Operational Excellence

in the Pharmaceutical Industry

Edited by
Thomas Friedli
Michael Kickuth
Frank Stieneker
Peter Thaler
Jürgen Werani

EDITIO CANTOR VERLAG

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Preface

More than 20 years have gone since we established the expression "lean production" for a set of Japanese techniques which changed the whole competitive landscape of the automotive industry in the 1980s giving way to fundamental changes how production is done in industry after industry.

The concepts described in our book "The Machine that Changed the World" and further elaborated in our later publications have been widely copied throughout the world. But there remains healthy debate regarding the extent to which the philosophy behind these techniques is applicable.

The results of the benchmarking study in the pharmaceutical industry that is described in this book are a further proof that "lean thinking" knows no industry barriers. If pharmaceutical companies want to stay ahead of competition they should have a look at the evidence presented in this book an draw their conclusions!

Prof. Dr. Daniel T. Jones
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Prof. Dr. Daniel T. Jones is author of „The Machine that Changed the World: the Story of Lean Production", „Lean Thinking: Banish Waste and Create Value in Your Corporation" and "Lean Solutions: How Companies and Costumers can Create Value and Wealth together", all of them together with James P. Womack.

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Introduction

When we came together in mid 2003 we had a vision in mind: the vision of a pharmaceutical company operating like Toyota, reducing every kind of waste, steadily optimizing the way how things are done and systematically nurturing a culture of continuous improvement. For us there were clear signs that a radical rethinking of pharmaceutical manufacturing would be necessary in order to ensure a sustainable future. Based on this understanding we started the biggest benchmarking project ever seen in pharmaceutical manufacturing; being well aware that at the beginning of the transformation of the U.S. and German car manufacturing industry was also a benchmarking study that had been documented in the famous book "The machine that changed the world" by James Womack and Daniel Jones. The results of our study and an outlook on the future of pharmaceutical manufacturing are described in this book.

We start with a look on the changing environment for pharmaceutical companies by working out the challenges they are facing. Then we develop the model we used for our study. This model shows our understanding of "Operational Excellence". We go on with a description of what we found in plants all over Europe and draw a conclusion concerning the importance of Operational Excellence for overall sustainable superior performance of a pharmaceutical company. In chapter IV we refer to a sample of different case studies. Each of them highlights a particular aspect of successfully striving for Operational Excellence. We end chapter IV with a stage model for launching an Operational Excellence program derived from the study of the cases. Lastly, in chapter V we develop the picture of the pharmaceutical plant of the future.

The way to Operational Excellence is a journey. This journey is long and often hard but it is quite clear that all companies that hesitate to take this journey, that are hiding themselves behind regulations, are risking their future. We hope that with this book we give some valuable advice on starters of how to make things happen; whilst also offering to all the others already on the road some guidance on the way.

We would like to thank all the people that helped to make this project happen and to all of the authors who provided us with their know-how. Especially we would like to thank

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Thomas Friedli, Michael Kickuth,
Frank Stieneker, Peter Thaler,
and Jürgen Werani

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List of Abbreviations

APV	International Association for Pharmaceutical Technology
ADMET	Analytical, Distribution, Metabolism, Excretion and Toxicology
AMT	Advanced Manufacturing Technologies
ANOG	Analysis of Goodness
API	Active Pharmaceutical Ingredient
APS	Advanced Planning Software
BPR	Business Process Reengineering
C&E	Cause-and-Effect
CAQ	Computer Aided Quality
CEO	Chief Executive Officer
CFO	Chief Financial Officer
cGMP	Current Good Manufacturing Process
CMO	Contract Manufacturer Organization
CP	Combination Pack Line
CTQ	Critical to Quality
DMAIC	Define, Measure, Analyze, Improve, Control
DOE	Design of Experiments
DPMO	Defects Per Million Opportunities
DS	Drug Substance
EAI	Enterprise Application Integration
EM	Efficient Manufacture
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration
FIFO	First-In-First-Out
FMEA	Failure Mode and Effect Analysis
GFT	Gelatin Filled Tanks
GMP	Good Manufacturing Process
HCM	Hard Capsule Machine
IEA	Industrial Excellence Award
JIT	Just-in-Time
KPI	Key Performance Indicator
MIT	Massachusetts Institute of Technology

