The role of management in lean implementation: evidence from the pharmaceutical industry

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Abstract

Purpose – The purpose of this study is to investigate how soft lean practices moderate the performance effects of hard lean practices. The authors provide new evidence from the pharmaceutical industry, which is characterized by a highly regulated and technical environment and has been largely uncharted in the lean literature.

Design/methodology/approach – Based on a review of the literature, the authors define a set of soft and hard lean practices. The authors test the hypotheses using factor analysis and moderated hierarchical linear regression on a unique dataset containing survey data and real performance measures of 351 pharmaceutical plants.

Findings – The results show that soft lean practices can be both enabling and constraining. When management engages in performance measurement, visualisation and employee empowerment the relationship between hard lean practices and performance is positively moderated. On the other hand, when managers emphasise goal setting and work standardisation the performance outcomes are reduced.

Practical implications – Effective lean managers build organisational commitment by motivating other employees to implement lean. They use performance measurement, visualisation and employee empowerment to focus on the "why". Less effective managers engage in commanding and micro-management. Such managers focus on the "what" by using practices like goal setting and work standardisation.

Originality/value – This article contributes to the literature on lean management by empirically testing the moderator-variable interaction effects between soft and hard lean practices. In addition, it adds new evidence from the important pharmaceutical industry.

Keywords Lean production, Soft lean practices, Moderating effect, Pharmaceutical manufacturing

Paper type Research paper

1. Introduction

To remain competitive, firms seek to improve their operations continuously. Inspired by the success of the Toyota Production System (TPS)—popularised as "lean production" by Womack *et al.* (1990)—manufacturers use holistic and company-specific lean programmes (Netland, 2013). Yet, despite widespread popularity and numerous scientific studies confirming the positive effects of lean on firm performance (Abreu-Ledón *et al.*, 2018; Bloom *et al.*, 2019; Negrão *et al.*, 2017), many companies struggle to succeed with their lean programmes (Holweg *et al.*, 2018; Losonci *et al.*, 2017; Marodin and Saurin, 2015). Despite its industry-specific peculiarities, the pharmaceutical industry is no different in this regard (Friedli *et al.*, 2013, 2018).

Lean programmes can be conceptualised as sets of organisational practices that work synergistically to improve the value creation processes (Shah and Ward, 2003).

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Prior literature has shown that lean programmes consist of both technical (hard) and human-related (soft) components (Cua *et al.*, 2001; Furlan *et al.*, 2011; Hadid and Mansouri, 2014). Yet, only a few studies methodologically distinguish between these two concepts to investigate their interplay and separate performance effects (for recent exceptions, see Bortolotti *et al.*, 2015; Kristensen and Israelsen, 2014; Nielsen *et al.*, 2018).

To date, the existing lean research provides only a limited understanding of how soft lean practices impact performance in manufacturing organisations. Specifically, lean research studying the lean-performance relationship is highly skewed toward hard lean practices. Despite a few early studies on the social and behavioural aspects of lean systems (e.g. Emiliani, 1998; Emiliani and Stec, 2005; Liker, 2004; Spear, 2004; Spear and Bowen, 1999), it is only recently that these aspects have received significant research interest (e.g. Arellano *et al.*, 2021; Cadden *et al.*, 2020; Camuffo and Gerli, 2018; Galeazzo *et al.*, 2017; Netland *et al.*, 2015; Saabye *et al.*, 2022).

This study addresses this gap by building on prior research that has already indicated interactions between hard and soft lean practices. As in every socio-technical system, manufacturing firms can only achieve the best outcome by simultaneously emphasising practices from both the social and the technical systems (Trist, 1981). Bortolotti *et al.* (2015), for example, found that manufacturing plants employing hard lean practices were more successful when simultaneously using soft lean practices, such as employee training. Similarly, Hadid and Mansouri (2014) argue that the investment in lean supportive practices can mitigate the negative effect of factors inhibiting the effect of technical lean practices. To illustrate, empowerment or training of employees can alleviate the resistance to change during the process of lean implementation.

The novelty and contribution of our study lie in the interpretation and empirical testing of soft lean practices as *moderators* of the relationship between hard lean practices and operational performance. We think that this does not only contribute to the understanding of lean in the scientific community but can also help managers adapt their behaviours and chose appropriate methods to support their organisations in the implementation of lean.

Studying lean implementation in the pharmaceutical sector is another contribution of this study as it has received limited attention in extant research. It represents a special setting for studying lean implementation due to its highly regulated and technology-intensive manufacturing environment, which inevitably affects the interaction among humans as well as between humans and the technical system. In this setting, we develop theoretically grounded hypotheses relating to the moderating role of soft lean practices on the link between hard lean practices and operational performance. We test them by performing exploratory factor analysis (PCA), confirmatory factor analysis (CFA) and ordinary linear least squares (OLS) regression on survey data from 351 pharmaceutical plants. We thereby contribute to the ongoing discussion on the role of management in lean programme implementations.

2. Theoretical background and hypothesis development

Lean has become a topic of great interest across many industries and academic disciplines (Danese *et al.*, 2018; Jasti and Kodali, 2015; Netland and Powell, 2016). In this section, we first review the conceptualisation of hard versus soft lean practices and then develop our hypotheses.

2.1 Hard and soft lean practices

Shah and Ward (2003) provided one of the most often used conceptualisations of lean production when they defined it as a system composed of four bundles of practices: Just-in-Time (JIT), Total Quality Management (TQM), Total Productive Maintenance (TPM) and Human Resource Management (HRM). Each of these bundles again consists of a set of practices. The JIT bundle aims to identify and eliminate all forms of waste in production (Ohno, 1988; Sugimori *et al.*, 1977). Common JIT practices are, for example, *set-up time reduction* or *pull production* with *Kanban* (Cua *et al.*, 2001). The TQM bundle aims at continuous improvement of product and process quality (Shah and Ward, 2003). Typical TQM practices are *process management*, *customer involvement* and *supplier quality management* (Flynn *et al.*, 1995; Pettersen, 2009). The TPM bundle is oriented toward maximizing equipment effectiveness by keeping machines in excellent working conditions to avoid breakdowns or delays. Examples of TPM practices are *autonomous* as well as *planned maintenance* and *housekeeping* (Cua *et al.*, 2001; Shah and Ward, 2003).

In addition to the technically oriented constructs (JIT, TPM and TQM), Shah and Ward (2003) included HRM as a fourth, more socially oriented bundle of practices. Typical HRM practices include *self-directed teams*, a *cross-functional workforce* and *committed leadership* (Shah and Ward, 2003). In contrast, Cua *et al.* (2001) did not view HRM as a separate bundle but saw corresponding soft practices as cross-cutting the three hard bundles of practices. Other authors are less concerned about whether these soft practices should be seen as "lean" and suggest that they are simply good management practices supporting any kind of production system (Höök and Stehn, 2008; Pettersen, 2009). In whatever way these social constructs are included, the majority of the literature agrees on the importance of human-oriented practices for lean success (Bai *et al.*, 2019; Camuffo and Gerli, 2018; Liker, 2004). Furthermore, as Bortolotti *et al.* (2015) pointed out, separation of hard versus soft lean practices can be worthwhile, as it can potentially enhance the understanding of how to achieve a successful implementation of lean programmes.

As we are interested in understanding the role that management practices play in successful lean implementation, we take on a socio-technical perspective and first separate hard from soft lean practices (Bortolotti *et al.*, 2015). We conceptualise hard lean practices as a bundle of technically oriented JIT, TQM and TPM practices (Cua *et al.*, 2001). As a counterpart to hard lean practices, we consider soft lean practices as organisational practices related to the *management* of the social system. We view *practices* as the organised constellation of activities related to the organisation's technical and social system (cf. Schatzki, 2012). Accordingly, we define lean implementation as the organisational adoption of lean practices.

