



Implementation of ISO 9001 in SMEs: A Systematic Literature Review

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Abstract—This research aims to determine the implementation of ISO 9001 by SMEs to obtain information about the current trend of implementing ISO 9001 in obtaining certification. This study uses a systematic literature review analysis to identify, evaluate, and interpret the findings of primary studies from Scopus and Science Direct indexed publications in the last 10 years. Research on the application of ISO 9001 to SMEs mostly focuses on the benefits of implementation, certification, models of implementation, locus of application, and the latest version of QMS for SMEs. The model for implementing ISO 9001 in SMEs is related to models of fuzzy sets, genetic algorithms, decision-making, benchmarking, and quality control processes in the manufacturing industry. There is a sizeable gap between Small and Medium Enterprises and Large Enterprises in implementing ISO 9001. The more relevant difficulties experienced by SMEs in implementing ISO 9001 are top management commitment, performance measurement, and lack of customer interest in ISO 9001.

Keywords — quality management system, ISO 9001, SMEs

I. INTRODUCTION

ISO 9001 is an international standard set by the ISO, used as the most popular Quality Management System (QMS) internationally and most widely implemented by organizations [1]. For acceptance and recognition in international trade, the Standard Development Organization (SDO) has adopted this standard identically to become a national standard. It has become the Standar Nasional Indonesia (SNI) ISO 9001:2015 in Indonesia. Adopting this standard in an organization's quality management system encourages its application level through a process approach at every stage of work [2]. Implementing ISO 9001 provides better insight into company operations with accurate and comprehensive process control as a prerequisite for business management and optimization of organizational performance. The needs of customers and all stakeholders, including meeting government regulations, is the main goal of implementing ISO 9001 organizations [3].

In 1987, the ISO 9001 standard was first developed, adopted from the UK Standard BS 5750, which has three system models that can be adapted to the organization's scope. [2]. Next is the second version in 1994, the third version in 2000, and the fourth version in 2008, and the last version is

version 2015 (ISO 9001: 2015). ISO 9001:2008 is more customer-focused and less biased towards the manufacturing sector [1]. In contrast, the 2015 version combines a process approach with risk-based thinking, using the Plan-Do-Check-Act cycle at all organizational levels [3]. In ISO 9001, organizations must follow quality management principles to ensure quality products or services. The scope of the ISO 9001 standard is a process and evidence-based approach that focuses on customers, employee engagement, and relationships with other stakeholders [4].

ISO 9001 plays a role in helping organizations carry out quality system documentation that applies to all types of industries or organizations, all types and quantities of products, both goods and services, including small and medium enterprises [3]. ISO 9001 is beneficial for SMEs to help improve organizational effectiveness, minimize risk and costs, and increase customer satisfaction and trust from related parties [5]. The implementation of ISO 9001 by SMEs also provides economic and financial benefits [6][7][8]. Quality management is an important aspect of the organization, so many organizations apply and certify the products or services produced. The benefits obtained when implementing ISO 9001 make SMEs increasingly trying to meet customer needs by delivering high-quality products [9].

However, some researchers are not convinced by the positive relationship between the implementation of ISO 9001 and the benefits obtained and express suspicions that the effect of ISO 9001 certification practices is unclear or absent [10]. Certification activities and compliance with ISO 9001 standards require time, energy, and organizational resources [9]. There are obstacles in the successful implementation of ISO 9001 related to demands for time, money, high costs, documentation, and human resources, which can damage the efficiency of the standard and increase the risk of its use [11]. The paradox of the benefits of implementing ISO 9001 makes it an interesting issue to study in the future [12]. The financial benefits of ISO 9001 certification are not convincing; some SMEs report no financial benefits, and some report that the financial benefits are indirect and intangible [13]. SMEs that cancel ISO 9001 certificates or do not carry out maintenance and re-certification indicate that SMEs do not receive sufficient benefits plus the high cost of maintaining ISO 9001 certification, consisting of annual fees for management system certification bodies, quality management system consultants,

and special staffing needs [14]. It has not been studied and explored in depth regarding the main issues of implementing ISO 9001 and its certification [9].

