A model to assess readiness and evaluate the return of Lean Six Sigma implementation, with a pilot study in an Italian Pharmaceutical Company

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Abstract: At a time in history when uncertainty dominates markets and the international context, Lean Six Sigma is a performance improvement approach that can provide robustness toward the present and ensure greater security toward the future. Despite the continued popularity of Lean Six Sigma, along with many success stories, there still are many cases of unsuccessful implementation, mainly due to organizations not being ready and the inability of Lean Six Sigma projects to provide a return on investment. In this paper, the authors, based on a literature review, propose an innovative model to assess the readiness of an organization for Lean Six Sigma implementation and to prioritize improvement projects by estimating their Return on Investment. The readiness assessment is based on the analysis of critical success factors together with the ability to contribute to business objectives. The Return on Investment is estimated by introducing innovative measures such as Return On Muda, Return On Variability, Return On Quality, Return On Satisfaction and Return On Engagement. The model has been tested in an Italian pharmaceutical company. The result of the application shows what steps the company must take to ensure both economic and cultural returns, as well as the success of Lean Six Sigma projects.

Keywords: Lean Six Sigma, Pharmaceutical Industry, Organizational Readiness, Return On Investment, Lessons Learnt

1. Introduction

The advent of Industry 4.0 has exponentially facilitated the globalisation of markets, transforming industries and work dynamics. This has led to sectors where competition extends beyond local and national boundaries, including companies from all over the world offering an array of products and services to meet similar needs. Here, Industry 4.0 is driven by the digitisation and integration of vertical and horizontal value chains, as well as digitisation of product service offerings, digital business models, and customer access (Lekara Bayo and Onyenma, 2019). Globalisation has presented numerous challenges for the industry, stemming from cultural disparities, consumer tastes, laws, and societal differences. Furthermore, it has exposed the global value chain to environmental disasters and geopolitical conflicts (Ma, Li and Pan, 2023). Moreover, industries grapple with issues surrounding proper and sound business management, encompassing financial and operational aspects. In this historical industrial period, one of the most difficult sectors where firms are striving to meet customer needs is the pharmaceutical industry. Pharmaceutical companies are beset with a market where there are:

1. The randomness in the discovering of new molecules is growing;
2. The competition is becoming increasingly more complicated to manage due to high costs and low success rate in R&D, alongside lengthy research and development;
3. High–quality standards and regulatory burdens in accordance with Good Manufacturing Practices, require compliance with variations in national practices;
4. Global supply chain, plant operations, and global governance complexity to achieve the highest level of competitiveness, while the costs continue to rise (Laínez, Schaefer and Reklaitis, 2012).

In this regard, pharmaceutical companies are increasingly seeking continuous improvement tools to improve their flexibility in the market, reduce internal costs and minimize waste and non-value-added activities, like Lean Six Sigma (Božanić, 2010). Lean Six Sigma (LSS) is a company-wide operational methodology that was born through the combination of Lean and Six Sigma, oriented to process improvement. The objectives of this approach can vary, such as reducing lead time, increasing productivity and efficiency, and increasing the perceived quality by customers, working in both service and manufacturing sectors, focusing on waste reduction through DMAIC (Define – Measure – Analyze – Improve – Control) methodology. The use of continuous improvement tools, linked to an increase in perceived quality, such as Lean Six Sigma, should aim to develop a culture of continuous improvement, based on a different approach. If, up to now, a lot of work has been done on

big changes, it is necessary to work on the organisational environment, people's perceptions, and approach to problems. This involves developing a culture focused on continuous improvement, based on a data–driven and systemic approach (Sharma and Kumar Sharma, 2020; Vicente, Godina and Teresa Gabriel, 2024). Despite the strong interest in implementing Lean Six Sigma projects, the literature highlights the enormous difficulties in prioritising and implementing Lean Six Sigma projects and the low success rate of continuous improvement projects (Albliwi *et al.*, 2014). While various papers define Critical Success Factors (CSFs) to assess preparedness in various sectors (Vaishnavi and Suresh, 2020), and other papers provide a method using fuzzy logic(Abbes *et al.*, 2022a), very few seem to emphasise the importance of aligning projects with the organisation's mission and vision, or evaluating the Return On Investment (ROI) in the process selection process. Thus, the following research questions were formulated:

RQ1: How to estimate the Return On Investment of Lean Six Sigma Projects?

