



QUALITY MANUAL QM0492 ISO 13485 SUPPLEMENT III

REV. ORIG

Foreword

This document defines the quality management system requirements to be applied when processing product for clients within the medical sector as specified in ISO 13485.

This document is supplemental to the Avnet Quality Manual and must be used in conjunction with that Manual when processing medical devices in ISO 13485 certified facilities. When processing medical devices all quality system requirements defined in the Quality Manual must be adhered to, as well as the additional requirements defined in this Supplement.

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4.0 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

4.1 General Requirements (Quality Manual Section 14.0)

NOTE: Documents which define the key ATS business processes are specified in Appendix XI.

4.2 Documentation Requirements (Quality Manual Section 15.0)

4.2.1 General Requirements (Quality Manual Section 15.0)

f. Other Documents - Supplemental

No documents specified by national or regional regulations have been identified for application to Avnet's business.

When such requirements become known, they will be implemented into the Avnet's build instructions.

Manufacturing Process Documents - Supplemental

Files are maintained for each type or model of medical device which either contains or identifies documents defining product specifications and QMS requirements. These documents define the complete manufacturing process.

4.2.3 Control of Documents (Quality Manual Section 15.0)

Retention of Obsolete Controlled Documents - Supplemental

At least one copy of obsolete controlled documents and changed process documents are retained as specified by the customer, regulatory agency and Avnet, as applicable.

Changes to Documents - Supplemental

Changes to documents are reviewed and approved by the original approving function or by an alternate designated function that has pertinent background information upon which to base the decision for a change.

4.2.4 Control of Quality Records (Quality Manual Section 16.0)

Records Retention - Supplemental

Records are retained for a period of time at least equivalent to the lifetime of the medical device, as defined in Avnet procedures, but not less than two years from the date of product release or as specified by relevant regulatory requirements.

5.0 MANAGEMENT RESPONSIBILITY

5.5 Responsibilities, Authority and Communication (Quality Manual Section 6.0)

5.5.1 Responsibility and Authority (Quality Manual Section 5.0)

5.5.1.1 Interrelation of Personnel - Supplemental

a) The interrelation of personnel who manage, perform and verify work affecting quality has been defined by top

management. Job descriptions are utilized to define the responsibility and authority for employees through the organization. The interrelation of personnel who manage, perform, and verify work affecting quality and who need the independence, freedom and authority to perform these tasks are defined in key process procedures.

5.5.2 Management Representative (Quality Manual Section 7.0)

- c. Promotion of Awareness - Supplemental
The Management Representative has been given the responsibility to promote awareness of regulatory requirements throughout the organization. Currently there are no projects requiring special regulatory requirements for medical customers. When projects are identified that require special regulatory requirements, the management representative will be notified.

5.6 Management Review (Quality Manual Section 8.0)

5.6.2 Review Input

- h. New or revised regulatory requirements - Supplemental
New and or revised regulatory requirements will be included as an input to management review.

5.6.3 Review Output

- a. Improvements - Supplemental
Improvements identified to maintain and/or enhance the effectiveness of the QMS and processes will be included as an output from management review.

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources (Quality Manual Section 10.1)

- c. Regulatory and customer Requirements - Supplemental
Resources are provided to meet regulatory and customer requirements.

6.3 Infrastructure (Quality Manual Section 10)

Maintenance Activities and Maintenance Records - Supplemental
Requirements for maintenance activities have been documented, including the required frequency when the maintenance activities or lack of maintenance activities could affect product quality. Records of the maintenance performed are maintained as required by the records procedure.

6.4 Work Environment (Quality Manual Section 10)

- a. Documented procedure - Supplemental
Documented requirements for health, cleanliness and clothing of personnel have not been established, since contact of personnel and the product or work environment does not adversely affect the quality of the product.

- b. Work Environment Condition - Supplemental
No work environment conditions have been identified that could have an adverse effect on product quality; therefore requirements for work environment conditions, monitoring and controlling these environmental conditions have not been documented in procedures and work instructions.
- c. Personnel temporarily working under Special Environmental Conditions - Supplemental
No personnel have been identified to work temporarily under special environmental conditions within the work environment to require appropriate training or supervised by trained personnel.
- d. Arrangements for contaminated product - Supplemental
Product supplied does not have the potential to contaminate other product, the work environment or personnel.

The organization does not supply invasive medical devices; therefore work environment controls applicable to devices of that nature in terms of health, cleanliness and sterilization (and training and monitoring to those requirements are not applicable.

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization (Quality Manual Section 12)

- e. Risk Management - Supplemental
Verification and validation of product design including risk management resides with the customer, as the customer maintains design ownership.

7.2 Customer-related Processes (Quality Manual Section 13)

7.2.2 Review of Requirements Related to the Product

- a. Documented Product Requirements - Supplemental
All product requirements, including those given verbally are documented for subsequent review and approval.

