

# Comprehensive DoE capabilities for Synthesis, Process Development and Manufacturing of Novel Chemical Entities (NCE's)



Consistency



Better Yield



Reduced Cost



Shorter Time



Experienced Team

The Design of Experiments (DoE) methodology integrates mathematical and statistical techniques to create efficient, balanced, and cost-effective experimental designs. These designs enable researchers to discern the relationship between controlled and uncontrolled factors and process outputs. Applied across product/process design, development and manufacturing processes, DoE is a potent tool for optimizing processes, enhancing product quality, and enhancing efficiency during scale-up and large-scale manufacturing.

Aragen has a dedicated scientific team for conducting the design of experiments for all client projects related to discovery chemistry, process research, development, chemical development solutions, as well as chemical manufacturing solutions for synthesizing, scaling-up, and manufacturing novel chemical entities, including pharmaceutical candidates, fine chemicals, specialty chemicals, APIs, and biological products. Our DoE experts have designed efficient strategies to provide higher yields within short turnaround time and lower expenses.

## Advantages of DoE

- Changing multiple factors at the same time to study the impact using less number of experiments.
- Provides accurate information to design and develop new processes and products, thus minimizing the time and resource requirements.
- Deriving an understanding of multiple factors interaction unlike OFAT study where one factor interaction is studied.
- Enhancing product and process robustness.
- Helps to understand possible variabilities and reducing process.
- To avoid fluctuations or variability.
- Maximizing quality and profitability of product.

## Capabilities

- Advanced DOE software 'MODDE® 13.0.2' and 'Design of expert 10.0.3.1' in use.
- Optimization of an existing process.
- Document support post DOE study for regulatory filling.
- FTE collaboration for DOE based process developments programs.
- Dedicated Team of Experts.
- Project management support to ensure seamless execution.

## Key Highlights

- Strategic approach towards DOE process optimization for GMP & process validation programs.
- Proven track record in technical problem-solving in synthesis of regulatory starting & API molecule for leading global pharma companies.
- Controlled chiral purity & critical specified impurity.
- Identification of critical process parameter like pH and equivalent of reagent which shows significant impact on purity of API.
- Checked robustness of the process in many GMP and API projects.
- Developed the analytical methods using AQbD which involves DOE.
- Validated the analytical methods using design space.
- Handled products from milligram to multi kilogram scale.

Let's begin the conversation

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