RQ2: How to link ROI, business strategy and CSFs to prioritise the implementation of LSS projects?

Therefore, the objective of this paper is to present a model that supports companies in assessing their readiness to implement Lean Six Sigma projects, prioritised through an ROI assessment, developed for LSS projects, basing projects on company strategy. Following this brief introduction, the rest of the paper is organised as follows. Section II presents a literature review of the main methods and results in assessing an organisation's readiness to implement Lean Six Sigma projects. Section III proposes a model and methods for calculating ROI in LSS projects. Section IV illustrates the application and the results of the application in a pharmaceutical company. Finally, the last section presents conclusions and reflections on research development.

2. Literature Review

Lean Six Sigma has become a powerful methodology, increasingly sought after by companies, to instil a culture of continuous improvement and generate a high process improvement impact, spreading across a multitude of sectors (Antony, Snee and Hoerl, 2017). The research background traced to a small number of causes, found regardless of the scope and size of the project, such as lack of top management support and leadership, lack of competence of Lean Six Sigma teams, defect project selecting opportunities, lack of training, cultural change; lack of organisational strategy, voice of the customer (Gerger and Firuzan, 2012). Organizations need to understand in which of these areas they are lacking and how to improve their processes. Several studies have investigated the construction of Critical Success Factors, in various industrial and service sectors, like Food Industry in (Azalanzazllay *et al.*, 2022) and Healthcare service in (McDermott *et al.*, 2022). The research emphasises the importance of analysing company preparedness, highlighting its importance in each sector. Employees are able to use CSFs to evaluate LSS readiness at the pre-implementation stages. However, among these studies, it is unclear how to select Lean Six Sigma projects and prioritise them, despite the company's preparation. There may be areas of the company where a LSS project could be implemented because it is impacted by only a few CSFs, as studied in (Shokri, Waring and Nabhani, 2016), allowing LSS readiness to be assessed by company areas, however, CSFs do not seem to be linked with specific projects, so it is necessary to link these factors to projects, for getting a better evaluation. Every project and initiative has a cost, in terms of humour, time and budget, for companies and their employees. The realisation of a project, whatever it may be, can't disregard a financial evaluation, for example through the calculation of the Return On Investment. The calculation of ROI in LSS projects is as fundamental as it is complex, due to the transversality of the methodology and the inherent difficulty of calculating financial indicators. Some studies, such as (Al-Odeh, 2020) and (Venugopal and Van Der Veen, 2013) have tried to highlight possible ways of calculating ROI in LSS. However, these approaches are never integrated with a strategic analysis, CSFs, or do not seem to use ROI as a project prioritisation indicator. An analysis of all these elements is necessary for organisations in today's uncertain organisation sectors. The plan's utilisation of resources and the alignment of these to business objectives, ensures the consistent use of resources and identifies all potential issues for improvement, to ensure the success of LSS projects. Although, assessing the readiness of an organisation to implement performance improvement projects, calculating ROI and prioritising everything, aligning each element to the business strategy, is an on-going challenge for companies. Although what has been said thus far shows how many studies have defined the importance of these aspects, it is not possible to overlook the high failure rate and the high difficulties in realising business performance improvement projects, such as LSS projects, that a non-integrated evaluation on CSFs, ROI and project prioritisation cannot remedy. Therefore, our work attempted to define a model that integrates all these aspects, assessing the company's ability to realise LSS projects, arguing the importance of an economic evaluation through an unstructured ROI and highlighting the importance of alignment with corporate strategy. Indeed, by implementing the model in a pharmaceutical company, it is possible to determine the importance of a structured approach in the selection, evaluation and implementation of Lean Six Sigma projects.

