

SUPPLIER QUALITY REQUIREMENTS (SQRs)

09/16/13, Rev. 1 QMS-P018

SUPPLIER QUALITY REQUIREMENTS

Q01 MANDATORY COMPANY APPROVAL OF SUPPLIER CHANGES

When specified on individual Purchase Orders, Excalibur requires manditory written approval for any change to supplier's product or services.

Q02 OPTIONAL COMPANY SOURCE INSPECTION

Excalibur reserves the right to inspect any and/or all work on this Purchase Order at the supplier's facility. The supplier will be notified in advance of shipping date if Excalibur source inspection is required.

Q03 PRODUCT ASSURANACE SYSTEM REQUIREMENTS

The supplier shall have Product Assurance system and procedures detailing the following minimum requirements:

- 1. Safety
- 2. Training / Certification
- 3. Record retention
- 4. Traceability
- 5. Procurement control
- 6. Manufacturing, fabrication, process control
- 7. Metrology control
- Stamp control
- 9. Non-conforming product control

The supplier's product assurance system is subject to initial survey and approval by Company. Subsequent surveys or audits, including subtier supplier and processors may be conducted before or after issuance of a Purchase Order. The supplier shall be notified of deficiencies and shall follow-up and ensure that deficiencies are promptly corrected. Corrective action shall be subject to review and approval by Company's Quality Assurance.

Q04 QUALITY PROGRAM REQUIREMENTS

The seller shall have developed and maintain a quality program within the organization.

Q05 INSPECTION SYSTEM REQUIREMENTS

The seller shall have developed and maintain an inspection system within the organization.

Q06 NOTIFICATION

Any deviation to Excalibur's requirements set forth in this Purchase Order shall be documented, and Excalibur notified, for communication and approval of disposition prior to product shipment from supplier's facility.

Q07* METROLOGY / ACCURACY

All test and measurement equipment used in the performance of this Purchase Order shall be certified against a standard having greater accuracy. Random and systematic error in any article or material measurement process shall not exceed 10% of the tolerance of the parameter being measured.

Q08 * CERTIFICATION OF COMPLIANCE

The seller shall include with each shipment copies of a certifying statement that attests to the seller's compliance with all the requirements of the Purchase Order. The certificate shall be signed by an authorized representative of the supplier.

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Q09 RIGHT OF ENTRY / CUSTOMER ACCESS

Access to your facility (documents, personnel, equipment, material and facilities) shall be made available to Excalibur Lab Specialists, Inc., and regulatory agencies, to determine and verify the quality of the work, records, and material.

Q10 SUBCONTRACTING WORK

Seller is prohibited from subcontracting any portion of the work to be performed as specified in this Purchase Order, unless authorized by the buyer in writing.

Q11 RECORDS

Seller shall maintain records of manufacturing and traceability of materials used in the fabrication of the product produced in fulfillment of this Purchase Order. The records shall be maintained for a period fo 7 years after completion of the Purchase Order and be made available for review to the buyer upon request.

Q12* SERIALIZATION

Each item furnished on this Purchase Order will be identified with a non-recurring serial number. Where the size of the item prohibits identification, the serial number will be marked on an identification tag or label and be securely attached to each item.

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^{*} Starred items are specific to the Receiving process