

# SOLVED WITH

VISION & PRECISION

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## Continuous manufacturing: The alternative to batch manufacturing

The pharmaceutical industry is facing increasing pressures on quality, pricing and productivity. The traditional batch method of manufacturing oral solid dose medications has limited scope to address these needs. Thermo Fisher Scientific offers a new alternative to batch manufacturing.

Continuous manufacturing can deliver higher quality oral solid dose products, with greater flexibility and a reduced total cost of supply.

### A new paradigm in manufacturing oral solid dose products

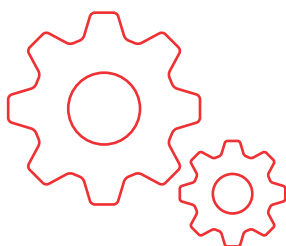
Continuous manufacturing represents a new paradigm in manufacturing oral solid dose products. In a continuous manufacturing process, products are produced via an integrated series of modular unit operations. The raw materials are fed into the process and converted into the oral solid dose product at a continuous rate without interruption.

In continuous manufacturing, the equipment is smaller compared to a batch process producing the same product, yielding operational and running efficiencies. The equipment used to manufacture the product during development phases is also used to manufacture the product commercially. This eliminates the need for expensive scale up studies and dramatically simplifies process validation, whilst reducing the amount of API

required during development. Real time monitoring and the high level of automation of continuous manufacturing equipment enables a steady state of control. Therefore, continuous manufacturing processes can produce more consistent, high-quality products, with excellent productivity and an inherent Quality-by-Design (QbD) approach to manufacturing.

Continuous manufacturing is a very flexible method for manufacturing oral solid dose products, as output is adjusted by simply changing the duration of the process. An upsurge in product demand can therefore be reacted to quickly, thus reducing the risk of drug shortages.

Our experts at Thermo Fisher Scientific can help you take advantage of the numerous benefits of continuous manufacturing for your oral solid dose product. They can quickly technically assess the probable suitability of your product for the continuous manufacturing method.



## Why continuous manufacturing?

- **Minimize API requirements during development**

Process development studies are smaller and require less API.

Scale up studies are not required.

- **Shorter development timeline**

Continuous real time monitoring and feedback control allows for easier optimization of processing parameters.

- **Improve quality and consistency of products**

The steady state of control achieved by the automated process results in the production of a consistent, high quality product.

- **Respond rapidly to changes in market demand**

The flexibility of the processes allows for a quick reaction to an upsurge in product demand, reducing shortage risks.

- **Reduce total cost of supply**

Achieve total cost of supply benefits as a result of increased speed to clinic or market, lower cost of quality, elimination of scale up activities, reduction of API use, and reduction of inventory due to flexible batch sizes.

## Continuous manufacturing programs

- **Proof of concept**

A series of studies to determine the feasibility of continuous manufacturing.

- **Clinical trial supplies**

Develop the process and manufacture the materials required for your clinical trials.

No scale up studies required for commercial scale manufacturing and simplified process validation.

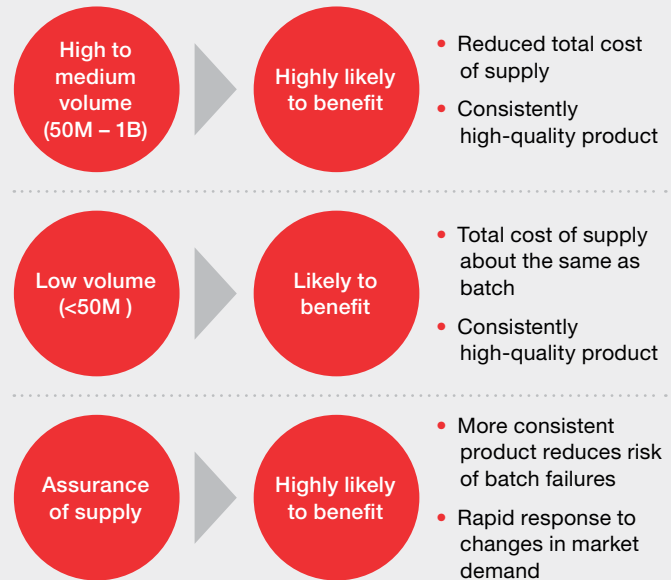
- **Commercial supply**

Develop the process for commercial manufacture.

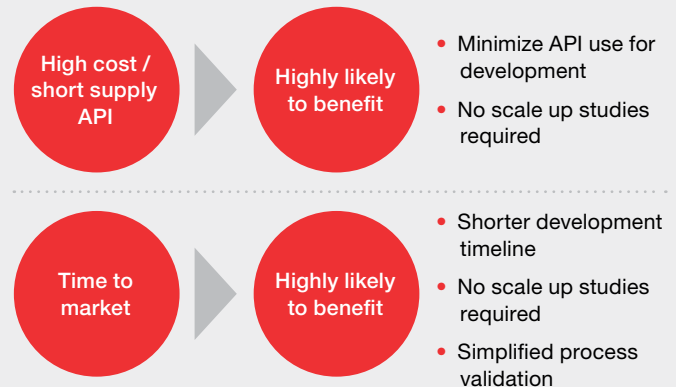
Meet market demand with flexibility.

## Deciding if you will benefit from continuous manufacturing

### Commercial Supply



### Development Programs (Phase II / III)



Contact us to discuss the advantages of continuous manufacturing for your oral solid dose product.