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The Compliance of Medical Equipment Design Technology against Indonesian Medical Regulatory Board

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Abstract

The government policy on Indonesian National Health program demands adequate supply of medical devices in terms of the number and type of equipment. Currently, there are about 90% of the medical devices are obtained through imports and 10% are sourced locally. In 2035, the Health Ministry has projected to reduce their dependency to imported devices up to 35% through a localization program which to be accelerated by domestic industry. During the implementation effort, the progress is rather slow due to technology limitation coupled with acute shortage of expertise in the area of medical device products. This technology is scarce but it is a foothold for the development of safe and effective as intended use and shorter time to market. In this study the medical device's design technologies are examined to established the regulatory requirement and specifications. A paper review on medical devices technology and regulatory were done to formulate a systematic approach to identify the design requirement to meet the required standards. The main requirements are functionality, usability, safety and conformity against standards.

Keywords; *Medical Devices, product design technology, design requirements, regulatory requirement , systematic approach.*

I. INTRODUCTION

Medical Devices is defined as "any instrument, equipment, tool, material, or other item, whether used alone or in combination, including software needed for the proper application intended by the manufacturer to be used by humans for the purpose of diagnosis, prevention, monitoring, treatment , or reduction of disease, replacement, or modification of anatomic or physiological processes, and conception control. "[4]. Medical devices are an excellent resource for improving diagnosis and management of disease.

The Government of Indonesia in 2015 [1] in the National Industrial Development Master Plan (RIPIN) has determined that Medical Devices are the mainstay industry that will be developed from 2015 - 2035. The selection of medical devices is inseparable from the Indonesian government's policy on National Health Insurance (JKN) which triggered an increase in demand for medical devices to exports and imports over the past 4 years, can be seen from the average growth of Indonesia's medical device exports reaching 7.7%, while import growth for medical devices reached 12.7% [2].

Of the demand for domestic medical devices 90% of them are met through imports, only 10% are supplied from domestic industries. The target of RIPIN medical devices is towards independence of the domestic medical device industry in 2035, so as to ensure that the target can be achieved the President of the Republic of Indonesia issues presidential instructions to accelerate the growth of the medical device industry [3]. The president's instruction was followed by a decision of the

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minister of health with the action plan for the acceleration of the medical device industry as a technical guide for its implementation [4].

In the RIPIN, the types of technology of medical equipment have been formulated to be developed to ensure the independence of the medical device industry as shown in figure1.

No	Industry Priority	Technological Needs Developed		
		2015-2019	2020-2024	2025-2035
(1)	(2)	(3)	(4)	(5)
2	**Industry Pharmaceutical, Cosmetics And Medical Devices**	1. Product design	1. Product Design	1. Product Design
		2. Micro scale Measurement	2. Micro and nano scale measurements	2. Micro and nano scale measurements
		3. Electromagnetics	3. Electromagnetics	3. Electromagnetics
		4. Microelectronics	4. Micro-nano-bio electronics	4. Micro-nano-bio electronics
		5. Biomedical technology	5. Biomedical technology	5. Biomedical technology
		6. Automation and robotics	6. Automation and robotics	6. Automation and robotics
			7. Micro-nano-bio material	7. Micro-nano-bio material
			8. Pneumatic	8. Pneumatic
			9. Nuclear	9. Nuclear

Figure 1. Technology Needs for Medical Devices [1].

From Figure 1 can be seen that the technology of product design in every phase of development is always programmed, this indicates that the need for innovation in medical devices must indeed be mastered properly from the upstream. This means that the mastery of medical device innovation technology in Indonesia is still very weak, and efforts to accelerate are constrained by limitations in the mastery of technology in designing medical devices. This technology is a foothold in the development of medical devices that are safe and effective as intended use, and can be marketed in a short time.

Deepening is needed so that this product design technology is truly mastered because medical devices that are not well designed when placed on the market and have failed, and if the product class is class II or class III, there is a high possibility of "fatal failure" that can occur resulting in death in patients and in medical personnel or damage to health facilities and the environment.

