Future Plan of PMDA for the next five years

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PHARMACEUTICALS AND MEDICAL DEVICES AGENCY (PMDA), JAPAN
Outline of PMDA
Pharmaceuticals and Medical Devices Agency

PMDA’S SAFETY TRIANGLE

Unique Three-pillar System Securing Nation’s Safety

- Review
  - Reduction in risk

- Japanese Citizens

- Safety
  - Continuous risk mitigation efforts

- Relief
  - Relief measures for health damage caused by risk factors
PMDA Forum as the 10th Anniversary

2014. 2. 8. Tokyo

Guest speakers: Prof. Guido Rasi (EMA); Mr. Jüng H. Schnetzer (Swissmedic); A/Prof. John C W Lim (HSA); Dr. Chung Seung (MFDS); Dr. M. Hayatie Amal (NADFC); Mr. Kees de Joncheere (WHO); Dr. Margaret A. Hamburg (FDA, video presentation)
## Strategies and Measures for PMDA Innovation

<table>
<thead>
<tr>
<th>Issues with PMDA (past 5 years)</th>
<th>Basic policies to address the issues</th>
<th>Efforts made so far</th>
</tr>
</thead>
<tbody>
<tr>
<td>◆ Shorten review time</td>
<td>◆ Philosophy (Mission Statement)</td>
<td>• Increase staffs</td>
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<tr>
<td>• Reduce drug lag</td>
<td>◆ Regulatory science</td>
<td>• Enhance training program</td>
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<tr>
<td>• Reduce device lag</td>
<td>◆ Global partnership (Win-Win Relationship)</td>
<td>• Academic cooperation</td>
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<tr>
<td>◆ Strengthen and enhance safety measures</td>
<td></td>
<td>➢ Science Board</td>
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<td>➢ Joint Graduate School Program</td>
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<td>➢ Human resource exchange program</td>
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</table>

**Pharmaceutical affairs are the ultimate medical ethics, and regulatory science is the underlying science.**

- Increase staffs
- Enhance training program
- Academic cooperation
  - Science Board
  - Joint Graduate School Program
  - Human resource exchange program
- Industry-Government-Academia collaboration
- Pharmaceutical affairs consultation
- Cross-sectional project within PMDA
- IT-based safety measures
  - MIHARI Project
  - Project for developing medical information database infrastructure
- Risk Manager (RM)
- Risk Management Plan (RMP)
- GLP, GCP, GMP, QMS inspection programs
- Adverse health effect relief system
- International strategic plan
- International liaison officers to US and EU
- Global partnership with US, EU, and Asian countries (ICH, IMDRF, PIC/S, etc.)
PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

We conduct our mission in accordance with the following principles:

• We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.

• We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.

• We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.

• We play an active role within the international community by promoting international harmonization.

• We conduct services in a way that is trusted by the public based on our experiences from the past.
Shortening Review Period

With the increase of increase personnel and development of ability, PMDA has shortened review period while applications increasing.

In terms of 2013, data is accumulated until the end of October.
Improvement of Safety Measures

Collection of Information → Analysis

New Risk management system

Assessment of Safety measure effects → Planning and Implementation of Safety measures

Hypothesis → Evaluation of hypothesis

Goal

- Prevention of serious drug safety-related crisis from Japan
- Effective encouragement of proper drug use.
- Ensuring credibility to post-market safety management system.
correspond better to the characteristics of innovative new medicines in all phases from seeds to practical use

- Science Board
- Pharmaceutical Affairs Consultation on R&D Strategy
- Personnel Exchanges
- Advanced Review and Consultation with e-Submitted Study Data (ex. Modeling & Simulation)
- Improvement of Safety Measures
Achievement of Bilateral Activities

* MOU between the Chinese SFDA (present CFDA) and the Japanese MHLW, under which PMDA supports cooperative activities
All the players in good harmony

Review
Safety
Relief

REGULATORY SCIENCE
INTERNATIONAL COOPERATION

Philosophy
The Japanese Government issued the important policies which require PMDA to strengthen the organization both in size and in quality.

