



ISO 9001:2008 Implementation In a SME: A Case Study

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ABSTRACT

ISO 9001:2008 Quality Management Systems (QMS) standard was published as a standard that contains the requirements which an organization needs to fulfil to achieve customer satisfaction through consistent products and services that meet the customers' requirements. The standard accreditation allows the companies regardless of its size, type and product or service to compete in the business. However, most of the standard's implementation models developed focused on large organizations structure. Thus, there is a need for a suitable model to guide small and medium enterprises (SMEs) in implementing ISO 9001:2008. By referring to available published models and framework, eliminating some unnecessary steps and simplifying available implementation processes; this paper provides a simple yet practical model for SMEs to start their quest towards accreditation. The model covers all eight QMS principle in ISO 9001:2008. The model was then implemented as a case study research in one SMEs' company in Malaysia. The result shows that the model is practical as it helps the company to achieve ISO 9001:2008 accreditation.

Keywords: Case Study; ISO 9001:2008, implementation model, Malaysia, SME

INTRODUCTION

Putting quality first is fundamental to the long-term survival of every company. Therefore, quality has emerged as a strategic competitive tool for organizational success (Magd & Curry, 2003). However, many companies have failed in competitive

market because they have neglected quality management system (QMS) in favour of fast delivering of product. Many failed to understand that inspection and examinations do not create quality, but quality is built during the product development process by having a good QMS. Companies with effective QMS will not only have a structured product development process but also production system and marketing process. Based on the situation, various standards were introduced as a benchmark of good QMS. The standards act as objective

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evidence to customers to show how well the company performs in producing and maintaining high quality products.

One of the standards for QMS is ISO 9001:2008 (referred as ISO 9001 throughout this paper). It is one of the ISO 9000 series of standards that formalizes systems to evaluate the ability of an organization to consistently design, produce and deliver quality products and services (Magd and Curry, 2003). This standard is the revised version of ISO 9001:2000 produced by the International Organization for Standardization (ISO). The focus of this new version is on its application for all organizations regardless of the size.

The standard consists of eight QMS principles which reflect the management's best practice and is designed to enable a continual improvement of the business, its overall efficiency and its capability in responding to customers' needs and expectations. The eight principles are:

1. Customer focus
2. Leadership
3. Involvements of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approaches to decision making
8. Mutually beneficial supplier relationships

The first QMS principle emphasis the importance of organizations to understand current and future customer needs so that these organizations can meet the

requirements in their operation and also strive to exceed the customer expectations. The understanding should be portrayed in the company's policy and objectives. Then, the leadership as the second QMS principle highlights the role of leaders in establishing unity of purpose and direction of the organization. Effective QMS only happens with good leadership especially from the top management in the company because top management has the authority to ensure that all ISO 9001's requirements are implemented.

The standard also regards the involvements of people at all levels as the essence of an organization. This third principle emphasized the employees' full involvements in implementing ISO 9001 and their contribution to the organization's benefits. The fourth QMS principle is about a structured process approach in management. This is because a desired result is effectively achieved when operating and production activities and related resources are properly managed. The fifth principle is system approach to management in QMS. In order to be accredited with ISO 9001, the process of identifying, understanding and managing system needs to be structurally implemented so that it helps the organization in achieving its policies and objectives.

The sixth principle in QMS is the continual improvement of the organization's overall performance. Every company accredited with the ISO certification will undergo yearly audit to check the management system; therefore, it is important for the company to make

continuous improvement as its permanent objective. The seventh principle is about the factual approaches to decision making. This is important because effective and reliable decisions can only be achieved based on logical and intuitive analysis of data and information gathered in the organization. Then, the final principle emphasized in ISO 9001 is the mutual beneficial supplier relationship. This principle is required in QMS because the organization and its suppliers are interdependent, thus both should enhance their ability to create high quality product and the lowest price possible.

There are about 158 countries adopting the standard, thus it allows companies around the world to work together in manufacturing good quality product without worrying the standard of management system at their acquaintance even though the other companies are situated in other regions or countries (International Standard Organization, 2006). The collaborations are usually conducted to expand businesses and minimize transportation cost especially for products. Therefore, in order to choose reliable acquaintance, companies can check whether other companies are accredited with ISO 9001 or not. As mentioned, the standard also enables small and medium enterprises (SMEs) to compete with bigger organizations in the business by having recognition for their QMS.

However, most ISO 9001 implementation models developed in books or journals addressed large company culture and work structure. ISO 9001 researchers

and consultants usually provide a rigid and lengthy generic documentation programme or computerized system which is suitable with various departments and job scopes in large companies. Here, problems that may occur are, guidelines suggested by the consultants are too complicated, as most of them are based solely on their experiences in big companies, giving little idea to SMEs how the implementation really work.

The other critical issue that will have to be considered when discussing the ISO 9001 implementation is the fact that ISO 9001 consists of sets of requirements, thus there are different approaches that could be used to meet the requirements of each element in the standard. SMEs characteristics are different in comparison with large organizations structure, systems, procedures, culture, behaviours, human resources, market and customers (Abdul-Samat & Kamaruddin, 2006; Yusof & Aspinwall, 2000a, 2000b, 2001). However, it does not mean that SMEs need to do major changes in their management system to comply with the requirements. The SMEs only need to adapt their system according to ISO 9001 requirements. In doing so, they need a simple and concise implementation model as a guideline to fulfil the requirements and get accredited.

In some cases, SMEs assign the whole responsibilities of their ISO 9001 implementation process to consultants. This happens because they do not understand their own capabilities or advantages and they do not have simple implementation model to refer to. The situation becomes

a great squander to SMEs in ISO 9001 implementation. Therefore, this paper is written with an aim to develop a simple and concise model that will help SMEs to implement ISO 9001. The focus is to tailor the SME's culture and structure to satisfy the ISO 9001:2008 requirements. The model is developed to assist SMEs to be accredited with the standard. The standard is a proof that a company has a good QMS and is capable in producing high quality products or services. This will allow SMEs to compete with large companies in their business area.

