

## Chapter 2

# OPEX: A Definition

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*There is no clear-cut definition of Operational Excellence (OPEX) in theory or practice. Especially the inflationary use of the term for almost every launched improvement activity rather obscured than clarified its meaning. In some companies it has been used synonymously for cost-cutting, in others similar to Six Sigma or lean production. This chapter explains our understanding of, and our philosophy behind, OPEX. Based on this understanding we discuss the benefits of striving for OPEX in the Pharmaceutical Industry. We start with a short story from a completely different field, the management of a major airline's baggage handling department. This will foster the understanding of hindrances to excellence in today's companies. We proceed with examining existing excellence models, and derive common elements. This sets the stage for the introduction and the explanation of the St.Gallen OPEX Model. We then conclude this chapter with our definition of Operational Excellence.*

### The Impact of KPIs on Excellence: A Story from Baggage Handling

Some time ago, a major airline asked us for support in the improvement of their daily operations. They planned the roll-out of a global training program as an answer to several problems they had identified at their globally scattered hubs. They thought these problems could be boiled down to failures and shortcomings of the airline's baggage handler crews. The airline blamed the baggage handlers for frequently losing and damaging passengers' bags, or simply causing the bags to be late. The costs for these failures amounted to \$5 million a year. Before we got

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involved, efforts were made to find an internal solution to this problem. Soon the airline was sure that poor qualification in baggage handling was the main reason. Several solutions were discussed, from “fire them, and hire better ones”, “train them” to “train their supervisors in motivational techniques”. In the end, the airline preferred the idea of “sustain and train”, and we were engaged to develop a customized training for the airline’s baggage handlers.

Before we started, we challenged some of the conclusions made. As we had previously experienced situations in which solutions were derived without really identifying, let alone understanding underlying problems, we suggested taking a closer look first. Simple training staff was not necessarily the answer to the real problem the airline was facing; damaged and delayed bags could be the result of something rather than the actual cause of the problem. Thus, we started by trying to get to the bottom of what might be going wrong. Under the disguise of setting up a training program, we conducted several interviews with employees from all hierarchical levels. We gained our first insights from the airline’s management. Every morning at 9:00 am (EST) the station managers engaged in a key event – a conference call between all station managers and headquarters. The aim of these conference calls was to discuss basically two topics: yesterday’s financials, and on-time departures.<sup>1</sup> Financials were seldom the issue. If managers, however, poorly performed with regards to on-time departures, they were publicly rebuked during the conference call – something everybody tried to avoid. Excluding external factors such as bad weather conditions or heavy air traffic, we identified four groups of potential causes for delayed departures. Firstly, passenger service, i.e. check-in agents and other ground staff responsible for getting people on-board. Secondly, catering; if the crew has to wait for the meals to be boarded this can delay departure. Thirdly, the maintenance crew that is responsible for routine and unplanned maintenance. And, finally, the baggage handlers.

Subsequent interviews with baggage handlers revealed that for them it was essential “to get the plane off on time” but if that was not possible to at least “make sure it was not their department taking the count”. We observed a very self-focused behavior of a mere consideration of the baggage handlers’ own process steps, referred to as silo mentality. If it became obvious to the baggage handlers that they would fail to meet a slot, they conveniently pushed remaining bags aside, lost them, or put them on another plane, etc. so as not to be the cause of a late departure. Obviously, both customers and airline suffer from such behavior, but at least the baggage handling department looks well. In another incident, a baggage handler took a screwdriver from his pocket and stuck it in the conveyor belt, thereby causing it to halt. The malfunctioning belt became a maintenance issue and the incident thus disappeared from the record of the baggage handling department.

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<sup>1</sup> For those who do not know, on-time departure is a big issue in the airline business. Slots for departures are short and scarce, and to miss one means to be delayed for to another one. That is, however, costly.

Again, customer and the airline suffered, but the baggage handling department looked well.

During our interviews, we observed a distinct silo orientation that came from only being worried about the own department and measured by just one metric: on-time departures. There is no doubt that on-time departure is a good metric; why, however, only use one, neglecting other reasonable measures of performance like number of lost, damaged, or late bags? We concluded that the baggage handlers were capable of doing their job right, and it was not a skill or knowledge deficiency that caused problems. Rather, the baggage handlers had to work in an environment in which the only set standard was punctuality of the planes. Until then, nobody had been blamed or penalized for damaging, delaying, or losing bags, as long as the plane took off in time; it was only “on-time departures” that was relevant, and the baggage handlers’ behavior was a consequence of this fact.

This case is a very good example of how a performance measurement system works and sometimes might fail. The baggage handlers were behaving very rationally given the environmental system they worked in. Measuring an entire system’s performance by solely assessing a single metric (or metrics focusing on a very narrow area), lacking a holistic, balanced perspective of the system, evokes an equally narrow-focused working behavior among employees. Similar stories could be told about companies only focusing on costs.

Shortcomings like these – and their behavioral consequences – have been taken into account in the design of the St.Gallen Model for Operational Excellence. Likewise, existing excellence models and their underlying logic have been a major source of inspiration for our OPEX model. In order to support the understanding of the St.Gallen Model for Operational Excellence selected models that inspired us are introduced in the following.

