

Continuous manufacturing (CM): A game changer for pharma

Why will CM be the next generation on quality?

Batch processes have quality traps because with batch processing, you check the quality after you have finished a batch. Imagine that you have made several batches and, only after they are all done, you realise some of them don't meet the required specifications. That is a problem, because you have to toss out entire batches.

In continuous manufacturing (CM), it is a whole different ball game. You can identify or even predict issues with product quality while the process is ongoing. If there is a problem, you can fix it in real time, and you won't end up throwing away whole batches.

In batch processes, there is also this assumption that raw materials and APIs stay the same throughout production. But what if there are tiny, unnoticed variations in your materials that can affect the final product's quality? Batch processes may miss these issues, but CM keeps an eye on everything, constantly measuring and adjusting.

Early adopters of CM can dominate the market once the original drug goes off-patent. That is a compelling incentive for generics companies. Moreover, generic products regularly grapple with quality issues, like variations in particle size distribution or challenges in converting products efficiently. CM can be their problem-solver. It lets them focus on improving these aspects of quality, making their products more competitive.

For the large innovator pharmaceutical companies with a broad range of products, CM streamlines tech transfers.

You can have the same equipment for R&D and commercial manufacturing, so transferring technology is a piece of cake. It is quick, easy and cost-effective.

Speed to market is a big deal for them too, but the third and crucial benefit for innovators is reputation. With CM there is less waste, and less water and energy consumption resulting in a lower CO2 footprint. Their reputation in the market shines even brighter.

So, it is about staying competitive, improving quality, speeding up the process, and maintaining a stellar reputation. These are the compelling reasons why different types of companies are making the shift to CM. It is the future of pharmaceutical production.

There is a perception that CM is a Western thing, but since the end of 2022, the Chinese government has given a clear message to their industry. At the start of that year, they said that they will support Chinese companies in adopting CM. In India, CM has been on the radar for a while, particularly in the API space. But now, it is shifting. They are slowly moving towards using CM for drug product manufacturing as well. It is like a turning point. And it is not just an Asian thing; this wave of CM adoption is happening globally. CM is becoming the new norm.

Reference:

<https://www.specchemonline.com/index.php/feature-article-cphi-expert-continuous-manufacturing-game-changer-pharma-worldwide>