The Impact of a Quality Management System (QMS) on the Scientific Software Development Process – A Case Study of a Small Company

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Abstract *— Developing software for scientific applications is an intricate and multifaceted process that requires meticulous attention to detail. Implementing a QMS to provide a comprehensive framework that integrates all quality processes to mitigate inefficiencies such as waiting times and over-processing waste is essential. This study evaluated the effectiveness of the QMS and its potential impact on this particular software development process, employing statistical analysis. Historical data was compared with simulated data to assess proposed optimizations before and after implementation. The statistical analysis included a range of techniques, such as ANOVA, Hypothesis Testing, Regression Analysis, Capability Analysis, and others. It demonstrated potential significant improvements across all evaluated variables in the final software product, including deviations during validation, change controls, time to complete a product (hours), and corresponding labor costs (dollars). A QMS provides a foundation to prevent quality issues, improve customer satisfaction, reduce rework costs, and boost profits. It's a smart investment for companies seeking measurable benefits.*

Key Terms *— Quality Management System (QMS), Quality Practices, Scientific Software Development Quality Control, Scientific Software Productivity.*

INTRODUCTION

The significance of quality management cannot be overstated in the context of businesses. Quality management is a critical pillar that continues to gain relevance over time. It encompasses all tasks and activities necessary to maintain a desired level of excellence and is a crucial component in achieving operational success. According to the American Society for Quality (ASQ), a Quality Management System (QMS) is a documented system that outlines procedures, processes, and responsibilities for achieving quality policies and objectives. This system helps to coordinate and direct an organization's activities towards meeting customer and regulatory requirements while also improving efficiency and effectiveness, leading to operational excellence. Implementing a QMS is essential for streamlining processes and reducing waste. While it is typical for large corporations to have a QMS in place, it can make a significant difference in small businesses and be the determining factor between success and failure.

Company X is a small business that develops new technologies that contribute to better pharmaceutical solutions and improved Critical Quality Attributes (CQA) analysis in Research and Development (R&D) and manufacturing. The company has developed cutting-edge hardware and software modules for studying CQA, which demands complex feasibility studies, data analysis, scientific design, and coding to generate algorithms and produce the final product. Due to the elaborate process behind software development, the absence of a QMS creates inefficient practices. As the company embarks on its commercialization journey, the need for a QMS has become imperative and urgent.

LITERATURE REVIEW

In 2016, a study conducted by Zimon delved into the effects of quality management systems on small and medium-sized organizations. The findings brought to light the significance of including specific objectives and expectations regarding quality operations, which is a crucial component of QMS. Moreover, the study revealed

that 70% of these organizations reported favorable results after the implementation of a standardized QMS. Another research paper by Pawar et al. (2020) in India focused on the implementation and importance of Quality Management in Diagnostic Laboratories during the COVID-19 pandemic. The study concluded that the introduction of a QMS enhanced the quality of laboratory procedures by minimizing errors and augmenting efficiency, eventually resulting in timely and accurate services for patients. However, the research also emphasized the importance of extensive monitoring and documentation for sustained success.

According to a study conducted by Pambreni et al. (2019), the implementation of total quality management (TQM) can lead to improved performance for Small and Medium Enterprises (SMEs) in the service sector of Malaysia. The study evaluated four categories, namely customer focus, continuous improvement, strategic base, and total employee involvement, using questionnaires to gather data, test hypotheses, and perform multiple regression analysis. Notably, the results indicated that all four categories had a positive influence on organizational performance. According to Jaiswal & Garg (2019), a positive correlation exists between TQM and productivity in software development organizations, particularly in areas concerning customer focus and continuous improvement.

In a study by Mohamed (2022) regarding the effect of QMSs on small businesses, a case study of Somalia, a QMS is the foundation of a quality organization. As the study confirmed, while many small organizations may not have substantial resources to invest in quality management, it may still be done successfully. Effective QMSs are rigorous procedures that may continuously raise the economic and quality value of products and services. They work to improve customer experiences, which is critical for a small business's client retention. A robust QMS will facilitate effective and efficient methods during commercialization. Such measures will ensure that the company can maintain its leadership position by effectively implementing best practices.

METHODOLOGY

The present study employed the DMAIC methodology to evaluate the impact of implementing a QMS on the scientific software development process of this small organization. The investigation involved a comparison between the before and after scenarios to determine the possible areas for optimization. To begin with, a Value Stream Map (VSM) was utilized to document the current scientific software development process, along with the resources and time required for each task. The Voice of the Customer (VOC) was captured to comprehend the actual process, with inputs from top management and employees. A new VSM was created to describe the optimized process based on the framework supported by the implementation of the QMS. Historical data was analyzed to identify deviations during final product validation, change controls, hours required to complete a final product, and associated labor costs. A simulation program was utilized to emulate the software development process of new products without implementing a QMS, aiming to reach a sample size of n=20. Additionally, data was extrapolated and then simulated for an n=20 based on the proposed and optimized VSM, including the number of hours required to complete a final product and associated labor costs. The simulation for the number of deviations during validation and the number of change controls per product was rooted in the goal of attaining a 50% reduction for both metrics with the implementation of the QMS. Statistical analysis was performed to measure the before and after scenarios, including descriptive statistics, time series charts, analysis of variance (ANOVA), capability analysis, and measurement error and variation metrics. hypothesis testing and regression analysis were conducted during the analysis phase. For the improvement phase, a cause-and-effect diagram was developed to categorize the causes of

a problem. Lastly, a before and after capability analysis was executed for the control phase.

RESULTS AND DISCUSSION

An analysis of four key variables was conducted, including the number of deviations encountered during the validation process, the number of change controls linked to a product, the hours required for the completion of a final product, and the corresponding labor costs. For the study, data was collected through VOC, interviews, historical data, and projections of potential data.

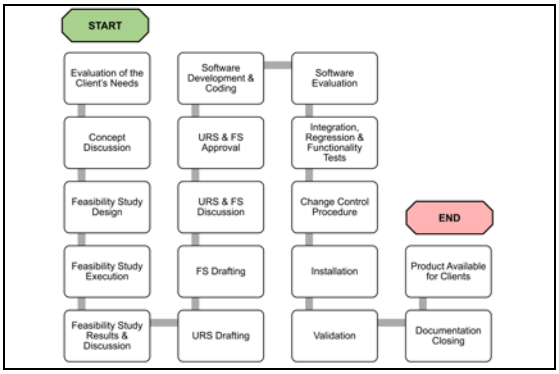


Figure 1
Software Development Process Before the Proposed Optimizations

Figure 2
Software Development Process After the Proposed Optimizations

Table 1
Deviations During Validation and Number of Change Controls Associated with a Product Before the Proposed Optimizations

Product	Deviations During Validation	Associated Change Controls
A	2	6
B	1	4
C	3	1
D	3	1
E	1	6
Average	2	4
Std	0.894	2.510

Table 2
Labor Costs ($) and Time (Hours) Range Required to Complete a Product Before the Proposed Optimizations.

	Labor Cost Range ($) Before QMS	Time Range (Hours) Before QMS
minimum	$64,650.00	765
maximum	$109,650.00	1245
Average	$87,150.00	1005

Table 3
Historical Data Concerning Labor Costs ($) and Time (Hours) Based on Five Previously Developed Products

Product	Labor Cost ($)	Time (Hours)
A	$64,650.00	765
B	$75,900.00	885
C	$87,150.00	1005
D	$98,400.00	1125
E	$109,650.00	1245
Average	$87,150.00	1005
Std	$17,787.81	169.706

Table 4
Labor Costs ($) and Time (Hours) Range Required to Complete a Product After the Proposed Optimizations

	Proposed Labor Cost Range ($) After QMS	Proposed Time Range (Hours) After QMS
minimum	$47,600.00	609
maximum	$63,100.00	789
Average	$55,350.00	699

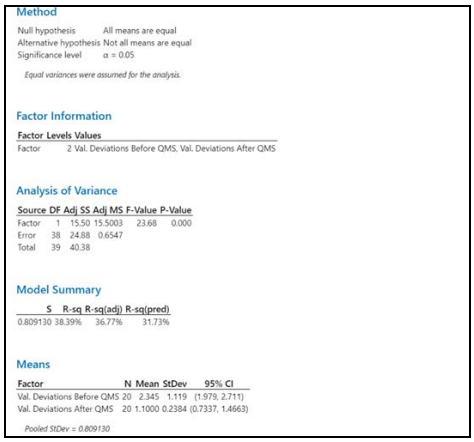
Table 5
Potential Data Concerning Labor Costs ($) and Time (Hours) for the Next Five Products to be Developed Based on the Proposed Optimizations

Product	Proposed Labor Costs ($)	Proposed Time (Hours)
A	$47,600.00	609
B	$51,475.00	644
C	$55,350.00	699
D	$59,225.00	744
E	$63,100.00	789
Average	$55,350.00	697
Std	$6,126.91	65.161

Variable	N	N*	Mean	SE Mean	StDev	Minimum	Q1	Median	Q3
Val. Deviations Before QMS	20	0	2.345	0.250	1.119	0.000	2.000	2.445	2.890
Val. Deviations After QMS	20	0	1.1000	0.0533	0.2384	0.8000	1.0000	1.0000	1.2000
Change Controls Before QMS	20	0	4.925	0.527	2.355	1.091	3.600	5.554	6.109
Change Controls After QMS	20	0	2.362	0.248	1.109	0.550	1.800	1.800	3.050
Costs ($) Before QMS	20	0	101380	3784	16924	51574	104938	104938	104938
Costs ($) After QMS	20	0	57494	1425	6372	43096	55350	58413	61477
Time (Hours) Before QMS	20	0	1098.3	43.5	194.5	665.6	1005.0	1174.7	1174.7
Time (Hours) After QMS	20	0	736.1	19.7	88.2	631.8	648.1	729.6	811.0

Variable	Maximum
Val. Deviations Before QMS	5.560
Val. Deviations After QMS	1.8000
Change Controls Before QMS	8.618
Change Controls After QMS	4.300
Costs ($) Before QMS	122726
Costs ($) After QMS	67604
Time (Hours) Before QMS	1344.4
Time (Hours) After QMS	957.6

Figure 3
Before vs. After Proposed Optimizations Descriptive Statistical Analysis



Method

Null hypothesis All means are equal
Alternative hypothesis Not all means are equal
Significance level α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	2	Val. Deviations Before QMS, Val. Deviations After QMS

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	15.50	15.5003	23.68	0.000
Error	38	24.88	0.6547		
Total	39	40.38			

Model Summary

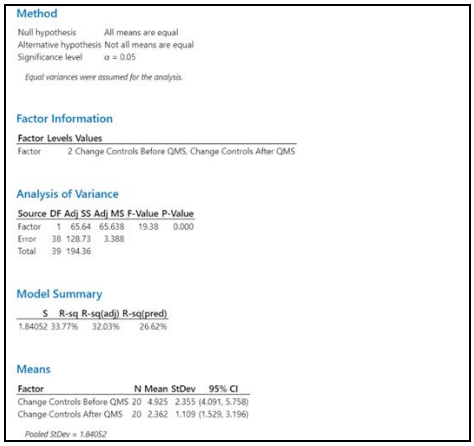
S	R-sq	R-sq(adj)	R-sq(pred)
0.809130	38.39%	36.77%	31.73%

Means

Factor	N	Mean	StDev	95% CI
Val. Deviations Before QMS	20	2.345	1.119	(1.979, 2.711)
Val. Deviations After QMS	20	1.1000	0.2384	(0.7337, 1.4663)

Pooled StDev = 0.809130

Figure 4
Analysis of Variance for Deviations During Validation Before vs. After the Proposed Optimizations



Method

Null hypothesis All means are equal
Alternative hypothesis Not all means are equal
Significance level α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	2	Change Controls Before QMS, Change Controls After QMS

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	65.64	65.638	19.38	0.000
Error	38	128.73	3.388		
Total	39	194.36			

Model Summary

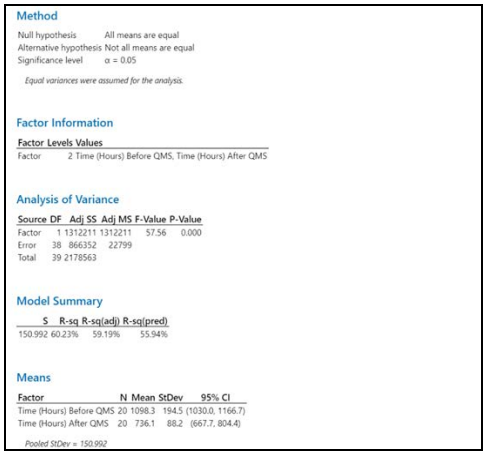
S	R-sq	R-sq(adj)	R-sq(pred)
1.84052	33.77%	32.03%	26.62%

Means

Factor	N	Mean	StDev	95% CI
Change Controls Before QMS	20	4.925	2.355	(4.091, 5.758)
Change Controls After QMS	20	2.362	1.109	(1.529, 3.196)

Pooled StDev = 1.84052

Figure 5
Analysis of Variance for Change Controls Before vs. After the Proposed Optimizations



Method

Null hypothesis All means are equal
Alternative hypothesis Not all means are equal
Significance level α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	2	Time (Hours) Before QMS, Time (Hours) After QMS

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	1312211	1312211	57.56	0.000
Error	38	866352	22799		
Total	39	2178563			

Model Summary

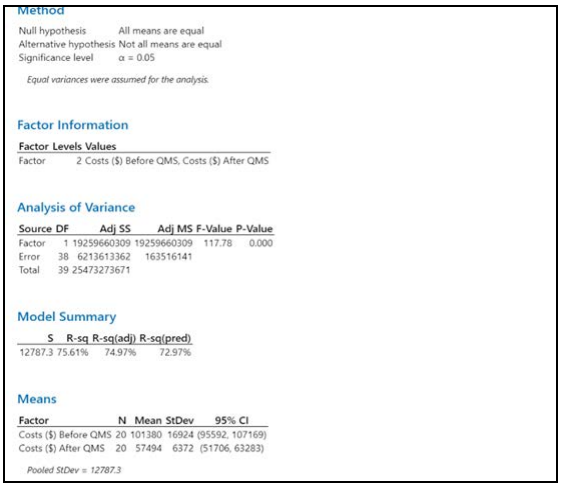
S	R-sq	R-sq(adj)	R-sq(pred)
150.992	60.23%	59.19%	55.94%

Means

Factor	N	Mean	StDev	95% CI
Time (Hours) Before QMS	20	1098.3	194.5	(1030.0, 1166.7)
Time (Hours) After QMS	20	736.1	88.2	(667.7, 804.4)

Pooled StDev = 150.992

Figure 6
Analysis of Variance for the Time (Hours) to Complete a Product Before vs. After the Proposed Optimizations



Method

Null hypothesis All means are equal
Alternative hypothesis Not all means are equal
Significance level α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Factor	2	Costs ($) Before QMS, Costs ($) After QMS

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Factor	1	19259660309	19259660309	117.78	0.000
Error	38	6213613362	163516141		
Total	39	25473273671			

Model Summary

S	R-sq	R-sq(adj)	R-sq(pred)
12787.3	75.61%	74.97%	72.97%

Means

Factor	N	Mean	StDev	95% CI
Costs ($) Before QMS	20	101380	16924	(95592, 107169)
Costs ($) After QMS	20	57494	6372	(51706, 63283)

Pooled StDev = 12787.3

Figure 7
Analysis of Variance for the Labor Costs ($) to Complete a Product Before vs. After the Proposed Optimizations

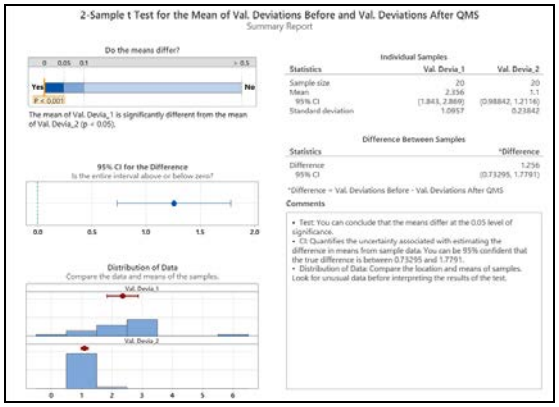


Figure 8
2-sample t-test for the Mean of Deviations During Validation Before vs. After the Proposed Optimizations

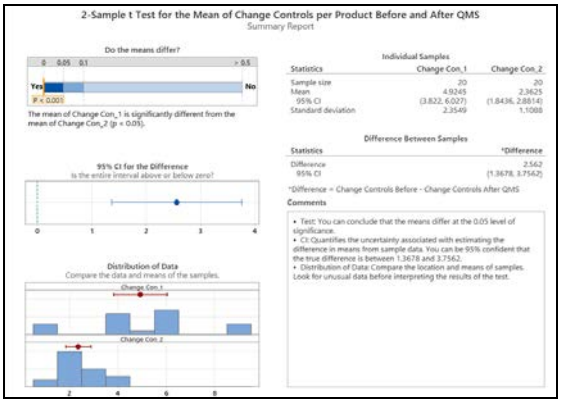


Figure 9
2-sample t-test for the Mean of Change Controls Before vs. After the Proposed Optimizations

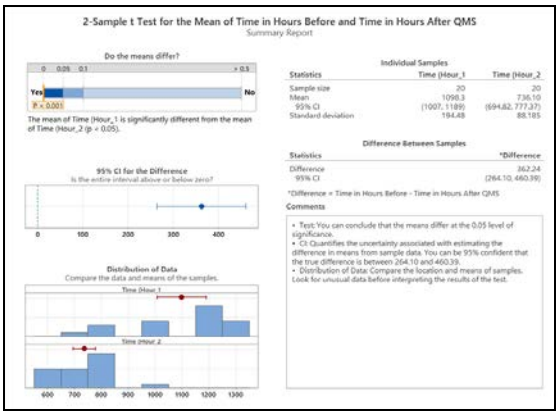


Figure 10

2-sample t-test for the Mean of Time (Hours) to Complete a Product Before vs. After the Proposed Optimizations

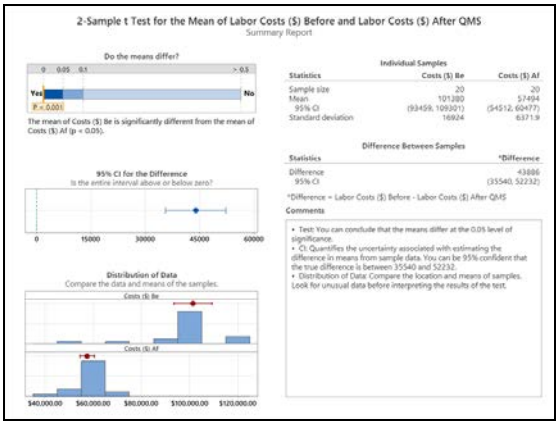


Figure 11

2-sample t-test for the Mean of Labor Costs ($) to Complete a Product Before vs. After the Proposed Optimizations

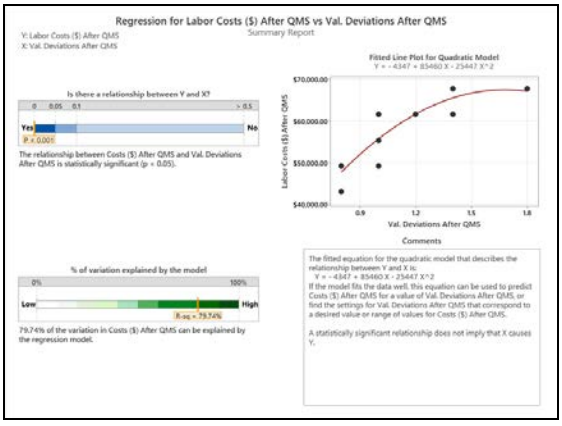


Figure 12

Regression Analysis for Labor Costs ($) vs. Deviations During Validation After the Proposed Optimizations

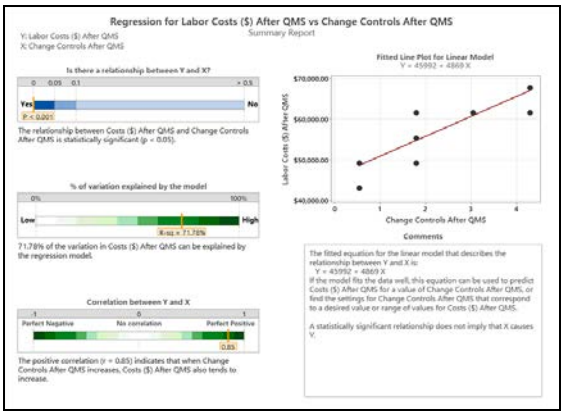


Figure 13

Regression Analysis for Labor Costs ($) vs. Number of Change Controls After the Proposed Optimizations

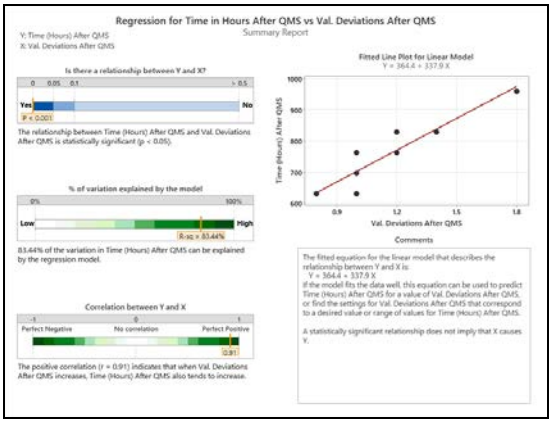


Figure 14

Regression Analysis for Time (Hours) vs. Deviations During Validation After the Proposed Optimizations

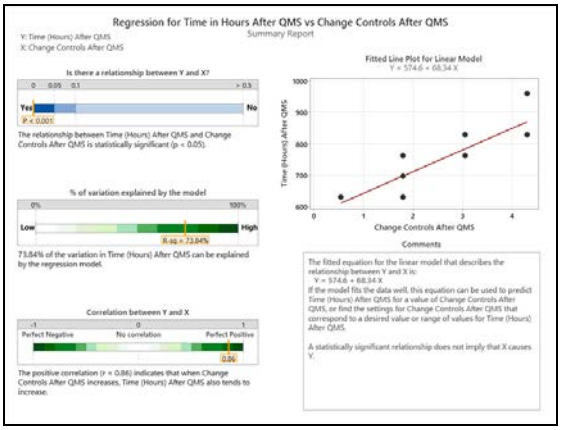


Figure 15

Regression Analysis for Time (Hours) vs. Number of Change Controls After the Proposed Optimizations

Figure 16
Before/After Capability Analysis for Deviations During Validation Before vs. After the Proposed Optimizations

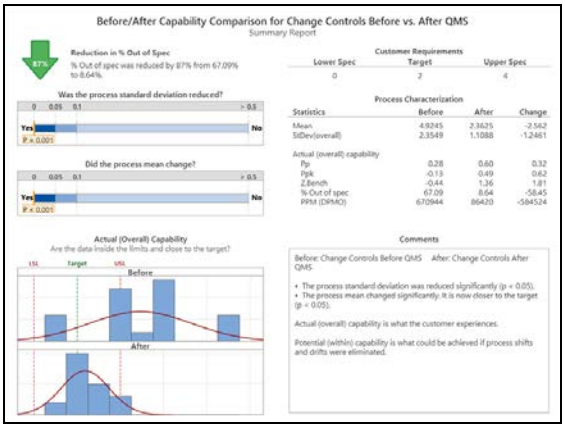


Figure 17
Before/After Capability Analysis for Number of Change Controls Before vs. After the Proposed Optimizations

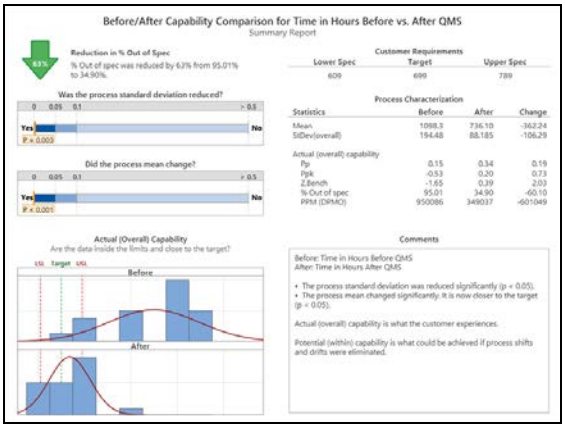


Figure 18
Before/After Capability Analysis for Time (Hours) Before vs. After the Proposed Optimizations

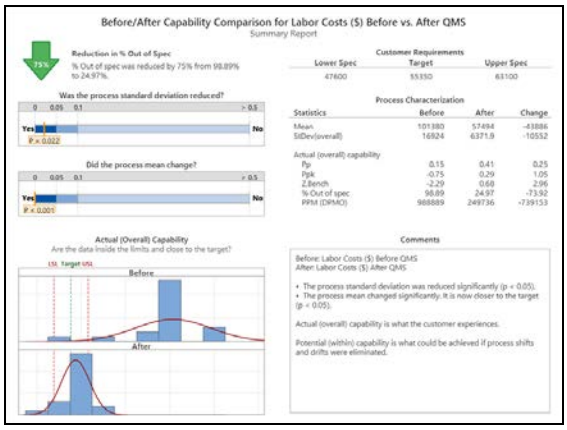


Figure 19
Before/After Capability Analysis for Labor Costs ($) Before vs. After the Proposed Optimizations

Tables 1, **2**, and **3** exhibit historical data that predates the proposed optimizations (before QMS implementation). A simulation for n=20 was executed based on a smaller sample size of n=5 founded on previous historical data.

Tables 4 and **5** exhibit potential projected data based on the proposed optimizations (after QMS implementation). A simulation for n=20 was executed utilizing a smaller sample size of n=5 founded on previous projected data.

Figure 3 shows a detailed statistical data analysis that includes the mean, standard deviation, minimum, maximum, and median. Before applying the QMS and the proposed optimizations to the scientific software development process, the validation process indicated an average of 2.345 deviations, which is projected to decrease to approximately 1.100 after implementation. The average number of change controls associated with a product was roughly 4.925 before the QMS, but it is expected to reduce to around 2.362 after implementation. The average labor costs were $101,380.00 before the QMS, but it is expected to decreased to $57,494.00 after implementation. Lastly, the duration required to finalize a software product was 1,098.3 hours before QMS implementation, which it is expected to dropped to 957.6 hours according to the proposed QMS for this specific organization.

Figures 4-7 summarize the ANOVA analyses results with null hypothesis H_0: all means equal and

alternative hypothesis H_1: not all means equal, using a significance level of 0.05. For all four categories, the tests yielded p-values of 0.000. For the number of deviations, the factor explains 38.39% of the variation in the response, and the means analysis indicated that the standard deviation decreased from 1.119 to 0.238. Moreover, the 95% confidence interval was adjusted from 1.919, 2.711 to 0.734, 1.466. Similarly, for the number of change controls, the factor explains 33.77% of the variation in the response, and the means analysis demonstrated that the standard deviation decreased from 2.355 to 1.109. The 95% confidence interval was adjusted from 4.091, 5.758 to 1.529, 3.196. For the time (hours), the factor explains 60.23% of the variation in the response, and in the means analysis, it can be observed that the standard deviation decreased from 194.5 to 88.2. The 95% confidence interval was adjusted from 1,030, 1,166.7 to 667.7, 804.4. Lastly, for the costs ($), the factor explains 75.61% of the variation in the response, and the means analysis revealed that the standard deviation decreased from $16,924.00 to $6,372.00. The 95% confidence interval was adjusted from $95,592, $107,169 to $51,706, $63,283. For all the categories, the p-values were lower than the significance level. P-values lower than the significance level are statistically significant and provide strong evidence to reject H_0 and accept H_1; thus, the means before and after implementing the QMS and the proposed optimizations to the scientific software development process are not equal. These conclusions are further supported by analyzing the F-value, which for all four variables is higher than the F-critical value of 4.098 for a significance level of 0.05. Since the F-values exceed the F-critical values, it supports rejecting H_0.

Figures 8-11 include the 2-sample t-test analysis. The null hypothesis states that H_0: $\mu_1 - \mu_2 = 0$, and the alternate hypothesis assumes that H_1: $\mu_1 - \mu_2 \neq 0$. The test used a significance level of 0.05 and found that the p-values were less than 0.001 for all four categories. A p-value less than 0.05 is statistically significant. Based on the findings, H_0 is rejected, and H_1 is accepted. For the number of deviations, the actual difference is between 0.733 and 1.779, with a 95% confidence. If the actual means differ by 0.582, there is a 60% chance of detecting a difference for a significance level of 0.05 and a sample size of 20. However, if the means differ by 0.853, the possibility of detecting a difference increases to 90%. For the number of change controls, the actual difference is between 1.368 and 3.756, with a 95% confidence. If the actual means differ by 1.336, there is a 60% chance of detecting a difference for a significance level of 0.05 and a sample size of 20. However, if the means differ by 1.958, the possibility of catching a difference increases to 90%. Concerning the time (hours), the actual difference falls between 264.10 and 460.39, with a 95% confidence. If the actual means differ by 109.68, there is a 60% chance of detecting a difference for a significance level of 0.05 and a sample size of 20. However, if the means differ by 160.71, the possibility of detecting a difference increases to 90%. Finally, for the labor costs ($), the actual difference is between $35,540.00 and $52,232.00, with a 95% confidence. If the actual means differ by $9,320.90, there is a 60% chance of detecting a difference for a significance level of 0.05 and a sample size of 20. However, if the means differ by $13,659.00, the possibility of detecting a difference increases to 90%.

Figures 12-15 include the regression analysis after implementing a QMS and the proposed optimizations to the scientific software development process. For the labor costs ($) vs. the number of deviations during validation, the p-value was less than 0.001, which is smaller than the significance level of 0.05, indicating a statistically significant relationship between the time in hours and the number of deviations in validation. The percent of variation explained by the model was 79.74%. However, the fitted line plot adopts a quadratic model. Therefore, further analyses are required to ensure the regression results are reliable and valid. The labor costs ($) versus the number of change controls indicates a p-value of less than

0.001, which means a statistically significant relationship exists. The model explains 71.78% of the variation, and the correlation between Y and X is 0.85, which is positive. The analysis of time in hours versus the number of deviations during validation suggests a p-value of less than 0.001, which means a statistically significant relationship exists. The model explains 83.44% of the variation, and the correlation between Y and X is 0.91, which is positive. The analysis of time in hours versus the number of change controls reveals a p-value of less than 0.001, which means a statistically significant relationship exists. The model explains 73.84% of the variation, and the correlation between Y and X is 0.86, which is positive. These correlations imply that when X increases, Y also tends to increase.

Figures 16-19 include the before/after capability analysis after implementing a QMS and the proposed optimizations to the scientific software development process. A comprehensive capability analysis was conducted for the current process (before the optimizations). This analysis revealed that the process was not capable, as evidenced by the presence of small or negative values for C_p, C_{pk}, P_p, and P_{pk}. Additionally, it was determined that the process was not centered overall or between the specification limits. Based on the simulated potential data considering the proposed optimizations, a before/after capability analysis was performed to assess the possible reduction in these categories. However, it is essential to consider several factors when conducting a capability analysis, including stability, the number of subgroups, normality, and data quantity. Experts in the field recommend collecting at least 25 subgroups over an appropriate period to capture various sources of process variation and obtain precise capability estimates. Furthermore, having more than 100 observations for reasonably accurate estimates is advisable, as fewer observations can lead to less precise estimates.

For the number of deviations, the analysis indicates that the out-of-specification percentage decreased significantly from 64.31% to 0.01%, representing almost a 100% reduction. A p-value of less than 0.001, which is lower than the significance level of 0.05, indicates a decrease in process standard deviation and a change in process mean. P_p and P_{pk} values increased from 0.30 and -0.11 to 1.40 and 1.26, respectively, while C_p and C_{pk} improved from 0.38 and -0.14 to 1.28 and 1.15.

For the number of change controls associated with a product, the analysis indicates that the out-of-specification percentage decreased significantly from 67.09% to 8.64%, representing an 87% reduction. P_p and P_{pk} values increased from 0.28 and -0.13 to 0.60 and 0.49, respectively, while C_p and C_{pk} improved from 0.26 and -0.12 to 0.54 and 0.45. For the labor costs ($) associated with a product, the results indicate that the out-of-specification percentage decreased significantly from 98.89% to 24.97%, representing a 75% reduction. P_p and P_{pk} values increased from 0.15 and -0.75 to 0.41 and 0.29, respectively, while C_p and C_{pk} improved from 0.16 and -0.77 to 0.35 and 0.25. For the time (hours) associated with a product, the results indicate that the out-of-specification percentage decreased significantly from 95.01% to 34.90%, representing a 63% reduction. P_p and P_{pk} values increased from 0.15 and -0.53 to 0.34 and 0.20, respectively, while C_p and C_{pk} improved from 0.16 and -0.54 to 0.45 and 0.26. In summary, the analysis of the trend in before and after capability reveals that both P_p & P_{pk} and C_p & C_{pk} have become closer after implementing the QMS and the proposed optimizations. This indicates that the process must be more centered between the specification limits than the previous. However, more effort is needed to attain values that are more appropriate.

CONCLUSION

The statistical analysis was conducted using Minitab Statistical Software. A descriptive statistics summary indicated a disparity between data before and after implementing the proposed QMS. It was observed that standard deviations exhibited lower values after the QMS implementation than before. It is essential to recognize that the standard

deviations following QMS implementation may not be small independently but relatively smaller than those measured before QMS implementation. This leads to the concentration of data around the mean after QMS implementation, resulting in a distribution closer to normal. An ANOVA analysis was performed to compare the variances across the means of the two groups (before vs. after the proposed QMS implementation). The analysis revealed a statistically significant difference in the mean for all four categories between the two groups at a significance level of 0.05. H_0 stipulates that all means are equal, and H_1 assumes that not all means are equal. The resulting p-values of 0.000, which are less than the significance level, provided strong evidence to reject H_0 and accept H_1. Therefore, in conclusion, the mean for both groups - before and after QMS - are not equal. This conclusion is further supported by the analysis of the F-values, which exceeded the F-critical value (4.098). As the F-values exceeded the F-critical value, H_0 is rejected.

Before implementing a QMS for all four categories, the capability analysis for the data resulted in low and even negative values for P_p, P_{pk}, C_p, and C_{pk}, indicating poor process performance and data out of the desired specification limits. For the capability analysis after the QMS implementation, the projected results showed an increase in all capability statistics. The out-of-specification percentage decreased significantly from 64.31% to 0.01% for the number of deviations during the final product validation, from 67.09% to 8.64% for the number of change controls associated with a product, from 98.89% to 24.97% for the labor costs ($), and from 95.01% to 34.90% for the time (hours) to finalize a product. In summary, the analysis of the trend in before and after capability reveals that both P_p & P_{pk} and C_p & C_{pk} have become closer after implementing the QMS. This indicates that the process must be more centered between the specification limits than the previous state (without QMS). Acknowledging that this scenario does not necessarily signify that the process is in control or functioning optimally is imperative. It may require multiple attempts to achieve the intended outcome. Nonetheless, enhancements in the process capability metrics and a decrease in out-of-specification proportion indicate progress in the right direction.

Upon examination of data about variation metrics, including the standard deviation and MAD, the most noteworthy aspect is the decrease in the variation coefficient for both metrics after fully integrating the proposed QMS.

Through a comprehensive evaluation concerning the hypothesis testing 2-sample t-test for all categories, it has been determined that the means before and after implementing the proposed QMS exhibit significant differences. All p-values were found to be less than 0.001, which indicates statistical significance and provides robust evidence to reject H_0 and accept H_1 at a significance level of 0.05. The results of all tests confirm that the means before QMS implementation not only differed but also exceeded the potential means after implementation. In addition, the regression analysis findings suggest a positive correlation between Y and X for some of the variables including the labor expenses ($) versus change controls, time in hours versus deviations during validation, and time in hours versus change controls, indicating that as X increases, Y tends to increase. However, further evaluation is required to understand how labor costs relate to the quantity of deviations during validation following QMS implementation.

Based on the analysis of historical data and the simulation of projected data, the statistical analysis has shown significant optimization post-QMS implementation for all variables evaluated. To further this study, it is recommended that a data collection plan be implemented as part of the QMS to monitor the four metrics under evaluation and prove the proposed optimization with actual data. Once data is collected, running a pilot project to emulate the real scientific software development process per the optimized VSM and comparing results against historical data is essential. It is crucial to compare new data against previous products of similar complexity. Repeat statistical

analysis and assess if the difference for all four variables is still significant at a significance level of 0.05. Additionally, comparing results against those of other small companies in a similar scenario is recommended. Regarding software development for this small company, additional recommendations for future improvements may include integrating the Plan-Do-Check-Act cycle into the software development process to ensure the best process performance. Some methods may require multiple optimization iterations before reaching their most suitable state and sustainability. A code system based on software complexity (e.g., 1-basic, 2-intermediate, and 3-advanced) may be created. Assigning a potential code associated with software complexity is possible. Through the data collection process, it is feasible to measure the time (hours) to complete a final product based on its complexity. This metric may assist in measuring the efficiency of the programming step, software engineers, and the process and assess the optimal distribution of resources for each type of product depending on its intricacy.

Implementing the proposed QMS will formalize and standardize processes, resulting in a marked improvement in the scientific software development process and, ultimately, increased profitability. Furthermore, the QMS will provide a framework for identifying and addressing potential issues before they can adversely impact the quality of the final product, thereby enhancing customer satisfaction and reducing the risk of costly rework. Adopting a QMS is a strategic investment that will yield a range of tangible benefits for the company shortly.

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