Introduction to PMDA's International Strategic Plan 2015

September 3, 2015

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Menu for each of you

Our recommended contents

Menu of each product type

for Regulatory authorities | for Healthcare professionals | for Academia | for Business

PMDA's International Strategic Plan 2015

PMDA's International Strategic Plan 2015

IMDRF 7th Management Committee in Tokyo

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International Activities

2015 announce

2015 年 06 月 26 日

PMDA 国際戦略 2015

PMDA の第一の責務は、レギュラトリーサイエンスに基づき、よりよい医薬品・医療機器・再生医療等製品などが、より早く、より安心して使用できる環境を日本国民のために創出することである。グローバル化が進展し、医薬品・医療機器・再生医療等製品などが国、地域を越えて世界規模で開発・製造・流通するようになった今日、日本国民の保健衛生・健康寿命の更なる向上を図るためには、我が国自らが努力することはもちろんのこと、他の国・地域の規制当局、企業、アカデミアと緊密に協力することが不可欠である。このように共通の課題に向けた国際的な協力関係の構築は、我が国のみならず世界の保健衛生の向上にも大きく貢献することになる。

このような状況の下、PMDA は、厚生労働省の国際薬事規制調和戦略（平成 27 年 6 月）も踏まえ、おおむね第 3 期・第 4 期中期計画期間中（2014 年度～2023 年度）に取り組むべき国際活動を以下のように定める。これに基づき、PMDA が有する科学的知見、人的資源、電子的情報等を最大限に有効活用しつつ、日本を含む世界共通の利益の最大化に向けて積極的に取り組んでいく。

ビジョン I：先駆的な取組みによる世界への貢献

レギュラトリーサイエンスに基づき、世界に先駆けた承認審査、安全対策の成果を世界に発信することにより、世界の人々の

PMDA International Strategic Plan 2015

June 26

The primary responsibility of the Pharmaceuticals and Medical Devices Agency (PMDA) is to provide a reliable regulatory environment that enables quicker access to more effective and safer medical products including pharmaceuticals, medical devices, and cellular and tissue-based products for the people of Japan. Regulatory science forms the basis of PMDA's activities. As the development, manufacture, and distribution of products are becoming increasingly globalized, PMDA must increase its efforts to cooperate closely with foreign regulatory authorities, as well as industry and academia, in order to meaningfully contribute to the health and healthy life expectancy of the people in Japan. Such collaboration to overcome common public health issues will greatly promote public health in Japan and globally.

In view of the abovementioned situation as well as the Regulatory Strategy Initiative set forth by the Ministry of Health, Labour and Welfare (MHLW) in June 2015, PMDA has established the following strategic plan on international activities that will be conducted in the period defined in the 3rd Mid-term Plans (FY 2014–2023). PMDA will strive to implement the strategy to maximize the health benefits to Japan and the world, by effecti

Vision I: To

Structure of the Strategic Plan

VISION 1:
To contribute to the world through regulatory innovation

VISION 2:
To maximize the common health benefits to other countries/regions

VISION 3:
To share the wisdom with other countries/regions

Vision I
To contribute to the world through regulatory innovation

Strategy 1:
Taking the lead, and disseminating the information around the globe

Roadmaps to implement Strategy 1

Taking the lead, and disseminating the information around the globe

	3rd Mid-term Plan				4th Mid-term Plan		
			In 3 yrs		In 5 yrs		
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	[illegible]	FY 2023
Regulatory Science Center	Preparation			Establish and operate Regulatory Science Center			
Product Review	Prepare and publicize guidelines and Points to Considers (Science Board, cross-product projects, designated projects, etc)						
	Strengthen trainings on data analysis		Conduct pilot for cross-product analysis		Begin full-scale use of cross-product analysis to establish guidelines		
	Intensify cooperation and periodical discussion with overseas regulatory authorities / disseminate information to overseas						
Post-Mkt Safety	Manage quality and upgrade MID-NET systems			Maintain MID-NET regularly (system upgrading as necessary)			
	Pilot pharmacoepidemiological analysis for safety evaluation			Full-scale utilization for safety evaluation			
	Plan 3rd party utilization process						
	Intensify cooperation and periodical discussion with overseas regulatory authorities / dissemination of information to overseas						