- **Japan Revitalization Strategy - JAPAN is BACK -** (Cabinet Decision on June 14, 2013)
- **Health and Medical Strategy** (Agreed by related Ministers on June 14, 2013)
Japan Revitalization Strategy - JAPAN is BACK -
(Cabinet Decision on June 14, 2013)

Extended national “Healthy life expectancy”

<Future vision of the society>
The society where people can receive necessary healthcare services at the most advanced level in the world

Foster the industry specialized in extended healthy life, by developing innovative pharmaceuticals, medical devices and regenerative medicines first in the world, and by introducing these products to the market through speedy review process.

Measures

- Strengthen PMDA organization both in size and in quality
  - While maintaining a keen attention to post marketing product quality and safety, further reduction of review time (achieve “0” review lag) and improved quality will be pursued.
  - Enhancement of Pharmaceutical Affairs Consultation on R&D Strategy
  - Establishment of the Medical Information Databases

*Reform of regulation and system to accelerate generative medicine research and environmental improvement for practical use of regenerative medicine products are required.
Health and Medical Strategy
(Agreed by Chief Cabinet Secretary, Minister of Health, Labour and Welfare and other related Ministers on June 14, 2013)

Basic philosophy (Three philosophies)
- Realize extended healthy life society
- Contribute to economic growth
- Contribute to the world

Measures

- Establish organization to promote research and development
  ~ Prepare "All Japan" support system ~
  - Establish control tower function (New organization)

- Strengthen PMDA
  - Further reduction of review time (achieve “0” review lag)
  - Expand and enhance the pharmaceutical affairs consultation on R&D strategy program
  - Establishment of the medical information databases
  - Promote PMDA’s own analysis and study of clinical data
  - Utilization of Science Board, Global harmonization etc.

※Development of the security evaluation system using iPS cells is required for better new drug development
Regulation considering **Regenerative Medicines** Character
- Creation for Regenerative Medicines regulations
- Introduction of approval system with condition/period

Regulation considering **Medical Devices** Character
- Independent Chapter for “Medical Devices”
- Third party certification system
- Quality Management System (QMS)
- Other revisions related to medical devices
- Regenerative and Cellular Therapy Products, and Gene Therapy Products

**Strengthen Safety Measures** regarding Drugs, Medical Devices
- Specify relevant party’s obligation to ensure quality, safety, and efficacy of drugs and medical devices.
- MAH’s obligation to notify revised Package insert reflecting the latest findings
Outline of 3rd mid-term plan

In the 5-year plan, we are planning to

- Improve both review and safety measures implemented by PMDA

  【Operational matter】

- Increase the number of staff
  ( 751 in FY2013→1065 in FY2018 )

  【Organizational matter】
3rd 5-year mid-term plan of PMDA (FY2014-2018)

Major challenges

- Shortening the time to approval & High quality review/consultation services
- Enhancing safety measures
- Globalization

Specific measures

- Accelerated review process
  (Improvement of approval predictability)
- Improvement of prior assessment
  (substantial acceleration of approval review process)
- Drastic improvement of consultation service
  - Improvement of pharmaceutical affairs consultation service on R&D strategy
  - Improvement of clinical trial consultation service
- Readiness for introduction of risk management plan
- Utilization of medical information database

Advanced Review/Consultation System

Goal

- Development of Japan’s original innovative drugs and medical devices
- Marketing of cellular and tissue-based products
- Activation of the industry
- Extending health and life span of Japanese people
- Contribution to global medicine

Human Resources with excellent skills

主要是751名员工增加到1,065名。
**3rd 5-year mid-term plan of PMDA (FY2014-2018)**

**Major challenges**

- Shortening the time to approval & High quality review/consultation services

**Specific measures**

- Accelerated review process (Improvement of approval predictability)
- Improvement of prior assessment (substantial acceleration of approval review process)
- Introduction of approval system with condition/period for Regenerative Medicines
- Drastic improvement of consultation service
  - Improvement of pharmaceutical affairs consultation service on R&D strategy
  - Improvement of clinical trial consultation service

**Advanced Review/Consultation System**

**Enhancing safety measures**

**Globalization**

**Goal**

- Development of Japan’s original innovative drugs and medical devices
- Marketing of cellular and tissue-based products
- Extending health and life span of Japanese people
- Contribution to global medicine
- Activation of the industry

