Risk management prioritization in medical device SMEs based on AHP analysis

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STRUCTURED ABSTRACT

Purpose - Risk management is crucial for the longevity of companies and it is also required by many standards and regulations, such as ISO 9001 and ISO 13485. Particularly for the medical device industry the standards are stricter, due to the level of risk that products can represent. However, each standard is particular on its requirements and establishing the risk management process can be challenging, namely for small and medium-sized enterprises (SMEs). This research aims to identify and prioritize the key features for the risk management of medical device SMEs.

Design/methodology/approach - The Analytic Hierarchy Process (AHP) was applied as follows: from the literature review and the above-mentioned standards the authors defined the problem, objectives, alternatives and identified 5 evaluation criteria and 8 evaluation subcriteria, organized in the hierarchical structuring of four matrices, which were the basis for data collection and analysis. Five experts from Brazilian and Portuguese companies operating in the sector were interviewed and asked to evaluate each of the matrices, establishing the relative importance among the criteria, for the calculation of local priorities.

Findings - The results led to the involvement of employees as the most important criterion for risk management, followed by employees training and qualification. Organizational culture was listed as the least important criterion, with four of the five evaluators considering training and qualification as a way to work towards a cultural change and encourage risk-based thinking.

Originality/value - Recent researches highlight the need for methodological and scientific support on risk management for the companies. This paper provides discussion regarding whether the literature reflects the reality of organizations and how the process is considered by them.

Keywords: Quality Management System, Risk Management, Analytic Hierarchy Process, Small and Medium-Sized Enterprises.

Paper type: Research paper.

INTRODUCTION

Managing risks is an intrinsic activity to organizations that along with quality management, becomes fundamental for the good performance and longevity of organizations (ISO, 2015; Luburić, 2018). Small and medium-sized enterprises (SMEs) from the medical device industry are exposed not only to risks inherent to their processes, products, and services, but also to external factors that can positively or negatively impact their activities and survival (Cusmano et al., 2018; Williams et al., 2019). In this context, standards for Quality Management Systems (QMS) arise, such as ISO 13485:2016 which is specific to the medical device sector and has its structure established based on ISO 9001:2015 (ISO, 2016).

The implementation of ISO standards as well as the operationalization of risk management are considered major challenges for SMES (Vasile, 2017; Fonseca and Domingues, 2018; Cusmano et al., 2018) and as a consequence, standards can be interpreted and implemented inconsistently (Wu et al., 2019). Standards are often implemented in companies only due their regulatory nature, as an obligation that only in few cases has its benefits considered (Ritcher and Sereșeanu, 2015; Guerra-Bretaña et al., 2017). In this context, practitioners and researchers discuss that companies are influenced by their interpretation of standards and regulations, especially in the field of risk management, and once their practices meet the standards and are validated in audits, they do not engage in the improvement of the process and opt for the isolated use of widespread methods (Onofrio et al., 2015; Guerra-Bretaña et al., 2017).

According to Björnsdóttir et al. (2021), the ISO standards that require risk management practices do not have definition and uniform description about the process, which makes its implementation even more challenging for organizations. The authors highlight the need for methodological and scientific support, as well as assistance in understanding the risk management process and its relevance to the context of companies (Björnsdóttir et al., 2021; Crovini et al., 2020). Thus, it becomes relevant to explore the scenario of companies in the sector and their risk management practices, in order to identify whether the literature reflects the reality of organizations and how the process is considered by them.

This work has as main objectives: to identify the key features for the risk management of medical device companies, both from literature and the standards applicable to the sector; to analyze and prioritize the criteria from the companies' perspective, through the application of the Analytical Hierarchy Process (AHP) method. The research had as object of study 05 small-sized companies inserted in innovation ecosystems, which operate in the medical devices sector and have a structured Quality Management System.

THEORETICAL BACKGROUND

Medical device industry

The medical devices sector is an industry of great value in the global scenario, with the European Union accounting for the second largest market in the world (Manita et al., 2019). In Portugal, exports in health have grown more than 100% in the last 10 years, and one of the main factors of the country's competitiveness is the high quality and degree of specialization of both the scientific industry in these areas and the available human resources, with emphasis on global cost (AICEP Portugal Global, 2020). In Brazil, the productive chain of the medical devices sector has a participation of 0.6% of the Brazilian GDP (Gross Domestic Product), with more than 13,000 companies that generate around 140,000 jobs, being composed mostly of micro and small companies (ABIMED, 2020).