2.2 Hypothesis development

Most studies identify positive performance effects of lean on firm performance (Bloom *et al.*, 2019; Moyano-Fuentes and Sacristán-Díaz, 2012; Netland *et al.*, 2015), but there are still reports of no effects or even negative ones (Wemmerlöv, 2021). Put simply, many companies struggle to implement lean. As the mere implementation of tools and techniques – such as 5S or Kanban – will not suffice, it seems that the lean-performance relationship is *contingent* upon other variables.

While lean has often been reduced to a system of technical practices, the literature on critical success factors of lean suggests that human-related aspects play a central role in the success of lean adoption (Achanga *et al.*, 2006; Netland, 2016). Several studies focus on the direct effects of human aspects on performance in lean contexts (e.g. Camuffo and Gerli, 2018; Galeazzo *et al.*, 2017; Netland *et al.*, 2015), but we found no empirical study that takes on a contingent perspective by viewing human-oriented management practices as moderators of the lean-performance relationship.

Our main hypothesis is that soft lean practices strengthen the effect of hard lean practices. Hence, we examine the role of soft lean practices as moderators of the relationship between hard lean practices and performance. We do so by first hypothesising a direct positive relationship between hard lean practices and operational performance. Second, we expect the effectiveness of hard lean practices to depend on the support by soft lean practices. We, therefore, set forward a set of hypotheses relating to the interaction effects of soft lean practices on the relationship between hard lean practices and operational performance.

Specifically, we hypothesize moderator-variable interactions. Contrary to independent-variable interactions where each variable has an effect on the dependent variable, the moderating variable has no direct effect on the dependent variable (Luft and Shields, 2003). Despite being tested identically, the difference matters for the theoretical argumentation and development of hypotheses (MacKinnon, 2011; Tanriverdi and Venkatraman, 2005), which we elaborate on in the following. To confirm the existence of a moderator interaction effect, we also hypothesize a direct effect of soft lean practices on operational performance. Figure 1 provides an overview of our general research model.

Prior research has extensively studied the performance effects of lean practices (Cua *et al.*, 2001; Furlan *et al.*, 2011; Galeazzo and Furlan, 2018; Netland *et al.*, 2015; Shah and Ward, 2003). Generally, there is consensus that lean positively relates to operational performance (Bevilacqua *et al.*, 2017; Godinho Filho *et al.*, 2016; Vinodh and Joy, 2012), with some exceptions (Negrão *et al.*, 2017). While a positive relationship should therefore be expected, we include this hypothesis because our research setting – the pharmaceutical industry – differs from other industries in several important ways and has received only limited attention (see Friedli *et al.*, 2013, for a notable exception).

Pharmaceutical manufacturing sorts as process industry. Compared to discrete manufacturing, process industries have in general more equipment, higher volumes, lower variety, inflexible layouts, complex product changeovers, time dependence of the process and limitation of throughput by equipment rather than workforce (Abdulmalek *et al.*, 2006). In addition to the mentioned issues, fixed batch sizes, the complicacy of spontaneously stopping or starting processes and the difficulty of moving manufacturing assets in classical cellular arrangements make it difficult to realize JIT principles, such as pull production or continuous flow (Abdulmalek and Rajgopal, 2007; King, 2009). This, however, only means that such circumstances can make the implementation of hard JIT practices more difficult, but if successfully implemented, could help pharmaceutical companies reduce inventory among other benefits.

On the other hand, as the output is largely dependent upon manufacturing equipment, TPM practices can play an even more important role in the pharmaceutical industry compared to discrete manufacturing (King, 2009). As opposed to JIT, certain TPM practices are to some extent implemented in the pharmaceutical industry by default. For example, pharmaceutical regulations require manufacturing companies to keep their workplace clean and organized according to certain standards, which is a goal that is also followed by lean housekeeping tools, such as 5S. Moreover, being one of the most strictly regulated manufacturing industries, pharmaceutical firms pay a lot of attention to controlling their quality. Hence, TQM is an effective set of tools for them to manage their process stability and consistency. Statistical process control is one of these tools that pharmaceutical

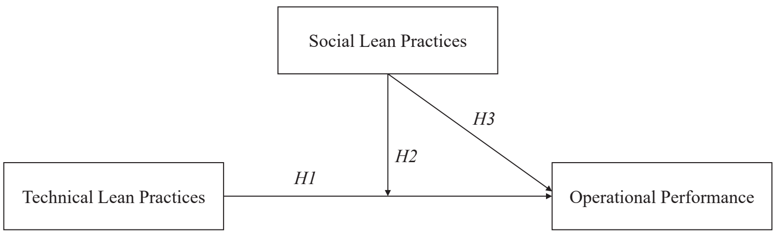

Figure 1.
Conceptual framework

manufacturers can employ just as well as in discrete manufacturing, as mathematical models can be developed independently of the environmental circumstances of the production system (cf. Floyd, 2010).

The pharmaceutical industry also has additional constraints in very strict market access regulations that limit or slow down the changes that can be imposed on the processes. Moreover, pharmaceutical products are often subject to large market volatility and unpredictability (consider, for example, Tamiflu or COVID-19 vaccines). These important characteristics assumedly affect the way hard lean practices can be employed and how they affect firm performance (Lyons *et al.*, 2013). Nevertheless, pharmaceutical companies are seeking to implement lean like other industries (Friedli *et al.*, 2013). The empirical evidence, while limited, further indicates a positive effect of lean implementation on firm performance in pharmaceutical companies (Boltic *et al.*, 2016; Friedli *et al.*, 2013). We therefore hypothesise

H1. The application of hard lean practices is associated with better operational performance in pharmaceutical manufacturing firms.

Soft lean practices aim at managing the social system of the organisation and involving all organisational members in lean thinking and acting. To define an appropriate set of management practices that serve as soft lean practices, we have reviewed prior literature. Kennedy and Widener (2008) propose a framework of management practices associated with lean manufacturing that we used to inform our choice of practices. We adopt *employee empowerment*, *training*, *visualisation*, *work standardisation* and *performance measurement* as soft lean practices in our study. Further, we add *goal setting* to our set of practices, as the literature also suggests that it has performance effects (Bortolotti *et al.*, 2015; Earley *et al.*, 1990; Locke and Latham, 1990). Our theoretical argument for its inclusion is that externally imposed goals establish performance standards that can have an effect on the behaviour of employees. As employees are provided challenging but attainable goals matched with strong self-efficacy beliefs, they develop congruency between personal and organizational goals that supports motivation and, as a consequence thereof, higher performance levels (Appelbaum and Hare, 1996). Further, the formulation of common goals makes it easier for employees and teams to establish clarity of targets and reach consensus, which helps streamline the organization and can affect teamwork positively (Hong *et al.*, 2004). Building on such common ground, it is easier for the organization or single teams to standardize and consistently follow hard lean practices, which can improve their performance effects. Overall, we find that our selected soft lean constructs are commonly applied in manufacturing organisations to manage the implementation of lean (Camuffo and Gerli, 2018; Netland *et al.*, 2015; Nielsen *et al.*, 2018; Shah and Ward, 2003). In the following, we explain the related hypotheses.