Empirical evidence regarding the implementation of ISO 9001 by SMEs needs to be recognized because SMEs have a major influence on economic and social development. In Indonesia, significant economic growth cannot be separated from the role of small and medium enterprises (SMEs) supporting export and import growth. SMEs in Indonesia have an influence of 61.1% on GDP, with the percentage of business actors at 89% nationally [15]. Meanwhile, the contribution of the movement of micro-scale businesses to the Gross Domestic Product (GDP) in 2020 was only around 37.3%, a decrease of up to 38.14% compared to the previous year [16].

This paper presents a qualitative approach using an in-depth literature study to investigate the implementation of ISO 9001 by SMEs so that information is obtained about the current trend of implementing ISO 9001 in obtaining certification. There are limitations and gaps in the literature discussing the application of ISO 9001 specifically to SMEs. The authors highlight these factors, helping to prepare SMEs as future users of standards to better benefit from implementing standards.

II. METHOD

This research uses Systematic Literature Review (SLR) analysis to identify, evaluate, and interpret the findings of primary studies. The systematic review is very useful in

synthesizing various relevant research results. A systematic literature review aims to integrate the research results that have been done so that clear facts and information are obtained. An analysis was performed on the metadata (meta data-analysis/MA) to provide an aggregate description of how the academic results on implementing ISO 9001 in SMEs have progressed, which papers and authors are more prominent, how they are connected by the citations they share, and how they answer research questions. The metadata used is from articles indexed by Scopus and Science Direct in the last 10 years (2013-2022) by analyzing many articles on a subject, author, title, keywords, abstract, and references. Statistical analysis of data collected using the VOS viewer application. The aim at this stage is to obtain a comprehensive view and overall reliability of the literature review results [17]. Meta-analysis is also a way of synthesizing findings using quantitative techniques [18].

III. RESULTS AND DISCUSSION

In the early stages, metadata analysis was carried out by applying ISO 9001 to documents published in Scopus and Science Direct within the last 10 years of publication, from 2013 to 2022. The search results used the keywords "ISO 9001 AND SME OR SMEs OR Small Medium Enterprise OR Small Medium Enterprises" in titles, abstracts, and keywords with document types being journals and international conference proceedings, including review articles in them, to obtain 158 publication documents indexed by Scopus and 9 documents indexed by Science Direct. A summary of the metadata is presented in Table 1.

Table I. Summary Of Meta Data

No	Year	Country	Subject area	Journal
1.	2022 (11)	Greece (10)	Business, Management, Accounting (58)	Total Quality Management And Business Excellence (11)
2.	2021 (11)	Portugal (10)	Engineering (44)	International Journal Of Quality And Reliability Management (6)
3.	2020 (11)	Italy (7)	Decision Sciences (20)	International Journal For Quality Research (4)
4.	2019 (8)	Poland (7)	Computer Science (17)	International Conference On Quality Engineering And Management (3)
5.	2018 (14)	Brazil (6)	Social Sciences (7)	TQM Journal (3)
6.	2017 (11)	Spain (6)	Economics, Econometrics and Finance (6)	ACM International Conference Proceeding Series (2)
7.	2016 (9)	Germany (5)	Environmental Science (5)	Benchmarking (2)
8.	2015 (12)	India (5)	Materials Science (5)	Fibres And Textiles In Eastern Europe (2)
9.	2014 (10)	Indonesia (5)	Mathematics (5)	International Journal Of Automotive And Mechanical Engineering (2)
10.	2013 (7)	Morocco (5)	Chemical Engineering (4)	International Journal Of Industrial Engineering And Management (2)

There is a lot of research on implementing ISO 9001 by SMEs with an average of 10 publications in the last 10 years. Greece was the country that conducted research and publications, while Indonesia was in 9th position with 5 studies. The subjects that are the most research areas are business, management, and engineering-related accounting. The application of standards in Indonesia is due to having a legal basis related to standardization and conformity assessment, including the organization responsible for managing them. Implementing this standard is also supported by the total number of businesses in Indonesia, which was recorded at 26,422,256 businesses spread across 13 business categories and divided into SMEs of 26,073,689 businesses and Large Medium Enterprises of 348,567 businesses. [19].

The existence of a government organization that manages standardization activities, including the implementation of ISO 9001 and the potential of implementing organizations, makes the application of ISO 9001 a strategic research object.

