THE ROLE AND STRATEGY OF MEDICAL MANUFACTURING TECHNOLOGY CENTER IN KOREA

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Abstract

The medical manufacturing industry constitutes a growing sector for better healthcare in Korea. Population aging demands various interventional procedures and minimal invasive therapy. The consumption of medical devices such as catheters used for the interventional procedures or the minimal invasive therapy is rapidly increasing. However, the Korean medical market relies on imports for more than 80% of the medical devices. The Ministry of Trade, Industry & Energy (MOTIE) has supported the project for the establishment of Medical Manufacturing Technology Center (MMTC) in order to foster the industry manufacturing medical devices since 2013. This paper presents the roles and main strategies of MMTC for promoting innovation in the industrial sector.

Key words: *Industry-Institute Cooperation, Medical manufacturing, Health care, Medical consumables, Mold technology*

1. INTRODUCTION

The market of health care has become bigger because protecting and promoting the health is a key priority of Korea. Health care is not only for patients, but also for the healthy, which makes it possible for the market of medical devices to expand. The Korean medical devices industry has undergone dramatic changes in the past several years. In 2012, the market for medical devices in Korea was over 4.2 billion USD. The global medical industry is undergoing changes led by seven new medical markets (China, Brazil, Mexico, Korea, India, Turkey, and Russia) that are increasing by 12%-13% annually (Pei 2009). It is expected that the market will increase more and more owing to growing aging population. Financing innovative medical devices is an important challenge for Korean policy makers related in industrial sector.

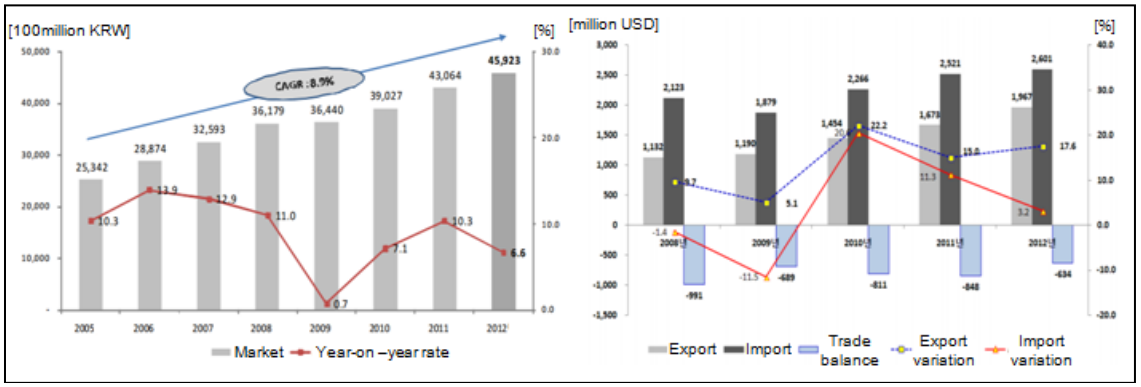


Fig.1. the situation of the Korean medical devices market

The term ‘medical device’ in Korean Medical Devices Act (Article 2) means an instrument, machine, device, material, or any other similar product specified in the following subparagraphs as one used, alone or in combination, for human beings or animals:

- A product used for the purpose of diagnosing, curing, alleviating, treating, or preventing a disease;

- A product used for the purpose of diagnosing, curing, alleviating, or correcting an injury or impairment;
- A product used for the purpose of testing, replacing, or transforming a structure or function;
- A product used for birth control.

As the diagnostics and medical treatment is advanced, the innovation of medical devices is demanded more and more. There has been increasing interest and demand for interventional procedures and minimally invasive therapy to aid with new medical diagnostics and treatments (Kenneth et al. 2009). Many interventional procedures and minimally invasive therapy also involve the use of consumable medical devices such as catheters (Tania et al. 2012). Table 1 shows the major imported medical devices in Korea. The item with the highest increase in import ratio is an intravascular catheter. The most of catheters in the Korean market has been supplied from overseas manufacturers.