3. A model to assess readiness and evaluate the return of Lean Six Sigma project

The main elements concerning the development of a model to assess readiness and estimate the Return On Investment in order to increase the probability of success of Lean Six Sigma projects, based on a review of the literature, can be identified as:

- Evaluation and analysis of Critical Success Factors;

- Analysis of organisational needs and objectives;
- Evaluation of Return On Investment, aligned with objectives;
- Definition of a Lesson Learnt.

All these elements must be linked together through an approach that ensures flexibility and continuity in the application of the model: the PDCA cycle. Based on the above, the structure, approach, and dissemination of the Deming cycle in the industrial sectors were considered the best choice to create a model that could be operational, usable with familiarity, and iterative, guaranteeing continuity in its application. The model is based on a PDCA cycle, where:

- Plan: Managers should identify and evaluate Critical Success Factors, organisational needs and objectives, and estimate the ROI of the main LSS projects;
- Do: If the minimum conditions meet expectations, the Lean Six Sigma projects are implemented; otherwise, corrective actions to ensure sufficient conditions for success must be implemented;
- Check: The results achieved through the "Do" are evaluated.
- Act: The results achieved, shortcomings, and difficulties encountered are formalised through 'Lesson Learned'.

3.1 Critical Success Factors

For the assessment of Critical Success Factors, companies could set up two approaches:

- Questionnaires and interviews, based on likert scales from 1 to 5, based on respondents' perceptions;
- The Analytic Hierarchy Process (AHP), like in (Abbes *et al.*, 2022b), to assign priorities to factors.

Each Critical Success Factor should be characterized by three dimensions:

- Importance (I): how important it is, according to organisational perception, to the company's people and projects;
- Presence (P): how much it is perceived within the organisation;
- Influence (In): how much it influences, or is influenced by, other factors.

CSFs (Francescatto, 2023), an example found in **Table 1**, could be assessed through three matrices, one per characteristic. The CSFs can be calculated both at organisational level and for individual projects. There are several purposes for this approach:

- To assess the readiness of the organisation;
- For monitoring, in implementing improvement actions, the value of the factors over time;
- To define a minimum threshold of overall value that can serve as a sufficient and necessary condition to ensure the success of LSS initiatives;
- To assign priorities to Lean Six Sigma initiatives.

Table 1: Critical Success Factors

(1) Linking to business strategy
(2) Cultural change
(3) Linking project with customer expectations
(4) Linking projects with supplier expectations
(5) Organizational infrastructure
(6) Communication between different site functions
(7) Vertical communication
(8) Internal communication within the project reference department
(9) Training programs
(10) Time required for the project

Of course, there cam be more, but also less, CSFs, where it all depends on the sector and the maturity of the organization in identifying its critical success factors. Every organization and sector is different, so it is only fait that each one selects the best for itself.

3.2 Organisational needs and objectives

The needs analysis should be based on three elements:

- Purpose & Vision: Describing what the organisation is attempting to achieve in the long term;
- The current state: assessment of the knowledge, skills, resources, and operating conditions that the company believes it possesses, for realising Lean Six Sigma projects;
- Strategy: the element links "Purpose & Vision" and "current state", which should be integrated of Lean Six Sigma.

This step allows one to get to the point of defining what the organization's needs are, in terms of ovpportunities for improvement, and the formalising one's strategy, according to those needs.

3.3 Return On Investment

The proposed model serves as a tool for linking performance improvements with financial measures so that management has measure of likely financial outcomes and is able to target its continuous improvement activities, preventing the main causes of failure of Lean Six Sigma initiatives. The economic evaluation is built around the five main focused areas of LSS projects, such as waste reduction, reducing the randomness of processes, increased quality of products and services, increased customer satisfaction, and increased engagement. For each of these areas, a different type of Return On Investment may be evaluated, such as:

- Return On Muda (ROM): Proportional to waste reduction;
- Return On Variability (ROV): connected with the ability to govern the process;
- Return On Quality (ROQ): Proportional to the ability to meet a set of requirements;
- Return On Satisfaction (ROS): Linked to the ability to meet expectations;
- Return On Engagement (ROE): Measure of the company's ability to engage and motivate people.