Drawing on prior literature, a variety of potentially supportive effects of respective practices can be identified. *Employee empowerment* can help create a sense of responsibility by providing employees with the authority and means necessary to drive improvement activities (Fullerton *et al.*, 2013). For example, empowerment can make employees more attentive and caring when it comes to maintaining equipment as part of a TPM programme. Further, employees are more eager to accept and follow plans when they have been involved in the decision-making process and realise ideas or projects that they have conceptualised themselves (Dombrowski *et al.*, 2012; Poksinska, 2010). In addition, the empowerment of employees can encourage them to carry out experiments with the potential of learning more about the work environment and improving processes according to lean principles (Netland *et al.*, 2021; Nielsen *et al.*, 2018). In this context, the importance of learning has been recently demonstrated by Nielsen *et al.* (2021), who found that lean's effect on performance increases as employees who implemented lean were learning. Based on these arguments, we hypothesise

H2a. Employee empowerment positively moderates the relationship between the application of hard lean practices and operational performance.

Another main reason for the success of the TPS is the way Toyota has developed its employees (Liker, 2004; Spear and Bowen, 1999). Toyota has invested considerable resources in employee and supplier qualification programmes (Ohno, 1988). Accordingly, *training* of employees has been recognised as a potential success factor by numerous lean studies (e.g. Bortolotti *et al.*, 2015; Hadid and Mansouri, 2014; Kennedy and Widener, 2008; Netland, 2016). By qualifying employees in methods for eliminating waste, they can, for example, be equipped with skills that help them perform set-up time and cleaning time reductions more effectively (Ferradás and Salonitis, 2013). Further, cross-training of the workforce broadens their knowledge such that interdisciplinary tasks can be performed more efficiently (Boyer, 1996; McDonald *et al.*, 2009). We, therefore, hypothesise

H2b. Training positively moderates the relationship between the application of hard lean practices and operational performance.

Work standardisation in the form of standard operating procedures (SOPs) represents a third soft lean practice that can support lean programmes. SOPs structure the behaviour of employees by specifying process steps (Langfield-Smith, 1997). Through the formalisation of standards, knowledge can be replicated and the spread of lean principles throughout the organisation can be supported (Netland *et al.*, 2021; Secchi and Camuffo, 2016). Further, SOPs serve as a baseline for continuous improvement, which should be continuously updated to incorporate improvements (Nielsen *et al.*, 2018; Secchi and Camuffo, 2016). They can therefore serve as a platform to capture hard lean practices and apply them more consistently. Additionally, they can, for example, help to structure maintenance, planning, or documentation efforts as part of a lean programme and reduce errors when exercising them, eventually leading to better operational performance. Due to the general applicability of work standardisation, we see potential performance effects with all types of hard lean practices. Activities such as establishing a Kanban system to realize pull production (JIT), using statistical models to control process quality (TQM), as well as doing planned maintenance (TPM) can be all standardized by defining how they should be conducted. Hence, we hypothesise

H2c. Work standardisation positively moderates the relationship between the application of hard lean practices and operational performance.

Another way to guide the behaviour of shop-floor workers in the process is *visualisation*. Visualisation via visual boards, for example, directs the attention of employees to potential improvement areas on the shop floor (Liker, 2004). Further, visualisations can indicate deviations of current work processes or equipment from set standards (Emiliani *et al.*, 2003). This can, for example, help employees detect anomalies in the manufacturing equipment, whereupon they can inspect it and possibly conduct maintenance activities to prevent downtime, fostering the effective use of TPM practices. Visualisation of current performance ensures that employees receive feedback when changing the process and enables them to assess the effectiveness of their changes. Through visualisation, also transparency can be established (Adler and Borys, 1996), which allows employees to not only solve their problems but also help others (Nielsen *et al.*, 2018). This way, organisational learning and continuous improvement are supported, which supports the effects on operational performance (Galeazzo *et al.*, 2017). These arguments suggest

H2d. Visualisation positively moderates the relationship between the application of hard lean practices and operational performance.

Goal setting depicts a fifth critical aspect of lean success that is often emphasised in the lean literature. Malmi and Brown (2008) include the planning of goals and actions as a core element of social lean systems. Galeazzo *et al.* (2017) confirm this notion and add that a goals-management system can support organisational learning. Bhamu and Singh Sangwan (2014) point out that clear goal setting for everyone in the enterprise can avoid misconceptions about goals and attention being paid to the wrong things. Similarly, Bortolotti *et al.* (2015) highlight that by clearly communicating goals, team members' efforts are more likely to converge toward a common direction, leading to increased team effectiveness. Hong *et al.* (2004) carried out a study on the team-level and came to the same conclusion. Due to increased consensus, target clarity and common goals foster teamwork and their performance. This can support hard lean practices that are carried out in teams, such as cross-functional teams developing new products as part of a TQM initiative. Therefore, we hypothesise

H2e. Goal setting positively moderates the relationship between the application of hard lean practices and operational performance.

Lastly, *performance measurement* is also known to influence the behaviour in production systems. To make good decisions and respond to situations appropriately, performance information is needed for managers and employees. Examples of performance information can be data on process quality (e.g. defects). Information is thus considered a powerful tool, which can act like a "cueing device or tool for strategy implementation" (Earley *et al.*, 1990, p. 102). The measurement of operational performance provides such information and reflects outcomes that are important to improve upon. On the one hand, employees have better information about what to target when implementing hard lean practices. For example, knowing that unplanned maintenance has been an issue lately, employees can draw conclusions about when to focus on TPM practices, which could lead to more effective use of maintenance activities and ultimately to better performance. On the other hand, it can motivate employees to engage themselves more purposefully, leading to more effective performance improvement suggestions (Fullerton and Wempe, 2009; Said *et al.*, 2003). Due to the transparency it creates on respective performance metrics and potential motivational aspects, performance measurement is likely to support the performance effect of hard lean practices. In other words, without the support of performance measurement, hard lean practices will not show their full potential. We therefore hypothesise

H2f. Performance measurement positively moderates the relationship between the application of hard lean practices and operational performance.

By hypothesizing moderation effects, as opposed to independent-variable interactions, we implicitly assume that the moderating variable has no direct effect on the dependent variable (Luft and Shields, 2003). The reason why we think so is that we see a link between hard lean practices and the *technical system*, which is generating output and relate directly to operational performance. Soft lean practices only affect the *social system*, which operates the technical system. Hard lean practices are thus a vehicle to drive operational performance, whereas soft lean practices instruct employees on how to drive that vehicle.

The empowerment of employees alone will not guarantee performance improvements as long as they do not engage in changing processes for the better, which, in lean-aspiring companies, is generally accomplished by implementing hard lean practices. In a similar vein, merely training employees but not changing the technical system from push to pull production, for example, will obviously not have a performance effect but having trained employees who understand the actual purpose of pull production will rather make sure that pull practices have a performance impact. Moreover, the standardisation of work processes before improving them and without any consistent direction will not yield positive results. In contrast, employing lean principles and using them to redesign processes and standardise them will help companies achieve performance gains. Another example is that visualization alone will not help improve performance, as it does not directly affect changes in the technical system. It is rather meant to be a cueing device that helps employees direct their improvement efforts more consciously and thereby increase the effectiveness of hard lean practices like maintenance activities. It will only exert its performance effect in combination with other activities.

As regards goal setting, we also do not expect a direct effect on operational performance in the context of lean companies, as employees will channel their improvements through the implementation of hard lean practices and only having set goals will not change the performance of the operational system. Finally, performance measurement can alter employees' awareness for the relationship between the behaviour of processes and their outcome but it alone will not change the operational performance of a company. Only in combination with the right tools to enhance the processes, the employees' awareness will benefit the organization, as increased understanding of processes will help to trigger the right changes that will ultimately lead in operational improvements.

Overall, we therefore hypothesize that soft lean practices generally do not affect operational performance directly:

H3. The application of soft lean practices alone is not *directly* associated with higher operational performance in pharmaceutical manufacturing firms.

