Reclaiming Efficiency Amid Serialization Nightmares

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You *must* serialize if you are a pharmaceutical manufacturer or packager. You have no choice.

Each saleable unit of your product (think carton, tray and individual bottles) and homogeneous shipper (case) must be printed with a unique identifier. In a measure to curb drug counterfeiting, every product must be trackable and traceable from manufacturing to medicine cabinet. That is the rule. And, thanks to the U.S. FDA's recent one-year extension in enforcement of the Drug Supply Chain Security Act (DSCSA), the rule takes effect November 27, 2018.

As necessary as the law is, it almost certainly will affect your productivity: adding processes to any system rarely speeds it up at the outset. For some companies, serialization will be an inconvenience; for others, it will be a nightmare. But one strategy could help companies understand serialization-driven productivity loss, reclaim their accustomed level of performance and emerge from implementing serialization with better performance than ever—*overall equipment effectiveness.* (OEE)

OEE is a comprehensive measurement of line performance. It distills operations into a single metric that can be compared from one day to the next or from one shift to another. It is simplicity and clarity make it actionable.

Few companies really know their OEE number or track the variables that produce it. Like ROI, companies intuit whether it is good or bad rather than calculate it. There is value in quantifying it, however. When a company makes a major transformation, such as serializing production lines, the precise number gives you an objective baseline for improvement.

The beauty of OEE is its analytical power. It shows you where your most serious shortcomings are. It need not be complicated. In fact, it can be done with a pencil, paper and a stopwatch.

OEE = availability x performance x quality

OEE is a percentage—the higher the better—and it is easily calculated.

Availability is planned production time; for example, an eight-hour shift equates to 480 minutes. Subtract for worker breaks, say, two breaks of 15 minutes each and the per-shift availability comes to 450 minutes. If, on that shift, the company suffers 72 minutes of unscheduled downtime, the true availability is (450-72)/450, **or 84%.**

Performance is the actual rate versus the ideal run rate. Say, the ideal run rate is 60 cartons per minute; then the ideal production for that shift would be 22,680 cartons, 378 minutes of uptime. Instead, only 20,500 cartons are produced; so the actual performance rate is (20,500/378)/60, **or 90%.**

Quality is the share of saleable units versus the total number of units produced, including rejects. If 1,000 of the 20,500 cartons produced on the last shift were rejected, then the quality is (20,500-1000)/20,500, **or 95%.**

The OEE formula (**availability x performance x quality**) based on the situation described above is as follows: **84% x 90% x 95% = 72%**. The **OEE is 72%** out of a potential 100%.

Is that good? Well, it depends on the track record and complexity of the product. We have seen worse. Again, serialization adds processes that can slow down an operation. So where do we look to improve our OEE score? The first place would be the *availability* rating, since that metric is lowest of the three. *What caused the 72 minutes of downtime?* Address that, and the OEE will rise.

(Be careful, though. If materials are expensive, as they often are in pharma, the 5% of potential improvement on the quality metric (i.e., rejects) might be the biggest problem in the plant. But that is a bit of a curveball.)

OEE in Action

The best time to obtain an accurate OEE reading on a line is before turning on the serialization equipment. A baseline is important—preferably overall OEE, but at least OEE at the points certain to be affected by serialization.

Consider that with serialization, at a minimum, a serialized global trade item number (SGTIN) and a 2-D barcode with human readable characters are added onto each saleable unit. For parenteral drugs, each unit is a set of vials—perhaps five, ten, or maybe a tray of 25 or 50.

As a result, serialization problems are likely to crop up at the cartoning stage. One obvious pinchpoint is the creation of new labels or the redesign of existing labels, each of which will take time to print, probably even more than before. Changes may increase the risk of jamming, misprinting and otherwise failing in the printing, application and inspection phases. To minimize problems, take time prior to serializing to analyze labeling, measure it over a few shifts, and see how it varies from day to day.

