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RISK MANAGEMENT STRATEGIES FOR MEDICAL DEVICES: AN INTER-AGENCY AND MULTI-REGIONAL ANALYSIS

Authors: Renan James Lim, Oliver Alix and Venus Marie Rojas

Reviewers: Ramon Jose , El Rey Tabuzo, Fiel Amor Soliven and Maria Cristina Eco

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1. Introduction

1.1 What is a Medical Device?

The term, medical device, encompasses multiple products used by a variety of medical specialties and covers for a very wide population and with specific needs. Medical devices can come in different shapes, sizes, and functions – from as simple as a tongue depressor to as complicated as a heart pacemaker. The ISO 14971:2019 defines a medical device as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar articles that is intended for use by human beings only[1].

Medical devices have broad indications ranging from – (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury; (c) investigation, replacement, modification, or support of the anatomy or of a physiological process; (d) supporting or sustaining life; (e) control of conception; (f) disinfection of other medical devices; (g)providing information by means of in vitro examination of specimens derived from the human body. Moreover, medical devices are further differentiated from other products with medical purposes by the fact that its primary function is not attained mainly through any pharmacological, metabolic, or immunological action in the human body; however, it may assist in such actions. [1]To help ensure efficacy for claimed effects, short- and long-term safety must be ensured for users of these devices.

The use of medical devices is inherently accompanied by risks of varying degrees. As it is not possible to absolutely guarantee the safety of any medical device, manufacturers need to provide substantial evidence that the benefit of using their device greatly outweighs the risks.

This paper is written to provide a primer on medical device risk management and seeks to describe number of region-specific risk management strategies.

1.2 Why do Risk Management?

Risk management is a formal and systematic method that allows manufacturer's to claim the safety of their device in a way that is not based solely on subjective judgment[2].

Gradually, industries have now shifted to risk-based decisions that involve the identification and analysis of risks. The nature of the conclusions that arise from these is probabilistic. The medical device industry can benefit from the use of risk management for several reasons. This includes being saved from possible costs incurred by product recalls or lawsuits and making sure that the medical device design is cost-effective and not overengineered to avoid risks, which may be unnecessary and expensive [2].

Medical recalls cost a substantial amount for the company involved. It can be recalled that among the most expensive medical recalls in history involving the drugs Vioxx and Tylenol incurred their manufacturers a cost of around $4.7 billion and $100 million dollars, respectively [3]. For 2019 alone, the US Food and Drug Administration (FDA) listed more than forty medical devices on their website as part of the recalls issued due to the presence of unacceptable amount of risk identified in the use of these devices [4].

According to a report by Stericycle, majority of the product recalls in the medical device industry for 2019 were classified by FDA as class I, which means that there is a reasonable probability that the product can cause serious adverse consequences or death [5]. In a single-center retrospective case series done by

Sengupta et al (2019)regarding the recall of InSync III model 8042 cardiac resynchronization therapy pacemaker (CRT-P), it was shown that out of the 90 patients that were observed by the Minneapolis Heart Institute on 2015 after the said product was recalled, five had syncopal attacks, six had heart failure exacerbations, and one had cardiac arrest [6].

1.3 Risk Management – a Brief History

The principles of risk management have been applied for decades in several other areas such as in insurances, corporate finances, information technology, enterprises, large-scale investment projects and project management. It was formally studied and incorporated in several industries around the 1950s after World War II and eventually in the 1980s international regulations for risk management commenced [7].

Prior to the development of formal guidance in risk management for medical devices, several developed countries have individually applied their own methods of risk management to medical devices [8]. In the United States, it was by decree of the Medical Device Amendment (MDA) of 1976 that the Food and Drug Administration (FDA) was tasked to follow strict protocols that would ensure safety and effectiveness of medical devices [9].Meanwhile in Europe on 1985, a council resolution on a new approach to technical harmonization and standards was released. Within this document, it was emphasized that there must be essential requirements met, such as protection of health and safety before products are placed in the market [10]. Eventually on 1993, the Council Directive 93/42/EEC or the Medical Device Directive (MDD) was published [11].

