

Are the use of ditto marks and arrows for redundant information acceptable practices under CGMP for documentation?

In September, 2000 the FDA published Human Drug CGMP Notes (Volume 8, Number 3) and explained their position on this question.

Reference: 21 CFR Part 211, Subpart J, Records and Reports

No. While there is no specific FDA documentation or guidance that discusses the practice of using ditto marks and arrows in place of required information, the use of these instead of serial numbers, dates, test results, initials, or signatures is not fully informative. Ditto marks and arrows are not sufficiently descriptive where actual values are needed, and more importantly, cannot be directly related to the recorder.

Warning Letter Example:

This is an excerpt from an actual warning letter issued by the FDA.

“Batch production records are incomplete and fail to document that each significant step in the manufacturing operation was completed. For example, unique lot numbers are not assigned to filled cylinders of compressed medical Oxygen USP produced from each uninterrupted filling sequence, ditto marks are used to record information in lieu of actual data for pressure, temperature and purity, test results for purity are repeatedly recorded as 100%, and there is no documentation the batch records are reviewed by a supervisor prior to release for distribution.”