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## Clinical packaging process overhaul cuts cycle time by 55%

**A blockbuster oncology drug showed great promise in new indications, but the pharmaceutical company marketing the drug did not have the capacity to supply the 125,000 vials per month that would be needed to support its new clinical trials.**

Having worked with the Thermo Fisher Scientific team in the past, the Sponsor's manufacturing director approached us with this capacity issue. At first glance, it was a tall order to fill. Historical data collected at our Allentown, PA, site revealed that it could produce an average of 420 kits with 5 vials each shift. At that speed, it would take about 20 days to meet demand. But with time built in for quality reviews, the jobs had to be done in 9 days.

With this challenge on their plate, the Thermo Fisher Scientific engineers launched a production overhaul using lean manufacturing techniques, probing the packaging operations to find efficiency. Working backwards from the target rate of 125,000 vials, they started with a line balancing analysis and found a way to save 6 seconds for every kit produced. This small improvement made a large impact when packaging hundreds of kits at maximum speed. It was the first efficiency gain in what became a cascade of production improvements.

### Collaboration pays dividends

The Sponsor's director identified a potential for additional savings when he learned the booklet labels coming from a third party were causing delays. Pages were falling out due to poor materials of construction. Working with our Clinical Label Services team, the booklets were replaced with robust single-panel labels. The single-panel design was sufficient because information contained in the booklets was part of the labeling for each individual kit.

Additional time savings were achieved by modifying a work instruction (with Sponsor QA approval). The line was stopping because in some cases, tamper seals were applied before running the kits through the barcode scanners. This caused a deviation and shut down the line. The operations managers devised a method to quickly reprocess the kits while maintaining quality. If the two job steps are run out of order the process can be corrected without creating a deviation.

## Small changes, large time savings

There were other small changes that yielded big efficiency gains.

Monitors were relocated ergonomically within the packaging room to let operators view results on the screen every time they scanned a new kit. Before this process improvement, they had to glance away from the line for a second. Reducing small motions created significant time savings over the entire packaging run.

The drug is a monoclonal antibody and must be refrigerated, but it can be packaged in an ambient environment. When operators removed the product from storage, it took one hour at room temperature before the vials were properly conditioned for packaging. To fix this issue, work instructions were created to condition vials before the start of every shift. Incoming operators were able start packaging right away instead of waiting an hour.

## The team made a dramatic impact, achieving the 9-day cycle time

The Thermo Fisher Scientific engineers are still pushing the envelope on this process and expect to reduce cycle time even further to create a truly lean operation that can supply the growing clinical demand for this medication.