The International Organization for Standardization (ISO), an independent, international, non-governmental organization founded in 1947, also created standards related to safety principles and risk management for medical devices. In 1998, with the participation of 112 countries, they first published the ISO 14971. This standard outlined the process of risk analysis and management for medical devices and acts as the central standard for risk management in medical devices. The first edition of ISO 14971 was released on 2000, which was then revised into the 2nd edition on 2007. Prior to ISO 14971, there was still no international standard for risk management for medical devices. It was only on 2016 that the US FDA recognized ISO 14971:2007 as the appropriate standard for risk management. A harmonized version with the European standards, the EN ISO 14971:2012, was released to help identify discrepancies between the ISO 14971: 2007 and the current EU standards [2].

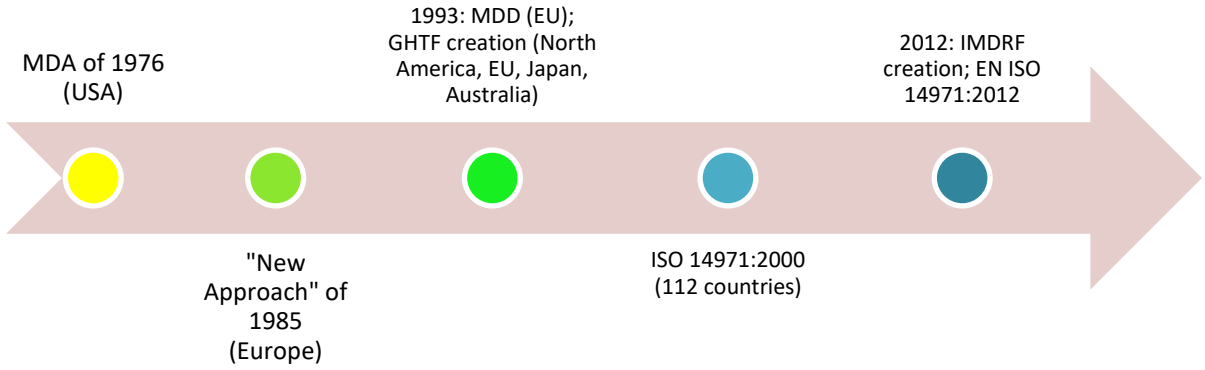

FIGURE 1: The History of Risk Management

On 1993 the Global Harmonization Task Force (GHTF) was created with the purpose of harmonizing the available national standards for the regulation of medical devices. The GHTF was the result of actions initiated by the government and medical device industry representatives from the countries of the European Union, USA, Canada, Japan, and Australia. Seeing the lack of well-established national policies and regulations on medical devices among developing countries, the GHTF aimed to provide a way for developing countries to have access to regulatory systems information similar to those of the developed countries. Through the harmonization of national standards, the selling of and access to medical devices are facilitated and the regulation barriers are minimized [12].The GHTF was disbanded on 2012 but its objectives and tasks were continued by the International Medical Device Regulators Forum (IMDRF).

The IMDRF came into conception on 2011 when authorities of the medical device regulation from the five founding countries of the GHTF (Australia, Canada, USA, EU and Japan) and the countries of Brazil and China met at Ottawa, Canada. After the GHTF agreed to disband, it was then replaced by the IMDRF. Its current members include the above-mentioned countries and the countries Russia, Singapore, and South Korea. The World Health Organization acts as an official observer of the IMDRF [13].

2. Risk Management for Medical Devices

2.1 The Vocabulary of Risk Management

Risk management – like most specialties – has its own jargon. To facilitate communication, a few terms are listed here:

Term	Definition
Basic Safety	Freedom from unacceptable risk directly caused by physical hazards when a medical device is used under normal condition and single fault conditions.
Harm	Injury or damage to the health of people, or damage to property or the environment.
Hazard Potential source of harm	
Risk	Combination of the probability of occurrence of harm and the severity of harm
Risk Analysis	Systematic use of available information to identify hazards and to estimate the risk
Risk Assessment	Overall process comprising a risk analysis and a risk evaluation
Risk Control	Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
Risk Evaluation	Process of the estimated risk against given risk criteria to determine the acceptability of risk.
Risk Management	Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk.