SMES AND ISO 9001:2008

There is no specific definition for small and medium enterprise (SME) yet most countries segregate the companies not based on their profit margins but based on the number of workers employed. For the U.S. Department of Commerce, SMEs are companies with 500 and below workers (Callaghan & Schnoll, 1997). For

Aldowaisan and Youssef (2004), companies with less than 100 workers are considered as small companies. The National SME Development Council in Malaysia has classified SME into three distinctive groups as in Table 1. The classification is based on the organization's annual turnover and/or number of employee, whichever is lower (SME Bank, 2009).

The primary difference between large and small companies culture is its management's role and involvement (Berg & Harral, 1998). Typically, the characteristics of the top management of an SME are:

1. Has greater interest and control of the firm through an ownership position.
2. More involved with daily operations in all areas.
3. Knows all employees and their strengths and weaknesses.
4. Understands, and can often perform, all activities or processes.

TABLE 1
SME Table 1: SME businesses classification in Malaysia based on annual turnover (Sources: <http://www.smebank.com.my>)

Size	Manufacturing	Services
Medium	More than RM 10 million – RM 25 million, OR Between 51 – 150 full-time employees	More than RM 1 million – RM 5 million, OR Between 20 - 50 full-time employees
Small	RM250,000 – RM 10 million, OR Between 5 - 50 full-time employees	RM200,000 – RM 1 million, OR Between 5 – 19 full-time employees
Micro	Less than RM 200,000, OR Less than 5 full-time employees Minimum RM 20,000 loan Funded by Special Programmes Deployed with partners/Agencies	Less than RM 250,000, OR Less than 5 full-time employees Minimum RM 20,000 loan Funded by Special Programmes Deployed with partners/Agencies

5. Knows the customer's representatives and understands customer needs and quirks.
6. Knowledgeable about the relative strengths and weaknesses of the firm's products/services as well as its competitors.

From these points, it can be summarized that the management in SMEs are experts of their system and have the authority over all operation unlike the management in large organizations that only know their own scope of work. Aldowaisan and Youssef (2004) stated some fundamental ways that the SMEs differ from large organizations. The first difference is the scope of SMEs is usually limited in terms of products/services, geographic location, market/customer base and technology used in operation. This is because SMEs have inadequate resources like money and employees. However, every employee in SMEs especially at the supervisor or managerial level is considered valuable. Their departure can cause disruption in operation for the reason of lack of employee to replace them.

Aldowaisan and Youssef (2004) also mentioned that there are typically no employees or departments with the exclusive responsibilities in SMEs. Every employee usually knows the whole SMEs operations and has no specific job description. It is different with large organizations which have various departments and every employee is assigned for specific tasks. Nevertheless, research done by Poksinska *et al.* (2006) showed that SMEs share the same

benefits as the large companies do in terms of the internal benefits: improved quality and management control, increased quality awareness, reduced poor quality costs and for external benefits: improved company's image and ISO 9001 standards accreditation as a marketing tool.

A survey conducted by Idris *et al.* (1996) showed the reasons which initiate the implementation of the ISO standards in Malaysian SMEs. The most important reason was a need to improve their business performance so they can be more competitive. Another reason was because ISO 9001 is a part of total quality management (TQM) which is widely implemented in large and successful companies. SMEs in Malaysia also implement ISO 9001 as demanded by the customers who want an objective proof that the company is producing good quality product or services in effective QMS. Aside from that, the implementation is conducted because ISO 9001 is accepted as good practice in the industry and their competitors are already certified.

Bayati and Taghavi (2007), Zaramdini (2007), and Singh and Mansour-Nahra (2006) conducted researches about the ISO 9000 certification in Tehran, Australia and United Arab Emirates respectively. These survey based-researches focused on the SME works and efforts to implement the ISO standards and the benefits from their work. The researches proved that the ISO accreditation can improve business and quality, reduce cost, and provide proper use of resources, resulting in a complete documentation and standardization of

procedures, while increasing customers' satisfaction to the SMEs at the same time.

Concerning the ISO 9001 implementation, some researchers focus on the methods used during the process. In the case study conducted by Lo and Humphreys (2000) in ten companies in Hong Kong, project management techniques was applied to develop a generic project network and resources loading profile for ISO 9001 implementation. Their objective was to ensure that the SMEs can use a benchmarking approach to efficiently plan the implementation of the ISO 9001. Two project management tools used were network analysis and resource analysis.

Tsim *et al.* (2002) used management activity as the key element in a model to assist certified companies to link their concerned areas with the ISO 9001 requirements. Emphasizing on top management responsibility towards the implementation, the information was used in the analysis to determine the areas for continual improvement. The importance of management contribution and measures of business and operating performance resulting from ISO 9001 standard implementation were also emphasized in Naveh and Marcus (2005).

DEVELOPMENT OF ISO 9001:2008 MODEL FOR SMES

Tailoring SMEs Characteristic for ISO 9001:2008 Implementation

Yusof and Aspinwall (2000a, 2000b, 2001) stated that SMEs face difficulties in implementing the ISO 9001 as they did

not have sufficient knowledge about it. The SMEs also lack of strategic thinking and employees to conduct the process. Aside from that, they have inappropriate motivation because the high costs for the implementation and accreditation processes. Berg and Harral (1998) stated that SMEs usually adopt typical, large organization models for ISO 9001. They tend to buy the ready-made documentation programme because of the limited number of management personnel to handle all management tasks and at the same time plan for the implementation and accreditation.

