

Celebrating MHLW's and PMDA's New International Strategic Plans
Expectations to the international strategic plans 2015
by MHLW/PMDA from Medical Devices Industry

Thursday September 3rd, 2015



***Expectations to the
international strategic plans
from an industry perspective***

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Vice Chairmen of JFMDA

CEO of JEITA Healthcare Industry Committee

Chairman & CEO of NIHON KOHDEN CORPORATION



Medical Devices supports

infrastructure of medical care over borders

医療機器は、国境を越えて医療基盤を支える

Speedy Respond to disease state and clinical needs

with safety and high reliability

医療ニーズに応じて、安全に高品質で、すばやく、タイムリーに

- ◆ **Role of Medical devices Industry & JFMDA**
- ◆ **Globalization of Medical devices and Medical engineering**
- ◆ **Expectations to the international strategic plans by MHLW/PMDA**
- ◆ **To be supportive Medical devices for infrastructure Medical Care**



Activities of JFMDA

**Speedy Respond to disease state and clinical needs
with safety and high reliability**

MHLW
METI
MEXT
Academia

AMED

PMDA

JFMDA

MEJ

JETRO

JICA

JABIC

**19 Specialized
Industrial Associations**

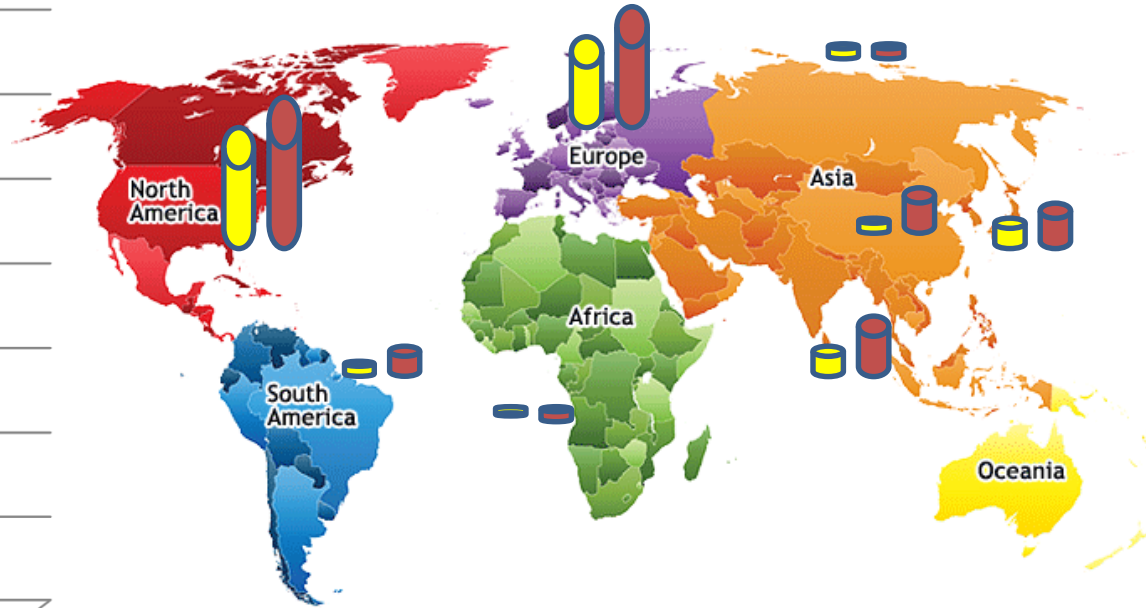
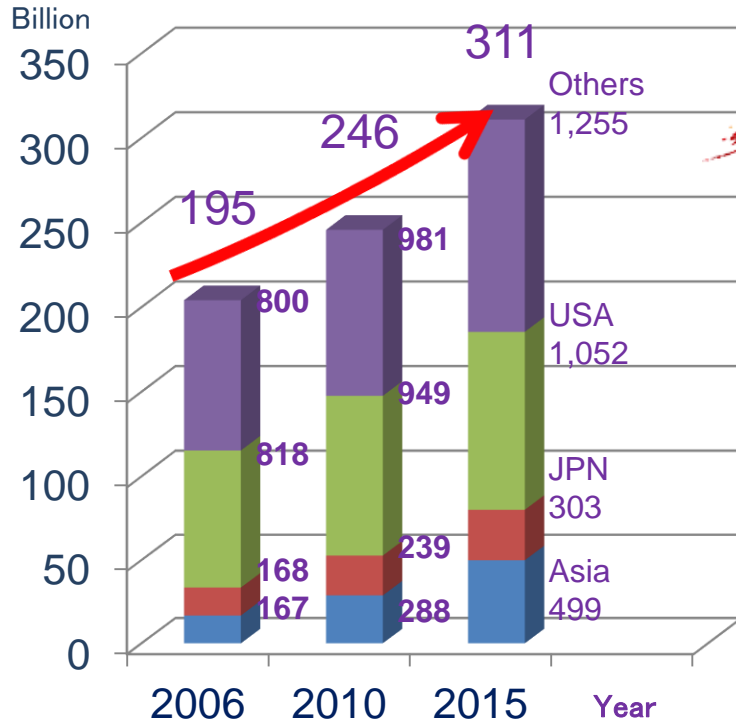


