For Early Access of Innovative Medical Devices to Patients

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Career
June 2017  Chairman, The Japan Federation of Medical Devices Associations
April 2015  Vice President and Executive Officer
President and CEO, Healthcare Group and Healthcare Company
April 2012  Vice President and Executive Officer
April 1982  Entered Kanagawa Works, Hitachi, Ltd
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2. Continuous engagement of the regulatory agencies and Creation of Innovative Medical Devices
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1. Introduction to the Medical Device Industry in Japan
1-1. JFMDA

JFMDA
Founded in 1984
21 Associates, 4,280 Companies
120,000 Membership Employees

Offering approx. 200,000 types of Devices
1. The foundation for a Growing Industry
   • Continuing Innovation – Applying new tech. ICT, AI
   • Introducing the Japanese Medical Device Industry to the world

2. Proposing New Policy and Cooperation with stakeholders
   • Quick and efficient Authorization process
   • Cooperation among medical site, academia, municipalities, relative industries

3. The Industry that can be Trusted
   • Compliance
   • Cyber Security
1-3. Characteristics of the Japanese Medical Device Industry

1. Globalization
   • 7 Jpn co. in the top 50 global co.
   • globalization R&D and Manufacturing

2. Entities sustaining the Jpn Medical Eco-system
   • 70% are SME*
   • Imported: JPY 1.4 trillion
   • 1,100 Distributers

3. Incubation of venture entities
   • Entities increased 5x in 5 years
   • Government incentive prog.

* SME: Small and Mid-sized Enterprises

Source: Statistics on Pharmaceutical and Medical Device Industry (FY 2015)
1-4. Cooperation between Medicine & Engineering

Clinical Needs
On-site Opinions

Hospital

Cooperation between Medicine & Engineering

BIODESIGN
The Process of Innovating Medical Technologies

NEEDS FINDING
NEEDS SCREENING
CONCEPT GENERATION
CONCEPT SCREENING
STRATEGY DEVELOPMENT
BUSINESS PLANNING

IDENTIFY
INVENT
IMPLEMENT

Symposium
Tokyo Women’s Medical University

Institute of Advanced Biomedical Engineering and Science
Faculty of Advanced Techno-Surgery

Practical Discussion

Reception of human resources

Company
Medical Company etc...

OJT Program

MDM J

JFMDA

MDPRO

JFMDA

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2. Continuous engagement of the Regulatory Agencies and Creation of Innovative Medical Devices
2-1. Industries’ Viewpoint

1. Innovation Environment Improved due to continuous regulation changes
   • Quick Development of Innovative Medicine, Medical Devices and Regenerative Medical Products
     “Sakigake(Precursor)” Designation system
     Conditional early approval system, etc.
   • “Pharmaceutical Medical Devices Act” (2014)
     Japan separated the regulations between Medicine and Medical Devices
   • Medical Device Lag shortened

2. Other Requests
   • Regulatory Science Initiative
   • Clinical Innovation Network

3. “Clinical Research Act”
   • 2018/4 executed
2-2. Early approval system

Conditional early approval system for regenerative medicine

“HeartSheet” Autologous Skeletal Myoblast Sheets

- A RM product for severe, ischemic heart failure.
- The 1st approved Cell Therapy product to treat severe, ischemic heart failure.
- For patients, who are non-reactive to conventional drug treatment, and in NYHA-III or IV, with LVEF <35%.
- Autologous, five (5) skeletal Myoblast sheets transplanted on the surface of the heart.

“Sakigake” Designation system

Tailor-made Heart Simulator

Medical information from hospital

Simulated heart model

Create patient specific heart model

* Application after Domestic Clinical Test

Provided by TERUMO CORPORATION

Innovative medical devices are reaching the patients faster

*: NYHA: New York Heart Association classification, I~IV
LVEF: Left ventricular ejection fraction, %

Provided by UT-Heart Inc. / FUJIFILM corporation
2-3. “Sakigake” for Medical Device

<table>
<thead>
<tr>
<th>Title</th>
<th>Overview</th>
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<tr>
<td>1  Titanium Bridge</td>
<td>Titanium Bridges with Hinged type plate for treatment for Adductor Spasmodic Dysphonia by Type 2 Thyroplasty</td>
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<tr>
<td>2  Artificial Trachea</td>
<td>Artificial trachea consisting of polypropylene mesh and collagen sponge</td>
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<tr>
<td>3  Boron-Neutron Capture Therapy System</td>
<td>Apparatus for irradiating neutron beam used for BNCT</td>
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3. New Rules for Innovative Medicine
3-1. Innovative Medical Devices in the foreseeable future

- Surgical Robots
- Precision Medicine
- Less-Invasive Therapy
- Artificial Tissues/Organs
- Practical use of AI
- Home Medicine

