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New Knowledge Management framework for manufacturing SMEs working in strictly regulated sectors

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Abstract

A new and practical Knowledge Management framework for manufacturing SMEs operating in strictly regulated sectors has been developed based on a research project focused on the aquisition, synthesis, internalisation and extension of the knowledge and requirements related to hazardous environments regulations. The study of KM theory and practice was focused on SMEs, manufacturing sector and compliance constraints. The project used a complex case-study centred methodology to create a compendium of knowledge based on the compliance requirements and on existing intangible knowledge. The resulting framework is suitable for use in similar situations, and it emphasises low resource use, cost-effectiveness and usability.

Keywords: KM Framework; SECI Cycle; Tacit Knowledge; Explicit Knowledge; ATEX Library

1. Introduction

This paper reports on the process of creating a new Knowledge Management (KM) framework for manufacturing SMEs working in strictly regulated industrial sectors. This project included acquiring, synthesizing, internalising, and extending the knowledge underpinning the development of machines that are compliant with the relevant regulations for hazardous environments. The research was carried out in a manufacturing SME engaging in small to medium scale engineering projects and which has only recently started working on strictly regulated environments projects. The research effort included both the traditional KM approach, but also the creation of a best-practice guide in order to meet the rapidly growing needs of the business.

2. Knowledge Management – theory and practice

2.1. Knowledge Management

Knowledge Management as a modern discipline is relatively new [1, 2] and organisational KM traces its origins to a 1991 article by Nonaka entitled, "The Knowledge Creating Company [3]. However, it can be argued that the origins of KM go back even further, with some authors tracing the origins of KM to the Resource-Based View of the firm [2, 4].

While there are several strands of thinking within academia and practice with regards to the exact definition of KM, three distinct views on KM could be identified: the *business perspective*, the *knowledge science perspective* and the

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process/technology perspective [1]. The business perspective of KM is that of putting in place the strategy, policies, and practices of best utilising the intellectual assets owned by a firm into favourable business results. The knowledge science perspective views KM as an enabler for intelligent behaviour and focusses on the tangible and intangible manifestations of knowledge. Finally, the process/technology perspective focusses on the storage of data with a view to making them easily available and as an enabler of effective decision-making. The predominant approach used in this project is the business perspective. The current work is explicitly geared towards enabling a manufacturing SME in developing and utilising its intellectual assets better.

Nonaka's theory has the Spiral of Knowledge concept at its core [5]. The author identified two broad types of knowledge: *tacit* and *explicit*. Tacit knowledge, also referred to as intangible knowledge, is usually very personal and hard to formalise and communicate while explicit knowledge, also called tangible knowledge, is readily available in a codified form, in regulations, databases, design diagrams or other forms [6]. Nonaka argues that tacit knowledge must be converted to explicit for it to become truly useful to the firm. The extension of knowledge to the firm's benefit occurs primarily in the interplay between the realms of tacit and explicit knowledge and that this is the purpose of KM and in a broader sense, of the firm. The Spiral of Knowledge or SECI Cycle concept considers four primary modes of knowledge conversion: (1) Socialisation—Tacit to Tacit; (2) Externalisation—Tacit to Explicit; (3) Combination—Explicit to Explicit; and (4) Internalisation—Explicit to Tacit (Fig. 1).

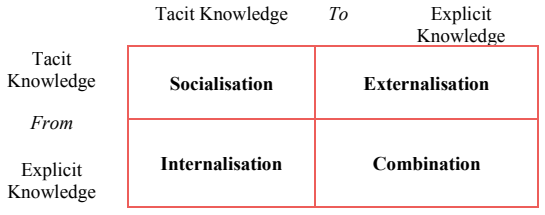

Fig. 1. The SECI Cycle [6]

The first step in the SECI Cycle is Socialisation and it involves the transfer of Tacit Knowledge from one person to another through shared experiences. The second step of the SECI Cycle is Externalisation and it involves the conversion of Tacit Knowledge to Explicit Knowledge. This conversion happens primarily in the context of concept creation and the Tacit Knowledge is converted into "metaphors, analogies, concepts, hypotheses or models" [6]. The Externalisation step is highlighted in the theory as being instrumental in the creation of Knowledge. The third step is Combination, and it involves combining different forms of Explicit Knowledge and then using that in novel ways including in the creation of new concepts. In the fourth step – Internalisation, individuals imbibe the Knowledge present in documents, manuals and other explicit sources of information and internalise this for future use. In many cases, this leads to the creation of a "tacit mental model" and the knowledge becoming a part of the organisational culture of the company. This Cycle is iterative and gives rise to different kinds of knowledge in different steps.