3. Research method

3.1 Instrument development and data collection

We focus on pharmaceutical manufacturing firms to study the role of soft lean practices during the implementation of hard lean practices. Pharmaceutical firms operate in a highly regulated environment, which offers a unique opportunity to study the impact of soft lean practices across many organisations with homogenous organisational contexts. To test our hypotheses, we conducted one of the world's most comprehensive academic surveys in the field of pharmaceutical manufacturing—considering the number of participating manufacturing facilities and the extent of the questionnaire.

Data were collected from 2004 to 2019 and contain a cross-section of 351 manufacturing facilities located in 37 different countries, with a majority of the sites located in Europe. Our data showed a similar distribution across three distinct types of pharmaceutical manufacturers: brand, generics and contract manufacturers. Thus, the sample allows generalisation about the effect of soft lean practices on lean production across different types of pharmaceutical manufacturing facilities. Table 1 provides an overview of the data distribution for the studied sample.

The questionnaire that was used for data collection consists of three sections. The first section collects contextual data, such as information on plant type, plant size, or the number

Region	Europe	274	78%	Plant type	Brand manufacturer	152	43%
	North America	39	11%		Generics manufacturer	92	26%
	South/Mid America	10	3%		Contract manufacturer	107	31%
	Asia	7	2%	Plant size	Small (<100 Employees)	69	20%
	Africa	21	6%		Medium (100–500 Employees)	216	64%
					Large (>500 Employees)	54	16%

Table 1.
Sample composition of responses ($n = 351$)

of products manufactured at the facility. The second section collects data on operational performance. The third section assesses implementation levels of lean practices. The items in our study are primarily drawn from the global world-class manufacturing study (Schroeder and Flynn, 2001), which we structured into TPM, TQM, JIT and human-related management practices, analogously to prior studies (Cua *et al.*, 2001; Flynn *et al.*, 1995; Shah and Ward, 2003). We thereby cover both hard and soft lean practices.

To ensure validity for pharmaceutical manufacturing, the measures were extended and adjusted to the pharmaceutical context. This means that we have reformulated some of the questions and added further questions with particular relevance to the pharma context (e.g. supplier qualification processes, audits, use of latest technology). The measurement instrument was then reviewed by seven pharmaceutical lean production experts to ensure that the measurements were appropriate for the pharmaceutical industry and interpreted correctly by target respondents. The fourth and fifth constructs, namely *Basic Elements* and *Effective Management System,* measure the implementation of soft lean practices, similarly to Cua *et al.*'s (2001) construct of cross-cutting common practices.

To reduce common-respondent bias, data were collected from multiple respondents per firm. Middle and top managers, such as plant managers, site directors, or lean programme managers, were asked to fill out the first two parts of the survey covering contextual and performance data. To ensure an objective lean maturity self-assessment, teams of company representatives from relevant cross-functions such as quality or maintenance were asked to *jointly* fill out the third part of the survey, thus avoiding bias from single respondents in the self-assessment. It was also highlighted that there were no correct or incorrect answers in the self-assessment. Bias from proximity and single respondent bias was further avoided by splitting the questionnaire into two parts with different respondents for the performance and lean maturity assessments. Since all respondents were either involved in leading or executing lean implementation at a site, it was ensured that all respondents were appropriate informants for data collection.

3.2 Measurement

The collected data facilitate an objective assessment of the effects of different hard lean practices on operational performance. In particular, our questionnaire has two benefits that distinguish it from most existing lean research.

First, it separates efforts from outcomes in the lean assessment, as it measures levels of lean practice application rather than asking for outcomes. Many other studies ask for the degree to which different lean principles are evidenced by outcomes (e.g. "We have low set-up times"). In contrast, our survey instrument explicitly asks for the organisational efforts applied to fulfil these principles (e.g. "We are continuously working to lower set-up and cleaning times in our plant"). By doing so, our database allows us to separate efforts from outcomes as part of the lean assessment, similarly to a recent study carried out by Nielsen *et al.* (2021). This has the advantage of creating more instructive insights for managers and allowing us to study moderation effects of soft lean practices, as their presence can be the determining factor for the outcome of hard lean practices.

Second, the survey instrument measures operational performance with actual performance metrics (e.g. the number of rejected batches as a percentage of all batches produced, annual cost of goods sold divided by the average finished goods inventory, etc.), thereby allowing a highly objective assessment of performance, as it does not include any personal feelings, opinions or tastes. Usually, academic lean studies measure operational performance predominantly in one of two ways: either by asking for percentages of performance change in a given time frame (such as the last three or five years) and by using rough ordinal scales (e.g. increase by less than 3%, by 3–5%, or by more than 5%), or by asking for a self-assessment against the performance of competitors in a similar time frame (e.g. different Likert scales indicating *worse*, *equal*, or *better*).

In contrast to most studies on lean that use performance proxies, our study uses *actual*, realised performance numbers (see Appendix 2), which is inevitably associated with a significantly higher effort of data collection. As a reward, our study facilitates more accurate and more objective insights into the relation between lean implementation and operational performance than the described alternatives. Yet, due to the high complexity of production systems and the associated high number of influencing factors on the performance of these systems, it could be difficult to establish a statistically significant effect using hard performance numbers. Asking for perceptive data about the changes in performance could be closer to capturing the cause-and-effect relationship. However, not only does it entail the risk of a response bias (i.e. the respondents' opinion influencing the measure), but it will also never be as accurate as realised numbers. Therefore, we perceived the benefits of real performance metrics to outweigh their drawbacks and opted for this approach.

Table 2 provides an overview of the measurements for dependent, independent and moderating variables. The data collected on lean practice implementation comprised both hard and soft lean practices.

To measure the implementation of hard lean practices, we used the constructs *TPM practices, TQM practices and JIT practices.* To construct a scale for hard lean practices, we used principal component analysis (PCA). Since we were interested in studying the effect of soft lean practices on the effectiveness of the entire lean system and given the high interrelation between hard lean practices outlined in lean literature (Shah and Ward, 2007), a one-factor model was considered adequate and confirmed by our extraction using PCA (cf. Table 4).

Category	Subcategory	Indicator
Soft lean practices	–	Employee empowerment
		Training
		Work standardisation
		Visualisation
		Goal setting
		Performance measurement
Hard lean practices	JIT basic techniques	Set-up time reduction
		Pull system production
		Equipment layout
		Schedule adherence
	TQM basic techniques	Process management
		Cross-functional product design
		Supplier quality management
		Customer involvement
	TPM basic techniques	Autonomous and planned maintenance
		Technology emphasis
		Housekeeping
Operational performance[a]	Quality – internal	Rejected batches
	Quality – external	Customer complaint rate
	Dependability – equipment	Unplanned maintenance
	Dependability – internal delivery	Production schedule adherence
	Dependability – external delivery	On-time delivery
	Speed – process time	Deviation closure time
	Cost – inbound inventory	Raw material turns
	Cost – outbound inventory	Finished good turns

Note(s): [a]Real performance indicators used for operational performance

Table 2.
Conceptualisation of soft lean practices, hard lean practices and operational performance

To develop individual soft lean constructs, we drew on items from the socially-oriented constructs in our survey ("Basic elements" and "Effective Management System"). For soft lean practices, we combined multiple survey items into six new constructs: *employee involvement (EE)*, *training (Tra), work standardisation (WS)*, *visualisation (Vis)*, *goal setting (GS) and performance measurement (PM)* (see Appendix 1 for further details). For this purpose, we first performed a content-based preselection of potentially suitable soft lean practices for each construct based on available survey items. Then, we verified the content-based preselection using CFA.