Mn	Manganese
MRP	Material Requirements Planning
NCE	New Chemical Entities
NDA	New Drug Application
NHS	National Health System
NPS	NextPharma Production System
NVA	Non-Value Adding
OEE	Overall Equipment Effectiveness
OPEX	Operational Excellence in the Pharmaceutical Industry
ou	output units
PAT	Process Analytical Technology
PGM	Pfizer Global Manufacturing
PhRMA	Pharmaceutical Research and Manufacturers of America
POMA	Pharmaceutical Outsourcing Management Association
PTS	Production Technology Support
QA	Quality Assurance
QC	Quality Control
QFD	Quality Function Deployment
R&D	Research and Development
RFID	Radio Frequency Identification
RFT	Right First Time
RFT LT	Right First Time Leadership Team
SIPOC	Supplier-Input-Process-Output-Customer
SME	Small and Medium-sized Enterprises
SMED	Single Minute Exchange of Die
SOP	Standard Operating Procedure
SPC	Statistical Process Control
TPM	Total Productive Maintenance
TPS	Toyota Production System
TQC	Total Quality Control
TQM	Total Quality Management
VA	Value Adding
VOC	Voice of the Customer
WIP	Work-in-progress

I Challenges in the Pharmaceutical Industry

Gerrit Reepmeyer and Michael Kickuth

"Today, there are few people that are not aware about the future challenges of the [pharmaceutical] industry: In the fundamental research sciences – molecular biology, genomics, chemical sciences and computer sciences there are interesting technical advancements – however the development of the institutional, regulatory and social political environment will put the future earnings potentials of this industry to the test."

Gary P. Pisano
Harvard Business School

In this chapter we describe the current industry environment for pharmaceutical companies to understand the role of manufacturing in this context. At the end of the chapter, we derive explicit requirements for manufacturing in the pharmaceutical industry.

I.1 Declining R&D Productivity

By definition, research and development (R&D) productivity is the ratio of input in R&D versus its output. The black-box in between consists of the drug development pipeline, new screening and research technologies, worldwide cooperation networks in clinical research and testing, and a whole new armada of licensing and cooperation agreements with competitors and biotechnology start-ups. Still, as a recent Reuters study shows, R&D performance of the major pharmaceutical companies is sub-optimal (Reuters 2003):

- Pipeline output is low and declining;
- Costs of R&D are rising rapidly, driven by larger and more complex clinical studies and expensive new enabling technologies;

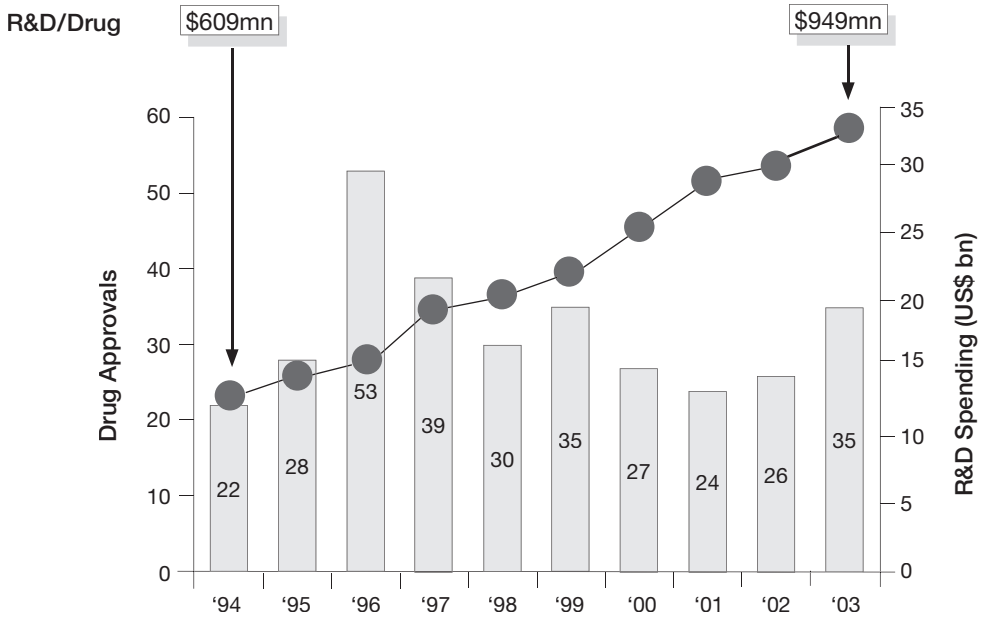

Figure 1: The widening productivity gap in drug discovery (Source: PhRMA 2004).

