

Implementing QbD into design of experiment methods and predictive modeling algorithms yield insight in a fraction of time, energy and material.

By the numbers

- Process characterization experiments were cut significantly from 70-80 to only 17
- Execution timeframe in months was shortened from 6 to only 1
- Studied 57 parameters, including third-order terms, instead of only 12 first-order and second-order terms

Background

The client is a contract manufacturing organization (CMO) developing a formulation process. The CMO's customer was a major pharmaceutical company.

The Challenge

In the early stages of the client's product development project for its customer, fast access to reliable quantities of material for preclinical and first clinical trials were vital for the business requirements and patients' needs. This required characterizing their manufacturing process. Typically, process characterization was completed in two steps. First, a screening design was completed to identify the most important factors. Second, a response surface model was built to identify precise targets and boundaries for optimal process performance. This conventional approach required too many experiments and risked not meeting objectives on time.

The Solution

We recommended that the client adopt modern predictive modelling techniques, including Model Averaging, ensemble models, and Auto-Validation, coupled with a superior screening design, which required only 17 runs. This approach enabled the client to get a more holistic perspective of its process characterization and was much less costly to execute.



Gain reliable insight on 57 effects, including higher-order terms, in only 17 runs from the expected 70 runs. The CMO's customer was impressed with the swift completion of the project, cost-effectiveness and the results.

The Benefit

The client gained reliable insights into its modernized process characterization, specifically 57 effects, including higher-order terms, in 17 runs. A classical DOE approach would have required at least 70 runs. The project was completed in less than one month, and well under budget. Confirmation trials proved that the predicted optimal settings were very effective. The CMO's customer was impressed by the project's swift completion, cost-effectiveness, and the noticeable results.

 **The Challenge**
Conventional experimental methods extended the time and costs

 **The Solution**
Coupling advanced DOE methods with the latest predictive modelling techniques

 **The Benefit**
Rapid development of a reliable manufacturing process in a fraction of the expected time and cost

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