*International Journal of Accounting and Economics Studies*, 13 (2) (2026) 133-138

**International Journal of Accounting and Economics Studies**

*Website: www.sciencepubco.com/index.php/IJAES*
*https://doi.org/10.14419/709jt646*
***Research paper***

# Strategic Integration of Lean Six Sigma and Agile Project Management in Pharmaceutical Marketing Operations in The US: A Hybrid Framework for Competitive Advantage

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*Received: October 18, 2025, Accepted: January 11, 2026, Published: February 15, 2026*

**Abstract**

Purpose: This study aims to examine the combined application of Lean Six Sigma (LSS) and Agile Project Management (APM) practices in improving competitive advantage within pharmaceutical marketing, with Organizational Adaptability serving as a mediating variable.
Approach: A quantitative research design was employed, using a survey completed by 375 professionals from the US pharmaceutical marketing industry. Data were analyzed using Partial Least Squares Structural Equation Modeling (PLS-SEM) through SmartPLS software.
Results: The results indicate that LSS implementation has a significant positive impact on competitive advantage ($\beta = 0.334$, $p = 0.000$). APM implementation also positively affects competitive advantage, though the impact is less significant ($\beta = 0.127$, $p = 0.010$). Additionally, Organizational Adaptability was found to significantly mediate the relationship between the independent variables (LSS and APM) and competitive advantage ($\beta = 0.425$, $p = 0.000$).
Conclusions: The findings suggest that combining LSS and APM can lead to a stronger competitive advantage in the pharmaceutical marketing sector. Policy implications emphasize the importance of organizational adaptability in a dynamic regulatory environment. Future research should explore the applicability of this hybrid model in other sectors and assess its long-term impact on organizational competitiveness.

***Keywords***: *Agile Project Management; Hybrid Framework; Lean Six Sigma; Organizational Adaptability; Strategic Integration.*

## 1. Introduction

The US pharmaceutical industry is a highly vibrant and competitive industry, characterized by fast innovation, formidable regulations, and growing demands to bring products to the market speedily [1]. The U.S. also has the largest share in the pharmaceutical market in the world, with leading top pharmaceutical firms such as Pfizer, AbbVie, and Johnson & Johnson, among others, generating substantial revenues. Extensive R&D investment and prices of prescription drugs are key to proceedings in the industry, and the pharmaceutical spending in the U.S. in 2023 has reached over USD 700 billion [2]. Marketing strategies in the industry tend to fail to match the necessity of reduced product life cycles, shorter market entry periods, and the same rate of ever-changing regulations. As per the study [3], conventional marketing methodologies and project management techniques have often compromised the effectiveness of campaign delivery and product launches, and incurred excessive operational expenses.
Organizational adaptability is a crucial factor that determines the successful merger of LSS and APM into pharmaceutical marketing activities. The study [4] describes how an organization can adjust to the dynamics of the market, new technologies, and new regulatory environments swiftly. Organizational adaptability in the context of the US pharmaceutical industry, where flexibility is an essential factor, allows organizations to adopt new methodologies or change their marketing strategies to meet the requirements. As per the study [5], it ensures that LSS and APM are integrated, enabling the organization to enhance efficiency in its operation, promote innovation, and maintain a competitive edge even in a dynamic market.
In response to these pressures, the integration of LSS and Agile Project Management APM practices has risen in popularity in different markets, presenting a dual advantage: process flexibility and optimization [6] [7]. According to a study [8], Lean Six Sigma is aimed at minimizing waste and inefficiencies, whereas Agile is based on iteration and flexibility, letting the implementation undergo rapid changes according to market tendencies. The harmonization of the processes through an integration of these methodologies can also improve the pharmaceutical marketing operation by making it solidify cooperation and accelerating time-to-market. Additionally, merging LSS and APM enables organizations to manage risks, create gapless improvement, and gain competitive advantages in the competitive market [9].

