Roles of Clinical Engineers in Medical Device Development

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Hiroki Igeta, MSc, BEng, CCE ¹ ³
Jun Yoshioka, M.P.A.S, CCE ² ³

ASO Iizuka Hospital ¹
Yamagata University Hospital ²
Japan Association for Clinical Engineers (JACE) ³
Agenda

- Clinical engineer system in Japan
- Recent movement of medical device development in Japan
- Expected roles of CEs in medical device development
- Introduction of a case of ASO Iizuka Hospital as an example
Clinical Engineers : Japan

- Clinical Engineer License System
  Established in 1987
  National License

- Education
  4 years education in university
  or
  3 years education at a polytechnic college
The Facts

Operating Equipment in the Clinical Environment 40%
- Respiratory therapy
- Perfusion (HEART-LUNG machine)
- Dialysis (Dialysis equipment)
- Operative treatment (Surgical equipment)
- Intensive care units
- Cardiac catheterization
- Hyperbaric oxygen therapy
- Other treatment (defibrillators)
- Pacemakers
- Implantable cardioverter defibrillators (including CRT-D)

Service Delivery Management 20%
Patient Safety 20%
Healthcare Technology Management (HTM) 20%
Japan Association for Clinical Engineers (JACE)

JACE was established under the approval of the Ministry of Health, Labor, and Welfare (MHLW) in March 2002.

The objective of JACE is to contribute to the promotion and development of the nation’s medical care and welfare through the raise of professional ethics of CEs, enhancement of their professional knowledge and skills, and improvement of reliability of equipment-based medical care and welfare, including life-support systems.

35,000 licensed Clinical Engineers in Japan
15,000 of them are the members of JACE
Social Mission of CE

Safety Assurance And Effectiveness of Medical Equipment

Reduce Healthcare Cost

Disseminate Optimal Care

Improvement of Medical Technology

Establish the Medical Device Management System
Japanese Medical Device Market

Market Size of Medical Device
espicom "Medistat Worldwide Medical Market Forecasts to 2017"

Market Share of Top 30 Device Manufacturers
Rodman Media "TOP 30 MEDICAL DEVICE MANUFACTURERS (by FY12 revenue)"

Japanese Market Size of Medical Device and the Import Rate

<table>
<thead>
<tr>
<th></th>
<th>Domestic Market (billion JPY)</th>
<th>Import Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic</td>
<td>1256.4</td>
<td>51</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>612.6</td>
<td>28</td>
</tr>
<tr>
<td>Total</td>
<td>2386.0</td>
<td>44</td>
</tr>
</tbody>
</table>

MHLW "Annual Report on Statistic of Pharmaceutical Industry"
Japanese Trade Balance of Medical Devices

Data from: MHLW "Annual Report on Statistic of Pharmaceutical Industry"
Recent Movement


The policy is a mix of the “three arrows” for reviving the Japanese economy:

(1) Aggressive monetary policy
(2) Flexible fiscal policy
(3) A growth strategy that encourages private sector investment

From: The office of the Prime Minister of Japan
Three Action Plans of “Japan Revitalization Strategy”

“Japan Revitalization Strategy” sets three action plans detailing concrete initiatives for the realization of growth:

- Plan for the Revitalization of Japanese Industry
  Strengthen industry base

- Strategic Market Creation Plan
  Turn challenges into new markets

- Strategy of Global Outreach
  Tap into expanding global markets

From: The office of the Prime Minister of Japan
Market Size

Population Trends of Japan

Data from “Bureau of Statistics of the Ministry of Internal Affairs and Communications”

Estimating Future Medical Expense in Japan

Data from “Japan Medical Association Research Institute”
Government Policies in Medical Device Industry

(Ministry of Economy, Trade and Industry)

Device development through medical-engineering collaboration
  Promoting new entrants from outside industry or start-up companies
  Promoting device development based on clinical needs

Most advanced medical device development
  Promoting advanced medical technologies by “industry-government-academia” collaboration

Business environment improvement to meet regulatory system

Capturing medical device market abroad
Barriers of Device Development

- Strict regulatory and time consuming approval process
- Difficulty of fundraising
- Seeds or academic oriented development
- Lack of human resources in project management
The Situation is Changing

Strict regulatory and time consuming approval process
   Central and local governments are implementing variety of aggressive measures and taking strong actions

Difficulty of fundraising
   Variety of public subsidies
   Increasing public and private financing institutions

Seeds or academic oriented development
   Some movement of shifting to needs oriented development

Lack of human resources in project management
   Education courses in some universities
   e.g. Biodesign course in three universities
Medical-Engineering Collaboration

- Poor evaluation of needs and ideas (clinical perspective)
- Lost in translation between the industry and clinical field

- Industry:
  - Manufacturer
  - Small Enterprise
  - Dealer
  - R & D

- Academia (university)

- Hospital:
  - Physician
  - Nurse
  - Technician
  - Admin
  - R & D

- Local government

- AMED: Japan Agency for Medical Research and Development
- NEDO: New Energy and Industrial Technology Development Organization
- PMDA: Pharmaceuticals and Medical Devices Agency
- JAAME: Japan Association for the Advancement of Medical Equipment

Japan Association for Clinical Engineers (JACE)
Why Clinical Engineer?