When it comes to SMEs inserted in innovation ecosystems, the creation, development and growth of innovative companies are fundamental aspects in the improvement of economic and social factors of the countries. In addition, innovation ecosystems provide the involvement of several actors, promoting the emergence of interconnection structures between academia, government and companies (Anprotec, 2019; RNI, 2021). However, the growth of small businesses is related to their practical skills of strategy and business management (Williams et al., 2019), but such activities are considered major challenges for SMEs and relevant factors to their survival (Cusmano et al., 2018; Riascos et al., 2020; Björnsdóttir et al., 2021). The highly dynamic and competitive environment of the medical devices sector requires companies to invest heavily in innovation of their products and processes to maintain competitiveness (Cusmano et al., 2018; Miclăuş et al., 2019; BBC Research, 2021). In this sense, the complexity of the sector covers many different aspects, including those associated with regulations.

QMS, regulations and standards

Each country establishes its regulatory requirements based on international standards and its own context. However, some critical elements are common among them, such as the "product" and its "use" (Gudeppu et al., 2020). According to Lobato (2018), ISO 14971 (risk management) and ISO 13485 (quality management system) are some of the main regulations applicable to companies in the medical devices sector. In Brazil the regulations established by ANVISA (Agência Nacional de Vigilância Sanitária) and INMETRO (Instituto Nacional de Metrologia, Qualidade e Tecnologia) are legal requirements, and the compliance with the good manufacturing practices defined in the RDC No. 16/2013 (ANVISA, 2013), associated with the application of risk management, are essential for the good performance and compliance of companies in the sector (SILVA, 2019). In the Portuguese scenario, the country has INFARMED (Autoridade Nacional do Medicamento e Produtos de Saúde) which is responsible for regulating and supervising the medical devices sector, based on the European

Union's General Good Practice Guide (EU GMP) for licensing medical device manufacturers (INFARMED, 2022). The sector is also regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (Official Journal of the European Union, 2020), and all medical devices need the CE marking (TAYLOR et al., 2020). Even if ISO 13485 is not compulsory in some countries, any actions go through requirements related or based on the standard.

ISO 13485 has its structure based on ISO 9001 and determines as a requirement for its implementation, the adoption of the vocabulary established in ISO 9000:2015 (ISO, 2016). This relationship is based on the strong influence and dissemination of ISO 9001 in the quality management of companies. However, due to the great focus of this standard on customer satisfaction and continuous improvement, at each ISO 13485 update its requirements become more specific and focused on product and user safety (Sheffer et al., 2019; Hrgarek and Bowers, 2009).

Unlike ISO 9001, the standard ISO 13485 maintains in its scope the preventive actions requirement (item 8.5.3), which is associated to the risk management (ISO, 2016), making no mention of the concept of risk-based thinking adopted by ISO 9001:2015. Despite the different approaches, according to Geremia (2017) both standards are very important guides for manufacturers of medical devices, once both address risks as a fundamental aspect for organizations. However, the risk approach is one of the most challenging requirements for SMEs when implementing ISO management standards (Vasile, 2017; Fonseca and Domingues, 2018).

Risk management

The priority of a medical device is safety followed by efficacy, performance and usability (Kadambi and Alagumalai, 2020). In this context, managing risks becomes a fundamental part in the decision-making related to the objectives of the organizations (Geremia, 2017) and managing risks of medical devices requires an approach more directed to the safety of the product and its user (Malins et al., 2015), which makes complete sense if we consider that the application of medical devices takes place in contexts of patient’s vulnerability (Israelski and Muto, 2004; Li, 2019). Li (2019) highlights that as medical device manufacturers, it is critical to adopt risk management and quality control practices, both from a regulatory perspective and from the perspective of quality assurance of the product and its processes.

The standard ISO 14971:2019 establishes the requirements for risk management of medical devices, focusing on people and their safety starting with the patient, extending to the operator and other users and devices in the environment (Sauter et al., 2015; ISO, 2019). However, the existence of regulatory requirements does not imply in the use of specific methods and each organization defines the practices and tools that better fit their contexts to be adopted (Onofrio et al., 2015; Wang and Moczygemba,

2015), which lead to different interpretations and procedures, even for companies with similar characteristics.

