

# The future of continuous manufacturing in pharma

Batch processing has been the standard manufacturing method used by the pharma industry for the last 50 years. But recent advances in manufacturing technology have resulted in a faster, more efficient process known as continuous manufacturing. How do the two processes compare? Is pharma ready for widespread adoption?



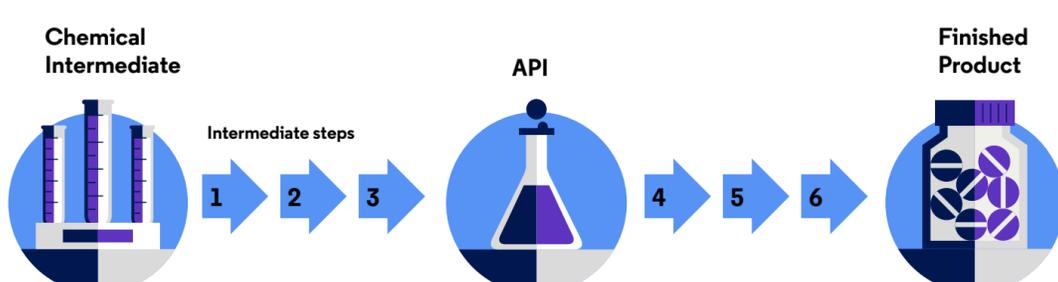
**“One of today’s most important tools for modernizing the pharmaceutical industry is a process known as continuous manufacturing.”**

**Scott Gottlieb, M.D., Former FDA Commissioner & Janet Woodcock, M.D., Director of Center for Drug Evaluation and Research**

## How does each process differ?

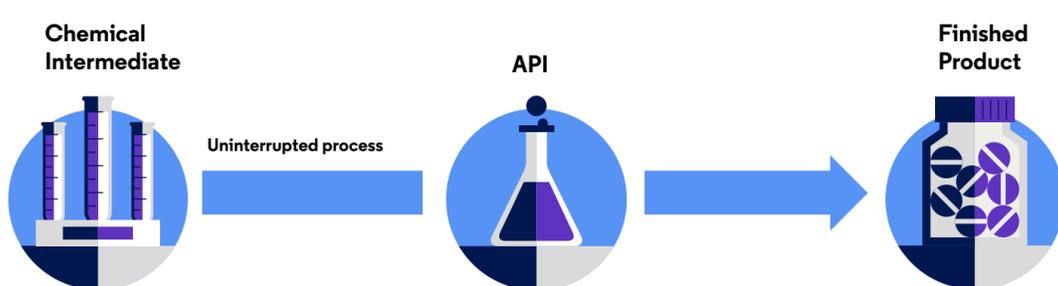
### Batch processing

Involves multiple discrete steps



### Continuous manufacturing

Is an uninterrupted process



## Pros and cons of batch processing and continuous manufacturing

### Batch processing

- ✔ Relatively **low set-up costs**
- ✔ **Easily tailor each batch** to be unique
- ✔ **Some flexibility** if additional product capacity is required
- ✘ **Accommodates certain drugs** that can only be manufactured in batches
- ✘ **Dependency on completion of previous step** for next step to begin
- ✘ **Hold times** between steps for offline quality testing
- ✘ Hold times and transportation - **takes months**
- ✘ Large-scale equipment, **larger footprint**
- ✘ **Multiple sites** in multiple regions
- ✘ **Risk of degradation** — product waste?
- ✘ **Multiple touch points** during the manufacturing process

### Continuous manufacturing

- ✔ **Nonstop, efficient**, high-throughput manufacturing
- ✔ **Doesn’t have the stop times to allow for chemical reactions**, when needed
- ✔ **Greater ability to respond to market changes**, with longer or shorter runs
- ✔ **No hold times**
- ✔ **Faster** — takes days
- ✔ **Smaller footprint**, reduced energy needs
- ✔ **One site**
- ✔ **Reduced opportunity for contamination** and product waste
- ✔ **Reduced risk** of human error
- ✘ Relatively **high initial investment**
- ✘ **One drug only** per manufacturing run

## Is continuous manufacturing worth the investment?



Has potential to improve product quality and ensure consistency



Addresses many underlying causes of drug shortages and recalls



Detects issues before a failure occurs through automated monitoring

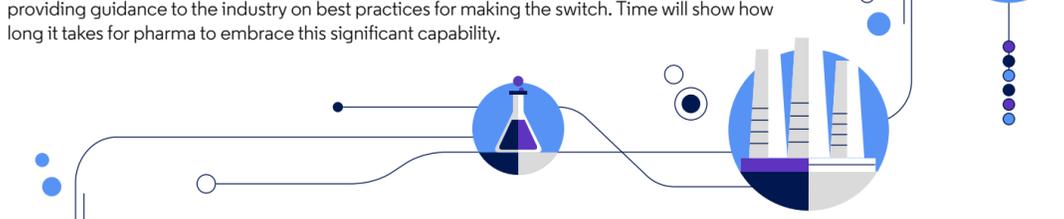


Reduces waste since smaller amounts of defective reagents can be isolated

## Modernizing the manufacturing process to bring treatments to patients

Continuous manufacturing clearly meets the industry’s demands for consistently made products, faster product development, reduced costs and increased manufacturing flexibility.

Although this approach is new, regulatory authorities see its value and have made progress in providing guidance to the industry on best practices for making the switch. Time will show how long it takes for pharma to embrace this significant capability.



**“Continuous manufacturing helps to ensure consistently-made products, allows manufacturers to more easily scale their manufacturing operations to meet demand, and can help reduce drug shortages.”**

**Scott Gottlieb, M.D., Former FDA Commissioner & Janet Woodcock, M.D., Director of Center for Drug Evaluation and Research**

## Be ready for the adoption of continuous manufacturing and draft guidance by regulatory authorities.

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