However, very little has been done on research exploring the ways through which Lean Six Sigma and Agile can be strategically included in the pharmaceutical marketing work environment in the US, which can be utilized in deriving some gains. The study's problem is in the fact that there is no existing research on the alignment of Lean Six Sigma (LSS) and Agile Project Management (APM) in the US pharmaceutical marketing sector [10]. The current project management and marketing procedures and processes are not effective with the growing need for operational efficiency, flexibility, and faster product releases. The current study is essential because it examines how the hybrid LSS-APM methodology can be applied to address such challenges in a way that builds operational efficiency and a competitive edge in a highly emerging regulatory context. The research attempts to fill this void by investigating the potential application of a hybrid model that would integrate the ideas of both LSS and APM with a view to enhancing the competitive advantage, the operational excellence, as well as the marketing efforts in the US pharmaceutical industry.

The pharmaceutical marketing sector in the US has been facing numerous challenges in a highly competitive and regulated market [10]. Due to the influence of a need to bring new products to market quicker, reducing operational expenses, and navigating complex regulations, most businesses are unable to adapt to the demands of the modern marketing processes. Past research on Lean Six Sigma (LSS) and Agile Project Management (APM) utilization has been largely focused on the usage in operational and manufacturing areas and less on how it is utilized within pharmaceutical marketing [6] [8]. Furthermore, very minimal research has been conducted to study the pivotal issues of the US pharmaceutical sector regarding marketing activities in terms of working with the intricate regulations and shortening product introduction schedules. The study [9] does not discuss the framework of LSS and APM combination within the context of pharmaceutical marketing, although they state the importance of the optimization of processes and flexibility in rival markets. The study addresses this gap by examining the possibility of integrating LSS and APM in enhancing business operations efficiency and competitiveness within the US pharmaceutical marketing environment, which is of benefit to the industry players as well as the researchers.

Although both Lean Six Sigma (LSS) and Agile Project Management (APM) have proved successful in many industries to enhance the effectiveness of operations and operational flexibility, there is no research that has been done regarding their use in pharmaceutical marketing operations in the US [20]. The current body of literature has not given much consideration to how these methodologies, when used together, can specifically address the challenges that are quite peculiar to the pharmaceutical firms in the US. This paper aims to fill this gap by examining the possible advantages of implementing LSS and APM in the pharmaceutical marketing processes, in a bid to streamline the operations, accelerate the time-to-market of the new product release, and embrace the cross-functional alignment. The study will offer a good perspective with regard to how this hybrid model can create a competitive advantage in the pharmaceutical industry in the US.

The study holds significance as it can be assessed in making marketing efforts more effective, reducing the wastage of resources, and refining inter-divisional functions in the pharmaceutical industry. The implications of this study will provide viable information to the pharmaceutical industries that want to be competitive in an environment that is fast-changing environment. This study is further applicable in other countries than the US because the hybrid framework may be imposed on the pharmaceutical marketing process in other parts of the world facing such issues. With the help of Lean Six Sigma and Agile Project Management, pharmaceutical companies may change the way they market their products and, as a result, will be able to launch their products in a shorter span of time, offer better ROI, and establish a better position in the market.

## 2. Methods

The given study represents quantitative research that uses a survey research design to analyze how Lean Six Sigma and Agile Project Management integration have been affecting the competitive advantage of pharmaceutical marketing activities in the US. The independent variables in this study consist of LSS Implementation and APM Implementation, whereas the dependent variable is Competitive Advantage in Pharmaceutical Marketing. A quantitative approach is a suitable method for studying numerical data and statistical analysis [11].

A total of 500 questionnaires were distributed among professionals belonging to pharmaceutical marketing in the US, while 375 valid questionnaires were returned, resulting in a response rate of 75%. The final sample comprises respondents who had direct experience with Lean Six Sigma and Agile Project Management so that the research would be relevant to those processes. The sample size of the study involved 375 respondents which were sampled using a convenience sampling technique. This sampling method is suitable for selecting respondents of the marketing profession with experience in working with Lean Six Sigma and Agile Project Management, providing valuable information about how these methods work in the industry and what their effects are. As per the study [12], the convenience sampling approach ensures that the study collects the data of a group of professionals directly involved in the processes being examined without necessarily requiring extensive resource allocation. Additionally, the convenience sampling, though convenient in terms of obtaining more experienced practitioners, created bias in sampling, restricting the ability to generalize the results to the more general populations or less experienced groups.