New Approval system and Operating Process must be found to handle New Technology
3-2. The Third AI Boom

Knowledge Form

Data

Rules

Equation

Neural Network

Machine Learning

Fuzzy inference

Planning

Knowledge representation model

Quiz (’11)

2nd generation AI

3rd generation: Deep Learning

1st generation AI


1st generation AI

2nd generation AI

3rd generation: Deep Learning

Knowledge representation model

Planning

Chess (’96)

Go (’16)

Cat (’12)

Shogi (’13)

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3-3. Hitachi AI Technology/H

Characteristics

「Multi Purpose AI」
… Not Exclusive AI

Goal Setting & Final Decision done by man

Self Learning and evolved to solve problems given by man.
Create of thinking patterns having more value than those of man.

Current System
Data Learning /Monitoring
Adaptive Control

Hitachi AI Technology/H

Goal
KPI
3-4. Applying AI in Medicine (1)

Expectations by Using AI (Deep Learning, Machine Learning)

・Create new diagnosis and new treatment methods
・Building a national infrastructure providing uniform accessibility to advanced medicine
・Reducing the workload of healthcare personnel so that they may concentrate on patients

6 Major Areas as defined by MHLW

- Support Image diagnosis
- Genome Medicine
- Pharmaceutical R&D
- Diagnosis & Treatment
- Nursing Care
- Surgery Support

http://www.mhlw.go.jp/stf/shingi/other-kousei.html?tid=408914
3-4. Applying AI in Medicine (2)

Building foundation for AI dev.

- High quality supervised data with easy access
- National Data platform

Clinical Site Refinement using AI tech.

Enhance AI Dev. AI

Data

Adapt

Data base

Clinical Site

Improve quality of healthcare

Source: MHLW

Regulations to ensure quality and safety of AI

- Deep Learning:
  Functions are continuously changing while algorithm are black boxed
- Issues with SaMD (Software as Medical Device)
  Frequent software version ups, etc.
3-5. Next Generation Operating Room using IoT
3-6. Cyber Security for the IoT age

Gov./Industry are realizing the growing cyber security risk and placing them in high priority

ICT-ISAC JAPAN
ICT Information Sharing And Analysis Center Japan

JE-ISAC
Japan Electricity Information Sharing and Analysis Center

Facility to train and verify cyber attacks

Hitachi, Ltd.
3-7. Cyber Security in the Medical field

- Guidelines made for Cyber Security for Medical Devices (2015/4)
- Products: ① Security by Design, ② Life cycle management
- Cooperation in the Eco-system: Medical device manufacturers, IT vendors, Med. facilities, Security Monitoring Agencies, Municipalities

![Diagram showing security levels, security governance, and security by product with various components like security policy, governance model, security program framework, 3rd party evaluation, risk assessment, security requirements, events, incidents, external communications, education, training, and monitoring.]

Source: Deloitte Tohmatsu Consulting LLC
3-8. Regulatory Affairs supporting Medical Innovation

Making regulations for medical devices utilizing new technology and innovations
  • New Regulatory Affairs based on Regulatory Science
  • Quick approval of software (SaMD) including AI

Ideal Regulatory Affairs system
  • Quickly provide new therapy to patients
  • Sustain the safety and effectiveness of the medical device(s)

Contributions from the Industry
  • Early cooperation with the Regulatory Agencies
  • Approval system which is practical
4. Global Cooperation
4-1. Expanding the Japanese Medical Method

Examples using Endoscopy, out of many cases

Project “Advanced Endoscopy Training Center for Indonesia” (2014)

FS “Mekong Surgical Training Center and Russia Endoscopy Surgical Training Center” (2015)

FS “Promotion of the Japanese method of Endoscopy surgery in Russia” (2016)

Pictures provided by Olympus Corp.
4-2. Toward “ONE QMS” on next step of MDSAP

- **USA**
- **CAN**
- **AUS**
- **JPN**
- **BRA**

**MDSAP**

- Consolidated Multiple QMS requirements
- Single Audit based on Multilateral QMS requirements

**In future**

- Harmonized QMS requirements
- Real single Audit

**[Unique QMSs]** \(\Rightarrow\) **[All over QMS]** \(\Rightarrow\) **[ONE QMS]**

**Administrative Burden**

**Merit of Manufacturer**
4-3. Toward “W/W Approval Review”

1. Increase the cooperation of bilateral approval review

2. One Application, Once Review, W/W Approval
4-4. Harmonization to Convergence

- Experiences of advanced efforts in each country should be taken in global activities such as IMDRF

- Contributions from the Industry for Regulation Global Harmonization
  - Proactive proposals to the WG of IMDRF
  - Domestic Deployment of IMDRFs Decisions
Contributing to the advancement of medicine and the growth of the medical device industry by developing and providing ever-improving medical equipment and medical technology