**Human Resources with excellent skills**

- 751 staffs → 1065 staffs
### New Target of Review Time

#### New Drugs (Priority)

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<thead>
<tr>
<th>Fiscal Year</th>
<th>Percentile</th>
<th>Review Time</th>
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<tbody>
<tr>
<td>2013</td>
<td>50% (median)</td>
<td>9 months</td>
</tr>
<tr>
<td>2014</td>
<td>60%</td>
<td>9 months</td>
</tr>
<tr>
<td>2015</td>
<td>60%</td>
<td>9 months</td>
</tr>
<tr>
<td>2016</td>
<td>70%</td>
<td>9 months</td>
</tr>
<tr>
<td>2017</td>
<td>70%</td>
<td>9 months</td>
</tr>
<tr>
<td>2018</td>
<td>80%</td>
<td>9 months</td>
</tr>
</tbody>
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#### New Drugs (Standard)

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<tr>
<td>2013</td>
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- **3rd mid-term plan**
- **2nd mid-term**

*7.2 months (Result)*

*11.3 months (Result)*
To achieve new target

In order to achieve new target, we will take these measures.

• Reinforcement of Prior Assessment Consultations (substantial acceleration of approval review process)

• New approval system with condition/period for Regenerative Medicines

• Improvement of consultation service

We can shorten review time of new drugs which were not covered in target time before.

We need more reviewers.
Reinforcement of Prior Assessment Consultations

Quality
- Drug substance, product specification, stability, etc.

Stability of Drug Product

Carcinogenicity

Non-Clinical
- Toxicology, Pharmacology, and ADME

Gradual evaluation based on each test result

More smooth reaction by applicant

Front-loaded review in practice by prior assessment

Start without waiting until whole test results are ready.
New Approval System for Regenerative Medicines

【Current System】
Clinical Research → Clinical Trial (confirmation of efficacy and safety) → Approval → Marketing → Informed Consent and Post Market Safety Measures

【New System】
Clinical Research → Clinical Trial (confirmation of probable benefit* and safety**) → Provisional Approval with condition → Marketing (further confirmation of efficacy and safety) → Application → Approval or Expiration of provisional approval → Informed Consent and Post Market Safety Measures

※Earlier Patient Access！

* Probable benefit: Confirmation of efficacy with small patient population.
** Safety: Earlier detection and evaluation of adverse events.
Valley of Death
- Shortage of funds, Knowledge on Regulation and development strategy

Basic Research
Pharmaceutical and Medical Devices candidates

Quality Study
Non-Clinical Study
Clinical Trial
Up to the level of POC studies*

Strategic Consultation

Introductory Consultation
- Explain procedure
- No Charge
- 657 Consultations

Pre-Consultation
- Sort out issues
- 30 min, No Charge, Not binding
- 753 Consultations

Face-to-Face Consultation
- Scientific discussion
- 2 hours, Charged, Binding, Minutes
- 193 Consultations

Practical Use
Innovative Products originated from Japan

* Further studies are handled by the Regular Consultation

7/1/2011 – 3/31/2014

DIA 2014
50TH ANNUAL MEETING
3rd 5-year mid-term plan of PMDA (FY2014-2018)

**Major challenges**

- Shortening the time to approval & High quality review/consultation services
- Enhancing safety measures
- Globalization

**Specific measures**

- **Accelerated review process** (Improvement of approval predictability)
- **Improvement of prior assessment** (substantial acceleration of approval review process)
- **Drastic improvement of consultation service**
  - Improvement of pharmaceutical affairs consultation service on R&D strategy
  - Improvement of clinical trial consultation service
- **Advanced Review/Consultation System**
- **Introduction of approval system with condition/period for Regenerative Medicines**
- **Readiness for introduction of risk management plan**
- **Utilization of medical information database**

**Goal**

- **Activation of the industry**
- **Extending health and life span of Japanese people**
- **Contribution to global medicine**
- Development of Japan’s original innovative drugs and medical devices
- Marketing of cellular and tissue-based products
- Readiness for introduction of risk management plan
- Utilization of medical information database
- Enhanced safety measures
- Human Resources with excellent skills (751 staffs → 1065 staffs)

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**Special mention**

DIA 2014 50th Annual Meeting
Priority Issues to be Consolidated for Post-Marketing Safety Measures

