



Institute for Technology Management

University of St.Gallen



International Benchmarking Study:

Operational Excellence in the Pharmaceutical Industry

Industry Report

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“Until now we have not seen any industry where lean thinking can not work; and so achieve maximised value for the customer and minimized waste along the whole value chain. However, the maximisation of customer value is difficult in industries such as the pharmaceuticals or defence, where there is no consistent perception or articulated definition of value. In the health-care sector the person that has to pay for a service is different from the person that uses the service. In that case: who should be responsible for defining value?”

Adapted from a comment by James P. Womack, co-founder of Lean Production.

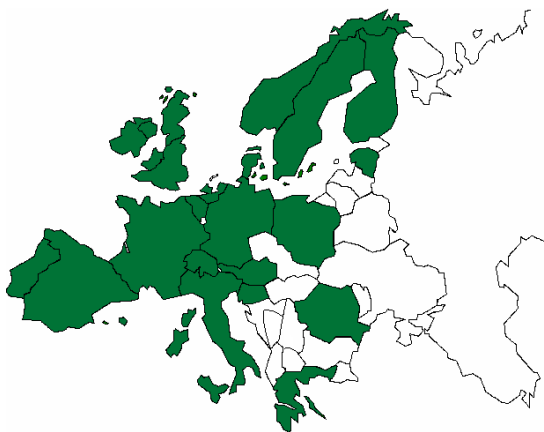
About the Project

The project ‘Operational Excellence in the Pharmaceutical Industry’ aimed to analyse the current status of the Pharmaceutical Industry with regard to Operational Excellence. Whilst other industries have enthusiastically adopted lean thinking practices and other basic principles of Operational Excellence to manufacturing, there was no empirical evidence to support if those principles had been adopted by pharmaceutical companies. Hence, the study aimed to explore the following questions:

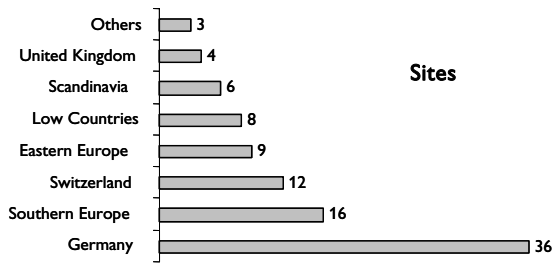
- What are the relevant industry forces that shape the structure of the pharmaceutical industry?
- How do companies respond to these forces? What drives pharmaceutical companies to become ‘operationally excellent’?
- Due to the sector’s specific characteristics: what are the main levers to increase operational performance in the pharmaceutical industry?
- To what extent are practices of Operational Excellence (especially lean manufacturing practices) currently implemented?
- Is there any empirical evidence to support the notion that implementation of Operational Excellence practices drives performance up?
- Does Operational Excellence matter in an industry that can be characterized as R&D and marketing driven?

The study was conducted between August and November 2004 by personally addressing some 400 managing directors, site-leaders and Vice-presidents - Operations of pharmaceutical companies across Europe. Ninety-five organisations and production plants from 20 different European countries participated in the study to explore in great detail whether the hypothesis of James Womack is valid: that the pharmaceutical industry is truly an industry which is lagging behind other industries with regard to lean thinking.

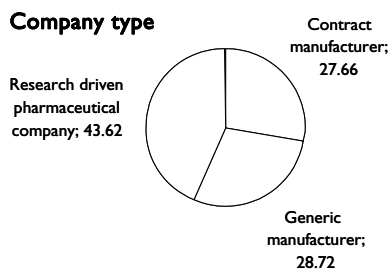
Consequently we tackled three classes of pharmaceutical organisation: first, the research driven pharmaceutical companies, then generics companies and finally the contract manufacturers.



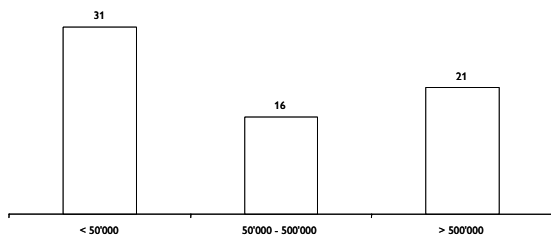
Geographical distribution of the participating plants (I)



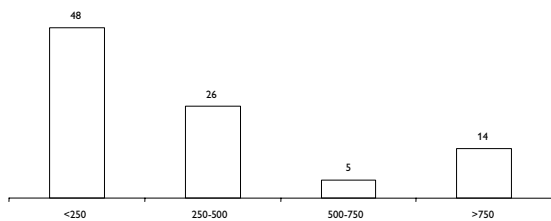
Geographical distribution of the participating plants (II)



Types of companies that have participated



Average sales revenue of the participating companies (in 1'000 €)



Average number of employees of the participating plants

Executive Summary

There is a strong consensus among the participating companies that the driving forces on the pharmaceutical industry are currently changing. The principal factors pressurising the growth opportunities and high returns on investment will be a declining productivity in R&D, the increasing buyer-driven pressure on pricing, the significant threat of substitute products and an increasing rivalry among existing competitors. Furthermore, changing customer preferences will lead to an increasing variability in demand; and thus adding further complexity to the pharmaceutical supply chain.

From an operations perspective, the pharmaceutical industry has not undergone major operational improvements in the recent past. This becomes most evident when taking continuous improvement measures (e.g. number of suggestions per employee, average cost savings due to suggestions etc.) that provide some indication of the ongoing improvement programs in this industry. Moreover, much of the industry does not even track such performance indicators.

Quality-wise, there is still a significantly strong trade-off between either low inspection costs or low complaint rates; which indicates that only a few companies have managed to build-in quality to their processes and products. From a 'total productive maintenance' perspective, the Overall Equipment Effectiveness of plant and equipment is low; and, notably, the level of unplanned maintenance is higher than in other sectors.

Concerning the management of inventory, practices based on a just-in-time philosophy are very rarely implemented in the pharmaceutical industry. Obviously implementing just-in-time principles has not been a major concern for the industry, as the level of implementation is the lowest among all sector-categories. On the performance side, there is a significant gap between most of the industry and a smaller number of high performing plants. Whilst it is not unusual for pharmaceutical companies to have stock turns of 2-3, there are plants that out-perform even other industry standards. Nonetheless, as most companies have been lagging behind other industries, the question arises whether Operational Excellence may not deliver at all the desired effect on overall business performance.

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The data provided evidence that Operational Excellence explains about 20% of variance in Return on Sales (ROS) for pharmaceutical companies. Furthermore, companies that are 'operationally excellent' could gain even greater market share when compared to others in their industry.

For companies that do not want to jeopardize their future growth by cutting R&D investment or marketing budgets, Operational Excellence could become the silver bullet for sustaining current double-digit ROS ratios.

The pharmaceutical industry is changing:

Increasing industry dynamism

The pharmaceutical industry is in the middle of a major change: findings from our study suggest that the rate of innovation is expected to decrease significantly. Some 67% of all participating companies is currently anticipating a decreasing rate of new drugs launched on the market. At the same time, 65% of the participating companies expect their costs of R&D to increase. Taking those figures, one can expect a dramatic drop in R&D productivity for an industry that is mainly research-driven.

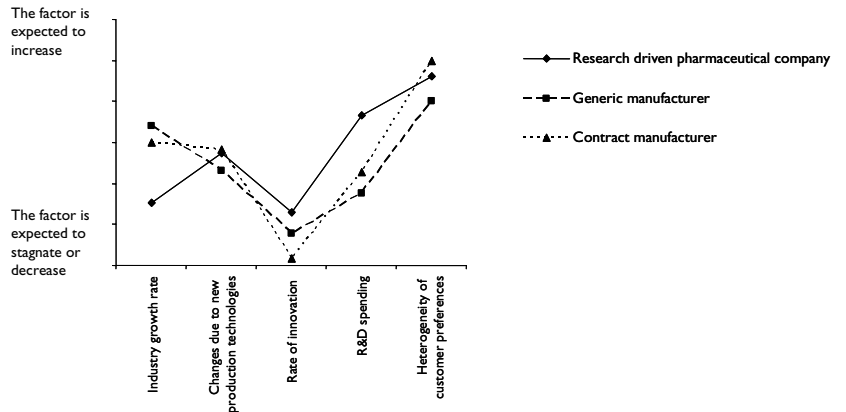
Nevertheless, there are high expectations for possible growth; for example 67% of companies expect their revenues to keep on rising. However, the challenge is, how will the companies meet their growth expectations in an environment which is characterized by a declining product pipeline.