Table 1 Major imported medical devices (unit: m USD)

Line of goods	Export	Import	Trade imbalance	Remarks
Catheter and etc.	15.041	92.374	-77.333	HS90183920(as of 2010), IAW Customs Service
Trocar and etc.	2.145	24.175	-22.030	HS90183990(as of 2010), IAW Customs Service
Artificial kidney filter	32.511	93.066	-60.555	HS90183990(as of 2010), IAW Customs Service
Soft lens	47.516	60.148	-12.632	As of 2009, IAW Korea Health Industry Development institute

The Ministry of Trade, Industry & Energy (MOTIE) has supported the project for the establishment of Medical Manufacturing Technology Center (MMTC) in order to foster new industry manufacturing consumable medical devices such as catheters since 2013. Investments to R&D and commercialization of innovative technology have become one of the priorities for fostering new industry. MMTC has provided a basic infrastructure of R&D and commercialization for SMEs (Small and Medium sized Enterprises) in the field of medical devices manufacture. This paper presents the roles and main strategies of MMTC for promoting innovation in the industrial sector.

2. ESTABLISHMENT OF MEDICAL MANUFACTURING TECHNOLOGY CENTER

2.1. The role of MMTC

The focus of the MMTC is to conduct two activities. One is to support research and development to advance the manufacturing technology for SMEs. Among the manufacturing technology, medical mold is required as a production fundamental technology to high value added consumable medical devices. The range of the medical molding technology includes precision polymer molding, metal molding and high efficiency manufacturing system. All developing and manufacturing system related in medical devices have to consider the implication of international regulation or standards. Some devices such as catheters are all designed to transport fluid, be it cerebrospinal fluid, blood, urine or other fluids, within, or out of the body (Richard & Jonathan 2014). A stent is placed in the body to create a passage between two hollow spaces. There are a wide variety of stents used for different purposes, from expandable coronary, vascular and biliary stents, to simple plastic stents used allow the

flow of urine between kidney and bladder (http://en.wikipedia.org/wiki/Stent). Those devices need processing sterilization to cope with international and domestic regulation. The sterilization system is also provided by MMTC.

The other is to support commercialization of new products and networking between companies. It is anticipated that the developed technology and products will be commercialized if a parts maker meets the needs of the final medical device makers. However, the medical device industry shows vulnerable structure in Korea. There is absence of industrial value chain system due to severance between medical device makers and parts makers. Moreover, there is high foreign dependence on key parts, retarded commercialization of R&D outcomes. Most Korean parts makers are still concentrated on semiconductor or electronic electricity industry, although the market share and income have been decreased. The role of MMTC is to induce parts makers of the major industries into the medical device industry. The staff of MMTC offers consultation services for parts makers who need information and guidance to expand their business into medical industrial area. The parts makers will meet new business partners manufacturing final medical devices. Therefore, MMTC establishes one-stop value chain through business-to-business network between medical device makers and parts makers. The members of medical community are over 50 companies organized by MMTC. MMTC has coordinated the cooperative R&D between the members.

2.2. Construction and installation

Korea Institute of Industrial Technology (KITECH) has established the MMTC funded by The Ministry of Trade, Industry & Energy (MOTIE) in 2013. The KITECH is a key public research institute leading innovation of manufacturing technology in other to make SMEs globally competitive. MMTC has to contribute to growth of manufacturing industry through development, application and commercialization of manufacturing technologies and supports for SMEs as a department of KITECH. The construction and installation of MMTC have been scheduled from 2013 to 2017. The total amount of budget is 30 million USD to complete the project. MMTC is currently under construction at Yeongcheon Free Economic Zone where provides systematic investment management services for international enterprises. MMTC is not only for Korean companies, but also for foreign companies in the medical devices industry. The location, situated on a 1,334 acre site, allows for easy future expansion. MMTC's facility and equipment team has taken the lead role in design and fabrication of the innovative layout, functionality, and reaction fixtures that are being installed.