## **A Review of Excellence Models: From Toyota to the EFQM Model for Excellence**

Over the last decades, a number of excellence models have been established across all industries. When we first started to discuss Operational Excellence (OPEX), our assumptions and understanding were strongly influenced by these models. Yet, they only laid the foundations and set directions for our first research but were not deterministic. We started off with a general understanding of excellence, and while researching it in manufacturing companies in general, and pharmaceutical companies in particular, our own understanding of what constitutes OPEX crystallized little by little. To fully understand the St.Gallen OPEX approach, it is helpful to foster an understanding of the aspects that were major contributors to our research in excellence. In the beginning, one of the central cornerstones of our understanding was the Manufacturing Management Quality Model from Loch and Chick (2006). Their model was very inspiring for us, since it operationalized the

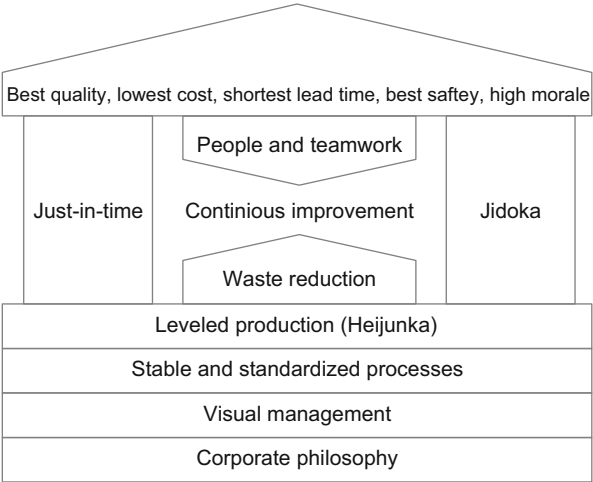


Fig. 2.1 The Toyota Production System (Liker 2004)

hitherto fuzzy term of Management Quality with a strong focus on manufacturing. Since then, several other excellence models and their perception within the industry have influenced our definition and understanding of OPEX. Here, we present a selection of these models, and derive their commonalities.

*The Toyota Production System (TPS)*

Studying “lean production”, one will inevitably come across the Toyota Production System (TPS). This system had evolved over nearly half a century before it was noticed by practitioners and scientists outside Toyota, and it has truly changed the world. Nowadays, it is considered one of the most acknowledged systems in modern manufacturing (Liker 2004), widely spread across all industries and no longer limited to Japanese automotive shop floors (Spear and Bowen 1999).

TPS is frequently and metaphorically described as TPS House Diagram (see Fig. 2.1). The House Diagram comprises various distinctive elements that are depicted in a house-like shape. The house-like structure represents Toyota’s philosophy on interrelations between practices – the stability of a house depends on the stability of its architecture. Weak elements or weak links undermine the whole system. Each element of the TPS by itself is decisive and the structure is supported by mutual reinforcement of its elements (Liker 2004).

However, TPS is not a toolkit or just a set of lean tools. It is a sophisticated system in which every single element contributes to the whole. The first element, the roof of the house, represents Toyota’s ultimate goals: best quality, lowest cost, and shortest lead time. The roof is held up by three pillars. The outer two pillars are

“just-in-time”, the highly publicized and most visible characteristic of TPS, and “Jidoka”, the Japanese synonym for stopping the production and never letting a defective part pass into the subsequent process step. The center of the system is constituted of people, as the system banks on their capabilities and continuous improvement. Finally, the foundation comprises various elements that all provide stability to the system: leveled production, stable and reliable processes, visual management, and a commonly shared corporate philosophy (Liker 2004).

### ***Malcolm Baldrige National Quality Award (MBNQA)***

The origin of the Malcolm Baldrige National Quality Award (MBNQA) dates back to August 1987, when former U.S. President Ronald Reagan signed a state-subsidized initiative for achievements in quality improvements. Back then, quality of American products and services among other manufacturing capabilities clearly lagged behind global competitors (Wheelwright and Hayes 1985). In order to overcome these shortcomings, a national campaign was initiated that targeted not only quality improvements, but also in an increase in productivity. Similarly to the Japanese *Deming Prize*, arguably the world’s most well-known quality prize, the MBNQA promotes the introduction of a Total Quality Management (TQM) model by awarding a prize for achieving superior performance compared to other participating U.S. companies.

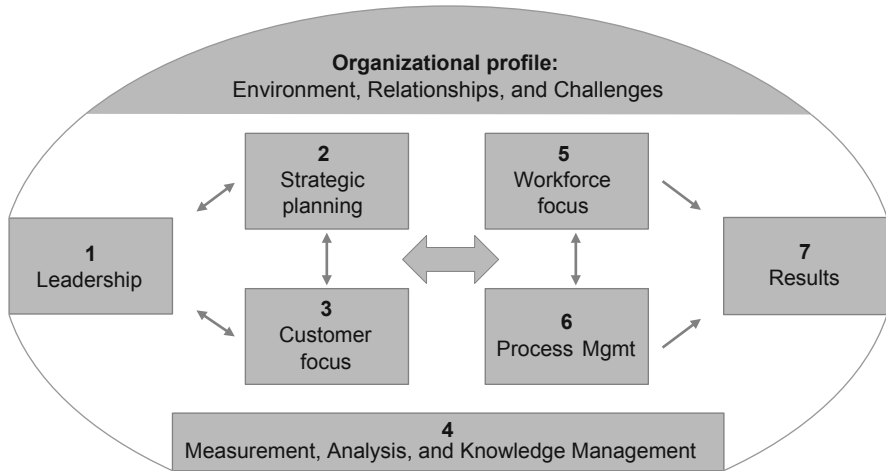
The underlying TQM model comprises three sequential layers that progressively become more detailed. The first layer includes seven interrelated categories referred to as Examination Categories (Fig. 2.2, NIST 2009):

While the next two layers further detail each category and make these assessable they build the most important constituents of a modern and effective quality system.