Highlighting how different economic returns may be impacted by the same improvement, and only the managers' experience, knowledge, and skills will be critical in assessing the extent of the impact on different areas. For example, a lead time reduction initiative could be driven by a reduction in the Muda, resulting in a decrease in variability, an improvement in the business process quality, and, therefore, a consequent increase in customer satisfaction, all ensured by better employee involvement. All of this provides insight into how it is not necessary to estimate all individual economic returns for each project, as there will be projects with an impact, for example, exclusively on a single "Return On", while other projects will have a more global impact. This depends on the context, goals, strategy, project scope and business decisions. In the pre-launch phase of the initiatives, managers need to calculate the estimate on the ROI of the individual categories, which can be evaluated through different methods, an example could be:

$$ROM = \left[\frac{U * (C_{MP} + C_V + C_P + G) - I_M}{I_M}\right] * 100$$

$$ROV = \left[\frac{U * (C_P + C_{PF} + C_G) - I_V}{I_V}\right] * 100$$

$$ROQ = \left[\frac{V + F + U * C_{NQ} - I_Q}{I_Q}\right] * 100$$

$$ROS = \left[\frac{U * (C_G + C_S) - I_S}{I_S}\right] * 100$$

Where:

- U: the number of units saved as a result of the initiative;
- C_{MP}: the cost of the raw materials;
- C_V: the variable costs;
- C_P: the cost per person-hour;
- G: the cost of inventory;
- C_{PF}: cost of finished product;
- C_G: cost of complaint handling;
- C_{NQ}: cost of no-quality;
- C_S: cost of managing replacements;
- V: sales increase;
- F: loyalty of new customers;
- Ii: Share of investment directly attributable to the "I" area, with i ∈ {Muda, Variability, Quality, Satisfaction, Engagement}.

Each formula is not specifically detailed because it requires contextualization in the project. These are only application examples, modifiable according to sector, project and purpose. For example "U", the units saved as a result of the initiative, could be either a reduction in waste, reconditioned or reprocessed products. Return On Engagement does not present any quantification because, on one hand, people development impacts all other economic returns, and on another hand, it is difficult to define an economic return regarding 'people development'. The use of ROI was a choice related to its possibility to be adapted to the individual project purpose. Other methods, such as Net Present Value and Payback Period, were also evaluate. However, these methods were linked to a global project evaluation, not able to be clustered for the individual Lean Six Sigma Project purpose.

3.4 Lesson Learnt

The start of a new project is always a delicate phase, as management demands tangible results. All projects are unique, and this uniqueness generates a high level of risk and unpredictability in its activity. However, in such situations, the highest level of waste can result from mismanagement of lessons learnt: the failure to draw from previous projects to mitigate risk and unpredictability. This section is intended to emphasise the importance of proper lessons learnt management and its utilisation for multiple purposes, such as increased engagement, development of a process-managed organisation, and greater likelihood of success. Effective Lesson Learnt management does not rely solely on formalising them at

the end of a project, but in managing and collecting over time.

4. A model application in an Italian pharmaceutical company

The pharmaceutical industry has been growing steadily in recent years, but changes in demand, industrial expirations, and rising R&D costs have generated the need to constantly search for new ways to reduce costs (Nenni, Giustiniano and Pirolo, 2014). The application of a structured approach to identify opportunities for process improvement is therefore crucial in this industry. For the scope of the research, we developed a case study on the application of the model in a pharmaceutical company to provide an example of how it is necessary to employ a structured method to prioritise and implement performance improvement projects. The case study pertains to a pharmaceutical company's plant that produces products based on active pharmaceutical ingredients. This plant employs approximately 500 employees, and its annual production is sold on the global market. The implementation of the model involved many brainstorming sessions with management. The model was applied to assess the organisation's readiness to implement some Lean Six Sigma projects. The project process followed specific stages:

- Definition of business objectives and requirements, based on market and site performance;
- Identification of projects feasible for implementation, aligned with the business objectives and needs;
- Assigned of scores to critical success factors related to business projects;
- Estimation of the economic return of individual projects;
- Prioritisation of projects based on economic return, objectives and critical success factors.