- Heavy competition from follow-on drugs, a decrease of the period of market exclusivity and falling numbers of new product launches make it difficult to replace revenues lost through patent expiry;
- Protracted clinical trials and administrative procedures reduce the marketed shelf life of patented products.

In addition, R&D expenditures of the pharmaceutical companies worldwide have grown constantly over the last decades (in relative terms, from 11.4% of sales in 1970 to 18.5% in 2001), and – according to PhRMA – the major US and European companies invested more than USD 33 billion in R&D in 2003 alone (PhRMA 2004). But since the mid-1990s, the launch of new molecular entities on the market has declined or has been constant at best (Figure 1). The number of new drugs approved by the Food and Drug Administration (FDA) in the United States fell to just 24 in 2001, although this number slightly improved in 2002 and 2003. The long average lead time in pharmaceutical R&D cannot be used as an excuse because, firstly, the greatest R&D expenses are in the final phases of drug development (within just a few years of market introduction) and, secondly, because the observed trends in the 1990s were already present in the decades before.

Consequently, drug development costs per new drug approval are constantly increasing. In 1976, it cost USD 54 million to develop a new drug, USD 231 million in 1987, and about USD 280 million in 1991 (DiMasi 2001). This number has grown to close to USD 1 billion by now. Even though it is not legitimate to make a direct comparison between R&D spending and R&D productivity, the tendency of increasing R&D costs per drug is certainly a concern for the top management in pharmaceutical companies.

III.4 Linking Operational Excellence to Overall Plant Performance

Michael Kickuth and Thomas Friedli

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.

Analyzing 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 argument that certain leverages of Operational Excellence directly influence overall plant performance.

III.5 Does Operational Excellence Matter from a Corporate Perspective?

Michael Kickuth and Thomas Friedli

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 analyzing 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 strong predictor for the operational performance of its world-wide operations network; and thus for its overall business performance.

Analyzing 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; and around 13% of variance in overall business performance (which is an aggregated super scale measuring increase in sales, increase in ROS and increase in market share of the company; see Figure 25).

Companies that have a high level of implementation of JIT, TPM, TQM principles, also have an effective management system, and 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". However, the data also provides strong evidence that today most of the industry is far from excellent.

The OEE results were reviewed with shift personnel and, more importantly, with the staff employed by Johnson Controls, to which the Hull factory outsourced all of its first line maintenance and changeover activities. "When we initially outsourced maintenance to Johnson we were getting too many arguments about whether lines were working well or not and whether changeovers could be completed more quickly," recalls Haswell. The use of factual ACTIVA data helped overcome these problems.

In addition, Johnson Control's engineers video-recorded and documented each changeover, developing standard procedures for them – along with an associated target time. Critically, adds Haswell, there is also an improvement target for each changeover, with a plan for achieving it, and the resources required to bring the plan to fruition.

But slicker changeovers were not the only source of improved effectiveness. As engineering support manager Barry Jones relates, projects were also targeted on improving the operation of individual lines – boosting the 'efficiency' aspect of the OEE measure. When you looked closely at what was going on, it was surprising how much slack had crept in over the years, as lines had been added-to, and new capabilities built-in he says. Certainly, a simple re-balancing exercise on the eleven year old multi-product Marchesini tablet line proved this by yielding significant improvements, forcing as many operations as possible to be carried out in parallel, rather than in series. Once again, identifying the bottlenecks and taking action to balance lines brought immediate benefits.

Philosophy of OEE

- Very self-critical but produces results
- Use analysis to determine cause
  - Equipment
  - Material
  - People
- Continually review/re-visit/re-focus
- Overall Equipment Effectiveness "Hard" Measure
  - 100 sachet/min design speed
  - 6,000 sachet/hour output
  - 16 x 6,000 = 96,000 expected over two shifts
  - 48,000 produced at 100 % quality
  - i.e. only 50 % efficient
- OEE = Availability x Performance Rate x Quality Rate

But further potential remained, particularly when the line operators were brought in to suggest improvements. Photocells placed at right angles to the line, for example, would occasionally interpret the gap between cardboard trays of products as indicative of no tray being present – and consequently erroneously stop the line. It was, observed Jones, a problem that operators had been living with for years. But placing the photocells diagonally instead of at right angles solved the problem for good: the photocell beam of light was always interrupted by a tray, except when one genuinely was not there.

