# Biotechnology & Life Sciences

# How to close the 'OEE gap' in pharmaceutical manufacturing

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***On the surface, the European pharmaceutical industry is well-positioned for growth.***

***With a projected CAGR of 4.59% [1] between 2025 and 2030, and many organisations already at advanced stages of their digital transformation journeys [2], the outlook is undeniably positive.***

***However, while the future growth potential is clear, manufacturers are also facing several present-day cost pressures. These range from longer-term challenges such as sustained high energy and labour costs to more recent ones including the US-imposed tariffs on European pharmaceutical imports in 2025.***

***OEE is typically determined by three key factors: availability, performance and quality.***

An essential question therefore emerges: how can pharmaceutical manufacturers take advantage of growing demand for their products while remaining agile in their operations?

In the early part of the 2020s, largely driven by the increase in demand following the COVID-19 pandemic, the go-to option for pharmaceutical manufacturers has been capital expansion projects.

CapEx spend dropped in the years after the pandemic; however it seems to be picking up again in specific growth areas such biologics and peptides. While there is no doubt that expansion projects will increase capacity, they will also incur significant time and investment. What's more, there is no guarantee the demand will have remained the same upon completion of the construction and validation processes. Due to the volatile environment and rapid regulatory changes, a capital investment will also increase the risk level for the company.

If the in-demand line is not already running 24/7, an alternative solution could be to add another shift team. While this avoids the need for CapEx investment and validation, it can still take a long time to find, hire and train a new operations team; especially given the well-documented shortage of skilled workers.

The third option is to improve the performance of existing lines. One of the most effective indicators of production performance is Overall Equipment Effectiveness (OEE), which quantifies the ratio of actual productivity to potential productivity if all operations ran without interruption, speed loss, or quality deviations. This negates the need for significant investment in new equipment or operators and enables sites to dial production volumes up or down to cope with any fluctuations in demand.

While this may seem the most obvious solution on paper, implementing it is not without its challenges.

## Understanding OEE

OEE is typically determined by three key factors: availability, performance and quality.

Availability is influenced by downtime, both planned, such as changeover and set-up time; and unplanned downtime such as breakdowns and reactive maintenance. Performance is a measure of throughput relative to design speed and indicates if the equipment is fit-for-purpose. Quality is the ratio of conforming to non-conforming output.

Crucially, these are all areas the operational team on the shop floor can actively influence without incurring significant investment cost.

When it comes to benchmarking OEE however, the pharmaceutical industry tends to lag behind other process industries. For example, sites in the chemical manufacturing industry typically run at between 70-92% OEE [3].

However, recent data suggests the top decile of pharmaceutical manufacturers of sterile products only achieve 49% OEE. Worryingly, the median OEE recorded was 23% and the bottom quartile recorded just 10% OEE [4].

While there is plenty of room for improvement, even among high-performing organisations, there remains a huge gap between the average OEE of sites in the pharmaceutical industry and those in other process industries. This is the 'OEE gap' we need to close.

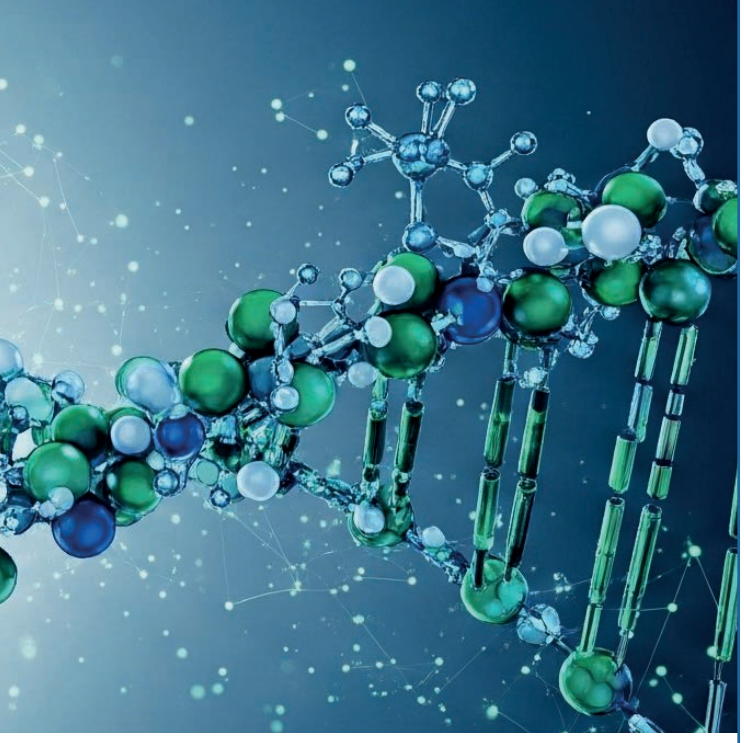
But how do we do that? There are five steps that any pharmaceutical manufacturer can take to start improving their OEE.

**1) Real-time production data – connecting IT, OT and IoT to create transparency and support efficient operations**

Real-time production data is the baseline of any OEE production methodology. However, there is a common misconception that when it comes to data, quantity equates to quality. In realty, the best data is data you can use right away.

