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Defining the “c” in cGMPs

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“if it is a drug and the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice.” However, the question of “what is current” is often open for debate and constantly evolving as exemplified by the number of documents issued over the last few years by the Food and Drug Administration (FDA). Documents issued by such organizations as the International Conference on Harmonization (ICH) aimed at harmonizing the various worldwide regulations...