New Regulation in Japan and Future Direction of PMDA

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Today’s Topics

1. Current situation of PMDA
2. New Regulation in Japan
3. Strategies and Measures for PMDA Innovation
Pharmaceuticals and Medical Devices Agency

Major Services
- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials
- Safety Measures
- Relief Services

Unique Three-pillar System
Securing Nation’s Safety

PMDA Homepage: http://www.pmda.go.jp/english/index.html
### Strategies and Measures for PMDA Innovation

<table>
<thead>
<tr>
<th>Issues in the past</th>
<th>Basic policies to address the issues</th>
<th>Efforts made so far</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ Drug / Device lag</td>
<td>◆ Philosophy <em>(Mission Statement)</em></td>
<td>● Increase staff members</td>
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<tr>
<td>◆ Insufficient Safety measures</td>
<td>◆ Regulatory science</td>
<td>● Enhance training program</td>
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<td></td>
<td>◆ Global partnership <em>(Win-Win Relationship)</em></td>
<td>● Academic cooperation</td>
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<td></td>
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<td>● Industry-Government-Academia collaboration</td>
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<td>● Pharmaceutical affairs consultation</td>
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<td>● Cross-sectional project within PMDA</td>
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<tr>
<td></td>
<td></td>
<td>● IT-based safety measures</td>
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<tr>
<td></td>
<td></td>
<td>● Risk Manager <em>(RM)</em></td>
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<td></td>
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<td>● Risk Management Plan <em>(RMP)</em></td>
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<td></td>
<td></td>
<td>● GLP, GCP, GMP, QMS inspection programs</td>
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<td></td>
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<td>● Adverse health effect relief system</td>
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<tr>
<td></td>
<td></td>
<td>● International strategic plan</td>
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<td></td>
<td></td>
<td>● Global partnership</td>
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</tbody>
</table>

**Pharmaceutical affairs are the ultimate medical ethics, and regulatory science is the underlying science.**
Japan’s Performance on NDA Review

“Japan’s PMDA and Health Canada may have had the most notable improvements over the past decade.”
Regulatory Affairs Professionals Society  14 January 2015
Continues Risk Management through Product Life-cycle

<table>
<thead>
<tr>
<th>Phase</th>
<th>Regulatory Tool</th>
<th>Person in Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Development Phase</td>
<td>Development Safety Update Report (ICH E2F)</td>
<td>Review Team (consultation)</td>
</tr>
<tr>
<td>NDA Review Phase</td>
<td>Risk Management Plan (ICH E2E+α)</td>
<td>Review Team (NDA review)</td>
</tr>
<tr>
<td>Post-Marketing Phase</td>
<td>Periodic Benefit-Risk Evaluation Report (ICH E2C(R2))</td>
<td>Review Team (Re-examination) &amp; Safety Team</td>
</tr>
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</table>

DSUR

RMP

Currently PSUR

PBRER

DIA DEVELOPE INNOVATE ADVANCE
Today’s Topics

1. Current situation of PMDA
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Revision of Pharmaceutical Affairs Law

1. Strengthen safety measures regarding drugs and medical devices
2. Revise medical device regulations based on its characteristics
3. Introduce cellular and tissue therapeutic product regulations based on its characteristics

PAL has been renamed as
“Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics”

= Pharmaceutical and Medical Device Act,
or “PMD Act”.
Expedited approval system under PMD Act (Time-limited Conditional Approval)

Conventional Regulatory Approval Process

1. Clinical research
2. Clinical trial (evaluation of efficacy and safety)
3. Approval
4. Marketing

Regulatory System That Facilitates Early Practical Application of Cellular or Tissue-based Products

1. Clinical research
2. Clinical trial (prediction of efficacy and assurance of safety)
3. Conditional approval for a limited time period
4. Marketing
5. Approval or Withdrawal of the time-limited conditional approval
6. Continued marketing (if approved)

Faster access of patients to new products is expected.

Each patient is informed of the risks of the product and consent is obtained from the patient, while post-marketing safety measures are taken.
Today’s Topics

1. Current situation of PMDA
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## Six regulatory innovations in Japan

<table>
<thead>
<tr>
<th>Stage</th>
<th>Agendas for PMDA</th>
<th>Supporting Initiatives</th>
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<tbody>
<tr>
<td>Development</td>
<td>○ Support for promising seeds to forward the development.</td>
<td>→Pharmaceutical Affairs Consultation on R&amp;D Strategy (from July 2011)</td>
</tr>
<tr>
<td>Review</td>
<td>○ Approaches to cutting-edge technologies</td>
<td>→Science Board (from June 2012)</td>
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<td>○ Early practical use of regenerative medical products.</td>
<td>→Time-limited Conditional Approval (from November 2014)</td>
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<td>○ Encouraging Japan-first development and approvals.</td>
<td>→SAKIGAKE designation system (from FY 2015)</td>
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<td>○ Improve efficiency of development</td>
<td>→Advanced review system (under development)</td>
</tr>
<tr>
<td>Post-marketing</td>
<td>○ Utilize medical information database</td>
<td>→MIHARI project (from FY 2009)</td>
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</table>
PMDA’s next step

PMDA is currently working on the new international strategic plan to further promote internationalization.

The plan includes

- Enhancing dissemination of information
- Internationalization of pharmaceutical regulations
- Work sharing.
- Contribution to the regulatory harmonization
PMDA for the World - To create society to receive the essential forefront medicines -

- Swift approvals of innovative products
- Review
- Convey Japanese technology to the world
- Cooperate with all agencies in the world
- Swift relief for occurred health damage
- Japanese Citizens
- Safety
- Relief
- Contribute to the world’s medicine

Regulatory Science
Thank You

For Win-Win Relationship

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