Increasing heterogeneity of customer preferences

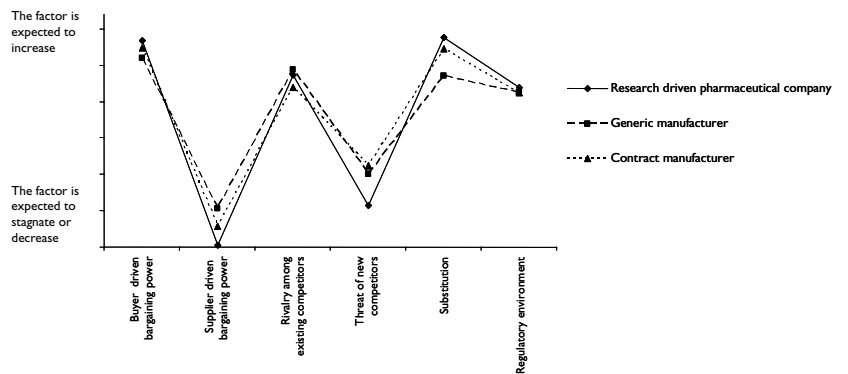
A further indicator that is invariably used to characterize an industry is the expected change in customer requirements; those changes brought about by a growing diversity of customer preferences. The findings suggest that 83% of companies expect an increasing heterogeneity of the customer preferences. This measure aligns with the current development in other industries; and from an operational perspective one can assume that this will lead to a higher complexity when efficiently handling products.

Increasing industry rivalry

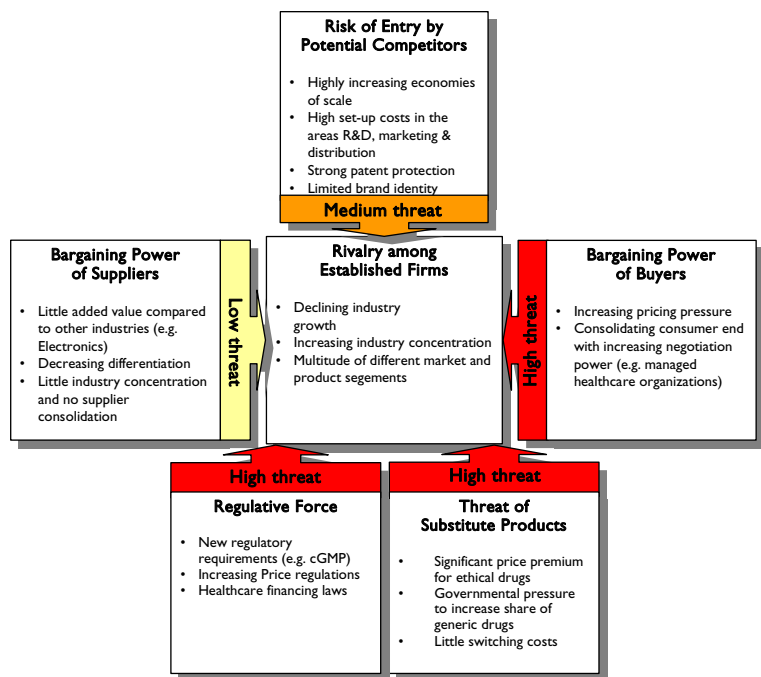
Whilst the pharmaceutical sector used to be the most profitable industry in the world (Pisano,



Growing Dynamism and heterogeneity of customer preferences



Growing industry rivalry (I)



Growing industry rivalry (II)

International Benchmarking Study: Operational Excellence in the Pharmaceutical Industry

2003), there are certain indicators that leads to the assumption that the attractiveness (as a measure of profitability) of this industry will decline. To respond to this issue we analysed the balance of power among various industry stakeholders. Among six factors that shape the competitive dynamics of an industry, four factors are expected to cause a significant pressure on pharmaceutical companies. The highest obstacle is expected to come from the increasing buyer-driven bargaining power and an increasing threat of substitute products. Almost 90% of all companies expect an increasing pressure from those sides. This goes in hand with an increasing rivalry among existing competitors (82%) and changes due to new regulatory requirements (78%).

Only the impact of new market entrants and the threat of an increasing supplier-driven bargaining power are anticipated to remain stable or even possibly decline.

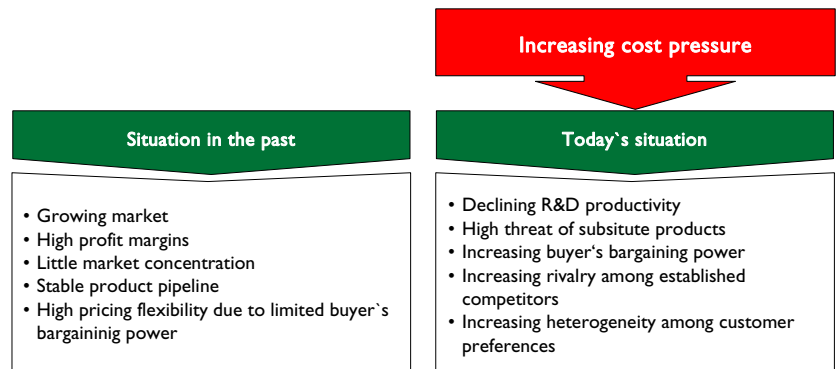
Hence, the threat of substitute products and the increasing bargaining power of buyers seem to be the major issues for today's pharmaceutical companies.

Despite potentially attractive profit margins and a favourable balance of power, with respect to suppliers and new market entrants, the pharmaceutical industry will be a challenging sector to be in. It seems that the current development from actions of government, institutional agencies and the wider social issues, demands a strategy that also has to consider efficiency issues. What used to be a safe haven for market leaders will become increasingly recognised as a substitution market. Hence, the industry is facing a situation in which it has to tackle declining R&D productivity while simultaneously improving the efficiency of its operations.

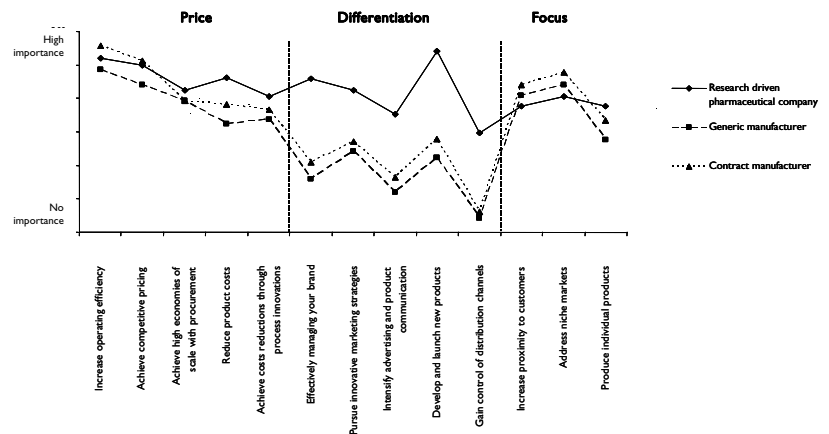
Operational efficiency could address upcoming challenges

In responding to the forces of change in the business environment, pharmaceutical companies are increasingly following competitive strategies that are based on reducing cost drivers.

Among a set of twelve alternative strategic initiatives, the option of improving operating efficiency was rated with the highest priority when



Changing industry situation



Strategic response – How will companies cope with changing environment?

asked 'how important it is in meeting business strategy'. Some 90% of companies are planning to give a greater attention to improving operational issues. The three most important initiatives in meeting business strategy were identified as:

- Increase operating efficiency
- Address niche markets
- Achieve competitive pricing

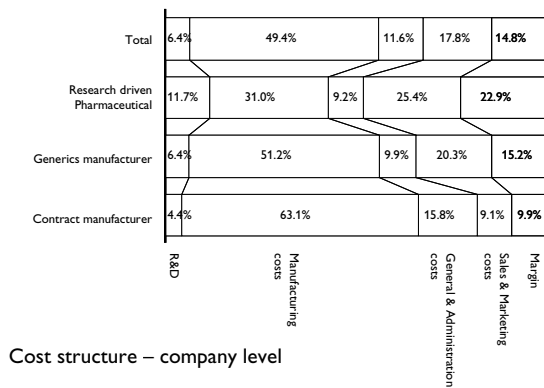
An increasing share of companies seem to pursue a strategy that is based on cost issues. Obviously efficiency improvements in the operational processes of procurement, production and logistics are becoming more crucial.

