

# • DMIC Director

### >>> Representative career

| Work Place (Department)  | Title                  |
|--|------------------------|
| Department of Medical Device Industry, Dongguk University  | Head of Department     |
| The Korea Society of Food, Drug, Cosmetics Regulatory Science  | Vice-President         |
| 'Dongguk University Medical Devices Innovation Center' Designated by Ministry of Health & Welfare                          | Center Director        |
| Korean Society of Medical & Biological Engineering   | Director               |
| Department of Medical Biotechnology, College of Life Science & Biotechnology   | Professor              |
| Ministry of Strategy & Finance (Financial Project Assessment Advisory Committee)   | Civil Committee Member |
| Journal of the Korean Society of Precision Engineering   | Edition Staff          |
| Ministry of Knowledge Economy (Next Generation Technology Development Project Technology Committee_Medical Devices Branch) | Committee Member       |

### **≫ Major Career**

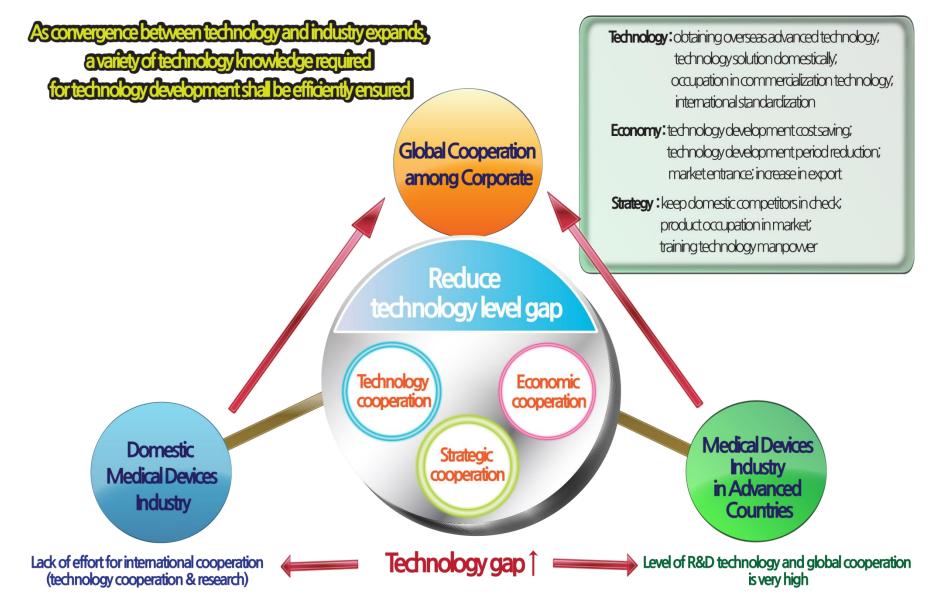
| Work Place (Department)  | Title                            |
|--|----------------------------------|
| National IT Industry Promotion Agency (IT R&D Promotion Business Planning Committee) | Committee Member                 |
| Ministry of Health & Welfare (Medical Devices Committee)                             | Committee Member                 |
| Ministry of Food & Drug Safety (Internal Regulation Evaluation Committee)            | Advisory Committee Member        |
| National Institute of Food & Drug Safety Evaluation (Professional Committee)         | Advisory Committee Member Energy |

### Ways for Medical Devices Industry to Have Competitive Power

- While medical devices industry is a new growth engine industry, global corporate emerges and unsatisfactory in creating premium jobs.
  - Total number of manufacturing companies is 2,277; average production per company is KRW ₩1.7 billion; average employees are 15.5
  - Rate of operating profit ('12): 16.8% for global top 15 companies; domestic 11.6% for top 15 companies
- In the advanced countries the electronic companies entered into medical devices sector showing high growth rate, whereas in Korea, it is centered on venture company, which is limited in its scale expansion
  - Sales of number 1 company in Korea, Samsung Medison, is KRW # 290 billion.
     Samsung Medison began as the first venture company and has grown as it is.
  - Among global top 10 companies, electronic companies (3 companies), pharmaceutics (3 companies) and distributors (1 companies) are parent companies.
- Need to advance industrial structure through supporting excellent companies in other industries such as IT, electronics and machine in their entrance into medical devices industry
  - If Korea with advanced IT and machinery industry enters into medical devices industry with high value added and combines the strengths of other industries, advancement of industrial structure
  - may be possible (proportion of IT industry in domestic GDP in 2nd quarter, '13 is 13.2%)

