Marion Weinreb
& Associates, Inc.

FDA Warning Trends in 2013: MWA Recommended Focus Points

Subpart C, Design controls, 21 CFR 820.30

- Establish and maintain adequate procedures for validating the device design, including software validation and risk analysis, where appropriate. Review DMRs and DHFs and verify that adequate validation and risk management reports are maintained and up-to-date.
- Establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.
- Review DHFs. Verify that design verification activities are adequate and procedures are established for verifying that that the design output meets the design input requirements.

Subpart M, Records, 21 CFR 820.198

- Manufacturers should establish procedures for receiving, reviewing, and evaluating complaints by a formally designated unit or group. The procedure must include provisions for determining whether an investigation is necessary, and the requirements for reviewing, evaluating, and investigating complaints involving the possible failure of a device, labeling, and packaging to meet any of its specifications.

Subpart J, Corrective and Preventive Action, 21 CFR 820.100

- Establish and maintain corrective and preventive action procedures that include requirements for ensuring the corrective and preventive action is effective, and adequately document corrective and preventive action activities and/or results.

Subpart G, Production and Process Controls, 21 CFR 820.70

- Establish and maintain adequate procedures to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, and control and monitor environmental conditions that could reasonably be expected to have an adverse effect on product quality.
- Validate computer software for its intended use according to an established protocol when computers or automated data processing systems are used as part of production or the quality system.
- Establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met.

Subpart G, Production and Process Controls, 21 CFR 820.75

- Establish a procedure for validation of processes when the results of a process cannot be fully verified by subsequent inspection and test.
- Establish procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.
- Continually review and evaluate the processes and perform revalidation where appropriate.

Part 803, Medical Device Reporting

- Develop, maintain, and implement written Medical Device Reporting (MDR) procedures; including:
    - instructions for conducting a complete investigation of each event and evaluating the cause of the event,
    - state who makes the decision for MDR reportability,
    - the transmission of complete medical device reports to FDA, as required by 21 CFR 803.17(a)(3), including:
        - The types of information to be included on the FDA Form 3500A;
        - How all information reasonably known will be transmitted;
        - The circumstances under which a supplemental or follow-up report is needed and the requirements for such reports; and
        - The address for submission of MDR reports: FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.
- The procedure must describe how it will address documentation and record-keeping requirements, as required by 21 CFR 803.17(b), including:
    - Documentation of adverse-event-related information maintained as MDR event files;
    - Information that was evaluated to determine if an event was reportable;
    - Documentation of the deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable; and
    - Systems that ensure access to information that facilitates timely follow-up and inspection by FDA.