As a consequence of the requirements and needs of organizations, quality management, the process of medical device development and risk management have become an integrated activity (Miclăuș et al., 2019; Kirkire et al., 2018). Also, to establish the risk management process requires considering comprehensive aspects that permeate the entire organization, ranging from its services and products to its business strategies, which involves different sources of risk (Geetha et al., 2020; Waters and Sobral, 2019; Kirkire et al., 2018; Hale et al., 2020).

The involvement of top management in the process becomes a widely discussed aspect in the literature and considered crucial in providing clear guidelines for assessing risks and defining strategies for monitoring and control (Rane and Kirkire, 2016; Hrgarek and Bowers, 2009; Ritcher and Sereșeanu, 2015). Furthermore, some authors also emphasize the importance of a multidisciplinary team for a successful risk management process (Kuhl et al., 2020; Geetha et al., 2020). Thus, the development of this research is based on the need evidenced in the literature to conduct studies that can contribute to organizations in the establishment and implementation of their risk management practices, guiding their practices to an approach that encompasses all relevant aspects, both from the regulatory and practical aspects.

RESEARCH METHOD

Analytic Hierarchy Process (AHP)

In order to achieve the objectives, the authors applied the AHP technique, a systematic method of synthesizing priorities structured by means of a hierarchy, very effective to solve problems of multicriteria decision for the most diverse areas and sectors (Saaty, 1980; Salgado et al., 2015). The AHP was developed by Saaty in the 1970s and until today it is the most used multicriteria method worldwide, providing the analysis of problems through hierarchical groupings, which allow the comparison in pairs of criteria, for the attribution of weights and priorities and also for the quantification of qualitative variables (Saaty, 1980; Saaty, 2013)

The mathematical modelling of the problem based on the AHP method, consists of three main steps: identification of decision criteria; definition of weights and priorities; synthesis of results (Salgado et al., 2015). In addition, to conduct the method the evaluators must be selected, in a number that the researchers judge suitable, avoiding large samples. The value judgments (or comparison) are attributed by the evaluators within matrices of pairwise comparison, where the criteria are evaluated

according to their relative importance. In other words, it is a numerical representation that expresses the priorities of a particular group of experts (Mendes et al., 2016).

To standardize the evaluation, Saaty established a scale of degrees of importance (see Table 1) and from these judgments, the weights and priorities of the criteria and alternatives are inserted in a matrix Aij, where the data are paired, followed by the eigenvectors' calculation, which refers to the local priorities (Salgado et al., 2015).

Table 1: Scale for criteria pairwise comparison (adapted from Saaty, 2013)

Importance level	**Description**
1	The two criteria are equally important
3	One criterion is hardly more important than the other
5	One criterion is rather more important than the other
7	One criterion is much more important than the other
9	One of the criteria is extremely more important
2, 4, 6, 8	Intermediate values between adjacent opinions

In this method, the relative importance is obtained using the eigenvector w of the comparison matrix A, where λmax is the maximum eigenvalue (Equation 1). Given n alternatives {A1, A2, An}, the evaluator performs the pairwise comparison, for all possible pairs of alternatives, and a matrix A is obtained, where the element aij shows the preferential weight of Ai obtained by comparison with Aj. The eigenvalue is the consistency measure of a comparison matrix, calculated according to Equation 2, where λ = n which, in turn, refers to the matrix order.

$$Aw = \lambda max.W \tag{1}$$

$$\mu = (\lambda - n)/(n - 1) \tag{2}$$

After obtaining the eigenvectors, Saaty (2013) proposes the calculation of the Consistency Index – CI (see Equation 3), for which it is also considered a kind of scale, with values for the Random Consistency Index - (RI) that depends on the matrix size, as shown in Table 2. For the experts' judgments to be considered consistent, the CI should be less than or equal to 0.10, while obtaining indices greater than 0.20 suggests that the expert revalue their judgments (Mendes et al., 2016; Saaty, 1980).