However, the first layer of the framework shown in Fig. 2.2 has from top to bottom three basic elements. Firstly, the *Organizational Profile*. It sets the context for the way any organization operates. A company’s environment, working relationships as well as strategic challenges and advantages provide an overarching guide for any organization’s performance management system. Secondly, the *System Operations*, composed of the six Baldrige Categories (1-3, 5-7) as shown in the center of Fig. 2.2. The leadership triad is represented by categories 1-3, emphasizing the importance of a leadership focus with regards to both strategy and customers. Categories 5-7 constitute the results triad, highlighting workforce and processes that do the work that yields the performance of a company (NIST 2009).

Obviously, all actions within *System Operations* point towards results. The central relationship between category 1 (leadership) and category 7 (results) is indicated by the horizontal arrow in the center of the framework. Thereby, also the linkage between the two triads is indicated, which is critical for organizational success.

Thirdly, and finally, the *System Foundation* is illustrated in category 4. The aspects addressed in this category (measurement, analysis, and knowledge management) are considered critical with regards to an effective management of an



**Fig. 2.2** The model of the Malcolm Baldrige National Quality Award (NIST 2009)

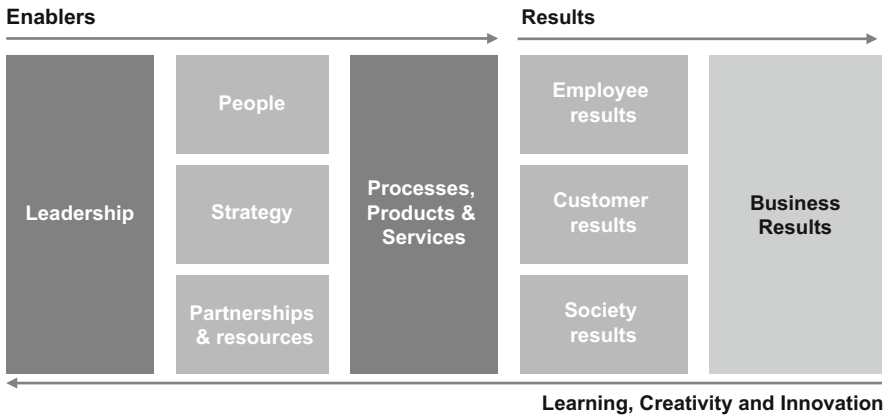
organization. Moreover, these aspects support a fact-based and knowledge-driven system for the improvement of an organization's performance and competitiveness (NIST 2009).

### ***European Foundation of Quality Management (EFQM)***

In the European business environment, the journey to excellence is mainly led by the excellence model of the European Foundation of Quality Management (EFQM). Introduced in 1991, it comprises all aspects and tasks of a corporate management and thus also serves as a leadership framework at large. It has been revised four times (1999, 2002, 2010, 2013) in order to comply with the latest achievements of management science. However, the general architecture of the model remained untouched (Seghezzi et al. 2013).

The EFQM Excellence model is a framework to facilitate the understanding and management of the complex environment today's organizations are forced to operate in. The underlying philosophy of the model is that sustainable success of any organization relies on strong leadership and a clearly communicated strategic direction. Each organization is responsible for a continuous training of its workforce as well as the development and improvement of partnerships and processes in order to provide its customers with value-adding products and services. Thus, an effective implementation of the right approaches supports the organization in meeting its own and its stakeholders' expectations (EFQM 2012).

Figure 2.3 illustrates the EFQM Excellence. It comprises nine interrelated criteria. Five of these are related to the potential of a company referred to as *Enablers*; the remaining four criteria constitute the *Results* section. The Enabler section subsumes dimensions that are considered as decisive for a sustainable



**Fig. 2.3** The EFQM model for Excellence (EFQM 2012)

long-term success. Accordingly, the Results section represents that the aspired outcome of all organizational efforts is an improvement of business results (EFQM 2012; Seghezzi et al. 2013).

Like the American Malcolm Baldrige Award, the EFQM model initially evolved from concepts and philosophy of Total Quality Management (TQM). The need for commonly applicable leadership frameworks for corporate management, however, led to a revision of the model in 1999. This entailed a shift of the model’s philosophy. As such, the EFQM model nowadays is no longer based on the TQM philosophy but rather incorporates each characteristic of excellence. Along with broadening the model’s focus, EFQM defined excellence as superior practices by the management of an organization and by the achievement of its results (Seghezzi et al. 2013).

The criteria of the EFQM model work in a cause-and-effect relationship between Enablers and Results, as indicated by the interconnecting lines. These lines also point to the necessity to clearly align the different parts of an organization to achieve sustainable excellence. Each criterion is subdivided by a varying number of characteristics that describe their meaning. The characteristics themselves, however, are not mandatory and can be adapted to each organization’s philosophy. Also, the weight of the nine criteria is optional; for applicants of the EFQM award, EFQM introduced a predefined weight to assure equality for all participants.

