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SUBJECT: Product Assurance Requirements		

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***Signatures on File**

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REVISION / CHANGE LOG

DCO#	Revision	Change	Page(s) Affected	Date
201803602	**A**	**Document replaces QA2028 - Appendix**	**-**	**3/15/2018**
201901640	**B**	**Update Paragraph 17**	**7**	**1/29/2019**
202011802	**C**	**Document title change**	**1**	**11/03/2020**
202101018	**D**	**All sections replaced "vendor" with supplier.**	**All**	**1/27/2021**
202109104	**E**	**Add requirement under 2. Records & 10. Nonconformance relating to notification of nonconformances per DFARS 252.246-7003,(b)(1) and apply to Critical Characteristics for all CSIs for which Critical Characteristics have been identified.**	**4, 6**	**09/07/2021**
202203006	**F**	**Remove "Proprietary" from the footer**	**All**	**03/16/2022**
202204010	**G**	**Add exception to PAR 19 requirement and update PAR 24**	**7, 8**	**06/27/2022**
202211157	**H**	**Clarify PAR 8 requirement**	**6**	**12/14/2022**

SUBJECT: Product Assurance Requirements

1. PURPOSE:

GENTEX is committed to meeting our customers' expectations by delivering products and services of superior quality, which perform to, or exceed the technical specifications and meet safety requirements. GENTEX relies on our partnerships with our External Providers and their sub-tier suppliers to achieve this. Our Quality Management System (QMS), including our supplier evaluation and qualification process is compliant to the latest AS9100 standard(s). To maintain compliance, we have developed Product Assurance Requirements (PARs) which are applicable to all Purchase Orders for products and services which go into a delivered product. All material furnished must be as specified on the drawing, purchase order, and/ or any technical documentation submitted as an addendum to the purchase order. Any deliverable against the purchase order will be subject to these PARs and GENTEX inspection and approval after delivery. GENTEX reserves the right to reject and return at the risk and expense of the External Provider such portion of any shipment which may be defective or fail to comply with specifications, without invalidating the remainder of the order. If goods delivered under this purchase order are rejected, they will be held for disposition at the External Provider's risk and expense.

All External Providers must be committed to the highest standards of ethics and business conduct. They must comply with applicable statutory regulations, honor commitments and act in good faith. External Providers must not offer, promise, or provide, directly or indirectly, anything of value (including business gifts or courtesies) with the intent or effect of inducing anyone to engage in unfair business practices. Suppliers will avoid involvement in activities that may be perceived as a conflict- of-interest.

External Providers support product safety by ensuring robust management of special requirements, critical items and key characteristics. If there are concerns with respect to product safety, External Providers will communicate them to GENTEX.

Acceptance of a GENTEX purchase order implies that the External Provider will ensure that its employees and sub-tier suppliers are aware of:

- Their contribution to product or service conformity
- Their contribution to product safety
- The importance of ethical behavior

2. DEFINITIONS:

PAR	Product Assurance Requirement
COC	Certificate of Conformance
FAI	First Article Inspection
PO	Purchase Order
CSI	Critical Safety Item
DFARS	Defense Federal Acquisition Regulation Supplement

FAR	Federal Acquisition Regulation
OEM/OCM	Original Equipment Manufacturer/ Original Component Manufacturer

3. APPLICABLE DOCS:

QA2028	PAR Guidelines for Purchase Order
PUR2006	Purchasing
	Shelf-Life Calculator

4. SAFETY:

N/A

5. TRAINING:

All applicable employees and suppliers

6. EQUIPMENT:

N/A

7. PROCEDURE:

1. **Quality System**
   All external providers of products and services shall document and maintain a Quality system meeting the requirements of an established and recognized standard(s), such as ISO9001, AS9100 or ISO17025.

2. **Records**
   The supplier shall maintain records of all inspections and tests performed on representative lots/material delivered to GENTEX, and records of all incoming materials acceptance documentation. GENTEX reserves the right to request or review on site any inspection or test records used to form the basis of acceptance. All inspection records and/or certifications must be retained for a period of seven (7) years, unless otherwise specified in the PO.

   Gentex CSI (Critical Safety Item) records shall be made available to the Buyer for inspection within 2 business days after request. Procured CSI parts and processing operations; the Supplier and Supplier sub-tiers shall ensure CSI technical quality requirements and/or quality data are traceable to the date and location that the CSI were produced/repaired.