$$CR = CI/RI \tag{3}$$

Table 2: Random Consistency Index (Saaty, 2008)

n	1	2	3	4	5	6	7	8	9	10
RI	0,00	0,00	0,58	0,90	1,12	1,24	1,32	1,41	1,45	1,49

The AHP is widely applied in the area of quality management for decision making and prioritization related to regulatory requirements, total quality management aspects, selection of certifying bodies, among others (Alvarenga et al., 2018; Lewis et al., 2005; Salgado et al., 2015; Souza-Mendes et al., 2016). In this research, the method is used to identify the most relevant criteria for risk management in the medical devices sector, from the judgments of 05 experts from medical device SMEs, who are described in Table 3. The selection of companies with distinct characteristics was chosen in order to analyse the relationship between the type of each company's QMS certification and its evaluated priorities, since despite being structured in alignment to ISO 9001 and ISO 13485, each company approach risk management in a distinct manner.

Table 3 – Experts characterisation

Company	Founding Year	ISO standards	Expert	Country
Company A	2007	-	Quality Director	Brazil
Company B	2012	ISO 13485	QMS responsible	Brazil
Company C	2007	ISO 13485 e ISO 9001	Development Agent	Brazil
Company D	2011	ISO 13485 e ISO 9001	Technical Director	Portugal
Company E	2016	ISO 13485	Regulatory Affairs Manager	Portugal

Definition of criteria and hierarchical structure

The selection of criteria and respective groupings were made based on the literature and considering some of the main standards applicable to the sector, such as ISO 13485, ISO 14971 and ISO 9001. Through Table 4 it is possible to identify each criterion, sub-criterion, its detailing and references considered. After the criteria definition, the hierarchical structure of the problem was established (see Figure 1), presented to the experts along with instructions for filling out the matrices and guidelines for the judgments.

Table 4 - Definition and detailing of criteria and sub-criteria related to risk management

Criterion	Sub-criterion	Description	References
Employee involvement (EI)	Strategic level (SL)	Leadership involvement on risk management	Rane and Kirkire (2016), Mendes et al. (2016)
	Tactical level (TL)	Managers and coordinators involvement…	Kuhl et al. (2020), Ritcher and Sereșeanu (2015)
	Operational level (OL)	Operators (shop floor) involvement…	Geetha et al. (2020), Schmuland (2005)
Organizational culture (OC)	-	To have quality and risk management as part of the company's culture, encouraged by leadership	ISO (2015), Mendes et al. (2016)
Terms for risks approach (RA)	Risks as opportunities and threats (OT)	Positive and negative aspects of the risks considered in the management process	Aggarwal and Aggarwal (2016), ISO (2015)
	Risks as failures/hazardous situations (FH)	Negative aspects of risks, considered as product failures or dangerous situations for the user	ISO (2016, 2019), Caines et al. (2015)
Training and qualification (TQ)	-	Training on concepts related to risk management, both addressed by the applicable standards and associated to the companies' practices	Geetha et al. (2020), Rivas et al. (2014), Wang and Moczygemba (2015), Kirkire et al. (2018)
Risk sources (RS)	Product and user - technical (PU)	Technical issues related to possible risks in product design, development and use	ISO (2020), Malins et al. (2015), Li (2019)
	Process - tactical (PR)	Tactical issues related directly or indirectly to production/product	Michael et al. (2018), Pane et al. (2019), Guerra-Bretaña and Flórez-Rendón (2018)
	Business and market - strategic (BM)	Strategic issues that may impact products and processes in the long term	ISO (2015), Hale et al. (2020), Águas and Sobral (2019), Kirkire et al. (2018)

The experts of companies A, B, C and E were interviewed and received information about the problem, objectives, use of the method and filling out the matrices. Furthermore, the matrices were sent by means of an Excel spreadsheet with the structured problem (Figure 2) and four matrixes to be filled in: the family matrix (5x5), in which the criteria of level 1 of the matrix (EI, OC, RA, TQ, RS) were evaluated; the 2x2 matrix, concerning RA sub-criteria (OT and FH); and two 3x3 matrices, with the EI and RS sub-criteria SL, TL, OL and PU, PR, BM, respectively. Data collection was finalized in January 2022.

