitted to Helmer Scientific.

7.16 IDENTIFICATION AND TRACEABILITY

7.16.1 The supplier shall properly identify product throughout the realization process and establish a system that identifies the production status, verifies product acceptance with regards to inspection and testing and properly controls product disposition.

7.16.2 The supplier shall create a traceability method for unique identification of each part or material lot, unless otherwise agreed upon by Helmer Scientific. The supplier shall work with Helmer Scientific to develop and approve an acceptable method, location, and content for marking the product. The supplier shall maintain records for this section in accordance with 7.3 of this agreement.

7.17 HANDLING, STORAGE, PACKAGING, AND DELIVERY

7.17.1 The supplier shall implement procedures for the preservation of Helmer products up to the point of delivery to Helmer Scientific.

7.17.2 The supplier shall properly manage shelf life of perishable products, prevent use of obsolete product, and ensure stock rotation.

7.17.3 The supplier shall package product to ensure product integrity and cleanliness during transport to Helmer Scientific. Packaging shall meet all applicable shipping laws, codes, and regulations. Changes or improvements to packaging shall be communicated by the supplier prior to implementation. See paragraph 7.14.5 of this agreement.

7.17.4 Packaging shall be identified with the following:

- ❖ Helmer Scientific Part and Revision
- ❖ Quantity
- ❖ Lot # (if applicable)
- ❖ Date of manufacture
- ❖ Purchase Order number
- ❖ Gross weight
- ❖ Other specified requirements
- ❖ Special storage or handling requirements.

7.18 CONTROL OF NONCONFORMING PRODUCT

7.18.1 The supplier shall implement a procedure to define the controls, related responsibilities, and authority to manage non-conforming product.

7.18.2 The non-conforming product must be contained until the supplier can scrap, rework, or obtain deviation approval from Helmer Scientific. Refer to section 7.14.5 of this agreement.

7.18.3 The supplier shall create process work instructions to define and control rework and repair processes. Approval from Helmer Scientific on rework and repair processes does not relieve the supplier of any liability regarding product quality.

7.18.4 All corrected non-conforming product must be re-verified to demonstrate conformity to the requirements. The supplier must properly identify each product or package as repaired or reworked.

7.18.5 The supplier shall immediately notify Helmer Scientific of any defective products found at their facility that may have been delivered to Helmer Scientific and/or its customers.

7.18.6 The supplier shall maintain records of the non-conformance and subsequent actions taken. Helmer Scientific reserves the right to audit any non-conformances. Helmer Scientific may issue a Supplier Corrective Action Request (SCAR) for supplier identified non-conformances with the product(s).

7.18.7 Nonconforming Product or its components returned to the supplier by Helmer Scientific shall be analyzed by the supplier within the timeframe specified by Helmer Scientific or a timeframe that has been agreed upon by both parties taking into consideration the risk associated with the nonconformity. Helmer shall supply sufficient information regarding failure mode and customer use conditions if applicable. The analysis results shall provide an understanding of the root cause of the failure and either the actions to be taken by the supplier that will prevent further occurrences of the nonconformity or

justification for no action. All investigations, analyses and corrective actions must be conducted, and all related records and reports must be generated and maintained, in accordance with all applicable regulations. Supporting documentation for each analysis and investigation shall be made available to Helmer Scientific.

7.19 CORRECTIVE ACTIONS

7.19.1 Helmer Scientific may issue a Supplier Corrective Action Request (SCAR) in the identification and resolution of non-conformance detected at Helmer Scientific's facilities and by our customers. The SCAR may be issued based upon, but not limited to; incoming inspections, in-process rejects, customer rejects, field failures, packaging, or labeling issues.

7.19.2 When a supplier receives a SCAR, form Q1F008, Helmer Scientific 48 hr. - 30-day policy shall be followed. If the supplier fails to respond appropriately, the supplier may be placed on Hold and placed on the Probationary Supplier list until resolution.

a) Within 48 hours the supplier shall identify and contain all suspect products, determine, and provide notification of quantity of suspect material in route to Helmer Scientific and provide interim plan for supporting Helmer Scientific production with certified product.

b) Within 30 calendar days the supplier shall confirm the corrective action plan has been documented and provide the date or starting serial number for the implementation. If supplier is not able to respond with effective corrective action within this timeframe, a formal response must be received and accepted by Helmer.

7.20 WARRANTY PROCESS

7.20.1 Helmer Scientific establishes a 10-year warranty for the performance of the equipment. The supplied product warranty shall be a minimum of 2 years, unless supplier's warranty extends beyond 2 years. Warranty start date is defined as the Helmer ship date of the end use equipment to the customer.

7.20.2 Components of the equipment that may have contributed to the failure of the equipment may be returned to Helmer for further analysis. Helmer will perform an analysis of the failures after receipt of product. Once a supplier defect has been identified, the nonconforming product will be returned to supplier for further review, (upon supplier request).

7.20.3 The 2-year supplier warranty shall cover the cost of the product replacement, (new component & installation). Credit will be taken for the defective product that is within the supplier warranty period.

7.20.4 If a persistent, latent defect is detected past the warranty period, (failure rate >2%), both parties agree to negotiate in good faith to share the expenses related to the recovery plan. This period not to exceed 5 years past part warranty period.

Please sign and return this page to jmyers@helmerinc.com

Supplier Quality Agreement Acknowledgement

As the authorized representative of Click or tap here to enter text., I acknowledge that we have read and fully understand all elements of the Helmer Scientific Supplier Quality Agreement.

Authorized Representative		
	Print Name	*Title*
	Signature	*Date*
Quality Representative		
	Print Name	*Title*
	Signature	*Date*

Helmer Scientific

Supply Chain Representative		
	Print Name	*Title*
	Signature	*Date*
Quality Representative		
	Print Name	*Title*
	Signature	*Date*