PMDA’s effort to accelerate medical devices development
-Introduction of PMDA’s development support systems

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Office of Medical Devices I
Today’s Topics

• Introduction
• What is “Device Lag”?  
• Acceleration of Medical Devices development 
• Overview of PMDA’s development support systems
# Review Teams for MDs/IVDs

<table>
<thead>
<tr>
<th>Team</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team 1</td>
<td>Field of ophthalmology, otorhinolaryngology</td>
</tr>
<tr>
<td>Team 2</td>
<td>Field of dentistry</td>
</tr>
<tr>
<td>Team 3</td>
<td>Field of neurosurgery, cardiology, vascular surgery, respiratory</td>
</tr>
<tr>
<td>Team 4</td>
<td>Field of neurosurgery, cardiology, vascular surgery, respiratory (electronic devices)</td>
</tr>
<tr>
<td>Team 5</td>
<td>Field of gastroenterology, urology, gynecology</td>
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<tr>
<td>Team 6</td>
<td>Field of orthopedics, plastic surgery, dermatology</td>
</tr>
<tr>
<td>Team 7</td>
<td>In vitro diagnostic medical devices</td>
</tr>
<tr>
<td>Team 8</td>
<td>Others</td>
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Quantitative Increase and Background of Medical Device Reviewers

AP started
“Device Lag” means the period of lag between US Approval of medical devices and Japan Approval.
Review Times for Medical Devices

<table>
<thead>
<tr>
<th>Category</th>
<th>FY</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<tbody>
<tr>
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<tr>
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<td>FY</td>
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<td>100%</td>
<td>98.4%</td>
<td>90.2%</td>
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<td>Improved (w clinical data, 60%tile)</td>
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<tr>
<td></td>
<td>FY</td>
<td>100%</td>
<td>100%</td>
<td>97.6%</td>
<td>82.6%</td>
<td>17.0%</td>
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<tr>
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<tr>
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<td>98.8%</td>
<td>98.2%</td>
<td>93.8%</td>
<td>63.9%</td>
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What is “Device Lag”

• “Device Lag” means the period of lag between US Approval of medical devices and Japan Approval
Pharmaceutical Affairs Consultation on R&D Strategy

**Valley of Death**
- Shortage of funds, Knowledge on Regulation and developmental strategy

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**Basic Research**
Pharmaceuticals and Medical Devices candidates

**Strategic Consultation**

- Quality Study
- Non-Clinical Study
- Clinical Trial (Up to POC studies)

**Practical Use**
Innovative Products

- Further studies are handled by the Regular Consultation

**Consultation on quality and battery of pre-clinical, including examining tumorigenicity, biological ingredient safety**

**Consultation on endpoints or sample size of early clinical trial**

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**Flow of Strategy Consultation**

- Introductory Consultation (684)
- Pre-Consultation (813)
- Face-to-Face Consultation (209)
  (7/1/2011 – 6/30/2014)
Initiative to facilitate development of innovative drugs, medical devices and cellular and tissue-based products

- Support establishment of evaluation system for safety and efficacy with R&D as the basis at research facilities researching technology
- Enhance human resources between universities, NIHS, PMDA, and train resources adept in RS

Human resource development by personal exchange

Dispatch reviewers

Academia

Accept researchers

Learn innovative technologies

Accelerated higher quality review

Develop regulatory science experts

Promote proper R&D

Early development of standards and/or guidelines, etc

Promote implementation of innovative technologies (Eliminate drug lag and device lag)
Establishment of Science Board

The Science Board was established in May 2012 to discuss how PMDA can better cope with products with advanced science & technology, in each developmental stage such as basic research, development support, product review, and post market safety measures.

Board members

Academia (Knowledge of the Latest Innovative Technologies)
PMDA’s Consultation Menu

Very early stage
- Pre-development consultation
  - Market and Literature Surveys

Non-Clinical
- Quality Consultation
  - Stability Test
  - Biocompatibility Test

CT required?
- Consultation on Clinical Evaluation
  - Performance Test

CT
- Exploratory Clinical Test
  - Electrical Safety Test

Pre-application
- Development of Application Dossier
  - Clinical Test for Verification

Pharmaceutical Affairs Consultation on R&D Strategy
- Prior Assessment Consultation
PMDA’s Consultation

Number of consultation for medical devices

<table>
<thead>
<tr>
<th>FY2010</th>
<th>FY2011</th>
<th>FY2012</th>
<th>FY2013</th>
<th>FY2014</th>
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<tr>
<td>106</td>
<td>140</td>
<td>168</td>
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<td>207</td>
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Number of pharmaceutical affairs consultation on R&D Strategy for medical devices

<table>
<thead>
<tr>
<th>FY2010</th>
<th>FY2011</th>
<th>FY2012</th>
<th>FY2013</th>
<th>FY2014</th>
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<tbody>
<tr>
<td>-</td>
<td>6</td>
<td>5</td>
<td>38</td>
<td>16</td>
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</table>
Further Collaboration with Industry

To further shorten the development period, we need ・ ・ ・

- **Applicant’s cooperation**
  - appropriate evaluation of the devices
  - suitably-preparation of application documents

- **Oversea manufacturer’s cooperation**
  - giving accurate information to Japanese distributors
  - quick response to inquiry from Japan

- **Joining the meeting with PMDA in early stage**
Thank you!!

http://www.pmda.go.jp/