Regulatory Science Center

3rd Mid-term Plan				4th Mid-term Plan		
		In 3 yrs		In 5 yrs		
FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	~	FY 2023

Preparation

Establish and operate Regulatory Science Center

Regulatory Science Center

Regulatory Decisions & Safety/Efficacy Estimation on Next-Level Science

- New Guidelines
- Counsel on R&D based on cross-product analysis
- Risk Evaluation with Pharmaco-epidemiological ground

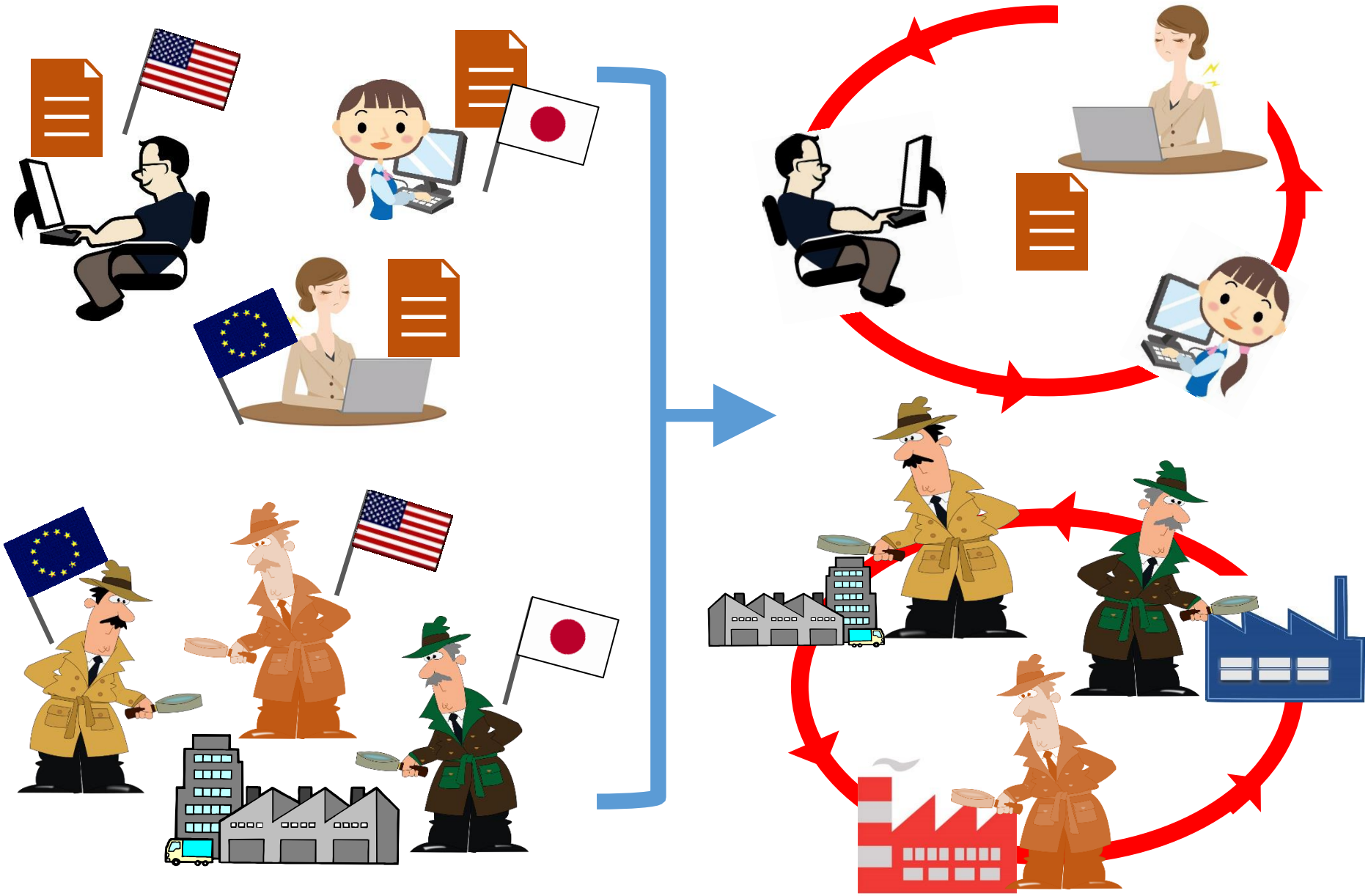
Vision II:
To maximize the common health benefits to other countries/regions