Medical devices are products that are strictly regulated in their use ranging from premarket to postmarket. In Europe it is regulated to use MDR regulations, the US FDA, Indonesia AMDD etc., so that before a medical device is placed on the market the medical device must already have a marketing authorization [5] which guarantees that the product meets (in accordance with) regulatory requirements.

Medical devices are products with a very broad spectrum of products ranging from contraceptives, contact lenses, hospital beds, operating tables to pacemakers, each of which has a different level of security class. So for the successful mastery of product design technology, it is necessary to deepen its technology upstream, which is related to the product requirements from various aspects ranging from technical functions, operational ease to security aspects and the calculation of the risk of failure.

The purpose of this research is to provide the design requirements needed in the medical devices product development process so that the process can be done quickly and correctly, it is hoped that the resulting product can be immediately placed on the market and can meet the design criteria that have been set to provide assurance that the medical devices that is designed is can be used safely,effectively, good quality and useful according to its intended use.

II. METHODOLOGY

To obtain the design requirements for the design of medical devices, the methodology used is a literature review including product development standards, product safety standards, good manufacturing practices (GMPs), and product regulation. By using a systematic approach to information from the literature, it is then formulated and compiled into the mainrequirements for the design of medical devices.

III. LITERATURE STUDY

3.1 Systematic Approach

This design process methodology is referred to as the systematic approach methodology [10]. This approach can be illustrated as a black box (fig 2), which is connected directly to input and output. In general, input and output systems can be classified

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as energy, materials and signals, and in the box, function words are written, which are function statements that must be solved as expected outputs from this approach.

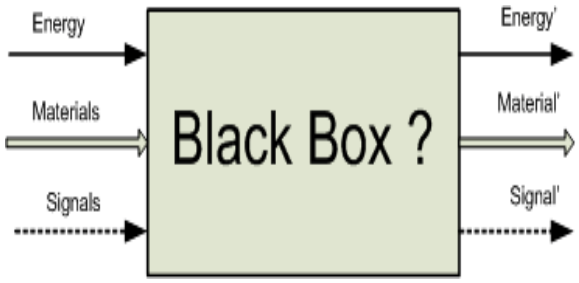

Figure 2.Energy, material and signal conversion. Solution not yet known; tasks or functions that are explained based on input and output, Pahl and Beitz [10]

Start with the overall function and then use it to structure the function, as shown in figure

The function structure is a detailed description of each specific function that is arranged to fulfill the overall function. Each special function must be unique that can complete the function as the focus as possible and the right solution can be proposed accurately as needed by the design requirements. If a function in the structure of a function cannot be defined as a unique function, it must be used again into sub functions consisting of unique functions

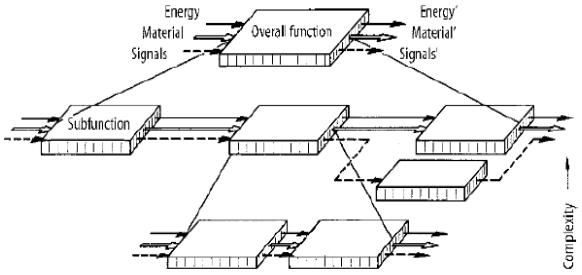

Figure 3. Building the structure of functions by breaking down the overall function into sub-functions, Pahl and Beitz [10]

3.2 Types of Medical Devices

With such a broad spectrum of products, these medical devices are classified into various types of medical devices, namely:

1. Medical devices: frombandages, tongue depressors, thermometer,contact lens, stetoskop, splints, first-aid kits, breathalysers, heart valves and imaging quipmentAs defined in Medical Devices Directive (MDD) 93/42/EEC [9]and PMK No. 62 2017[5].
2. Medical devices In-Vitro: reagents, control standards, test-kits, equipment intended for the in-vitro examination of human specimens e.g. blood grouping reagents, pregnancy test kits, Hepatitis B test kits.As defined in In-Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC [10] and PMK Nomor 62 tahun 2017[5].
3. Medical devices Active Implantable: aktiv (i.e. termasuksumberenergi) implantsataupartial implants e.g. heart pacemakersAs defined in Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC [13] and PMK No 62 2017[5].

