DEVELOPMENT OF BIOMEDICAL ENGINEERING IN THAILAND

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ABSTRACT

Biomedical engineering (BME) is multidiscipline to fulfill a gap between science, medicine, and engineering. The development of BME in Thailand is from medical electronics to handle the electronic repair center and to design the medical equipment and devices. Many challenges are facing the development of medical devices in the past, current, and the next decade essentially on the basis of the quality of patient care. There are three essential roles to support biomedical engineering improvements in healthcare technology and equipment, i.e., human resource production in biomedical engineering professionals, engagement with governmental organizations, and linkage to the industrial branches. This article, therefore, presents these key players and their roles in the BME development in medical services and professional practice to expand healthcare services beyond the hospital.

Keywords: Biomedical engineering, Medical devices, Medical hub, Patient care.

1. INTRODUCTION

World health organization (WHO) has defined 'Biomedical Engineer or similar disciplines as who passes qualifying biomedical engineering (BME) professionals to design, evaluate, regulate, maintain and manage medical devices, and train on their safe use in healthcare systems[1]. A primary objective is to safely and effectively connect devices and patients' use to save their lives. Referring to the professional responsibility, biomedical engineers have to apply their knowledge and skills in engineering and medical science to design, invent and develop medical equipment and devices. They also provide for verifying and validating biomedical software, managing hospital systems and modules, and studying new technologies to support clinical services in the main goals of screening, diagnosing, treating, and preventing diseases. The global innovation index (GII) has reported that the transformation of medical technology and advancements will change the world in the next decade[1-3]. This would prompt governments and foundations to consider the priorities of growing in the medical hub as a healthcare industry for future investment.

Consequently, biomedical education, clinical research, and supporting accredited standard facilities are proliferating. In 2018, global spending on health reached 8.3 trillion dollars, dominated by more than 75% of the United State and Europe regions compared to China and India[4]. Meanwhile, Thailand has reported statistically exporting medicaments for therapeutic or prophylactic purposes more than 2,900 million dollars in 2018[4]. The government's policy of care under the Ministry of Public Health reiterates that Thailand will be a hub of wellness and medical services by 2025[5]. New technologies embedded in an intelligence system will disrupt the medical devices and evolve to blockchain[6], cloud-based data analysis[7, 8], Internet of Things (IoT)[9, 10], intelligent wearables [11, 12], as well as epidemic prevention devices[13-15]. It is to improve in quality and quantity of population health through health technology policies and national health plans, financial resources, and medical technology. However, it is quite difficult in developing countries to solve all healthcare-related problems using affordable and in demand technology to all populations.

The key components, including BME professionals, governmental organizations, and industries serving in the medical system, are shown in Figure 1, where the universities or educational institutions are the central interfaces of these key components. The BME professionals acquire their knowledge, skills, and experiential learning in various areas involving academic core courses. Their competencies and skills are certified, but their attitudes have to be validated under the supervision of a government organization's professional qualification institution. Therefore, professions' understanding of roles plays significantly to the patients during the care process and make them feel comfortable in safety. In the meantime, the government organizations support units in terms of policies and regulations, also giving fellowships and funding through academic institutions. With consolidation of resources, particularly financial sector and infrastructure, allocates health improvement in health services to reach both equity and efficiency. The industrial sector with a massive potential in manufacturing is directly influent in care delivery and technological transformation of launching medical products and health services in markets toward users. Models of business are thus related according to the policies of the government organizations. The responsibility of the industrial sector thus plays a role from

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public to private health patients. This article intends to present the role of these key components driving the BME, especially in Thailand, pointing out perspectives and awareness in standard accreditation before exporting workforce the medical healthcare system.