TABLE 1:SPECIAL VOCABULARY OF RISK MANAGEMENT [2]

2.2The Risk Management Process

In the life cycle of a medical device, risk management can be done in all the phases – from pre-marketing, to sales and advertising, and finally to post-marketing. It is a meticulous process that involves the cooperation of the manufacturer, the vendor, the government, the user, and the public [14]. Risk management is defined in the ISO 14971:2019 as the systemic application of management policies, procedures, and practices during the analysis, evaluation, controlling, and monitoring of risks [1].

Being a set of procedures, risk management is not simply a linear process, but instead it is a series of steps that can go in both directions and can interact with each other. Roughly, a risk management plan involves risk assessment, risk control, evaluation of overall residual risk, risk management review, and production and post-production services (see figure 2)[15]. Identifying and managing risks in medical devices, however, is not very straightforward because of their sheer number, the multitude of functions they can have, and the rate at which innovation constantly modifies their features [2]. Moreover, it is impossible

to absolutely quantify risks and thus international standards like that of the ISO only help to estimate and evaluate these risks [14].

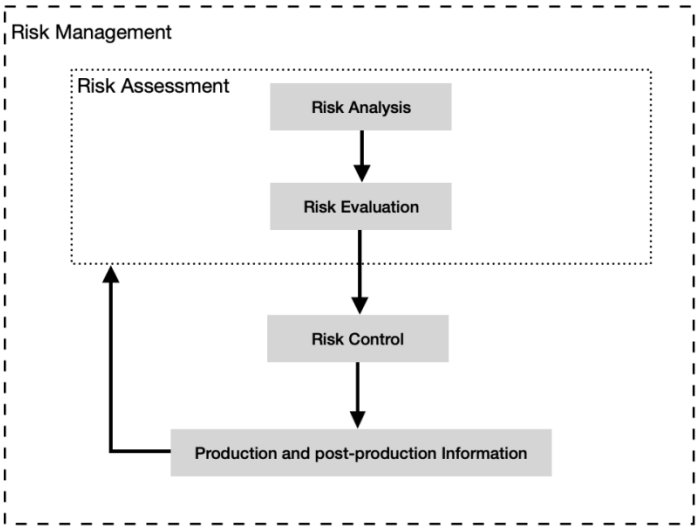

FIGURE 2: ISO 14971 Risk Management Processes [2]

In the risk management process outlined by ISO 14971:2019, the procedure starts with risk assessment. Risk assessment involves risk analysis and evaluation. It is a step that is done through the help of experiences of healthcare providers and other allied health professionals and on safety engineering [12]. In analyzing risks, it is important to be able to specify the intended use of the product and to take note of its features that indirectly affect its primary function, which together characterizes the performance of the device. This is because the safety of the device can be approximated through its performance. A malfunctioning device or a device that is not optimal in performance is potentially hazardous, thus performance evaluation and hazard identification go hand-in-hand[15].

Risk analysis involves identification of all possible hazards posed by the medical device [2,15]. Hazard identification is a subjective matter, which is apparent in the fact that each country or region may adapt their own specific method of hazard classification for medical devices. In the United States, for example, medical devices are classified into three levels according to risks – Class I, II, and III, which is based on the level of control needed to assure the safety and effectiveness of the device [16]. The European Union, on the other hand, has a classification that also has three levels but is based on the intended purpose for use of the device. The higher the Class number, the greater the assessment required for that device. Moreover, Class I is subdivided into sterile (Is) and with measuring function (Im), while Class II medical devices are subdivided into IIa and IIb [17].

The GHTF published on 2006 a unified classification of medical devices according to hazards they pose. Under the GHTF medical device classification, there are four levels of classification for medical devices – Class A, B, C, and D, with Class A posing the lowest hazard and D with the highest hazard (see Table 2). The rules of the GHTF classification does not only involve the assessment of present hazards but must also consider any future innovation on the device [18].