However, a business strategy based purely on cost issues appears not pay off, as a high R&D ratio seems to boost profitability. While companies with a R&D ratio lower than 5% have an average Return on Sales of around 10%, companies with an R&D ratio of more than 10% have

an average Return on Sales of some 20%. Conversely, pharmaceutical companies increasingly question whether solely focusing on R&D will be a sustainable strategy in future. With cost of sales of around 30%, manufacturing accounts for the second highest cost factor among the research driven pharmaceutical companies in our sample. Among generic manufacturers, this ratio rises to about 50%; and more than 60% among the contract manufacturers.

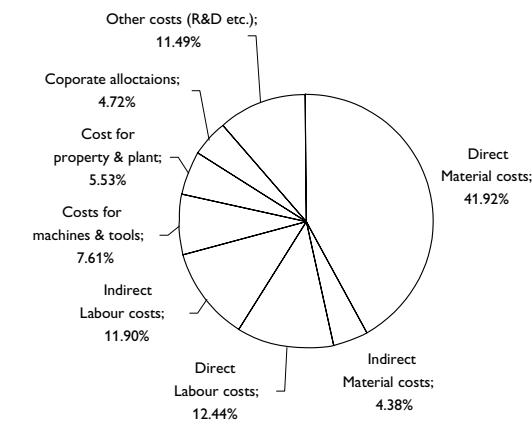
**Cost savings potential -
What is the main leverage
for streamlining Operations?**

Taking a closer look at manufacturing costs in the pharmaceutical industry at the level of the production unit, it is an interesting exercise to discover what the main leverage for streamlining manufacturing operations is. The combined cost of purchased materials, direct and indirect labour and equipment costs account for the highest portion of the overall manufacturing costs.



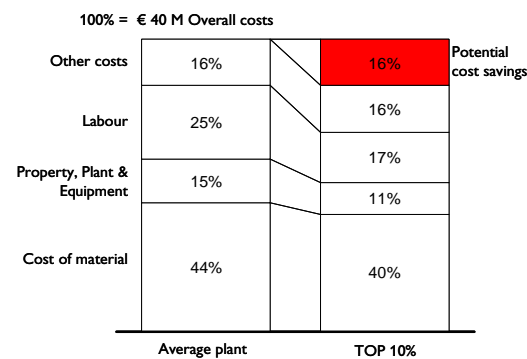
Cost structure – company level

Comparing the 10% best performing plants in the sample with the average plant, identifies potential cost savings that could add up to around 16% of the total costs of a typical manufacturing plant. With an average total cost of around 40 M € for a typical manufacturing plant, this can be translated into around 6.5 M € annual cost savings. Some of the biggest differences between an average plant and the best performing plants are described below:



Cost structure – plant level

- A difference of around 1.5 M € in comparison to the average costs for QS/QA per direct labour between the top 10% and the peer group.
- A difference of 1.4 M € in comparison to the costs for maintenance per direct labour between the top 10% and the peer group.
- A difference of 840.000 € lower annual depreciations (if assuming a 5 year depreciation time for excess capacity investments) when comparing the asset utilization of the top 10% with the peer group.
- A difference of 710.000 € by taking the internal quality performance (e.g. scrap rates, number of rejected batches etc.) between the top 10% and the peer group.



Cost savings potential

Analysing the capital employed, the story does not look much better. The 10% low performing plants have in average finished goods stock turns of approximately two. Applying an average gross margin of around 60% for pharmaceutical products, the typical plant in our sample employs around €45 M working capital in its inventories. Taking the very low debt/equity ratio of most pharmaceutical companies, the cost of capital for keeping those stock levels can easily add up to more than 5 M € a year.

Extrapolating those figures to the potential cost savings over the lifetime of a \$1 billion-a-year blockbuster drug, then efficient manufacturing could translate into around €500 M overall cost savings.

However, to realise those cost reductions, it is important to find out more about the 'mechanisms for deployment of Operational Excellence in the pharmaceutical industry.

**Linking Practice to Performance:
Testing the Operational Excellence model**

The overall hypotheses of the project "Operational Excellence" is that the right implementation of modern principles of operational excellence will lead to a significantly higher performance among pharmaceutical manufacturing plants and thus lead to a higher overall business performance of the company.

The basic model for testing that hypothesis has been developed by analysing current integrated production systems from the automotive industry.

The questionnaire comprised five subcategories; with each category representing a major principle of Operational Excellence. Each of the subcategories is presented below:

The element: Total Quality Management (TQM)

Within the subsystem of TQM we examined whether the company has an integrated production system that

- aims to be continuously improving and sustaining quality products, processes and the overall company quality;
- is implemented across several functions (manufacturing, supplier-management, R&D)
- and is based on a quality culture that addresses all direct and indirect employees, rather than solely employees in QS/QA departments.

The main objective of the TQM System is to significantly increase quality performance (e.g. scrap rates, complaint rates etc.)

The element: Total Productive Maintenance (TPM)

Within the subsystem TQM we examined

whether the company has an integrated production system that

- is designed to efficiently manage fixed assets throughout the life cycle (machines and equipment, property etc.);
- and pursues a manufacturing based strategy that includes the effective use of process technology.

The main objective of the TPM System is an efficient management of fixed assets while effectively using new process technology.

The element: Just in Time (JIT)

Within the subsystem JIT we examined whether the company has an integrated production system that

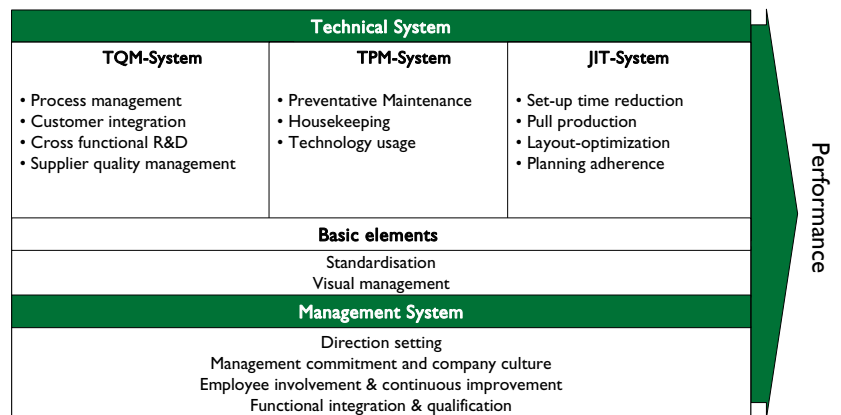
- aims at continuously reducing all forms of waste, especially by reducing inventory and unnecessary delays in flow time;
- and simultaneously increasing flexibility and service-levels.

The main objective of JIT is the reduction of working capital by simultaneously increasing service-levels.

The Basic elements:

This section explores the two basic elements of standardisation and visual management, because they support a successful implementation of TQM, TPM and JIT-principles, as

- standardisation helps companies to improve their products, their processes and their equipment through continuous improvement



Operational Excellence framework

while simultaneously reducing costs of maintenance, quality insurance etc.;

- and visual management provides the workforce with updated information of process and performance information and assists the deployment of a decentralised workforce organisation

The main objective of the basic elements is to support the deployment of TQM, TPM and JIT principles

The Management system:

Within the management system we explored whether the production site has a management system that

- is managed by clear and consistent objectives;
- provides personal leadership for quality improvements and management commitment;
- has a high level of employee involvement; and thus
- enables a continuous improvement and learning process; and
- provides flexibility through cross-functional workforce qualification.

The main objective of an effective Management system is a learning organisation that is managed by clear objectives

Linking TQM to Quality performance

TQM is an integrated management philosophy and set of practices that emphasises, among other things, continuous improvement, meeting customers' requirements, reducing rework, process-redesign, increased employee involvement and team work, team based problem solving, constant measurement of results and closer relationship with suppliers.

