

Quality by Design Scope of Work Tool

Background Information

1. Why is the experimental study being performed?
 - a. What question is to be answered by the study?
 - b. Why is this question important within the context of the overall research program?
2. What is the dosage form (liquid, solid, ointment/cream, liquid-filled gel cap, liquid-filled hard cap, other)?

Experimental Factors

1. What are the experimental factors (inputs) that are proposed for this study (e.g., API characteristics, time, temperature, ingredient ratios, mixing, concentration, equipment, etc.)?
2. What is currently known about these factors?
 - a. What are the current setpoints for these factors?
 - b. What are the proven acceptable ranges for these factors?
 - c. What setpoint values have resulted in failures? What specific process or product attribute failures were observed in these cases?
3. What is known about the effect of moisture upon the process / product?

Experimental Responses

1. What are the experimental responses (outputs) that are proposed for this study (e.g., blend uniformity, flowability, compressibility/hardness, friability, dissolution, assay, chromatographic purity, related impurity levels, total impurities, yield, stability, labor and material costs, etc.)?
2. Are there product-specific requirements that require assessment in this study (e.g., active extractability, tamper resistance, light sensitivity, etc.)?
 - a. What measurements are being performed to assess these responses?
 - b. What is the inherent variability in the measurement of the response(s)?

Resolution

1. What level of resolution is required in the study?
 - a. Critical Process Parameter Screening Level (Resolution III, estimation of main effects, identification of confounded two-way interactions)

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- b. Process Design Space Level (Resolution IV, estimation of main effects, and all two-way interactions)
- c. Process Optimization Level (Resolution V, estimation of all main effects, interactions, and a detailed assessment of the response surface within the design space)

Timeline and Budget

1. What is the timeline for completion of the study?
2. How long does each individual run take to perform?
3. What is the overall budget for performing this work?