Another potential inefficiency is in the packing phase. During a manual packing process, operators may have simply grabbed product off the end of the line and packed it into shippers. Serialization (if the business has decided to aggregate) requires them to scan each item barcode either with a hand scanner or fixed scanner. This adds time and potentially requires another full-time employee. And it adds complexity. If you a scan is missed, this means possibly spending half an hour pulling part and repacking a pallet.

OEE helps to analyze how the existing packing process and identify potential points of failure. Does the company require additional staff to scan? Or can the existing crew handle it? What are the equipment needs? Hand scanners are versatile but fixed scanners may be more robust.

Another potential cause of serialization slowdowns is new software required for serialization. Take a good look at the vendor’s support and the training level of internal staff. To be resilient requires the ability able rebound swiftly from any disruptions.

Before turning on serialization, do timed walkthroughs of pinchpoints like these to get a baseline OEE, i.e., a picture of the *before* condition. And when serialization is turned on, get a baseline of the

after condition. See how the OEE changes. Analyze the availability, performance and quality. Look at the biggest efficiency erosion factors first.

What OEE Can Find

The six big OEE losses that occur on pharmaceutical packaging lines are:

Availability Losses

- Equipment failure (unplanned stoppage or downtime): Is the company performing a lot of unplanned maintenance? Are replacement parts and packaging materials at the ready?
- Setup and adjustments: Is everything loaded properly? Are changeovers taking a long time?

Performance Losses

- Idling and minor stops: Are there frequent and annoying jams and/or misaligned sensors? Are workers taking mini-breaks between breaks?
- Reduced speed: Is equipment poorly maintained or outdated? Are packing materials out of spec?

Quality Losses

- Defects: Why are products being rejected at a certain rate? How can defects be minimized? For example, are rejects created every time the line is restarted?
- Reduced yield: Can activities that do not add value be eliminated? Is automation possible? Is there a way to reduce waste at start-up?

A positive outcome from this effort may be removing some issues that existed PRIOR to implementation of serialization. In other words, you may claw back some OEE gains that were not obvious before.

The People Factor

People are a flash point for serialization. As with any change, serialization can shock plant culture and it demands deliberate change management. People, not processes or equipment, are the agents of change. As manufacturing processes change to support serialization, expect to hear protests. *“We have always done it this way!”* Embrace the conversation. *“Yes, there is a reason we did it that way. There are also good reasons we are changing our ways. See if you agree.”*

To get good levels of adoption from employees, involve them early. Invite their insights. Often the person closest to the problem—an operator or technician—has a deeper understanding of the process than the supervisor or plant manager. Many plants have fostered change by monitoring and reporting OEE daily. Often companies create competitions between shifts. Top-performing shifts get pizza on the company, an extra-long break on Friday, or some other prize.

Equipment

Sometimes, however, the answer to better OEE lies in new equipment. One company saved $100,000 per line per year by replacing human product inspectors with machine vision. Performance and quality increased; there were fewer rejects and interruptions of the line. Customer satisfaction rates also improved, as did morale, as inspectors were reassigned to roles where they could have more success.

Another company dramatically improved OEE by installing a software solution to digitally measure OEE across each piece of equipment on each of several lines. Since most of the equipment was automated, the change was a matter of programming and installing sensors. The company could then record downtime, analyze downtime codes, and perform root cause analysis every week. *“What happened with line 7? What was going wrong? Team, here are the codes and their frequencies. And here is how we fix it.”*

Although the analysis is automated, human beings interpret and validate it. This large contract manufacturer saw operating costs plummet, uptime soar, throughput increase, and a 30% improvement in OEE across *13 lines.*

Conclusion

Serialization is important to the industry and the FDA, not to mention patients around the world. Although it can be viewed as a burden, it is one that can be turned into an asset. While there will probably be some performance loss at the outset of serialization, this can be mitigated. Scrutinize the likely pinchpoints, pick the lowest-hanging fruit first and continually improve.

OEE is a powerful tool for this analysis and improvement plan. Some will use it. Some will not Although companies must serialize to comply., a few will end up with a distinct competitive advantage through maximal efficiency.

About the Author

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