Finally, we used eight real performance metrics to measure the actual operational performance of a plant. All performance measures were calculated in such a way that higher values indicated better performance, also variables such as inventory or time. More details about the metrics definitions and operationalisation, such as units, positive direction and normalisation can be found in Appendixes 2–4. To ensure a comprehensive assessment of operational performance, we measured performance in dependability, speed, cost performance and quality (Ferdows and De Meyer, 1990). To identify relevant metrics for measuring performance in the four dimensions, we drew on key objectives of TQM, JIT and TPM as formulated in the literature as guidance because, in conjunction, they facilitate operational effectiveness and efficiency (Cua *et al.*, 2001). TQM aims at eliminating defects and reworking to increase quality (Brown and Mitchell, 1991). For quality performance, we distinguished between an *internal* and *external quality* performance dimension as per Shah *et al.* (2017) and used the metrics *rejected batches* and *customer complaint rate* as respective internal and external performance indicators. JIT aims at reducing waste in production flow to achieve low inventory levels (Shah and Ward, 2003). We used the metrics *production schedule adherence* and *on-time delivery* as measures of internal and external dependability and further used the metrics *raw material turns* and *finished good turns* as indicators for inventory levels. Finally, as the primary objective of TPM is to maximise equipment effectiveness and stability to avoid breakdowns or delays (Cua *et al.*, 2001), we included equipment as the third dimension of dependability performance and used the metric *unplanned maintenance* as a measure of equipment dependability. Since linear hierarchical regression requires point estimates and thus a single score for the dependent variable, we calculated a single performance score for each plant by averaging the scores of the eight underlying performance metrics.

3.3 Common method bias

To avoid common method bias, our study follows Podsakoff *et al.*'s (2003) recommendations. Method bias from proximity was avoided by assessing lean practice implementation and operational performance in physically separated sections. The subjectivity of the performance assessment was avoided by asking for data on actual performance metrics. To also maximise objectivity for lean implementation self-assessment, study participants were asked to form a team of multiple respondents from different relevant functional areas and fill out the self-assessment jointly. Overall, we received responses from three to five respondents per plant.

3.4 Control and moderator variables

We used site size as a control variable in the quantitative analyses since several lean researchers have pointed out that the size of a company can affect the level of lean implementation (Shah and Ward, 2003; Tortorella *et al.*, 2018). To control for company site size, we followed common classification in operations management research and distinguished between large sites on the one hand (≥500 employees) and small or medium-sized sites on the other hand (<500 employees) (e.g. Lyons *et al.*, 2013; Tortorella *et al.*, 2019;

Youn *et al.*, 2012). To allow generalisation across distinct pharmaceutical site types, we further considered the site classifiers *brand manufacturers*, *generics manufacturers and contract manufacturers* as control variables [1]. We also tested the age of machinery equipment, level of automation and the number of manufactured products at the site as control variables but did not find any other significant results. Thus, we included only site size and the three distinct site types in the hierarchical regression models.

Since we are studying the role of soft lean practices on the relationship between hard lean practices and operational performance, we used each of the six soft lean constructs as moderators in our regression. The measurement items for the soft lean constructs provided values on a Likert scale from 1 to 5. We used standardised values for the predictor and moderator variables and tested for multicollinearity to ensure that it was not an issue (Aiken *et al.*, 1991). All variance inflation factors in our regression models did not exceed 1.18 and were thus below the threshold of 4.0, suggesting that multicollinearity was not a concern. We also verified that our data met the normality, linearity and homoscedasticity requirements for regression analysis (Hair *et al.*, 2006). We then calculated one interaction term for each soft lean construct with the hard lean practice construct, summing up to a total of six interaction terms (HLP × EE, HLP × Tra, HLP × WS, HLP × Vis, HLP × GS, HLP × PM).

4. Results

4.1 Construct validity and reliability

To ensure one-dimensionality of the six individual soft lean practices, we used CFA (see Table 3). All factor loadings ended up well above 0.5 (with one exception at 0.42), which generally meets the suggested threshold by Hair *et al.* (2006). Following Hu and Bentler (1999), our model showed further good fitness indices. Results of the χ^2 test were below the threshold of 3 (χ^2/df = 1.994), the Comparative Fit Index (CFI) was considered high (CFI = 0.95) and the Root Mean Square Error of Approximation (RMSEA) was only slightly above the threshold of 0.05, but still below 0.08 (RMSEA = 0.056), which is considered as good model fit. To test reliability, Cronbach's α was calculated and was greater than 0.7 for each construct, indicating satisfactory construct validity (Hair *et al.*, 2006). Convergent validity and discriminant validity were further tested under consideration of composite reliability (CR)

Construct	Item	Factor loading CFA	Composite reliability (CR)
Employee empowerment	EE1	0.790	0.763
	EE2	0.633	
	EE3	0.732	
Training	Tra1	0.773	0.804
	Tra2	0.922	
	Tra3	0.559	
Work standardisation	WS1	0.655	0.772
	WS2	0.733	
	WS3	0.792	
Visualisation	Vis1	0.793	0.792
	Vis2	0.842	
	Vis3	0.702	
	Vis4	0.419	
Goal setting	GS1	0.764	0.799
	GS2	0.779	
	GS3	0.722	
Performance measurement	PM1	0.666	0.757
	PM2	0.886	

Table 3. Soft lean practice measurement items, CFA factor loadings and construct reliability

	Mean	S.D	Component Hard lean practices
Set-up time reduction (JIT)	2.91	0.74	0.771
Pull system production (JIT)	2.78	0.64	0.526
Equipment layout (JIT)	3.04	0.81	0.665
Schedule adherence (JIT)	3.50	0.67	0.727
Process management (TQM)	3.20	0.79	0.736
Cross-functional product design (TQM)	3.39	0.93	0.558
Supplier quality management (TQM)	3.35	0.62	0.522
Customer involvement (TQM)	3.60	0.74	0.497
Autonomous and planned maintenance (TPM)	3.55	0.68	0.665
Technology emphasis (TPM)	2.88	0.72	0.639
Housekeeping (TPM)	3.92	0.86	0.578
Eigenvalue (variance explained)			4.40 (40.01%)
Cronbach's α			0.842

Note(s): Extraction method: Principal component analysis

Table 4. Hard lean practice construct: Means, standard deviation and factor loadings

and the average variance extracted (AVE), respectively (Hair *et al.*, 2006; Zait and Bertea, 2011). The recommended values of CR > 0.7 and AVE > 0.5 were exceeded for all six soft lean constructs, thereby indicating good convergent and discriminant validity. Further, we support discriminant validity by showing that the square root of average variance extracted exceeded all other correlation coefficient values (see Table 5).

To create a scale for the hard lean practice measure, we used 11 variables measuring TPM, TQM and JIT practices as independent variables in the PCA. Table 4 shows the means and all factor loadings for the extracted component. The means range from 2.78 to 3.92, which is a spread that indicates a preference of certain hard lean practices over others. Set-up time reduction and pull system production, both JIT practices, were applied least intensely. Overall, TQM and TPM practices, such as autonomous and planned maintenance, customer involvement and housekeeping were applied more strongly, which is not surprising in an equipment-heavy and quality-oriented industry like pharmaceuticals.

The factor loadings of the constructs were all above 0.4. The component had an eigenvalue of 4.40 with a Cronbach's α of 0.842. The one-factor model explained 40.01% of the variation. Consequently, the hard lean practice score was calculated as a one-factor variable including the 11 factor scores underlying the constructs TPM, TQM and JIT practice.