3.3 Medical Device Product Development Process

The development of medical devices is a long process from premarket activities, clinical trials, registration of medical devices to the ministry of health, to the activities of placing products on the market which are then followed by postmarket activities. Isa T Santos [11] described this process as shown in Figure 4 and in the context of the product life cycle shown in Figure 5.

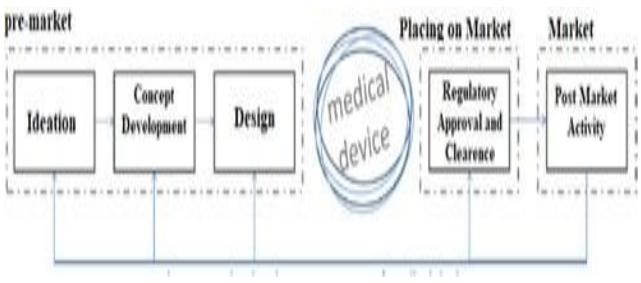

Figure 4. The process of developing medical device products [13]

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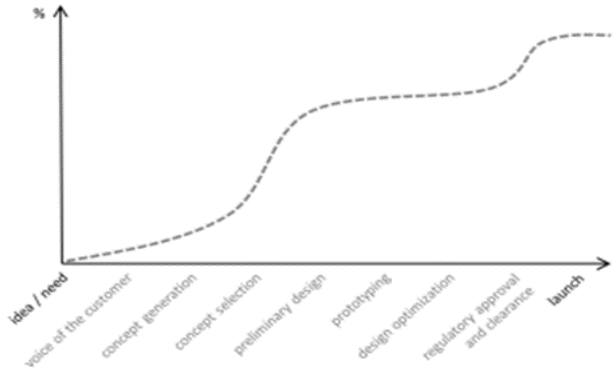

Figure 5. Life cycle of medical device products [13]

To get certainty that medical devices can fulfill the useful function of some developers of medical equipment products using the "water fall" model as shown in Figure 6. In this model at each stage of the process a review is carried out, the design output is verified as being compatible with the design input, and the product is validated compliance withuser requirements.

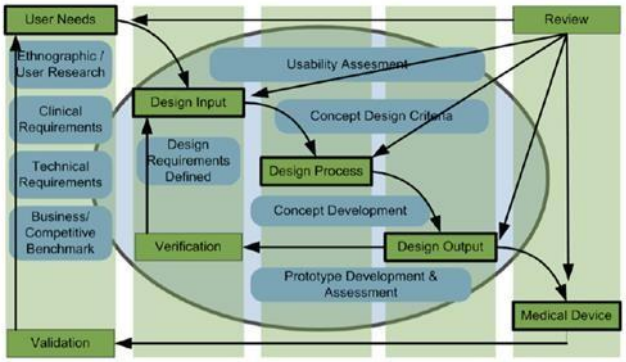

Figure 6. Water Fall model in the process of developing medical device products.

Indonesian Medical Devices Regulation Industry and medical device business regulations in Indonesia in the form of schemes ranging from pre-market to post-market are shown in figure 7. While the rules that become the basis of reference are the regulations of the minister of health, namely:

a. Permenkes No. 1189 / VIII / 2010 Concerning Certificates of Production of Medical Devices and Household Products [4]
b. Permenkes No. 1191 / VIII / 2010 Concerning Distribution of Medical Devices and Household Health Products [6]
c. Regulation of the Minister of Health of the Republic of Indonesia Number 62 Year 2017 Concerning Circulation of Medical Devices, In Vitro Diagnostic Medical Devices and Household Health Supplies [5]
d. Permenkes Number 20 Year 2017 Regarding Good Manufacturing Practices of Medical Devices and Household Health Supplies[7].