We defined the following practices to be core elements of the TQM system: process management, supplier quality management, customer integration and cross-function product development. Furthermore we also analysed the impact of cross-functional teams as this practice is often linked with better quality performance, too.

We define **process management** as documenting, measuring and improving processes, and

thus reducing process variances to a minimum level. A high-level of documentation and standardisation usually goes in hand with human and organisational dysfunction (unmotivated workforce, high absenteeism etc.); hence job-enrichment was developed as an antidote a few decades ago. However, successful process management is more likely to manifest from peers working in **cross-functional teams** than from industrial engineers. TQM specialists suggest that companies should choose vendors primarily on the basis of quality, rather than solely on product price. Moreover **supplier quality management** aims at integrating suppliers into the internal quality system (e.g. by jointly developing processes) to ensure high quality levels. To achieve excellent quality, it is essential to know what customers want and to provide products to meet their requirements (**customer integration**). Furthermore, TQM specialists suggest that **cross functional product development** should help to translate customer requirements into high quality products.

The next question is how to measure TQM performance. According to Professor Cooney, at MIT, in the past pharmaceutical companies saw manufacturing simply as a matter of compliance with regulatory requirements. Hence, high quality performance in terms of low complaint rate levels used to be a crucial performance indicator for most of the industry. However, solely using complaint rates as a key performance indicator can not provide us the answer to whether TQM is widely implemented in the pharmaceutical industry or not. For example, the quality of finished products that are shipped to the final customer can have high reliability with respect to its specific product characteristics. Yet that high quality may be achieved with high inspection costs. As this example illustrates, the final product might have a high quality, while the approach to achieving it is not consistent with a TQM approach, which is based on a 'build-in quality' philosophy. A fundamental premise of TQM is that the costs of poor quality (such as inspection time, rework, lost customers etc.) are far greater than developing processes that produce high quality products. We decided to measure both the final outcome (which is hopefully a low complaint rate) and the internal measures (e.g. cost of quality, number of people working

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in the QS department) to provide us with an answer to whether high quality is a result of 'good inspection' or 'good processes', and thus support a TQM philosophy.

Practices of TQM	TQM Performance measures
Process management	Complaint rate, Service level,
Team work / Cross functional training	Rejected batches, Supplier quality level, Cost of quality (QS / QA costs vs. overall costs, QS / QA costs vs. number of volume-dependant employees)
Supplier quality management	
Cross-functional product development	

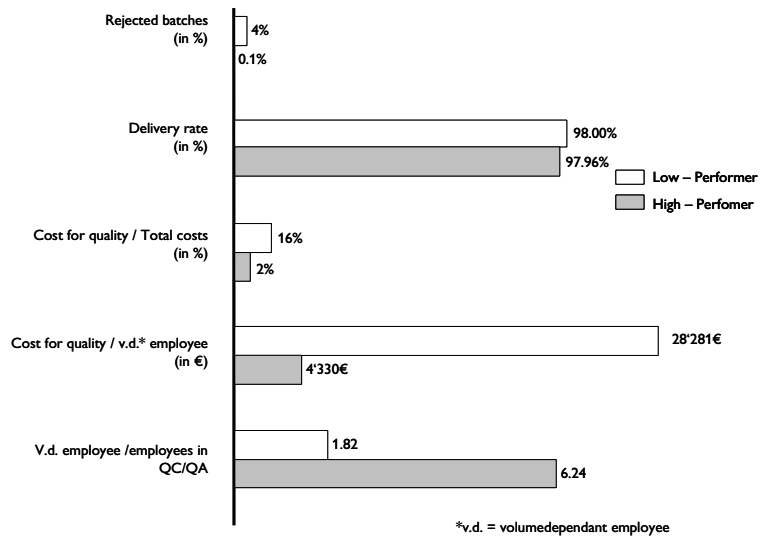
Outcomes:

The pharmaceutical industry is world class with regard to (external) customer-oriented quality performance measures. With an average complaint level that is far lower than 1%, the industry seems to be not far from excellent.

Hence, the next question: is high quality 'built into the system', or is it a result of high inspection activity/cost? Taking into account the high regulatory requirements from the FDA and other registration agencies, the answer is not surprising: 'it is a result of high inspection costs'. Companies that are performing well in terms of external quality performance are having much higher inspection costs than their low performing peers (in terms of external quality performance metrics).

As there seems to be a trade off between high quality and low quality costs, the question is whether there is a way to stop this vicious circle. The figures provide an indication. Whilst team work and cross-functional training, as well as cross-functional product development, do not seem to have an impact on any of the quality performance indices, it appears that the integration of external partners into the quality system seems to pay off (e.g. suppliers, customers).

Strongly supported by our data is the basic assumption of TQM that quality can only be achieved when companies know what customers want. Plants that are frequently getting feedback from their customers on quality and delivery performance and are frequently surveying their customer's requirements are performing much better than those that have not integrated their customers into their quality system.



TQM performance measures

Measure \ Practice	Complaint Rate	Rejected badges (internal)	Supplier Quality Performance	Cost of QS/QA	Overall TQM performance
Management Commitment	●				
Process management					○
Cross-functional product development					
Customer integration	●				
Team work/Cross-functional training					
Supplier quality management		○	○		

● much higher performance ○ higher performance

Linkages between TQM practices and TQM performance

Companies that integrate their suppliers into their quality systems, likewise, seem to perform better. Companies that jointly develop their processes with their suppliers, and put high emphasis on quality aspects among their suppliers, have a higher supplier-quality performance, as well as lower internal rejection rates.

A further underlying assumption of TQM is that a quality improvement process must begin with top management commitment. This must emanate from senior managers as they create the organizational system that determines how products and processes are designed and supported. Strong management commitment to quality and its improvement leads to a higher performance, in terms of lower complaint rates and high service levels. Even though some of those practices do not have an impact on external quality performance, they can affect internal quality per-

formance indices (e.g. number of rejected batches). However, none of them help to lower quality costs. Interestingly, the only practice that helps break-up the vicious circle of quality performance and quality costs is, process management.

The high impact of process management as a means for increasing the overall TQM performance sounds surprising, as the pharmaceutical industry is an industry in which a wide range of operating procedures have to be documented to gain approval for operating a plant. However, this exemplifies the point that solely documenting a process does not help to improve it. Those companies that have understood that the main objective of process management is to reduce uncontrolled variances in processes or outcomes are those that have managed to have high quality performance whilst not incurring higher costs of quality control. It is noticeable that besides documenting processes they also measure the quality of their processes. Moreover, these companies make use of statistical process control data to reduce variances. Furthermore, they are trying to identify root causes of variability and are continuously taking appropriate steps to improve processes.

Known information provides us with sound evidence that the latest initiatives launched by the FDA to reduce manufacturing costs, offer a great opportunity for pharmaceutical companies to reduce operating costs. Undoubtedly such initiatives are leading the pharmaceutical industry along the right direction. Regulatory guidance on Process Analytical Technologies (PAT) will allow pharmaceutical companies to continuously monitor process variability, and thus help improve manufacturing processes. Furthermore, the risk-based Current Good Manufacturing Processes (cGMP) will free-up the industry from prescriptive rules; and hopefully help by substituting "non-value-adding documentation" with a state-of-the-art process management system.

Linking TPM to maintenance performance

The pharmaceutical industry is a truly highly capital intensive industry. As much of its fixed assets are tied up in plant and equipment, an efficient usage of these resources should reduce capital employed. Furthermore, stable-running machines and equipment helps in designing stable processes; and thus increase planning adherence. Such measures are a crucial element for implementing a JIT system. Therefore in the next phase of our work we analysed the impact of Total Productive Maintenance (TPM) on operational performance measures that are closely linked to equipment utilisation and maintenance.

TPM is designed to maximize equipment effectiveness, improve overall efficiency by establishing a comprehensive productive-maintenance system during the life of the equipment, whilst spanning all equipment-related fields such as: planning/buying, use, maintenance, etc. Moreover, it engages the participation of all employees, from plant management to shop-floor workers; and so promotes productive maintenance through motivational management techniques and voluntary small-group activities.. TPM is usually divided into short-term and long-term elements. In the short-term, attention is focused on an **autonomous maintenance** program for the production department, a planned and **preventive maintenance** program for the maintenance department, and skill development for operations and maintenance personnel. The long-term elements focus on new equipment usage and design to help eliminate all sources of lost equipment time.