4.2 Pearson correlations

To understand the interrelation between individual soft lean constructs, correlations among the six constructs are presented in Table 5. First, the results showed a strong correlation among all control constructs ($p < 0.01$) indicating high interrelation among the constructs.

Construct		Mean	S.D	AVE	EE	Tra	WS	Vis	GS	PM
Employee Empowerment	EE	3.582	0.858	0.52	*0.721*					
Training	Tra	3.381	0.784	0.587	0.461**	*0.766*				
Work Standardisation	WS	3.657	0.800	0.531	0.530**	0.489**	*0.729*			
Visualisation	Vis	2.894	1.006	0.502	0.673**	0.441**	0.471**	*0.708*		
Goal Setting	GS	3.964	0.779	0.571	0.687**	0.544**	0.646**	0.650**	*0.755*	
Performance Measurement	PM	3.877	0.933	0.614	0.567**	0.363**	0.529**	0.510**	0.661**	*0.784*

Note(s): **Significant at the $p < 0.01$ level, square root of average variance extracted in the diagonal

Table 5. Correlation, mean and standard deviation of soft lean practices

These findings correspond well to the findings of Nielsen *et al.* (2018) who found similar significant correlations between individual soft management practices. Second, correlations among the six constructs were positive, suggesting that pharmaceutical companies follow a comprehensive approach where the implementation of one construct goes hand-in-hand with the implementation of the others. Third, *training* showed on average the lowest correlation coefficients with other control constructs (on average $r = 0.383$), suggesting that it is coupled more loosely to the other control constructs. Finally, *goal setting* and *employee empowerment* showed on average the highest correlation coefficients (on average $r = 0.638$ and $r = 0.584$), signifying the highest interconnectivity with other soft lean practices.

4.3 Linear hierarchical regression

To test our hypotheses, we calculated a hierarchical set of ordinary least square linear regression models. In these models, we considered the effects of hard lean practices and soft lean practices on operational performance. We further calculated interaction terms between each of the soft lean constructs with lean practices (e.g. HLP × Vis) and tested their effects on operational performance (aggregation of the performance metrics outlined above). Also, we included control variables in the model, such as *site type* and *firm size*.

Table 6 shows the hierarchical linear regression results with control variables, the two types of lean practices, plus their interaction terms as independent variables and performance as a dependent variable. We reported the unstandardised regression coefficients given the prior standardisation of the moderation variables (Goldsby *et al.*, 2013). The results show that the contextual factors plant size and plant type accounted for a small but significant amount of variance (adjusted $R^2 = 0.038$, $p < 0.001$). The inclusion of hard lean practices and individual soft lean practices resulted in a change of R^2 to 0.162. Subsequent additional inclusion of the interaction terms further improved the model and explained variance of 23.1%. Five out of six interaction terms showed statistically significant effects.

	Model 1	Model 2	Model 3
Size	−0.001**	−0.001***	−0.001***
Brand manufacturer	0.237	0.093	0.206
Generics manufacturer	−0.015	−0.017	−0.023
Contract manufacturing organisation (CMO)	−0.502**	−0.330	−0.319
Hard lean practices (HLP)		0.361**	0.387***
Employee empowerment (EE)		0.075	0.116
Training (Tra)		0.109	0.076
Work standardisation (WS)		0.071	0.058
Visualisation (Vis)		−0.077	−0.129
Goal setting (GS)		−0.083	−0.142
Performance measurement (PM)		0.126	0.179*
HLP × EE			0.290**
HLP × Tra			−0.113
HLP × WS			−0.292***
HLP × Vis			0.259**
HLP × GS			−0.221*
HLP × PM			0.171*
Adj. R^2	0.038	0.162	0.231
ΔR^2	0.060	0.153	0.091
F-value	2.788	4.674	3.539
P-value of *F* statistic	0.028	0.000	0.003

Note(s): $*p < 0.1$; $**p < 0.05$; $***p < 0.01$

Table 6. Results of OLS regression analysis ($n = 351$)

The results confirm our first hypothesis and show a positive effect of hard lean practices on operational performance. For the remaining hypotheses, some soft lean practices showed significant moderating effects on the relationship between hard lean practices and operational performance. The three soft lean practices *visualisation, performance measurement and employee empowerment* showed a significant positive effect, whereas *work standardisation* and *goal setting* had a statistically significant negative effect. Since *training* did not show a significant interaction with hard lean practices, we only find evidence in support of hypotheses 2a, 2d and 2f. Lastly, we confirm our third hypothesis, as we find soft lean practices to have no direct effect on operational performance.

5. Discussion

Our findings confirm that soft lean practices affect the implementation of lean programs. First, we show statistically significant correlations between individual soft lean practices, which suggests that they might be commonly applied together in pharmaceutical manufacturing firms. This raises the question of whether companies blindly apply them all together as common practice without considering the individual effects each of them might have on the effectiveness of hard lean practices. Current approaches for lean implementation in these firms are, therefore, potentially not optimised for an effective interplay between both hard and soft lean practices.

Second, the results of our linear hierarchical regression show significant interaction effects between soft lean practices and the technical lean system. More specifically, the regression results reveal two-directional interaction effects on operational performance. Some soft lean practices support the relationship between hard lean practices and operational performance, some do not, and some even undermine it with a negative effect. Interestingly, soft lean practices do not show significant performance effects in isolation, which can be due to not affecting the technical system directly but only the social system. These findings expose a conditionality for the effect of soft lean practices on operational performance that is dependent on the technical lean system (cf. Beraldin *et al.*, 2019; Galeazzo and Furlan, 2018).

Accordingly, pharmaceutical manufacturing companies should implement hard lean practices if they want to improve their operational performance. Further, managers are advised to pay close attention to the behavioural implications of soft lean practices for the effect of hard lean practices, as these interactions can enhance but also weaken operational performance. We discuss these implications in the following sections.

5.1 Enhancing the performance effect of lean

We find significant, positive moderation effects for *visualisation*, *employee empowerment and performance measurement* and thus confirm the three corresponding hypotheses. Regarding visualisation, our results confirm that the use of real-time performance charts, technical documents and visualised workplace information on the shop floor increases the positive effect of hard lean practices on operational performance. Such measures can help to raise the employees' awareness of potential improvement areas and the understanding of how their work relates to other work activities (Liker, 2004; Nielsen *et al.*, 2018), which ultimately leads to effective use of hard lean practices.

We find similar effects for employee empowerment, as shop-floor workers' involvement in writing policies and procedures, decision-making authority and engagement in suggestion programmes supported lean effectiveness. Such empowerment of people can go hand-in-hand with an increased sense of responsibility, which is also what Lincoln and Kalleberg (1990) identified as a characteristic of Japanese workers. Once employees feel responsible for certain tasks, they do not do them just because they are being told to do so but start being concerned about the quality of their output, which reflects their behaviour as well as its potential consequences (Hackman and Oldham, 1976). This in turn reduces the risk of employees only *copying* hard lean practices into already existing organisational habits (corruption of lean practices) instead of *transforming* existing processes for the sake of actual performance improvement (cf. Lozeau *et al.*, 2002).

The third positive moderation effect we identify is related to *performance measurement*. Continuous, real-time measurement of quality, use of statistical process control and the linkage of process measures to plant objectives create comprehensive awareness of plant performance (Bunderson and Boumgarden, 2010; van Dun and Wilderom, 2021). Well-informed employees can therefore more easily align their behaviour with lean manufacturing objectives by, for instance, deciding where to lower set-up times or how to reduce batch sizes (Liker, 2004; Nielsen *et al.*, 2018). In addition to that, the awareness caused by performance measurement can create a feeling of responsibility and promote employees' commitment to improvement activities (van Dun and Wilderom, 2021; Fullerton *et al.*, 2014).