Despite the divergent views in literature as to the true nature of knowledge and what constitutes KM, there is broad evidence that KM initiatives are beneficial to firms which effectively practice it. KM initiatives improve efficiency, innovativeness and general firm performance [2, 7, and 8]. They also help drive down costs by allowing standardised solutions to be reused, allowing for quicker service [9]. But KM initiatives have the potential to create problems within an organisation. Knowledge capture is a time-consuming and expensive task. Tacit knowledge must be converted into explicit knowledge if it is to be shared successfully with a wider audience. Many KM initiatives fail because of low usage and usability [1 and 10].

2.2. Knowledge Management in SMEs' practice

Small and Medium Enterprises (SMEs) tend to have certain common characteristics which pose distinct challenges from a KM perspective. While they are often highly innovative, flexible, and capable of delivering highly personalised service, SMEs usually operate under tight resource constraints, primarily in terms of capital and human resources [11, 12 and 13]. Many SMEs are owner-run and tend to be defined by their qualities and experiences. They are also characterised by a flat hierarchy with relatively informal interaction and procedures between management and staff [12, 13]. There is a high focus on day-to-day operations, leaving insufficient time to work on strategic issues such as KM. Due to resource constraints, systematic KM approaches are lacking in most SMEs. The scholarly consensus regarding KM in SMEs is that they are characterised by an "informal, short-term approach" [12]. In the context of Nonaka's SECI Cycle, the socialisation aspect dominates in SMEs with the other three facets of the SECI cycle being completely overshadowed by socialisation [14, 15]. Combination of knowledge is done by the owner and internalisation occurs through apprenticeship-based training. This is connected to the fact that owing to the lack of systematic KM approaches, most knowledge resides in the mind of key individuals and in some cases, with the owner(s) themselves [11, 15]. There is generally a lack of explicit knowledge repositories in SMEs and a limited reliance on technology for knowledge management [14]. Despite this relative lack of focus on KM, it remains hugely significant to SMEs as it forms the basis for its competitive advantage. The potential for knowledge loss is a distinct possibility as knowledge is restricted to one person or a few persons at most and this could pose an existential threat to the company. Most SMEs try to counter this threat through redundancy in knowledge storage, by emphasising on creating deep levels of common knowledge in employees at different levels of the organisation, so that the business is not severely affected by any one person leaving the organisation [14, 16]. KM guidelines intended for SMEs are often inappropriate as they treat SMEs as similar organisations to large firms and do not consider inherent characteristics that underpin their competitive advantage, especially responsiveness and flexibility [16]. The limited availability of resources in an SME has a detrimental effect on their innovation capabilities. Consequently, internal sources of innovation are unlikely to be sufficient to effect change.

2.3. Knowledge Management in the manufacturing sector

KM is an important activity in modern manufacturing firms. KM in engineering and manufacturing represents an important facet of a firm's competitive advantage [17]. The ability to manage and exploit knowledge has been identified as the main source of competitive advantage in manufacturing. KM in manufacturing firms tends to be extremely wide-ranging and is present in nearly all the functional aspects of manufacturing, including design, production, supply chains and IT/IS [18]. The sector is characterised by heavy emphasis on protecting technical and process knowledge, and this is often challenging in an open communications environment. The growth of ICT technologies has been a major supporting factor in the increase in KM initiatives in engineering and manufacturing firms. In a cross-sectional survey, all respondents perceived KM activities to be contributing to improvements in manufacturing performance in their respective firms. The authors found clear correlation between KM and manufacturing performance [17].

