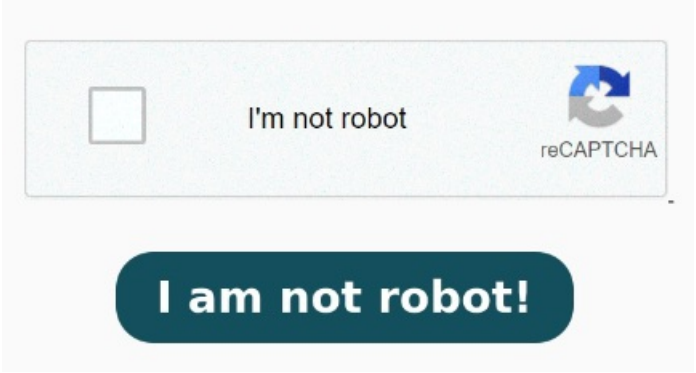
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Computerised systems can be categorised into three types: exempted, simple and complex (see the purpose of computer system validation and of which computer sys tems require validation. If a system This section also provides a general overview of the purpose of computer system validation and of which computer systems require validation. This means descriptions of functions, performances and When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended Validation Process. There are four life cycle phases of a computer system WHAT IS CS/ PLC VALIDATION. The purpose of the validation process is to provide a high degree of assurance that a specific process (or in this case computer system) will consistently produce a product (control information or data) which meets predetermined specifications and quality attributes It provides a suitable approach to compliance with all types of computer systems, according to national and international regulations; based on the guidelines established in the GAMP®Guide ISPE, providing an understanding of the logics of work, definition of scope, and selection of the validation strategy that best suits the system to validate A validated system ensures accurate results and reduces any risks to data integrity. The next section presents a working definition of computer systems validation by examining the work of R.C. Branning. A subsequent section describes the validation life cycle approach to computer systems A subsequent section describes the validation life cycle approach to computer systems validation consistent quality. The next section precise and detailed description of each of the essential requirements for the computer system and external interfaces. The range of activities required to validate a computerized system is determined by its GAMPsoftware and hardware categorization, GxP impact, applicable electronic records and electronic signatures requirements, data integrity, and its risk-based lifecycle approach. The same principles are applied in computer system validation to a computer system or an information technology system. Through this Computer Systems Validation (CSV) is a procedure used to secure (and document) that a computer based systems will produce information or data that meet a synchronize According to both American FDA and UK MHRA, computer system validation is defined as "Confirmation by examination and provision of objective evidence that software This section also provides a general overview of the purpose of computer system validation and of which computer systems require validation. This document applies to all types of computerised systems used in OMCLs. However, depending on their complexity, the extent of testing and documentation will differ. The next section presents a working definition of computer systems validation by examining the work of R.C. Branning. Computer system validation checks the effectiveness and the efficiency Computer Systems Validation (CSV) is a process used to ensure (and document) that a computer based systems will produce information or data that meet a set of defined requirements. Computerized Systems Validation is the documented proof enabling to conclude with a high degree of assurance that a computerized system operates as defined in its The components of a computer system which can cause failure or unexpected behavior, and which represent the real reasons for computer system validation, are discussed in An industry shift in validation practices is happening, as Life Sciences clients' successfully embrace a 'risk-based Computer Systems Validation (CSV) approach'. It's important to maintain quality standards in pharma since non-conformance can have far-reaching consequences.