Autonomous maintenance can be described by considering the four main goals of the TPM program. First, the program brings production and maintenance people together in teams (**teamwork**) to stabilize conditions and halt deterioration of equipment. Second, by effectively developing and sharing responsibility for the critical daily maintenance tasks, production and maintenance people are able to improve the overall 'health' of the equipment. Through autonomous maintenance, operators learn to carry out important daily tasks that maintenance people rarely have time to perform. These '**housekeeping**' tasks include cleaning and inspecting, lubricating, precision checking, and other light maintenance.

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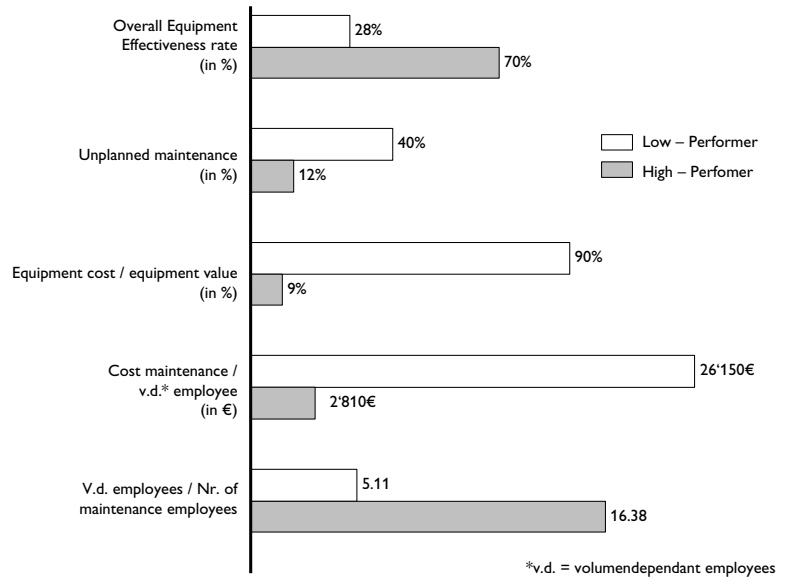
nance tasks. Third, TPM is designed to help operators learn more about how their equipment functions, what common problems can occur and why they occur, and how those problems can be prevented through early detection and treatment of abnormal conditions. This **cross-training** allows operators to maintain equipment and to identify and resolve many basic equipment problems. In a TPM program, maintenance technicians are held accountable for completing maintenance tasks within a scheduled time-frame, while still meeting production requirements. By using standardised operating procedures, such **standardisation** helps to increase schedule compliance, which is an important indicator for the health of a TPM system.

While we mainly focused our analysis on the short-term aspects of TPM, we also wanted to explore whether the way how technology is used in pharmaceutical plants had an impact on TPM performance measures. The main question was whether proprietary **development of process technology** or just applying **standardised supplier technology** helps to improve TPM performance measures.

Practices of TPM	TPM Performance measure
Preventive maintenance	Unplanned maintenance, Overall Equipment Effectiveness (OEE), Equipment costs vs. machinery value, Volume-dependant employees vs. maintenance employees
Standardisation	
Housekeeping	
Team work / Cross functional training	
Effective technology usage	

Outcomes

There seems to be a fairly high level of implementation of TPM practices in the pharmaceutical industry. With an average level of implementation of 67%, it is the most widely used Operational Excellence practice. However, on the performance side, the pharmaceutical industry is far from excellent. With an average Overall Equipment Effectiveness (OEE) rate of about 50%; and with the lower percentile having an average rate of 20%, clearly there is room for improvement. Most of the companies that we have talked with during our plant visits, supplied data that was based primarily on "soft measures". These data gave allowances for interruptions, such as planned maintenance and material shortages; but



TPM performance measures

Measure / Practice	Unplanned Maintenance	Overall Equip. Effectiveness	Maintenance Costs/mach. value	Volumedep./ maintenance employees
Preventive Maintenance	●			
Standardisation	●			○
Team work/Cross-functional training		●		
Housekeeping				
Standardised supplier technology			●	●
Proprietary process development			higher costs	

● much higher performance ○ higher performance

Linkages between TPM practices and TPM-performance

did not count line stops of less than five minutes. Finding a consistent, reliable measure based on an OEE philosophy looks like a first step that is needed for improving equipment utilisation. Reducing the level of unplanned maintenance should be a second action. With an average level of unplanned maintenance of approximately 30%, many companies seem to have problems with running stable manufacturing processes. As stable running equipment directly influences JIT-performance (e.g. Work-in-process due to buffer stocks) or TQM (e.g. scrap rates), unplanned maintenance is a crucial indicator for assessing TPM-performance. However, the data provides evidence that a high level of unplanned maintenance correlates with high equipment utilisation rates. This indicates that plants operat-

ing at peak capacity may potentially encounter more equipment and process problems and thereby affect product quality.

It is apparent that the pharmaceutical industry operates a trade off between unplanned maintenance and a high utilisation rate. The challenge is how to cope with the current strategy. Analysis of the data suggests that the preferred option would be to first reduce unplanned maintenance. The data provide evidence, that unplanned maintenance levels are intercorrelated with the number of rejected batches and associated with higher Work-in-Progress stocks; which support the notion that each single element of an integrated production system is highly intercorrelated with others. There is strong empirical evidence that shows that autonomous and planned maintenance helps bring down unplanned maintenance levels. Companies with a formal preventive maintenance program with maintenance plans, checklists, standardized functional descriptions and a high level of employee participation (e.g. involvement of the operator into the decision making process when purchasing new machines) have significantly better performances. Furthermore, a high level of functional integration simultaneously helps to increase equipment utilisation.

Whilst preventive maintenance helps to support stable processes, the greatest leverage for reducing overall maintenance costs is linked to using appropriate equipment. Companies that are actively developing proprietary equipment have significantly higher maintenance costs than companies that (mostly) rely on their equipment vendors. The ratio, in terms of volume dependant employees versus maintenance employees, is also far higher among companies that are placing a high emphasis on developing proprietary equipment. This indicates that maintenance of proprietary developed equipment leads to significantly higher maintenance effort. Obviously, most of the companies that are actively developing proprietary equipment pursue a strategy to gain competitive advantage from a pharmaceutical-technology perspective and not from a TPM-perspective; as one of the main objectives is to design easy-to-use, stable equipment that helps to reduce set-ups and maintenance time.

Linking JIT to JIT-performance

While undertaking plant visits in the pharmaceutical industry, we observed that companies tended to be over-stocked compared to other industries that we have experience of. In the past, the limited productivity of the working capital employed came from high safety stocks, as companies were eager not to lose a single sale due to the high gross margins attached to each product. However, whilst gross margins, especially in the generics industry, tend to be much lower, and the cost-to-volume ratio of drugs is much higher than in most other industries, it is interesting to explore whether Just-in-Time practices could help to eliminate waste (especially working capital employed) and thus lower manufacturing costs. Furthermore, a comprehensive JIT-program can help to cope with increasing complexity brought about from heterogeneous customer requirements and smaller average lot sizes that will expose pharmaceutical plants in the future.

We analysed the level of implementation and the impact of JIT-practices by linking four basic principles of JIT to anticipated performance measures; such as inventory turn over. Whilst **pull-production** helps in reducing overproduction, and thus inventory, **set-up time reductions** can help to reduce the average lot size and enables an improved material flow throughout the manufacturing processes. Furthermore, process stock will be reduced by implementing a pull-production philosophy. It should be noted that a planning process with a high **planning adherence** is becoming a crucial element when implementing JIT-programs. Apart from waste caused by overproduction and excess inventory, an integrated JIT program also endeavours to reduce all kind of excessive movement caused by excess material and handling movement. Hence, **lay-out optimization** is a further basic principle of JIT implementation.

We expect plants with a low level of implementation of JIT practices to have long set-up times, high cycle times, low inventory turns and a moderately low planning adherence.