Similarly, it was possible to fine-tune individual operations. On the tray loader unit within the line, for example, a mechanical arm pushed each tray into the plastic film in which it would be shrunk wrapped. At the point of actual insertion into the film, the speed of the push needed to be very slow, so as to avoid jams or other difficulties that would stop the line. Yet the mechanical arm as originally commissioned worked at this slow speed throughout its entire operation cycle – even when withdrawing, when the speed of the movement was irrelevant. Jones and colleague Paul Kennedy re-programmed the arm so as to initially push at high speed, then more slowly, and then withdraw once again at high speed.

Such minor tweaks to a line may not sound much – but taken together, they added up to a considerable improvement, says Brooke. Jones and Kennedy also fine-tuned the internal commands of the line's programmable logic controllers, trimming as much as three-quarters of a second from some of their cycle times, thus cutting operation times to the minimum. They also ensured that each station "stopped empty" in the event of a shutdown, which made re-starting the line much simpler and speedier. Tiny incremental improvements, to be sure – but improvements that eventually boosted throughput from 12 packs per minute to 16 packs per minute, yielding a whopping 30% increase in capacity.

There are times of the year when that capacity is extremely useful indeed, stresses Brooke. During the peak of the annual cold and flu cycle, medicine demand massively outstrips production: the last two winter peaks, he notes, have seen three months' production of Lemsip sachets sold in a single week. So while the Marchesini line's ability to churn out additional packs of the admittedly less widely consumed Lemsip capsules comes in handy, the ability to respond rapidly to change in demand for the core sachet Lemsip product is vital.

This, as it turns out, was another aspect of the factory's operations that won plaudits from the Best Factory Awards judges. Characteristically, the approach adopted is a blend of several elements of manufacturing management, ranging from top-level forecasting and inventory planning at one end of the spectrum to detailed engineering-based improvements at the other.

Maximise production efficiencies

Broadly speaking, explained planning manager Bill Maxwell, the factory aimed to produce in excess of the level of demand in the period April to August, and to produce at least at the level of demand (or higher, if possible) during the period September to March. However, he adds, pure-and-simple inventory building is a sub-optimal solution, and so the factory has tended to build its inventory in 'campaigns'. The intention of this, he explained, was not only to maximise production efficiencies, but also to free-up productive capacity during the times of peak demand – so that during these times, the equipment would be running, more or less continuously, on the strongest selling pack sizes and flavors. To reinforce this, an additional filling line was purchased. Where there were originally two lines, one filling two sizes of Fybogel, while the other filled Lemsip, the additional line can handle both Fybogel and Lemsip, enabling the original Fybogel line to concentrate on maximising the output of a single pack size. With planned inventory buildings of Fybogel, therefore, the additional line can be switched almost entirely to Lemsip, effectively doubling capacity, while at the same time, thanks to fewer changeovers, reducing the filling cost per sachet.

Still further productive capacity is obtained through the use of labor contracts that enable filling lines to switch from two-shift working to three-shift working at short notice, in exchange for a shift premium. "Formally, the notice period is five days, but we can often switch more quickly," says Brooke. With a corps of key operatives trained to man any of the three lines, each shift can be buffered with enough temporary labor to enable two

Figure 55: Inside the IT-Cockpit: One person a time is able to monitor and control all the operations.

to monitor and control operations 24 hours per day. The furnace was revamped and relined in the Spring of 2004 a major upgrade was completed that took 3 months. As a result, its uptime is expected to go above 99 %. The cooling system was upgraded, and an improved off-gas washing system installed, which reduced emissions and improved efficiency simultaneously.

The improvements included investments in safety; for example, several certifications were achieved (ISO 9001 version 2000, OHSAS 18001), which included a number of procedure changes. As a result, the plant has worked over 2000 days without a single accident. During the furnace relining, 140 people from 40 companies worked for 75000 hours without a serious accident. The 5S programs helped lead to ISO14001 Environmental certification in September 2001, a first for a ferro alloy furnace, followed by the UJC Environmental prize in November 2001.