3. Challenges for Knowledge Management in strict compliance environments

KM is highly useful tool in environments where strict regulations are in place. Ontology-based systems are the most used KM tool in ensuring compliance to strict regulations. KM in strict compliance environments also has a heavy focus on automation while relying on the knowledge of domain experts. Certain approaches to modelling of regulations for regulatory compliance purposes require programming knowledge while other systems have certain limitations in the way they model regulations [19]. Ontology-based solutions are powerful tools that can effectively capture knowledge surrounding legal compliance while being capable of supporting multi-level legal concepts with an intuitive interface. They serve to reduce error and labour requirements in the actual compliance management process. However, they require extensive support from legal experts for their initial development, and also for continued updating. This inherently makes it more suitable for large businesses with a larger resource-base and with the necessary scale to take advantage of the tool. For example, few prominent examples identified in the literature are in the financial industry in Italy [20] and pharmaceutical manufacturing [21].

The literature review reveals a diverse landscape within KM, especially as it applies to an SME manufacturer seeking to develop knowledge in specialised applications as in this case. The review also indicates that KM in manufacturing SMEs is not as well-understood as in larger firms and this poses a challenge in approaching the present KM effort. Hence the focus of this research is to operationalise the SECI Cycle within the company in a cost-effective manner.

4. Methodology

The case-study based qualitative method was considered to be the most appropriate approach to cover all the challenging circumstances described above. A case-study based qualitative approach is primarily useful in addressing questions of "how" and "why" and this is especially true when an "extensive and in-depth" description is required [22], as is true in this case. The market dependent and consequently unpredictable nature of ATEX-related development work within the firm made the use of other approaches highly problematic. The case study method allows the use of an abductive reasoning approach that would be needed to create a best practice guide incorporating disparate sources of information. With further development, a novel framework for KM in SMEs with stringent compliance needs was created from this. Within the overall case-study based abductive-reasoning approach the primary methods used were interviews, and document analysis. As most knowledge is tacit and personal in the initial stages of development, the use of interview is indispensable in capturing it. New knowledge is often known only to a small number of experts or even just one [1]. As a result, several interviews with experts are necessary in KM projects, both to understand various requirement and for the actual knowledge acquisition. In this project 3 unstructured (1 with the MD and 2 with the Chief Designer) and 6 semi-structured interviews were carried out (4 initially and 2 for follow-up questions, all with the Chief Designer). The unstructured interviews took between 15 and 20 minutes while the semi-structured interviews were much longer at about 35 to 40 minutes, as they dealt with specific topics and standards. Interview notes were taken, and key concepts were identified, and this was used for correlation with other information sources. Except for the last 2 interviews (which were online), all other interviews were carried out at the company premises. Document analysis is another well-established method in qualitative studies. Document analysis can be extremely useful as information contained in documents are stable and specific [22] and it tends to be highly cost-effective [23].

4.1. Overall approach, context and adherence to SECI cycle

In order to operationalise the SECI cycle within the company the KM project was divided into the three phases: (1) Planning; (2) Implementation and (3) Continuous Improvement. The Planning stage corresponds roughly to Socialisation step of the SECI cycle while the Implementation stage corresponds roughly to Externalisation and Combination steps. The final product is a body of knowledge suitable for Internalisation. This correspondence is not perfect as each stage contained all four elements of SECI cycle in varying degrees.

The methodology adopted in this research effort has been informed by requirements along three major lines: (1) Ensure compatibility with the size, scale and nature of the manufacturing SME (2) Ensure the integrity of the research in terms of established best-practices in KM and allied fields; (3) Ensure that the unusual nature of the primary subject-matter was taken into consideration. The focus of the manufacturing SME was to have a body of knowledge regarding ATEX regulations and standards that could be used as an operational tool/aid to streamline the design, manufacture, and compliance of ATEX-rated or ATEX-compliant equipment within the company's product portfolio. The requirements were consistent with the characteristic nature of KM in SMEs as identified in literature with the KM initiative being considered complementary to the high degree of socialisation within the

firm. The resource-constrained nature of the firm also ruled out any use of advanced techniques such as an ontology-based solution or even a strict modelling approach. In a typical KM initiative, it is common to use a combination of several data collection methods and combine the data collected into a cohesive whole for the creation of the knowledge base [1]. This approach is well supported in literature [22] and this has been adopted in this project as well, as seen below. This is to ensure that both tacit and explicit knowledge are captured and the two often require different approaches for effective knowledge capture [1]. The capture and consolidation of tacit knowledge was of particular importance as it is considered to be rich and detailed information on factual, conceptual, expectational and methodological fronts [24]. This includes personally held observations, judgements, hypotheses and reasoning strategies that may be held unconsciously. In ensuring compliance to highly complex regulations and standards, the tacit knowledge held by experts is critical in ensuring an effective approach to the problem. As Dalkir pointed out [1], the "explicit knowledge tends to represent the final product, whereas tacit knowledge is the know-how or all of the processes that were required in order to produce that final product".