4.1 Organisational needs and objectives

Three possible objectives were identified to guide future Lean Six Sigma initiatives, with a decision to prioritise them. Highlighting the true urgencies of the industrial site relies on the relevance the objective could have at the organisational level. Specifically, the priorities assigned are:

1. Improving the quality of internal processes;
2. Enhancing the production efficiency of the site;
3. Reducing non-value-added activities.

A. Projects identification

From the analysis of the objectives, four projects were identified:

- Project 1 – Increase the yield of product "A";
- Project 2 – Reduce the cycle time of the line inherent to product "B";
- Project 3 – Improve the lead time of the "C" department;
- Project 4 – Reduce Non-Value-Added activities of people working on product "B".

Where these projects could be an invaluable initiatives for the company because they are based on key business goals and needs.

4.2 Critical Success Factors assessment

The analysis of Critical Success Factors for each projects covered ten factors, the same in **Table 1.** For each of the factors, two dimensions were assessed using a Likert scale from 1 to 5: Presence and Importance. During this initial application, management decided not to evaluate the influence of factors on themselves, deeming it too time–consuming and costly for an initial application. However, this aspect is to be implemented in future applications. The evaluations, depicted in **Table 2**, linked with **Table 1**, were carried out through an extended period of observation, brainstorming and questionnaires with the various department heads. For each CSFs was assigned a presence score, to assess how predominant its presence is in the organization, and an importance score, to assess how important its presence is to the success of the respective project.

Table 2: Critical Success Factors evaluation

CSFs	Project 1		Project 2		Project 3		Project 4	
	P	**I**	**P**	**I**	**P**	**I**	**P**	**I**
(1)	5	4	5	4	5	4	4	4
(2)	1	3	1	4	1	4	1	5
(3)	5	3	3	3	3	3	4	3
(4)	1	3	1	3	1	3	1	3
(5)	4	4	4	3	4	3	4	4
(6)	1	1	2	4	3	4	1	2
(7)	2	4	2	4	3	4	2	4
(8)	3	4	4	4	4	4	4	5
(9)	4	4	4	4	4	4	4	4
(10)	4	4	4	4	4	4	4	4

Upon observing **Table 2**, it is apparent that there are broad areas for improvement to increase the likelihood of success of Lean Six Sigma initiatives, where the company should prioritise improvement activities accordingly.

4.3 Return On Investment evaluation

The evaluations were carried out through indicators such as Return On Muda, Return On Variability, Return On Satisfaction and Return On Quality, excluding Return On Engagement due to the above. These indicators were found to be central to the evaluation because the company, should it decide to launch such initiatives, would be able to understand early on which initiative would provide it with the greatest return. Additionally, a key aspect is the ability to understand how to orient each initiative. Orienting a project towards different goals, such as reducing variability or increasing customer satisfaction, generates varying levels of investment and economic return. The economic returns calculated for the various projects are shown in **Table 3.**

Table 3: Return On Investment Evaluation

RO..	Project 1	Project 2	Project 3	Project 4
Muda	+50%	+60%	-	+18%
Variability	+25%	+33%	-	+42%
Satisfaction	-	-	+27%	-
Quality	+24%	+16%	+32%	-

In evaluating these economic returns, it is important to recognize that they are heavily influenced by the level of investment required to implement the initiative, and that they do not appear to be cumulative among themselves, as improving a specific area would have an impact on the entire process. Return On Engagement was not included in the evaluation, as it was deemed dependent on the project team and the actual engagement of management during implementation. Since this evaluation was conducted prior to team selection, it was not possible to qualitatively assess the ROE. It is necessary to consider how the same project can be observed through different perspectives using this method. An example on Project 3 can be observed in **Table 4**.