CLASS	RISK	RULES
Class A	Low risk	• All non-invasive medical devices intended for channeling or storing body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body • e.g.: thermometer, tongue depressor
Class B	Low-moderate risk	• All surgically invasive medical devices intended for transient use • All active therapeutic medical devices intended to administer or exchange energy • e.g.: hypodermic needle, suction equipment
Class C	Moderate-high risk	• All non-invasive medical devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids intended for infusion into the body • All implantable medical devices, and long-term surgically invasive medical devices • e.g.: mechanical ventilator, bone fixation plate
Class D	High risk	• All medical devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the medical devices • All medical devices manufactured from or incorporating animal cells, tissues and/or derivatives thereof, rendered nonviable, or cells, tissues and/or derivatives of microbial or recombinant origin • e.g.: heart valve, implantable pacemaker

TABLE 2: Risk Classification of Medical Devices

The potential hazard of a medical device is in turn directly proportional to the stringency of requirements for regulation [18]. For devices, most especially those classified under the high-risk category, pre-market evaluations such as pre-clinical data from bench testing, observational studies, and sometimes randomized clinical trials (RCT) are warranted before a product is cleared or approved by a regulatory

body. After market activities may include post-marketing surveillance and registry data to further assess benefits in a wider population and to look for long-term adverse-event (AE) signals [18].

After the potential hazards of the medical device are identified and the device has been classified accordingly, risk estimation for each hazard is done. This is considered as the final step in risk analysis, wherein the severity of each harm is identified, and the probability of this occurring is estimated [15]. Risk estimation can be done in three ways – qualitative, semi-quantitative, and quantitative. Among the three, the quantitative method is the most preferred and is further discussed on the section of Risk Estimation in this paper [2].

The next step under risk assessment involves risk evaluation, which makes use of specific criteria for risk acceptability to evaluate the estimated risks that were defined and identified during risk analysis. The criteria for risk acceptability must be included in the risk management plan and is created based on applicable standards (preferably harmonized ones) or state-of-the-art information and/or by subject expert opinion and the policy defined by the top management or the individuals who direct and control the business unit/corporation. It is during risk evaluation that it is decided upon whether the estimated risks are acceptable or not. According to ISO 14971, risk evaluation should be done for each hazard, each hazardous situation, and in the overall use of the device [2, 15].

After risk assessment, manufacturers need to specify measures to reduce the risks identified. These measures are called risk controls and must be able to decrease the risks to As Low As Reasonably Possible (ALARP) or as As Far As Possible (AFAP) according to ISO 14971:2007 and EN ISO 14971:2012, respectively [2]. Several options for risk control are available to manufacturers. The first one is to ensure that the design and manufacturing process is inherently safe. This option is the most preferred however if this is not possible, then the manufacturer must implement protective measures in the design and manufacturing of the medical device. The third option is to provide users with safety information, such as instructions for use, warnings, and contraindications [15].

After risk controls are implemented or put in place, the amount of risk that remains is called the residual risk. This residual risk also needs to be estimated and evaluated. This step is similar to the risk evaluation prior to the incorporation of risk controls. The evaluation of residual risks should make sure that these risks are reduced to as ALARP or AFAP and using similar risk acceptability criteria previously described during risk assessment. If the residual risks are deemed still reducible then more risk controls are incorporated, and residual risk evaluation is again done. The residual risk evaluation also needs to be performed for each hazard and each hazard situation. When the residual risks are already reduced to ALARP or AFAP, overall residual risk is then computed, and a benefit-risk analysis is performed to determine whether the benefits of using the device outweigh the residual risks. ISO 14971:2019 requires the manufacturer to document the method and the acceptability criteria used in evaluating the overall residual risk [2,15].

To ensure completeness of the risk management process, ISO 14971 requires the manufacturer to review the risk management plan after the development of the design of the device, before its commercial distribution. In this step, the manufacturer makes sure that the risk management plan was properly executed. A risk management report (RMR) is then prepared and kept among the important files related

to the device. The RMR contains a summary of the Hazard Analysis Report (HAR), which describes most of the details of the methods used in the risk management process of the specific device [2, 15].