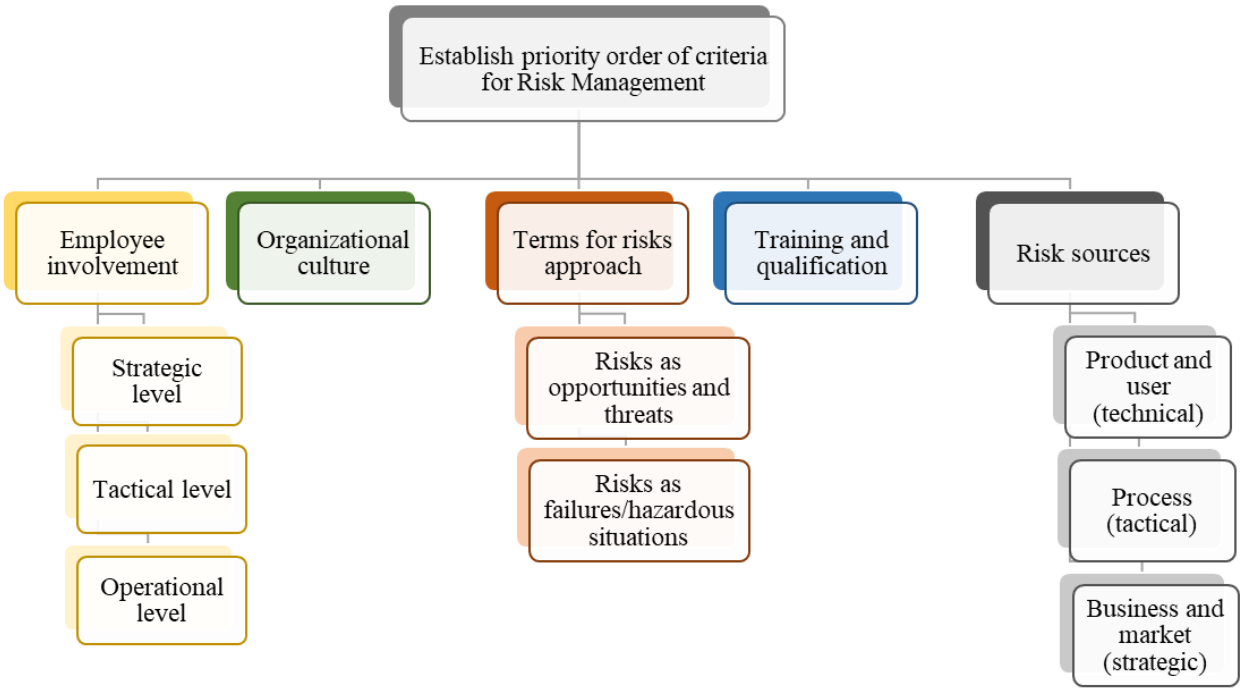

Figure 1 - Hierarchical structure of the problem

Data collection and analysis

From the pairwise comparisons carried out individually by each one of the five evaluators, the matrices were filled in and the tables composed by the individual evaluations, and respective local prioritization eigenvectors were calculated together with the consistency indexes, in the following order: Table 5 referring to the family matrix, of level 1 criteria; Table 6 referring to the matrix of subcriteria associated with the terms for risks approach; Table 7 referring to the matrix of subcriteria associated with employee involvement; and Table 8 referring to the matrix of subcriteria of risk sources. For the judgments with consistency indexes higher than 0.10, the researcher requested that the experts revalue their considerations, however, even after a new analysis they chose to keep the importance ratings, which they deemed to be coherent (Company D - family matrix - CI 0.18; Company C and Company E - 3x3b matrix - CI 0.12).