Figure 1 and Figure 2 show the number of documents from each author and each affiliation. The author's data shows that nothing is dominant or prominent in a writer who publishes research on applying ISO 9001 to SMEs. Slightly different for affiliates. There is one affiliate that is most dominant with more publications, but not much different from the ranking below it. One author or affiliation does not dominate research on applying ISO 9001 to SMEs, although some publications have more citations than others.

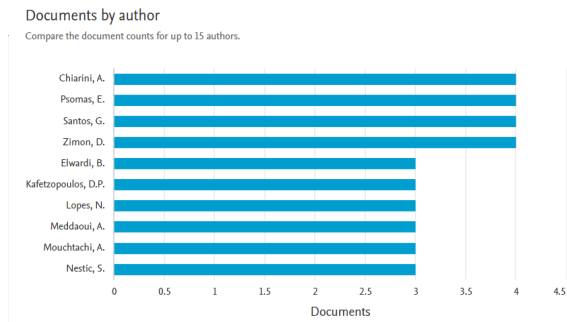


Figure 1. Number of published documents by author

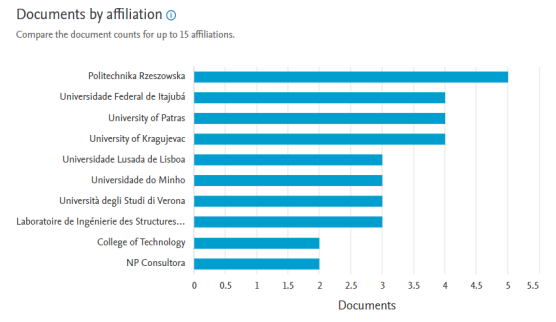


Figure 2. Number of published documents by affiliation

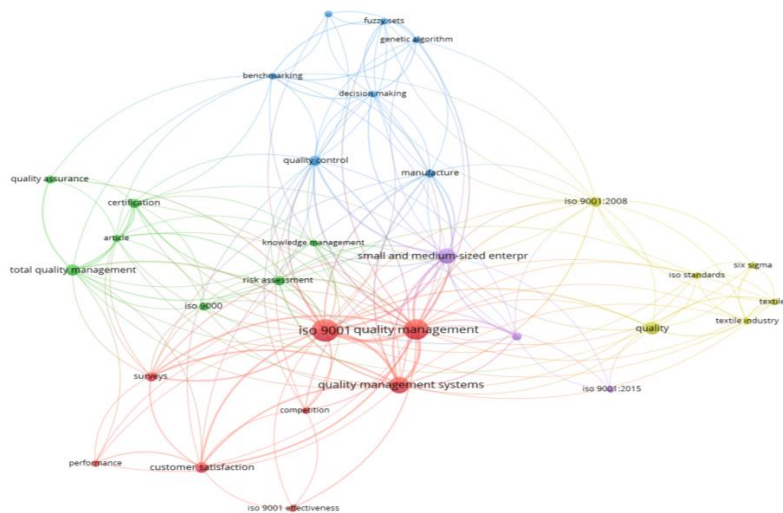


Figure 3. Linkage of research keywords in ISO 9001 on SMEs

The next analysis is grouping keywords in clusters to determine the linkages between studies. The result is 5 main clusters, which are shown in different colors. The first cluster is indicated by a red cluster related to the benefits of implementing ISO 9001. Then, the purple cluster relates to the latest QMS and SME implementation versions up to the last. Each cluster has keywords from a publication of research results connected to the others through citations, including the relationship between publications between clusters. Based on Figure 3, out of 167 research publication documents, are 31 keywords used by at least 4 publications, divided into 5 clusters and 180 networks.

The first cluster with red nodes symbolizes or is related to the benefits of implementing ISO 9001 standards, namely

business competition, customer satisfaction, organizational effectiveness, and performance, as a quality management tool and quality management system. Implementing ISO 9001 by SMEs provides benefits related to the economy, both tangible and intangible, in the form of business profits [7]. The main benefits SMEs get from ISO 9001 certification are better working conditions, compliance with laws, and better internal communication about risks and hazards [5]. Implementing ISO 9001:2008 standards influences the successful implementation of Lean Six Sigma (LSS) as a quality management system [1]. ISO 9001-certified SMEs benefit from improving quality, productivity, personnel participation, efficiency, product image, and market share [13]. ISO 9001 certification is useful for removing many barriers preventing them from entering and expanding the market [20].

