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OPERATIONAL EXCELLENCE: CHANGES IN THE PHARMACEUTICAL INDUSTRY.

1| INITIAL SITUATION

While in the past, pharmaceuticals created value from intellectual capital and exclusivity on the market, increasingly, leading industry companies across the world are finding themselves faced with a new reality: their business model based on “blockbuster drugs” as the only source of cash flow is being replaced by a highly volatile market environment and sinking R&D productivity. A brief overview of issues facing the industry makes the scale of the oncoming challenges clear:

- new legislation and the growing influence of a range of decision makers in health policy;
- sinking R&D productivity, as identifying and marketing promising product innovations becomes an increasingly costly and risky undertaking;
- pressure on costs as health ministries and insurers worldwide increasingly turn to cheaper generic alternatives;
- strong growth in the over the counter (OTC) and homeopathy markets;
- changes in the classic role of the patient, who is becoming a customer with an increasing influence on the market.

In the recent past, product quality and reliable supply were still the key criteria, but now the issue of costs is becoming increasingly central as the pharmaceutical sector enters the same territory as other industries such as Automotive have been navigating their way through for several decades now.

By extension, this means that pharmaceuticals can and should learn from the experience of companies in other industries, laying operational excellence and efficient production as the cornerstones of their strategies. This will mean moving away from static manufacturing processes and a mentality of “that’s how we always done things around here” to a dynamic organisation built around the philosophy of the continuous improvement process (CIP).

The key to lasting success and true excellence, however, is more than just the kind of process rationalisation approach based on lean principles which can already be found in many larger pharmaceuticals, but also includes a focus on and the active involvement of staff, as well as long-term productivity management.

2| POTENTIAL – BENCHMARKS

Examining the costs structures of companies in the pharmaceuticals industry, there are significant differences between, say, a globally active, research-heavy organisation (approx. 30% of overall costs stemming from product manufacturing), a maker of generics (product manufacture costs at 50%), and a pure-breed supplier (approx. 60%). (See fig. 1)

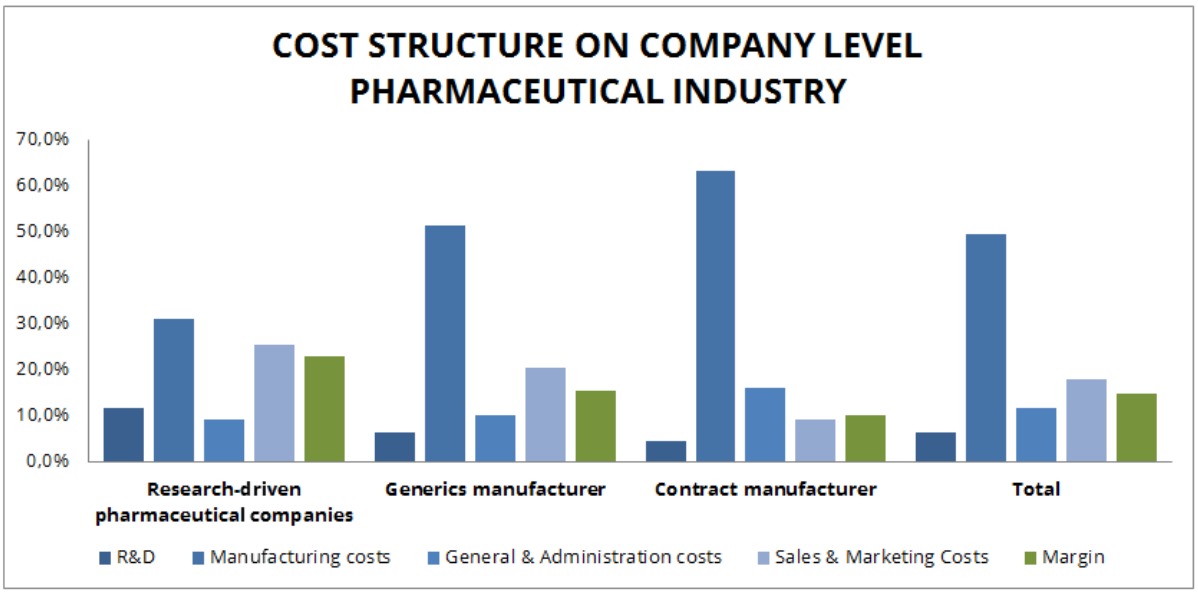


Fig. 1: Costs structures on a company level in the pharmaceutical industry

Breaking down these manufacturing costs, the principle items on average are materials (approx. 44%), staffing (approx. 25%), and machinery, property, and facilities (approx.. 15%). (See fig. 2)

Previous benchmark studies for reference production sites have shown an average potential for 16% of savings, with the greatest differences being calculated for quality assurance (QA) / quality control (QC), maintenance, machinery use, and high productivity. (See fig. 3)