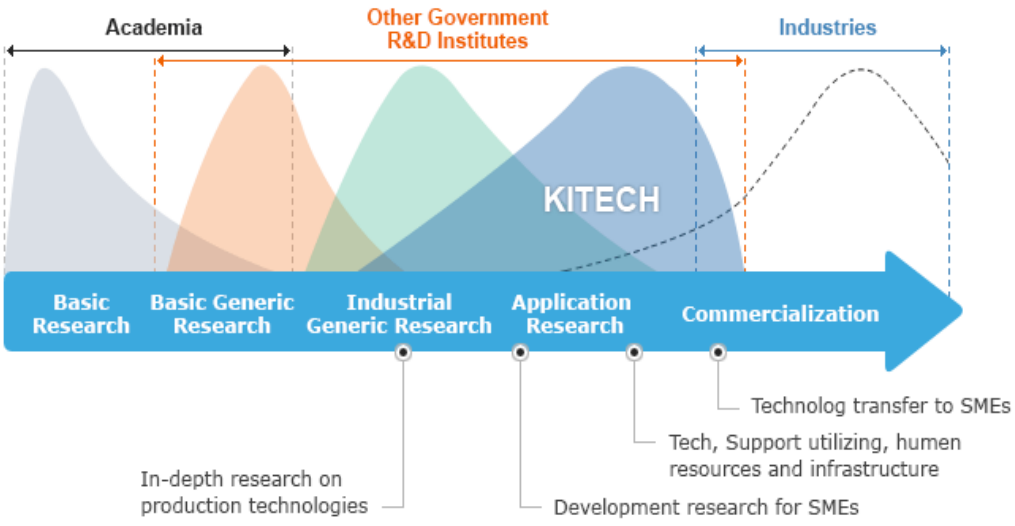


Fig.2 The rage of KITECH's activity



Fig.3 The imagination of the building MMTC

Various facilities and equipment are being installed to support R&D and trial-fabrication of three main areas (precision polymer molding including injection and extrusion, metal molding and high efficiency manufacturing system including QA /QC system and sterilization). The installation has been completed through a five-phase process.

Phase 1: Systems for design, Extrusion equipment of multi-lumen medical and Design of Electron beam sterilization facility have been started to be installed since 2013.

Phase 2: The construction of Electronic beam shielding facility has been proceeding since 2014.

Phase 3: Electronic beam generator, medical multi-shot injection molding equipment and cleanroom facility will be introduced into new building of MMTC in 2015.

Phase 4: It is supposed to finish installation of Electron beam sterilization facility and introduce medical injection molding equipment for small parts, medical vertical injection molding equipment, catheter manufacturing system and high resolution 3D CT scanner in 2016.

Phase 5: Medical LSR injection molding equipment and extrusion equipment of multi-layer medical tubing will be added into MMTC in 2017.

