Britest Problem Solving through Process Understanding—Particle Coating for Controlled Release

Challenge

Controlled release drug capsules are filled with coated spheroids, which in turn contain the active pharmaceutical and other ingredients. After transferring the process to new manufacturing equipment, Quality Control personnel at a major pharmaceutical manufacturing business found a change in the rate of release of the active pharmaceutical and needed to understand the reasons for this variation.

Approach

Britest facilitators applied the Britest toolkit to analyse both the spheroid coating process and the physical processes taking place during drug release. This included; a detailed description of the sequence of tasks and intermediate states encountered when transforming starting materials into products; information-rich visualisations of the release process at different size scales and over time; and key information capture and analysis related to balancing parallel rate processes during application.

By identifying key product performance criteria and relating these to the behaviour of the coating process and equipment, potentially crucial process parameters identified were subsequently confirmed through targeted experimentation. The understanding gained enabled the client to identify the root cause of the issue and make minor engineering modifications that returned the product to its previous behaviour.

Benefits

- Problem solving energy and effort focused on key processes and equipment
- New understanding rapidly identified root cause
- Release response in product successfully returned to target profile
- Costs of poor quality avoided
- Operational advantages of ability to produce on new equipment secured

By rooting team thinking in fundamental chemical and physical processes and engineering principles, Britest lets problem solvers move beyond addressing symptoms into understanding and controlling underlying root causes.

Key Features:

Customer

Major pharmaceutical manufacturer

Industry - Application Area

Pharmaceuticals – process/product quality problem solving

Challenge

Change in product quality upon transfer to new manufacturing equipment.

Solution

Britest study of critical production and performance processes to inform improved process control strategy

Outcomes

Product successfully returned to target profile after minor engineering modifications to equipment Poor quality costs avoided and operational advantages of new equipment secured.

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Generating value from process understanding