7.2.3 Customer Communication

- d. Advisory notices - Supplemental
Central point of contact has been established in departmental areas (i.e. sales, engineering, etc.) for order handling/status/and change requests and disseminating advisory notices.

7.3 Design and Development

NOTE: Product design is not performed. Product design is the responsibility of the customer.

7.4 Purchasing (Quality Manual Section 17)

7.4.1 Purchasing Process

- a. Documented Procedure - Supplemental
Procedures have been established to control the quality of purchased products from franchised suppliers, non-franchised suppliers and value added subcontractors and to ensure that purchased product and/or services conform to specified requirements.

7.4.2 Purchasing Information

- d. Traceability - Supplemental
Traceability is maintained from receiving to shipping to the customer, as applicable and records maintained.

7.4.3 Verification of Purchased Product

- c. Verification Records - Supplemental
Records of the verification of the product are maintained in accordance with the records retention procedure.

7.5 Production and Service Provision (Quality Manual Section 20)

7.5.1 Control of Production and Service Provision

7.5.1.1 General Requirements - Supplemental

- b. Documented procedures, documented requirements, and reference materials and reference measurement procedures - Supplemental
Work instructions are available as necessary to adequately perform work.
- g. Labeling and packaging implementation - Supplemental
Labeling and packaging requirements have been implemented and controlled as required by customer requirements within build instructions.
- h. Records of batches of medical devices - Supplemental
Identification and traceability of individual batches of medical devices is maintained. This includes traceability of system components to the assembly level, where required. The identification and traceability is recorded and identifies the amount manufactured and amount approved for distribution. The record is verified and approved.

7.5.1.2 Control of production and service provision-Specific requirements - Supplemental

- 7.5.1.2.1 Cleanliness of Product and Contamination Control - Supplemental
- 7.5.1.2.2 Installation Activities - Supplemental
- 7.5.1.2.3 Servicing Activities - Supplemental

7.5.1.3 Particular Requirements for Sterile Medical Devices
- Supplemental

The above clauses 7.5.1.2.1 through 7.5.1.3 are not applicable to Avnet's business.

7.5.2 Validation of Processes for Production

7.5.2.1 General Requirements - Supplemental

All production processes are validated internally and as requested by the customer.

- a. Defined Criteria - Supplemental
Criteria for the review and approval of the processes is defined in the build instructions.
- b. Approval of equipment and qualification of personnel - Supplemental
Equipment is designated within the build instruction and controlled per the equipment calibration and maintenance process. Personnel are qualified in accordance with the training process.
- c. Use of specific methods and procedures - Supplemental
Methods and procedures have been documented, implemented and controlled per the document control process.
- d. Requirements for records - Supplemental
Control of records and the maintenance of the required records are as specified in the records procedure and records retention chart.
- e. Revalidation - Supplemental
Revalidation as applicable is specified within the build instructions.
- f. Documented procedure for validation of computer software - Supplemental
Validation of computer software is documented unless deemed as inappropriate.
- g. Records of computer software validation - Supplemental
Records of computer software validation are maintained in accordance with the records procedure unless deemed as inappropriate.

7.5.2.2 Particular requirements for sterile medical devices
- Supplemental

No sterile medical devices are processed by Avnet.

7.5.3 Identification and Traceability (Quality Manual Section 21)

7.5.3.1 Identification - Supplemental

- a. Documented procedure - Supplemental
The identification of product is documented within the integration and packaging procedures.
- b. Returned product - Supplemental
A documented procedure defines how medical product that has been shipped and returned is identified and distinguished from conforming product.

7.5.3.2 Traceability - Supplemental

7.5.3.2.1 General - Supplemental

A documented procedure has been established for traceability. The procedure defines the requirements for product traceability and the records to be maintained.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices - Supplemental

Avnet does not produce any active implantable medical devices or implantable medical devices.

7.5.3.3 Status Identification - Supplemental

Identification of the status of the product is maintained throughout production, storage, installation, and servicing of product. This includes inspection and test status. Product is only released after it has met all inspection and test criteria; where deviation to a process is required, it is documented through issuance of a Quality Bulletin.

7.5.5 Preservation of Product (Quality Manual Section 25.0)

7.5.5.1 Documented procedures or work instructions - Supplemental

Documented procedures and/or work instructions are maintained for preserving the conformity of product during internal processing and delivery to the customer.

7.5.5.2 Documented procedures or work instructions for product with limited shelf-life or special storage conditions - Supplemental

There is no product which has limited shelf-life or special storage condition requirements.

7.6 Control of Measuring and Monitoring Devices (Quality Manual Section 22.0)

7.6.1 Documented Procedure - Supplemental
Subject matter experts determine the monitoring and measurement activities appropriate to demonstrate conformity of product to predetermined requirements that are documented within procedures and build instructions or subsequent customer inspection instructions.