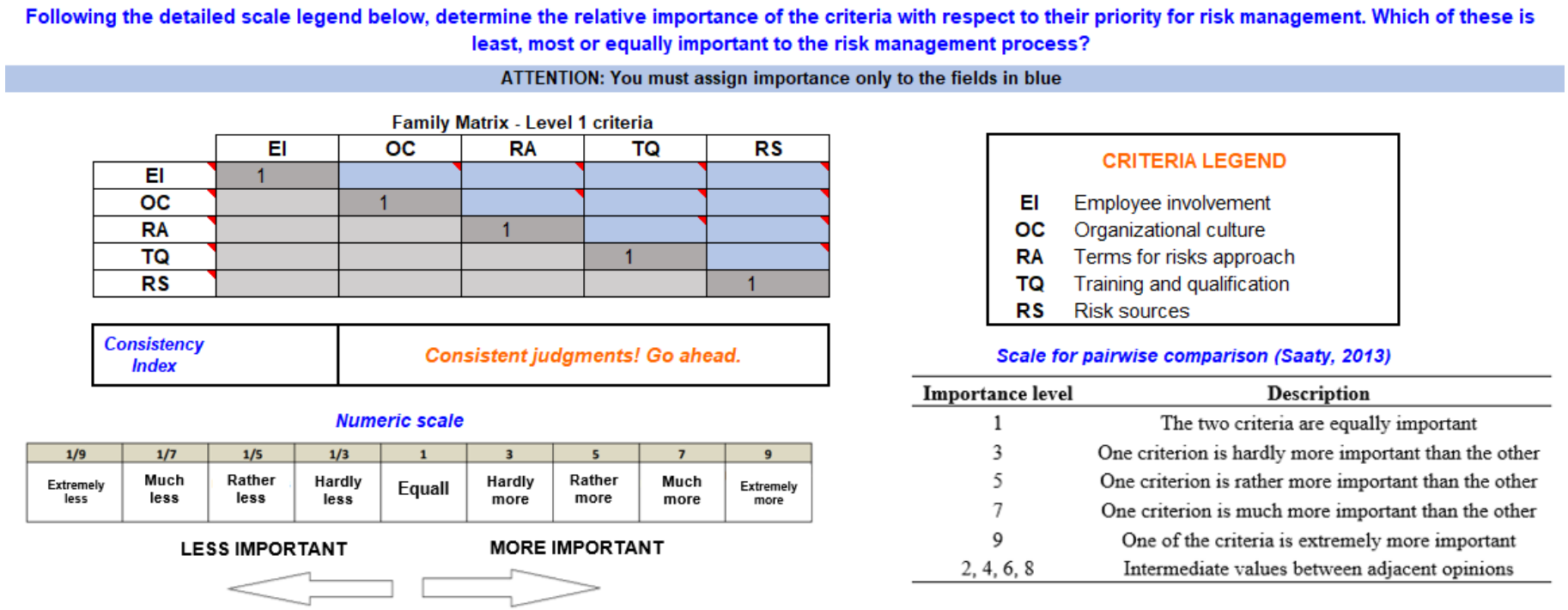

Figure 2 - Model of the Excel spreadsheet sent to the evaluators for the Family Matrix

In the analysis of the Family Matrix (Table 5) the Company A, which does not have a certified QMS, considers as the most important criterion the involvement of employees, followed by training and qualification, and as least important, the definition of the terms for risks approach. The judgments of the specialist from this company are in line with the assessments of Companies B and E, both certified by ISO 13485, which consider the same criteria as the most important, disagreeing only on the least important, which for both experts is the organizational culture. The judgements of Companies C and D, certified by ISO 13485 and ISO 9001, diverge a little more than the others: for Company D, the organizational culture is the second most important criterion in risk management, the first being the involvement of employees and the least important being the sources of risk.

Table 5 - Comparison matrices with experts' judgements for the family matrix

Company A	**EI**	**OC**	**RA**	**TQ**	**RS**	**Local priority**	**CI**
EI	1	3	5	1	5	0.389	
OC	1/3	1	3	1	3	0.204	
RA	1/5	1/3	1	1/3	1/3	0.062	0.08
TQ	1	1	3	1	1	0.214	
RS	1/5	1/3	3	1	1	0.132	
Company B	**EI**	**OC**	**RA**	**TQ**	**RS**	**Local priority**	**CI**
EI	1	3	3	3	3	0.404	
OC	1/3	1	1/3	1/3	1/3	0.074	
RA	1/3	3	1	1	1	0.166	0.07
TQ	1/3	3	1	1	3	0.214	
RS	1/3	3	1	1/3	1	0.142	
Company C	**EI**	**OC**	**RA**	**TQ**	**RS**	**Local priority**	**CI**
EI	1	1	1	5	1	0.204	
OC	1	1	1/3	5	1/3	0.167	
RA	1	3	1	3	1	0.265	0.08
TQ	1/5	1/5	1/3	1	1/3	0.063	
RS	1	3	1	3	1	0.265	
Company D	**EI**	**OC**	**RA**	**TQ**	**RS**	**Local priority**	**CI**
EI	1	5	7	7	7	0.534	
OC	1/5	1	5	3	5	0.214	
RA	1/7	1/5	1	3	5	0.124	0.18
TQ	1/7	1/3	1/3	1	5	0.090	
RS	1/7	1/5	1/5	1/5	1	0.038	
Company E	**EI**	**OC**	**RA**	**TQ**	**RS**	**Local priority**	**CI**
EI	1	3	3	1	1	0.271	
OC	1/3	1	1/3	1/3	1/3	0.074	
RA	1/3	3	1	1/3	1	0.142	0.05
TQ	1	3	3	1	3	0.334	
RS	1	3	1	1/3	1	0.179	