Participation

Engineering improvements relied significantly on employee participation at all levels. Ideas from suggestion boxes chosen for implementation were moved forward with significant direction from the suggestor, usually the person responsible for the process. Ideas from suggestion boxes that were not chosen for study involved management describing why the idea would not be pursued with the employee that suggested it.

Improvement projects ebb and flow; but in the long run average-out to an acceptable level. The engineering manager estimates that every employee spends about 30 minutes per day, representing about 6 % of work time, on improvement activities that are non-productive in the very short term. Although the big improvements stem from engineering-driven changes, the continuous improvements efforts by all employees do contribute significantly, perhaps around 30 %, to the overall productivity progress. This is remarkable – again half as many improvements come from many operator ideas as from big engineering improvements.

Training and Development

Employees were offered technical training, and language courses. Exchange programs were set up for visits between CVRD in Brazil and RDME in France lasting a week, 3 months or a year. A strong mentorship program linked employees to others to improve process knowledge and workforce renewal. A results-participation scheme provided reinforced the motivation for the workforce.

Training (9 days per employee and year in Grande-Synthe, corresponding to 8% of total salary costs, which is high in comparison to other companies across industries) includes on the job training, job rotation, visits to Brazil (for managers and high-level technicians), as well as specialized technical training courses. As the HR manager comments, "We were 'franco-français', but now we have a more international outlook. For example, 25% of our people have taken a course in English or Portuguese."

Communication

The new style of communication was characterized by Mr. Nepomuceno as requiring "Big ears and a small mouth". By 2001, office space was significantly reorganized, so that many walls were removed. The few offices with walls maintained an "open door" policy, which was perceived to be key to resolving problems before they became crises. Internal newsletters and magazines were established.

This was further extended and made extremely visible with the construction of a new administration building: offices were completely abandoned; now, everyone sits in an open space, not even separated by cubicle walls, including top management. Everyone can see everyone else all the time. "This was difficult, as it does not correspond to traditional French management culture. But people have accepted it, and now it feels good because we can very easily communicate with one another."

Personnel Policies: People at the Centre

The emphasis on teamwork, and the recognition of the contribution of all employees, is pervasive and consistent; it has become part of the company culture. It starts at the top when Luis Carlos Nepomuceno states that "Good motivated people are the way to success"; and lives the motto in his behavior. Moreover, it continues when the engineering manager, Marcelo Rocha, goes to talk to the control operators at the furnace. The atmosphere is one of pride, where everyone is willing to take an extra step on their own initiative.

In addition to the further evolution of culture, new official reward schemes are being introduced. For example, a profit sharing ("intéressement") based on company results, combined with group-based and individual bonuses. In addition, every employee is assigned a "Godfather", a more senior mentor who helps him or her in career planning. Also, everyone has a yearly performance review and goal setting conversation with his/her superior. And employees have the possibility of progressing in their career if they so desire – for example, the CFO started as a purchasing clerk. HR has databases with career status, development needs and succession planning for every employee.

In this atmosphere, the collaboration with the unions has become constructive and collaborative (although not without challenges). Marcelo Rocha comments, "Before I came here, I did not believe that it was possible to be open and listen to the workers, undertake measures to the environment, AND be highly productive, all at the same time. The key is motivated people – it IS possible to constructively work with people here. At home, people do not have the mindset to change. This is one of the main lessons I will take home with me."

2. Reconfigure the plant network

In the past, if a pharmaceutical company wanted to sell its products in a foreign country, it would often have to make concessions. Among those was building a manufacturing plant in the country, staffing it with local workers, and entrusting it to a local manager, who in most instances, acted autonomously, accountable only to top- and bottom-line performance. As a result of such regulatory and governmental constraints, pharmaceutical companies saw a proliferation of their plants and distribution centers around the world. Rather than having a plant network that was build up on an overall operations strategy, the network was more like a loose confederation with far more facilities and capabilities than needed. As the global situation has changed, and many regional plant barriers have disappeared, these plant networks do not comply anymore with today's changing requirements towards flexibility and efficiency. G. K. Raju states that pharmaceutical companies increasingly have to question themselves why they are manufacturing in a certain country. The more pharmaceutical companies will raise that question, the more will countries like China and India be taken into consideration. As long as gross margins on drugs are as high as today, questions on intellectual property are overriding the question of manufacturing costs. With lower gross margins sticking to the products, this might change in the future. However, especially in the case of India, manufacturing costs are just one issue. With its history of more than 30 years of "process patents"[28], India nurtured a pharmaceutical industry which is very competitive with regard to process innovations. Hence, Indian companies are not just cheap, they are often also very advanced on the process side of drug development and manufacturing.