Figure 7. Schematic of Medical Device Regulation System

3.5 Safety Requirements for Medical Devices Safety requirements for medical devices in

the medical device industry generally follow the scheme of the IEC in this case using the structure of the IEC 60601-Series Module [12] as shown in figure 8.

This scheme consists of collateral standards in part 1 of generic standards and special standards in part 2 in the form of product standards. In part 1 in the collateral standard ISO 14971 [13] is placed relating to risk management which is used to accommodate the issue of failure that must be managed adequately from the concept stage to production with the intention to eliminate the occurrence of failure due to failure of the product in showing its best performance.

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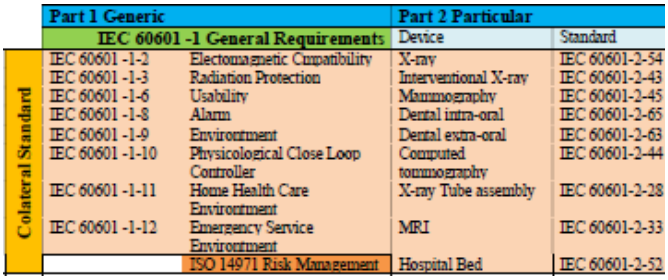

	Part 1 Generic		Part 2 Particular	
	IEC 60601 -1 General Requirements		Device	Standard
Colateral Standard	IEC 60601 -1-2	Electomagnetic Compatibility	X-ray	IEC 60601-2-54
	IEC 60601 -1-3	Radiation Protection	Interventional X-ray	IEC 60601-2-43
	IEC 60601 -1-6	Usability	Mammography	IEC 60601-2-45
	IEC 60601 -1-8	Alarm	Dental intra-oral	IEC 60601-2-65
	IEC 60601 -1-9	Environment	Dental extra-oral	IEC 60601-2-63
	IEC 60601 -1-10	Physicological Close Loop Controller	Computed tommography	IEC 60601-2-44
	IEC 60601 -1-11	Home Health Care Environment	X-ray Tube assembly	IEC 60601-2-28
	IEC 60601 -1-12	Emergency Service Environment	MRI	IEC 60601-2-33
		ISO 14971 Risk Management	Hospital Bed	IEC 60601-2-52

Figure 8.Module Structure of IEC 60601-Series medical device safety requirements.

3.6 Indonesian Medical Device Industry Opportunities and Challenges

The current existence of the medical device industry can be represented by the Association of Indonesian Medical Device Manufacturers (ASPAKI). ASPAKI data [15] states that the condition of the medical device industry in Indonesia is:

- Number of manufacturers of medical devices 275 companies
- The number of ASPAKI members is 85 companies
- Large Medical Devices Market is US $ 4.5 bn
- Manufacturing capability of US $ 1.45 bn
- Import US $ 3.65 bn
- Export US $ 0.8 bn

Products manufactured by domestic medical device manufacturers are [15]:

- Hospital furniture
- Sphygmomanometer, Stethoscope, Nebulizer
- Electromedic (infant incubator, nebulizer, O2 concentrator, dental chair, dll.)
- Disposables (syringes, urine bags, infusion set, masker, dll.)
- Medical Apparels (operating gown, bed sheets)
- Consumable (reagensia, anti septic, band aid)
- Others

3.7 Literature Compilation is related to Product Design activities.

From the literature study to the relationship of literature with aspects of product design and development activities shown in table 1. Sources of literature used include regulations on medical devices, safety standards, standards for good manufacturing practices (GMPs), publications in the form of articles or studies on medical devices.