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Practices of JIT	JIT Performance measure
Pull-production	Set-up times, Cycle times,
Set-up time reduction	Finished goods inventory
Planning adherence	stock turn over, Work in
Lay-out-optimization	Process stock turn over
	(WIP), Raw material turn
	over, production-against-
	schedule, volume flexibility

The outcomes:

In terms of JIT implementation the pharmaceutical industry seems to be lagging behind other industries. The average level of implementation of JIT practice (57%) is the lowest score among all four major categories. Especially in terms of pull production, there seems to be a low level of implementation. However, on the performance side, there are companies in the sample that are having high stock turns even when compared to other industries. While the top 10%, in terms of stock-turns, has in average raw-material turns of 35 and finished goods inventories of about 13, these measures do not give the total picture.

However, there are several interesting outcomes if viewed from a less aggregated level. Companies that performed well, in terms of high stock turn-over, had also worked intensively on reducing their set-up times. They had previously implemented a philosophy of flow production; and in particular their work-in-progress stocks were much lower than those of their peer group.

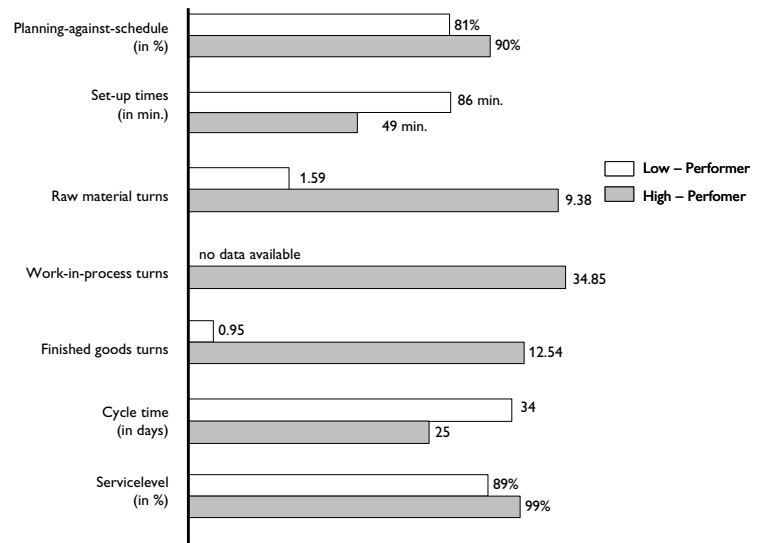
The main leverage for reducing stocks, while simultaneously sustaining high service levels, are similar to those of other industries.

They understood that flexibility for most of the pharmaceutical plants is determined by adaptability at their packaging line; and thus have extensively worked at reducing set-up times in this area. They typically have set-up times in their packaging center of some 40 minutes on average.

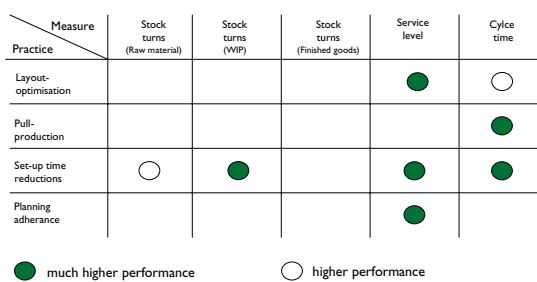
Based on their high flexibility they have very short freezing periods (between 2-3 days) and thus a very high planning adherence of around 98-99%.

By managing to reduce their set-up times, and having optimized their machine layout, they could reduce their cycle times to between 15 days (Liquids) and 25 days (solids).

While moving their stocks quickly through the



JIT performance measures



Linkages between JIT practices and JIT performance

manufacturing process with reduced Work-in-Process (WIP) and stock turns of about 35.

The statistical data indicates that there is a very high correlation between the average set-up time at the packaging line and the average WIP and raw material turns in the manufacturing process. As the packing line seems to be a bottleneck for most pharmaceutical plants, a reduction in set-up times would have the highest impact on WIP and raw material turns; and would also improve the average cycle times of the pharmaceutical plant.

Interestingly, even among the top 10%, companies did not make extensive use of common pull-practices such as kanban or other standardised demand-triggered replenishment signals. Successful companies appeared to have put greater emphasis on set-up time reduction and layout optimisation. The question arises, whether a pull system is an approach that can be transferred to the pharmaceutical industry with its

specific demands and sourcing patterns. Obviously, within the inventory management field, there is no "one-size-fits all" approach that can be applied for every pharmaceutical company. Today, pharmaceutical products are not as customized as automobiles. Furthermore, many drugs do have very stable demand patterns and there are certain "best-selling pack sizes" where it can be useful to build up inventory in "campaigns" to free-up productive capacities during times of peak demand.

However, things are changing. Some 83% of all respondents expects an increase in heterogeneity of customer preferences. The more that drugs will be manufactured with different packaging sizes, forms or "flavours", then the more traditional push approach will not be suitable for sustaining current service levels while not having huge inventories.

Linking the Management system to management performance

An effective plant management starts with clear **direction-setting**. Short of a clear direction, actions can, at best, be partial and, at worst, be confusing; due to communication remaining incomplete and ambiguous. A lack of direction-setting should lead to a **higher fluctuation**, and a low level of workforce participation. However, a workforce that is eager to contribute to the goals set by the management, but lack proper know-how to do so, can not support those goals. Hence, **qualification and employee development** is an essential tool to enhance **employee involvement**. As there is delegation of more complex decisions - e.g. like autonomous problems solving – then this can only be successful if employees are given the chance to acquire new knowledge. Consequently, employee development is a basic pillar for goals set by the plant management.

However, the organisational structure of a production plant also has to support employee participation. Today's pharmaceutical plants are more complex and capital intensive than in the past. A plant that is eager to respond quickly to changes in its environment needs organisational structures that increasingly delegates decisions at the shop floor level. Hence, as part of this research we measured the level of **delegation** by

analysing the **level of hierarchies** in the organisation, the **overhead ratio** and the level of implementation of team work on the shop-floor. However, many scholars have outlined the obstacles of implementing work teams. One major obstacle is inadequate cross-functional training of the workforce. Hence, **cross-functional training** is an enabler to enhance employee involvement. Workers must understand a variety of job skills to perform multiple team-based tasks. It is the key step in implementing self-directed work teams. Worker involvement and functional integration should help plants to become less vulnerable to fluctuation and absenteeism of the workforce. Furthermore, worker involvement and functional integration with changing requirements should also help to bring down fluctuation and rates of absenteeism.

Besides designing an effective organizational structure and setting clear directions, many scholars state that **management commitment** is a crucial element when it comes to the deployment of a well defined strategy. We expect that a high level of management commitment will foster employee participation and help to achieve objectives set by the plant management.

Practices of the management system	Management performance measures
Direction setting	Fluctuation, Absenteeism,
Management commitment	Number of suggestions per employee, Savings due to suggestions per employee,
Employee involvement & cont. improvement	lean hierarchy (level of hierarchies, overhead ratio),
Functional integration	employee flexibility (level of different job tasks performed by workforce)
Qualification & employee development	

The outcomes:

Do the management system of pharmaceutical manufacturing plants support world class manufacturing? The answer is: 'it depends'. Whilst in terms of fluctuation and absenteeism or employee development, the companies that have participated in this research are not far away from 'excellent organisations in other industries', the pharmaceutical industry seems to lag behind other industries when it comes to continuous improvement. While this measure has become one of the key measures in other industries, such as the automotive industry, the number of suggestions is in average one suggestion per em-

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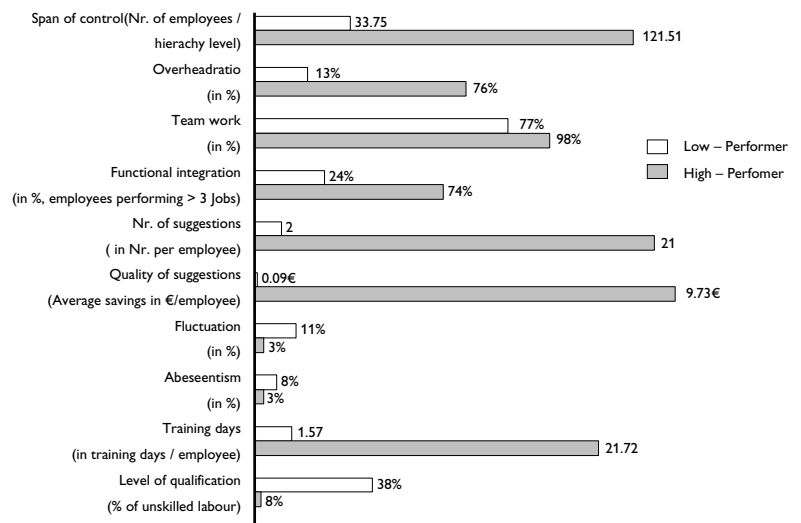
ployee. This picture is more daunting when cost savings due to improvement suggestions are considered. There are a few companies generating between 200,- and 1000,- EURO cost reductions per employee per year. However most of the participating companies did not measure this index. Some 64% of all plants did not measure the number of suggestions per employee, and 68% of all plants could not provide data concerning cost reductions brought about from suggestion schemes.