Regarding the terms for risks approach analysed in the 2x2 Matrix (Table 6), experts from companies A, D and E consider "opportunities and threats" as the most important criterion; while companies B and C consider "opportunities and threats" and "failures and dangerous situations" as equally important criteria for risk management.

Table 6 - Comparison matrices with experts' judgements for the 2x2 matrix (RA)

Company A	**OT**	**FH**	**Local priority**
OT	1	3	0.750
FH	1/3	1	0.250
Company B	**OT**	**FH**	**Local priority**
OT	1	1	0.500
FH	1	1	0.500
Company C	**OT**	**FH**	**Local priority**
OT	1	1	0.500
FH	1	1	0.500
Company D	**OT**	**FH**	**Local priority**
OT	1	3	0.750
FH	1/3	1	0.250
Company E	**OT**	**FH**	**Local priority**
OT	1	5	0.833
FH	1/5	1	0.167

Although the involvement of employees was considered most important in risk management by all experts (in first and second places), the judgements of the subcriteria related to it presented divergences (Table 7). It was not possible to identify a relationship between the ISO certification of each company and the local prioritization established by the experts judgements: the involvement of strategic level employees is considered more important in risk management by Company B, certified only by ISO 13485, and by Company D, which has QMS certified by both ISO 13485 and ISO 9001; for the expert of Company C, which also has both certificates, the involvement of employees from the three organizational levels is equally important for the process; while for Company A, which has no certified QMS, and for Company E, certified in ISO 13485, the tactical and operational levels are equally more important in terms of involvement in the risk management process, considering the involvement of employees from the strategic level as less important.

Table 7 - Comparison matrices with experts' judgements for the 3x3a matrix (EI)

Company A	**SL**	**TL**	**OL**	**Local priority**	**CI**
SL	1	1/3	1/3	0.143	
TL	3	1	1	0.429	0.00
OL	3	1	1	0.429	
Company B	**SL**	**TL**	**OL**	**Local priority**	**CI**
SL	1	3	3	0.600	
TL	1/3	1	1	0.200	0.00
OL	1/3	1	1	0.200	
Company C	**SL**	**TL**	**OL**	**Local priority**	**CI**
SL	1	1	1	0.333	
TL	1	1	1	0.333	0.00
OL	1	1	1	0.333	
Company D	**SL**	**TL**	**OL**	**Local priority**	**CI**
SL	1	5	5	0.714	
TL	1/5	1	1	0.143	0.00
OL	1/5	1	1	0.143	
Company E	**SL**	**TL**	**OL**	**Local priority**	**CI**
SL	1	1/3	1/3	0.143	
TL	3	1	1	0.429	0.00
OL	3	1	1	0.429	

The same occurs in the analysis of risk sources considered in the process, compared in the 3x3b matrix (Table 8). Product and user risks are considered more important for risk management according to the judgements of experts from Companies B and E and, equally more important to the subcriterion business and market risks, for Company D. For Company C, business and market risks are the most important subcriterion for risk management, being process risks considered less important. On the other hand, for Company A, process risks are the most important subcriterion for risk management.