A key factor in this KM initiative was the legally sensitive nature of the subject matter and the need for complete adherence to all relevant standards. The standards applicable in an ATEX-related project come from several different sources including EU Directives [25, 26] and from industry standards produced by several different sources. There are also a wide variety of sources internal and external to the firm that provide information regarding ATEX compliance.

5. The Knowledge Management project

5.1. The company

The company in which the KM project was undertaken is a bespoke engineering SME which has 4 major product/service offerings: HVAC (production and installation), laser cut parts, bespoke engineering equipment and on-site servicing and maintenance of equipment (own or third party). On analysis of the Company's customer portfolio, it was clear that the highest value customers (for bespoke engineering equipment) were predominantly from the food and pharmaceutical industries. As the needs of these customers developed, there was a clear business need for systematic acquisition and management of ATEX-related knowledge to cater to this segment better.

5.2. ATEX library creation

The objectives and steps undertaken in the three phases of the project are outlined in Fig. 2. In the Planning Phase**,** Step 1 was carried out based on EU primary legislation while the Review of Documentation (Step 3) included selected secondary legislation and standards already compiled by the company. Assessment reports from notified bodies on previous projects and articles from trade magazines on hazardous environments were also included in this step. The review of primary legislation was of high importance as it was vital to understand the essential characteristics of the ATEX regulatory regime.

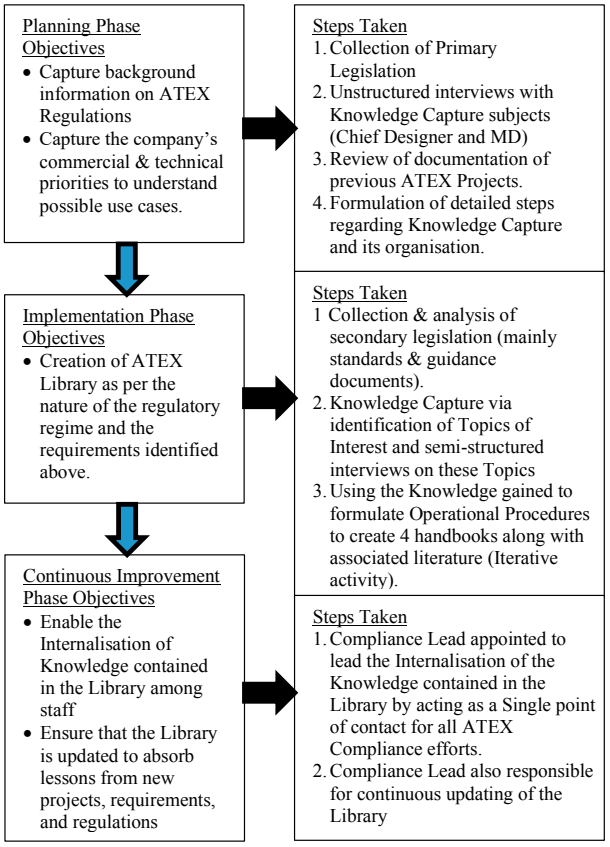

Fig. 2. ATEX Library Creation Phases & Steps

The ATEX Directives of the European Union (EU) [25, 26] represent a major pillar of EU Safety law and deals with the safety requirements in hazardous environments. ATEX Directives consists of two distinct but closely related directives from the EU: one that deals with hazardous workplace environments and a second one that deals with the equipment to be used in hazardous environments. Non-compliance with the ATEX Directives imposes strict penalties on the firm and on its designers [27]. Hence, compliance with ATEX Regulations can be regarded as a market qualifier for many products. A major challenge while dealing with ATEX-related information is the large number of overlapping standards that should be used for ensuring compliance. In this context, finding and applying standards that apply to the company was a key challenge. From Steps (2) and (3), the main requirements of the company regarding the study were established.

