Regulatory Basis:
FDA Quality Systems Regulations

Sec. 820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured and that meets the requirements of this part.

Sec. 820.22 Quality audit.

Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

Sec. 820.25 Personnel.

Each manufacturer shall have sufficient personnel with the necessary education, background, training and experience to assure that all activities required by this part are correctly performed.

Sec. 820.40 Document controls.

Each manufacturer shall establish and maintain procedures to control all documents that are required by this part. The procedures shall provide for the following:

(a) Document approval and distribution. Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part.

(b) Document changes. Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise.

Sec. 820.60 Identification.

Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mixups.

Sec. 820.70 Production and process controls.

Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications.

Where appropriate, primary data should be placed in tables and/or plotted. Primary data and other attachments, including videotape and any type of electronic data storage medium, should follow good documentation practices. Attachments should be referenced in the relevant section of the test documentation.

The attachment itself should also be identified appropriately, for example, by protocol or report section, test number or attachment number. It is recommended that where there are multiple pages/items within an attachment that the number submitted is also recorded in the test documentation and/or on the attachment.

When transforming or plotting data, an individual other than the executor should verify the accuracy of the data transcribed. For data that is plotted, a printout of the data tables from the software used to generate the plot should be attached to the report. The data table printout may be signed instead of the graph.

The results of the test execution should be reviewed by QA and the system owner, at minimum, typically as part of the validation report.

Validation Reporting

Reports should describe the results from the planning and testing and should be approved by QA and the process/system owner, at minimum. The content of the report should include, or reference, the following:

- The planning or test document, including scope;
- Summary of the results obtained;
- Analysis of the results, where appropriate. For a process, this may include:
- Review of critical process parameters from validation batch/lot production records;
- Comparison with previously produced batches (commercial, development, or biobatches), where applicable;
- Summary and resolution of any manufacturing, laboratory or testing deviations observed;
- Report conclusions, including clear statement of validation status of system/process; for example:
- "System qualification has been successfully completed without deviation and the system is suitable for use."
- "Process validation has been successfully completed for product Y, all deviations have been resolved and the process is suitable for routine manufacturing."
- "Cleaning validation has been successfully completed for 2 runs of product X. One further run is required to complete the validation study."
- Recommendations or corrective actions needed; and
- Attachments (including raw data or summary of raw data).

When writing a report, consider the need for a "stand-alone" document, for example, one that is intended for an external reviewer or inspector. In this case, it may be of benefit if the report does not require the reviewer to frequently refer to the protocol or other