The EFQM model serves as a guideline for companies that pursue excellence. An organization’s current status of excellence can be determined via self-assessment. The assessment starts with a holistic consideration of all nine criteria, the definition of improvement potentials and how these might be achieved. It is a recurring cycle that is based on the EFQM’s RADAR method, a logic procedure to systematically and holistically assess the nine criteria of the EFQM model. The acronym RADAR represents each step of the underlying method, i.e. *R* for the first assessment of the Results, *A* for the Approach chosen to improve the organization, *D* for the Deployment of the approach, *A* for the Assessment, and *R* for the final Review of the achievements (Seghezzi et al. 2013).

## Conclusion

The major commonality of all excellence models is their pursuit of superior operational performance. Besides this overarching principle, the three discussed models have several more commonalities that are relevant in the context of operational excellence.

One central aspect of the three models is their strong focus on *leadership* for any kind of organizational improvement. Even though TPS does not explicitly visualize *leadership* in its house diagram,<sup>2</sup> studying the Toyota Way reveals that leadership is an important tenet. Its long-term consistency supports the organizational culture that is necessary to create an environment for a learning organization. It is mandatory for Toyota's leaders to teach their subordinates the corporate way. Thus, they do not only have to understand but also to live the philosophy (Liker 2004; Spear and Bowen 1999). This understanding sets the basis of TPS. As such, Corporate Philosophy is visualized as the foundation of the framework that stabilizes the entire system. The model of the MBNQA ranks leadership first, distinguishing the seniority of leadership and forms of governance and social responsibilities from each other. The EFQM model views leadership as equally important and thus as well starts its assessment with this aspect. The model considers leaders as paragons for the entire organization who develop a company's vision, mission, values and ethical principles (Seghezzi et al. 2013).

All three models consider *people* as an organization's most valuable resource. TPS visualizes the workforce in the center of its house diagram in order to stress their importance for the company. Both MBNQA and EFQM emphasize that it is an organization's workforce that creates value. Thus, it is the organization's responsibility to train and reward employees in order to increase their motivation, well-being and satisfaction.

A focus on the company's *strategy* is explicitly noted by MBNQA and EFQM only. MBNQA examines on the one hand the development of the strategy and on the other hand its deployment in general. EFQM regards strategy as being aligned with the needs and expectations of stakeholders. Furthermore, the strategy is based on a company's performance and capabilities (Seghezzi et al. 2013). That said, it becomes obvious that TPS also considers strategy, as illustrated by the roof of the house diagram.

The EFQM model is the only model to name *resources* as worth considering when striving for excellence. The model provides a framework to assess the sustainable handling of resources, whether they come from suppliers or assets like buildings, financials, and materials. From a technical point of view, TPS also reminds to sustainably manage all organizational resources. According to Ohno (1988) the underlying philosophy of TPS is the absolute elimination of waste.

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<sup>2</sup> In this edition we rely on the TPS model as described by Liker (2004). In our first edition "Operational Excellence in the Pharmaceutical Industry" we illustrated two versions of TPS, the "classical version" and the "Genba Kanri" version (Friedli et al. 2006). These two do also not visualize "leadership".



Excessive resource consumption conflicts with this philosophy. Moreover, TPS' just-in-time pillar requires a moderate handling of resources to allow flow production triggered by customers' pull and thus avoiding escalating inventories.

The last communality we would like to describe is the necessity of *process* consideration that is acknowledged by each of the three models. TPS, basically, banks on stable and standardized processes. Stability and standardization build the prerequisite for measuring and improving the processes. Accordingly, EFQM also views processes as an enabler and evaluates how well a company designs and improves its processes to add value for its customers and stakeholders. The framework of the MBNQA additionally distinguishes value creation and support processes for its assessment.

These commonalities have been a major influence for us. We consider their evaluation mandatory in assessing a plant's operational excellence level, i.e. they serve as integral parts in our model. And yet, it is not the communality that makes models special but their subtle differences. Some of these differences, too, served as important influences on our model of OPEX.

In the design phase of our OPEX model we were looking for a strong technical focus. This was supported by TPS. The production system provided us with a multitude of ideas how to organize operations from management to shop floor. Moreover, TPS entailed an abundance of literature examining (discrete) manufacturing operations in various industries. These as well have been considered and if necessary been translated into a pharmaceutical context. However, since our objective was (and still is) the identification of ways to sustainably improve operational performance of pharmaceutical companies in general (Friedli et al. 2006), inspired by the MBNQA, we embedded our OPEX model in a rich set of questions to describe the organizational profile. The consideration of these structural factors allows the comparison of pharmaceutical operations of production plants of all sizes, and from all over the world. An indication of improvement potential and the subsequent derivation of approaches and initiatives to fill those gaps can only be realized properly if there is a certain transparency of "what is done already" and "what is the outcome". Thus, we borrowed the Enabler-Result-logic from the EFQM, implemented it in our own model, and operationalized it with commonly applied lean practices.

## The St.Gallen OPEX Model

Our original model from 2006 is shown in Fig. 2.4. It includes several sub-elements, each of which in itself represents an important part that contributes to the overall success.<sup>3</sup> Yet, these distinctive elements reinforce each other. According to this

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<sup>3</sup> Cf. for a more detailed description of our model Friedli et al. (2006), p. 47ff and Friedli et al. (2010), p. 18ff.