Even though emerging off-shore opportunities for building up manufacturing capacities abroad might look promising, many western pharmaceutical companies are facing a situation of excess capacity. Especially in the field of chemical production there is a lot of excess capacity. Mergers and acquisitions have led to varied portfolios, manufacturing redundancies and excess capacity. Some global pharmaceutical companies like GlaxoSmithKline have already restructured their manufacturing operations and have reduced their number of plants significantly. While some companies prefer to sell their plants to contract manufacturers, some prefer to close plants as they are especially afraid of transferring valuable knowledge to buyers from India or China. *"Those companies that are most interested in buying excess production capacity in Europe from us come from India. However, we do not want to nurture potential future competitors"* says one executive manager of a pharmaceutical company that is currently restructuring its production network.

Summarizing the current situation, one major structural change should be the centralization of supply chain management. No longer will an individual manager make a unilateral decision about building a new plant. Thinking globally, the company will design its manufacturing operations to support overall needs. Furthermore, companies can optimize their sourcing and achieve better economies of scale. Each plant within in the network has to play a certain role within the plant network which is derived from the overall operations strategy of the company.

However, this approach does not mean that each plant in the network is dedicated to a certain product. This approach usually does not fit with today's changing requirements towards flexibility. Again the configuration of the plant network should start by answering two basic questions:

28 In 1970, India introduced „process patents" which, unlike patents in the US or Europe, allowed innovators to protect the way they made drugs, rather than the molecules themselves.

- What is the primary strategic reason for the factory's location?
- What is the scope of its current activities?

Based on the answers of these questions, managers can use a framework Kasra Ferdows (1997) developed to categorize plants and to determine how to expand their roles (see Figure 62).

According to this framework, foreign factories can fall into any of the six categories. ① An *offshore factory* is established to gain access to low wages or other factors integral to low-cost production. Its responsibilities are limited to the low cost production of specific items that are then exported either to further work or for sale. Such a factory is not expected to be innovative, its managers follow the instructions, methods, and plans handed down to them, and they rely on others to provide the expertise in new processes, products and technologies. ② A *source factory* also is established to gain access to low-cost production, but unlike an offshore factory it has the resources and the expertise to develop and produce a part of a product for the company's global markets. ③ A *server factory* is a production site that supplies specific national or regional markets. ④ A *contributor factory* both serves a local market and assumes responsibilities for product customization, process improvements, product modifications, or product development. ⑤ An *outpost factory* is established primarily to gain access to the knowledge and skills that the company needs. ⑥ Finally a *lead factory* has the ability and knowledge to innovate and create new processes, products and technologies for the company (Ferdows 1997).

When performing the plant audits, we observed that there were several indicators that provided evidence that few pharmaceutical companies have already structured their plant network based on a thorough overall operations strategy. One plant of a European pharmaceutical company that we have visited explained us that they had to handle very complex processes as they were producing solid forms for the European and for the Japanese market. However, the management complained that the customer requirements and the requirements in terms of QC/QA for the Japanese market are totally different. Therefore, the company had to set up a totally different QC/QA process for products for the Japanese market that was causing a lot of trouble as the process and planning complexity exploded.

Furthermore, some employees even had to be trained in Japan to perform certain jobs. Even though, building up a dedicated *server factory* in the Japanese market might not be an answer, the question arises whether a local contract manufacturer could not perform that process cheaper and better.

3. Make or Buy or Ally: Define the role of suppliers and contract manufacturers

The example of the European pharmaceutical company struggling to meet the requirements of the Japanese market shows that the time of doing everything by itself is over. However, based on the statements of Daniel Vasella and other executives we talked with, the big pharmaceutical companies remain very concerned with controlling supply.