# Problems in Medical Devices Industry Infrastructure & Their Solutions

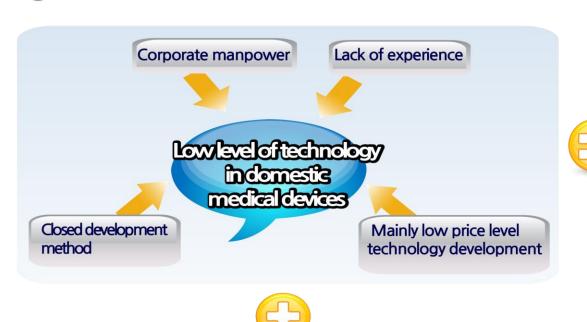




## **Future of Localization of Medical Devices**



### Accelerated Localization of Medical Devices





### 'Open Innovation' Support Center

- Provide market-focused idea
- Provide production infrastructure (technology, equipment, manpower)
- Technology service support (dinical, permission/license, insurance, marketing, etc)

# What is Open Innovation?



A strategy that saves necessary resources and time for innovation and maximizes the performance of innovation by extending R&D activity limited inside organization to the outside of organization so as to utilize external idea and R&D resources together



# Main Issues of the Recent Medical Device Development



### **Developing Leading Technology to Create New Market**

- Pushing leading technology-oriented R&D that can create a market
- Securing new growth engine through active technical investment in the medical device sector
- Securing R&D Portfolio to cope with uncertainty

### Uplifting development speed to advance into the market right on time (Time-to-Market)

- Securing capability to develop any products following rapidly-changing customer's needs right on time
- Securing partnership and networking with external technology for quick market release

### Securing R&D Efficiency to Maximize Profit Creation

• Fallen Return On Investment of R&D due to shortened product lifecycle

# Major Needs in Failure of Idea Development

### Failure in Identifying Customer Needs

- customer, patients, doctor, hospital, general consumers
  - What product will be sold well?
- Begin depending on technology characteristics of developers
  - To whom will the product be sold?

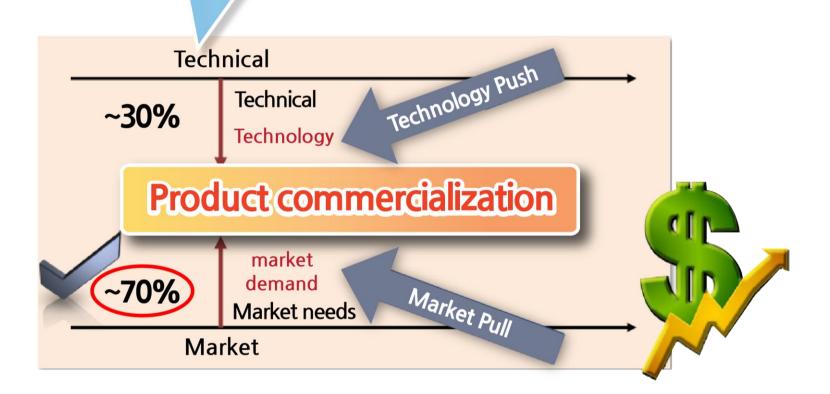


### Strategic absence of customer needs solution

- absence of strategy itself or absence of choice of strategy
- User Demands
- if technology is excellent but does not meet user requirements, commercialization will fail
- Market Demands
- if the number of users is small, commercialization fails

# What is the starting point in idea development?

The company which succeeds in idea commercialization transforms the market demand into product rather than focusing on technology



# Dongguk Medical Devices Innovation Center

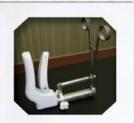


DMIC adds values to your medical device idea



Development of and support to trial product











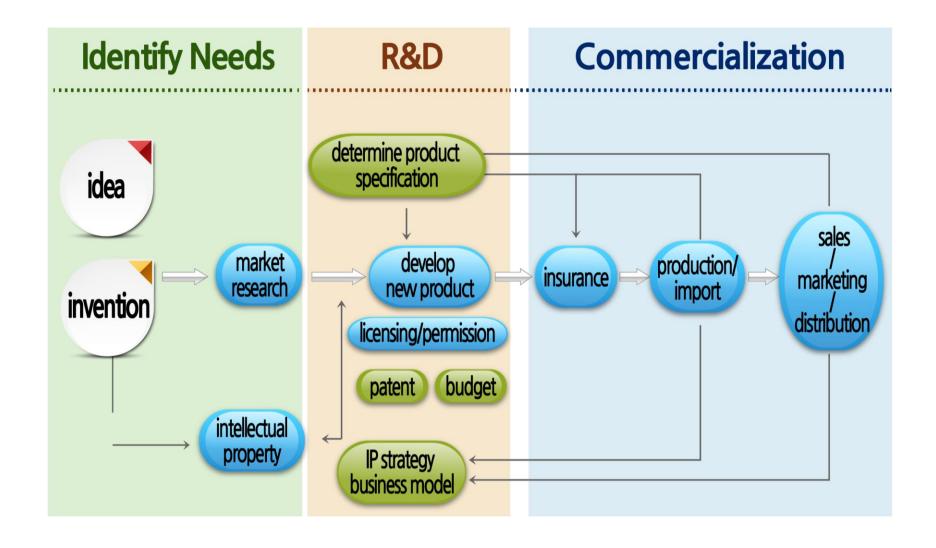


### Support center for making global test product to "Create High Value"



- » Building active excavation system of idea
- Building efficacy evaluation system
- Establishing test product development promotion process
- » Establishing technical right securing system of idea
- Fostering T-C-E special workforce