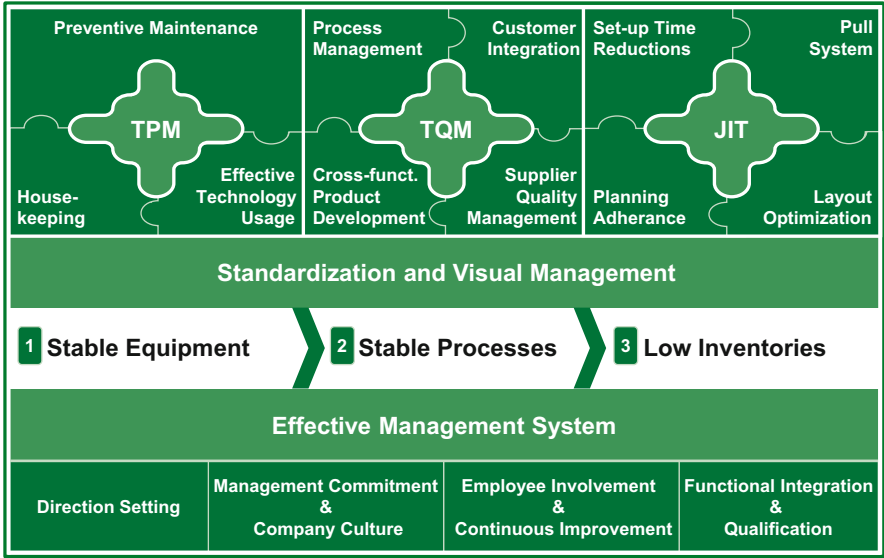


Fig. 2.4 The St.Gallen Model for Operational Excellence

model, manufacturing is viewed as a system in which single elements or interventions have both a direct and indirect impact on other elements.

On the highest level of abstraction, the OPEX reference model can be divided into two larger sub-systems: First, there is a technical sub-system which can be regarded as a tool-kit, comprising practices like Total Productive Maintenance (TPM), Total Quality Management (TQM) and Just-in-Time (JIT), and structuring them in a consistent manner. Second, there is a “social” sub-system which takes up the quest for an operational characterization of management quality and work organization. This second system focuses on supporting and encouraging people to continuously improve processes.

*The Technical Sub-system*

The objective of the technical sub-system is to analyze the implementation level of “technical” practices, which can be classified as either (core) principles or techniques/tools. Principles usually span a multitude of techniques and tools. For example, JIT is considered a core principle of OPEX as it is rooted in the notion of eliminating waste, and provides a multitude of techniques such as “Single Minute Exchange of Dies” (SMED) to achieve this goal. During our first plant visits in the pharmaceutical industry back in 2004, we realized that most lean tools (e.g., Poka Yoke, Andon etc.) were not known well. Consequently, the model was structured using the high-level principles of operations management without trying to mix them with single tools.

Most of the major widespread operations management principles (TPM, TQM, JIT) usually aim at a certain area of concern (e.g., low equipment availability, low quality, high inventories). Most companies implement them in order to address exactly these concerns. We have chosen the three most widespread “three letter acronyms” as the most important principles for our OPEX model. Analyzing the first data we collected using our model, it became clear that these principles are heavily interconnected. There seemed to be a logical sequence in their implementation, namely:

1. TPM (Total Productive Maintenance)
2. TQM (Total Quality Management), and
3. JIT (Just-in-Time).

We have structured the technical sub-system of our model according to this sequence.

With its focus on achieving the goal of “one-piece flow” and minimal buffer inventory, the JIT concept requires stable and robust processes. With its strong emphasis on variance minimization, the TQM concept can be regarded as a complementary concept to JIT as it should lead to a less variable (i.e. better controlled) and more stable manufacturing process that, in turn, reduces the need for safety stock buffers. In mass production, the break-down of a machine usually does not create a sense of urgency. The maintenance department is scheduled to fix it while inventory keeps operations running. However, in a JIT environment, equipment break-downs will soon lead to production downtimes and thus may bring about a crisis. Hence, the concept of TPM, in which everyone learns how to clean, inspect and maintain equipment, becomes a crucial element of an excellent production environment. Without TPM, the goals of TQM cannot be achieved, as there is no stable process based on unstable equipment. The mastering of TPM and TQM are prerequisites to be able to take out waste without facing the danger that the whole underlying system starts to crash.

For each of the core principles, several sub-elements were introduced.

### ***Total Productive Maintenance (TPM)***

We defined the following elements to be the major principles of TPM: “preventive maintenance”, “autonomous maintenance”, “housekeeping”, “cross-functional training” and the “effective technology usage”.

TPM is designed to maximize equipment effectiveness, improve overall efficiency by establishing a comprehensive productive maintenance system during the life cycle of the equipment, whilst spanning all equipment-related fields such as planning/buying, use, maintenance etc. Moreover, TPM involves the participation of all employees, from plant management to shop floor workers and thus promotes productive maintenance through motivational management techniques and voluntary small group activities. TPM is usually divided into short-term and long-term

elements. 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. On the other hand, the long-term elements of TPM focus on the usage of new technology, which should be designed to support people and processes but has to prove its reliability.