5.2 Inhibiting the performance effect of lean

The significant negative effects found in this study for the interaction of *work standardisation* and *goal setting* with the technical lean system might be surprising at first. However, we find literature that takes the risk of counterproductive consequences of both constructs similarly into account. Examples include *selective attention* and *illusion of control* (Franco-Santos and Otley, 2018), *inertia* and *disempowerment* (Bititci, 2015), *reduction of intrinsic motivation and employee engagement* (Sitkin *et al.*, 2010), or *lack of learning and innovation capabilities* (Adler and Borys, 1996).

SOPs are often associated with higher product quality and performance (Kennedy and Widener, 2008). However, Adler and Borys (1996) also highlight that these often lead to inefficient workarounds or barriers to improvement because they are often not designed to aid the user or to enable continuous improvement. In the pharmaceutical industry, SOPs primarily serve a regulatory role, ensuring that procedures are carried out correctly (Friedli *et al.*, 2010). This falls short of the broader lean vision of ensuring a company-wide and ongoing effort for improvement (Liker, 2004; Ohno, 1988). Thus, in pharmaceutical manufacturing, procedural regulation could act as a barrier for improvement, particularly given the fact that changes in regulatory procedures can require resource-intensive regulatory validation.

In terms of *goal setting*, lean literature emphasises the importance of clearly communicating goals for lean success. However, recent literature also highlights potential counterproductive consequences of directive performance management, including the selective focus on target metrics to the detriment of other important aspects of performance (Franco-Santos and Otley, 2018). Some of the latest research further suggests that these side effects of directive performance management are more likely to appear in complex and regulated organisations such as pharmaceutical manufacturing firms (Franco-Santos and Otley, 2018; Tan and Rae, 2009). Liker (2004) emphasised the danger of selective attention to strict goal setting and noted that employees "will work to make the numbers regardless of quality" (p. 141). Thus, our findings are closely related to the question of how goals are set and communicated in pharmaceutical manufacturing firms. It also shows that this may either enable an organisation-wide pursuit of holistic lean goals or hinder it by leading to the pursuit of more selective performance objectives.

5.3 Enabling versus coercive effects on the workforce

The formalization of processes can either have an *enabling* effect or *coercive* effect on the workforce (Adler and Borys, 1996), which could explain the different outcomes we observed with the application of soft lean practices. Enabling forces occur when employees are supported in dealing with contingencies that arise when doing their work. This can be guidelines for solving problems in case of breakdowns, transparency about the progress or quality of processes, global transparency about issues that go beyond an employee's primary scope like information on the strategic orientation, or flexibility in terms of having options to choose from, or even developing new ones, when solving tasks. On the contrary, coercive mechanisms force employee's efforts and compliance by limiting their freedom when executing their tasks and discouraging any deviation from the standard procedure (Adler and Borys, 1996). They can cause feelings of powerlessness, alienation and psychological stress for employees and ultimately lead to negative performance effects (Adler and Borys, 1996; Kakabadse, 1986). In the lean context, enabling mechanisms tend to be favoured and produce better results compared to coercive mechanisms (Kristensen, 2021; Mehta and Shah, 2005).

Among the positive moderators, we identify a notable commonality. All of them support organisational commitment and involvement by facilitating employees to implement lean, which reflects the concept of enabling mechanisms well. By increasing the responsibility and performance awareness of employees as well as the information available on the shop floor, employees are better equipped and potentially more motivated to engage themselves in continuous improvement. This is confirmed by Hirzel *et al.* (2017) who show that employee empowerment promotes commitment to continuous improvement activities. The importance of this finding is stressed by Angelis *et al.* (2011) who stated that lean programmes neither inherently support nor impede commitment, but the design of policies and practices does so.

Regarding the negative moderators, we find a commonality in that they reflect a more commandment-oriented management approach rather than one that is commitment-oriented. As opposed to the positive moderators that support facilitation and empowerment, goal setting and standardisation of work traditionally aim at imposing guardrails and constraints on employees that may divert them from the common lean goals and thus could hamper a successful lean implementation (Beraldin *et al.*, 2019; Mawritz *et al.*, 2014; de Treville and Antonakis, 2006). Managers who tailor the management infrastructure too much toward commanding and micro-management may, therefore, restrict their employees, depriving them of opportunities to initiate improvements and running the risk of losing the broader vision for the actual purpose of their lean programmes. We, therefore, conclude that a commandment-oriented use of instructions and objectives as limiting and rigid measures could have exhibited coercive forces and was possibly the reason for the observed negative effects.

5.4 Enabling potential of standardisation and goal setting

In the previous section, work standardisation and objectives received a negative connotation. In the following, we intend to put this into a different perspective. While instructions and objectives prescribe how work should be done, they can also be very supportive of lean by providing employees with opportunities for continuous improvement, given employees have the freedom and authority to act on them (cf. Giddens, 1984; Liker, 2004).

To illustrate this with an example, standardised work set-ups in pharmaceutical firms are examples of organisational infrastructure that influence the actions of the workforce. They constrain human behaviour and innovation, as they specify how procedures are to be performed. By the same token, they can also enable the workforce to perform their tasks more efficiently or can act as a basis for continuous improvement (Adler and Borys, 1996). Liker (2004, p. 147) noted that "standards have to be specific enough to be useful guides, yet general enough to allow for some flexibility." Similarly, Camuffo and Gerli (2018) distinguish a good lean manager as someone who does not micromanage but develops standards in collaboration with their team and uses them as a baseline for continuous improvement.

Correspondingly, the other soft lean practices, *employee empowerment, performance measurement, visualisation, training and goal setting,* can also enable and constrain individual actions depending on how managers interpret them.

We conclude that by determining the organisational infrastructure for lean implementation, managers take on a crucial role in enabling or constraining greater worker commitment to successfully implement lean. There is a fine line between commitment-oriented and commandment-oriented management, which can be crucial for the success of lean implementation.

6. Conclusion

Many manufacturing companies have been struggling with the effective implementation of lean programmes. The purpose of this study was therefore to help reduce the number of these cases by providing a better understanding of how *soft lean practices* influence the success of lean programmes in pharmaceutical manufacturing companies. To fulfil this purpose, we analysed global survey data and established relationships between three constructs: *soft lean practices*, *hard lean practices* and *operational performance*.

As many researchers do not clearly separate between soft and hard lean practices, our first contribution was to create a theoretical setting that explains how organisational behaviour in manufacturing firms can be influenced and to separate hard lean practices from soft lean practices. By distinguishing hard from soft lean practices, it was possible to study their impact on performance separately as well as their interaction effects. Particularly, the latter have not been studied to such an extent before, to the best of our knowledge, despite numerous studies indicating that the success of lean programmes depends on human factors (e.g. Bortolotti *et al.*, 2015; Camuffo and Gerli, 2018; Netland *et al.*, 2015). By adding interaction terms between soft lean practices and hard lean practices to our model, we increase the model fit and find significant moderation effects, which suggests a contingent relationship between lean and operational performance.

Second, our results further provide empirical evidence for the collective use of soft lean practices and their effects, which have not been studied comprehensively before in pharmaceutical lean programmes. The pharmaceutical industry differs significantly from discrete manufacturing and presents individual characteristics, that have significant effects on the interaction between the social and technical production system. We delineate these characteristics and discuss how they influence the use of soft lean practices and their effects on the link between hard lean practices and operational performance.