- Specialized in medical devices
  - HTM
  - Safety Education for staff and patients

- Working in the clinical field
  - Respiratory therapy
  - Perfusion (HEART-LUNG machine)
  - Dialysis (Dialysis equipment)
  - Operative treatment (Surgical equipment)
  - Intensive care units
  - Cardiac catheterization
  - Hyperbaric oxygen therapy
  - Other treatment (defibrillators)
  - Pacemakers
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Engineering knowledge

Medical knowledge

Close relationship with physicians, nurses, other medical professions.
Expected Roles of Clinical Engineers in Device Development

- Evaluation of needs and ideas
- Translation between industry and the medical field
- Promotion of the activities
- Gathering information and summarization
JACE and Prefectural Association for CE

Introducing needs and ideas by clinical engineers at exhibitions, expos, trade shows

Introducing needs and ideas at medical-engineering collaboration matching events

http://www.hospital-expo.jp/

http://www.medtecjapan.com/
JACE and Prefectural Association for CE

What are the advantages for hospitals? CE?
IP?

Need to establish a continuing mechanism.

JACE is considering to establish a new board or commission for medical innovation and medical-industrial collaboration.
Case of ASO Iizuka Hospital

<table>
<thead>
<tr>
<th>Establishment:</th>
<th>August 1918</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital Division:</td>
<td>Community Health Care Support Center</td>
</tr>
<tr>
<td>Beds:</td>
<td>1116 beds</td>
</tr>
<tr>
<td>Wards:</td>
<td>32 wards</td>
</tr>
<tr>
<td>Staff:</td>
<td>2451</td>
</tr>
<tr>
<td>Physician</td>
<td>298</td>
</tr>
<tr>
<td>Nurse</td>
<td>1103</td>
</tr>
<tr>
<td>Technician</td>
<td>533</td>
</tr>
<tr>
<td>(Clinical Engineer 65)</td>
<td></td>
</tr>
<tr>
<td>Administrator, etc.</td>
<td>517</td>
</tr>
</tbody>
</table>

Clinical Department: 39

Internal Medicine, Hepatic Medicine, Gastrointestinal Medicine, Respiratory Medicine, Endocrine & Diabetic Medicine, Blood Medicine, Primary Care Medicine, Psychosomatic Internal Medicine, Collagen Diseases & Rheumatism Medicine, Radiology, Psychiatry, Pediatrics, Nephrology, Cardiology, Surgery, Digestive Organ Surgery, Respiratory Organ Surgery, Pediatric Surgery, Orthopedics, Dermatology, Plastic Surgery, Urology, Obstetrics & Gynecology, Ophthalmology, Otorhinolaryngology, Neurosurgery, Neurology, Cardiovascular Surgery, Dentistry & Oral Surgery, KANPO medicine, Anesthesia, Rehabilitation, Pathology, Emergency Section, etc.
Roles of Clinical Engineers in AIH

Dept. of Clinical Engineering

ICU
Hemodialysis Center
Kaita Hospital (Group Hospital)

Apheresis Center
Operation Room Perfusion
Endoscopy Center
HBOT
NICU

Cardiac Cath. Lab
Cardiac Rhythm Management (Pacemaker, ICD, CRT)

ME Center (management and maintenance)

Innovation Promotion Office

a case of ASO Iizuka Hospital
Innovation Promotion Office

- Needs and Ideas Management
- Intellectual Property Management
- Education
- Medical Engineering Partnership
  (Local government, university and AIH)
- Coordination with Partner Institutes

Staff

- Physician 1
- Clinical Engineer 3
- Administrator 3

a case of ASO Iizuka Hospital
What can we do as a hospital?

Advantages as a hospital

Could be possible as a hospital

Idea

- Needs Finding
- Needs Evaluation
- Idea Generation
- Idea Assessment
- IP Survey
- Patenting
- Idea Identifying

Prototyping

- Animal Test
- Preclinical Test
- Clinical Trial
- Regulatory
- Into the Market

*a case of ASO Iizuka Hospital*
Industry-Government-Academia Collaboration

Medical-Engineering Collaboration

ASO IIZUKA HOSPITAL

Fukuoka Prefecture

The organization to promote the Health-care And Medical device Industry in K(O)yushu

Center of Iizuka Research and Development
Iizuka Research and Development Organization

Iizuka City

Kyutech
Kyushu Institute of Technology

Japan Association for Clinical Engineers (JACE)

a case of ASO Iizuka Hospital
Conclusion

Majority of Japanese clinical engineers work in active medical fields

Japanese government encourages and promotes medical device development under the new growth strategy.

Industry-government-academia collaboration and medical-engineering collaboration are promoted and are now practiced in many areas.

Clinical engineers are expected to play their roles in medical device development especially in medical-engineering collaboration.

- Needs and ideas collection and evaluation
- Interpreter between the industry and clinical field
- Promotion using the networks though the organizations
Thank you for your attention

Sheep-Rin

Hiroki Igeta
ASO Iizuka Hospital
higetah2@aih-net.com