The SMEs will purchase a generic documentation programme that only requires them to simply inserting the organization's name in ready-made forms. However, almost all purchased documentation programmes were based on large companies' models. The documentation covers almost all departments available in large organizations. Thus, these programmes can create more problems than what they can solve for small organizations because of a large number of forms and documents need to be attended to. SMEs usually do not have specific departments like purchasing, quality assurance, research and development and also safety departments. Therefore in the end, SMEs will be entangled in a web of useless documentation which is not applied to them. Some SMEs give up their implementation process when this problem occurs, making them wasting their money and effort.

Another problem is SMEs fails to determine the type of management

documents that are required by ISO 9001. Usually, SMEs already have most of the required documentation, but because the lack of understanding of the standard, their documents are not linked to ISO 9001. Actually SMEs only need to be standardized without having to totally alter their system. SMEs can actually create a customized documentation strategy that will provide them with the maximum benefit for a minimum outlay of resources. They will need documentation only to the extent that its absence adversely affects product's quality, both current and overtime. The documents bridge the gap between an activity's written requirements and the task performed. This way, activities are ensured to be conducted according to QMS in ISO 9001.

Callaghan and Schnoll (1997) suggested that with an effective use of resources and the help of experts, small companies can overcome the obstacle to obtain the ISO 9001 registration. By pooling together resources, supply chain management is better controlled and managed while providing a one-stop solution similar to larger organizations' (Sitathan, 2003). External costs associated with the implementation and registration processes are directly proportional to the company's size. Thus, the smaller the company is, the smaller the fees associated to it. It was suggested that problems like limited resources of capable employee and overlapping of responsibilities in small companies are solved by assigning external consultants towards ISO 9001 accreditation.

However, it is recommended that they do not solely rely on expert guidance like

consultants especially one who has little experience with SMEs. As SMEs depend on relatively high levels of employee empowerment, they have the ability to control their own journey towards ISO 9001 accreditations. It is vital for the SMEs to recognize this in their documentation and quality control plans to avoid further problem in the future with the ISO 9001 requirements. ISO 9001 requires a simple and concise model to give accurate information for the implementation process, trained workers to implement it, and cooperation from top to bottom management to ensure its success. All these elements should be integrated together to gain accreditations.

Model Development

To accomplish the aim in producing a model for implementation in compliance with the ISO 9001, available models in literatures are reviewed. Deros *et al.* (2006) defined a model as a set of simplified theoretical principles and practical guidelines to carry out benchmarking implementation and adoption, which can enhance the chance of success that are easy to understand, efficient and can be implemented at reasonable costs and time. According to Yusof and Aspinwall (2000a), a good model that suits the SMEs characteristics are:

- Systematic and easily understood;
- Simple in structure;
- Have clear links between the elements and steps outlined;
- General enough to suit different contexts;

- Represent a road map and a planning tools for implementation;
- Answers “how to?” and not “what is?”; and
- Implementable at reasonable cost and time.

A good model can link up the benchmarking concept and practical application because it guides the organization in adopting and implementing the activities in a more systematic, comprehensive, controlled and timely manner (Deros *et al.*, 2006). There are various implementation model and steps developed in the literatures. These divergences somehow bring confusion to some first timer in the implementation task especially for the SMEs’ representative. According to Voehl *et al.* (1994) there are only two steps necessary for achieving ISO 9001 certification; they are (1) design and implementation of a quality system that meets the requirements of the standard, and (2) a successful assessment completed by a suitable assessor body.

One example of complex implementation steps was created by Lo and Humphreys (2000). They developed a network design which consists of 27 activities starting from appointing the management representative and setting up the steering committee, up to the certification process. The activities are listed in Table 2. Another example was by Johannsen (1996) who detailed out seven stages in the preparation of QMS for a company. In the surveys done by Fuentes *et al.* (2000), 18 implementation activities were suggested to companies in pursuing ISO 9001 certification.

Yaacov (1995) provided 12 major steps to achieve certification as listed in Table 2. The author also built up an ISO 9001 project activity chart that shows the model towards accreditations as shown in Fig.1. The model has ten basic steps to implement ISO standard, starting from the act of gaining information up to registration of the standard. The model was built for the SMEs application, with a suggested third party ISO assessment.

The other model for ISO 9001 implementation was by Motwani *et al.* (1994). The implementation steps were prepared as shown in Fig.2. This model was based on a case study conducted to illustrate how a big US manufacturing organization achieved their ISO 9001 certification. Starting in January 1991, the company formed a task team at the managerial level to study the need to pursue ISO 9001 registration and finally after two years, in December 1992, the company was registered and proudly received their certificate. Since then, the company has maintained its registration, continues the internal audits and sets continuous improvement goals. As illustrated in Fig.2, there were eight major steps towards the ISO accreditation in the company.

Based on the available steps and models reviewed, a new model towards ISO 9001 accreditation was built as guidance for the SMEs to implement the ISO 9001. Focusing on a simple and practical model, the steps were developed to enable the SMEs to comply with the eight QMS elements and ISO 9001 requirements. Only the important steps for ISO 9001 accreditation

were selected from the literatures while redundant and repetitive steps were merged or eliminated. Any elaborate and complex steps were also avoided. The model is illustrated in Fig.3.

The model consists of six steps. This model focuses on the full understanding of ISO standards before choosing a suitable standard for the company. The first step is to gather as much data as possible.

