Good Manufacturing Practices—Steps to Improve Quality

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1 GOOD MANUFACTURING PRACTICES: GOOD BUSINESS PRACTICES

With the advent of Current Good Manufacturing Practices (CGMP) in 1978 (1) came a major shift in the way the Food and Drug Administration (FDA) enforces drug quality in the pharmaceutical industry. Simply stated, the quality of a product is no longer determined by the results of end-product tests alone. It must also be documented that product has been manufactured, packaged, and held according to the written procedures that comply with CGMP regulations.

In fact, the Food, Drug, and Cosmetic Act goes so far as to say that a drug product shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices (2). Therefore, regardless whether a drug product is materially defective, deviations from CGMP regulations cause drug products to be adulterated within the meaning of the Act, and violative articles are subject to seizure and condemnation in district courts.

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