Table II. Grouping of Keywords According to Cluster Ties

No	Cluster 1 (Red)	Cluster 2 (Green)	Cluster 3 (Blue)	Cluster 4 (Yellow)	Cluster 5 (Purple)
	Benefits of implementing ISO 9001	ISO 9001 Certification	ISO 9001 Implementation Model	QMS variants and locus of application	The latest version of QMS and SME implementation
1.	Competition	Article	Benchmarking	ISO 9001:2008	ISO 9001:2015
2.	Customer satisfaction	Certification	Decision making	Iso standard	Risk management
3.	ISO 9001	Iso 9000	Fuzzy sets	Quality	SMEs
4.	effectiveness	Knowledge management	Genetic algorithm	Six Sigma	
5.	Performance	Quality assurance	Key performance indicator	Textile industries	

No	Cluster 1 (Red)	Cluster 2 (Green)	Cluster 3 (Blue)	Cluster 4 (Yellow)	Cluster 5 (Purple)
	Benefits of implementing ISO 9001	ISO 9001 Certification	ISO 9001 Implementation Model	QMS variants and locus of application	The latest version of QMS and SME implementation
6.	Quality management	Risk assessment	Manufacture		
7.	Quality management systems	Total quality management	Quality control		
8.	surveys				

The second cluster, with the green color node, relates broadly to ISO 9001 certification. ISO 9001 certification has been carried out by millions of organizations around the world [14]. Certification is an acknowledgment by a management system certification body for implementing ISO 9001 by an organization, usually in the form of a certificate [21]. ISO 9001 certification for SMEs benefits SMEs' value and image [22]. Good knowledge management in the implementation of ISO 9001 has an impact on sustainable SME performance [23]. The knowledge base of SMEs can enhance sound decision-making and contribute to sustaining and expanding competitive advantage sustainably based on proper knowledge management. [24].

The third cluster with a blue node color relates to the model or framework for implementing ISO 9001. Integrating lean manufacturing with ISO 9001 and VDA.6 norms can be used as a model for implementing ISO 9001, especially for SMEs with difficulty implementing [25]. Applying ISO 9001 to SMEs can improve quality, gain competitiveness, and overcome adversity [26]. QMS ISO 9001:2008 in SMEs, if assisted by a decision support system to create awareness and control, will result in quality improvement throughout the organization [27]. The use of software tools to automate the process of documenting and generating reports in a quality

management system can help decision-making to improve the overall performance of ISO-certified SMEs, increasing the performance of SMEs by 10% [28]. A new fuzzy model is proposed for evaluating and improving the quality of processes based on ISO 9001 [29].

The fourth cluster relates to variants and locations of implementation of ISO 9001, which are marked with yellow nodes. ISO 9001 applies to all types of industries or organizations, both goods and services, including small and medium enterprises [3]. ISO 9001 certification improves company performance, regardless of geographic location, industry, or size [30]. At the same time, the latter is a cluster with purple nodes related to the latest version of QMS and SMEs. ISO 9001:2015 is the latest quality management system standard update with the main update regarding aspects of the organizational structure as the High-Level Structure (HLS) [23]. Risk-based thinking (RBT) is required in implementing ISO 9001:2015 [31]. Although the implementation of ISO 9001 provides benefits for SMEs, SMEs face several obstacles and challenges. The obstacles are the lack of resources and knowledge, and the environment and work organization are not supportive, work methods and product quality are still low [32].