TABLE 2
List of authors and suggested steps for ISO 9001 accreditation

Authors	No. of Steps	Steps
Voehl <i>et al.</i> (1994)	2	Design and implementation of a quality system that meets the requirements of the standard Successful assessment completed by a suitable assessor body
Lo & Humphreys (2000)	27	Appoint management representative (MR) and set up steering team Assessment Set up work groups Documentation Training 1 Documentation Training 2 Draft the quality assurance manual (QAM) Refine the QAM Approve the QAM Draft the company operations procedures (COPs) Refine the COPs Approve the COPs Draft the work instruction (WI) Refine the WIs Approve the WIs Awareness training Quality training ISO requirements training Internal audit training Implementation training Implement the new system Internal audit Update the procedures Restructure Implement the changes QAM review by certified body Formal audit by certified body Complete corrective action Certified by certified body
Johannsen (1996)	7	Defining scope –selection of services and/or products Definition of policy, goals and responsibilities as regards of quality Analysis of processes Choosing a focus Selection of standards and requirements Design and quality manual Drawing up procedures and instructions

Table 2 (continued)

Fuentes <i>et al.</i> (2000)	18	Creation of improvement teams Creation of evaluation and the recognition systems Creation of participatory systems Redesign and improvement of the existent documentation system Documentation of other processes not included in the ISO standard Benchmarking activities Improvement of the existing indicator's system Design of new control indicator's systems Analysis and improvement of existing processes Development of a continuous training plan for all employees Customer satisfaction analysis Employee satisfaction analysis Customer participation in product design Customer participation in the processes of production/delivery of the product Documentation and publication (internally) of goal achieved Transfer of more autonomy of employees (task control/task decisions) Co-operation with suppliers Monitoring reference models of a broader scope than ISO (e.g. European Quality Prize or Malcolm Baldrige National Quality Award)
Yaacov (1995)	12	Management commitment and ISO steering committee Assess current system and prepare implementation plan Train management, internal auditors, and documentation Begin new processes, documentation, and internal auditing Select independent third-party registrar Continue training and educate all employees on ISO 9000 Continue process, documentation, and internal auditing Pre-assessment and corrective action ISO registration assessment Corrective actions to resolve nonconformities Registration certification Periodic surveillance audits
Motwani <i>et al.</i> (1994)	8	Awareness stage Management decision and commitment Initial preparation Preparation of quality manual Pre-audit assessment Initial audit Follow-up audit and final assessment Registration

Then the fundamental step is to build up a team and educate the employees for the implementation processes. The next step is to document the company's quality management system, implement it, and validate the system by conducting internal audits. After that, the company needs to

carry out corrective and preventive action system as conducted in step five of this model. Any incompliance of the QMS should be revised from step three when documentation system is build. The final step is to prepare the company for ISO 9001 assessments before being audited and

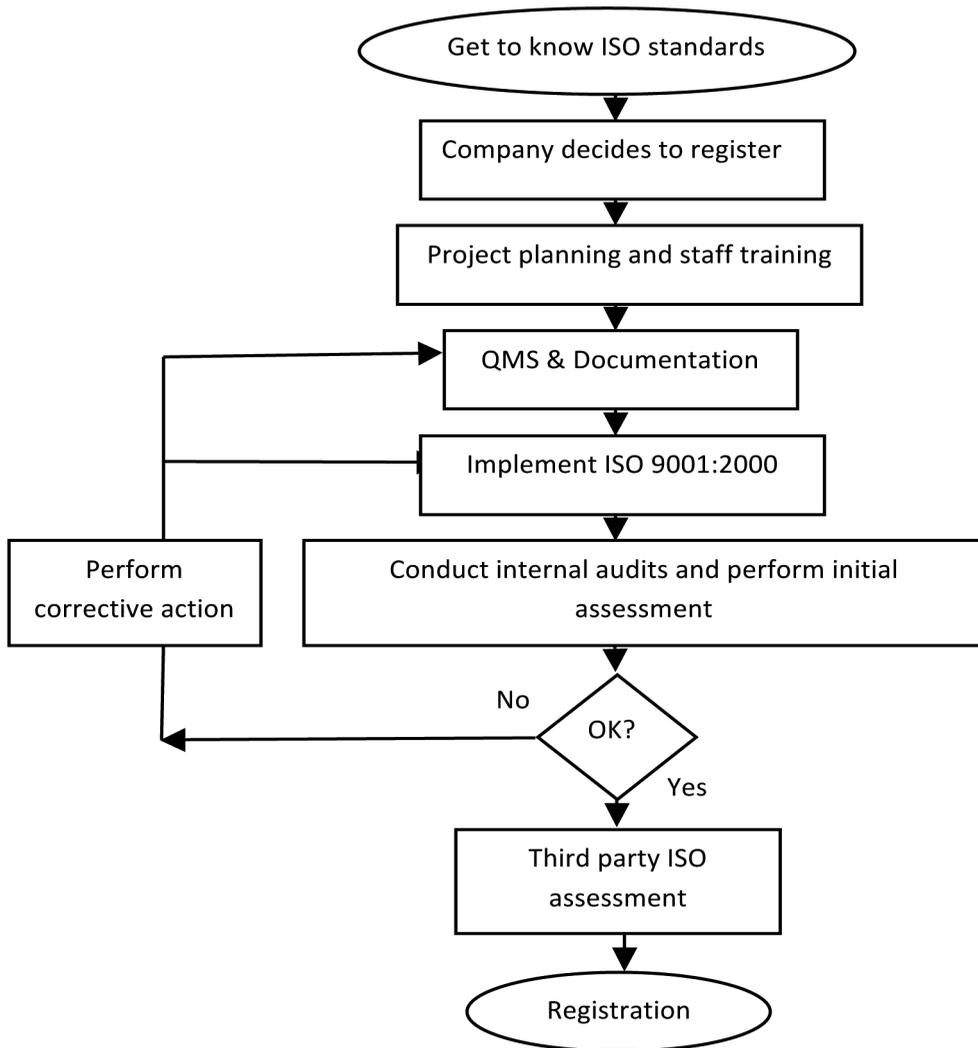


Fig.1: ISO 9001:2000 project activity chart (Yaacov, 1995)

then finally receiving the accreditation. In order to show the effectiveness of the developed model, it is adopted in one of a pharmaceutical company as a case study. Further discussions on the model and the steps involved are discussed in the next section.

ISO 9001:2008 IMPLEMENTATION PROCESS AT THE PHARMACUETICAL PACKAGING COMPANY

Overview of the Company

A case study was conducted in a pharmaceutical packaging manufacturer in east Malaysia. Incorporated in July 2005,

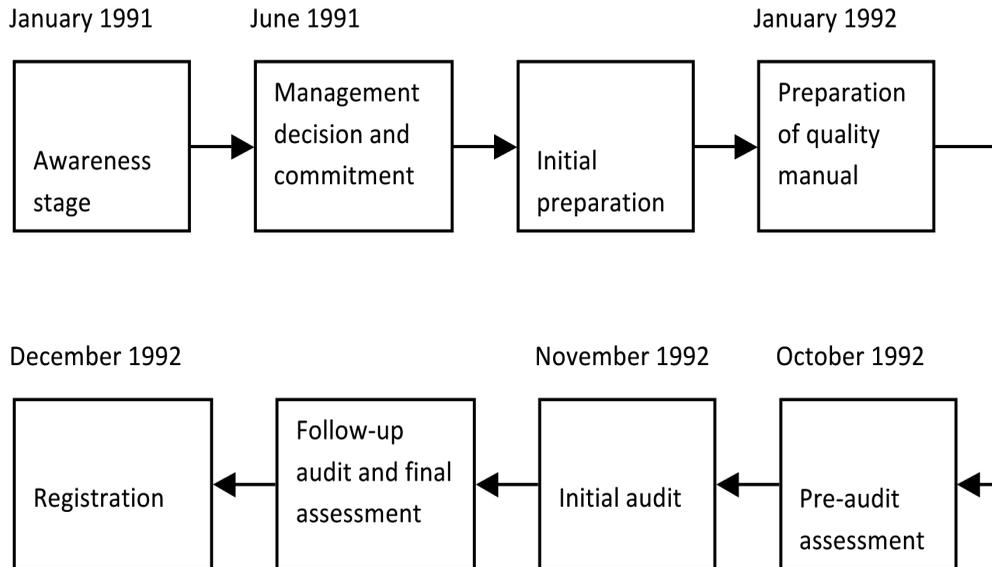


Fig.2: Model to ISO 9000 registration – by the case study corporation (Motwani *et al.*, 1994)

the company core business activity is manufacturing of pharmaceuticals plastic products like bottle, canister insert, bottle caps, and others. The main processes involved are injection moulding, blow moulding and auto-capping process. It is a small enterprise with 36 full time employees which fits the criteria of the SMEs listed in Table 1. As the number of employee is small, there are typically no specific employees or departments with an exclusive responsibility. Nevertheless, each employee understands the whole operation in the SME.

The company is responsible to supply the pharmaceuticals products to one of the ISO 9001:2008 accredited companies in Malaysia. This company has already undergone a second-party assessment conducted by their customer to ensure their management system is complied with the

ISO 9001 requirements. The second-party assessment is when the customer performs its own assessment of the supplier's quality system using the ISO 9001 criteria as a guideline and judgement. Realising the importance of the ISO 9001 accreditation and to ensure their collaboration goes well, the management decides to implement the ISO 9001 by adopting the model developed in this research.

The Implementation Process

In order to validate the effectiveness and practicality of the model developed, the model was implemented in the Production Department of the company under study.

