# Rapid optimisation of a new process in pharmaceutical manufacturing

# Challenge

Britest

Pfizer Ireland needed to deliver a new 2nd generation Active Pharmaceutical Ingredient (API) process for an existing product, based on novel chemistry, and including a biocatalytic step.

Key targets were: reduced product cost, increased throughput, reduced process footprint, and maintenance of API quality.

The new process had to be delivered to very tight timelines, requiring an efficient experimental plan that delivered maximum value.

The team decided that a structured approach using the Britest toolkit was the best way to ensure optimisation of the new process.

# Approach

An experienced Britest technical facilitator worked with the client to deliver a tailored process insight study over two 2day sessions spanning one month. The first session was cofacilitated by Britest, the second entirely in-house, and participants were targeted to get input from across Pfizer globally.

The Britest toolkit was used to identify priorities for process improvement, build process understanding, build a prioritized experimental plan, and develop a novel analytical strategy.

# Benefits

- Knowledge gaps identified and next steps agreed
- Rapid and effective experimental prioritisation 15 key experiments selected from 100 possibilities
- Support with facilitation helped to build rapid understanding of process across the technical team
- Increased corporate understanding on how to apply Britest to a biocatalytic process
- Rapid improvements in yield led to a process that met targets for reduced plant footprint and increased throughput

The Britest approach helped us spot our knowledge gaps and prioritize the experiments needed to plug them.

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Generating value from process understanding



## Client - Pfizer Inc.

#### Industry - Application Area

Active Pharmaceutical Ingredient (API) manufacturing, process improvement

## Challenge

Rapid implementation of a new biocatalytic process in high value operations

## Solution

Tailored Britest process understanding study and technical facilitation with global participation

## Outcomes

Experimental prioritisation - 15 key experiments from 100 possibilities. New process delivering required increased throughput of in-spec product





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