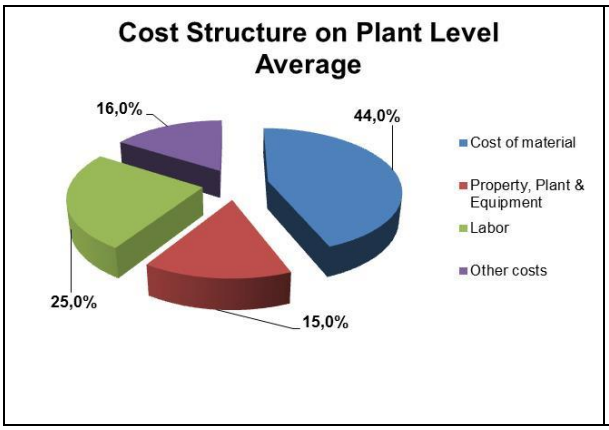


Fig. 2: Cost structures for pharmaceuticals sites

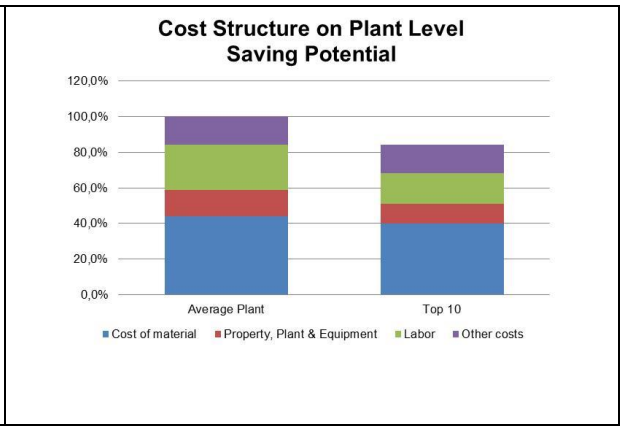


Fig. 3: Average potential for savings for individual sites

Our experience from a wide range of optimisation projects across a range of pharmaceutical production sites confirms these figures with regard to the scale of the differences between individual areas; if anything, however, we consider the overall average savings potential of 16% to be a rather conservative estimate. Depending on the precise area of operations and the level of excellence found at the production site in question, we are used to seeing potential for optimisation of between 20% and 30%, sometimes even more (excluding outlay for materials).

In both our preliminary scans for potential savings and our projects to implement the options we have identified, we follow the basic lean process optimisation principles; efficient and coordinated purchasing of materials is essential, as is an understanding of the actual performance of the resources to hand. Consistent application of this information once acquired represents a crucial element of a closed management system, and is the foundation on which resources can be used as required and in an efficient manner.

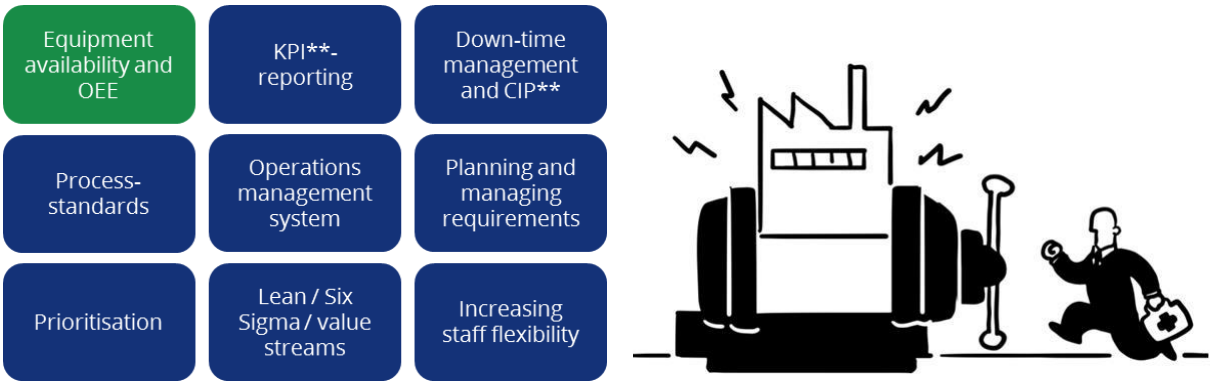
In our experience, the most important KPIs and levers for increasing and documenting performance are:

- systematic recording for time lost and a permanent time resource management system based on this;
- specific documentation of actual overall equipment effectiveness (OEE) using best demonstrated practice for resource capacity;
- implementing requirements-orientated capacity and resource planning;
- using KPIs in closed management system circles in order to steer productivity;
- creating resource flexibility.

