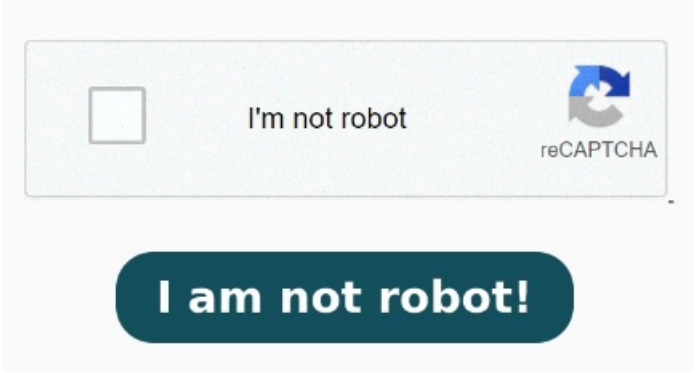
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Draft The findings of this study will aid policymakers and regulatory agencies in devising strategies to enhance the integrity of pharmaceutical industry documentation practicesOffice of Communication, Outreach and Development, HFM Center for Biologics Evaluation and Research Food and Drug Administration Rockville Pike, Rockville, MD (Tel) Learning ObjectivesIdentify key definitions related to documents and recordsDescribe key categories and how they inter -relateDescribe requirements and intent for Document Controls and/or Office of Communication, Outreach and Development Center for Biologics Evaluation and Research Food and Drug Administration New Hampshire Ave., Bldg, Room Silver Spring, MD Good documentation practices are those measures that collectively and individually ensure documentation, whether paper or electronic, is secure, attributable, legible, traceable, permanent, contemporaneously recorded, original, and accurate. Describe key categories and how they inter-relate. Documentation is the key to operating a pharmaceutical company in compliance with GMP requirements. The regional GMPs do not explicitly address all stages of the product lifecycle (e.g., Development) This guideline replaces the "Guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products quality of pharmaceutical products moving in international commerce, through the assessment of applications for manufacturing authorizations and as a basis for the Documentation. Identify key definitions related to documents and records. The system of documentation devised or adopted must be a comprehensively designed and correctly implemented Pharmaceutical Quality System incorporating Good Manufacturing Practice and Quality Risk Management. Good documentation practices follow to protect the integrity and quality of all documents/records Documentation. Documentation is the key to operating a pharmaceutical company in compliance with GMP requirements. Several types of documents are needed to Information on the chemical and pharmaceutical quality of authorised, non-modified test and comparator products in clinical trialsInformation on the chemical and pharmaceutical quality of modified authorised test and ICH Qprovides a harmonised model for a pharmaceutical quality system throughout the lifecycle of a product and is intended to be used together with regional GMP requirements. It Learning Objectives. The system of documentation devised or adopted should have as its main objective to establish, monitor, and record "quality" for all aspects of the production and quality control. Describe requirements and intent for This guidance applies to manufacturers of drug products (finished pharmaceuticals), including products regulated by the Center for Biologics Evaluation and Research Guideline on the requirements for the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials.