

HOW ISO QUALITY MANAGEMENT STANDARDS CHANGE THE COMPANY LEVEL OF EXCELLENCE? STUDY CONDUCTED ON TWO COMPANIES OF POLISH DNA SEQUENCING INDUSTRY USING THE BUSINESS IMPROVEMENT MATRIX

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Abstract

This study examines the level of excellence of two companies, using Business Improvement Matrix (BIM), which is based on European Foundation of Quality Management's Model of Excellence. It compares those organizations and shows how their quality management systems make an effect on BIM results. The researched companies are genXone S.A., which is in the process of implementing a quality management system compliant with ISO 13485: 2016, and Centrum Genetyki Medycznej GENESIS Sp. z o.o., certified with ISO 9001: 2015 since 2018. Both of them belong to sequencing industry in Poland, using new generation sequencing. This study shows that the company that has implemented its quality management system and has fully adopted its standards achieved a higher level of excellence than the company that just started the process of implementation of their quality management system.

Keywords

Business improvement matrix; Quality management; Continuous improvement; Level of excellence.

Introduction

This study presents the results of Business Improvement Matrix (BIM) for two organizations at different stages of their quality management systems: genXone S.A., a company in the process of implementing a quality management system compliant with the ISO 13485: 2016 standard, and Centrum Genetyki Medycznej GENESIS Sp. z o.o., ISO 9001: 2015 certified since 2018. The BIM allows for the assessment and comparison of their achieved "level of excellence" [1]. It has been shown that ISO quality standards influence the results of BIM assessment.

There are different studies presenting the relationship between ISO quality standards and EFQM model. In general, the conclusions say that there is a positive correlation between ISO 9001 certification maturity and EFQM business excellence model results [2], but these studies have been purely theoretical. There was also a study conducting the analysis and comparison of impact on the communication system and external relations at schools that implemented EFQM model versus the ones that implemented ISO certificates [3], but it did not measure how the ISO standards changed the EFQM model results. There have not been any studies done to compare two similar companies that differ in their quality management systems maturity stages to evaluate how ISO quality standards, such as ISO 9001:2015 and ISO 13485:2016, affected the results of the Business Improvement Matrix. These are important studies not only for scientific research purposes, but also for practical use, for all organizations seeking comprehensive improvement of their management systems, as well as

for all companies currently having a management system compliant with ISO standards and wanting to find a tool to measure their progress on the path of continuous improvement.

1 Quality Management

In ISO 9000, quality is defined as the degree to which a set of inherent characteristics of an object fulfils requirements [4]. Taking this into account, quality management is the act of managing processes that allow us to obtain a given degree of meeting these requirements. It can also be defined as “act of overseeing all activities and tasks needed to maintain a desired level of excellence”, as stated by Adam Barone [5]. The best-known systems for quality management are standards issued by International Organization for Standardization, also known as ISO [6].

1.1 ISO Quality Standards

ISO 9000 family of quality management systems are one of the most used QMS tools today [6]. Not only do companies by their own decide to start implying ISO quality standards, but also the customers, investors and other third parties may demand them to be certified by ISO. It is worth mentioning that ISO 9000 family is not the only quality management system provided by ISO organization: there are different sector-specific versions of it, one of which is ISO 13485:2016, which is a comprehensive management system specifically for the manufacture of medical devices [7].

1.2 European Foundation of Quality Management and its Model of Excellence

EFQM is a non-profit membership foundation in Brussels, established in 1989 to increase the competitiveness of the European economy. They invented an EFQM model [8]. This model provides a framework allowing organizations to determine their current "level of excellence" and where they need to improve their efforts. The model also helps to ensure that business decisions incorporate the needs of all stakeholders and are aligned with the organization's objectives. It consists of 9 areas, as listed below [1]:

1. Leadership (how management and all managers behave and act to inspire and drive culture change towards a quality orientation)
2. Policy and strategy (whether the policy and strategy are formulated, reviewed, and improved in line with the EFQM management concept)
3. People (how the company unleashes the full potential of its employees)
4. Resources and Partnership (how financial, information, material, and technology resources are effectively used to support corporate policies and strategies)
5. Processes (how critical processes are applied and controlled to ensure continuous improvement of the enterprise)
6. Customer oriented results (how the customer evaluates the quality of products and services)
7. Staff oriented results (how the employee assesses the benefits of employment in the enterprise and his own contribution to its development)
8. Society oriented results (what are the relationships of the company with the local community and the impact on the natural environment)
9. Key performance results (to what extent the company achieves the planned goals)

1.2.1 Business Improvement Matrix

Business Improvement Matrix (BIM) is a self-assessment tool designed by EFQM organization for companies to provide them with a tool for rating their current “level of excellence”, getting the possibility of comparing oneself with competing enterprises and setting a further path to development [1].

- a) The matrix consists of 9 sections (columns), where each section is assigned 10 criteria, reflecting the degree of excellence of a given organization within a given area. To fill the matrix, the company If no actions have been taken to develop or implement an action plan for a specific level – answer NO, the matrix field remains blank, the organization receives 0 points.
- b) If an approach to the problem has been taken and / or documented and a record of each implementation is available, or in the case of the results section if the approach has been taken and is starting to deliver results – answer DURING IMPLEMENTATION, the matrix field is marked in yellow, corresponding to 0.5 points.
- c) If the records show that the approach has been fully implemented and adopted by the company, or if the implemented approach is a complete success – answer YES, the field is marked in green, corresponding to 1 point. [1]

The points from each section are summed up and the result is obtained by the product of the sum of points and the weight of the section, according to the EFQM model [1]:

- Leadership: ×10
- Policy and strategy: ×8
- People: ×9
- Resources and Partnership: ×9
- Processes: ×14
- Customer oriented results: ×20
- Staff oriented results: ×9
- Society oriented results: ×6
- Key performance: ×15

Examples of criteria from Leadership section:

- 1) Managers develop their own awareness of Total Quality Management (TQM) and company improvement. This process is deeply rooted and can be sustained despite personnel changes.
- 2) Managers decide to take measures that increase quality awareness among employees. They assess and develop this awareness (e.g., by using leaflets, providing educational materials on quality).

Each criterium is becoming more complicated and harder to achieve with each level in the matrix, which means it is easiest to achieve criteria number one and hardest to achieve criteria number 10.

2 Research Subject and its Objective

The aim of the research is to examine the impact of ISO quality management standards on the company level of excellence, measured with Business Improvement Matrix assessment. The subject of the study are two companies: genXone S.A. and GENESIS Sp. z o.o. Both organizations belong to the genetic sequencing industry, however GENESIS Sp. z o.o. has

implemented the ISO 9001: 2015 management system since 2018, and genXone is only currently in the process of implementing ISO 13485: 2016.

3 Results

Comprehensive interviews were conducted with representatives of the surveyed companies. During the interviews, all the criteria of the matrix were discussed, and the interviewees presented the degree of fulfillment of the given requirements in their organizations. Based on their responses, the BIM fields were completed.

Tables 1 and 2 show the results of the BIM assessment for genXone S.A. and GENESIS Sp. z o.o. The companies scored 395 points, and GENESIS Sp. z o.o. scored 780 points correspondingly. Both organizations achieved a really high score for companies that did not implement EFQM model in their policy. The author of this article suggests that the high results were scored due to the industry of those companies, since laboratories and science-oriented enterprises need to conform to strict laws imposed by the government.

It would be worth considering for both organizations to take additional steps that they could take to improve their level of excellence as measured by the MDP matrix. Examples of paths towards continuous improvement would be, for example, starting activities influencing the local environment of the surveyed companies, working on improving customer satisfaction processes at GENESIS Sp. z o.o. or completing the processes under implementation at genXone S.A. in genXone S.A. additionally, it is suggested to repeat the tests after receiving the ISO 13485: 2016 certification in order to set new goals for continuous improvement.

Tab. 1: Results of genXone S.A., company in the process of implying ISO 13485:2016 standards

No.	Leadership	Policy and Strategy	People	Partnerships and Resources	Processes	Customer Oriented Results	Staff Oriented Results	Society Oriented Results	Key Performance Results
10.									
9.									
8.									
7.									
6.									
5.									
4.									
3.									
2.									
1.									
GREEN	4	6	3	6	0	3	0	0	2
YELLOW x0.5	2	1.5	2	0.5	2.5	0	2	1	1.5
SUM	60	60	45	58.5	35	60	18	6	52.5
genXone S.A.									395

Source: Own

Tab. 2: Results of GENESIS Sp. z o.o., company certified with ISO 9001:2015 since 2018

No.	Leadership	Policy and Strategy	People	Partnerships and Resources	Processes	Customer Oriented Results	Staff Oriented Results	Society Oriented Results	Key Performance Results
10.									
9.									
8.									
7.									
6.									
5.									
4.									
3.									
2.									
1.									
GREEN	10	9	8	10	9	6	9	0	6
YELLOW x0.5	0	0.5	0	0	0.5	0	0.5	1	0.5
SUM	100	76	72	90	133	120	85.5	6	97.5
GENESIS Sp. z o.o.									780

Source: Own

Conclusion

Based on the presented study, it can be concluded that the level of organizational excellence, measured with the Business Improvement Matrix is affected by implementation of the quality management system of ISO standards. It is evident not only by the very high result of GENESIS Sp. z o.o., but also due to the fact that genXone, which is in the process of implementing ISO standards, has a lot of answers “DURING IMPLEMENTATION”. The company has a lot of room for development: the completion of the implementation of all the criteria marked in this way will increase its score to 531 points, i.e. by 34%. The results also highlight the differences between the two companies, their politics and structure, but the fact that GENESIS Sp. z o.o. holds up so well the developed QMS practically eclipsed all issues in which genXone has advantages over GENESIS Sp. z o.o. such as technology or fact being a joint stock company. This research shows how important conforming to the ISO quality standards is in the process of measuring the level of excellence with EFQM model and how much it can affect the end result.

The limitations of this study include a small sample size and limited scope of discussion: the author recommends conducting further studies with an increased number of analyzed companies at various stages of implementation of different quality systems. Future studies would be able to describe correlation between implementing ISO quality standards and achieving higher results from EFQM model more efficiently with more data gathered in practical research. Future studies could analyze a specific company in its implementation of ISO quality standards and measure its level of excellence, investigate how these standards operate in different industries, or compare companies that have not implemented ISO

standards but have implemented EFQM models on how their performance is changing during the implementation and certification of the ISO standard.

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JAK NORMY ŘÍZENÍ KVALITY ISO MĚNÍ ÚROVEŇ FIRMY? STUDIE PROVEDENÁ NA DVOU SPOLEČNOSTECH POLSKÉHO ODVĚTVÍ DNA SEKVENOVÁNÍ ZA POUŽITÍ MATICE PRO ZLEPŠENÍ PODNIKÁNÍ

Tato studie zkoumá úroveň excelence dvou společností pomocí Business Improvement Matrix (BIM), která je založena na modelu excelence Evropské nadace pro management kvality. Porovnává tyto organizace a ukazuje, jak jejich systémy managementu kvality ovlivňují výsledky BIM. Zkoumanými společnostmi jsou genXone S.A., která je v procesu implementace systému managementu kvality v souladu s ISO 13485: 2016, a Centrum Genetyki Medycznej GENESIS Sp. z o.o., certifikované podle ISO 9001: 2015 od roku 2018. Obě společnosti patří do odvětví sekvenování v Polsku s pomocí sekvenování nové generace. Tato studie ukazuje, že společnost, která zavedla svůj systém řízení kvality a plně přijala své standardy, dosáhla vyšší úrovně excelence než společnost, která proces implementace svého systému řízení kvality právě zahájila.

WIE VERÄNDERN DIE NORMEN DER QUALITÄTSTEUERUNG ISO DAS NIVEAU DER FIRMA? EINE STUDIE DURCHGEFÜHRT AN ZWEI FIRMEN DER POLNISCHEN DNA- SEQUENZIERUNG INDUSTRIE UNTER VERWENDUNG EINER MATRIX ZUR VERBESSERUNG DER GESCHÄFTSQUALITÄT

Diese Studie untersucht das Niveau der Exzellenz zweier Firmen mit Hilfe der „Business Improvement Matrix“ (BIM), welche auf dem Modell der Exzellenz der Europäischen Stiftung für Qualitätsmanagement basiert. Sie vergleicht diese Organisationen und legt dar, wie deren Systeme des Qualitätsmanagements die Ergebnisse der BIM beeinflussen. Bei den Zielfirmen handelt es sich um genXone S. A., welche sich im Prozess der Implementierung des Systems des Qualitätsmanagements in Übereinstimmung mit ISO 13485 befindet, und Centrum Genetyki Medycznej GENESIS Sp. Z o.o., welche seit dem Jahr 2018 nach ISO 9001: 2015 zertifiziert ist. Beide Firmen gehören in Polen zum Zweig der Sequenzierung mit Hilfe der Sequenzierung der neuen Generation. Diese Studie legt dar, dass die Firma, welche ihr System der Qualitätssteuerung eingeführt und ihre Standards voll angenommen hat, das höhere Exzellenzniveau erreicht hat als diejenige Firma, welche den Prozess der Implementierung ihrer System der Qualitätssteuerung erst begonnen hat.

JAK NORMY ZARZĄDZANIA JAKOŚCIĄ ISO ZMIENIAJĄ POZIOM DOSKONAŁOŚCI PRZEDSIĘBIORSTWA? BADANIA PRZEPROWADZONE NA DWÓCH FIRMACH POLSKIEJ BRANŻY SEKWENCJONOWANIA DNA Z WYKORZYSTANIEM MACIERZY DOSKONALENIA PRZEDSIĘBIORSTWA

W niniejszym opracowaniu zbadano poziom doskonałości dwóch firm przy użyciu Macierzy Doskonalenia Przedsiębiorstwa (MDP), opartej na Modelu Doskonałości Europejskiej Fundacji Zarządzania Jakością (EFQM). Porównano te organizacje i pokazano, jak ich systemy zarządzania jakością wpływają na wyniki MDP. Badane firmy to genXone S.A., która jest w trakcie wdrażania systemu zarządzania jakością zgodnego z normą ISO 13485:2016 oraz Centrum Genetyki Medycznej GENESIS Sp. z o.o., certyfikowane wg ISO 9001:2015 od 2018 roku. Obie firmy należą do branży sekwencjonowania w Polsce, wykorzystującej sekwencjonowanie nowej generacji. Badanie to pokazuje, że firma, która wdrożyła swój system zarządzania jakością i w pełni przyjęła swoje standardy, osiągnęła wyższy poziom doskonałości niż firma, która dopiero rozpoczęła proces wprowadzania swojego systemu zarządzania jakością.