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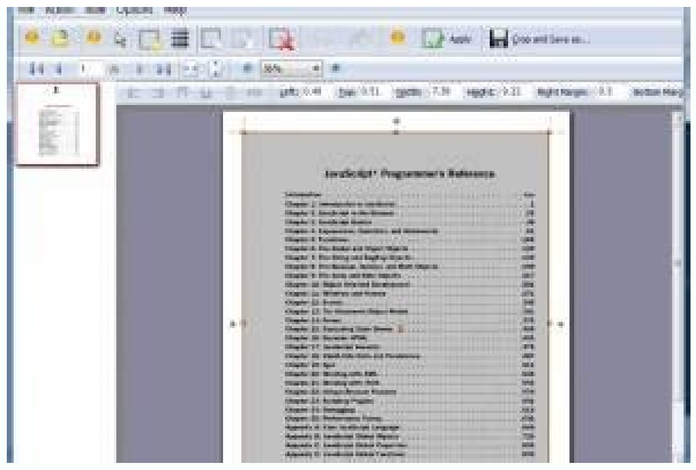

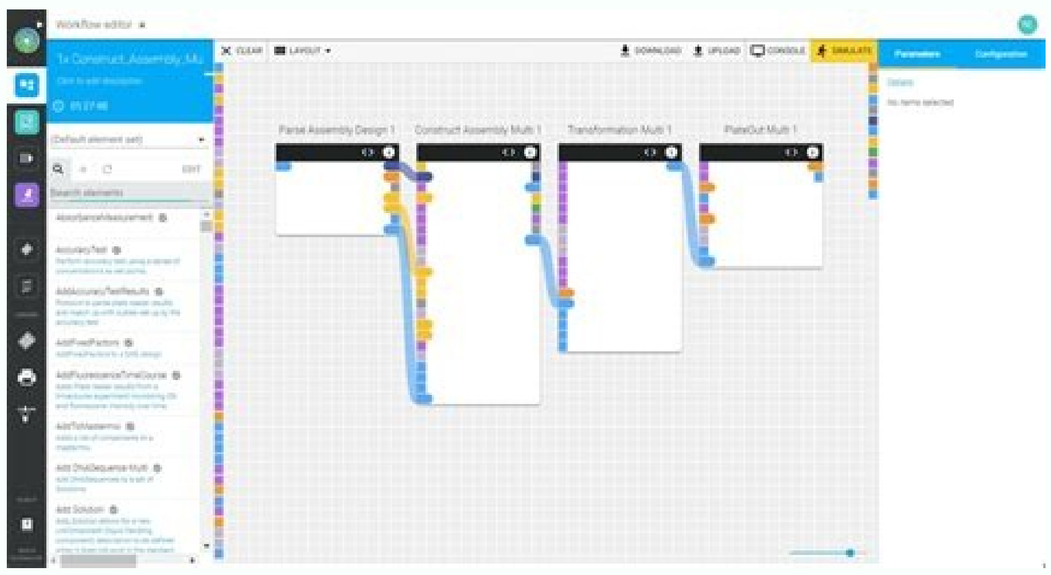

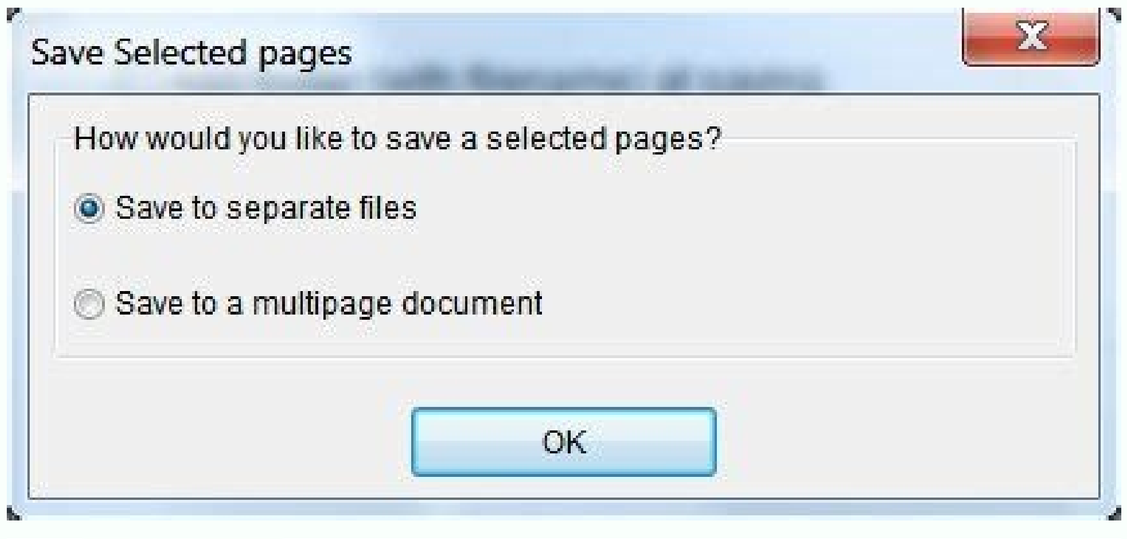

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By Elle Smith Adobe InDesign is an industry-standard page layout program used by designers, art directors, typesetters and electronic production artists. When a new document is opened, InDesign defaults to a single page. If you select "Facing Pages," or add additional pages, the document spread option places two pages side-by-side on the pasteboard. InDesign offers an option to allow multiple spreads to be preserved when an extra page is added or removed. Launch InDesign. Select "New" from the "File" menu to open a new document. Add at least four pages in the text field next to "Number of Pages." Check the box next to "Facing Pages" to view the spreads together on the screen. Click "OK." Select "Windows," then scroll down to "Pages" to open the "Pages" panel if it is not already open in the workspace. Click on the page spread icons in the panel. Click the small arrow in the upper left corner of the "Pages" panel to bring up a side menu. Uncheck "Allow Document Pages to Shuffle" from the menu. InDesign will preserve the multi-spreads if pages are added, removed or rearranged. Click the small arrow on the upper left corner of the "Pages" panel to bring up a side menu. Select "Insert Pages" to insert a new page into the middle of the spread. Alternatively, click the thumbnail of a page, and drag it next to an existing single page in the spread. 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 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 MDR Regulations - 21 CFR 803 Remember when reviewing complaints to check for MDR reportable events. The Compliance Program requires an MDR inspection every time a GMP inspection is made of a medical device manufacturer. CDRH has included in the Compliance Program guidance for evaluating a manufacturer's compliance with the requirements of the revised (July 31, 1996) MDR regulation. The Establishment Inspection Report (EIR) must state that complaints, service records, etc. were reviewed for MDR reportability, that the firm's MDR procedures were reviewed and whether the firm was found to be in compliance with the MDR regulations. Observations related to the MDR regulations should be noted on the FDA 483 or discussed with management as appropriate. For further guidance on MDRs, see CP7382.830 and the guidance manual dated March 1997 issued by CDRH/Division of Small Manufacturer's Assistance (DSMA), "Medical Device Reporting for Manufacturers" . Establish and Maintain Procedures for Performing and Verifying that the Servicing Meets Specified Requirements, and for Analyzing Reports - 21 CFR 820.200(a) and (b) Manufacturers must analyze service reports, and where necessary, with appropriate statistical methodology in accordance with 21 CFR 820.100 (e.g. frequency distribution charts, Pareto analysis or other analytical methods). Documentation for this should be established under corrective and preventive action in accordance with section 21 CFR 820.100. A