Summary - Evaluation of Changes for Potential Impact on Process Validation

This guidance applies to validated processes and identifies examples of changes for which examining the validation impact of a change should be considered. This evaluation should include assessment of the validation impact of the change. Major changes require validation, while documented evaluation of minor changes are typically documented using the site change management system.

Evaluating proposed changes to a process shall include a documented assessment of the validation impact of proposed changes. Assessment of the validation impact of minor changes is typically documented using the site's change management work process.

Every proposed change should be assessed to determine the potential impact of the change and to consider the potential impact to product quality from the adopted change.

Evaluation of the quality impact of the change should take place as close as practical to the step in the process where the change was made. The system owner or Technical Services may typically propose the change and should participate in assessing the impact of the change. The Quality organization must be included in approval of the assessment of impact of the change to a validated process.

Types of Major Changes and Points to Consider with this Change

Type of Major Change	Points to consider with this change
A change to the API or DP manufacturing process or technology, such as: • Change in critical unit operations (e.g., addition, deletion, change in order of steps, repetition of an existing unit operation on a routine basis); • Change of source or specification of a critical material (e.g., regulatory intermediate or API starting material); • Modified operating conditions (e.g.time, temperature, pH, reagent stoichiometry) that impact CQAs; • Change that could impact acceptable microbiological quality of the product.	Validation of part or all of process is recommended. Process validation is needed if a change in the process is expected to have measurable impact on product quality or process performance, as determined by risk assessment. Is the change supported by data from a development lab? Is the process still capable of providing good quality product if a material specification is relaxed? Tightening of a specification may not require validation as this will typically not challenge the capability of the process. Is stability of API or DP affected? See also example 1 in the text.

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