Quality by Design Scope of Work Tool For

Analytical HPLC Method Development

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 are the known vulnerabilities of the analytical method?

Experimental Factors

1. What are the experimental factors (inputs) that are proposed for this study (e.g., column type, solvent composition, flow rate, injection volume, analyte concentration, run time, gradient profile, column compartment temperature, sample prep hold time, etc.)?
2. What is currently known about these factors?
    a. What are the current settings for these factors?
    b. What setpoint values have resulted in failures? What specific failures were observed in these cases?

Experimental Responses

1. What are the experimental responses (outputs) that are proposed for this study (e.g., precision, accuracy, linearity, specificity/resolution, column stability, etc.)?
2. What is the acceptable level of variability in these response(s)?

Resolution

1. What level of resolution is required in the study?
    a. Critical Parameter Screening Level (Resolution III, estimation of main effects, identification of confounded two-way interactions)
    b. Method Design Space Level (Resolution IV, estimation of main effects, and all two-way interactions)
    c. Method 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

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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?