

## **Summary - Critical Process Parameters for Drug Product**

Guidance for evaluating a process to identify and define the critical process parameters.

A methodical approach should be taken to determining and defining critical process parameters.

A flowchart of the process and a list of the critical quality attributes (CQA) are useful tools for identifying and assessing the parameters of the process. An understanding of the concept and relationship between normal operating range (NOR) and proven acceptable range (PAR) is necessary in establishing the range for a critical process parameter.

### **Critical Quality Attributes and Critical Process Parameters**

The critical quality attributes must be defined prior to assessing the manufacturing process for critical parameters.

### **Method of Defining Critical Process Parameters**

Certain steps of the manufacturing process will affect the CQAs. A critical step may have one or more critical process parameters (CPP).

Alternatively, a critical step may not have any critical process parameters if it can be established that the parameter(s) in question has a NOR that is strictly controlled well-within the PAR.

One way of determining what is a critical process parameter is to begin with the CQAs. The degree of control over the parameter will determine if it is critical. It is possible to have a critical step that does not contain any critical parameters if control of process parameters is tight. The step is critical but complete control over the parameters leads to defined noncritical process parameters. Critical parameters identified during the research and development phase are not necessarily reflective of production scale equipment.

### **Defining Ranges for Critical Process Parameters**

An understanding of each parameter is necessary before defining a parameter as critical. Parameters may be defined as critical depending on their effect on critical quality attributes, ability to be controlled, and the process design and capability. While knowledge of PAR values for a given parameter is important information for determining critical process parameters, it is the NOR that is used during process validation. Process validation requires equipment qualification and process data that supports the ability to control the process within the NOR, at a minimum.

Evaluate every possible combination of manufacturing process parameters. Instead, it is of the most benefit to document a thorough understanding of the process and the process parameters.

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