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Guide to Inspections of Medical Device Manufacturers December 1997 [Previous Page] [Table Of Contents] [Next Page] 2. Quality System Requirements - 21 CFR 820.5 and 21 CFR 820.20 All manufacturers of medical devices are required to establish and implement a quality system tailored to the device manufactured. Each manufacturer must prepare and implement all activities, including but not necessarily limited to the applicable requirements of the QS/GMP, that are necessary to assure the finished device, the design process, the manufacturing process, and all related procedures conform to approved specifications. The term "quality system" as specified in the GMP encompasses all activities previously referred to as "quality assurance" which were necessary to assure the finished device meets its predetermined design specifications. This includes assuring manufacturing processes are controlled and adequate for their intended use, documentation is controlled and maintained, equipment is calibrated, inspected, tested, etc. Some manufacturers may use the terms "quality control" or "GMP Control" or "quality assurance" instead of quality system. It doesn't matter what term is used as long as the quality system concept is understood and implemented. Historically, "quality control" has meant inspection and test which, although the primary mechanisms for detecting defects, only set aside nonconforming product and do not prevent the deficiency which caused the defect. Quality assurance activities are intended to prevent the production of non-conforming products and include quality control activities. A quality system applies to the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. The GMP is based on this umbrella concept of a quality system and is designed to prevent the design or production of nonconforming product. A manufacturer's implementation of the QS/GMP is implementation of a quality system. One aspect of a quality system is that it will identify, recommend, or provide solutions for quality problems and verify their implementation, as stated in 21 CFR 820.100. Trend analysis is a method of complying with this QS/GMP requirement. Process and product accept/reject data collected by the firm through their documented systems, along with the complaint system, can be used in identifying conditions or situations which might not be apparent, or may be dismissed as isolated incidents. Once identified, measures can then be implemented to control or eliminate their recurrence. Investigators should not make general FDA 483 observations that a manufacturer does not have a quality assurance system. If an adequate response is expected from the manufacturer the charge must be more specific and point out the controls that are missing or believed inadequate. The firm must have a written quality policy. Management with executive responsibility (has the authority to establish and make changes to the company quality policy) must assure the policy is understood and implemented at all levels of their organization. The policy does not need to be extensive. Some of the best policies are only one to two sentences in length. Personnel are not required to be able to recite the policy but they should be familiar with it and know where to obtain it. The firm's organizational structure must be adequate to ensure devices are designed and manufactured in accordance with the QS/GMP. The organizational structure should ensure the technical, administrative, and human factors functions affecting the quality of a device are controlled. These functions may involve hardware, software, processed materials or services. All such control should be towards the reduction, elimination, or ideally, the prevention of quality nonconformities. Manufacturers must assure personnel involved in managing, performing or assessing work affecting quality have the necessary independence and authority to perform those tasks. Organizational freedom or independence does not necessarily require a stand-alone group. However, the responsibility, authority and independence should be sufficient to attain the firm's stated quality objectives. Adequate resources must be available for the quality system to assure the firm's stated quality objectives can be achieved. Resources include monetary, supplies, etc. as well as personnel resources. The firm must appoint a management representative who is responsible for ensuring the quality system is effectively established and maintained and who will report on its performance to management with executive responsibility for review. Management with executive responsibility is required to periodically review the quality system for suitability and effectiveness. The review shall measure the firm's quality system against the QS/GMP and the firm's own stated quality objectives as defined in their quality policy. Both the appointment and the reviews must be documented. There must be written procedures for conducting these reviews. As stated under Quality Audit above, these procedures can be inspected and the firm must certify in writing, if requested, that the firm has complied with this QS/GMP requirement. The firm must have a written quality plan that defines the relevant design and manufacturing quality practices, resources and activities and how they intend to meet their quality requirements. In addition, written quality system procedures and instructions are required. [Previous Page] [Table Of Contents] [Next Page] Return to: Page Top | Inspection Start Medicine Matters is a place to share department news in a way that is accessible to all and discuss issues and challenges important to our faculty, staff and academic medicine overall... read more » Guide to Inspections of Medical Device Manufacturers December 1997 [Previous Page] [Table Of Contents] [Next Page] 11. PMA Devices - 21 CFR 814.20 and 814.39(a)(4) If any PMA devices are manufactured at the facility being inspected, determine whether this manufacturing site was approved in the original PMA or a PMA supplement, even if only partially manufactured at the inspected site. Report discrepancies in the EIR and notify CDRH, HFZ-306 (Field Programs Branch).. 