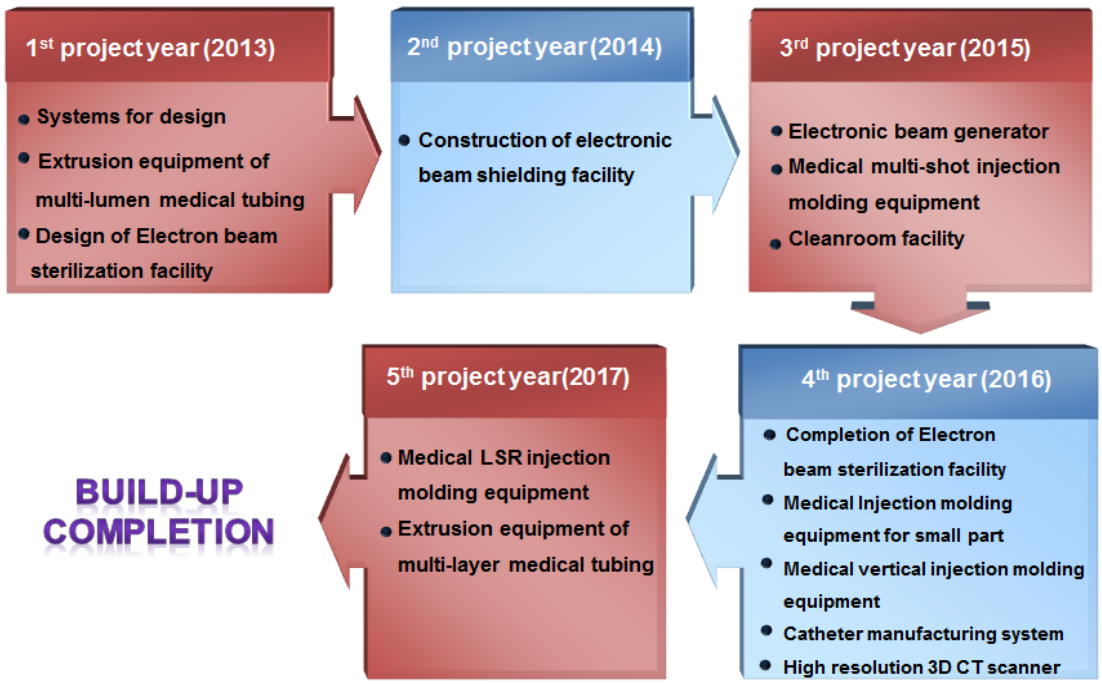


Fig.4 The schedule of installing facilities and equipment

3. STRATEGY FOR FOSTERING THE MEDICAL DEVICES INDUSTRY

Developing industrial cluster as a new different strategy has been introduced to foster innovative industry in Korea. Industrial cluster was defined as a group of establishments geographically centralized, which either share a common set of input needs, or rely on each other as supplier or customer. In an industrial cluster, there is not only a core value system that includes suppliers, competitors, customers and associated enterprises of industry, but also a support value system that includes universities, research institutions and intermediary organizations of science and technology (Jia et al. 2010).

There are several week points to complete medical devices industrial cluster in Korea (Fig.5). Most of medical devices makers are meager-sized compared with those of major industries such as automobile, semiconductor, and electronic electricity industry. It is very hard to secure medical grade of final products for the medical devices makers with their manufacturing technology and infrastructure. Moreover, there are few specialists in parts materials of medical devices. Most of the medical parts and materials have been imported.

MMTC has been supporting not only medical device companies but also parts makers in order to compensate the week points and foster the industrial cluster specialized in the field of medical devices. Fig. 6 shows the main strategy of MMTC for fostering the medical devices industry.

MMTC has been leading parts makers through technical supports in the section of tool design and optimization, manufacturing and processing, development of mass manufacturing process, and mass production of component under GMP environment. The parts makers supplying core parts to large companies such as Samsung and LG have been induced from major industry into the medical device industry by MMTC. Currently, they need to prepare for economic recession of the major industry. The medical devices industry has been focused as one of the new growth engine industry in Korea. The inducement strategy into the medical devices industry shall provide business diversification and growth opportunity for the parts makers. MMTC shall supply technology and facilities for them until they can make and sell the developed medical parts. The medical device companies will meet the new business partners supplying the core parts and customers by MMTC's mediation.