Autonomous maintenance can be described by considering the four main goals of a TPM program. First, the program teams up production and maintenance people 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 equipment. Third, TPM is designed to help operators learn more about how their equipment functions, what common problems can occur, why they occur, and how these problems can be prevented through early detection and treatment of abnormal conditions. This cross-functional training allows operators to maintain equipment and to identify and resolve many basic equipment problems. Fourth, in a TPM program, maintenance technicians are held accountable for completing maintenance tasks within a scheduled timeframe while still meeting production requirements. By using standardized operating procedures such standardization helps to increase schedule compliance which is an important indicator for the health of a TPM system.

### ***Total Quality Management (TQM)***

When taking a closer look at the concept of TQM, one will find that TQM is a very rigorous problem-solving approach that is based on facts rather than on gut feeling. Today, the concept of Six Sigma has become much more popular than the term TQM. The difference between these two concepts lies in Six Sigma’s even stronger orientation on the statistical measure of sigma (standard deviation). Companies which have truly internalized the principles of TQM or Six Sigma also try to set up operations as experiments to continuously isolate variables that cause deviation, mastering them and, by doing so, being able to continuously improve their processes.

However, TQM goes far beyond statistics. TQM is about management commitment; it is a philosophy of excellence, customer focus, continuous process improvement and people and supplier development. We defined process management, customer integration, supplier quality management and cross-functional product development to be the core elements of a TQM system.

Process management is defined as documenting, measuring, analyzing and improving processes, thus reducing process variances to a minimum level. Process management includes all common tools of quality management aiming to find and control root causes of deviation (e.g., Cause and Effect Diagrams, Pareto Analysis, Design of Experiments, Statistical Process Control etc.). A high level of

documentation and standardization usually goes hand in hand with human and organizational dysfunction (e.g., unmotivated workforce, high absenteeism etc.). In addition, successful process management is more likely to be achieved by peers working in cross-functional teams than by industrial engineers. TQM specialists suggest that companies should choose vendors primarily on the basis of quality rather than solely on the basis of product price. Moreover, supplier quality management aims to integrate suppliers into the internal quality system to ensure high quality levels. To achieve excellent quality, it is essential to know what customers want and to provide products to meet their needs (customer integration). TQM experts point out that cross-functional product development should help to translate customer requirements into high quality products.

### ***Just-in-Time (JIT)***

Due to the fact that in most industries the heterogeneity of customer requirements has significantly increased, JIT manufacturing for most companies has become a crucial element to increase flexibility without building up huge inventories. We defined “pull production”, “setup time reduction”, “layout optimization” and “planning adherence” to be the sub-elements of a JIT production.

Whilst pull production helps to reduce overproduction, inventory and setup time reductions can help to decrease the average lot size. Besides, it can enable a smooth material flow within the manufacturing process. With the need for standardized, stable, reliable processes we regarded the element “planning adherence” as a further element of JIT. Planning adherence, which means smoothly leveling out the production schedule in both volume and variety, should keep the JIT system stable and allow for minimum inventory. Apart from waste caused by overproduction and excess inventory, an integrated JIT program also endeavors to reduce all kind of excessive movements caused by material and handling. Hence, layout optimization based on close arrangements of people and equipment in a processing sequence is an additional principle of JIT implementation.

### ***Basic Elements***

After structuring the OPEX model according to the three elements TPM, TQM and JIT, we realized that there are some common practices shared by all three sub-systems, and are not unique to each of the programs. These are, for example, cross-functional training, employee empowerment and teamwork, standardization and visual management. We decided to differentiate between technical practices such as standardization, and the more socially oriented aspects such as employee empowerment or cross-functional training (which we will discuss later).

The following two technically oriented practices cannot be solely related to JIT, TQM or TPM: standardization and visual management. We call them basic elements because they can be regarded as basic prerequisites for successfully implementing TQM, TPM as well as JIT principles. As Imai (1986) explained in his book on continuous improvement, it is impossible to improve any process before it has been standardized, and thus stabilized. Standardization not only refers to processes; it also includes the standardization of technology and equipment. Standardization can be regarded as a common supportive element for TPM, TQM and JIT. A further basic element is visual management. It provides the workforce with updated information on process and performance data which assists the deployment of TPM, TQM and JIT principles (e.g., visual management can provide timely information regarding JIT-related data as, for instance, the actual take time to enhance flow as well as TQM- or TPM-related information such as process variability or equipment reliability to improve problem solving).

### ***The Social Sub-system: Management System***

Based on different sources, we developed a management quality model the objective of which can be summarized as follows: “Motivating and aligning people to work for a common goal”. To achieve a common goal, employees need autonomy, they need to feel that they have control over their job and belong to a team (people involvement). Targets have to be clear and consistent, as well as challenging (direction setting) and supported by senior management (management commitment). Feedback on progress needs to be given frequently and in a timely manner, and multiple skills should be developed according to individual potential (functional integration and people development).

#### ***Direction Setting***

We completely agree with Skinner (1974), Hayes et al. (2005) and Loch et al. (2004) that the implementation of certain practices only makes sense if the management has formulated a strategy that is based on clear and consistent objectives. However, we decided to merge the integration variable and the direction setting variable because they are strongly correlated and conceptually interlinked.

#### ***Management Commitment***

Evidence from several studies supports that management commitment is a crucial element for facilitating change processes, which is a prerequisite for process

improvement. Especially TQM literature stresses management commitment as one of the key success factors. A quality improvement process must begin with the management's own commitment to quality. However, management commitment is not just vital for rolling out a TQM program; it is equally important for rolling out a JIT and TPM program. The management has to promote a culture which supports people in doing their work.