Obviously there will not be a fundamental shift towards strategic outsourcing of certain functions that are not regarded as core competencies Martin Joyce, president of the Pharmaceutical Outsourcing Management Association (POMA) agrees with that opinion: *"We are seeing more vividly that truly strategic outsourcing never really took hold in the industry"* (Kager and Mozeson 2000). Another executive of a big pharmaceutical company we talked with stated: *"I see this [outsourcing] rather opportunistic. In case that there is an opportunity to capitalize on external capacity or capabilities we are making use of it. However, I do not believe that there is a general tendency towards strategic partnerships with external suppliers."*

A. General questions

Please, click on the picture to zoom

	Contact information		
A01	Family name		
A02	Given name (s):		
A03	Position or Role:		
A04	Company name:		
A05	Production site:		
A06	Telephone:		
A07	Fax:		
A08	E-Mail:		
A09	Address:		

All data should refer to the year 2003. If the data is not available yet, please take data from 2002!

	How many production sites does your company have?		
A10	Number:		

	What was your sales revenue in 2003?				
A11/A12	Currency				(in Millions)

	Please fill in the cost structure of your company as a percentage of sales (Approximate figures are sufficient):	
A13	R&D:	
A14	Manufacturing Costs:	
A15	General & Administration costs:	
A16	Sales & Marketing costs:	
A17	Margin:	
A18	Total:	**0%**

	Compared to your competitors, indicate the development of your company on the following dimensions within the last 3 years ...						
		Significantly Lower		Average		Significantly Higher	Don`t know
A19	... Marktet share:	○	○	○	○	○	○
A20	... Sales growth:	○	○	○	○	○	○
A21	... Return on sales:	○	○	○	○	○	○

	Please indicate your company type		
A22	Pharmaceutical company with R&D	○ yes	○ no
A23	Generics manufacturer	○ yes	○ no
A24	Contract manufacturer	○ yes	○ no
A25	Miscellaneous:		

Business environment

For the pharmaceutical industry, how would you classify the expected rate of change of the following dimensions within the next years?

	Dimension	Definition	Strongly decrease		Stagnate		Strongly increase	Don`t know
	Dynamism							
A26	Growth	Expected growth opportunities	○	○	○	○	○	○
A27	Production technology	Changes because of new production technologies	○	○	○	○	○	○
A28	Rate of innovation	Rate of launches of new drugs on the market	○	○	○	○	○	○
A29	R&D spending	R&D expenditures as a percentage of sales	○	○	○	○	○	○
	Heterogeneity of customer preferences							
A30	Customer preferences	Changes due to growing diversity of customer preferences	○	○	○	○	○	○
	Hostilty/Rivalry							
A31	Customer-driven	Changes due to increasing bargaining power of customers (e.g. increasing bargaining power of health insurances)	○	○	○	○	○	○
A32	Supplier-driven	Changes due to increasing bargaining power of suppliers (e.g. increasing price pressure of raw material suppliers)	○	○	○	○	○	○
A33	Existing competitors	Changes due to increasing rivalry among competitors (e.g. rivalry due to increasing market concentration)	○	○	○	○	○	○
A34	New entrants	Changes due to new market entrants (e.g. Start-ups in the field of Biotech)	○	○	○	○	○	○
A35	Substitution	Changes due to increasing substitution of original products (e.g. Substitution through generic products)	○	○	○	○	○	○
A36	Regulatory environment	Changes due to new regulatory requirements (e.g. FDA)	○	○	○	○	○	○

Business strategy

Rate the following competitive initiatives and how important they are in meeting your business strategy

		No importance		Important		Very important	Don`t know
	Price						
A37	Increase operating efficiency	○	○	○	○	○	○
A38	Achieve competitive pricing	○	○	○	○	○	○
A39	Achieve high economies of scale within procurement	○	○	○	○	○	○
A40	Reduce product costs (e.g. reduce complexity of the products)	○	○	○	○	○	○
A41	Achieve costs reductions through process innovations	○	○	○	○	○	○
	Differentiation						
A42	Effectively managing your brand	○	○	○	○	○	○
A43	Pursue innovative marketing strategies	○	○	○	○	○	○
A44	Intensify advertising and product communication	○	○	○	○	○	○
A45	Develop and launch new products	○	○	○	○	○	○
A46	Gain control of distribution channels	○	○	○	○	○	○
	Focus						
A47	Increase proximity to customers	○	○	○	○	○	○
A48	Address niche markets	○	○	○	○	○	○
A49	Produce individual products (e.g. special pharmaceutical forms)	○	○	○	○	○	○