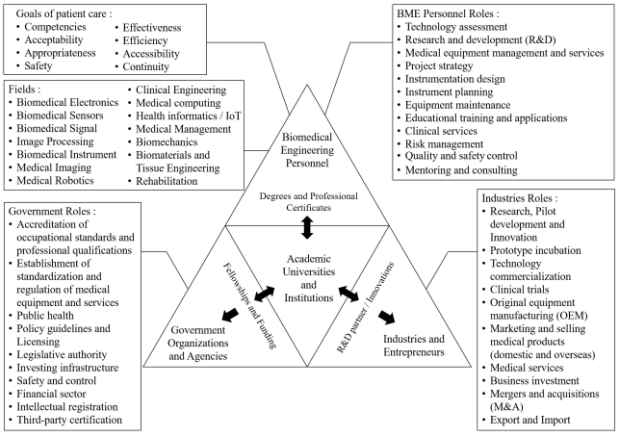

Figure 1. Linkage triangle of key components required in BME development.

2. HISTORY OF BME IN THAILAND

BME in Thailand [16] has been evolved from 'Biomedical Electronics' in the Faculty of Medicine Siriraj Hospital, which is the oldest medical school of Thailand operated by Mahidol University. In that era, there was necessary to employ maintenance services for medical equipment, but it was still lacking. In 1976, Professor Dr. Dithi Chungcharoen, M.D., and Professor Dr. Chusak Vechaphaet, M.D., found the Electronic Equipment Unit (EEU) to take responsibility and restore full functionalities of medical equipment. Biomedical electronics has been developed as the new field of fulfilling studies knowledge-gap between electronic engineering and medicine. It embedded the skills of design, construction, and maintenance of medical equipment to the appropriate improvement of quality of population's life and healthcare. In 1982, Professor Dr. Chusak Vechaphaet explored research and development program for biomedical instrumentation and initiated the Diploma in Medical Equipment Technician. The first batch of 450 medical equipment technicians was graduated during 1982 – 2000. Although the government has been promoted for civil servant jobs entitled a hospital medical equipment technician, just a few graduates carried in the position at that time. It was because of the interruption timing in the production of graduates and the numbers of graduates were offered exclusively to work with the private sectors. A group of professional biomedical engineers has realized to establish an organization to foster the growth of career paths in BME for graduates, precipitate the BME profession act in Thailand, and organize activities in network of collaboration underneath the Thai Association for Medical Instrumentation (ThaiBMI). Soon thereafter, medical device companies and industries[17] established the Thai Medical Device Technology Industry Association (THAIMED) to hold active roles in the medical device industry covering any services to enable medical device trading and coordinate with the government for regulatory requirements. Since 1989, the membership of THAIMED has currently stood at 114-member industries, which are distributors, traders, importers, exporters, and manufacturers of medical products. Later in 2007, the Thai Biomedical Engineering Association (ThaiBME) was established to connect members working in BME, including academic institutions and promote the BME research[18]. Figure 2 shows the timeline of the essential evolutions of biomedical engineering in Thailand since its establishment.

As known, the BME is a broad interdisciplinary regime consisting of research and innovation in various areas. BME educations in the Asia-Pacific region[1, 16, 19] are classified into bioinstrumentation focusing on the electronic and mechanical devices used to monitor, evaluate and treat biological systems of cells, tissues, or humans. Biomedical materials and tissue engineering field is a new paradigm science regarding biomimicry approach, and seeking current bioactive materials available for improving state-of-the-art patient care. Biomechanics is a particular study on biological structures and functionalities to understand and optimize the mechanical interaction of the human body with the environment. Bioinformatics links biological data science and information in high-throughput experimental data fed in new clinical analysis. Clinical engineering refers to special professional skills to support and deliver healthcare technology to patients, including medical imaging engineering. Furthermore, rehabilitation engineering is a branch of the systematically engineering field of design and development to deal with problems of those with disabilities.

Thailand has successfully established BME academic curriculums since 1982 and until now. These efforts have reinforced the growth of BME professionals in the region and produced a workforce in BME at different levels in universities. Currently, there are 14 universities in Thailand supported tertiary institutions. As shown in Table 1, there are Mahidol University (MU), King Mongkut's University of Technology North Bangkok (KMUTNB), Rangsit University (RSU), Chiang Mai University (CMU), Chulalongkorn University (CU), Srinakharinwirot University (SWU), Prince of Songkla University (PSU), Thammasat University (TU), Burapha University (BPU), King Mongkut's Institute of Technology Ladkrabang (KMITL), King Mongkut's University of Technology Thonburi (KMUTT), Navamindradhiraj University (NMU), Christian University of Thailand (CUT), and Suranaree University of Technology (SUT). The BME educational programs at the postgraduate and undergraduate levels are now offered in these universities with respect to the timeline. In addition, the medical device technician program graduates have already approved their accreditation of degrees and professional by the Office of the Civil Service Commission (OCSC) since 2003 for the government institutions and in 2015 for private institutions. This leads to an acceleration of rapidly development for high technology and biomedical sectors.