Based on the information collected in the Planning Phase, it was decided to proceed with a KM effort centred on codification of the ATEX Knowledge to create a compendium called the ATEX Library. This library would contain the procedures currently used by the company to deal with ATEX development programmes along with their rationale, coupled with an array of supporting information. Wherever possible, these procedures would be refined based on new knowledge acquired through a detailed analysis of new information and all steps in this phase would be informed by the information collected in the Planning Phase. In the Implementation Phase of the work, the actual Knowledge Capture was carried out.

Topics of Interest were identified from the primary and secondary legislation and associated literature. This was a complex process with several standards dealing with the same topic in varying degrees of detail. At this stage, semi-structured interviews were carried out with the Chief Designer to ascertain the level of detail needed in the ATEX Library as it was necessary to find the appropriate balance between usability and comprehensiveness. Once the level of detail required was established, formulation of Operational Procedures was carried out along with a further collection of associated literature to ensure that the procedures had ample supplementary information, should the user of the library decided to review and/or modify them at a later date. Further semi-structured interviews with the Chief Designer established the relevance and integrity of the Operational Procedures developed and derived input as to the logical organisation of these procedures in the Library. There was a significant amount of iterative activity between this step and the previous one, when the formulation of procedures often revealed a new Topic of Interest that required the collection of further knowledge and supporting information regarding it. In the final step of the Implementation Phase, the formulated procedures were organised into four handbooks with appropriate commentary and along with supporting documents. In the Continuous Improvement Phase, the ATEX Library is used by the Engineering Team with the Compliance Lead acting as a Single point of contact regarding all ATEX Compliance efforts. The Compliance Lead holds the responsibility for ensuring that the changing priorities of the company and its customers are accurately reflected in the contents of the ATEX Library and that lessons learned from new products and projects are added.

5.3. ATEX library – structure and description

The ATEX Library consists of four handbooks and a collection of associated literature. The four handbooks are: (1) Quick Reference Handbook (QRH); (2) Design Guidelines Handbook (DGH); (3) Conformance Handbook (CH); (4) Manual Preparation Guidelines (MPG). The QRH is designed to be the high-level reference document for all matters relating to ATEX. As such, it introduces the major terms and concepts relating to ATEX and gives the scope and limitations of the ATEX Library. It lists the legal obligations of the manufacturer under the ATEX Regime and describes the contents of the ATEX Library in some detail. It also includes a condensed version of information dealt with in detail elsewhere in the ATEX Library. The DGH gives the General Design Principles and the design procedures needed to design an ATEX-rated or ATEX-compliant equipment from scratch. Desirable and undesirable elements within the design are also given. The CH gives a highly detailed description of the ATEX Regime and serves as *ab initio* guide to newcomers in the field. It also details the procedure to conduct an Ignition Hazard Analysis, the completion of which is critical in ATEX compliance of non-electrical equipment. The document also gives the appropriate templates for all the documentation necessary to demonstrate conformance. The MPG deal only with the preparation of an Instruction Manual for ATEX-rated and ATEX-compliant equipment and comes with a customisable template.

6. A Knowledge Management framework for manufacturing SMEs working in strictly regulated sectors

Based on the successful KM effort described above a new framework for Knowledge Management in manufacturing SMEs is depicted in Fig. 3.

