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Role of 'c' in cGMP

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GMP is referred to as cGMP mostly in United States of America. The 'c' stands for current, reminding manufacturers that they must Gemploy technologies and systems which are up-to-date in order to comply with the regulation. Any company employs cGMP indicates that they are following 21 CFR 210 and 211 and no other. The cGMP regulations for drug contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of drug products. The regulations make sure that a product is safe for use and that it has the ingredient and strength it claims to have. The good manufacturing practices which were considered 10 years ago are not relevant today. Time and process have changed. Industry has to upgrade the GMP level in current context. What is good today may not be relevant after 10 years. Hence, emphasis is on word "current". GMP has to be updated time to time in order to comply with the standard guidelines. The upgradation of various facilities in manufacturing area with better environment control is required from time to time. In the quality control laboratory, HPLC, GC and other instruments are to be upgraded. As per the current guidelines, we need to have a procedure for backup, restoration and archival of the electronic data inside the instruments. With changing geographies and temperature, i.e., environment conditions across the globe which may be attributed mainly because of the global warming, it is imperative to change the stability conditions, as per the current WHO guidelines, from 25 oC/60% RH to 30 oC/75% or 30 oC/65% in almost all the countries of Asia Pacific and Africa continent.

Biography

Abha Doshi is a Principal of MET Institute of Pharmacy, Mumbai, India. She has 20 years of teaching and administrative experience and 3 year of industrial experience in production in Ranbaxy Laboratories Ltd. She has guided many MPharm students and presented research work in various national and international conferences. She has published many research articles in national and international journals.

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