Pharma Change Control

Strategies for Successful Company-Wide Implementation

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Principles of Change Control

As a rule, before a company can manufacture a drug, it must first gain approval from the appropriate federal agency to make sure it meets quality, efficacy and safety requirements.

But in order to follow Good Manufacturing Practices (GMP), manufacturers must comply with numerous requirements. Firms must document instructions for manufacture and quality control procedures. They must specify materials needed and define the basic conditions required for a reproducible quality, such as suitable rooms, qualified facilities, trained personnel and type of documentation (See Figure 1).

Before a company can implement these requirements, it needs a regulatory body to review their suitability for the intended purpose. In the theoretical approval model, regulatory authorities carry out the review as part of an authorization procedure. If approved, applicants receive a notice that the product is suitable and authorized for use. Pharmaceutical manufacturing companies must prove the suitability of apparatus/facilities and procedures with qualification/validation. In these cases, someone responsible must sign the qualification/validation report confirming suitability and authorization for use.

The principle that companies must adhere to suitable requirements is not only valid the first time a drug is manufactured or the first time a facility follows a procedure. They must follow and adhere to these requirements throughout the whole history of a drug or procedure.

Just as firms must document the entire batch history, they must also document requirements, such as written specifications for materials or directions for procedures. Firms must also document each change control for the requirements.

As a result of scientific/technical development, changes to the legal basic conditions, or business restraints, manufacturers typically have to redefine, modify, enhance, or cancel requirements again and again in practice. In turn, this change to previously approved requirements requires a review and authorization procedure to keep the system in its original state of proven suitability. This is the task of the change control.