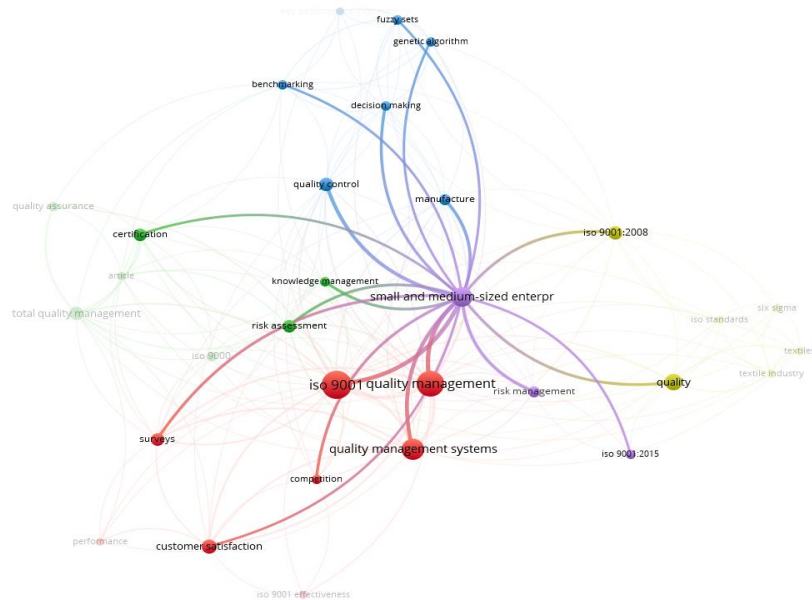


Figure 4. Position of SMEs in ISO 9001 research

Implementing ISO 9001 in SMEs is the object of research related to all clusters. Regarding the first cluster (benefits of implementing ISO 9001), the application of ISO 9001 to SMEs is related to business competition, customer satisfaction, and implementation of Quality Management

Systems (QMS). The second cluster (ISO 9001 certification) relates to certification activities or processes, risk assessment, and knowledge management. Whereas in the third cluster (ISO 9001 implementation model), SMEs' application of ISO 9001 is related to models of fuzzy sets, genetic algorithms,

decision-making, benchmarking, and quality control processes in the manufacturing industry. The last cluster (variant of QMS and locus of application) related to SMEs' implementation of ISO 9001 is the quality aspect and the version of ISO 9001 in 2008. Related to the model or framework for implementing ISO 9001 by SMEs, the use of fuzzy sets and genetic algorithm approach in implementing ISO 9001 in SMEs can provide an assessment of the quality of the production process, ranking indicators, optimization, and provide a basis for the success of improving the quality of the production process [33]. The effectiveness of implementing ISO 9001 in SMEs can be assessed from the aspects of continuous improvement, prevention of non-conformities, and customer satisfaction [26]

There is a sizeable gap between Small and Medium Enterprises and Large Enterprises in implementing ISO 9001 [34]. Company size affects the level of implementation of ISO 9001, for large companies usually get better results with greater tolerance for change due to the introduction and maintenance of QMS. In contrast to SMEs, the implementation level will be challenging and have constraints. Large companies have greater importance for ISO 9001 certification, namely for managerial and marketing. Whereas for SMEs, it is more towards achievement badges, not yet being used as a managerial and marketing tool.

One of the forms and evidence of the implementation of ISO 9001 is an internal audit activity to assess the level of implementation of ISO 9001 by an internal organization. This audit aims to measure performance and will become a problem when considered only an administrative and bureaucratic activity [14]. More relevant difficulties SMEs experience in implementing ISO 9001 are top management commitment, performance measurement, and lack of customer interest in ISO 9001 [35]. Reduced customer interest in ISO 9001-certified suppliers because certification does not automatically translate into providing a quality product or on-time delivery [14]. Quality issues are important for achieving competitiveness in providing products and services to consumers [3].

IV. CONCLUSION

The implementation of ISO 9001 provides benefits for SMEs both internally and externally. Even so, in some cases, the benefits for SMEs are not obtained, and it is unknown that it even becomes a business burden for SMEs. Research on the application of ISO 9001 to SMEs mostly focuses on the benefits of implementation, certification, models of implementation, locus of application, and the latest version of QMS for SMEs. The model for implementing ISO 9001 in SMEs is related to models of fuzzy sets, genetic algorithms, decision-making, benchmarking, and quality control processes in the manufacturing industry. The use of fuzzy sets and a genetic algorithm approach in implementing ISO 9001 in SMEs can provide an assessment of the quality of the production process, rank indicators, optimize, and provide a basis for the success of improving the quality of the production process. There is a sizeable gap between Small and Medium Enterprises and Large Enterprises in implementing ISO 9001. The more relevant difficulties experienced by SMEs in implementing ISO 9001 are top management commitment, performance measurement, and lack of customer interest in ISO 9001.

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