3. Government Source Inspection

Government Source Inspection is required prior to shipment from your plant. Upon receipt of this order, promptly furnish a copy to the government representative who normally services your plant so that appropriate planning for government inspection can be accomplished. GENTEX has notified the appropriate government representative.

4. Certificate of Conformance

A certificate of conformance signed by a quality assurance representative of the organization must accompany each lot of material and/or parts submitted to GENTEX. The certificate will indicate that the parts or materials supplied against the purchase order agreement meet all drawing and/or all purchase order requirements. Certificate must state that all inspection records and/or certifications are on file and available for GENTEX examination. Certificate must include GENTEX part number, revision, quantity shipped and Purchase Order number.

5. Inspection Report

The Supplier shall furnish a copy of the final inspection report, signed by the Quality Control Manager or his authorized representative (if applicable). The report shall be identifiable to each Supplier lot item furnished and must represent the lot being shipped, and include the GENTEX part number and revision as part of the report heading or information. The report must include all critical dimensional characteristics required by the drawing (unless otherwise agreed by GENTEX Quality Personnel), including tolerance bands and drawing notes information. Sampling inspection to ANSI/ASQ Z1.4 or Z1.9 is acceptable. Nonconforming materials may only be included if processed IAW PAR-10.

6. Identification and Traceability

The seller shall maintain a system to identify sources of all materials, components, parts and maintain records:

- The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.
- When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish appropriate controls for the media.

Where Traceability is a requirement, the seller shall include:

- Identification to be maintained throughout product life.

- The ability to trace all products manufactured from the same batch of raw material or from the same manufacturing batch to the destination (e.g., delivery, scrap).
- For an assembly, the ability to trace its components to the assembly and then to the next higher assembly.
- For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

7. Physical marking

All parts on this order shall be marked with a lot, batch number or contract number etc. see purchase order notes for details.

8. First Article Inspection Report

SAE AS9102 first Article Inspection (FAI) is **required prior to the first delivery of the product baseline configuration**. FAI shall be performed on the first unit/assembly produced and shall be performed in accordance with all the requirements defined in SAE AS9102 (latest revision). It shall be the responsibility of the supplier to ensure that they have completed an FAI to the most current revision of the drawing. If any of the following activity below occur then, an updated full FAI shall be submitted to Gentex:

- New part introduction
- New supplier or, new location of manufacture facility
- When part has not been manufactured for more than two (2) years
- When the customer is requesting

Partial (“Delta”) FAI shall be required as specified by GENTEX or if there are changes as defined in SAE AS9102. GENTEX Quality Representative reserves the right to perform some or all aspects of FAI activities at the supplier’s or GENTEX facilities. GENTEX disclaims responsibility for material delivered prior to FAI approval by GENTEX.

The FAI report shall have data representing results of Seller’s first article test/inspection, including actual dimensions or values for each specified characteristic and acceptance to all drawing notes. Copies of all material and or special processing certifications and bubbled drawing(s) shall be provided with the FAI report.

Note: Optional Fields 11, 12 and 21-24 on SAE AS9102 Form 1 are mandatory fields for all GENTEX procured parts. It is the Sellers responsibility to obtain Gentex

approval on the FAI Report prior to shipping production parts or as required in writing by GENTEX.

9. Counterfeit Work

The supplier shall certify that no counterfeit materials, parts, or components make up any portion or content of the shipment to GENTEX and documentation shall accompany the shipment along with our other Quality Assurance Requirements noted on your Purchase Order. The documentation shall attest to the validity of sub-tier components as being traceable to OEM/OCM sources, including authorized franchised dealers that, in no way are associated with Counterfeit Work. In lieu of a sentence or statement, submission of the organizations policy or procedure, regarding their handling of Counterfeit Work, can be submitted in whole and can be accepted on a case-by-case basis.

Counterfeit Work means work that is or contains items misrepresented by means of deception to make the buyer think the items were designed and produced under an approved system. The term Counterfeit Work includes work that has reached a design life limit or has been damaged beyond the point of rework and/or repair but is altered and misrepresented as if to be acceptable.

10. Nonconformance

The seller is not authorized to deliver any material, which deviates from the requirements specified on this purchase order. Such nonconformance must be identified, in writing by the Quality Manager, to GENTEX for approval prior to shipment. The supplier shall cooperate with the Corrective Action Process of GENTEX, which includes root-cause investigation and corrective action implementation and associated documentation, when it is determined that the supplier is responsible for the non-conformity.