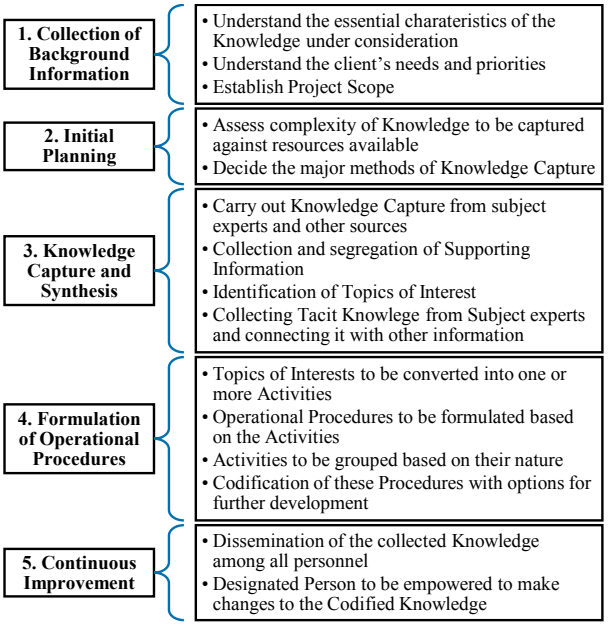

Fig. 3. The proposed Framework

(1) **Collection of Background Information:** The logical starting point for the proposed framework is the collection and review of background information pertaining to the scope of the project. If it is a regulatory regime that is under consideration, then it is essential to capture the nature and intent of the legislation rather than its strict requirements at this stage. It is also important to accurately understand the client's needs and priorities and connect it with the objective requirements of the legislation.
(2) **Initial Planning:** Once the background information has been collected it is necessary to decide on the major methods of Knowledge Capture.
(3) **Knowledge Capture and Synthesis:** A method or mix of methods are deployed for the collection and organisation of knowledge from human experts and from other sources, with an emphasis on identifying the Topics of Interest. Collection and segregation of supporting information is also a major priority in the Knowledge Capture stage with the creation of a supporting library of information. Portions dealing with the Topics of Interest should be noted for reference in the subsequent stages of the Project, considering the commercial, technical, and legal priorities found through the parsing of the background information. Of particular importance is the need to connect the tacit knowledge collected from the subject expert(s) with those contained in other sources, thereby contextualising it. This tacit knowledge includes the rationale for the decisions taken in similar projects to date and knowledge of actions of other firms in a similar environment.
(4) **Formulation of Operational Procedures:** In this stage, the previously found Topics of Interest are converted into

Activities for which Operational Procedures can be formulated. Usability is of extreme importance and hence, the creation of these procedures must have high levels of practitioner involvement. The formulated procedures must then be organised along major Groupings of Activities to form handbooks based on input from practitioners, among other factors.

(5) **Organisational Learning and Continuous Improvement:** In this stage, the results of the codification effort are to be disseminated among key personnel. Parallel to this, the procedures must be updated based on the evolving business needs and regulatory circumstance.

The framework described above represents an incremental approach to KM that is well suited to the characteristics of manufacturing SMEs. It is designed to overcome the low resource availability in an SME with minimal experience in formal KM processes and with comparatively lesser ability to access sophisticated solutions. The approach plays to the strengths of an SME: the narrow-focus approach towards KM ensures that high levels of top management support can be maintained as it is seen as contributing to operational success of the firm. Another major advantage is that as a high level of personalisation is already prevalent within an SME, the codification approach serves to complement it while ensuring that highly specific knowledge is protected from personnel attrition. While the framework is intended to create a body of knowledge that can used as a tool in operational settings, it is explicitly geared towards future integration into ontologies and databases and is meant to grow with the firm. It is important to note that the present KM effort was made possible with the collaboration and technical expertise of a university – partner in the project, indicating the need for an SME to tap into established knowledge networks as it works to upskill itself.

7. Conclusions

This framework is appropriate for strictly regulated industries and for manufacturing SMEs that are operating with relatively minimal resources in terms of time, investment, and expertise, reducing the entry barriers to such sectors. It takes a narrow-focus approach towards the regulations with the most important ones being identified from the KM client's perspective. This approach can be a limiting factor in the usefulness of the framework where more resources can be made available. It requires the final product to be subject to much more frequent update cycles than would otherwise be necessary. More work remains to be done in developing the framework for different sectors and applications as opposed to its current focus on manufacturing and regulatory compliance. The resources expenditure incurred on this project, while likely to be much smaller, is difficult to quantify when compared to a similar one at a much larger firm. Despite these limitations, the KM framework for manufacturing SMEs represents a valuable tool in reducing complexity of regulatory regimes and thereby having a major impact on development time and budget of new projects.