Table 4: Return On Investment

Project 3	ROQ: +32%	ROS: +27%
Investment in..	Training: +15% cost per person-hours; Equipment: +25% on batch value.	Equipment: +30% on batch value; People: +0,2 on FTE; Documentation: +3% on batch value.
Examination Items	Increased capacity to release good batches: +5%; Reduction in quality costs: +15% of batch value.	Late delivery penalties: +10% of the batch value; Batch replacement: +5% on batch costs; Release capacity: +1 batch/month.

The evaluations were the result of planned meetings with department heads, concerning the economic return.

5. Results and discussion

The analysis of goals and economic evaluations enable the company to direct its future Lean Six Sigma initiatives towards projects with high organisational impact and economic return. The results of the Critical Success Factors, however, highlight many areas needing improvement to maximise the likelihood of successful Lean Six Sigma Projects. Examining the results obtained from the analysis of Critical Success Factors reveals numerous areas for improvement in individual project focus areas. Consequently, these results highlight various opportunities for the organisation. Opportunities include projects with high economic returns and reduced payback periods, which would enhance the company's position in the market. Additionally, improving Critical Success Factors would increase the probability of success for individual projects and enhance the organisational environment, facilitating the implementation of future projects. The Lean Six Sigma model formulated is structured based on a PDCA cycle to implement any form of action, following proper planning and strategy to ensure maximum control of any process. The above pertains exclusively to the Plan area of the model, as the company will need to understand how to implement its plans and improve its assessment of Critical Success Factors in the 'Do' phase. In this regard, the company has decided to prioritise the selection of its projects based on:

- Alignment with business objectives;
- Return On Quality;
- Analysis of Critical Success Factors.

In this way, the company's first choice was Project 3.

6. Conclusion

The objective of this study was to present a model capable of assessing a company's readiness to implement Lean Six Sigma projects by selecting and prioritising them. This need arises from the ongoing challenge of applying the Lean Six Sigma methodology, in any industry, particularly during the pre-application phase, in which problems intrinsic to the company may emerge and require proper management. To achieve this purpose, it has been proven essential to present a structured model that, through a timely investigation and classification of the activities to be carried out, guides companies in increasing their ability to implement Lean Six Sigma initiatives. To this end, it is necessary to carry out real rediscovery activities of one's

own company, starting from people's expectations to reevaluating the alignment of Lean Six Sigma with one's own business strategy, to create a knowledge base of the company, which is essential to the fulfilment of the minimum requirements and the achievement of the maximum benefits of any performance improvement initiative. In applying the model, it should be emphasised that it should be a flexible tool for anyone intending to use it, rather than something prescriptive. Flexibility is the first step, for any organisation, or tool, to be successful in the market. In this regard, for future applications, it would be important to observe the application of the model over time, to evaluate how the organisation evolves and modifies the model to adapt it to its needs. This may involve integrating additional economic indicators, such as the Payback Period, or utilising the Analytic Hierarchy Process to study the critical success factors.

Further applications of the model across different sectors, with small, medium, and large companies, are necessary to understand how it is possible to identify a correct framework based on the sector and company size, and its potential evolutions.

References

Abbes, N. *et al.* (2022a) 'New Lean Six Sigma readiness assessment model using fuzzy logic: Case study within clothing industry', *Alexandria Engineering Journal*, 61(11), pp. 9079–9094. Available at: https://doi.org/10.1016/j.aej.2022.02.047.

Abbes, N. *et al.* (2022b) 'New Lean Six Sigma readiness assessment model using fuzzy logic: Case study within clothing industry', *Alexandria Engineering Journal*, 61(11), pp. 9079–9094. Available at: https://doi.org/10.1016/j.aej.2022.02.047.

Albliwi, S. *et al.* (2014) 'Critical failure factors of lean Six Sigma: A systematic literature review', *International Journal of Quality and Reliability Management*, 31(9), pp. 1012–1030. Available at: https://doi.org/10.1108/IJQRM-09-2013-0147.