Strategy 2:
Promotion of international regulatory harmonization and **global cooperation**

Strategy 3:
Increase efficiency of **inspections** that may lead to future international **work-sharing**

Strategy 4:
Contribution to international regulatory **harmonization activities**

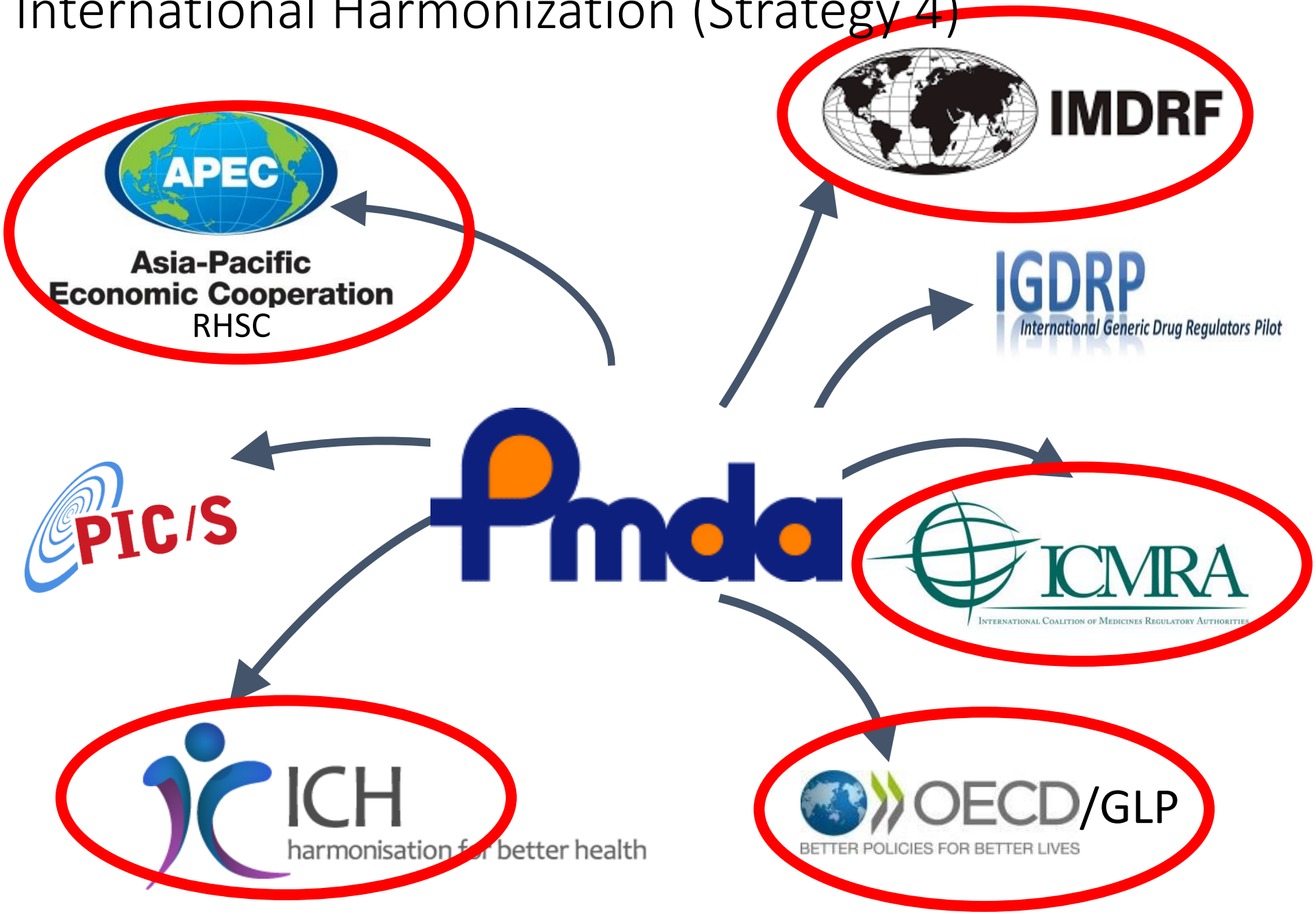
Work-sharing for efficiency (Strategy2, 3)



