§ 820.75 Process validation.

(a) Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.

(b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

(1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).

(2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.

(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

Subpart H—Acceptance Activities

§ 820.80 Receiving, in-process, and finished device acceptance.

(a) General. Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

(b) Receiving acceptance activities. Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.

(c) In-process acceptance activities. Each manufacturer shall establish and maintain procedures for acceptance of in-process product. Such procedures shall ensure that specified requirements for in-process product are met. In-process product shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:

(1) The activities required in the DMR are completed;
(2) the associated data and documentation is reviewed;
(3) the release is authorized by the signature of a designated individual(s); and
(4) the authorization is dated.