

# Continuous Manufacturing: Development, Optimization and Validation

## Challenge



Client lacks strategy for Continuous Manufacturing within QbD principles

- Client lacks experimental strategy to develop, optimize and validate a new Continuous Manufacturing (CM) process in Quality by Design (QbD) framework

## Solution



Phased approach to define design, validation and verification processes

- Proposed a phased approach to gain knowledge on the CM critical process parameters raw materials over the quality attributes
- Defined appropriate designs of experiment and correct CM process design space
- Proposed appropriate sampling plan for process validation
- Recommended strategies for continued process verification

## Outcome



Authorities granted Marketing Authorization for the first continuous manufacturing process

- All tasks delivered within defined time frame
- Marketing Authorization was first implemented in the pharma industry