The last step in the risk management process outlined by ISO 14971 requires manufacturers to collect and evaluate information about the medical device during both its manufacturing process and post-production. Monitoring and evaluation during the production phase aims to prevent the selling of defective or potentially hazardous devices while post-production monitoring aims to evaluate the device's performance in the field. If during the monitoring and evaluations at this step indicate that a certain risk is deemed unacceptable, the manufacturer is required to take action in the production process, e.g. by reviewing the risk management file to implement risk controls, or in the post-production phase including those devices already in the market[2, 15].

2.3 Risk Estimation

Clause 4.4 of ISO 14971 requires that an estimate of the risk associated with a hazardous situation be estimated by manufacturers. Figure 3 (see below) highlights that risk is the probability of sustaining harm in a hazardous situation. This means that it is possible that there is a higher risk present when a fairly frequent minor harm occurs compared to a severe harm with that rarely occurs.

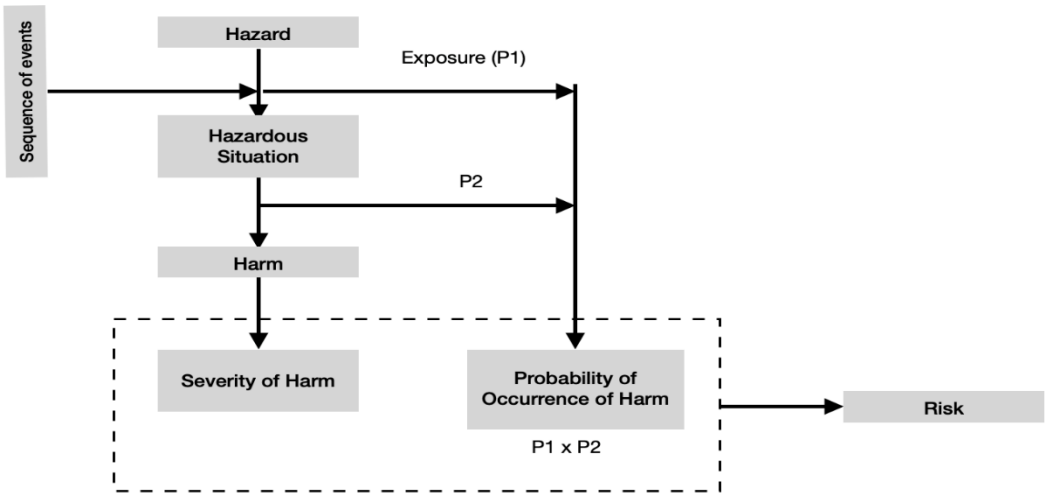

FIGURE 3: ISO 4917 Figure E.1. P1 is the probability of a hazardous situation occurring. P2 is the probability of a hazardous situation leading to harm [2]

A caveat that must be noted is that given a hazardous situation, different people will perceive different degrees of harm. Indeed, risk perception and tolerance are strongly influenced by human psychology [2]. For example, people tend to be more tolerant of natural risks than man-made risks. The same is true with how people are less forgiving in instances when children suffer an adverse event compared to when adults experience one [2].

3. Regional Approaches to Risk Management for Medical Devices

3.1 USA[11,12]

In the USA, the FDA's Center for Devices and Radiologic Health (CDRH) is in charge of regulating companies who manufacture, repackage, relabel, and/or import medical devices. A unique feature of the system in place in the US is that device classification is abbreviated to span only three classes. Regulatory control increases from class I to III.

Generally speaking, medical device manufacturers must comply with the following regulatory requirements if they wish to market their products in the USA: (a) establishment registration, (b) medical device listing, (c) premarket notification 510(k) or premarket approval (PMA), (d) investigational device exemption (IDE) for clinical studies, (e) labeling requirements, and (f) medical device reporting (MDR). To be succinct, most class I devices are exempt from Premarket Notification 510(k); most class II devices require Premarket Notification 510(k); and most class III devices require PMA. Figure 2 presents the FDA's approval process for a medical device.

