



Operational Excellence in the Pharmaceutical Industry

OPEX Scan: Analyze the Status Quo –
Structure the Future

Statements

“We saved 35% of total maintenance expenses and 20% of quality expenses and at the same time reduced our working capital by 6.8%.”

CEO of a major drug manufacturing company

“This benchmarking study represents the largest independent survey in the pharmaceutical industry and provides a comprehensive analysis to achieve significant productivity improvements for the participating companies.”

Prof. Thomas Friedli,
University of St. Gallen

“I was amazed at how many improvement opportunities were revealed by the team in such a short time and the technical and leadership professionalism the team conducted their task.”

Site Leader of a mid size drug manufacturing company

“In view of slackening innovation and increasing globalization, cost awareness becomes increasingly important. Unfortunately, many companies do not realize their savings potential early enough.”

Jürgen Werani, Ph.D.,
Schuh & Company

The Challenge

The pharmaceutical industry finds itself undergoing dramatic changes:

- The pharmaceutical industry will have to continue to implement cost cutting exercises globally. At the same time, pressure on governments and payers to honor pharmaceutical innovation will increase.
- Governments and payers will continue to cut costs by implementing cuts on drug price reimbursements. Although expenditures on drugs constitute merely 10% of the overall healthcare costs, it is easier to continue to target drug prices instead of putting the reform of the healthcare system on the political agenda.
- Industry will have to reduce costs without reducing quality. It's about excellence.

Pharmaceutical companies that are at the leading edge of Quality Compliance and employ programs such as Operational Excellence to increase efficiency will emerge as the true winners!

The Savings

Achieving significant savings through the implementation of an Operational Excellence program is quite common. Some examples of annual savings are, calculated for a manufacturing site with 300 to 500 employees:

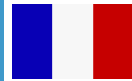
- \$5,000 of annual savings in maintenance costs per employee, translating into 35% of savings in total maintenance costs.
- \$3,500 in savings of quality costs per employee, representing 20% of annual quality expenses.
- A lead time reduction of 50% representing \$1.5 million of committed capital.

Unfortunately, only few companies are aware of these opportunities and how to easily achieve these savings.

Key cost cutting trends



- The National Institute for Health and Clinical Excellence (NICE) agree to risk-sharing after intense pressure from patient groups and physicians
- NICE expected to expand its remit - undertaking pricing, de-investment and a chargeable consultancy service to Pharma in designing clinical trials



- Reimbursement drug list reforms have been insufficient in cutting costs due to lack of physician compliance



- Germany continues to implement cost cutting policies that affect both Pharma & generic alike



- Referencing pricing has cut costs but it is partly responsible for a drop in investor confidence in Spain as a R&D center



- Italy to pay increased attention to pharmaceutical innovation, after decreases in pharmaceutical drug spending



- As Healthcare costs escalate, Medicare (part D) launches initiative to increase cost effectiveness



- Japan implements further price cuts but delays reforms to P&R system

Key cost cutting trends in the pharmaceutical industry

Lack of Capacity	Many Defects	Long Leadtimes
Low Asset Utilization	Poor Quality	High Inventories
Poor Safety Records	Poor Reliability	Poor Flow
Poor Flexibility	Low Capability	Bottlenecks
High Process Cost	Too Much Variation	Customer Complaints
Low Productivity	Lack of Control	Excessive Waste



Increase Value



Reduce Variation



Improve Flow

Typical issues of lacking process excellence

The Benchmarks

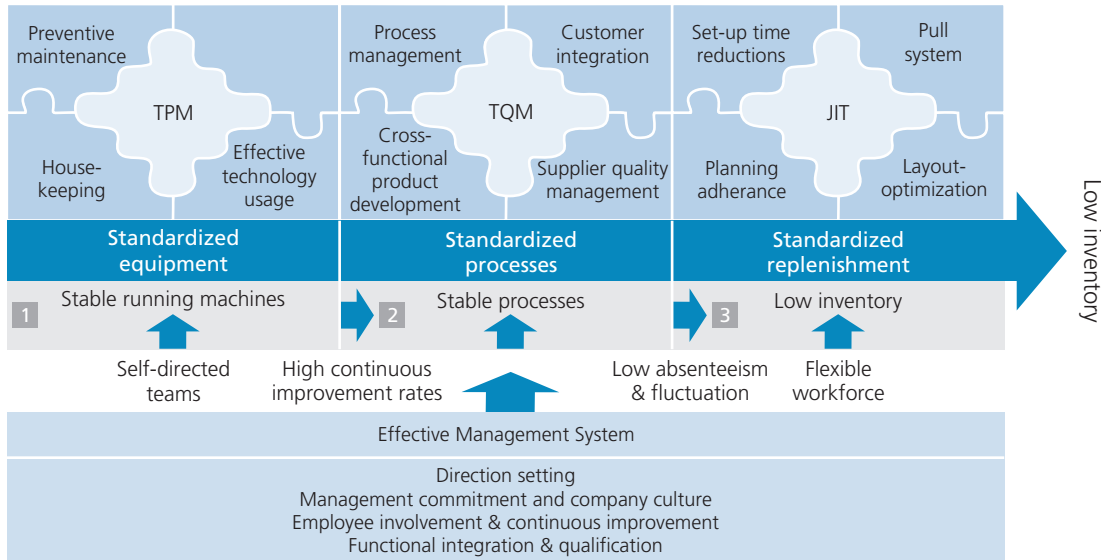
While most pharmaceutical companies consider themselves to be excellent examples of lean enterprises, the “Operational Excellence (OPEX) in the Pharmaceutical Industry” study of the University of St. Gallen, Switzerland reveals other results.