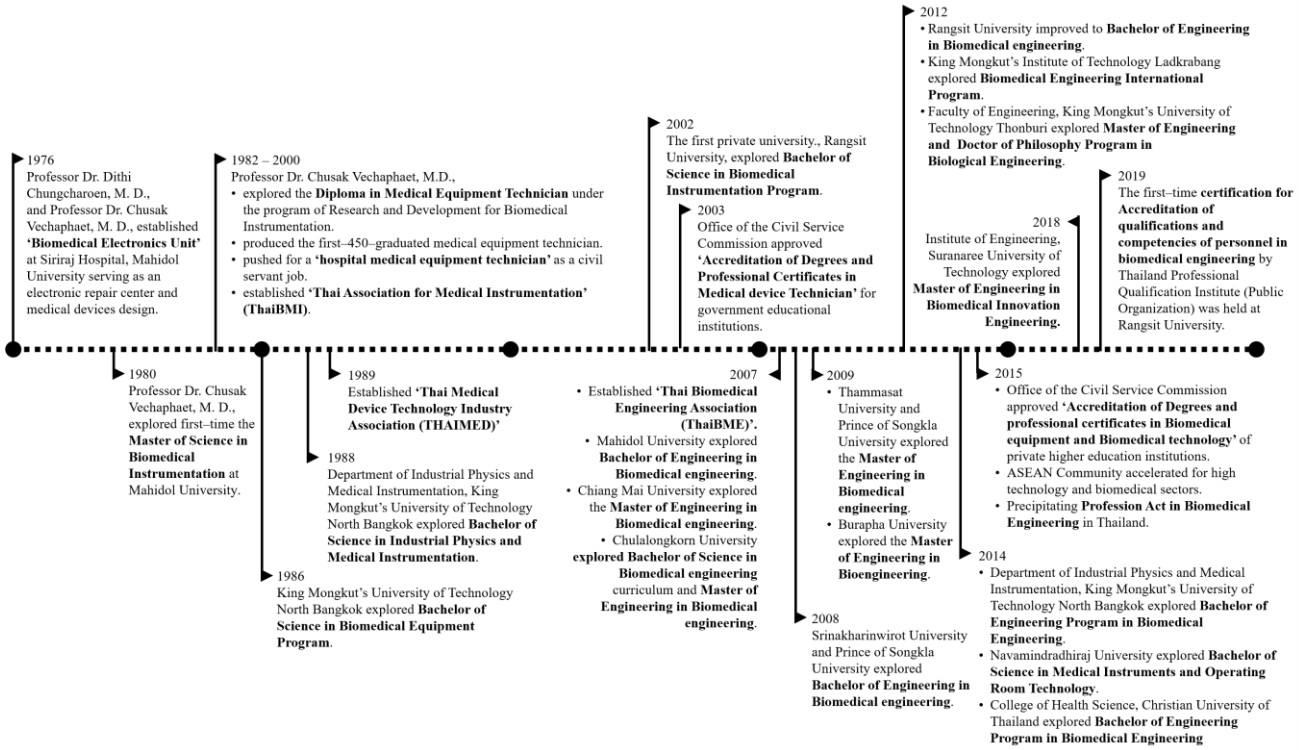

Figure 2. Evolution of BME in Thailand.

In 2019, the first-time certification and examination for accreditation of qualifications and competencies of personnel in BME were held at Rangsit University with certification body no. CB-0293-A[20]. This certification is accredited based on the international standard ISO/IEC 17024, which is an occupational requirement for bodies, by Thailand Professional Qualification Institute (Public Organization) (TPQI) and validated under the supervision of Thai BME professionals from associations and academic institutions.