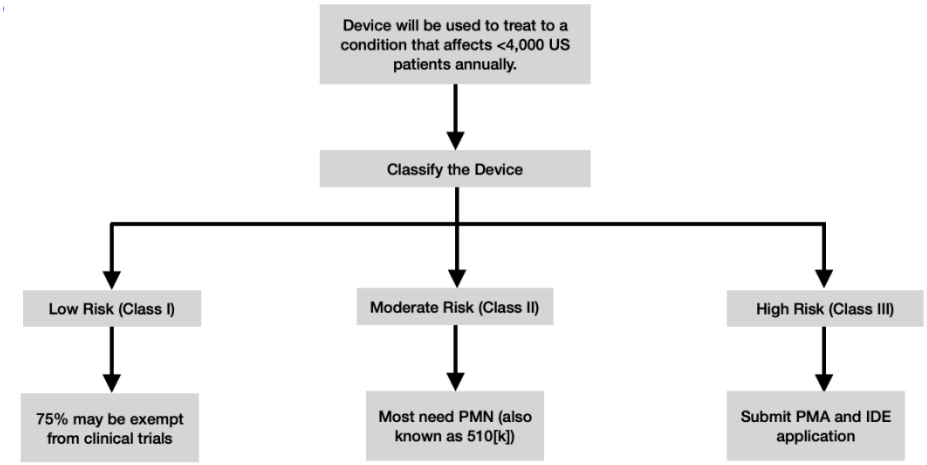

FIGURE 4: FDA Medical Device Approval Algorithm

The FDA's approval process is intended to provide consumers with the assurance that, once it reaches the marketplace, a medical device is safe and effective in its intended use. It takes roughly three to seven years for a medical device to be brought into the market. Thereafter, the FDA monitors the safety and performance of the device in the years to come.

As of June 27, 2016, the FDA recognizes compliance to ISO 14971:2007 as sufficient proof of safety [2].

3.2 EMEA[12,13]

In the EU, medical devices are regulated at the Member State level. The Medical Device and In-Vitro Diagnostic Devices Regulations have delegated these responsibilities to the European Medicines Agency (EMA) and member state accredited notified authorities in the evaluation of certain medical devices. These devices need to undergo a conformity assessment as proof that legal and safety requirements are met and perform as intended. The conformity assessment is essentially an audit of the quality systems of the manufacturer and the technical documentation of the product's safety and performance. Upon passing the conformity assessment, manufacturers may place a CE (Conformité Européenne) mark on their product. The process mentioned above is enacted under the stipulation of the Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In-Vitro Diagnostic Devices (IVDR). Three essential requirements must be fulfilled in order to be eligible for approval [2]:

1. The medical device must be safe when used as intended by the manufacturer
2. Their risks be outweighed by their benefits.
3. The risks be reduced as far as possible.

Central to the EU framework is the role of the EMA in approving the use and advertisement of medical devices. Medical devices may be further qualified as: (a) combination products, (b) devices with ancillary medicinal substance, (c) in-vitro diagnostics, (d) devices made of substances that are systemically absorbed, and (e) borderline products. Regardless of the classification, the EMA – via a centralized procedure – evaluates the safety and performance of these devices and is the source of scientific opinion when ambiguities arise.

Member states are given a staggered transition period to comply to the standards of the EU in order to benefit from the free movement of goods in between each member state. In light of the COVID-19 pandemic, this transition period has been se tat 26 May 2021.

3.3 Canada[14]

The Medical Devices Bureau of the Therapeutic Products Directorate (TPD) is the national authority that monitors and evaluates the safety, effectiveness, and quality of diagnostic and therapeutic devices in Canada. The TPD regulates medical devices by ensuring, to the extent possible, the safety, effectiveness, and quality of these products via pre-market review, post-market surveillance, and quality systems in the manufacturing process.

Prior to selling a medical device in Canada, manufacturers of class II, III, and IV must obtain a medical device license issued by the Medical Devices Regulations (MDR).Once a manufacturer applies for the said license, it will be the TPD responsible for review prior to approval by the MDR. Although the length of review varies depending on the device, class III and IV license applications have a target review time of 75 days and 90 days, respectively. Class II device license applications have a 15-calendar day target.

On the other hand, class I devices are only monitored through establishment licenses – which are, simply put, a means for the TPD to identify the establishments that manufacture and sell these products.

