OEE and Product Inspection
Efficiency in the Pharmaceutical Industry

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1 Introduction

Few industries are as heavily regulated as the pharmaceutical industry, as poor quality or otherwise defective pharmaceutical products can potentially have fatal results for end users. In particular, governments across the world are focused on preventing the spread of counterfeit drugs and have developed requirements for serialization of individual pharmaceutical packaging as a result. It is also expected that demand for pharmaceuticals will continue to experience dramatic growth, courtesy of increased life-expectancy across the population.

This requires the installation of new equipment and software which adds complexity to the production process. At the same time, part living longer is a greater reliance on regular use of pharmaceuticals. Keeping pace with this increasing demand and complying with various government and industry standards for quality, traceability and safety is the new state of affairs for the modern pharmaceutical manufacturer.

These conditions mean that manufacturers must perform a careful balancing act: weighing pressure to improve production speeds against the need to ensure compliance with government regulations. Measuring the effect that a change to the production process has on the overall efficiency of the manufacturing process becomes a crucial component of making improvements or other alterations to the production line. This measurement is one of the uses of Overall Equipment Effectiveness (OEE), a method of obtaining a complete view of the efficiency of a production process.

The purpose of this white paper is to provide an overview of the various components that go into measuring OEE, and then to discuss the ways in which product inspection equipment can affect OEE in the pharmaceutical industry.
2 Defining and Calculating OEE

OEE is defined as the ratio of actual production output divided by maximum potential output. Any number of factors can change this number; understanding how these factors are categorized is the key to knowing what to focus on in order to improve a production line’s OEE score.

These factors are organized in three distinct categories: Availability, Performance and Quality. Each of these factors is used to calculate the final OEE score, meaning that a change in any of these categories will in result in a change in OEE. Understanding what goes into each of these factors will in turn help determine where changes to the production process can be made in order to improve.

2.1 Availability

Availability is the measurement of how often the system is up and running as expected. It is calculated by taking the ratio of actual versus scheduled production time. Actual production time includes both planned stops (i.e. for product changeovers or scheduled maintenance) and unplanned stops which are significant such as a system fault or failure (longer than a few minutes). These are subtracted from the planned production time in a given day. Planned production time is determined by subtracting Schedule Loss (time where production is not going to be running, such as staff breaks or shutdowns) from All Time (which is every minute of the day).

Planned stops, such as product changeovers, are not included in Schedule Loss because these times can fluctuate; a product changeover may take longer than originally planned, or a quick break for maintenance may take longer to resolve due to the discovery of a significant issue with production equipment. On the other hand, operating hours will rarely, if ever, fluctuate, making their addition into Schedule Loss more appropriate. Other events can be included into a company’s Schedule Loss if they so choose, but it is highly recommended to keep the number of events which are classified as Schedule Loss as low as possible. Schedule Loss should only be events which have a fixed duration which does not fluctuate.

2.2 Performance

Performance is calculated by taking the run time and taking away any time spent due to Performance Loss. Performance Loss is defined as anything that causes the manufacturing process to run at less than maximum speed, i.e. a system capable of producing 400 parts per minute (ppm) running at 350 ppm. Causes of Performance Loss generally involve product misfeeds, jams, or a need for equipment maintenance.

2.3 Quality

Quality measures the number of products produced minus the number of products which fail to meet quality standards. This includes scrap as well as parts which require rework. A “good” product is defined as a product which passes successfully through the production process the first time. As reworked parts must go through an additional series of steps to become quality products, they are not defined as good products. When product inspection equipment is utilized, Quality scores are easy to determine, as the number of rejected products is easily accessed and can be quickly compared to the total number of products inspected.
2.4 What is a Good OEE Score?

An OEE score of 100 would mean the production process is operating at peak efficiency, and is only a theoretical maximum – it is not actually possible. When most manufacturers begin measuring OEE, scores are usually low. It is estimated that most North American manufacturers have scores ranging from 40-50, meaning there is real room for improvement.