Table 1. Summary of the qualifications and programs of BME disciplines in Thailand.

Trial	Institution	Qualification	Program	Academic year started
1	MU[21]	M.Sc.	Biomedical Instrumentation†	1980-1994
		B.Eng.	Biomedical engineering	2007
		M.Eng.	Biomedical engineering	1998
		Ph.D.	Biomedical engineering	2010
2	KMUTNB [22, 23]	B.Sc.	Biomedical Equipment Program	1986
		B.Sc.	Industrial Physics and Medical Instrumentation	1988
		B.Eng.	Biomedical Engineering	2014
		M.Sc.	Medical Instrumentation	1999
3	RSU[24]	B.Sc.	Biomedical Instrumentation Program†	2002-2012
		B.Eng.	Biomedical Engineering	2012
		M.Eng.	Biomedical Engineering	2015
		D.Eng.	Biomedical Engineering	2019
4	CMU[25]	M.Eng.	Biomedical Engineering	2007
		Ph.D.	Biomedical Engineering	2010
5	CU[26]	B.Sc.	Biomedical engineering	2007
		M.Sc.	Biomedical engineering	2007
		Ph.D.	Biomedical engineering	2018
6	SWU[27]	B.Eng.	Biomedical engineering	2008
		M.Eng.	Biomedical engineering	2019
7	PSU[28]	B.Eng.	Biomedical Engineering	2008
		M.Sc.	Biomedical Engineering	2009
		Ph.D.	Biomedical Engineering	2009
8	TU[29]	M.Eng.	Biomedical engineering	2009
		Ph.D.	Biomedical engineering	2009
9	BPU[30]	M.Eng.	Bioengineering	2009
10	KMITL [31]	B.Eng.	Biomedical Engineering	2012
		M.Eng.	Biomedical Engineering	2005
		D.Eng.	Biomedical Engineering	2017
11	KMUTT [32]	M.Eng.	Biological Engineering	2012
		D.Eng.	Biological Engineering	2012
12	NMU[33]	B.Sc.	Medical Instruments and Operating Room Technology	2014
13	CUT[34]	B.Eng.	Biomedical Engineering	2014
14	SUT[35]	M.Eng.	Biomedical Innovation Engineering	2018

It is mentioned that '†' is discontinued.

3. PRODUCTION OF BME WORKFORCES AND THEIR ROLE IN CAREER PATHS

The number of workforces in BME at different levels in various fields has been produced to both public and private sectors. Usually depending on the aptitude to be equipped to work on the career path student chooses, different levels of courses are necessary to support for them as followings.

1) A diploma in BME is typically offered relative to a new interdisciplinary field of study and practical skills. It commonly provides hands-on workshops in the classroom and the laboratory, but there are also experiential opportunities for an internship with expertise relevant to cooperative entrepreneurs. The BME diploma mostly benefits students who seek newly-created specialties or

find their expertise for variety in career opportunities. In Thailand, the diploma in BME is usually contained in the course curriculums in vocational colleges. The graduate student who receives the diploma often chooses the public and private hospitals, medical device manufacturers, and equipment distributors. Other students are encouraged to study in a higher degree to increase their potential in the profession. Recently, the Department of Health Service Support (HSS)[36] has raised a program to produce biomedical electronic personnel in cooperation with the Office of Vocational Education Commission (OVEC) for high-vocational education schools and colleges. The course was the "Medical Electronics" piloted at Chiang Mai Technical College for the first time in Thailand at the level of high vocational diploma[37]. It was then expanded to other technical colleges in 7 provinces, i.e. Phitsanulok, Ratchaburi, Nonthaburi, Chonburi, Khon Kaen, Ubon Ratchathani, and Songkhla, where were ready to join the technical committee and medical manufacturing sector of the Ministry of Industry. The courses aim to train the personnel's performance involving human body's automatic mechanisms, basics of medical devices and equipment used in diagnosis, treatment, surveillance, rehabilitation, and engineering management in hospitals regarding repairing, calibration, testing and preventative maintenance on various types of medical equipment. The high vocational graduates and workforces are required to support in public and private hospitals.