Al-Odeh, M. (2020) 'Article ID: IJM_11_11_199 Cite this Article: Mahmoud Al-Odeh, Calculating Return on Investment for Continuous Improvement Activities: A Model and a Case Study', *International Journal of Management (IJM)*, 11(11), pp. 2102–2121. Available at: https://doi.org/10.34218/IJM.11.11.2020.199.

Antony, J., Snee, R. and Hoerl, R. (2017) 'Lean Six Sigma: yesterday, today and tomorrow', *International Journal of Quality and Reliability Management*, 34(7), pp. 1073–1093. Available at: https://doi.org/10.1108/IJQRM-03-2016-0035.

Azalanzazllay, N.N. *et al.* (2022) 'Uncovering Readiness Factors Influencing the Lean Six Sigma Pre-Implementation Phase in the Food Industry', *Sustainability (Switzerland)*, 14(14). Available at: https://doi.org/10.3390/su14148941.

Božanić, V. (2010) *259 Katarina Pavlović 1) Lean and Six Sigma Concepts-Application in Pharmaceutical Industry*. Available at: www.pharmafocusasia.com,.

Gerger, A. and Firuzan, A.R. (2012) 'REASONS OF FAILURE IN LEAN SIX SIGMA PROJECTS', International Journal of Multidisciplinary Thought, (3), pp. 123–130.

Laínez, J.M., Schaefer, E. and Reklaitis, G. V. (2012) 'Challenges and opportunities in enterprise-wide optimization in the pharmaceutical industry', *Computers and Chemical Engineering*, 47, pp. 19–28. Available at: https://doi.org/10.1016/j.compchemeng.2012.07.002.

Lekara Bayo, P. and Onyenma, O.U. (2019) 'Industry 4.0: Issues of Globalisation and Digitalisation of Work Force', *International Journal of Innovative Development and Policy Studies*, 7, pp. 18–28. Available at: www.seahipaj.org.

Ma, L., Li, X. and Pan, Y. (2023) 'Global Industrial Chain Resilience Research: Theory and Measurement', *Systems*, 11(9). Available at: https://doi.org/10.3390/systems11090466.

McDermott, O. *et al.* (2022) 'Lean Six Sigma in Healthcare: A Systematic Literature Review on Challenges, Organisational Readiness and Critical Success Factors', *Processes*. MDPI. Available at: https://doi.org/10.3390/pr10101945.

Nenni, M.E., Giustiniano, L. and Pirolo, L. (2014) 'Improvement of manufacturing operations through a lean management approach: A case study in the pharmaceutical industry', *International Journal of Engineering Business Management*, 6(1), pp. 1–6. Available at: https://doi.org/10.5772/59027.

Sharma, N. and Kumar Sharma, N. (2020) 'Benefits, obstacles, and future of six sigma approach'. Available at: https://doi.org/10.13140/RG.2.2.21819.44322.

Shokri, A., Waring, T.S. and Nabhani, F. (2016) 'Investigating the readiness of people in manufacturing SMEs to embark on Lean Six Sigma projects: An empirical study in the German manufacturing sector', *International Journal of Operations and Production Management*, 36(8), pp. 850–878. Available at: https://doi.org/10.1108/IJOPM-11-2014-0530.

Vaishnavi, V. and Suresh, M. (2020) 'Modelling of readiness factors for the implementation of Lean Six Sigma in healthcare organizations', *International Journal of Lean Six Sigma*, 11(4), pp. 597–633. Available at: https://doi.org/10.1108/IJLSS-12-2017-0146.

Venugopal, V. and Van Der Veen, J.A.A. (2013) *Decision Support Framework for Estimating Return on Lean Six Sigma Projects*. Available at: https://www.researchgate.net/publication/267926710.

Vicente, I., Godina, R. and Teresa Gabriel, A. (2024) 'Applications and future perspectives of integrating Lean Six Sigma and Ergonomics', *Safety Science*. Elsevier B.V. Available at: https://doi.org/10.1016/j.ssci.2024.106418.