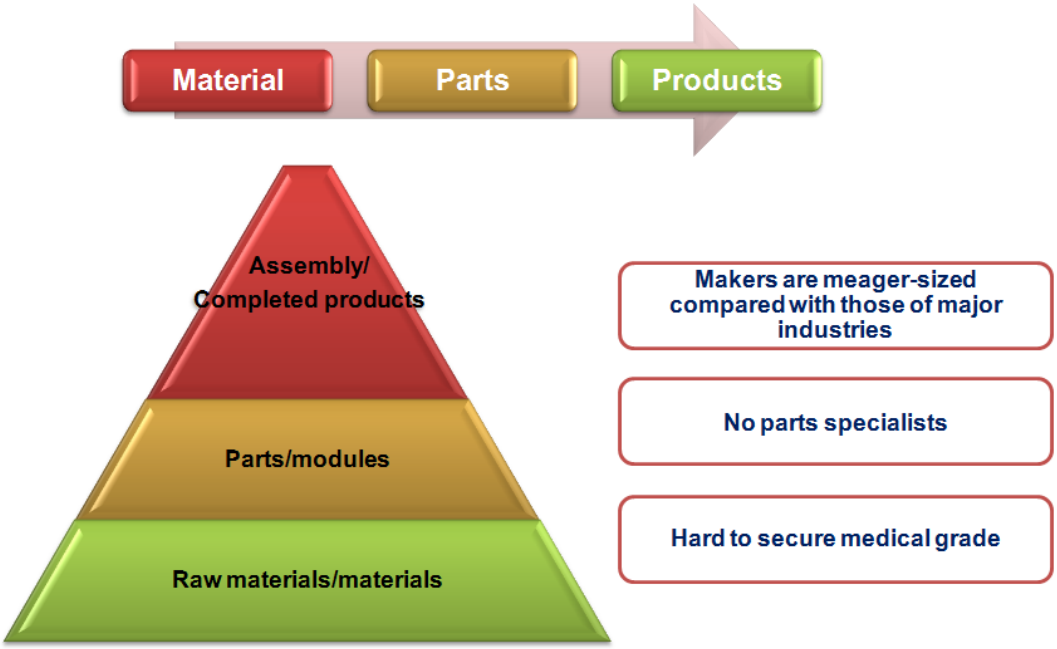


Fig.5 The current situation of medical devices industry value chain in Korea

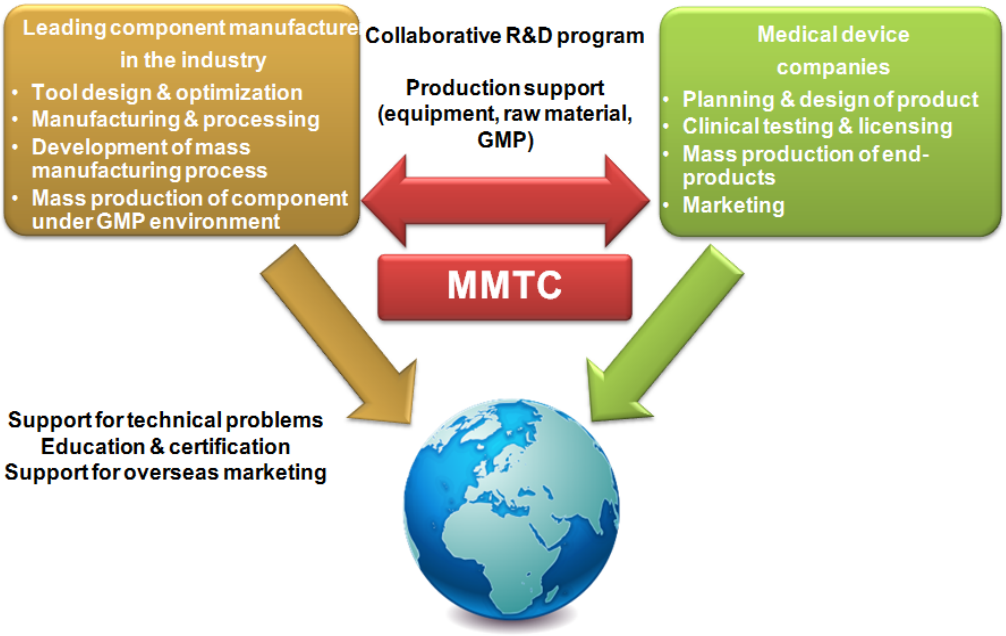


Fig.6 The role and strategy of MMTC for fostering the medical devices industry

4. SUMMARY

This paper shows the roles and strategies of MMTC for promoting the medical devices industry. Medical devices constitute a growing sector in Korea. Therefore, financing and supporting innovative medical devices is very important challenge for Korean industrial policy makers. Manufacturing technologies are expanding the capabilities of health care, with the resulting great economic opportunities serving as a driving force for innovation (Noemi 2011). The Ministry of Trade, Industry & Energy has supported the project for the establishment of MMTC in order to foster the industry manufacturing medical devices since 2013. The MMTC's main original contribution is in the inclusion of strategic interactions between parts makers and medical devices makers to develop and commercialize new products. MMTC has carried out making one-stop system for supporting SMEs including parts makers and final medical devices makers. The supporting system will be implemented from searching technical needs and customizing R&D to commercializing the developed products.

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