8.0 **MEASUREMENTS, ANALYSIS AND IMPROVEMENT**

8.1 General (Quality Manual 27.0)

c. Maintain effectiveness of QMS - Supplemental
Internal audits are conducted with the goal of continually improving the processes and maintaining the effectiveness of the QMS.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction (Quality Manual Section 9.0)

8.2.1 Customer Feedback - Supplemental
Avnet continually seeks feedback from customers to determine if their requirements are achieved. This feedback takes place during the prototype process and post build vehicles for product, process and business related feedback.

Customer Advisory Council and Avnet Customer Loyalty Program activities serve to proactively seek feedback from customers on a regular basis. Corrective and preventive actions are recorded within reports and the Process Improvement Request process.

No national or regional regulations have been identified that require Avnet to gain experience from the post-production phase for inclusion into the feedback system.

8.2.4 Monitoring and Measurement of Product (Quality Manual Section 21)

8.2.4.2 Active implantable medical devices and implantable medical devices - Supplemental
Not applicable to the products supplied.
Implantable devices are not being supplied.

8.3 Control of Nonconforming Product (Quality Manual Section 23)

8.3.1 Concession only if regulatory requirements met - Supplemental
The responsibility for review and disposition including acceptance of product under concession is only authorized if regulatory requirements have been met. Records of the identity of the person (s) authorizing the concession are maintained.

- 8.3.2 Control of Reworked Product - Supplemental
Instructions for rework, including re-inspection are accessible to and utilized by the appropriate personnel. Reworked product is re-inspected in accordance with the designated processes, build instructions and/or applicable quality plans, work instructions, and workmanship standards. The documentation for rework is subject to the same review and approval as the original build documentation.
- 8.4 Analysis of Data (Quality Manual 9.0)
 - 8.4.1 Documented Procedure - Supplemental
Data analyzed to determine the effectiveness of the QMS includes process, product, customer satisfaction (feedback), supplier performance, and trends identifying opportunities for improvement within the business as described in the Analysis of Data procedure.
 - 8.4.2 Data analysis results records - Supplemental
Records of the results of the analysis of data are maintained in accordance with the record retention procedure.
- 8.5 Improvement (Quality Manual Sections 10 & 28)
 - 8.5.1 Continual Improvement
 - 8.5.1.1 General - Supplemental
The nonconforming procedure includes the requirements for issue and implementation of advisory notices.
Customer complaint investigations are recorded and maintained within the corrective action system. If a customer complaint is not followed by a corrective/preventive action, the reason shall be authorized and recorded. If investigations determine that the component manufacturers or subcontractors contributed to the customer complaint, corrective actions shall be obtained from them.
Notification to regulatory authorities of any adverse events shall be made as required by national or regional regulations require.
 - 8.5.2 Corrective Action (Quality Manual Section 24)
 - d. Updating documentation - Supplemental
Documents are updated, if appropriate, as a result of actions identified.
 - e. Recording results of any investigations - Supplemental
Results of corrective action investigations are recorded.
 - 8.5.3 Preventive Action (Quality Manual Section 24.3)
 - e. Recording results of any investigations - Supplemental
Results of preventive action investigations are recorded.

ATS BUSINESS PROCESS DOCUMENTS

DOCUMENT NO.	TITLE
KP03-0002	ATS BUSINESS SYSTEM OVERVIEW
KP01-0001	STRATEGIC PLANNING PROCESS
KP06-0004	CONTROL OF RECORDS
KP06-0001	CONTROL OF DOCUMENTS
KP02-0001	BUSINESS MANAGEMENT SYSTEM REVIEW PROCESS
KP05-0001	COMPETENCE, AWARENESS AND TRAINING
WI02-0025	ESD
KP08-0004	ACS-DE PROTOTYPE PROCESS
KP08-0003	PRODUCT CHANGE REQUEST
KP08-0002	FIRST ARTICLE & VALIDATION PROCESS
KP10-0001	ACS ORDER SCHEDULE
KP09-0001	SUPPLIER QUALIFICATION & DISQUALIFICATION PROCESS
KP08-0001	REQUIREMENTS DEVELOPMENT
KP08-0005	INTEGRATION BUSINESS DEVELOPMENT-QUOTE PROCESS
KP13-0003	CONTROL OF NCM PRODUCT
KP10-0004	PPRODUCT INTEGRATION & FINAL PROCESS
KP04-0001	EQUIPMENT CALIBRATION & MAINTENANCE
W127-0190	INBOUND/OUTBOUND
W102-0006	QUALITY BULLETIN
KP12-0001	INTERNAL BUSINESS ASSESSMENT
KP14-0002	CORRECTIVE & PREVENTIVE ACTION
KP03-0002	BUSINESS SYSTEM OVERVIEW
KP13-0001	FAILURE EVALUATION
KP13-0004	ANALYSIS OF DATA
KP13-0002	PROBLEM SOLVING PROCEDURE