Table 1. Literature Design and Development of Medical Device Products

Author	Titles/Years	Issue
ISO 9001: 2015	Quality management systems, 2015	General Quality management systems
ISO 13485 :2016	Medical devices - Quality management systemsRequirements for	Quality management systems of Medical Devices, year 2003
	regulatory purposes, 2016	
PMK No20: 2 017	Cara PmbuatanAlatKesehatan yang baik (CPAKB), 2017	Good Manufacturing Practices of Medical Devices Indonesian version
ISO 14971 : 2007	Medical devices Application of risk management to medical devices, 2007	It specifies a process identify hazards associated with medical devices
Europea n CounsilDirective 93/42/EEC	Medical Device Directive , 1993	Concerning medical devices
PMKN o. 1189 / VIII / 2010	ProduksiAlatKesehatan Dan PerbekalanKesehatanRumahTangga,	Regulation of Production Certification of Medical Devices and Household

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	2010	Products
PMK No62 : 2017	IzinEdarAlatKesehatan, AlatKesehatan Diagnostik In Vitro Dan PerbekalanKesehatan RumahTangga.	Regulation of Circular Permit for Medical Devices, In Vitro Diagnostic Medical Devices and Household
Isa C.T. Santos	Product development methodologies: the case of medical devices, 2013	propose new-product development methodology to assist the medical device industry to optimize their processes and develop relevant solutions.
Christo pher Don Simms	An analysis of the management of packaging within New Product Development: An investigation in	examine how the development of a new product's packaging is managed and integrated into the new product development
	the UK food and drinks sectors	(NPD) process of firms;
Santos. Et al	Medical devices specificities:opportunities for a dedicated product development methodology	identified and the most relevantlegislation is reviewed providing the foundations for a dedicated product development methodology.

IV. DETERMINATION OF DESIGN REQUIREMENTS

4.1 Overall Function

From the purpose of this study, the overall function of the activity can be described as shown in Figure 9. In this picture the input relation to the blacbox in the form of product classification, regulation system adopted, safety standardization and clinical investigation must be transformed into product requirements grouped in aspects of function, safety standards, regulation and clinical.

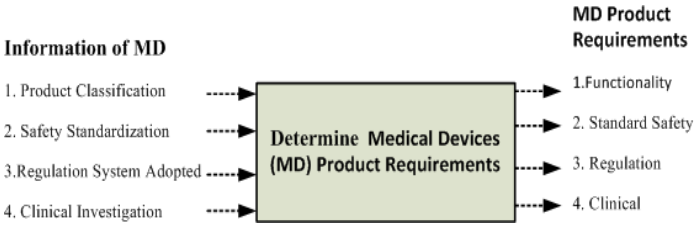

Figure 9. Overall Function of Research Activities

4.2 Function Structure

From the overall function in Figure 9 based on the input, set the functions of activities required to be able to determine the overall requirements for the design of medical equipment products consisting of activities:

1. Determine Functionality and intended use for the product
2. Determine Standard Safety of the product
3. Determine Product Compliance with standard
4. Determine regulation requirements of the product
5. Determine Requirement of Product Registration
6. Determine clinical investigation requirements of the product
7. Determine total design requirement of Medical Devices Product

The output of this activity is:

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S_1=Functionality/Intended use

S_{21}=Standar Safety

S_{22}= Testing

S_{31}= Regulation(general)

S_{32}=Product Registration

S_4 = Clinical Trial

S_{all} = Overall MD Design Requirements The relation of input and output according to the

function of the activity is arranged into the

functional structure of the activity to obtain information on the design requirements of the product design activities for medical devices as shown in Figure 10.