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References

[1] Dalkir K. Knowledge Management in Theory and Practice. Routledge; 2013.
[2] Darroch J. Knowledge management, innovation and firm performance. J of Knowledge Mgmt 2005; 9(3):101–115.
[3] Crane, L. A new taxonomy of knowledge management theory and the turn to knowledge as constituted in social action. J of Knowledge Mgmt Practice 2013; 14(1):1-20.
[4] Alavi M, Leidner DE. Review: Knowledge Management and Knowledge Management Systems: Conceptual Foundations and Research Issues. MIS Quarterly 2001; 25(1):107-136.
[5] Nonaka I. The Knowledge-Creating Company. Harvard Business Review, Nov-Dec 1991; 96-104
[6] Nonaka I, Takeuchi H. The Knowledge-Creating Company: How Japanese Companies Create the Dynamics of Innovation. New York: Oxford University Press; 1995.
[7] Davenport TH, Prusak L. Working knowledge: how organizations manage what they know. Boston: Harvard Business School; 1998.
[8] Rašula J, Vukšić VB, Štemberger MI. The Impact of Knowledge Management on Organisational Performance. Economic and Business Review 2012, 14(2);147-168.
[9] Hansen MT, Nohria N, Tierney TJ. What's Your Strategy for Managing Knowledge? Harvard Business Review, Mar-Apr 1999; 106-116.
[10] Schütt P. The post-Nonaka Knowledge Management. J of Universal Computer Sci 2003; 9(6):451-462.
[11] Wong KY, Aspinwall E. Characterizing knowledge management in the small business environment. J of Knowledge Mgmtt 2004; 8(3):44-61.
[12] Zieba M, Bolisani E, Scarso E. Emergent approach to knowledge management by small companies: multiple case-study research. J of Knowledge Mgmt 2016; 20(2):292-307.
[13] Durst S, Bruns G. Knowledge Management in Small and Medium-Sized Enterprises. In: J. Syed et al, eds. The Palgrave Handbook of Knowledge Management. Springer International Publishing; 2018. p.495-514.
[14] Desouza KC, Awazu Y. Knowledge management at SMEs: five peculiarities. J of Knowledge Mgmt 2006; 10(1):32-43.
[15] Cerchione R, Esposito E, Spadaro MR. A literature review on knowledge management in SMEs. Knowledge Management Research & Practice 2016; 14(2):169-177.
[16] Coyte R, Ricceri F, Guthrie J. The management of knowledge resources in SMEs: an Australian case study. J of Knowledge Mgmt 2012; 16(5):789-807.
[17] Tan LP, Wong KY. Linkage between knowledge management and manufacturing performance: a structural equation modeling approach. J of Knowledge Mgmt 2015; 19(4):814-835.
[18] Gunasekaran A, Ngai EW. Knowledge management in 21st century manufacturing. Intl J of Production Research 2007; 45(11):2391-2418.
[19] Dimyadi J, Amor R. Automating Conventional Compliance Audit Processes. In: J. Ríos et al, eds. Product Lifecycle Management and the Industry of the Future, Cham: Springer International; 2017. p.324-334.
[20] Boella G, Humphreys L, Martin M, Rossi P, van der Torre L, Violato A. Eunomos, A Legal Document and Knowledge Management System for Regulatory Compliance. In: M. De Marco et al, eds. Information Systems: Crossroads for Organization, Management, Accounting and Engineering. Heidelberg: Physica-Verlag HD; 2012. p.571–578.
[21] Sesen MB, Suresh P, Banares-Alcantara R, Venkatasubramanian V. An ontological framework for automated regulatory compliance in pharmaceutical manufacturing. Computers & Chemical Engineering 2010; 34(7):1155-1169.
[22] Yin RK. Case Study Research: Design and Methods. Sage; 2013.
[23] Bowen GA. Document Analysis as a Qualitative Research Method. Qualitative Research Journal 2009; 9(2):27-40.
[24] Wiig KM. Knowledge Management Foundations -- Thinking about Thinking -- How People and Organizations Create, Represent, and Use Knowledge. Arlington, Texas: Schema Press; 1993.
[25] European Union, 1999/92/EC—ATEX Workplace Directive 1999.
[26] European Union, 2014/34/EU—ATEX Equipment Directive 2014.
[27] UK Government, Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016 Guidance, 2016.