

## **Inspections, Compliance, Enforcement, and Criminal Investigations**

### **CPG Sec. 425.500 Computerized Drug Processing; Identification of "Persons" on Batch Production and Control Records (CPG 7132a.08)**

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#### **BACKGROUND:**

Section 211.188(b)(11) of the Current Good Manufacturing Practice Regulations requires that batch production and control records include documentation that each significant step in the manufacture, processing, packing, or holding of a batch was accomplished, including identification of the persons performing, directly supervising or checking each significant step in the operation.

Questions have been raised as to acceptable ways of complying with this requirement when the "person" performing, supervising or checking each step is, in fact, not a human being, but rather an automated piece of equipment, such as a computer system.

The intent of the regulation is to assure that each significant step in a process was, in fact, performed properly and that there is some record to show this. It is quite possible that a computerized system can achieve the same or higher degree of assurance. In this case it may not be necessary to specifically record the checks made on each of a series of steps in the production of the product.

#### **POLICY:**

When the significant steps in the manufacturing, processing, packing or holding of a batch are performed, supervised or checked by a computerized system an acceptable means of complying with the identification requirements of 21 CFR 211.188(b)(11) would consist of conformance to all of the following:

1. Documentation that the computer program controlling step execution contains adequate checks, and documentation of the performance of the program itself.
2. Validation of the performance of the computer program controlling the execution of the steps.
3. Recording specific checks in batch production and control records of the initial step, any branching steps and the final step.

NOTE: In assessing how well a computer system checks a process step it is necessary to demonstrate that the computer system examines the same conditions that a human being would look for, and that the degree of accuracy in the examination is at least equivalent.

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