### ***Employee Involvement and Continuous Improvement***

We also included employee involvement into our management quality model. We strongly believe that one major managerial challenge is to get all employees involved into continuously thinking about how to improve the current situation. This is only possible if process improvement is a common task for everybody and not just for few smart industrial engineers.

### ***Functional Integration and People Development***

A workforce that is eager to contribute to the goals set by the management but lacks proper know-how in to do so will fail in achieving them. If complex decisions are to be delegated, as it is the case in the concept of autonomous problem solving, this can only succeed if employees are given the chance to acquire new knowledge. Furthermore, the flexibility of the technical system we have introduced (especially the concept of mixed model production) requires a multi-skilled workforce that can perform different tasks. Consequently, functional integration and employee development is a basic pillar for the achievement of goals set by the plant management. We also introduced the aspect of feedback and reward as an enabler for motivation. Organizational scientists argue that rewards go beyond money. The important point is that positive or negative reinforcement ensues as quickly as possible after the action.

## **OPEX Defined**

Modern approaches to Operational Excellence (OPEX) have evolved from the understanding of lean production (Friedli and Schuh 2013) and are generally regarded as part of continuous, corporate improvement concepts. However, OPEX programs cannot be viewed as standalone nor as a new set of methods as they comprise and rely on several already established manufacturing concepts (Gronauer 2012). Since to date no uniform definition of OPEX exists, discussions of such programs are regularly complicated. The subsequent section aims at

overcoming this deficit by clarifying the scientific background before leading over to our definition of Operational Excellence.

The systematic discussion of OPEX can be traced back to Hayes and Wheelwright (1984) publishing their ground breaking book *Restoring our Competitive Edge* and emphasizing the relevance of manufacturing to retain competitiveness of the American industry. They argued that the competitive advantage of Japanese manufacturers stemmed from superior production capabilities, contrary to an erroneously assumed better product design, marketing ingenuity, or substantial financial strength. Whereas American companies lacked a consideration of manufacturing as a key to success, their Japanese competitors had already realized the benefits of streamlined operations as a competitive factor.<sup>4</sup> As such, the World-Class Manufacturing (WCM) project was initiated in order to identify critical success factors of successful manufacturing companies.

Based on the outcome of the WCM project, two dimensions can be distinguished in describing OPEX. The first dimension refers to the effectiveness of a production system, highlighting the role of manufacturing within an organization. The second dimension embraces the effectiveness of applied approaches and practices, and thus considers the utility of selected approaches in terms of their unique combination of different methods.

Discussing the effectiveness of production systems, Hayes and Wheelwright (1984) observed that the most successful companies of their study sample had established more advanced production systems than their competitors. These production systems supported the corporate strategy directly, while at the same time providing organizations with the opportunity to develop unique characteristics. The authors considered different success factors – referred to as competitive priorities – as a central aspect for developing these unique characteristics. These competitive priorities can be understood as distinctive dimensions like quality, cost, and time. By stressing dimensions differently, according to an organization's strategy, companies distinguish themselves from each other, creating their own competitive advantage. Moreover, Hayes and Wheelwright argue that companies should avoid the pursuit of competitive advantages in every dimension since it is “potentially dangerous, for a company to try to compete by offering superior performance along all of these dimensions simultaneously, since it will probably end up second best on each dimension to some other company that devotes more of its resources to developing that competitive advantage” (Hayes and Wheelwright 1984, p. 41). Rather, companies should focus on those dimensions in which they intend to develop their unique capabilities. In literature discussed as the idea of “trade-offs”, this has been widely acknowledged by various authors.<sup>5</sup>

Hayes and Wheelwright plead that building competitive strength is dependent on a set of approaches and manufacturing practices assigned to six world class dimensions. If combined in the right way, these practices enable companies to

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<sup>4</sup> Hayes and Wheelwright (1984), p. 12.

<sup>5</sup> Cf. Skinner (1974), Porter (1985).



achieve superior performance. These dimensions are categorized as training and qualification of employees at production (workforce skills and capabilities), technical competence of management, the organizational understanding of quality (competing through quality), workforce participation, the degree of proprietary process and machinery development (rebuilding manufacturing engineering), and finally organizational capability to achieve progress by continuous improvement processes (Incremental improvement approaches).

Schonberger (1986) considered 16 manufacturing principles to play a major role in WCM. He enriched the discussion by introducing Total Quality Management (TQM) and Just-in-Time (JIT) which then evolved to the central aspects of WCM. Hall (1987) brought in another set of criteria to describe excellence; most of these match the criteria introduced by Schonberger. Hall defines “Manufacturing Excellence” as a system that comprises JIT production, employee participation, standardized tools and machinery, supplier integration, and design-for-manufacturability.<sup>6</sup>

In the early 1990s, the excellence discussion started to change influenced by one of the most cited approaches in theory and praxis: lean production. First published by Womack et al. (1990), the concept of lean production, describing Toyota’s superior production system, took Western manufacturing plants by storm. Numerous empirical studies researching lean production and its constituents (TPM; TQM; JIT) revealed a strong correlation between so-called lean practices and operational performance, and thus contributed substantially to the concept’s global dissemination.<sup>7</sup>