Notification of nonconformance to be provided to the customer (when applicable) per DFARS 252.246-7003, subparagraph (b)(1), and shall apply to Critical Characteristics for all CSIs for which Critical Characteristics have been identified. For CSIs for which Critical Characteristics have not been identified, the Supplier shall use existing Material Review processes in effect at the Supplier and at sub-tier suppliers, providing notification if any nonconformance results in a safety impact.

11. Right of access

The GENTEX Corporation reserves the right of access to applicable areas of the seller’s facility where product acceptance activities take place (e.g., inspection and

testing) – not to include Supplier deemed proprietary areas. This includes right of access by GENTEX, GENTEX' customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable documentation and records with prior written consent between GENTEX and the supplier(s).

12. Process Control Plan

The Seller shall provide a Process Control Plan to serve as a basis for inspection and acceptance of the deliverable material when required by the customer, contract, or purchase order. The plan shall describe the quality requirements including identification of inspection points and resources to be applied to a specific product, project, or contract from materials receipt to shipping. The plan shall be submitted to GENTEX Quality Assurance for review and approval prior to execution of purchase contract.

13. Special requirements

(Reference _____) Fill in the blank with a reference (e.g., Statement of Work, GENTEX Customer requirements, requirements for test specimens (production method, number, storage conditions for design approval, inspection/verification, and investigating or auditing). Applicable requirements, including customer requirements shall be flowed down to the supplier including customer-approved special process sources and/or qualification of personnel as required.

14. Source Inspection

Items covered by this purchase agreement require GENTEX source inspection prior to assembly and/or shipment. GENTEX Purchasing department must be notified a minimum of three (3) working days to schedule source inspection. All applicable documents and inspection equipment must be made available by the supplier. Only parts which have been accepted by the Supplier may be submitted. Source inspection does not relieve the Supplier of any of the requirements of the purchase agreement, and GENTEX reserves the right to accomplish final acceptance at destination.

15. Country of Origin Certifications, Domestic Commodities and/or Hand or Measuring Tools

The supplier and all their sub tier suppliers shall provide certification of the qualified country of origin for all materials used to produce or supply product under this Purchase Order. The supplier and all their sub tier suppliers shall certify to the qualified country of origin per DFARS 252.225- 7012 (Preference for Certain Domestic Commodities) and/or DFARS 252.225-7015 (Restriction on Acquisition of

Hand or Measuring Tools). DFARS 225.872-1 provides a listing of those countries outside of the United States of America that are qualified to supply materials to this Quality Clause. The certification may be a separate document, or the supplier may incorporate the information into an existing Certificate of Conformance

16. Restriction on the Acquisition of certain Articles containing Specialty Metals

In accordance with DFARS 252-225-7009, it is the responsibility of the supplier and all their sub tier suppliers to provide certification of qualified country of origin for any material used in the production or supply of product in support of a government contract except as provided in paragraph (c) of this clause. Any specialty metals as defined in paragraph (a) incorporated in items delivered under this contract, not exempted, shall be melted, or produced in the United States, its outlying areas, or a qualifying country. DFARS 225-7002 provides a listing of qualified countries to supply materials to this Quality Clause. This certification may be a separate document, or the supplier may incorporate the information into an existing Certification of Conformance.

17. Change Approval

GENTEX products are typically “qualified” products, therefore, approval must be obtained from GENTEX in writing prior to making any changes to drawings, specifications, or other documents pertaining to this purchase order. Supplier shall notify GENTEX of changes in product and/or process, changes of manufacturing facility location, product obsolescence, changes of suppliers, damaged tooling, or tools requiring repair or modification, and obtain GENTEX approval. If there is doubt as to whether a change will affect GENTEX qualified products, GENTEX shall be contacted in writing to communicate the nature of the change, and to request approval for said change. Approval is to be provided through written communication.

18. Material Certification and Chemical/Physical Analysis of Raw Materials

One copy of each material certification as furnished by the raw material Supplier must be submitted for each lot of raw material used in performing to this purchase agreement, or, at GENTEX prerogative, a statement substantiating that physical and chemical test data are on file at the facility of the material supplier. The report shall be as provided by the mill or equivalent source, or as obtained by the Supplier from an accredited laboratory. A copy of the material Cert must be submitted with each shipment.