# Entire Processes of Medical Device Development



# **Active Searching System of Idea**

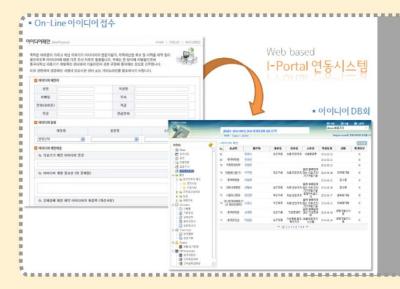


# Building open idea collection system



1. Building On-line System for idea receipt

" Open Innovation "



2. Building I-Portal System for integrated management of idea

"I-Portal" (Project Management System) shared by DMIC, Proposer, Developer, and Evaluator

# Idea Validity Evaluation System





1st prototype product can be drawn 'within 1 year'

#### ldea proposal

#### **Application staff**

- Evaluation and development support processor
- Guide to proposer's compensation rule

# 1<sup>st</sup>center review

#### Internal staff

- Proposal review
- Patent screening
- Similar product investigation
- Proposal feedback

### Examine ::

#### preceding technology

## Center-related patent law firm

 Proposal idea's novelty and progressiveness review and preceding technology examination

#### 2<sup>nd</sup> Expert

#### Group

#### External Specialist Group

 Validity evaluation on the technology / clinic / business value

# Final evaluation of idea

# Proposer / Developer/Center/ External specialist group

- Proposal idea orally
- Propose development plan

# Prototype development

#### **Kick-off meeting**

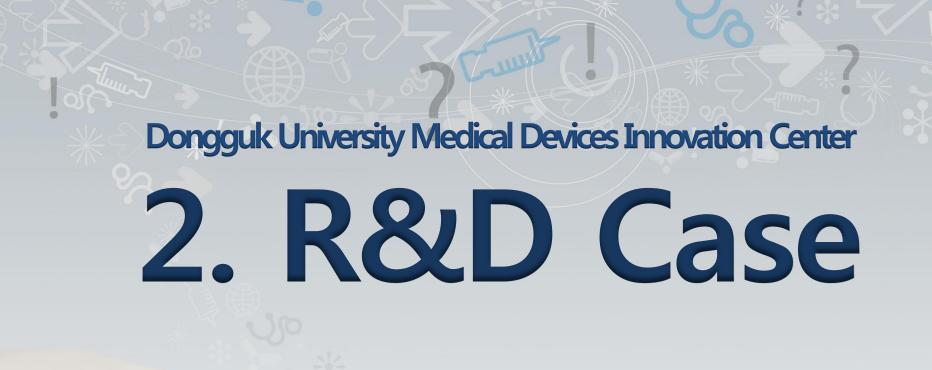
 Development plan adjustment

#### Monthly meeting

- Concept Design
- Design modification and supplementation
- Development progress
- Monitoring

#### Interim/Final Report

- Prototype review
- Prototype demonstration







### Current state of prototype production

#### Aorta Cartridge

An automatic reinforcing anastomosis stapler for safe and efficient arterial anastomosis operations







#### **Medical Headlamp** Development of a surgical headset with a lamp automatically controlled by the user's eves ▼ Proposed concept

#### Radial Artery Hemostat

A hemostat to stop bleeding after hipbone arteriopuncture for vascular intervention diagnosis and arbitrative treatment







#### Development of a Surgical Guide System

Development of an accurate surgical guide system to prevent side effects in mini implant procedures







#### Fingertip Microvascular Imaging System

To determine vascular conjugation procedure accuracy after finger mutilation or skin burns



#### Mobile Medical Imaging Service

Development of diagnostic medical image storage, progression and retrieval technology for mPAC service



#### Thorax Deformation Analysis Program

An assessment index analysis program for both before and after operations and preoperation planning for thorax anomaly patients









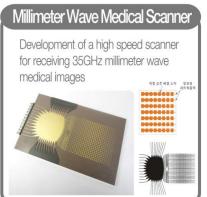


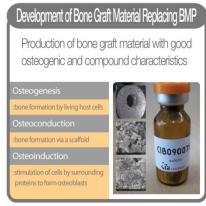


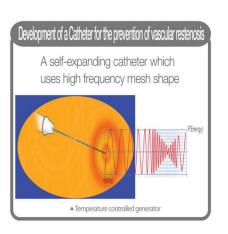


### Current state of prototype production

















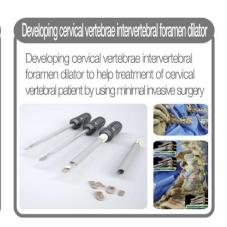


### Current state of prototype production



















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