Roles of CE in Medical Device Development

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Agenda

- Introduction of clinical engineer system in Japan
- Recent movement of medical device development in Japan
- Expected roles of clinical engineer in device development
- JACE Medical-Academia-Industrial Collaboration Committee
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%
Our Clinical Fields (a case of Aso Iizuka Hospital)
Japan Association for Clinical Engineers (JACE)

CE license holders: about 40,000
Members of JACE: about 16,000

Social Mission of CEs

- Disseminate Optimal Care
- Establish the Medical Device Management System
- Improvement of Medical Technology
- Reduce Healthcare Cost
- Safety Assurance of Safety and Effectiveness of Medical Equipment

JACE has 44 committees

From Japan Association for Clinical Engineer
(http://www.ja-ces.or.jp/ce/?page_id=613)
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>
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<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>
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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

Japanese government issued New Growth Strategy “Japan Revitalization Strategy - Japan is Back -“

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

Estimating Future Medical Expense in Japan

Data from “Japan Medical Association Research Institute”
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

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

Needs Ideas

Academia (university)

Local government

AMED
NEDO
PMDA
JAAME
etc.

<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>

<Expected Roles of Clinical Engineers>
- Evaluation of needs and ideas
- Translation between industry and the medical field
- Promotion of the activities
- Gathering information and summarization
JACE Medical-Academia-Industrial Collaboration Committee
(established in 2016)

Roles of the Committee

1) To promote medical device development based on clinical needs

2) To support our members in device development

3) To expand CEs’ fields and opportunities
Activities of the Committee

1) To promote medical device development based on clinical needs
   - Idea posting system on the web site of JACE
   - Needs/idea evaluation service by committee members and observers.
Activities of the Committee

2) To support our members in device development
   - Introducing CEs’ needs and ideas at medical-industrial matching events.
   - Introducing needs and ideas by CEs at exhibitions, expos, trade shows
Activities of the Committee

3) To expand CEs’ fields and opportunities
   - Medical device development could be a new field to use CEs’ engineering skills and their medical knowledge.

Population Trends of Japan

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

Number of Beds

Data from the Ministry of Health, Labour and Welfare

Number of Clinical Engineers (in clinical fields)
Conclusion

Majority of Japanese clinical engineers work in active medical fields.

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

Not many medical professions are involved in medical device development especially with IP strategies.

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

JACE established the “Medical-Academic-Industrial Collaboration Committee” to support the members in medical device development.