Roadmaps to implement Strategy 3

		3rd Mid-term Plan				4th Mid-term Plan		
				In 3 yrs		In 5 yrs		
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	~	FY 2023
Increase efficiency of inspections	GMP	Strengthen PIC/S activity						
		Conduct co-trainings and inspections with Asian Regulatory Authorities				Review report exchanges		
		Take steps towards MRA sign-offs						
	QMS					Review report exchanges		
		Promote up-skilling of inspections / conduct of co-inspections						
		Strengthen MDSAP activity						
	GLP		Actively lead OECD/GLP as a chair					
			Promote equalization of inspection skills within OECD					
	GCP			Plan a model for mutual use of US/EU/Japan inspection results			Set up a platform for GCP cooperation	
			Conduct workshops in emerging countries, and promote mutual acceptance of inspection results					

International Harmonization (Strategy 4)

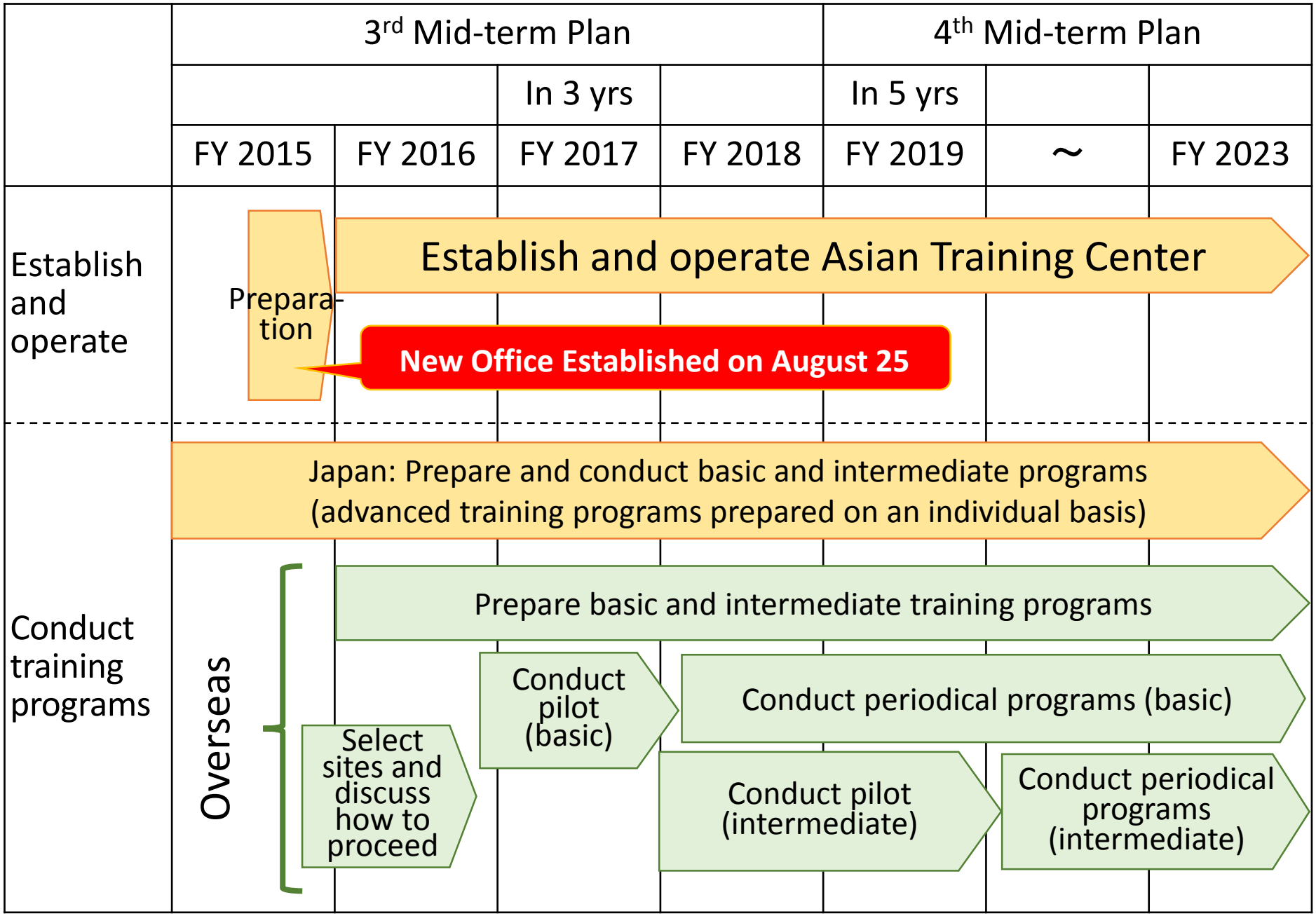


Vision III:
To share the wisdom with other countries/regions

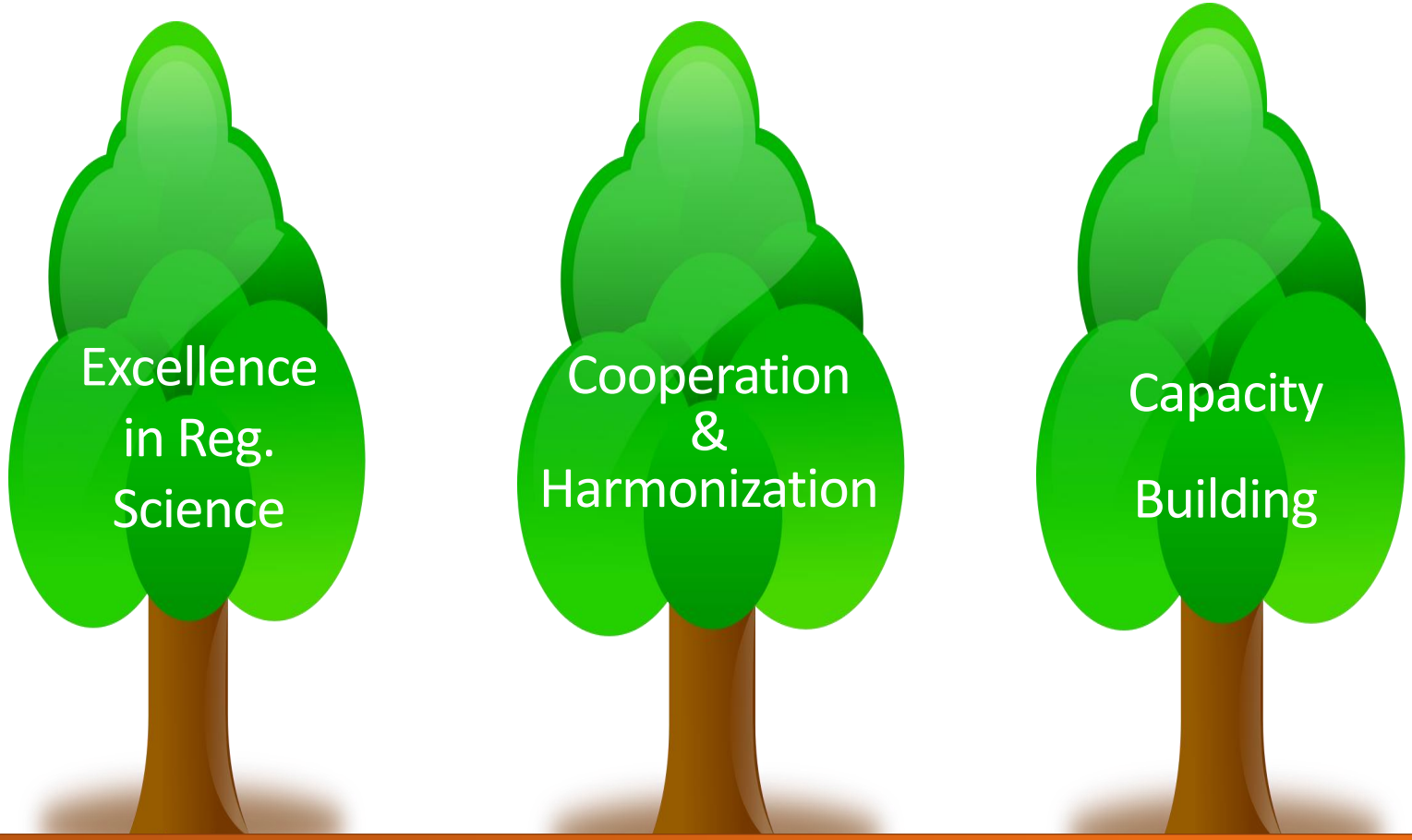
Strategy 5:
Provision of information and training programs that are essential for **building regulatory capacity** in partner countries

Roadmaps to implement Strategy 5

		3rd Mid-term Plan				4th Mid-term Plan		
				In 3 yrs		In 5 yrs		
		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	～	FY 2023
Asian Training Center	Establish and operate	Prepa-ration	Establish and operate Asian Training Center					
	Conduct training programs for pharmaceuticals and medical devices	Programs held in Japan: Prepare and conduct basic and intermediate training programs (advanced training programs prepared on an individual basis)						
			Program held in key ASEAN countries: Prepare basic and intermediate training programs					
			Overseas: Select sites and discuss how to proceed	Overseas: Conduct pilot (basic)	Overseas: Conduct periodical program (basic)			
					Overseas: Conduct pilot (intermediate)	Overseas: Conduct periodical programs (intermediate)		
Contribution to capacity building in Asia		Contribute to capacity building in Asia through activities such as APEC						
Provision of post-marketing safety information		Disseminate safety information in English, and respond to queries from Asia						


3rd Mid-term Plan
4th Mid-term Plan
In 3 yrs
In 5 yrs
FY 2015
FY 2016
FY 2017
FY 2018
FY 2019
～
FY 2023
Establish and operate
Establish and operate Asian Training Center
Prepara-tion
New Office Established on August 25
Conduct training programs
Japan: Prepare and conduct basic and intermediate programs
(advanced training programs prepared on an individual basis)
Overseas
Prepare basic and intermediate training programs
Select sites and discuss how to proceed
Conduct pilot (basic)
Conduct periodical programs (basic)
Conduct pilot (intermediate)
Conduct periodical programs (intermediate)

Asian Training Center



PMDA builds solid foundation for international operation

Excellence in Reg. Science
Cooperation & Harmoni-zation
Capacity Building
Fruitful International Activities

PMDA of the world, for the world.

Thank you for your attention!

Fruitful International Activities