**Medical Care
around the
world**





Global Market and Japanese Industry



(Source: Medistat Worldwide Medical Market Forecasts To 2015, Espicom)

- Medical Devices companies: 4,370
 (2,140 manufacturers, 2,230 sales companies)
 - Number of Workers: about 120,000 people
- Members: 19 associations*

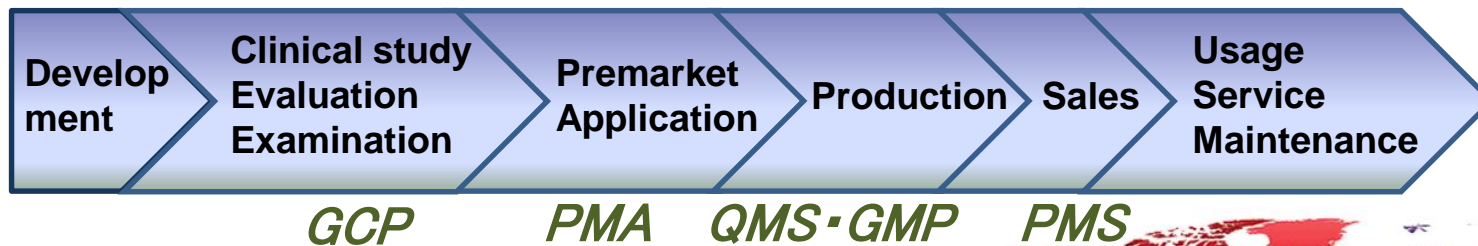




Globalization of Medical Devices Industry

We aim for considering **disease state and clinical needs** of the world and promoting **production** by consolidating advanced technology as well as productivity among the world.

We **adequately evaluate** that we contribute to medical for safety and reliability, and promote **rapidly** to provide **optimized medical devices**.



- *Global R&D, Production and Sales Network of Japanese Medical Devices Industry*
(Right: in case of Nihon Kohden)





For smooth operation in global market

JFMDA facilitate the ME industry environment for the smooth operation in global market, and promote cooperation with government in quest for Global Harmonization.



China - Japanese medical devices companies in China organize conferences and increases interchanges



Brazil - Request to improve regulatory operation through positive interaction with Government and Private Entities



Thailand - Inauguration of sectional committee of Drugs & ME in C.C. of Bangkok



Malaysia - Drive the session of Review before the commercial distribution of ME



Singapore - Kickoff of aggressive dialogue regarding ME regulation



Taiwan - Launch of GCP, Enrollment of medical devices, QSD/QMS, and WG of PMS in Taiwan and Japan

AMDD periodical dialogue with AdvaMed and EBC





Expectations to the international strategic plans

We expect and agree with PMDA that promote international harmonization and cooperation of regulatory strategy, which “Regulatory Science Initiative” would be spread to the world including Asia.

Aim for regulatory science center

To work on R&D of medical devices with innovative technology, “Regulatory Science Center” is crucial.

When ensuring Product Quality, Efficacy and Reliability, it is extremely important for all the people in the world to consider, based on common scientific infrastructure.

Aim for Asian drugs & medical devices regulatory training center

Japanese regulatory strategy putting a high value on quality for safety and reliability have influences in Asia.





Expectations to the global activities by collaboration

Industry, government and academia aim at the same goal.

We should enhance the partnerships

in order to improve environment of industrial activities

AMED: Project to realize innovative medical technologies
Project to promote medical engineering and medical devices
Project to establish open system infrastructure
for domestic medical devices development
Facilitating the Review and enhancing
quality improvement and safety precautions

PMDA: Enlarging counseling services for regulatory strategy
Improving safety policy using database
Operating international work-sharing in near future



To be supportive medical devices for medical care

We support medical infrastructure to ensure better use of medical devices.

■ For Safety usage

Establish Training Center and acquire knowledge of medical devices

■ For Reduction of Downtime and long-life usage

Promote training to improve the quality of service and maintenance, in case of medical devices malfunction

■ For Global Human resource development

Promote education and use personal around the world



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