A number of other approaches ranking among modern production management contributed to the understanding of OPEX. Yet, these approaches like time-based-manufacturing, agile or dynamic manufacturing have several similarities and overlaps. Looking at the definition of time-based-manufacturing, similarities with lean production become obvious: “Application of time compression techniques into every aspect of manufacturing system design which includes techniques such as pull system, cellular manufacturing, reengineering set-ups, quality improvement, employee involvement and dependable suppliers”.<sup>8</sup>

A multitude of studies analyzed the impact of modern manufacturing practices on organizations’ operational performance, and showed their effectiveness to be out of question. In fact, it is the context of their application that became the focus of interest.<sup>9</sup> Hayes and Pisano see the central characteristics of excellent manufacturing companies as follows<sup>10</sup>:

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<sup>6</sup> The approach “design-for-manufacturability” comprises various methods like QFD, House of Quality, etc. and strives for an engagement of production and other product development related departments at early stages of the development process.

<sup>7</sup> Cf. Sakakibara et al. (1997), Cua et al. (2001), Shah and Ward (2003) etc.

<sup>8</sup> Cf. Stalk and Webber (1993).

<sup>9</sup> Cf. Hayes and Pisano (1994), Pilkington (1998).

<sup>10</sup> Hayes and Pisano (1994), p. 78.

- Excellent manufacturing companies apply modern approaches and manufacturing practices to realize their manufacturing strategy. Their manufacturing strategy is derived from corporate objectives.
- By applying modern approaches and manufacturing practices, excellent manufacturing companies continuously develop new capabilities that provide them with a potential competitive advantage.

Yet, technical aspects summarized in manufacturing practices are only one element of modern OPEX approaches. Social aspects constitute another integral part. They can be considered as a decisive factor for the importance OPEX gained within manufacturing companies in the last years. Although social aspects in the context of manufacturing had been already acknowledged, it was Spear and Bowen (1999) who highlighted managerial and cultural aspects and their impact on the competitiveness of the manufacturing industry in their article *Decoding the DNA of the Toyota Production System*. Loch and Chick (2006) focused on the importance of managerial qualities to explain performance differences in manufacturing plants.

The explanations given above outline that performance of a manufacturing plant or of production in general is multi-facetted, and may only be described and explained by the interaction of different factors. Unfortunately, many approaches that define OPEX, whether they are practical or theoretical, are lacking a multi-facetted and holistic consideration. Moreover, single elements or initiatives are often picked out and treated in isolation, cf. Shah and Ward (2007).

Based on literature and our experience, we see OPEX as the balanced management of cost, quality and time while at the same time focusing on the customer needs. To achieve this end, OPEX comprises structural and behavioral changes thought to optimally support necessary activities. In order to maintain sustainability also in changing or volatile environments, OPEX has to be pushed by top management and has to be designed to engage every single employee (see also Chap. 7, Barriers and Success Factors). Obviously, OPEX is not only concerned with performance. It also encompasses the way leading to that superior performance, and practices that allow an organization to continuously improve itself.

Thus, our definition of Operational Excellence is as follows:

Operational Excellence constitutes the continuous pursuit of improvement of a production plant in all dimensions. Improvement is measured by balanced performance metrics comprising efficiency and effectiveness, thus providing a mutual basis for an improvement evaluation.

## ***Excellence in Pharma Manufacturing***

The above section aimed at explaining our OPEX model and our understanding of excellence in general. In the following we will transfer this understanding to excellence in pharmaceutical manufacturing. The performance of a manufacturing plant can be described in several ways. Obviously, high performance in a single

Key Performance Indicator (KPI) can be derived from a mere focus on that respective KPI. However, this is not the case for excellence. Our understanding of an excellent manufacturing site is influenced by the St.Gallen school of systems theory and cybernetics.

Thinking in systems determines the holistic consideration of the system (organization) itself. The systemic approach acknowledges that an organization is embedded in economy and society (Ulrich 1984). The complexity of situations and problems is recognized, and it is sought to consider them in their full context. Isolated consideration of single aspects and inexpedient problem definitions should be avoided (Ulrich and Krieg 1974). As there already is only a limited number of opportunities to monitor and interpret surrounding events and happenings, it is difficult, sometimes even impossible, to reflect interrelations objectively (Bleicher 1995). Thus, it might be misleading to artificially narrow down the horizon. The conscious management of those social systems and therefore an adaption of structures and people's behavior is an approach to mitigate these shortcomings. Moreover, evoking self-organized adaptations from the system itself requires approaches that are based on an evolutionary organizational development in contrast to the steering and directing of just a few managers. As such, also Bleicher (1995) concludes to strive for a holistic consideration in order to satisfy the connectivity of problems and interrelations within the social system.

That said, and referring back to the conclusions of the introductory baggage handler case, we rely on our model's entire technical sub-system in order to distinguish excellent plants from weaker performing ones. Transparent manufacturing operations of an organization are achieved by assigning a distinctive set of KPIs to TPM, TQM, and JIT. This, however, implies that excellent manufacturing sites have high performance on a holistic level instead of high performance on a single KPI only. Analyzing only a single KPI, even average or weak performing sites might excel. But due to the balanced approach of effectiveness and efficiency, overall performance of the manufacturing system is critical to qualify as operationally excellent (see Chap. 4 for detailed insights into KPIs and measured performance).

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