2) In academic education, including bachelor, master, and doctoral degrees in BME and related fields, are qualified in different programs of each institution shown in Table 1. It has been 45 years produced over 320 graduates a year supplying a medical system. Since BME is an emerging field, the curriculum significantly varies with an institution. Some BME programs have a series of tracks focusing on a particular field of study, but generally emphasizing a basic understanding of engineering, applied science and medicine. The strategic advantage of academic education is that the graduate will be accredited the professionalization of degree obtained from OCSC to recruit and appoint civil servants. Moreover, the graduates can submit the formal application for accreditation of the international standard ISO/IEC 17024 in the qualifications and competencies of personnel in BME, which are currently available.

The main career paths for the graduate paves on mostly choices[37]; 1) a hospital engineer responds to the management of the medical equipment in the hospital to ensure acceptable use and quality control before delivery and after use in various departments. 2) A product specialist provides advice on the use and capability of medical device to healthcare professionals and users to use the device to its fullest potential. The specialist has to understand the medical products related to what healthcare professionals require. 3) A sales representative sells medical equipment to hospitals by communicating and providing information about the equipment to the medical personnel involved in procurement. Some basic understanding of the equipment related to treatment must be understood in order to be able to explain device features to the physician and doctor as needed. Lastly, 4) a medical researcher invents and develops medical inventions and innovations to support modern and more complete treatments, which can be subdivided into many more disciplines as previously described. For example, the research study in the biomechanics of human sitting was used to design an ergonomic seat added on a regular chair that distributed the user's force evenly for more comfort and reduced pain during use[38]. The research study on biosensors has been presented a novel optical sensor with high sensitivity for diagnosis[39 – 41]. The development of biomaterials for tissue engineering scaffolds compatible with the cells with their biological property of biodegradability gives rise to the ideal soft tissue engineering applications and biofabrication in the future[42].

4. GOVERNMENT ROLE FOR BIOMEDICAL ENGINEERING DEVELOPMENT

As BME personnel, the global health and wellness provider, provide care to patients around the world. The responsibilities of BME personnel are therefore based on the effectiveness and efficiency of medical services. To ensure that patients can be accessible to appropriate medical services and safe treatment. To achieve the goals of the healthcare strategy, all BME personnel must have experience and practice in real sectors, including in the hospital and in the industry. Therefore, government organizations have come to play a supporting role in order to certify the BME personnel's competencies and attitude in accordance with occupational standards and qualifications of professional competence required. For Thailand, the TPQI is a nationalized government agency under the supervision of the Prime Minister to accredit and develop the occupational standards and professional qualifications system. This promotes opportunities for career advancement and free movement of the workforce, in particular the BME professional group of comprehensive medical care, both domestically and internationally[43]. It is integrated into the national strategies during 2018 – 2037 of medical industries to facilitate industrial and services development in the future [44]. According to Royal Thai government gazette announcement[45], there are four professional occupations of the workforce defined in BME accreditation at different classes as follows. There are 1) medical equipment technician assistant at the 1st and 2nd classes, 2) medical equipment technician at 3rd and 4th classes, 3) clinical technologist at 4th and 5th classes, and 4) biomedical engineer at level 4th - 8th classes can be qualified. For entire professional occupations have been extended more varieties divided into 43 occupations in the industrial section shown in Ref. [46]. Interestingly, the Council of Engineers Thailand (COET) has agreed and promoted the professional competency certification for biomedical engineers working in medical device industries in Thailand[47]. This meets the specified needs of the industrial sectors and the government policies.

For the public health system, large public or private hospitals, increasing concerns on the hospital's standards and accreditation is important. Currently, there are mainly two healthcare standards in Thailand, i.e., the hospital accreditation (HA) system as the national standard, in which the public sector and some private hospitals apply. HA[48, 49] is a self-learning process for promoting hospital quality and improvement of safety and healthcare services assessed by the Healthcare Accreditation Institute (Public organization)[50]. Another healthcare standard is the Joint Commission International (JCI) accreditation, an international standard addressing healthcare quality and safety improvement[51-53]. Both HA and JCI accreditations are the key-performance standards in healthcare systems verified by the government institution. The management of the hospital system to reduce risks, prevent accidents, and maintain safe conditions required in the standards covered works related to medical equipment are traditionally taken responsibilities by biomedical engineers at level 5th - 6th class [46] based on TPQI accreditation. BME professionals working in hospital and public health systems must ensure that the medical equipment and devices do work completely and normally in the complex systems, also business systems and organizational processes.

