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organizations, such as 21 CFR Part 11 of the FDA or EU GMP Guide Annex 11. This manual describes what is required from the pharmaceutical, regulatory viewpoint (in short: GMP environment), of the computer system, the software and the procedure for configuring

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GMP standard as a foundation for food safety management It is possible to control many of the potential hazards in a processing plant by using a standard set of principles and hygienic practices for the manufacturing and handling of food to manage food safety. These standard principles and practices are called good manufacturing practices (GMPs). They are sanitary and processing requirements ...

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Storage of critical records (e.g., GMP relevant must be secure, with limited access only for authorised persons. The storage location must ensure adequate protection from loss, destruction or falsification, and from damage due to fire, water, etc. Records which are critical to regulatory compliance, or to support essential business activities can be duplicated on paper, microfilm or ...

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The Good Manufacturing Practices (GMP) are defined in a multitude of laws, guidelines and guidance documents. In our series of GMP manuals and publications you will find compilations of the most important regulations, checklists and analyses on the GMP-compliant manufacture of medicinal products and active pharmaceutical ingredients.

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LOGO: GMP Manual (Based on cGMP requirements according to AO 153). Our Company Street Address City, State Country Postal Code. Page 1 of 18 Scope Write a paragraph here to clearly identify the scope of your system. Include the products, product categories, processes and production sites that are included in your system.. Normative References Administrative Order 153 issued by FDA.

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GMP manuals - GMP publications. GMP manuals offer the possibility to get detailed information about GMP requirements and their implementation. The most important GMP regulations of the US FDA and the EU should be readily available to anyone working in the GMP environment. For this reason, the FDA's cGMP Guide and the EU GMP Guide can be ordered as printed editions. You can order the GMP ...

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GMP documents, the WHO GMP guidelines (ref 27) present the principles of QA are to ensure that GMP and other regulatory codes (GLP - Good Laboratory Practice, and GCP - Good Clinical Practice) are respected; that responsibilities are clearly speci-fied; all testing, controls, calibrations, validations, etc are performed as specified; that products are not sold before the correct authorizations ...

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Good Manufacturing Practice (GMP) and Hazard Analysis and Critical Control Points (HACCP) are both systems intended to ensure the safety of food, chemicals and pharmaceuticals. GMP is the " first step " to food safety, as a series of principles to be fulfilled to ensure that products meet legal prerequisites for safety and quality. It can be one of the components of HACCP, which is a ...

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