Design and Development through Quality Management System – An Empirical Study Conducted in 385 Companies in Ten Countries

Karri Naveen, Research Scholar, Department of Mechanical Engineering, Lincoln University College, Malaysia
Research Supervisor: Prof. Dr. Rohan Senanayake, HOD Mechanical Engineering, Lincoln University College, Malaysia

Abstract — An empirical research study was conducted to determine the conformance to the Design and Development criteria of the Quality Management System among 385 organizations in ten countries. This kind of evidence based cross country meta-analysis is meager and hence an attempt has been made to fulfill this gap.

This Research Study is predominantly based on Primary Data collected by auditing 385 organizations spending 577 Mandays onsite by Interviewing, Observation and verifying Documented information.

If majority of the engineering firms adopt the requirements of Design and Deveopment as far as resanably practicable then producing world class products by MSME would not be impossible.

Index Terms— *Conformance, Design & Developmen, ISO 9001, Quality Management System*

1 INTRODUCTION

The yearly ISO Survey of Management Systems Certifications for the Year 2019; demonstrate that there are 883 521 legitimate ISO 9001 certificates issued worldwide by the certification bodies accredited by the IAF MLA Members. A slight addition of 0.5% was recorded in issuance of ISO 9001 Certifications worldwide when contrasted with the Survey aftereffects of earlier year because of non cooperation of some significant accreditation bodies in the 2019 study. Sector wise data indicate that the highest number of certificates issued were in "Basic Metal & Fabricated Products" industry under EA Code 17. This research study is inspired by the enourmous ISO 9001 certifications issued to mechanical engineering industries.

This research study is conducted to determine degree of conformance with the Design and Development criteria as per ISO 9001. An IRCA Audit Log is maintained duly endorsed by Certification Body and the individual Client as an objective evidence of on location visit to 385 organizations in ten nations. The Researcher had the applicable competency according to the EA Codes granted by the designated Certification Bodies working under the rules of Accreditation Bodies and International Accreditation Forum structure.

2 LITERATURE REVIEW

Very little exploration and examination has been done to decide the conformance to the necessity of Design and Development as per ISO 9001. A few Researchers have examined the advantages and effects of ISO 9001 accreditation.

Author	Description of research area	Year
Fonseca & Domingues	ISO 9001 provides universal recognition for business	2017
Fonseca	Correlation established with success of business	2015
Chatzoglou et al	ISO 9001 contribute to performance of organization.	2015
Tarí et al. and Boiral	state benefits of ISO 9001	2012
Zaramdini	identified benefits of ISO 9001.	2007
Douglas et al.	state that ISO 9001 help in marketing process.	2003
Casadesús et al.	ISO 9001 have internal and external benefits.	2000

RESEARCH GAP

There is a lack of research studies investigating the degree of conformity to Design and Development as per ISO 9001 from an Auditor's perspective and this research study aims to fulfil this gap.

RESEARCH METHODOLOGY

This research study began with the through review of Design and Development requirements in accordance with ISO 9001. A structured assessment was conducted in accordance with auditing techniques as per ISO 19001. This research work is descriptive by nature and predominantely based on primary source of data. To justify the study the researcher has considered the time period from year 2010 to 2020 and spent 577 mandays of auditing on site and gathered the research data through observation, interview and document verification.

An independent and impartial audit was conducted on a Sample size of 385 companies in UAE, Oman, Kingdom of Saudi Arabia,

India, Qatar, Kuwait, Malaysia, Australia, Bahrain & New Zealand. A five point Likert scale is adopted to determine the conformity against the Design and Development criteria determined in ISO 9001.

RELIABILITY ANALYSIS

Reliability analysis for 52 conformity assessment criteria was mapped against the 5 point Likert scale to determine the consistency. Cronbach's alpha indicate the conformity assessment to reach acceptable reliability with high consistency (α = 0.948).

Scale Reliability Statistics

	Cronbach's α
scale	0.948

RESULTS

Jamovi 1.2.27 open source software is used to analyse the research data. The results of the descriptive statisticsal analysis indicate the degree of conformity to the requirements of the Design and Development of ISO 9001 standard.

Fig.1 indicates the average value of Design & Development Variable is observed 3.89 due to the fact that; 164 out of sample of 385 companies have claimed exclusion for design and development criteria.

Fig. 1, Design & Development Applicability in Sample Size of 385 Companies

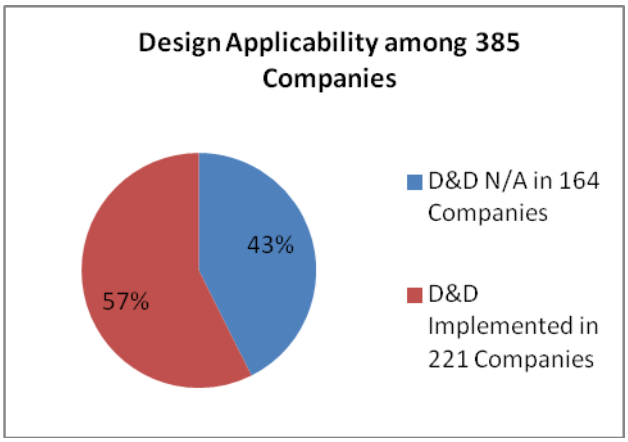


Table-2 indicate; In the Likert scale the degree of conformity to the requirements of Design & Development indicate that the least rating is 3 which contribute to 33.5%, rating 4 contribute to highest 43.1% and highest rating is 5 which is only 23.4%.

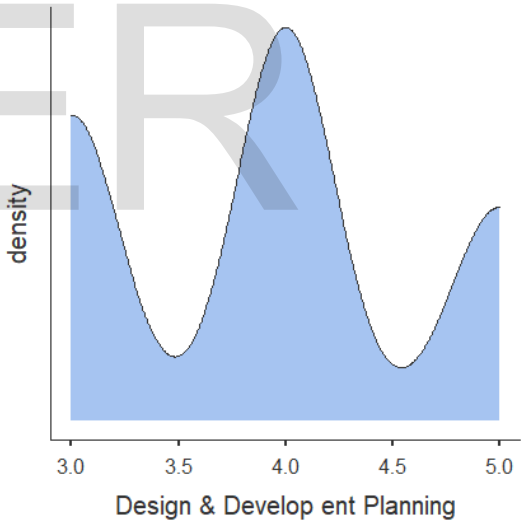
Table-2, Frequency

Frequencies of Design & Development Planning

Levels	Counts	% of Total	Cumulative %
3	73	33.5 %	33.5 %
4	94	43.1 %	76.6 %
5	51	23.4 %	100.0 %

Graph-1 indicate the density dispersal spread in 5 point likert scale to determine the degree conformance to the Design and Development requirements. The highest rated conformity assessment variable was"CA8.3 – Design & Development" (Average: 3.899083; Median: 4; Standard Deviation: 0.749131). Missing value indicate that the organizations sought Exclusion for the Design & Development and is not applicable to their quality management system.

Graph-1, Density of Design and Development



CONCLUSION

In order to maximize the benefit of implementing the Quality Management System in accordance with ISO 9001; engineering companies should invest in "Design and Development" and adopt the requirements of the standard instead seeking exclusion. Should ISO 9001 Standard make the Design and Development requirement mandatory for engineering companies then even MSME's can make world class products.

Scope for Future Work

This research study is supported by data gathered from a sample

size of 385 companies from ten countries, additional data collection could be carried out from other parts of the world in order to ascertain to what extent these conclusions are valid across the globe.

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