Inspections, Compliance, Enforcement, and Criminal Investigations

CPG Sec. 425.100 Computerized Drug Processing; CGMP Applicability to Hardware and Software (CPG 7132a.17)

Sec. 425.100 Computerized Drug Processing; CGMP Applicability To Hardware and Software* (CPG 7132a.11)

BACKGROUND:

The use of computers in the production and control of drug products is quickly increasing. Questions have been raised as to the applicability of various sections of the Current Good Manufacturing Practice Regulations to the physical devices (hardware) which constitute the computer systems and to the instructions (software) which make them function.

POLICY:

Where a computer system is performing a function covered by the CGMP regulations then, in general, hardware will be regarded as equipment and applications software1 will be regarded as records. The kind of record (e.g., standard operating procedure, master production record) that the software constitutes and the kind of equipment (e.g., process controller, laboratory instrument) that the hardware constitutes will be governed by how the hardware and software are used in the manufacture, processing, packing, or holding of the drug product. Their exact use will then be used to determine and apply the appropriate sections of the regulations that address equipment and records.

1Applications software consists of programs written to specified user requirements for the purpose of performing a designated task such as process control, laboratory analyses, and acquisition/processing/storage of information required by the CGMP regulations.

Material between asterisks is new or revised

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