The results were captured in a survey questionnaire of a 5-point Likert scale, with varying degrees of responses being Strongly Agree and Strongly Disagree. The respondents gave their opinions on the impacts of these aspects on their marketing plans and operations. Partial Least Squares Structural Equation Modelling (PLS-SEM) was used in analyzing the collected data. The PLS-SEM aligns with the current study due to the complex course of the relationship between latent variables in social science and is discrete in the nature of the data to be handled [13]. The process began with a Confirmatory Factor Analysis (CFA) of how well the presumably reliable measurement model measures or differentiates the constructs based on the quality of the items included. The composite reliability and average variance extracted (AVE) as key indicators of the validity of the model were examined. After the measurement model had been validated, the structural model was analyzed in order to investigate the correlations between the independent variables and the dependent variable in an attempt to define the impact of the integration of LSS and APM on the competitive advantage. The strength and direction of these relationships were determined by Path coefficient analysis.

Figure 1 below represents the conceptual framework of the study, where lean six sigma (LSS) implementation and agile project management (APM) implementation are independent variables, and competitive advantage is the dependent variable. Organizational adaptability acts as a mediator.

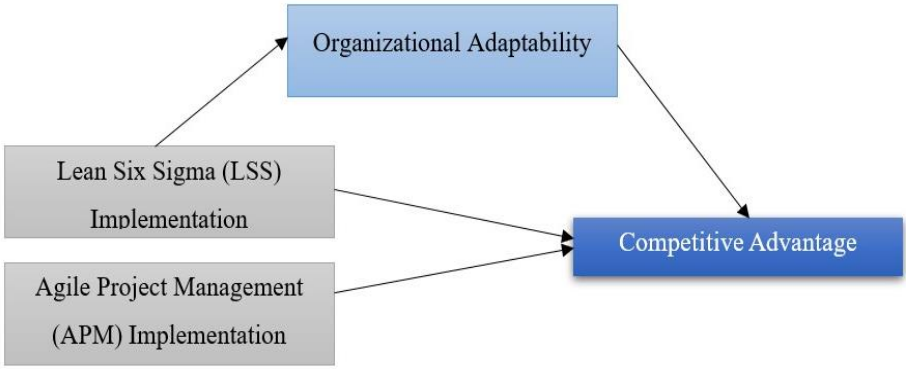


**Fig. 1:** Conceptual Framework.

# 3. Results and Findings

## 3.1. Demographics

As per Table 1, 66.67% of the respondents were male, making 250 people; 12.00 percent were females, or 45 respondents; 0.53% is considered other, consisting of 2 individuals; and finally, 0.27 percent (or 1 individual) did not specify gender. The age group shows the majority of respondents, 38% from 35-45 and 25% from 25-35.

**Table 1:** Demographic Table

| Demographic Factor | Category | Frequency | Percentage |
|---|---|---|---|
| Gender | Male | 250 | 66.67% |
| | Female | 45 | 12% |
| | Other | 2 | 0.53% |
| | Not feeling comfortable specifying | 1 | 0.27% |
| Age | 18-25 | 19 | 5% |
| | 25-35 | 94 | 25% |
| | 35-45 | 143 | 38% |
| | 45-55 | 90 | 24% |
| | More than 55 years | 30 | 8% |

## 3.2. Measurement model using confirmatory factor analysis

According to Table 2, the study applied Confirmatory Factor Analysis (CFA) to test the reliability, as well as the convergent validity of the measurement model, which is a prerequisite to confirm that the constructs are sufficiently reflected. The study [12] notes that CFA assists in validating that the observed variables correspond to their corresponding latent construct. The internal consistency of the constructs was measured using Cronbach's alpha and composite reliability, and the criterion of 0.7 and above has been suggested to be satisfactory [15]. The internal consistency measures have indicated that all the constructs have surpassed this level of threshold, and therefore, the reliability of the measurement model is validated in Table 1. In particular, the Cronbach alpha is 0.852, the composite reliability is 0.854, and thus the reliability of this construct is seen as acceptable. Agile Project Management (APM) Implementation has a Cronbach alpha of 0.815 and a composite reliability of 0.833, which falls above 0.7. The Competitive Advantage exhibits a Cronbach alpha of 0.885 and an overall reliability of 0.889, whereas the Organizational Adaptability has a major Cronbach alpha of 0.902 and an overall 0.902; thus, indicating once more the solidity of the model.

Factor loadings were also investigated to see how each indicator contributes to the constructs. According to the study [15], factor loading over 0.6 shows a significant contribution of items in their latent constructs. Table 1 demonstrates that all indicators have a factor loading within a strong range. The Lean Six Sigma (LSS) Implementation indicators used in this paper have factor loading ranging between 0.362 and 0.902, LSSI1 indicating the highest loading of 0.880. In the case of Agile Project Management (APM) Implementation, the loads of the factors vary between 0.786 and 0.901, with APMI2 having the highest load of 0.901. The loadings of the Competitive Advantage indicators range between 0.879 and 0.930, with CA2 having the highest loading of 0.930. The loading of the Organizational Adaptability lies between 0.906 and 0.929, with the largest loading being 0.929 for OA2. Although certain loadings, like the LSS Implementation (0.362) one, are lower, the ones mentioned affect their respective constructs. The values of the Average Variance Extracted (AVE) show high convergent validity, with all the constructs having a value higher than 0.7 that the indicators capture the latent constructs adequately.

**Table 2:** Reliability and Convergent Validity Testing

| Constructs | Indicators | Factor Loadings | Cronbach's alpha | Composite reliability | Average variance extracted (AVE) |
|---|---|---|---|---|---|
| Lean Six Sigma (LSS) Implementation | LSSI1 | 0.880 | 0.852 | 0.854 | 0.771 |
| | LSSI2 | 0.902 | | | |
| | LSSI3 | 0.852 | | | |
| Agile Project Management (APM) Implementation | APMI1 | 0.786 | 0.815 | 0.833 | 0.730 |
| | APMI2 | 0.901 | | | |
| | APMI3 | 0.871 | | | |
| Competitive Advantage | CA1 | 0.896 | 0.885 | 0.889 | 0.813 |
| | CA2 | 0.930 | | | |
| | CA3 | 0.879 | | | |
| Organizational Adaptability | OA1 | 0.907 | 0.902 | 0.902 | 0.836 |
| | OA2 | 0.929 | | | |
| | OA3 | 0.906 | | | |

According to Table 3, the study employed the Heterotrait-Monotrait (HTMT) ratio to conduct a rigorous test of the discriminant validity of the constructs, which was an important procedure to ascertain that each latent variable reflects a unique factor in the research model [16]. The discriminant validity plays a key role in ensuring that the relationships between constructs are not too close, as this would imply that there is multicollinearity and therefore the model will not be reliable. An estimate of the HTMT ratio, less than 0.85, indicates the existence of valid discriminant validity evidence that the constructs are dissimilar and do not actually measure the same latent dimension [15]. As Table 3 results indicate, all the HTMT between the key constructs are smaller than this threshold, which indicates the distinctiveness of each construct in the model. As an illustration of this, the ratio between Agile Project Management Implementation and Competitive Advantage is 0.617, meaning there is a moderate and clear relationship. Likewise, HTMT is 0.717 between Lean Six Sigma Implementation and Competitive Advantage, indicating that the two constructs, although being related, are differentiated in terms of their effects.
Furthermore, the ratios of HTMT coefficients of the associations between Lean Six Sigma Implementation and Organizational Adaptability (0.607) and between Agile Project Management Implementation and Organizational Adaptability (0.464) are lower than the critical value as well. This shows that these constructs are interconnected, although they all have their theoretical relevance. The HTMT between Organizational Adaptability and Competitive Advantage is 0.730, reconfirming a significant, but different relationship. These results confirm the discriminant validity of the measurement model, which makes the constructs empirically different and strengthens the quality of the research design and the relationships that are studied.

**Table 3:** Discriminant Validity

| | Agile Project Management Implementation | Competitive Advantage | Lean Six Sigma Implementation |
|---|---|---|---|
| Agile Project Management Implementation | - | - | - |
| Competitive Advantage | 0.546 | - | - |
| Lean Six Sigma Implementation | 0.617 | 0.717 | - |
| Organizational adaptability | 0.464 | 0.730 | 0.607 |