The TPD serves as the country's watch dog of medical devices after license approval to ensure their continued safety and effectiveness. Failure to reach the TPD's standards would mean the suspension or revocation of a license and the manufacturer may be asked to recall or refit their device.

3.4 Japan

In 2015, the Regulatory Information Task Force Japan Pharmaceutical Manufacturers Association published a guide entitled Pharmaceutical Administration and Regulations in Japan of which the main objective is to improve public health through regulations required to assure quality, efficacy, and safety of drugs, quasi-drugs, cosmetics, medical devices, and regenerative medicine products and to prevent hazard and expansion of hazard in public health caused by use of those products. It outlines the pharmaceutical laws and regulations, approved reference standards, drug development, approval, post-marketing surveillance, drug-safety information sharing, health insurance and drug pricing. While it is the main governing law, there is a special law governing medical devices

3.5 ASEAN

In the same year, the Association of South East Asian Nations (ASEAN) published a document entitled ASEAN Medical Device Directive outlining the need for and to adhere to guidelines and principles set for by the region with regard to medical device marketing, use and safety. It emphasizes the need for a regulatory body for each member state who will evaluate the device with regard to conformity with the agreement.

The agreement also introduced the Common Submission Dossier Template (CSDT), aiming to reduce differences in documentation format within the region. The information needed within the CSDT consists of executive summary, methods to demonstrate conformity, device description, design verification, and device labelling. Post marketing Alert System (PMAS) Requirements are also included which provides guidance on post-market obligations for device suppliers. The PMAS mainly deals with the following requirements: (a) Importation and/or distribution records (b) Complaint records (c) AE reporting criteria and reporting format and (d) Field Safety Corrective Action (FSCA) reporting format.

For the Taiwan Food and Drug Administration (TFDA), regulations for medical devices are governed by the Pharmaceutical Affairs Act. Medical devices are classified into 3 classes and 17 categories based on their levels of risk.

Class	Risk	Categories
I	Low	Clinical Chemistry and Clinical Toxicology Devices
II	Medium	Hematology and Pathology Devices
III	High	Immunology and Microbiology Device
		Anesthesiology Devices
		Cardiovascular Devices
		Dental Devices
		Ear, Nose, and Throat Devices

		Gastroenterology and Urology Devices
		General and Plastic Surgery Devices
		General Hospital and Personal Use Devices
		Neurological Devices
		Obstetrical and Gynecological Devices
		Ophthalmic Devices
		Orthopedic Devices
		Physical Medicine Devices
		Radiology Devices
		Other Categories Specified by the National Health Competent Authority

TABLE 3: TFDA Classification of Medical Devices

4. Conclusion

Medical devices range from simple implements to complex pieces of engineering – all of which are used on human beings. This nature of medical devices has rightly made it the subject of numerous measures to mitigate the possibility of causing harm to its end users. The process by which risk is systematically and methodically assessed and thereafter addressed is called risk management. This approach has been refined throughout the years and may come with variations per region. Fairly recently, attempts have been made to streamline these differences as expressed by ISO 14971:2007. This paper shows the differences among specific regions with regards to risk management in medical devices – and more strikingly, their similarities.

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6. Authors Profile

The MEDICAL DEVICE - COPY DEVELOPMENT TEAM is a highly diversified collection of meritocratic, goal-oriented and output driven individuals. The group is led by the project manager Tin who has 10 years of site research management and six years project management experience. The team lead Mon is a practicing orthopedic surgeon with special interests in Traumatology and Hip and Knee Arthroplasty. We have four clinical scientists – two physicians and two allied medical personnel. The two physicians includes Venus, who is a generalist with a strong background in clinical research with particular attention to infectious diseases, evidence-based medicine (EBM), and digital health; and Renan, who has a background in neurosurgery and artificial intelligence development. They are both currently pursuing post-graduate degrees. The two allied medical personnel includes Fiel, a registered clinical pharmacist with leadership experience as an Associate Editor in a healthcare publishing company; and El Rey, an experienced (10 years) OR nurse with roles and exposure to general, laparoscopic, plastic and reconstructive surgeries. Oliver, the medical affairs physician, is a clinical cardiologist with interests in cardiac imaging, medical education, clinical research, and EBM.

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