1. Strengthening of information gathering on adverse drug reactions and malfunctions
2. Organization of information on adverse drug reactions and systemization of evaluation and analysis
3. Establishment of the medical information databases
4. Establishment of a post-marketing safety system through information feedback
5. Fulfilling information distributed to general public related to Pharmaceuticals and Medical Devices Safety
6. Appropriate safety measures based on the Risk Management Plan
7. Reinforcement of safety measures adapted to new review system as well as consistently monitoring the safety of drugs from the clinical trial stage to post-marketing stage
8. Strengthening and improvement of follow-up on implemented safety measures
9. Organizing, evaluating, and analyzing information gathered from Vaccine Adverse Reaction Reporting System

We need more staff with excellent skills.
Pharmacovigilance measures JP, US, EU

**Pre-market review**
- ADR/AE reporting
- Pharmacovigilance plan For NME

**Approval**
- EPPV (NME 6mo.)
- Post-market commitment
- Periodic report

**Post-market**
- Spontaneous ADR, infection Reporting
- 6-10 years Re-examination
- Re-evaluation If necessary

**JP**
- RMP
- Streamlined risk management strategies

**US**
- REMS (high risk NME)
- Post-market Commitment If necessary
- Periodic report

**EU**
- RMP (NME)
- Post-market Commitment If necessary
- PSUR
- renewal
- renewal
Continues Risk Management through Product Life-cycle

<table>
<thead>
<tr>
<th>Phase</th>
<th>Regulatory Tool</th>
<th>Person in Charge</th>
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<tbody>
<tr>
<td>Clinical Development Phase</td>
<td>Development Safety Update Report (ICH E2F)</td>
<td>Review Team (consultation)</td>
</tr>
<tr>
<td></td>
<td>Risk Management Plan (ICH E2E+α)</td>
<td>Review Team (NDA review)</td>
</tr>
<tr>
<td></td>
<td>Periodic Benefit-Risk Evaluation Report (ICH E2C(R2))</td>
<td>Review Team (Re-examination) &amp; Safety Team</td>
</tr>
<tr>
<td>NDA Review Phase</td>
<td></td>
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<tr>
<td>Post-Marketing Phase</td>
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<thead>
<tr>
<th>Tool</th>
<th>Details</th>
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<tbody>
<tr>
<td>DSUR</td>
<td>Development Safety Update Report (ICH E2F)</td>
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<tr>
<td>RMP</td>
<td>Risk Management Plan (ICH E2E+α)</td>
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<td>PBRER</td>
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<tr>
<th>Details</th>
<th>Dates</th>
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</thead>
<tbody>
<tr>
<td>Risk Management Plan</td>
<td>Apr. 2013 - Currently PSUR</td>
</tr>
<tr>
<td>Development Safety Update</td>
<td>Apr. 2013 - Currently PSUR</td>
</tr>
<tr>
<td>Periodic Benefit-Risk Evaluation Report</td>
<td>ICH step5 May. 2013</td>
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</table>
Burden on HCPs should be taken into consideration.

**Concept of J-RMP**

**Safety Specification**
- Important Identified Risk
- Important Potential Risk
- Important Missing Data

**Pharmacovigilance Plan**
- Spontaneous reporting
- Research Report
- Foreign actions report

**Risk Minimization Action Plan**
- Package Insert Booklet of Precaution for Use

**Routine**
- Info Dissemination by EPPV
- Info for Health Professionals
- Drug Guide for patients
- Access restriction etc

**Additional**
- Enhancement of spontaneous reporting by EPPV
- Drug use – results survey
- Specified drug use survey
- Post Marketing Clinical Study
  (Includes PharmacoEpi Study) etc

**Additional RiskMAP**
- Additional PvP

**Additional PvP and / or RiskMAP?**
- Additional RiskMAP

**Need Additional measures? (Evaluation)?
- No**

**Evaluation**
- Yes

**Risk Evaluation**
- (Periodic Reporting)

※Burden on HCPs should be taken into consideration.
Information about the RMP

• About drug risk management plan (in Japanese)
  — Objective
  — Conceptual diagram
  — Relevant documents
  — Case Described of drug risk management plan
    http://www.info.pmda.go.jp/rmp/to_company.html

• Risk Management Plan Guidance (in English)

• Information page of RMP for company (in Japanese)
  http://www.info.pmda.go.jp/rmp/to_company.html
What is the Risk Manager?