### 3.3. Path analysis

According to Table 4, Structural Equation Modeling (SEM) was used to test the hypothesized relationships among Agile Project Management Implementation, Lean Six Sigma Implementation, Organizational Adaptability, and Competitive Advantage. The strength and significance of the path coefficients were determined through bootstrapping procedures, which corresponds to the best practice methodology [18]. The findings shows strong statistical impact of Lean Six Sigma Implementation on Competitive Advantage significantly and noticeably, with the path coefficient of 0.334, and P-value of 0.000. It implies that the implementation of Lean Six Sigma is indeed a major cause of competitive advantage in the pharmaceutical marketing industry. Agile Project Management Implementation, on the other hand, has a weak but positive effect on Competitive Advantage with a coefficient of 0.127, a P value of 0.010, and hence a significant but lesser impact than that of Lean Six Sigma. Also, Lean Six Sigma and Agile Project Management have a great impact on Organizational Adaptability since the coefficients are 0.448 and 0.165, and the P-value of 0.000 and 0.011. Moreover, Organizational Adaptability had a critical positive impact on Competitive Advantage with a path coefficient of 0.425, and a P-value of 0.000, thus revealing the pivotal mediating role of adaptability in competitive advantage.

**Table 4:** Structural Model

| | Coefficient | T statistics | P values |
|---|---|---|---|
| Agile Project Management Implementation -> Competitive Advantage | 0.127 | 2.567 | 0.010 |
| Agile Project Management Implementation -> Organizational adaptability | 0.165 | 2.552 | 0.011 |
| Lean Six Sigma Implementation -> Competitive Advantage | 0.334 | 6.533 | 0.000 |
| Lean Six Sigma Implementation -> Organizational adaptability | 0.448 | 7.858 | 0.000 |
| Organizational adaptability -> Competitive Advantage | 0.425 | 8.696 | 0.000 |

### 3.4. Model explanatory power

As per Table 5, the explanatory power of the model in the study is given in terms of the value of R-squared. The Competitive Advantage value is 0.547 since this value shows that about 54.7 percent of the variance in the competitive advantage would be accounted for by the independent variables in the model. This indicates a moderate-to-strong explanatory value, implying that the model accounts for a large amount of variability of competitive advantage. Organizational Adaptability has R square of 0.305, meaning that 30.5% of the variability in the construct is accounted for by the predictors, showing a moderate explanatory power for this construct.

**Table 5:** Predictive Relevance and Quality Assessment

| Variables | R-square | R-square adjusted |
|---|---|---|
| Competitive Advantage | 0.547 | 0.543 |
| Organizational adaptability | 0.305 | 0.301 |

## 4. Discussion

The findings of this study have valuable insights into combining LSS and APM as strategic needs in the pharmaceutical marketing sector, particularly in the US. The evidence confirms that LSS Implementation has a substantial contribution to competitive advantage, in line with different research findings that quote Lean Six Sigma's efficiency in minimizing waste, streamlining processes, and enhancing operational effectiveness [6] [8]. Lean Six Sigma has been widely accepted as having the ability to reduce inefficiencies and maximize process performance, which is necessary in industries like pharmaceuticals, where excellence in operations could be the driver of competitive advantage [10]. The positive relationship of LSS with competitive advantage recognizes the significance of process improvement in ensuring business success in the pharmaceutical marketing industry, where cost management and efficiency are critical in an attempt to stay competitive.
Similarly, the study established that APM Implementation has a positive relationship with competitive advantage, albeit being less than Lean Six Sigma. This is reinforced by a study [7], who argue that agile methods, with their focus on flexibility and iterative methodology,

allow organizations to react more effectively to changing market conditions and customer needs. This is particularly important in the pharmaceutical industry, where timeliness to market and the ability to quickly change marketing strategy flip-flops can spell the difference between success and failure for an organization.

Organizational Adaptability was also found to have a huge mediating influence on the relationship between both LSS and APM and competitive advantage, confirming that adaptability is an important factor in ensuring long-term success. This confirms the study [4], who posit that adaptive organizations are more prone to adopt new strategies and coordinate changes in the environment. Flexibility is critical for the pharmaceutical marketing industry, where firms need to manage constant changes in regulation, market forces, and consumer preferences. The study [19] noted that organizational flexibility is also a significant area of competitiveness, particularly in the introduction of new methodologies such as LSS and APM.

The findings of this research highlight the need to integrate Lean Six Sigma and Agile Project Management, not just to make an operation more efficient but also to make an organization capable of handling changing market dynamics. The integration of these strategies enables pharmaceutical companies to be agile while optimizing process improvement, resulting in a hybrid model that enables companies to better overcome market challenges. These results are not just valuable for the US pharma market but also for other international markets with the same type of challenges in competitive and regulatory environments.