12. Medical Device Tracking - 21 CFR 821 A determination must be made as to whether the firm manufactures any devices required to maintain device tracking data (see CP 7382.830 Attachment D). If so, determine whether the firm has device tracking procedures in place and if they are adequate to assure each device required to be tracked will be tracked to the actual end user, i.e. the patient. One method to do this would be to obtain a list of devices distributed during a given time frame and then look for those devices in the tracking database. If there is a complete lack of a tracking system, this should be cited on the FDA 483. Other observations should be discussed with the firm's management and reported in the EIR. The EIR must indicate whether or not the inspected firm makes any device subject to the device tracking requirements. If so, the EIR must include a statement that the firm's procedures, tracking database, etc. were assessed for compliance to the Medical Device Tracking Requirements (21 CFR 821). All FDA 483s or EIRs with medical device tracking observations must be sent to CDRH/Office of Compliance, Field Programs Branch (HFZ-306). COMPREHENSIVE DEVICE INSPECTION A comprehensive inspection is required to be done when performing a compliance inspection (OAI follow-up inspection) of a firm. It must include all of the items discussed under Directed Device Inspections as well as a determination of whether all previous FDA 483 observations have been investigated and corrective action has been implemented. Additionally, all other quality system requirements in the QS/GMP regulation should be inspected for compliance. 1. General Provisions - 21 CFR 820.1 and 21 CFR 820.3 All requirements of the QS/GMP regulation apply equally to manufacturers, large and small, foreign and domestic, of finished medical devices. Manufacturer includes any person or firm that designs, manufactures, fabricates, assembles, or processes a finished device. Remanufacturers (performs any act to a finished device that significantly changes the device's performance or safety specifications or intended use) must also comply with the QS/GMP regulation. Currently, they do not apply to refurbishers or third-party servicers (performs any act outside of the control of the original equipment manufacturer (OEM) that only restores the finished device to its original performance or safety specifications or intended use, or does not significantly change the original performance or safety specifications or intended use). [Previous Page] [Table Of Contents] [Next Page] Return to: Page Top | Inspection Start Guide to Inspections of Medical Device Manufacturers December 1997 [Previous Page] [Table Of Contents] [Next Page] 10. Design Controls - 21 CFR 820.30 From June 1, 1997 through May 31, 1998, all GMP inspections of medical device manufacturers will include an assessment of the firm's design controls utilizing the Design Control Inspectional Strategy (DCIS) included in CP7382.830 Attachment F (also available electronically on CDRH's home page and the Banyan Bulletin Board under DFI Live, Medical Device Reference Materials.) This strategy constitutes the method of conducting an inspection of design controls. For this first year, a transition period for design controls, no observation relative to design controls (or changes or software - see Moratorium memo dated June 6, 1997, Attachment B) will be included on the FDA 483 or used to support any regulatory action. If the design of a device is found to be unsafe or ineffective for its intended use, FDA can take action under other sections (non-GMP) of the Food, Drug and Cosmetic Act (FD&C Act). Observations relative to design control requirements, changes and software will be recorded on the DCIS report. The DCIS report will become part of the firm's EIR and will be available under Freedom of Information (FOI). Portions of the report may be purged to protect confidential and trade secret information. Therefore, it is important for the Investigator to identify which portions of the DCIS report the manufacturer considers confidential to assist the agency in its FOI determinations. Do not collect documents or records, during the transition year (June 1, 1997 - May 31, 1998) to document areas in need of improvement that are included on the DCIS report. Do not collect documents or records merely to assist you in writing the DCIS report. You will need to take good notes to assist you with this task or write the responses, etc. directly onto the automated report. Exception is the general design control planning procedure, if available, as noted on the Design Control Inspectional Strategy. The listed Areas in Need of Improvement should be written in the same manner required for an FDA 483 observation. [Previous Page] [Table Of Contents] [Next Page] Return to: Page Top | Inspection Start