The recommended target for a good production process depends in part on the industry in question, as more tightly-regulated industries may have a lower top possible score. The recommended target score for pharmaceutical manufacturers, and in fact all manufacturers, is 85, although any score in the 80s is considered to be ideal.

To calculate OEE, manufacturers require data on availability, performance and quality. These values are calculated first:

- **Availability** = Run Time / Planned Production Time
- **Performance** = (Ideal Cycle Time x Total Count) / Run Time
- **Quality** = Good Count / Total Count

Then these values are placed into the OEE calculation:

\[
\text{Availability} \times \text{Performance} \times \text{Quality} = \text{Overall Equipment Effectiveness (OEE)}
\]

![Figure 1. Sample screenshot of a typical X-ray inspection, with a real-time OEE calculation displayed.](image-url)
3 Pharmaceutical-Specific Challenges and OEE

Historically, pharmaceutical manufacturers have a fraught relationship with OEE, as scores tend to average lower than those of other industries – initial scores often range from 15-45. This is largely due to the increased number of small batch runs, which cut deeply into Availability scores as the number of product changeovers increase. In addition, the production process itself must go through the various required quality control and serialization steps, which adds more unavoidable Schedule Loss and gives any unscheduled downtime a negative effect on the score.

Every product changeover gives the opportunity for something to go wrong, be it incorrectly entering label information to loading the wrong size of carton. The more product changeovers a manufacturer must perform in a given day, the more opportunities for a problem exist. For pharmaceutical manufacturers, it becomes important to focus on the product changeover process, as it is there where the largest gains to OEE can be made – but it is far from the only place. The installation and use of product inspection equipment can have significant effects on each factor of the OEE calculation.

3.1 Effect on Availability

The most visible effect that product inspection equipment will have on the availability score of a production line will be negative. Extra time will be added to product changeovers, as the equipment will need to be changed over to new inspection profiles, and in order to ensure that inspections are being carried out effectively, it will be necessary to schedule Routine Performance Monitoring. Also, adding any equipment to a production line creates another point of potential failure – i.e. should the product inspection equipment in question break down it will cause unscheduled downtime.

These potential negative effects are counterbalanced by the benefits of in-line product inspection. By removing products which fail to meet quality control standards or governmental regulations, product inspection equipment can help to contribute to reduced re-work times, as defective product is removed earlier in the production process. This earlier detection and removal can prevent damage to production equipment further downstream, avoiding unscheduled downtime.

As for the negative effects themselves, they can be mitigated by the choice of supplier. Product inspection equipment with a proven track record of reliability and designs built for easy maintenance will reduce the chances of unscheduled downtime and require fewer scheduled performance monitoring tests. Product changeover times can be kept to a minimum or even reduced by inspection equipment that supports centralized control and automated profile changes, further reducing the negative impact of adding elements to the production line. Some product inspection equipment is able to screen multiple products using a single setting, eliminating the need to re-set between production runs.

From a pharmaceutical standpoint, this ability to streamline product changeovers is highly beneficial. Any errors which may arise during the changeover will be quickly identified – a vision system can identify mislabeled products, a checkweigher will reject anything which does not have the expected product weight. If enough of these errors occur in sequence, the equipment can be set to send an alert to production personnel in order to quickly catch the changeover error.
3.2 Effect on Performance

Like any production equipment, product inspection equipment has the potential to negatively affect performance in the event of a system failure or fault. Also, like any other piece of production equipment, this risk is mitigated by buying equipment with onboard diagnostics, maintenance scheduling capabilities and early warning alerts in the event of a performance issue. The sooner personnel are made aware of a system fault, the faster it can be addressed.

Run-time data displayed by product inspection equipment can also be used to diagnose the health of other production equipment. A repeated product defect of the same type can indicate production equipment in need of maintenance, and removing defective products from the line can help to prevent product jams and misfeeds. For example, an improperly closed carton could catch and jam production machinery, causing unscheduled downtime. A vision system would detect the open flap and remove the product in question from the line, preventing such an event. Should the defect continue to appear, personnel can be alerted, and the issue addressed.