Production sites in which **operative excellence** is applied across all interfaces (procurement, preparation, production, quality management, logistics, etc.) reach maximum flexibility and can

plan resource use in the long term, all the while being able to respond to changing customer requirements. Only with this kind of established, closed production management system will the next steps succeed: efficient steering of the whole supply chain, and then overall supply chain excellence. In the following, we go into more detail on increasing equipment availability and the correct application of OEE, which together form one of the most important elements in our portfolio of consultancy services.

OPERATIONS / OPERATIONAL EXCELLENCE COMPETENCIES



*KPI = Key Performance Indicator; ** CIP= Continuous improvement process

3| EQUIPMENT AVAILABILITY OEE

In the process industry, the capacity of production equipment is often not used to its full potential: time-consuming formatting, ramp-up, and cleaning downtime on multi-purpose machinery, as well as time-in-waiting and lost time are taken as inevitable, while process bottlenecks are frequently undiagnosed or left untreated.

WHAT IS OEE AND WHAT CAN IT TELL US?

OEE stands for overall equipment effectiveness, and is one of the most important indicators for managing equipment productivity, providing as it does a figure for the extent to which a production asset is being used. It measures the ratio of actual delivery (i.e. actual process performance) against maximum possible delivery (theoretical process performance) in the process chain; this can render process performance directly transparent and steerable by, for example, describing the proportion of value creation the equipment offers in relation to its maximum possible output.

Measuring and managing by reference to the OEE only makes sense when combined with long-term time resource management in which types of time lost which reduce maximum equipment effectiveness are continually recorded and systematically analysed, leading to measures for improvement being implemented as part of a CIP (continuous improvement process).

Taking into account the losses – reduced to a minimum of planned maintenance down-time by applying CIP – the equipment can be steered in response to market needs. (see fig. 4 also)

For companies, applying OEE correctly means that every increase in this measure can be quantified in Euros and scaled up into figures proving business success.

4|USING OEE TO OPTIMISE EQUIPMENT – A REAL-LIFE EXAMPLE

This real-world case-study (fig. 4) shows how a production asset continuously used for one single active ingredient was run following optimisation with regard to staff availability in a chemicals production company.

INITIAL SITUATION

Prior to optimisation, the company was marked by a high level of process variation due to weaknesses in process structure and uncontrollable time losses. As a direct result of these instabilities, staff were subject to sharp spikes in their work-load as it was almost impossible to plan resources to suit capacity, while annual production targets still had to be met. There was no permanent productivity or OEE management in place, meaning that the actual capacity of the equipment used remained unclear.

PROCESS OPTIMISATION AND IMPLEMENTING OEE MANAGEMENT

The first result of implementing measures for process optimisation and installing an appropriate OEE management was that resources for equipment cycles could be planned; following process optimisation using continuous improvement methods and with the actual equipment capacity available rendered transparent by OEE management, the annual production tonnage was reached without work-load spikes. Moreover, the equipment throughput could then be adapted to the actual staff resources in place in a proactive manner suited to requirements. The work-load spikes avoided by process stabilisation, OEE planning, and equipment steering led to both

an actual and a perceived reduction of staff stress as it was now possible to plan with the equipment in advance.

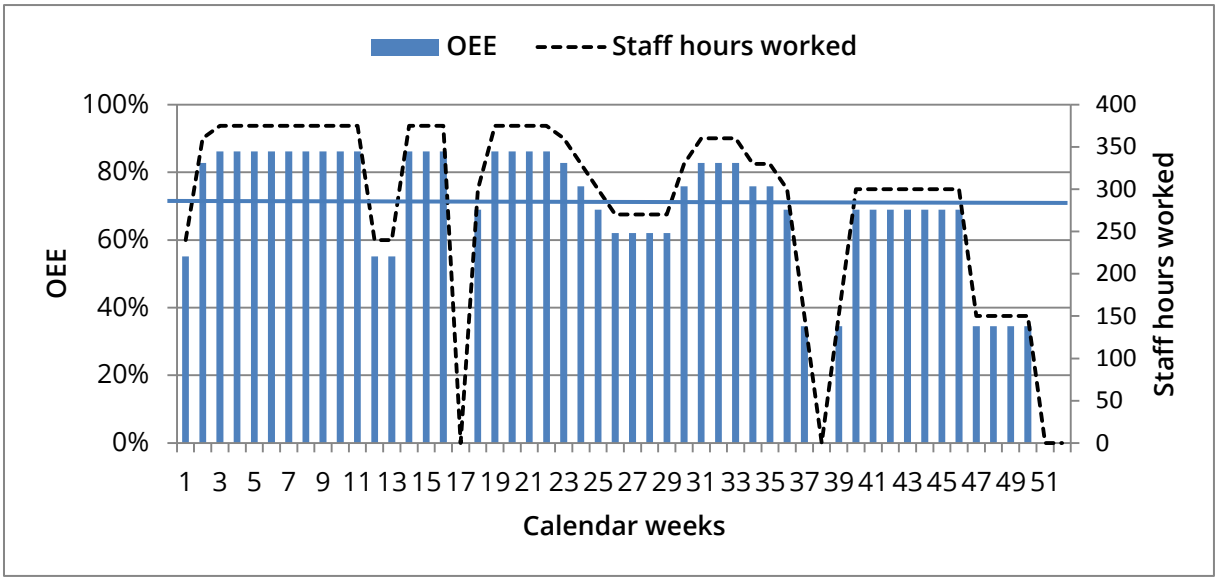


Fig. 4: OEE in an operational situation optimised for a production of 5 tonnes; average OEE measured at 71% (net opening time)