Step 1: Get To Know ISO 9001:2008

As shown in Fig.3, the first task in implementing the ISO 9001 is to study and

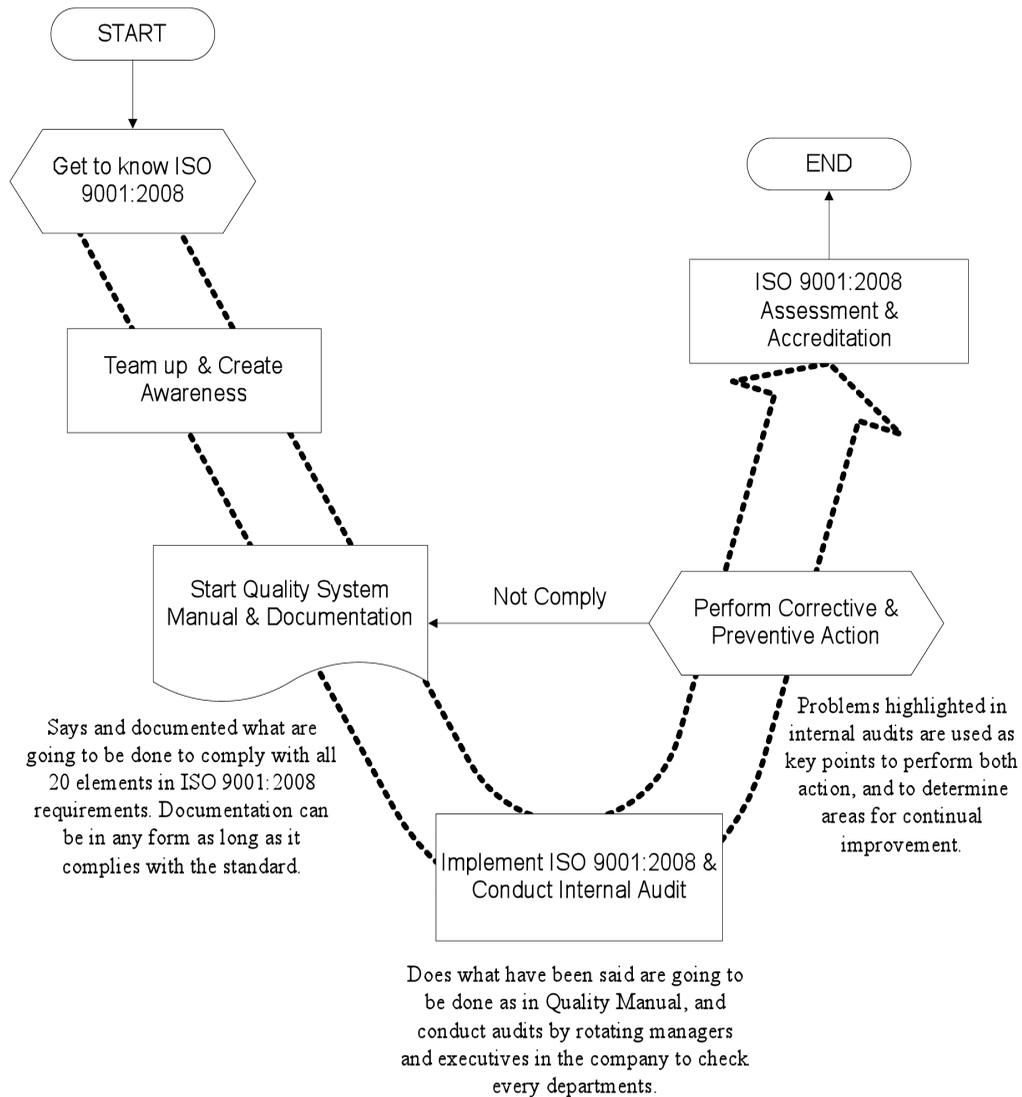


Fig.3: A model used for implementing ISO 9001:2008 in SMEs

understand the standard. The first step in the model is developed to accomplish the ‘leadership’ requirement in the ISO 9001 by focusing on commitment of the top management. The first reason why they have to commit is the need for resources like money and employee time that can only be authorized by the top management. Another reason is the leaders have to set

a positive example for the employees to follow. Thus, the top management in the company has demonstrated its commitment by being actively and visibly involved in the preparation process and being supportive for the company’s quality philosophy, quality management principles, continual improvement, and the process approach to the QMS.

In the first step, the company’s representatives which consist of one Production Manager and two Supervisors gathered information related to the ISO 9001 requirements from the internet, books and also from the International Standard Organization body available in Malaysia. They also enquired some information from consultants and registrars. The information was then organized and studied. This is to ensure they understand all requirements in the standard and the main steps in implementing ISO 9001. During this step, it is important to seek information from reliable sources like the International Standard Organization webpage and a certified company. Consequently, they know that the standard has 20 QMS elements requirements as stated in Clause 4.1 till 4.20 and as listed in Table 3.

TABLE 3
List of 20 elements of Quality Management System

ISO 9001 Clause	Elements of Quality Management System
4.1	Management Responsibility
4.2	Quality System
4.3	Contract Review
4.4	Design Control
4.5	Document & Data Control
4.6	Purchasing
4.7	Control of Customer-supplied product
4.8	Product Identification & Traceability
4.9	Process Control
4.10	Inspection & Testing
4.11	Inspection, Measuring & Test Equipment
4.12	Inspection & Test Status

Table 3 (continued)

4.13	Control of Nonconforming Product
4.14	Corrective action & Preventive Action
4.15	Handling, Storage, Packing & Delivery
4.16	Control of Quality Records
4.17	Internal Audits
4.18	Training
4.19	After-Sales Servicing
4.20	Statistical Techniques

Step 2: Team Up & Create Awareness

The second step is to form an ISO 9001 implementation team. As the company has very limited manpower, all representatives in the Production Department like production managers, supervisors and line leaders were assigned in the team. The team is named as ISO Steering Team. It also includes human resources manager as a representative from the company’s top management. The manager acts as the final decision maker in the team. Thus the implementation process is in line with the company’s policy and objectives. This gesture satisfies the QMS principle of ‘involvements of people’ **which includes employees, employers and also customers**. The team has a few important tasks. First, they develop an estimation of the effort in terms of costs for the external services and time for the internal tasks. At this point the estimation is not very precise due to many unknowns, but a range is developed within the actual costs so that the top management can understand the total cost to make a decision either to proceed with the implementation process or not.

Afterwards, the team sets an initial timetable for the project. During the implementation process, six months is allocated for the documentation processes and another two months for the auditing by the ISO 9001's consultant. Research conducted by Fuentes *et al.* (2000) stated that companies usually need six months for documentation and one month for auditing. The ISO Steering Team prepared an ISO 9001 plan covering the critical activities involved in planning, organizing, implementing, and controlling the project. The ISO 9001 standard requires controlled conditions for materials, equipments, processes, procedures, personnel, supplies, utilities and environments to produce quality products. The team spends two months on the processes.

The team's responsibilities also include:

1. Monitoring progress on the implementation plan, and making adjustment when needed,
2. Reviewing and approving policy documents and SOPs,
3. Approving proposed solutions to reduce gap in compliance,
4. Resolving operational disputes among departments and function especially during internal audit processes,
5. Reviewing and approving corrective and preventive actions,
6. Reviewing registrar proposals and selecting suitable registrar

Next, to commensurate with the decision to proceed, the ISO Steering Team begins publishing the information on ISO 9001 to all operators to create awareness. The team communicates with the operators on why their input and support is required in an attempt to enhance the quality and the ISO 9001 awareness. Aside from that, the company's Quality Policy and Quality Objectives are printed out and displayed together with some information regarding the ISO 9001 at the production floor as reminder that the company is aiming for accreditation. Since the budget allocated for training purposes is limited, managers and supervisors take advantages of their morning meeting to continuously educate the operators about the ISO 9001 while directing them to follow the company's standard operating procedures (SOPs) when carrying out daily tasks.

Step 3: Start Quality System Manual & Documentation

In the third step, the team starts to construct company's quality manual system and documentation according to the ISO 9001 requirements. The key to approach certification is to understand that it focuses on documentation. The requirements of the QMS principle accomplished in this step are 'customer focus, 'process approach' and also 'factual approaches to decision making'. As the nature of ISO 9001 requirements is general, the ISO Steering team starts to tailor each and every requirement to suit the company's systems. They documented all

the quality system processes related to the 20 elements as previously listed in Table 3. The team established the company's policies in accordance to the ISO 9001 standard. It maintains good controls by ensuring all processes are conducted according to the QMS requirements and, making sure all processes are consistent for all product batches. This is to guarantee that the company produces good quality products.

The ISO 9001 documentation system typically comprises four levels of documents. These are policy, procedure, practices and proof level. As illustrated in Fig.4, the main contribution in QMS is quality manual that contains the company's quality policy, quality objectives and other policies for each clause in ISO 9001. This is followed by procedures explaining what the company has done to meet the policies. Then each standard operating procedure (SOP) is put into practice in the production floor. The third level of the documentation system included work instructions, process specifications, and other clauses requirements like safety elements. The final level to complete the QMS is proof or records like postal order (P.O.), instrument documentation, maintenance record, house-keeping forms, failure analysis record and performance charts. Each and every document used in the Production Floor are compiled and recorded to show that the ISO 9001 requirements are implemented in the company. Table 4 contains the list of records required for the ISO 9001 accreditation.

TABLE 4
List of clauses and the records required for ISO 9001 accreditation

ISO 9001 Clause	Requiring records of:
5.6.1	Management reviews
6.2.2e	Education, training. Skills, and experience
7.1d	Realization processes and product-meeting requirements
7.2.2	Results of product requirements reviews and actions
7.3.2	Product requirement inputs
7.3.4	Results of design and development reviews and actions
7.3.5	Results of design and development verification and actions
7.3.6	Results of design and development validation and actions
7.3.7	Design and development changes
7.3.7	Results of review of changes and actions
7.4.1	Results of supplier evaluations and actions
7.5.2d	Results of process validation (where output cannot be verified)
7.5.3	Product traceability (when required by customer or other)
7.6a	Basis of calibration of monitoring and measuring devices
7.6	Validity of previous measuring result (when equipment is found not to conform)
7.6	Results of calibration and verification of measuring devices
8.2.2	Results of internal audits
7.2.4	Evidence of conformity and product actions
8.3	Nonconforming product and actions
8.5.2e	Results of corrective actions
8.5.3d	Results of preventive actions.

One important point to highlight in this case study is the company has a very limited number of employees in the Production

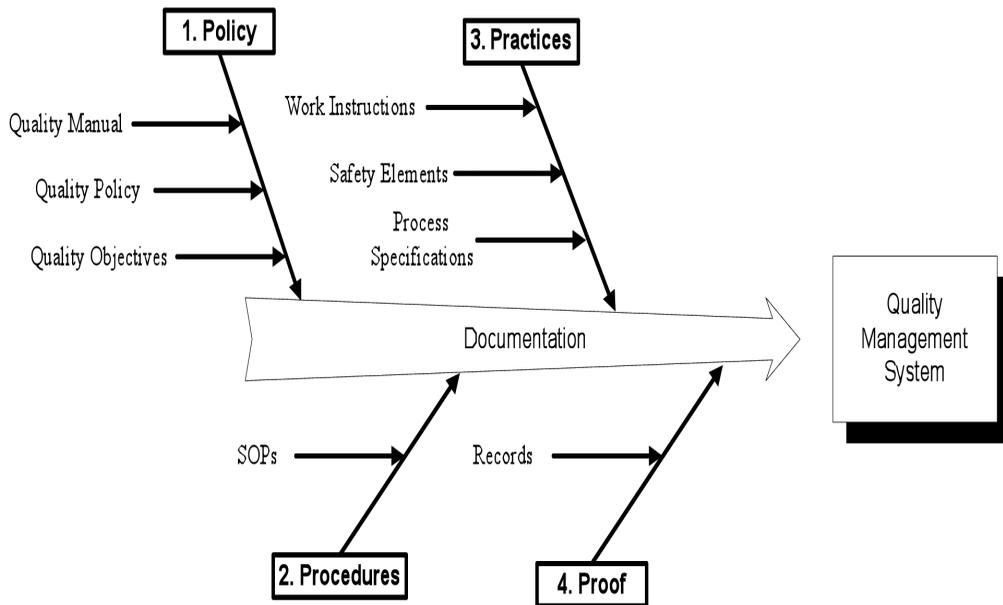


Fig.4: Four levels of documentation system in ISO 9001:2008

Department. Thus, the ISO Steering Team assigned line leaders and operators to build up their own documents and SOPs based on how they conduct their daily work or routines. Managers and supervisors give examples and guidelines of a good SOP and encourage the line leaders to work hand-in-hand with the other operators before submitting it to the ISO team for reviews. By involving them in the process, the ISO Steering Team not only saves time to compile all company’s procedures but also instil a sense of responsibility to the operators to work according to procedures they have developed. The team then monitored the implementation progress and made adjustments in their plan as needed. They reviewed and approved policy documents, standard operating procedures, and proposed solutions to gap in compliance

between available system in the company and the ISO 9001 requirements. *According to a publication by Fuentes et al. (2000), a typical firm would take about six months for the documentation process. However, the company under study only took three months to complete Step 3 because it is an SME.*

Step 4: Implement ISO 9001:2000 and Conduct Internal Audits

The next step is the company starts to implement the ISO 9001. The main concern here is to implement all the documented procedures in the quality manual developed in the previous step. In doing so, the company collects and keeps all records of their processes and systems and then conducts internal audits. As an example, all trainings in the company are documented in a training log which listed out the type of

training conducted, together with the details about the teaching materials and the level of employees taking part in it. There is also a section to record successful completion of training session of each job function in the production department. The training log is kept on record by the managers in the Production Department.