By analysing the management system of pharmaceutical plants we tried to find out the main levers for improving management performance, and in particular continuous improvement. By linking the implementation of the management practices with the management performance measures we found that the overall implementation of the practice is a strong predictor for management performance. The regression is highly significant and explains almost 30% of variance, which is fairly high for a regression with one independent variable (which is the practice variable) and one dependant variable (the performance measure).

On a less aggregated level, some of the hypotheses stated above were not supported.

When considering solely the implementation of self directed work teams, the results indicate that it does not have an impact on the average number of suggestions per employees. When combining team work with cross-functional integration, team work does boost the average number of suggestions per employee; and leads to a lower level of absenteeism.

However, a high level of team work goes in hand with a higher level of overhead, which contradicts our hypothesis that: 'group work should help to reduce the level of hierarchy and the overhead ratio, as more indirect work is supposed to be performed by the production teams'. The implementation of team work still needs a particular level of staff to support production teams; and has not managed to play the same role in decreasing the level of hierarchies and overhead like it has done in the automotive industry. Furthermore, cutting overhead seems to be a fairly simplistic way to reduce costs, but exaggerating it has a significant impact on absenteeism. Interestingly, the low performing plants



Management performance measures

Measure \ Practice	Fluctuation/ Absenteeism	Nr. of sugg. /employee	Average savings/ employee	Employee flexibility	Lean hierarchy
Direction setting		○			
Team work	○				higher overhead
Cross-functional training		●		●	higher overhead
Continuous improvement programs					○
Employee development			○		○

● much higher performance ○ higher performance

Linkages between Management principles and Management Performance

had the best performance in terms of management overhead ratio.

So, apart from team work and a certain level of support staff: 'which other levers do plant managers have to enhance a continuous improvement process?' While companies with a formal continuous improvement program based on quality circles, suggestions schemes etc. did not have a better performance in terms of quality and quantity of suggestions, it was seen that direction setting combined with strong management commitment tended to have a significant impact on the quantity of improvement suggestions. This shows that management has to have clear objectives and has to show personal commitment to the improvement process. However, the quality of the improvement process is heavily dependant on the number of training days. Plants with a higher number of training days per employee could realise higher cost savings per employee.

What about the qualification of the workforce? The major impact of qualification is in terms of overhead. Companies that have a low level of unskilled employees tend to have a significant better performance in terms of overhead. Arguably, a higher skill level helps plants to transfer indirect work to direct labour and, thereby, reduce the number of staff that is responsible for supporting the direct labour. Furthermore, a high level of qualification strongly correlates with quality performance (e.g. level of rejected batches). Those outcomes go in hand with our experiences when undertaking plant visits. When measuring employee development, the average number of training days per production worker was used. The results indicate that the pharmaceutical industry is performing quite well compared to other industries. However, most of the training is completed to cope with changing regulatory requirements (e.g. FDA). There is very little training with regard to continuous improvement (e.g. problem-solving skills, Kaizen workshops etc.). This also helps to understand why the pharmaceutical industry is characterized by a good performance in employee development (measured as number of training days) and the very low performance in terms of continuous improvement.

These results provide evidence that most of the pharmaceutical industry has not, as yet, successfully implemented current practices of work organisation. Companies that have implemented team work, cross-functional integration, quality circles, suggestions schemes etc. often do not perform better than their peers who still rely on a more Tayloristic work ethos. It seems that some of the companies are currently 'stuck in the middle'. While most of them have started to implement modern work practices, only a few have realised significant improvements.

Linking Operational Excellence to overall plant performance

While applying the Operational Excellence model we concentrated on internal operational performance measures, and attempted to discover how certain practices affect stock turns, scrap rates or other performance indicators that measure the efficiency of pharmaceutical plants. Though it is interesting to know whether a plant

is doing things right, it is at least as important to find out whether a pharmaceutical company is effectively using its operations to gain competitive advantage.

We measured effectiveness of plants on two levels. First we took an overall operational performance measure that comprised internal productivity measures, the dependability, the flexibility and the quality of a plant. While we mainly focused on the TQM section for internal quality measures, the external quality measure was based upon the complaint rate (as this measure provides insightful information of the quality of the final product as perceived by the customer).

Furthermore service level is addressed as this provides an answer to issues of dependability of a pharmaceutical plant. Besides cost, quality and delivery, the flexibility of a plant plays a major role when assessing its capability to react to changes in the market. Increasingly demanding and fragmented markets require manufacturing processes that can respond to the need for a variety of customized features. As flexibility is hard to measure by using quantitative data, we recoded plant managers' 'perception' of volumes, product mix- and product flexibility. These perceptions were aggregated to give an 'overall flexibility measure'.

JIT and TPM practices have the biggest impact on overall operational performance measures. Companies that have implemented JIT-principles, and are consequently reducing their set-up times, have optimized their plant layout to enhance short cycle times; and are now attempting to level capacity with current demand. These companies have significant higher service-levels and higher flexibility. Interestingly TPM practices seem to have an even higher impact on quality performance measures than TQM practices. While TQM has a significant impact on quality performance, a much higher variance of quality performance is explained by the implementation of TPM-practices. Obviously, stable running machines and equipment ensure better and more predictable quality; and simultaneously help to increase service-levels due to the lower levels of unplanned maintenance. Beside the implementation of JIT-practices, TQM does have an effect on flexibility. While JIT-practices mainly affect volume and product mix flexibility, the highest impact on new product flexibility comes from

implementing TQM practices such as cross-functional product development and customer integration.

Analysing the linkages between the level of Operational Excellence of a plant and its overall plant performance, we could present strong empirical evidence to support the view that certain leverages of Operational Excellence directly influence overall plant performance.

Measure \ Practice	Cost/ Productivity	Delivery (Service-level)	Quality (complaint rate)	Flexibility
TQM-System			○	○
TPM-System		●	●	
JIT-System		●		●
Management System				

● much higher performance ○ higher performance

Linkages between Operational Excellence and Overall plant performance

Does Operational Excellence matter from a corporate perspective? Linking Operational Excellence to Business performance

While our unit of analysis throughout the project was the pharmaceutical plant, one of the most interesting challenges was to find out whether Operational Excellence has any impact on overall business performance. The reason for that is, that few managers in the pharmaceutical industry view manufacturing as a primary source of competitive advantage. Most pharmaceutical companies do not want to lose sight of what they see as their true source of advantage: namely, product research and development. While our main purpose of the project was not to shift attention from R&D to manufacturing, we were curious to know whether Operational Excellence has any impact on business performance.

Within the survey, we mainly relied on objective measures based on financial or operational data. However, we chose to use qualitative perceptual measures to explore how the company performed from a corporate perspective. The reason for that was that most managers do know sufficiently well how their overall business is performing in their specific market compared to

their direct competitors (e.g. Sales, return on sales or market share) while there is a usually a lack of understanding with regard to operational performance figures (e.g. stock turns).

We did not expect Operational Excellence at one plant to have a major impact on business performance, as some of the bigger companies in the sample are managing complex production networks that often comprise more than 50 production plants around the world.

However, when linking Operational Excellence to business performance, the results provided evidence that Operational Excellence does significantly improve business performance. Plants that perform well in terms of Operational Excellence usually belong to a company that also significantly performs better in return on sales and market share when compared to its competitors. Furthermore, this correlation does not change significantly when analysing the linkage between Operational Excellence and business performance for smaller companies that have a single production site. Arguably, the degree of excellence of one single plant - or a few plants - in a global pharmaceutical company is a good predictor for the operational performance of its world wide operations network; and thus for its overall business performance.