determination should be made as to whether the firm has an adequate system in place for screening repair and service requests to assure whether any of these meet the definition of a complaint. Service reports initiated as a result of a complaint must be cross-referenced in the complaint handling system. NOTE, every service report is not necessarily a complaint. Determining MDR-Reportable Service Reports - 21 CFR 820.200(c) Remember when reviewing service records to also check for MDR reportable events. Any service report that represents an event which must be reported to FDA under part 803 or 804 of the MDR regulation must automatically be considered a complaint and receive appropriate follow-up under the requirements of section 21 CFR 820.198. Corrective and Preventive Actions - 21 CFR 820.100 It should be remembered the complaint section of the QS/GMP regulation (21 CFR 820.198(b)) refers to all complaints, whether or not a complaint represents a possible failure of the device. 21 CFR 820.198(c) requires all possible failures of devices to be investigated to determine whether the failure can be confirmed and/or cause of the failure can be determined. Once the failure is confirmed as an actual failure of the device, the Corrective and Preventive Actions section of the QS/GMP Regulation (21 CFR 820.100) takes effect. It is important to remember that at times trending or continual monitoring of complaints for specific failures can be a corrective and preventive action. This is especially true when a firm cannot determine the cause of the failure. A determination must be made as to whether the firm has established procedures for implementing corrective and preventive action. Determine if the firm screens repair and service requests and conducts trend analyses to identify premature failures within the warranty period, and to detect problems with particular components, subassemblies, or design. Any product failures within the warranty period are likely to be product design or GMP related. For example Product design related issues may be those related to electrical safety, EMC, consistent user error or robustness of the product to packing, handling, storage and shipping. GMP related issues are validation of assembling processes, screening and receiving, and in-process or finished device acceptance. Review records for investigations to identify common failure trends (e.g., by component, subassembly, manufacturing error, or employee training). Compare these trends with corrective action documentation. These common failure trends may provide clues to which areas or products to focus on during the inspection. Your inspection should include detailed inspection of documents maintained under the requirements of 21 CFR 820.100, Corrective and Preventive Actions. In particular, you should focus on reliability issues that have not been documented for corrective and preventive actions. The continued distribution of devices with a known problem should be noted on the FDA 483 (or DCIS report for design problems.) [Previous Page] [Table Of Contents] [Next Page] Return to: Page Top | Inspection Start

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