Table 8 - Comparison matrices with experts' judgements for the 3x3b matrix (RS)

Company A	**PU**	**PR**	**BM**	**Local priority**	**CI**
PU	1	1/3	1	0.200	
PR	3	1	3	0.600	0.00
BM	1	1/3	1	0.200	
Company B	**PU**	**PR**	**BM**	**Local priority**	**CI**
PU	1	1	5	0.480	
PR	1	1	3	0.405	0.03
BM	1/5	1/3	1	0.115	
Company C	**PU**	**PR**	**BM**	**Local priority**	**CI**
PU	1	3	1/3	0.286	
PR	1/3	1	1/3	0.140	0.12
BM	3	3	1	0.574	
Company D	**PU**	**PR**	**BM**	**Local priority**	**CI**
PU	1	5	1	0.455	
PR	1/5	1	1/5	0.091	0.00
BM	1	5	1	0.455	
Company E	**PU**	**PR**	**BM**	**Local priority**	**CI**
PU	1	3	3	0.574	
PR	1/3	1	3	0.286	0.12
BM	1/3	1/3	1	0.140	

RESULTS

The Table 9 describes the final prioritization of criteria, obtained from the arithmetic mean of the judgements of experts from companies A, B, C, D and E. Despite the existing divergences, data did not present a high standard deviation that would justify the use of the geometric mean. It can be seen that the most relevant criteria for risk management in the medical devices sector according to the participating experts is the involvement of employees (EI) at the strategic level (SL) with approximately 36%, followed by the tactical and operational levels considered by the experts as equally important. The second most important criterion for the process, according to the judgments, is training and qualification (TQ) and the criterion considered least important was organizational culture (OC), followed by terms for risks approach (RA) and risks source (RS), with about the same percentage.

Table 9 - Final criteria prioritization

Criteria	Global priority		Rank
Family Matrix - Level 1			
EI	0.368	36.8%	1º
OC	0.147	14.7%	5º
RA	0.152	15.2%	3º
TQ	0.183	18.3%	2º
RS	0.151	15%	4º
Matrix 2x2 - RA			
OT	0.667	66.7%	1º
FH	0.333	33.3%	2º
Matrix 3x3a – EI			
SL	0.387	38.7%	1º
TL	0.307	30.65%	2º
OL	0.307	30.65%	2º
Matrix 3x3b - RS			
PU	0.399	39.9%	1º
PR	0.305	30.4%	2º
BM	0.297	29.7%	3º

The experts' reports are in line with the studies identified in the literature, which characterize risk management as a practice that should be encouraged in organizations and that given its practical and normative rigor, is not something very intuitive for all employees, which leads to the need for knowledge dissemination about the process (Björnsdóttir et al., 2021; Crovini et al., 2020). Thus, it is possible to conclude that training and qualification in risk management, associated with the involvement of workers in the process, are means for the practices to be embedded in the organizational culture and therefore risk management becomes part of the culture of the company.

The terms for risks approach (RA) most important for carrying out risk management are risks as opportunities and threats (OT) with 66.7%, which is aligned with the requirements of ISO 9001 and the aspects discussed by Hale et al. (2020), Águas and Sobral (2019) and Miclăuș et al. (2019) that highlight the importance of considering all possible risks and benefits associated to the product. Finally, although the criterion risk sources (RS) were ranked 4th in the overall prioritization, the analysis of the subcriteria points to product and user (PU) risks and process risks (PR) as the most important for risk management, leading to business and market risks as less important. This can be explained by the fact that product and safety in terms of usability are critical factors in the medical devices sector. Generally, it was observed that being or not certified by ISO standards, especially regarding ISO 9001, has some relation with the experts' judgments, but it does not apply to all the analyses.

CONCLUSION

Through the AHP method it was possible to identify the most relevant criteria for the risk management process from the point of view of the experts from the medical device SMEs that was object of this study. Although the results cannot be generalized, the experts' judgments enable the identification of the scenario of the practices of these companies and therefore the establishment of recommendations that can be used as a basis for the development of new investigations. Thus, the research resulted in relevant analyses both for SMEs from the sector and for researchers, within the scope of risk management.

Considering the specificities of each company, namely regarding the certifications associated with QMS and risk management, it was expected that the behavior of the judgments would present some variation among the experts. However, the analysis of local priorities showed that there is similarity between some assessments. The research emphasizes that risk management is a comprehensive process and depending on the characteristics of each company and the interpretation of their experts, it can be understood and implemented in different ways.

Among the limitations of this research is the research method, both regarding the consistency index calculation and the number of evaluators. Although a large number is not indicated to avoid inconsistencies and complexity in the evaluations, it can bring a broader and more representative view of the problem. The development of this study enabled the analysis of the methods used by medical device SMEs for risk management, in progress for a new paper.

AKNOWLEDGEMENTS

This study was financed in part by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brazil (CAPES) - Finance Code 001.

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