19. Controlled Environment Requirements

For each item requiring controlled environment and/or storage, the Seller shall certify to the Date of Manufacture, Shelf Life and Storage Temperature or other environmental requirements. The remaining shelf life of each item shall be a minimum of 80% upon receipt by GENTEX. Exceptions to PAR 19 are handled on a case-by-case basis which will allow material to be brought in with less than 80% shelf life. This exception shall be documented on FRMQA4106 Request for Deviation or Waiver and will require the Quality Managers approval. Materials with limited shelf life, such as paint, epoxy, resins, adhesives, O-rings, elastomers, etc., shall be marked with the date of manufacture, lot/batch number, and expiration date on each container. Electronic components cannot exceed a date code greater than 18 months from specified dock date.

20. Proofread

The Supplier shall submit one copy of the artwork produced or processed on this purchase agreement to GENTEX the Supplier shall obtain a written acceptance from GENTEX Quality Representative before proceeding with production.

21. Calibration System

The Supplier shall provide and maintain a calibration system in accordance with ISO/IEC 17025, latest revision. If an outside supplier is used for testing or calibration, the supplier should be able to demonstrate technical competence to a laboratory standard such as ISO/IEC 17025, latest revision. Products and services provided by outside suppliers might require verification to the specified requirements. This system shall be verifiable by GENTEX surveillance.

22. Special Process Certificate

The seller shall provide a copy of a certificate for each special process used in the production of parts under the terms of the agreement. Cert must have GENTEX part number and revision.

23. Approval of Process Sources

GENTEX approval of Supplier ’s special process procedures and/or special processors pertinent to this order is required.

24. Material Furnished by GENTEX

Items manufactured under this purchase agreement shall be fabricated from materials furnished by GENTEX. The seller shall not substitute for, or dispose of, GENTEX-furnished material except as instructed in writing by the GENTEX Purchasing department. Unused material, properly identified, shall be returned with

the last shipment of fabricated parts. If required by contract or upon request the seller shall submit a certificate with each shipment of parts that reads substantially as follows: "(Seller Company Name) certifies that all materials used in the completion of GENTEX Purchase Order Number _____ were supplied by GENTEX, and no unauthorized substitution or disposal was accomplished." The seller shall provide a copy of the GENTEX shipping memo provided with the material, and a copy of the certificate.

25. Certified Supplier Program Requirements

For each item being shipped to GENTEX the Seller shall certify that the parts or materials supplied meet all drawings, specifications, and/or all purchase order requirements. Supplier shall supply Inspection Records, Test Reports, and SPC data as agreed with GENTEX Quality Representative and as called out in other QA Clauses on the PO. The Supplier shall be responsible for the conformity of all products purchased from sub-tier suppliers, including product from sources defined by GENTEX. Where GENTEX delegates verification activities to the supplier, the requirements for delegation shall be defined by GENTEX and a register of delegations shall be maintained by GENTEX. Supplier agrees to abide by all aspects of the Certified Supplier Program. Supplier is to stamp the shipper, C of C, and other related documents with the Certified Supplier Stamp.

26. Serialization

Each item furnished on this purchase order or contract will be identified with a nonrecurring serial number. Serial numbers will be furnished by GENTEX – Respiratory Products unless otherwise agreed by GENTEX.

7.1 Instructions for Certificate of Conformance/Shelf-Life Form

The attached exhibit is blocking numbered to correspond. (PAR 4, par 19)

Certificates of conformance are a requirement on all GENTEX Corporation purchase orders for parts and materials. Please use the information listed below to ensure the certificates of compliance are filled out correctly.

PAR 4

1). Date

2). Purchase Order Number

3). Part Number (P/N) and Revision Level

4). Specification Number

5). Quantity of the shipment (a certification is required with each shipment).

6). Applicable Lot Number; Serial Number; or Batch Number.

7). A statement to “certify that product, processes, or procedures are in compliance with all applicable specifications and/or drawings”, and records of inspection and testing are on file and available for review.

8). An authorized signature is required.

9). Title of the authorized individual.

10). Certificate should be on your company letterhead with address.

PAR 19

If the item you are supplying has a shelf life, the following information is required in addition to the 10 items above:

11). Shelf Life of your product.

12). Date of Manufacturing or Date of Shipment depending on the shelf life that you certify to.

NOTE: The Certificate of Conformance should accompany the product when being shipped or be mailed the same day. If the original is mailed, please fax a copy to the Purchasing Department at (909) 980-3097