Thailand is now a leader of Southeast Asia with 66 hospitals approved with JCI accreditation and ranked the fourth globally[54, 55]. So, Thailand is a preferred destination in affordable and qualitative medication and healthcare services regarding the potential of patient care and doctor and hospital qualities. Recently, the government has realized to move forward with the action plan to drive the development of Thailand by adopting holistically economic model of Bio, Circular, and Green (BCG) economies within seven years (2021 – 2027) due to the challenge of the increase demand for medical devices and the increased morbidity rate of the population dramatically[56]. The BCG model would lead the achievement of Thailand's stability, prosperity, and sustainability according to the philosophy of sufficiency economy after the novel coronavirus diseases (COVID-19) world. The medical devices sector is one of the crucial sectors that the government shifting Thailand into a central medical hub[57]. As promoted, a commercial market is turned on to support biomedical innovation, products and services giving rise to government procurement for Thai medical devices registered concerning international standards. Privileges in the government procurement of the private and public sectors include reductions of tax for the private hospitals that purchase the Thai registered products and promote BCG-related labels. The strategic development plan also encourages new business in both startup enterprises and incubating entrepreneurs based on the BCG economy model and funding[58] for investing infrastructure.

5. INDUSTRIAL AND BUSINESS TRENDS IN MEDICAL DEVICE INDUSTRIES

Nowadays, Thailand has tremendously increased demand for medical devices to support the aging society era. In 2019, Thailand was the highest trade country for medical devices in ASEAN with a surplus trade of 106 billion baht, where the import value was about 70 billion baht. The average growth rate was 8-10% higher than the global average growth rate of 5.2%[59]. Medical device manufacturers in Thailand have a total of 1,586 operators. According to the uses of medical devices, they can be categorized into 1) disposable medical products such as syringes, medical gloves, hypodermic needles, and medical tubes, 2) medical equipment such as wheelchairs, medical beds, surgery and dentistry units, and X-ray machines, and 3) reagents and screening test kits such as COVID-19 antigen test kits (ATK), blood glucose testing kits, and pregnancy tests, respectively. Among them, Thailand has produced most of the disposable medical materials up to 84% for exports. In contrast, most of the imports are medical devices such as ultrasound machines, X-ray machines, and ophthalmic instruments. The most important import trade partners are the United States, Germany, and China, respectively. In 2020, the market value of medical devices had continued growing according to the medical factors regarding the outbreak of novel coronavirus diseases (COVID-19). The investment has been raised for modern medical platforms and technological equipment. Private hospitals tend to expand the existing operations and investigate new sites.

Moreover, Boonlert et al.[59], the Thai Tool and Die Industry Association (TDIA) president has recently engaged with the TPQI to promote the professional competency qualification in medical device manufacturing to be accredited because of rapidly growing up of biomedical markets. The medical doctors and hospital staff who are influent on medical devices purchasing are concerned about safety and standards in medical precision as a priority. Hence, this will be an opportunity to promote domestically produced medical device products and support the agreement of ASEAN Medical Device Harmonization.

The challenges in medical device production during the pandemic crisis entering an aging society reflect that Thailand has an advantage in quality and medical service standards compared to ASEAN countries. Although raw materials and equipment are insufficient to support the demands, these are boosting factors to innovate advanced and modern medical devices that require high standards and confidentiality of services. Also, COVID-19 scenarios, there are many attempts to conquer these challenges for implementation in the medical device industries. The Board of Investment (BOI) of Thailand reported the status of the businesses in the medical devices from 2019 until June 2021 and analyzed by the Plastics Institute of Thailand [60, 61]. As seen in the trade value chart in Figure 3, the medical device products of Thailand during the pandemic of COVID-19 situation that are imported and exported include the disposable medical

materials and related products, durable medical equipment, and reagents and test kits. The import values of overall market have been stable, the export values tend to increase. In particular, the disposable medical materials and related products are the highest growth during these years with more effectiveness and timelier because BME personnel, government, and industry play as teamwork to conquer the worst pandemics with the best outcomes effectively and economically.