The results indicate that regulatory agility facilitated by policymakers and industry regulators should be encouraged to help move through approval more quickly and accommodate flexible compliance regimes that help to complement LSS and APM integration. Smoothed laws are capable of shortening the time-to-market, which directly affects financial results like ROI, cost-saving, and marketing efficiency, which are major issues in managerial accounting. The adoption of hybrid LSS-APM models by pharmaceutical companies is necessary to increase the reliability of processes and, at the same time, remain responsive to market changes. Competitiveness can also be enhanced by regulators by providing incentives to process-improvement projects, digital transformation, and adaptive capacity improvement so that firms can innovate fast whilst keeping quality and compliance standards high.

## 5. Conclusion

The study highlighted the need for integrating Lean Six Sigma (LSS) and Agile Project Management (APM) in the pharmaceutical marketing sector in the US. The study concluded that both LSS and APM contribute positively to competitive advantage, mediated by Organizational Adaptability. Integration of these two approaches is essential to improve operational effectiveness, flexibility, and business performance within the regulated and competitive context of the pharmaceutical industry. A key limitation of the study is that convenience sampling has been used, which has the potential to limit the results' generalizability to other groups. The analysis also only looks at the US pharmaceutical market, and the results may not capture all the complexities of other jurisdictions with differing regulatory structures.

Future research can further generalize the research by examining the use of the hybrid model that combines LSS and APM in different industries, particularly in industries with similar operational problems. It will be intriguing to carry out longitudinal research for measuring the long-run effects of such integration on organizational flexibility and long-run competitive advantage. Also included, perhaps, are other variables such as digitalization and customer-centric marketing strategies, which could further explain the evolution of the pharmaceutical marketing environment. The results from this research could also inform industry practice, enabling pharmaceutical companies to streamline marketing and stay in the lead position in a highly competitive and rapidly evolving market. Policy suggestions of regulatory responsiveness are relevant, but the debate does not emphasize the connection to financial performance, including the ROI of reduced time-to-market. The introduction of metrics that would directly relate regulatory responsiveness to the financial performance would enhance the managerial accounting relevance of the research.

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# Appendices

Questionnaire

1) Please specify your age:
i) 18-25
ii) 25-35
iii) 35-45
iv) 45-55
v) More than 55 years
vi)

2) Please specify your Gender:
i) Male
ii) Female
iii) Other
iv) Not feeling comfortable specifying

Based on your knowledge and experience, select any one of the options given below each of the following statements.

| | Strongly agree | Agree | Neutral | Disagree | Strongly disagree |
|---|---|---|---|---|---|
| **Lean Six Sigma (LSS) Implementation** | | | | | |
| • I believe that the implementation of Lean Six Sigma (LSS) has improved the efficiency of marketing operations in my organization. | | | | | |
| • I think that LSS has effectively reduced waste and inefficiencies in my pharmaceutical marketing processes. | | | | | |
| • I feel that the implementation of LSS has enhanced our organization's ability to meet regulatory and market demands. | | | | | |
| **Agile Project Management (APM) Implementation** | | | | | |
| • I believe that Agile Project Management (APM) has improved the speed of decision-making in our marketing campaigns. | | | | | |
| • I feel that APM implementation has made my team more flexible and responsive to changes in the market. | | | | | |
| • I think that APM has enabled better cross-functional collaboration within our organization. | | | | | |
| **Organizational Adaptability** | | | | | |
| • I believe that my organization can quickly adapt to changes in market conditions and regulations. | | | | | |
| • I feel that my organization is flexible enough to integrate new methodologies like LSS and APM into our operations. | | | | | |
| • I think that my organization can respond effectively to emerging market challenges without significant delays. | | | | | |
| **Competitive Advantage** | | | | | |
| • I believe that the implementation of LSS and APM has improved my organization's competitive advantage in the pharmaceutical market. | | | | | |
| • I think that the strategies employed in my organization provide us with a distinct edge over competitors in terms of marketing and product delivery | | | | | |
| • I feel that my organization's ability to maintain a competitive advantage is directly influenced by its operational efficiency. | | | | | |