The benchmarking study represents the biggest independent study of this kind ever conducted in the industry. In addition it provides a comprehensive analysis to achieve significant productivity improvements as mentioned above. Just some facts:

- 162 participating manufacturing sites

- 84 companies across Europe and North America
- Participants include R&D oriented companies, generics manufacturers, contract manufacturers, biotechnology companies and API manufacturers
- Company sizes range from 100 employees to well beyond 1,000 employees

The study is based on the belief that key performance indicators can only reveal a true reading when considered with site environments, structural factors, site management and its role within the network. Therefore the study considers the link between performance and its enablers.



TPM = Total Productive Maintenance
 TQM = Total Quality Management
 JIT = Just In Time

Source:
 University St. Gallen Institute of Technology Management

The University of St. Gallen OPEX Reference Model

The Findings

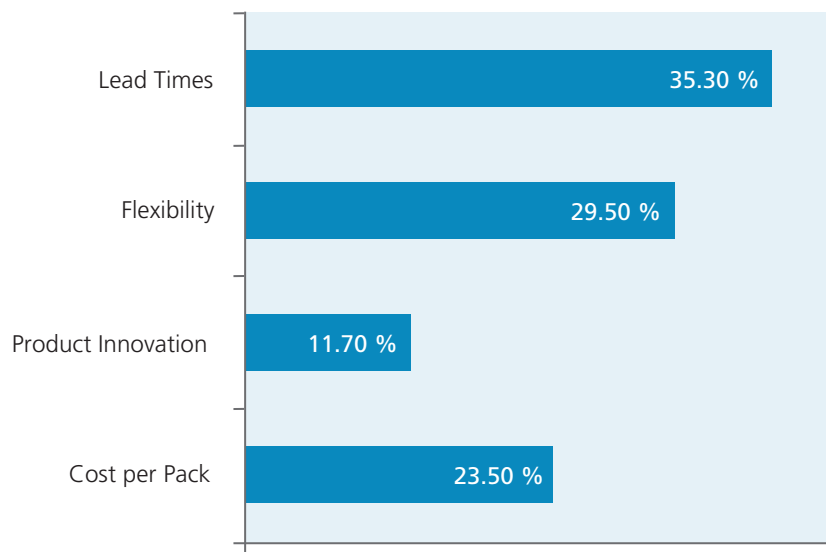
Besides the cost savings that were already mentioned, the benchmarking study and follow-on research studies revealed that while 88% of companies considered OPEX tools and principles important for their business environment, only 18% perceive that they have an OPEX culture.

Generally, companies fall into three categories:

- First movers, companies that started their OPEX program more than 5 years ago
- Followers, companies that started their OPEX initiative 2-5 years ago
- Laggards, companies that started their OPEX less than 2 years ago

While laggards claim that they can learn from first movers' mistakes, the study shows that in fact they make the same mistakes that first movers encountered when starting their initiatives. This gives first movers a significant advantage.

Operational Excellence programs do not primarily aim at short-term cost reduction. In order to remain competitive in a rapidly changing market environment, organizations need to increase flexibility, maintain quality and improve process flow. This requires a re-orientation of the ways of thinking and working. Operational Excellence supports this process and helps to achieve sustainable cultural change.



Respondents indicated different objectives of their Operational Excellence programs

Your Benefits

Our OPEX scan offers you a true comparison against other pharmaceutical companies. Find out whether you are a true leader or a laggard. The scan will provide three distinct outcomes:

1. An individualized comparison against your competitors and Top Performers based on the most comprehensive benchmarking database on Operational Excellence in the Pharmaceutical Industry including:

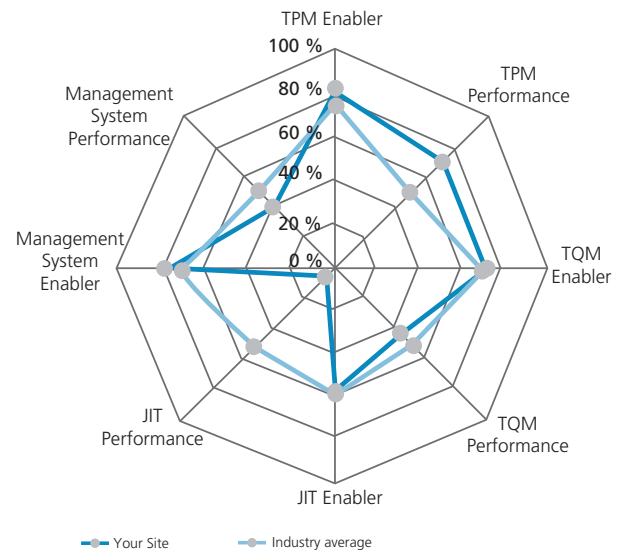
- Performance Rating of your site
- Implementation Rating of your site
- Total Productive Maintenance (TPM), Total Quality Management (TQM) and Just-in-Time (JIT) picture of practices that really drive Operational Excellence

2. A detailed TPM, TQM and JIT assessment for your plant including:

- Clear determination of any prerequisites for implementation
- Status quo of the implementation against state of the art knowledge
- Prioritization matrix considering individual plant objectives
- Definition of areas of improvement
- A leadership assessment
- An assessment of your readiness for change

3. A tailored master plan establishing the right enablers for TPM, TQM and JIT to improve your overall performance:

- Establish of a time horizon with goals
- Clear consideration of your capabilities and resource availability
- Specialized support by experts from the Schuh & Company network



Performance and enabling practice against industry level

Examples from our questionnaires

TPM Enabler: Preventive Maintenance	
D04 All potential bottleneck machines are identified and supplied with additional spare parts.	
→ High Performers know their bottlenecks better than others	
TQM Enabler: Cross-Functional Product Development	
E13 For product and process transfers between units or sites standardized procedures exist, which ensure a fast, stable and complied knowledge transfer.	
→ High Performers emphasize, stable and compliant knowledge transfer	
JIT Enabler: Planning adherence	
F29 A smoothly leveled production schedule is preferred to a high level of capacity utilization.	
→ High Performers focus on smooth production flows	
JIT Enabler: Pull Production	
F12 We mainly produce one unit when the customer orders one. We normally do not produce to stock.	
F13 We mainly produce according to forecast.	
→ High Performers produce to order rather than to forecasts	

Implementation Level
 ■ Your Site ■ Average Level ■ High Performer

Implementation rating compared to top performers

Our Approach

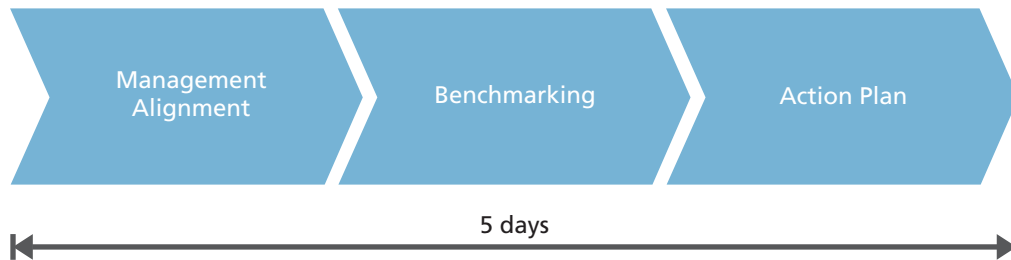
Schuh & Company offers an Operational Excellence scan in cooperation with two leading universities. Our scan offers you the opportunity to be compared against the industry's top performers. As a result, you will have a specific action plan outlining your next steps for achieving a true OPEX culture.

Throughout the scan we always focus on linking enablers ("How do you achieve excellence?") with the metrics ("What is excellence?"). We understand that the successful implementation and sustainability of the program matter most. Therefore, we follow a participative approach and work closely with company employees during the scan.

Our OPEX Scan relies on three distinct phases. We start with a management alignment during which we will meet with key employees and analyze the current situation. We gather information on existing initiatives and KPI's. Receiving a comprehensive overview of what has already

been achieved is the goal. Phase two is where the benchmarking takes place. We rely on a structured approach that includes in-depth interviews with individual employees, a structured questionnaire and muda walks. All results are aligned and compared to our benchmarking database. Consequently, you will see how you perform against the industry and your areas for most improvement will be identified. In the last phase, you will receive an action plan. The contents of improvement measures will be determined and activities will be prioritized. Of course, we will always keep your resource availability in mind during this phase. In a final management workshop, we will disclose and discuss our findings with your management team.

At the end of the five days you should have a clear understanding of how you perform against the competition and where your potential for improvement and savings lies.



The OPEX Scan

Company

Schuh & Company focuses on providing solutions and methods for managing the ever-increasing complexity of today's enterprises products and processes. With this approach the company established itself as implementation-oriented problem solver in the industry.

Today the company consists of about 40 people committed to ensure your company's success through their work as strategy and organizational consultants, as well as management coaches. Schuh & Company is headquartered in Aachen, Germany, with subsidiaries in St. Gallen, Switzerland (since 1991), and Atlanta, GA, USA (since 1997).

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