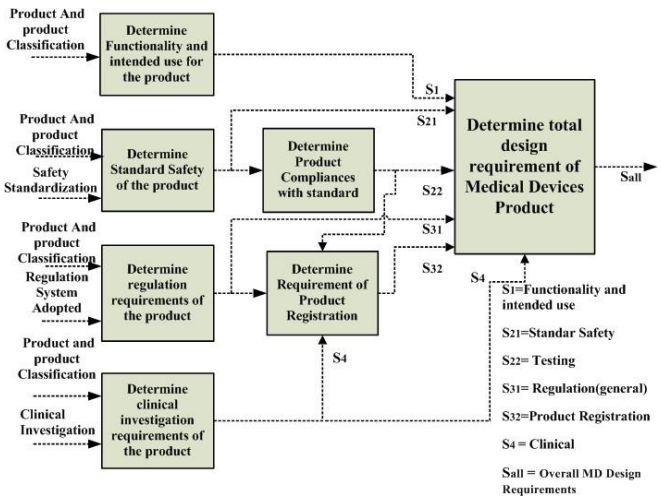

Figure 10. Functional Structure of Activities

4.3 Activity Analysis Determining Design Requirements

4.3.1 Determine Functionality For The Product.

To get the output of this activity, the input namely product and product classification, must be determined in advance for that reference to use products based on their categories [3] and classification of medical devices based on the risk of their use [5].

For product categorization globally it is usedmerger of two system the Universal Medical Device Nomenclature System (UMDNS) developed by ECRI (formerly the Emergency Care Research Institute) in the United States[16][17] and the Global Medical Device Nomenclature (GMDN), which is owned by the European StandardsOrganization [18].

The Medical Devices category includes [3]: Implant, Electromedics, Disposables & Consumables, Diagnostic reagent, Instrument Diagnostic, Hospital Furniture, PACS, POCT, Radiology dan Software & IT.

Risk Based Medical Equipment Classes [5] :

a. Class A raises low risk;
b. Class B raises low risk to moderate risk;
c. Class C raises moderate to high risk; and
d. Class D poses a high risk

After the product type and risk class are determined, design requirements are determined based on the functionality and use of the product (S1). The functionality is described from the intended use of the medical device.

4.3.2 Determine Standard of Safety of the product

The safety aspect of medical devices widely uses the IEC 60601 is a series standard as explained in chapter 3.5.The general standard IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - gives general requirements of the series of standards 60601 is a widely accepted as standard safety for medical electrical equipment. In many country the compliance with IEC60601-1 has become a requirement for the commercialization of electrical medical equipment.

Requirements of 60601-1 may be overridden or bypassed by specific language in the standards for a particular product. Collateral standards (numbered 60601-1-X) define the requirements for certain aspects of safety and performance, e.g. Electromagnetic Compatibility (IEC 60601-1-2) or Protection for diagnostic use of X-rays (IEC 60601-

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1-3) part 1 figure 8. The Collateral standard which is used in every medical devices is:

1. ISO 14971 : 2007 Risk Managements
2. IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

The basic concept of medical devices is safe and effective as intended use. Safety guarantee in use is in risk management starting from premarket to post market. The product must be able to meet the safety requirements, namely risk analysis for the possibility of failure in the use of the medical device. To overcome the possibility of failure in use, it is required to apply ISO 14971 Standard. Effectiveness in use must be ascertained and the design of medical devices must have formulated usability according to IEC 60601-6 (S21).

4.3.3 Determine Product Compliance with standard

This requirement in series 60601 is a special requirement according to the type of product to be designed. In series 60601 (fig 8 part 2 the standard examples are:

- IEC 60601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds
- IEC 60601-2-54 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 60601-2-65 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
- IEC 60601-2-66 Medical electrical equipment - Part 2-66:Particular requirements for the basic safety and essential performance ofhearing instruments and hearing instrument systems In the case of Indonesia, compliance with
- this standard has been regulated in Law No. 20 of 2014 [5] in this case the product conformity reference is to use the Indonesian National Standard (SNI), for example for patient bed products the standard is SNI IEC 60601-2-52 [16]. This standard is a standard that is adopted in full fromstandar series 60601 part 2 special standar IEC 60601-2-52 Medical electrical equipment - Part 2- 52: Particular requirements for the basic safety and essential performance of medical beds.