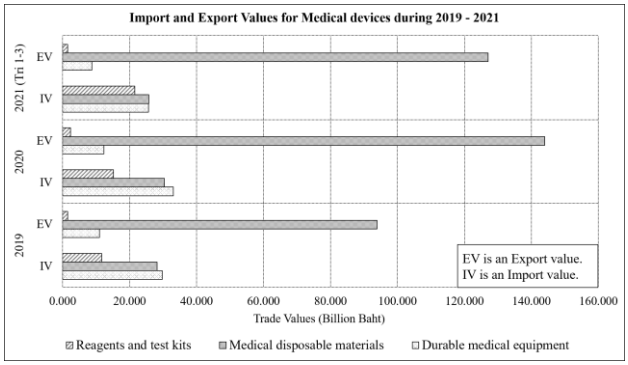

Figure 3. Trade values for the medical devices during 2019 – 2021 (Trimester 1-3), where the data is from the Plastics Institute of Thailand.

As seen, industry plays an important role in transferring technology to users in patient care system. The industry has increasingly adjusted technological manufacturing to develop the medical device activities by the following;

- participating in the design and research development with the BME personnel in the academic sectors and government organizations,
- incubating the innovation prototype to commercial product,
- participating in clinical trials,
- originally manufacturing and commercializing medical devices, and
- supporting the government to develop standards and accreditaitons.

Interestingly, there have been current and recent cases of the biomedical devices to develop university-linkage industry, for instance, the Biomedical Engineering Innovation and Service Center (BIS) at the College of Biomedical Engineering, Rangsit University has developed the innovation from biomedical engineering research which is a cost-effective neonatal bilirubin phototherapy equipment[63]. BIS has started producing this phototherapy equipment to be donated to the Soroptimist international Bangkok club to transfer to hospitals. For commercial use, it is in the process of commercial registration and further production agreement with the manufacturer[24].

The pandemics have greatly disrupted the medical industry. On the other hand, this has resulted in the rapid development of enormous medical technology, also in academic sectors. In another case, KMITL has developed medical equipment including the ventilator, the ozone generator for closed-system disinfection, the walk-through body temperature, the automatic robot for delivering food and medicine, positive-pressure and negative-pressure cabinets, and mobile swab test to be donated to the 1st Army Area for transferring innovations and technology to to hospitals in remote areas. This is to facilitate medical devices to fight for the spread of COVID-19 as well as reducing the risk and preventing medical personnel.

Therefore, we believe that the success of the development of medical devices is established from the linkage triangle of key components; the academic BME professionals are the ones who invent new technologies and create innovation with the support of government organizations and agencies for funding and transfer the new technology utilization to the people by the industrial sector.

6. CONCLUSIONS

Biomedical engineering is one of the essential parts driving the medical hub system. It has been 45 years of BME development, in particular in Thailand, since medical electronics originated. The BME sector explored earlier aims to produce the BME professional workforces for repairing and designing medical devices. BME career field was still less popular until the government organization approved the accreditation of degrees and professional for medical device technician program graduates. Currently, 14 universities in Thailand opening academic curriculums for undergraduate and graduate degrees have produced a large number of BME professional workforces to support the medical system and services. There are three essential players to take roles and responsibilities, i.e., BME professional workforces, governmental organizations, and the medical business and industries, driving together.

So far, high competitors in the global medical market, and Thailand has fast-growing medical export rate during a decade. Therefore, the Thai government includes the development of the medical hub into the National Economic and Social Development Plan and strategy based on the Bio-Circular-Green economic model to foster Thailand as a preferred destination in affordable and qualitative medication and healthcare services country. The achievement of the BME development is to reach the goals of stability, prosperity, and sustainability according to the philosophy of a sufficiency economic model in healthcare and medical services.

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