The third contribution of this study was to show that the application of common *soft lean practices* in lean systems can lead to positive but also negative performance effects. Our results showed that *soft lean practices* like *employee empowerment*, *visualisation* or *performance measurement* can indeed help support the effectiveness of lean programmes, whereas *work standardisation* and *goal setting* can show the opposite effect. Given these two-directional performance effects, while at the same time observing a unidirectional implementation of soft lean practices, we conclude that behavioural implications of soft lean practices play an important role in the implementation of lean systems.

6.1 Managerial implications

For managers, this study raises awareness regarding the socio-technical implications of implementing lean programmes. The implementation of lean includes both hard and soft lean practices that affect different parts of the organisation but are still interrelated. Due to the complexity of socio-technical systems (Soliman *et al.*, 2018), the successful implementation of lean depends on a delicate configuration of these parameters.

It has further been shown that potentially unintended consequences can result from the application of certain soft lean aspects in pharmaceutical lean systems. Managers, particularly in the pharmaceutical industry, are therefore advised to pay close attention to the definition of goals as well as standardisation policies, being aware of potential negative impacts on the effectiveness of lean efforts. Therefore, they should not be discouraged in their lean implementation efforts in cases of unintended consequences but should instead adopt a situational approach to soft lean practices integrating forms of both commitment and commandment in suitable ways.

6.2 Limitations and future research

This study focuses on the pharmaceutical industry, which is a highly regulated, technology-intensive context and includes industry-specific obstacles to change or improvement. It is therefore difficult to claim generalisation of our findings to other industrial contexts. Second, while quantitative models are well-suited for establishing correlational associations between variables, this does not necessarily imply causal relationships. We cannot rule out potential endogeneity issues. For example, better-performing plants might be rather able to afford investments in the implementation of hard and soft lean practices. Third, we cannot rule out the possibility of other firm- or plant-level variables being correlated with the independent variables but omitted by our model. Unobserved variables, such as past plant performance, could be actual drivers of the correlations we find. We are aware of these potential model misspecifications and did our best to rule them out, for example, by using different sets of control variables to see if estimates of our main and interaction effects change. And lastly, our moderated regression could only test two-way interactions, whereas the implementation of lean is a complex socio-technical undertaking that involves many more variables and effects at the same time. To some extent, our approach is therefore limited in capturing the whole picture of relevant effects, which could, however, be tackled in future research with qualitative research designs.

While the lean literature identifies the need for the optimisation of both the social and the technical lean sub-system (Bortolotti *et al.*, 2015; Hadid and Mansouri, 2014; Shah and Ward, 2003), contextual lean studies still provide little systematic guidance for implementing lean practices under consideration of both infrastructural and behavioural management aspects. In this light, contextual lean research would benefit from adopting more integrated perspectives that explicitly consider both dimensions. Thus, one pathway for further research is to explore how soft lean practices can support or even inhibit the performance effects of hard lean practices in different contexts.

In our study, soft lean practices alone did not show any direct performance effects. It is, however, questionable if this was due to the specific research setting in the pharmaceutical industry or if this is a generally occurring phenomenon. Future lean studies are therefore encouraged to emphasise the analysis of soft lean practices in other research contexts. It would be interesting to test if this effect can be replicated in different manufacturing industries to verify whether a successful implementation of lean actually depends strongly on the implementation of the technical aspects of lean, or if social aspects alone (e.g. empowerment or cross-functional teams) can already enhance firm performance.

Note

1. Brand manufacturers are pharmaceutical companies that produce regulatorily approved original brand-name drugs, for which they hold patents. Generics manufacturers produce drugs that are made of the same active ingredients as the original brand-name drugs after their patents have expired. Contract manufacturers are pharmaceutical contractors that produce drug products for pharmaceutical clients.

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(The Appendix follows overleaf)

Appendix 1

Item	Management control practice
EE1	Shop-floor employees are encouraged to actively drive suggestion programmes
EE2	Our plant forms cross-functional project teams to solve problems
EE3	We have implemented tools and methods to deploy a continuous improvement process
Tr1	Each of our employees within our work teams is cross-trained so that they can fill in for others when necessary
Tr2	At our plant, we have implemented a formal programme to increase the flexibility of our production workers. Employees rotate to maintain their qualification
Tr3	We continuously invest in the training and qualification of our workers. We have a dedicated development and qualification programme for our production workers
Std1	We emphasise standardisation as a strategy for continuously improving our processes, machines and products
Std2	We use our documented operating procedures to standardise our processes
Std3	Optimised operating procedures are documented as best-practice processes and rolled-out throughout the plant
Vis1	Performance charts at each of our production processes indicate performance objectives
Vis2	Charts showing current performance status are posted on the shop floor and visible to everyone
Vis3	Charts showing current tact times and schedule compliance are posted on the shop floor and visible to everyone
Vis4	Technical documents and workplace information are posted on the shop floor and are easily accessible and visible to everyone
GS1	Our vision, mission and strategy are broadly communicated and lived by our employees
GS2	The goals and objectives of the manufacturing unit are closely linked and consistent with corporate objectives. The production site has a clear focus
GS3	The overall objectives of the production sites are closely linked to the team or personal objectives of our shop-floor teams and employees
PM1	We continuously measure the quality of our processes by using process measures
PM2	Our process measures are directly linked to our plant objectives

Table A1.
Measurement items of soft lean practices

Appendix 2

Dimension	Indicator	Unit	Optimisation direction	Score calculation	Operational performance (range)
Quality	Rejected batches	%	Down	1−Percentile	Average of all eight calculated scores (0–1)
Quality	Customer complaint rate	%	Down	1−Percentile	
Dependability	Unplanned maintenance	%	Down	1−Percentile	
Dependability	Production schedule adherence	%	Up	Percentile	
Dependability	On-time delivery	%	Up	Percentile	
Speed	Deviation closure time	Days	Down	1−Percentile	
Cost	Raw material turns	1	Up	Percentile	
Cost	Finished good turns	1	Up	Percentile	

Table A2.
Operational performance measurement

Appendix 3

Indicator	Definition
Rejected batches	Number of rejected batches as a percentage of all batches produced
Customer complaint rate	Number of complaints as a percentage of all customer orders delivered
Unplanned maintenance	Proportion of unplanned maintenance work as a percentage of the overall time spent for maintenance
Production schedule adherence	Number of orders finished in the correct week and volume (±10%) of total number of orders planned for completion that week
On-time delivery	Perfect order fulfilment to your customer as percentage of orders shipped in time from your site (±1 days of the agreed shipment day), in the right quantity (±3% of the agreed quantity) and in right quality
Deviation closure time	Number of deviations per month that arise from raw materials purchased, production components (equipment) and product or process specifications
Raw material turns	Annual cost of raw materials purchased divided by the average raw material inventory
Finished good turns	Annual cost of goods sold divided by the average finished goods inventory

Table A3. Operational performance measurement definitions

Appendix 4

Measurement	Mean	S.D	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Rejected batches	0.522	0.299	–							
Customer complaint rate	0.515	0.296	0.118**	–						
Unplanned maintenance	0.522	0.286	0.020	0.049	–					
Production schedule adherence	0.459	0.279	0.089	−0.064	−0.023	–				
On-time delivery	0.477	0.280	0.065	0.035	−0.019	0.281***	–			
Deviation closure time	0.522	0.287	0.007	0.005	−0.065	0.019	−0.031	–		
Raw material turns	0.490	0.294	0.132**	0.053	−0.039	0.281***	−0.044	0.182**	–	
Finished good turns	0.495	0.292	0.134**	−0.093	−0.092	0.006	−0.242***	0.214**	0.346***	–

Note(s): $*p < 0.1$; $**p < 0.05$; $***p < 0.01$

Table A4. Correlation analysis of real performance metrics

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