In the case of conformity to standard requirements, after the type of product has been determined, design requirements (S22) based on the product standard are selected from the 60601 series or other standards and testing needs to be carried out including:

- Load and condition tests on components or parts throughout the realizationprocesses: test of materials, storage, production, assembly, package, andtransportation
- Integration tests among components
- Influence of environment on components throughout the realization processes:storage, production, assembly, package, and transportation
- Test of processes: performances and results
- Feasibility and applicability of processes (design rule check); ensuring that theprocesses are feasible and applicable for realization by analyzing the events ofthe process and the progress of the production—usually done by simulationsoftware
- Tests that are necessary to qualify a medical device for use (ones which provethat the medical device answers the intended use): safety tests, functionalitytests, and delivery of the medical device to users for test use
- Clinical evaluation investigations

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- Assembly and examination of prototypes
- Acceptance test to decide whether the medical device is ready before release
- Retests for validation when changes where implemented

4.3.4 Determine Regulation Requirements of the Product

Regulatory requirements relating to design for medical devices widely used are good manufacturing methods for medical devices as stated in ISO 13485 standard and for Indonesia cases this standard has been adopted as Minister of Health regulation number 20 of 2017 Regarding Good Manufacturing Practices of Medical Devices and Household Health Supplies.

Requirements relating to design activities from the regulatory aspect (S31) of ISO 13485 [11] are in clause 7.2, customer-related processes consisting of 3 sub-clauses, namely: 7.2.1 Determination of Requirements Related to the Product; 7.2.2 Review of Requirements Related to the Product Requirements; 7.2.3 Customer Communication;

Product requirements define the customer's expectations of the product; the customerformally communicates their needs through defined communication channels and transfer product specifications, including performance requirements.

Possible types of customer requirements include(S_{31}) :

- Product-related requirements such as functionality, quality, performance, safety,intended use
- Technical specifications of materials, parts, components, processes, the useofcertain equipments, and the qualifications of personnel
- Packaging and identification
- Transport and delivery specifications and schedules
- Storage and protection
- Certifications for standards

4.3.5 Determine Requirement of Product Registration

Every medical device product placed on the market must have been registered by the National Body which has the authority to register the product so that the product can be circulated in a country. Depending on the regulations used in a country such as FDA, SFDA, MDR, AMDD etc from this system the product registration requirements are set. For cases in Indonesia the product registration requirement (S32) is use the Regulation of the Minister of Health of the Republic of Indonesia Number 62 of 2017 [5].

4.3.6 Determine clinical investigation requirements of the product

Clinical studies, once rare for devices other than Class III

devices, are becoming much more frequently required and performed. Since 1991, Office of Device Evaluation (ODE) for the Center for Devices and Radiological Health (CDRH) of the FDA[20] has taken actions for imposingmore stringent requirements on clinical studies used tosupport device PMA applications. Clinical studies are alsobeing required more often to support performance claims in510(k) premarket notifications. The ODE focus on requiringcarefully designed clinical trials is based, in part, on the FinalReport of the Committee for Clinical Review, also known as theTemple Report.

For any clinical study of a device conducted under an IDE, the sponsoris required to submit an investigational plan, including a protocolfor the proposed study to ODE. The plan should describe three fundamentalclinical trial areas: study design, study conduct, and dataanalysis (S4). Each of these three elements needs to be carefully thought outin advance, long before the first patient is recruited into the study [20].

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4.4 Design Requirements

The design requirements used as input requirements for the design and development of medical devices products from chapter 4.3 have been analyzed for types according to the design aspects used, namely S1, S21, S22, S31, S32 and S4, the details of the requirements are not always exactly as presented on the analysis but the content is flexible following the type of product being designed.

Saal is overall design requirements are a compilation of all the requirements of each activity, which are:

Saal=S1+S21+S22+S31+S32 +S4

CONCLUSION

From this study it can be concluded that to make the design of medical devices that are safe, good quality and effective the design inputs needed are necessary to pay attention to aspects: Functionality and intended use of the product; Standard Safety; Product Compliance with standard; regulation requirements; and clinical test.

Using a systematic approach methodology each aspect of design input can be broken down into design requirements and all of the design requirements are compiled into Saal's overall design requirements.

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