The ISO Steering Team also starts educating and coaching an audit team on what they should check in the internal audit of the ISO 9001 standard. The audit team consists of two or three higher management from every department in the company. The audits are conducted to check whether the company complies with every clause in the standard as written in their quality manual and documentations. During the audit, critical, new and changes are audited more frequently and more in-depth than others. The internal auditing process gives employees a chance to learn more about the company's processes.

During the process, any data indicating a weakness exists (i.e. customer complaints or previous audit findings) is used to identify processes or departments that deserve more attention during the internal audits. An auditor looks for evidence of compliance to the requirements by asking questions like "Are the activities conducted as planned (i.e. as defined in the quality system documents)? Do managers have data that demonstrates process/system effectiveness? Are corrective, preventive or other improvement actions taken as planned? Are actions taken effective?"

Then, every department in the company receives Corrective or Preventive Action Requests (CARs/PARs) forms from auditors that highlighted areas which do not comply with the ISO 9001 requirements. For example, the most number of CARs in the company under study were issued to the Storage Department. They have incomplete records of material and spare parts. Their SOPs are also incomplete as they did not consist of the process flowchart.

Step 5: Perform Preventive and Corrective Action

Based on the flow chart in Fig.3, the fifth step in implementing the ISO 9001 in SMEs is to perform corrective and preventive action based on CARs and PARs. The forms consist of the information on the system like its strengths, weaknesses and ways to improve. Results from the internal audit are documented and used to carry out the corrective action. Upon receiving the forms, managers and supervisors in the department write and propose corrective action plan to counter the incompliance. They introduce changes based on the plan. Evidences of compliance are collected, for example, by interviewing people, observing activities and looking at records and procedures. Only after the auditor verifies that the corrective or preventive actions are taken that the CARs/PARs are closed. In two months, the company under study managed to close all the CARs and PARs issued to all departments.

Step 6: ISO 9001:2008 Assessment & Accreditation

The final step of the implementation process is selecting a registrar for the assessment process. There are three types of ISO assessment which are:

1. First party assessment: a self declaration accreditation by the company to their supplier and customer that they fulfill all or some of the requirements of ISO 9001:2000 standard.
2. Second party assessment: customer performs its own assessment of its supplier's quality system using the ISO 9001:2000 criteria as a guideline and judgment.
3. Third party assessment: contracts with an independent assessment agency to perform the accreditation.

The main characteristic to keep in mind when choosing a prospective registrar is to choose one which has experiences working with SMEs. This way, the registrar understands the SME's capabilities and does not burden them with unnecessary documents. Registrar should understand the basic requirements of the ISO 9001 and audit whether the SMEs comply or not to the QMS standard. Generally, when signing a contract with a registrar, it will include the Registration Audit, and Surveillance Audits. The Registration Audit is the initial audit that will be done to see if the company comply to achieve registration. After the process, the registrar will come back every 6 months or a year to check whether the organization

is maintaining the system and continuing to meet the ISO 9001 requirements or not.

In this case study, the company decided on a third-party assessment since they had already completed the ISO 9001 implementation process suggested by the model proposed in this paper. The company managed to pass the consultants audit and proceeded to apply for the ISO 9001:2008 accreditations. After 14 months since the company first knew and understood the ISO 9001:2008, they were successfully accredited with the standard. Now they have the objective proof that they are producing good products by implementing effective QMS. The standard allows them to compete with larger companies in terms of their product quality.

DISCUSSIONS

There are various models and steps of implementing the ISO 9001 and each varies according to the authors' point of views. These divergences somehow bring confusion to some first timer's in the implementation task especially for the SMEs' representatives. Realizing the problem, the model presented in this paper contains six simple yet applicable steps of implementation. The main significant of the model is it aids the SMEs companies to smoothly implement the ISO 9001 instead of relying on generic or computerized documentation system which is usually provided by a third party. The model also helps the SMEs to accomplish all eight main QMS requirements in the ISO 9001:2008 standard. Unlike 27 steps suggested by Lo

and Humphreys (2000) or 18 steps suggested by Fuentes *et al.* (2000), the model only consists of six simple yet practical steps. This way, the SMEs are not discouraged by a lot of activities towards accreditation.

When comparing the model and steps provided with other publications, the most significant difference lies in Step 6: ISO 9001 Assessment & Accreditation. As suggested in a model by Yaacov (1995) and illustrated in Fig.1, this step is situated at the second level. However in this paper, it is in the final step so that the SMEs' representatives start their own implementation journey before getting involved with the consultants or the registrar. Therefore, they do not spend too much time and money for the whole implementation process. With a clear understanding of what they are involved in, the SMEs will make a wiser choice of assessment body and at the same time capable to monitor their system so that it complies with the ISO 9001.

CONCLUSION

Quality includes everybody and everything that affects satisfactory performances or outcomes. To secure a place in the emerging market, companies must achieve internationally accepted quality management system (QMS) level. Therefore, this paper was written to build an alternative implementation model towards ISO 9001 accreditation which is the international standard for QMS. Focusing on the SMEs, the advantages of the model are it is simple yet comprises all major steps required to implement the ISO 9001. It is also

applicable for all industries with simple steps that give brief ideas of the tasks to be done in order to be accredited with the ISO 9001 standard.

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