Analysing the main Operational Excellence leverages, the statistical data provides evidence that Operational Excellence can explain around 20% of variance in return on sales improvement rates of pharmaceutical companies. Companies that have a high level of implementation of JIT, TPM, TQM principles, whilst also have an effective

Business performance \ Practice	Market share	Sales revenue	Return on Sales
Overall Operational Excellence level	○		●
TQM-System			●
TPM-System			○
JIT-System			●
Management System			●

● much higher performance ○ higher performance

Linkages between Operational Excellence and business performance

management system, performed much better in terms of return on sales growth than their industry peers. Furthermore, those companies could also significantly gain market share in their industry. Obviously, excellent operations do directly affect business performance of pharmaceutical companies.

So, returning to the main question of the project: 'Does Operational Excellence matter?' The data provides us with a clear answer: 'Yes, it does'.

A pathway to "Excellence": An outlook

With increasing market rivalry and lower growth rates, there will be an increasing cost pressure on pharmaceutical companies. In the pharmaceutical industry, world-wide sales have grown at an average annual rate of 11.1% from 1970 to 2002 (PhRMA 2003), today, these double-digit growth rates are strictly incorporated into the industry's overall growth expectations. However, as most of the industry expects the growth rates to decrease, a main leverage for maintaining current high company valuations is, to improve the return on sales while at least maintaining the capital employed. The three largest leverages for increasing profitability in the pharmaceutical industry are: Marketing, R&D and manufacturing. There are two factors that indicate to us that neither Marketing nor R&D costs will decrease, and thus help to cope with combating the challenge. Some 67% of all companies expect their R&D budgets to keep rising. Simultaneously, the average period between the launch of an innovative pharmaceutical drug and the launch of its "me-too" product has declined. The shorter this exclusive period becomes, the more emphasis that will be put on pushing a new drug into the market. Hence, we do not expect significant cost reductions in the field of R&D and marketing. One of the main leverages for increasing return on sales will be Operational Excellence.

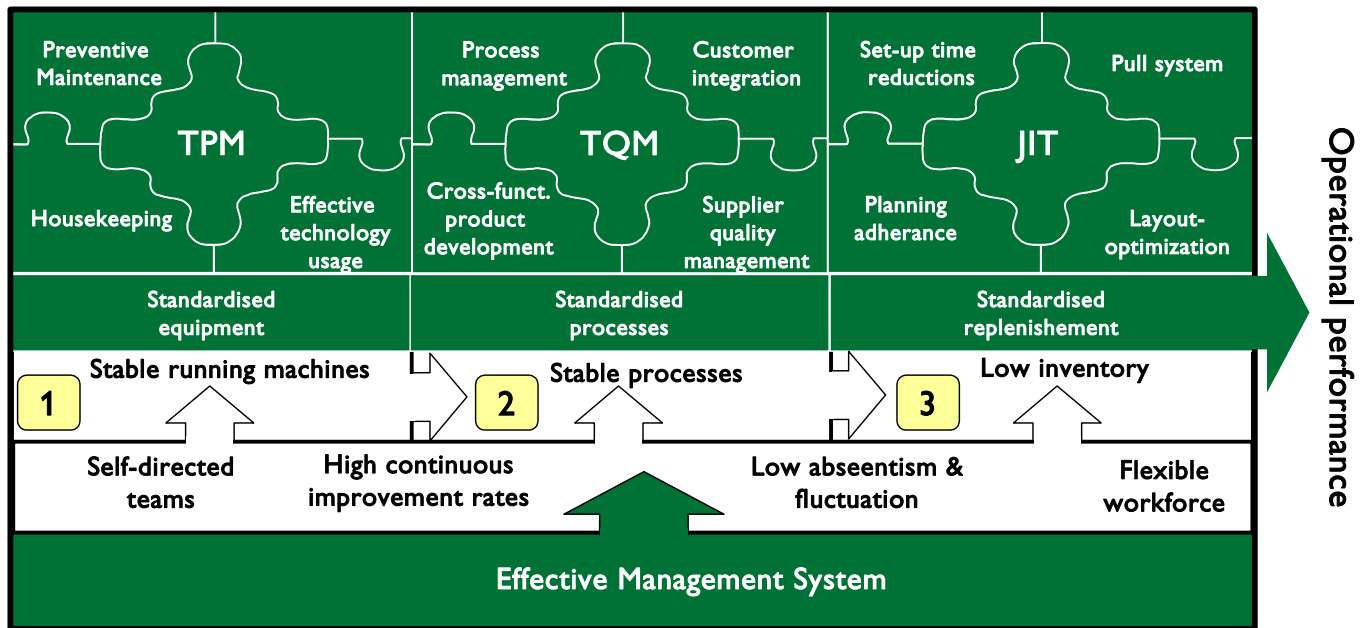
The report shows that regulatory obstacles and internal inertia have so far prevented a broad implementation of Operational Excellence practice. Results show that Operational Excellence does have an impact on both operational and business performance. We also present evidence – through statistical data – that Operational Ex-

cellence represents a system of interlocking parts. An operations improvement program that solely concentrates on one aspect – e.g. inventory reductions – will not yield significant operational improvements. To give an example: one of the best predictors for a high level of continuous improvement (measured as the number/quality of suggestions per employee) was the level of implementation of JIT-practices of a pharmaceutical plant. At first sight, this looks like a coincidental correlation between two independent factors. However, both factors are highly interrelated. A reduction in buffer stocks between manufacturing processes (measured as work in process stock) has to go hand in hand with the development of continuous improvement capabilities in the form of empowered/self directed work team capable of problem solving. Thus, the problem solving capabilities that arise as a result of empowered work teams can help boost performance by identifying root causes of quality problems and unstable running machines; and thus help to reduce safety stocks (measured as work-in-process stocks). The relationships between those factors are significantly correlated and show that an effective production system is an interrelated system of various aspects of Operational Excellence. Furthermore, it shows that there are key stages of Operational Excellence.

First, an Operational Excellence initiative should start with programs related to improving dependability of the core manufacturing processes. For example, reducing the percentage of unplanned maintenance, and capitalize on stable running machines could be a first step. Learning more about the process and reducing variances (e.g. by using Process Analytical Technology) could help to build in quality to the manufacturing processes and thus break up the vicious circle of high costs of prevention vs. high costs of failures and compliance. This research data provides evidence that companies that extensively make use of statistical process control, have lower cost of compliance, while mutually having moderate cost of prevention (e.g. Cost of QS/QA). Companies that have managed to develop a comprehensive internal process management system could proceed with their Operational Excellence program by integrating customers and suppliers into their quality system.

As soon as companies can capitalize on stable

International Benchmarking Study:
Operational Excellence in the Pharmaceutical Industry



Stages of Operational Excellence

running equipment, stable running manufacturing processes and reliable and integrated suppliers, a JIT-program could help to reduce buffer stocks and increase the flexibility. An effective management system has to support those manufacturing programs. While first it is important that the workforce understands the mechanism of a preventive maintenance philosophy, employee development in the next stage should focus more on quality improvements and ways to reduce variances in the manufacturing processes. In the last stage, employee development should foster ways and techniques to reduce set-up times and reduce non-value adding activities in the manufacturing processes.

Whilst not arguing that there is just one way of organizing an Operational improvement program, there are, however, certain contingencies between the different principles of Operational Excellence that restrict or reinforce the implementation of Operational improvement programs. This outcome is consistent with the (sometimes) painful experiences that the automotive industry has gained a couple of years ago. Today's, integrated production system in the automotive industry include identical practices, methods and tools that have previously been used ten years ago. What is new is not the knowledge about single methods like kanban, value stream mapping or Poka-Yoke, what is

new is more the understanding about the multiple dimensions of Operational Excellence that reinforce one another and produce their powerful effect; but only if used as a system. Those that have successfully managed to build an integrated production system have managed to use their operations as a competitive advantage. For some generics or contract manufacturing firms this could be a role model, too.



The project partners

University of St. Gallen Institute of Technology Management - TECTEM

The TECTEM is the professional services department of the Institute for Technology Management at the University of St. Gallen, Switzerland.

The Institute for Technology Management is one of the University's largest research organizations. It focuses on applied research. More than 75% of the Institute's revenues stem from industry projects. All research projects are conducted in close cooperation with corporate clients.

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