- **Development**: Review Department (Review Team)
- **Review**: Risk Manager (Act as Liaison)
- **Post-marketing**: Safety Department (Safety Team)

- Development of early post-marketing phase vigilance plan
- Advice on Drug’s post-marketing safety measures
- Evaluation of the result of post-marketing survey
医薬品リスク管理計画（RMP: Risk Management Plan）について

目的

医薬品の安全性の確保を図るためには、開発の段階から製造販売後に至るまで常にリスクを適正に管理する方策を検討することが重要です。これまでもICH-E2Eガイドラインでは、医薬品の既知のリスクや未知のリスク等を要約して「安全性検査事項」として取り上げ、医薬品安全性モニタリング計画を作成するように求めていましたが、医薬品のリスクを低減するための方法については記載していませんでした。

今般、医薬品安全性モニタリング計画に加えて、医薬品のリスクの改善を図るためのリスク最小化計画を含めた医薬品リスク管理計画（RMP: Risk Management Plan）を策定するための指針「医薬品リスク管理計画指針について」及び具体的な計画書の様式、提出などの取り扱い「医薬品リスク管理計画計画の策定について」がとりまとめられました。この指針の活用により医薬品の開発段階、承認審査時から製造販売後の全ての期間において、ペネフィットとリスクの評価・見直しが行われ、これまで以上に明確な見通しを持たせる製造販売後の安全対策の実施が可能となることを作業としております。

概念図

RMP全体のイメージ
Please Visit PMDA English website
This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

PFSE/SD Notification No. 0411-1
PFSE/ELD Notification No. 0411-2
April 11, 2012

To: Directors of Prefectural Health Departments (Bureaus)

From: Directors of Safety Division
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Director of Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Risk Management Plan Guidance

To ensure the safety of drugs, it is important to consider the ways to manage the risk

Publication of Risk Management Plan

Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare

Translated by Office of Safety I, Pharmaceuticals and Medical Devices Agency

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

PFSB/ELD Notification No. 0304-1
PFSB/SD Notification No. 0304-1
March 4, 2013

To: Directors of Prefectural Health Departments (Bureaus)

From: Director of Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Director of Safety Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Publication of Risk Management Plan

The Ministry of Health, Labour and Welfare (MHLW) previously issued notifications

Current RMP in Japan

Discussion & Agreement of RMP between PMDA and MAH before approval
- Are Healthcare professionals involved?

Most of products are required PMS.
- Are they sufficient and minimum?

Is RMP made based product’s character?

Is purpose of RM/data collection clear?
Table of Contents of RMP Guidance

1. Introduction
2. Risk Management Plan
3. Safety Specification
4. Pharmacovigilance Plan
5. Plan for Survey/Study on Efficacy
6. Risk Minimization Plan
7. Evaluation of Risk Management Plan and Report to PMDA
Challenges for the Future

• Evaluate after re-examination term
• Remove conditions of approval RMP
• Implement the RMP of generic drugs
Challenges for the Future

• We need more experiences about RMP review process between PMDA and MAHs
• Revise RMP by new information, if necessary
• Look for more efficient and meaningful post-marketing surveys
• Develop measures to minimize risks and to evaluate outcome of risk minimization activities
• It is important to achieve understanding of healthcare professionals
Initiative to Develop Infrastructure for Medical Information Database

Catch line: Provide safe and secure medical care by collecting 10 million patients scale medical information

- Build database hubs at 10 cooperating medical institutions nationwide such as university hospitals.
- Target is to make more than 10 million patients data ready for use in 2015.

<Expectations>
Faster and more appropriate safety measures by utilizing the database for safety study.
(Ex. Understanding of adverse reaction ratio, risk assessment, evaluation of safety measure effects, etc.)

Utilization by PMDA and researchers
Data collected at 10 hub medical institutions will be retrieved and studied for analysis and evaluation of adverse reactions

Cooperating medical institutions (10 University and group hospital sites)

Associated medical institutions of hub medical group

Tohoku U.  
NTT Hospital (group)  
U. Tokyo  
Chiba U.  
Kitasato U. (group)  
Kagawa U.  
Kyushu U.  
Saga U.  
Tokushukai (group)
Direction of Regulation Relating to Package Insert (For NDA)

Current System

- Draft of PI
  - Mandatory contents to be described in PI (Article 52)
  - Prohibition on Entries (Article 54)
- Submission of draft PI
  - The draft PI is to be submitted by the administrative direction
- Approval

Revised System

- Draft of PI
  - Mandatory contents to be described in PI (Article 52)
  - Prohibition on Entries (Article 54)
- Submission of draft PI
  - The draft PI and its supporting document should be submitted together with application materials
- Approval
- Notification of PI
- The notification of PI before marketing is now mandatory