Beyond detection of a problem after something goes wrong, inspection equipment can help to schedule maintenance. By studying the runtime data provided by inspection systems, manufacturers can study performance trends and better understand the best intervals to have between maintenance periods. Equipment designed with easily accessible parts helps to further reduce time spent on maintenance.

3.3 Effect on Quality

In the pharmaceutical industry, it is vitally important to only distribute product which meets the quality standards set out by industry best practices and government regulations. Automating the product inspection process allows manufacturers to know that every product on the line is being inspected, reducing the odds of a defective product making its way out of the production facility. Not just that, but often product inspection equipment can explain precisely what caused a product to be rejected, helping to identify recurring errors in the production process.

As the entire point of product inspection equipment is to contribute to quality control programs, it is not surprising that installation of such equipment will have a major impact on the quality score of a production line. In a theoretically perfect production process, product inspection equipment would not ‘produce’ anything. That being said, equipment that has been improperly set up or is in need of maintenance may produce false rejects which will incorrectly lower the Quality score of a production line – and waste additional time on rework which is not actually necessary.

When properly utilized, product inspection equipment quickly removes defective products and can be programmed to alert personnel to production errors quickly. This reduces the amount of poor quality product created, as the necessary corrections can be made before more rework is required. By helping to lower the amount of defective products, the overall Quality score can be dramatically improved.

3.4 Better Reporting

Beyond the increased detection and removal of defective products, inspection equipment’s other major contribution comes from its potential for better runtime data; being able to see not just how many good vs. bad products have passed through a system, but what caused products to be rejected, how fast the line ran and the results of the last Performance Monitoring Routine. This collection of inspection records allows manufacturers to demonstrate due diligence, ensuring compliance with various government regulations for the pharmaceutical industry. Furthermore, analysis of this data can help to illuminate areas for improvement, further increasing OEE.
4 Conclusion

It can be tempting to present OEE as the only metric needed in order to improve production efficiency, but OEE is not a cure-all. It is merely an effective way of examining the efficiency of certain aspects of the production process. Measuring OEE can highlight the areas that require improvement – Availability may be high, but Quality may be low, necessitating adjustments in one aspect of production versus another. Making these adjustments will require a closer look at production data than OEE provides, but OEE will tell manufacturers where to start looking.

A low OEE score does not mean a company is not profitable, or that it is doomed to fail, it merely indicates room for improvement. However, what constitutes a “low” versus a “high” OEE score may vary from industry to industry depending on the particulars of the production process. No matter how quickly a product changeover is executed, it will have an effect on a production line’s Availability. For pharmaceutical manufacturers running smaller batches, Availability scores will most likely be lower than a manufacturer running only large batches. The initial OEE analysis of a production process should include a realistic look at what the best possible scores will be, and improvements can be made from there.

When making these adjustments, it is also important to note that positive changes in one area may have a negative impact in another. Spending more time on inspection will improve the Quality score, but the additional time spent will lower Availability and Performance. Automated inspection can help to keep the added time to a minimum, but it will always have some kind of effect, and it is up to manufacturers whether or not the trade-off is worth it. In the pharmaceutical industry, the benefits will often outweigh the price paid in additional production time.

Undertaking the task of improving OEE can require an investment of both time and money, but the benefits make it worthwhile. When putting together a program, it can help to work with an equipment provider who is committed to system features that contribute positively to OEE. Systems which are programmed with support for PackML or other centralized control schemes can help make collection of data relevant to OEE calculations easy, and automating data collection also ensures more accurate measurements – human operators may forget or miscount, but a system will not.

Ultimately, OEE allows for the creation of a roadmap to improve production processes. It shines a light on areas which require closer scrutiny, and serves as a measurable indication of process improvements. When properly utilized, it is a critical part of the quality control process, increasing efficiency and profitability.
About Mettler-Toledo Product Inspection:

The Product Inspection Division of METTLER TOLEDO is a leader in the field of automated inspection technology. Our solutions increase process efficiency for manufacturers while supporting compliance with industry standards and regulations. Our systems also deliver improved product quality which helps to protect the welfare of consumers and reputation of manufacturers.

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