While it is a good idea to have a clear understanding of what the ideal '100% data solution' looks like, you shouldn't delay starting the process unnecessarily. It is much better to start early and add in additional data sources later.

Another key learning from many previous implementation



projects is the importance of starting with a 'clean' process data layer. This is typically where your historian or IoT data hub sits, and you would see your units such as product, batches, flow rates, start/stop information and error codes.

If someone makes a change in the OT layer such as changing a pump or sensor, the process data layer must also be updated to ensure all data is as clean and well-maintained as possible.

Once you have 'clean' data, the next step is to set clear benchmarks which can be used to measure performance against.

This is where intelligent operations platforms, increasingly used in the process industry, can support decision-making by consolidating critical information across systems into a single, accessible source of truth. This can demonstrably improve the information flow by routing data, notes, tasks and alerts directly to relevant team members.

Not only does this ensure that teams receive critical information when they need it, but it helps avoid the issue of too much or too little data, both of which can be costly.

Additionally, with automated reports for daily meetings and management updates, it can help boost teamwork and help resolve problems more quickly, leading to faster and more empowered decision-making.

**2) Human insight – empower operations though data and gather their insights direction on the shop floor**

Real-time operational data gives you valuable insights such was whether a line is running or not, and what the error code may be. This is often the stage many companies get to; however it is difficult to undertake any effective analysis using real-time production data alone.

The key to really unlocking the value of process data is to overlay it with human input. To do this, you need to ensure operators on the shop floor have access to both the data and a simple Human Machine Interface (HMI) which allows the operations team to input contextual information around the losses.

You can start with adding simple insights to existing data such as 'what was the reason for the losses?', 'what did the operator observe?' and 'what did they do?'. This could simply include planned stops, which may not be immediately obvious from the process data alone.

Ultimately, combining the contextual information with the production loss data transforms raw events into actionable knowledge and strengthens the basis for both root cause analysis (RCA) and process optimisation.

**3) Zero-loss mindset – refusing to accept any form of loss**

While loss contextualisation is a key task for operators on the shop floor, tackling losses more generally needs to become an integral part of an organisation's culture, and that starts with the leadership.

Shifting to a 'zero-loss mindset' is a highly effective tool for moving to a culture where everyone is encouraged to care about the small things. While 'zero losses' may never actually be achieved, adopting that mindset can help an organisation move away from a culture where five minutes of downtime isn't seen as a big deal to one where everyone cares about every minute.

***Ultimately, improving OEE should form part of any pharmaceutical manufacturer's growth plan***

Let me put this this into context. We recently worked with a pharmaceutical client that had been documenting losses for several months and noticed that one of their feed pumps stopped for 30 minutes every 48 hours.

Once the data became fully visible, it was evident that this recurring loss had persisted for over a year. Because they didn't have a 'zero-loss mindset' no-one seemed be concerned. Restarting the pump, and the associated downtime, just became part of their routine. RCA later revealed that such stoppages were largely avoidable, and their elimination led to a measurable increase in productivity without additional capital investment. Establishing standardised loss detection and mitigation protocols therefore provides a robust foundation for long-term equipment reliability and operational excellence.

**4) Root cause analysis and elimination of recurring losses**

For any OEE improvement strategy to be successful, you need to act once any outliers or patterns are spotted and get to the root cause of the problem.

The systematic digital documentation of RCA efforts ensures traceability and shared learning across teams. This can help create buy-in from stakeholders on the shop floor as they can see how their actions are having a positive impact and there's a high chance they will proactively contribute to the continuous improvement.

Recording the progress, as well as the human loss contextualisation mentioned earlier, also helps with the creation of a powerful knowledge base you can begin to leverage with AI.

Understandably, there is a lot of hesitation, especially on the shop floor, with many operators worrying about whether AI could be used to replace them.

However, AI has the potential to empower operators and really help them in their day-to-day life. For example, AI can be used to analyse contextual information in shift logs as well as loss accounting records and identify patterns which may not be immediately obvious. In turn, this can be used to inform better operator decision-making.

It can also support continuous improvement through better RCA and faster troubleshooting. AI tools within manufacturing intelligence platforms can help identify root causes of recurring downtime by analysing historical shift logs and structured operational records. Importantly, insights are typically drawn from validated operational data and historical records, supporting auditability and traceability.. Importantly, while some information is AI-generated to help structure the information, all the potential solutions are taken directly from past logs. This includes the relevant records under audit trail, created by an operator.

**5) Standardisation – turn aspiration into your daily reality**

The final point is to ensure any process changes become ingrained into day-to-day operation.

I'm sure we can all think of instances where a PDCA cycle (plan, do, check, act) has led to process improvements and reduced losses, but those insights were not digitally logged and became buried among individual pen and paper or spreadsheet notes.

Instead, using a digital platform as a single source of truth to log process improvements can avoid disparate information and communication silos, and ensure any changes quickly become standardised throughout your plant and your workforce.

## Final thoughts

Ultimately, improving OEE should form part of any pharmaceutical manufacturer's growth plan. With digital transformation journeys well underway, many of the data points and human insights are already available. Those organisations who can successfully integrate the two into their long-term working practices are best placed to close their own OEE gap, while those who can't will only see that gap continue to widen.

## References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