In case of non-compliance

- Order to Improve
  - Prevention of hazard (Article 77-4)
  - Order to improve management (Article 72-4)
  - Emergency Orders (Article 69-3)
- Penalty
  - Punitive Clause (Articles 84, 86, and 90)
3rd 5-year mid-term plan of PMDA (FY2014-2018)

**Major challenges**

- Shortening the time to approval & High quality review/consultation services
- Enhancing safety measures
- Globalization

**Specific measures**

- Accelerated review process (Improvement of approval predictability)
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- Readiness for introduction of risk management plan
- Utilization of medical information database
- Advanced Review/Consultation System

**Goal**

- Activation of the industry
- Extending health and life span of Japanese people
- Contribution to global medicine

- Development of Japan’s original innovative drugs and medical devices
- Marketing of cellular and tissue-based products

**Human Resources with excellent skills**

751 staffs → 1065 staffs
Advanced Review/Consultation System

**Analysis by PMDA**
- Giving additional scientific value to submitted data

**Cooperation with Academia**
- Disease model
- Objective B/R assessment
- Identifying AE-related factors etc.

**Regulatory Science**
- A rational & effective evaluation process for regulatory decision

**Practical use of Innovative Medical Products**
- Giving additional scientific value to submitted data

**Sophisticated NDA review**
- Each reviewer utilizes innovative assessment techniques

**Cross-Products Analysis**
- Innovative evaluation methods
- Active utilization of Modeling & Simulation
  - Disease model
  - Objective B/R assessment
  - Identifying AE-related factors etc.

**Sophisticated Consultation**
- More evidence-based consultation

**Effective and High Quality Review**
- More predictable efficacy/safety after approval
- Reduction of applicant’s work load
- More scientific regulatory decision

**Effective and Successful Development**
- Epoch-making proposal leading the world
- Proactive publication of guideline

We need more staff with excellent skills.
3rd 5-year mid-term plan of PMDA (FY2014-2018)

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Human Resources with excellent skills

- 751 staffs → 1,065 staffs

Introduction of approval system with condition/period for Regenerative Medicines

- Drastic improvement of consultation service
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Advanced Review/Consultation System

- Introduction of approval system with condition/period for Regenerative Medicines
- Drastic improvement of consultation service
  - Improvement of pharmaceutical affairs consultation service on R&D strategy
  - Improvement of clinical trial consultation service

Utilization of medical information database

- Development of Japan’s original innovative drugs and medical devices
- Marketing of cellular and tissue-based products
- Activation of the industry
- Extending health and life span of Japanese people
- Contribution to global medicine
**Roadmap for the PMDA International Vision**

**Five Important Areas Where RMs are needed**

1) **Response to advanced science and technology**
   - Proactively provide information about the policies for review and scientific consultation of cutting-edge products and recommendation for relevant guideline developments.
   - Introduce progressive analyzing and predictive methods.

2) **Improvement of international operation basis**
   - Improve the organizational structure enabling wide range international activities and cultivate new internationally minded personnel* in a prompt manner.
   *A personnel who has 1) good command of foreign languages, 2) an international human network, 3) abundant knowledge of his or her related area of expertise, 4) ability to make appropriate decisions under the given circumstances domestically and internationally, and 5) trustworthy international relations.

3) **Dissemination of English information on regulatory review of medicinal products, especially publication of review reports in English**
   - Increase the number of English version of review reports (aiming to cover all the necessary review reports in English in the future).

4) **Dissemination of information and international cooperation on safety measures**
   - Enhance exchanging information and establish a system to share evaluation reports with our overseas counterparts.
   - Enrich the contents related to safety information in the English website.

5) **Increase of the leverage of Japanese Pharmacopoeia (JP)**
   - Publish the newest JP version simultaneously in English and Japanese.
   - Enhance cooperative relationship with the USP, EP, WHO and each Asian pharmacopoeia.

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Note) As we have been committed to emphasize the activities with ICH, IMDRF and other foreign regulatory agencies, the effort should continue for the future development.

**We need more staff with excellent skills.**
Staff Size of PMDA

常勤役職員数（人）

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Note: The chart shows the staff size of PMDA from 2004 to 2018.
All the players in good harmony

Thank you for your attention