EFFECTS ON PRODUCTION MACHINERY AND OPERATIONS

Figure 4 shows that a majority of the annual production target was actually produced before the shut-down in week number 38; i.e. there were enough resources planned and available in this period of time. As a consequence, this allowed for a targeted slow-down in production during the summer holiday period in weeks 23 to 30, and then reductions towards the last month. In this way, by planning across the year as a whole, there were no spikes in work-load.

When viewed against the annual operating time of the production asset (net opening time), the OEE management implemented resulted in an average effectiveness of 71%; 9% of the missing percentage was due to unavoidable down-time, meaning that an overall potential for improvement of 20% remained - i.e. one fifth of the production asset in question was not being used in a productive fashion. Furthermore, four weeks of downtime were planned annually, meaning that the overall equipment availability was actually at 66%. To put it simply once again: for one third of the time, this asset was not being used.

The second result of this process is that the company running the production machinery now has the possibility of using the resources more flexibly or of upping outpout by 20% (in the example

at hand, this would correspond to an annual increase in active ingredient production of one tonne). The pharmaceutical company would therefore only be required to invest in additional production capacity if it wanted to increase output by more than this additional sum; this was an important piece of information for the directors of the organisation (and it came at an opportune moment).

The third result proceeds from the four weeks of planned down-time, which can be optimised to either increase capacity even further or as a buffer for unforeseen circumstances.

There is no reason that this principle cannot also be applied to multi-purpose production equipment; as opposed to mono-assets, techniques such as SMED (single-minute exchange of dye) can be used to produced additional productivity increases. Indeed, our experience is that the efficiency of process technology assets can be increased by an average of 15% (mono-product) or 20-25% (multi-purpose).

5| EFFECTS

In order to use production equipment effectively, it is crucial to know its actual availability. Due to depreciation and space occupied, process technology assets require considerable financial outlay even when not in use, and should therefore be permanently run at their optimum rate in accordance with requirements. It is also indispensable to understand actual availability before reaching investment decisions with regard to extending capacity; once actual availability is known, many investments may be revealed to be unnecessary if existing assets are run more efficiently. Furthermore, inefficiencies in the original asset are usually transferred to the next piece of machinery, meaning that companies can end up with two assets being used sub-optimally, opening up financial risks in times of economic hardship.

6| SUMMARY

Implementing OEE management allows for a transparent, stable production environment, generating lasting costs advantages and supporting pharmaceutical companies as they strive towards improved costs efficiency. Starting with continued active ingredient production or batch planning methods, and then moving to medical pharmaceutical production (in which the API is put into drug form), and finishing with packaging lines, this optimisation methodology can be

applied at all stages: **in our project experience, it is realistic to expect 20-30% increases in efficiency**.

Moreover, reliable production equipment is a key factor in guaranteeing reliability of supply; besides the proven costs advantages resulting from increases in productivity, customer satisfaction is a decisive result of structured OEE management. Given that human lives may in some cases depend on it, rapid and steerable product delivery is utterly crucial for pharmaceuticals; not only is the brand reputation of pharma companies built on it, but customers are often willing to pay a premium if a reliable supply can be guaranteed.

In the end, everyone is a winner: pharmaceuticals are able to cover increased market demand with existing production capacity, saving costs and making their processes more efficient and flexible; staff benefit from increased planning stability and less perceived stress at work – and customers can rely on delivery times.

POLARIXPARTNER will work with you through this overall optimisation process, applying its years of experience and expertise – and supporting you as you implement the measures identified. We look forward to hearing from you and learning about your situation.

7 | ABOUT THE AUTHORS – YOUR EXPERIENCED CONTACTS

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- More than 15 years' experience in manufacturing in the medicals, pharma, and chemicals sectors
- Productivity and efficiency in production and operations, quality management, supply chain & purchasing
- Implementation of planning and management systems
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- Project management and leadership
- Coaching in leadership, change management

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Dr. -Ing. Daniel Wothe – Principal

- More than eight years' experience in the manufacturing industry (pharma, chemicals, machine-building)
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8 | ABOUT POLARIXPARTNER

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