June 26, 2015.

PMDA International Strategic Plan 2015

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 and 4th Mid-term Plans (FY 2014–2023). PMDA will strive to implement the strategic plan in order to maximize the health benefits to Japan and the world, by effectively utilizing its human resources, scientific knowledge, electronic information, and by other means.

Vision I: To contribute to the world through regulatory innovation
PMDA will, based on regulatory science, promote public health globally by communicating the outcomes of its first-in-the-world product reviews, safety measures, and relief services

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

1) Provide consultations, conduct product reviews, and implement safety measures that matches top global standards by utilizing innovative technology

   (1) Establish the "Regulatory Science Center," to provide consultations, conduct product review, and implement safety measures based on the latest science (within 3 years). In the Center, in close collaboration with relevant academics, societies and industry around the globe, activities such as identification of safety risks using electronic medical records, simulation and model building based on clinical trial data across products will be conducted.

   (2) Promote discussions between industry, government and academia, such as holding symposia that lead to clinical use of innovative technology (e.g. cellular and tissue-based products) and implementation of related safety measures.

2) Proactively publicize globally the knowledge and experience of PMDA as a regulatory authority that contributes to improvement of the health of the people in Japan by managing products throughout their lifecycles, from consultations and product review to implementation of post-approval safety measures and provision of relief services

(1) While considering the needs of society, consider preparing technical documents that summarize the current views of PMDA, by taking into account the discussion at the Science Board. Develop guidelines on product evaluation and safety measures that utilize innovative technology. Such information will be disseminated to the world.

(2) Proactively publish or present the outcomes of regulatory science research in key journals or conferences so that they can be utilized in other countries/regions.

Vision II: To maximize the common health benefits to other countries/regions
PMDA will, in order to realize quicker access to more effective and safer medical products for patients around the globe, communicate more closely with countries around the world to promote regulatory harmonization and collaboration

Strategy 2: Promotion of international regulatory harmonization and global cooperation

1) Expediting the global utilization of the Japanese Pharmacopoeia (JP)

(1) Further expedite harmonization of the JP, the United States Pharmacopoeia (USP) and the European Pharmacopoeia (EP) through the activities of the Pharmacopoeial Discussion Group (PDG)

(2) Contribute to improving quality of pharmaceuticals that are globally distributed, by proactively incorporating in the JP the concept of quality assurance based on cutting-edge science, and by promoting JP as one of the reference pharmacopoeia in other countries/regions

2) Strengthening the communication with overseas regulatory authorities

(1) Expand the range of collaborative activities between regulatory authorities in Japan and the United States (US), the European Union (EU), and other countries, such as the current exchange of information under the Confidential Arrangements and discussions based on expert area clusters, while deepening the partnership between the regulators, and proactively exchange information throughout the stages from product development to product review, to post-approval safety measures.

(2) For medical devices, continue information exchange with the U.S. FDA, by way of the Harmonization By Doing (HBD) activities and other measures. Take actions to enhance

mutual understanding with other foreign regulatory authorities in terms of product development and regulations.

(3) Develop robust evidence in cooperation with foreign regulatory authorities, especially for orphan designated products for which only limited information is generally available, to maximize the benefit and minimize the risk of a product.

(4) Continue the expanded personnel exchange program with foreign regulatory authorities. In addition, in line with the harmonization and collaboration status of each country, consider other measures to enhance mutual understanding such as the establishment of overseas offices.

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

1) Streamline international collaboration in GXP/QMS inspections

(1) GMP inspections: Contribute to preparation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidelines and conduct of training programs, and promote collaboration with foreign regulators as a member of the PIC/S, by exchanging information such as inspection reports to ensure the functional equality of the inspection skills among regulatory authorities. In addition, promote mutual use of the GMP inspection results with regulatory authorities that have signed the Mutual Recognition Agreement.

(2) QMS inspections: Become the formal member of MDSAP Pilot, contributing to streamlining of the process of QMS inspections by utilizing the results of inspections performed by certified 3rd party organizations. In addition, promote global collaboration on the oversight of certified organizations by contributing to preparation of MDSAP guidelines, etc. In addition, promote actions to ensure functional equality of the inspection skills among regulatory authorities.

(3) GCP inspections: Establish a communication channel which allows for open discussion between the US, EU, Japan, and other countries on the mutual utilization of the GCP inspection results. Enhance collaboration with foreign regulatory authorities by actively exchanging information such as utilization of electronic data.

Strategy 4: Contribution to international regulatory harmonization activities

1) Proactively propose to create guidelines, etc. leading to common health benefit

(1) ICH: As a founding country of the ICH, continuously make efforts to propose and draft harmonized guidelines that are needed by participating countries, even after the establishment of a new organization that is scheduled to occur in 2016.

(2) IMDRF: Lead the establishment of the mid-term strategy for activities up to 2020, and endeavor to propose and draft harmonized guidelines that are needed by participating

countries.

(3) IGDRP: Promote the consistency of regulations set forth for generic drugs in Japan with international regulations, and seek to make proposals for international harmonization.

(4) OECD/GLP: Actively lead the initiative as a chair, to strive to enhance the scope and up-skilling of participating countries, and promote an increase in the number of participating countries.

(5) ICMRA: Promote activities for the formal inauguration of ICMRA, and through partnering with executives of foreign regulatory authorities, contribute to up-skilling of the regulators and effective harmonization of multi-lateral meetings.

(6) APEC LSIF RHSC: Promote regulatory harmonization and the establishment of training programs for regulators within the APEC region by activating all the projects as the co-chair.

(7) ISO/IEC: Actively participate in the development of international standards by proposing new topics to standard developing bodies such as ISO and IEC, so that such standards reflect the ideas from Japan, which may result in rationalized/expedited review.

(8) ICCR: Contribute to the harmonization of cosmetics regulations from the technical perspective.

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

PMDA will, by fully utilizing the accumulated knowledge and experience, contribute to the public health of partner countries/regions through provision of information and training that are essential for building regulatory capacity in those countries

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

1) Launch of "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs" and other programs

(1) Establish the "Asian Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs" that design training programs for regulators in Asia in response to the demand of Asian regulatory authorities or industry. The training will be provided continuously in key ASEAN countries or in Japan (within 3 years).

(2) Dispatch PMDA staff members to partner regulatory authorities and conduct on-the-job training that is needed by the partner country.

(3) Conduct training on guidelines agreed at ICH, IMDRF, IGDRP, ICCR, PIC/S, etc., and other knowledge and information needed in Asian countries and BRICs.

2) Interact with Asian and other countries to enhance mutual understanding and cooperation

(1) Deepen mutual understanding and trust of key ASEAN countries, China/Korea, BRICs, and other countries through bilateral meetings and symposia.
(2) Contribute to the improvement of safety measures in the Asian region, by providing Japan's safety information and responding to the diverse needs of partner countries.
(3) Collaborate in the areas of consultations and reviews to promote smooth product development in the Asian region.
(4) Enhance international regulatory harmonization and cooperation for over-the-counter (OTC) drugs by proactively participating in Self-CARER.

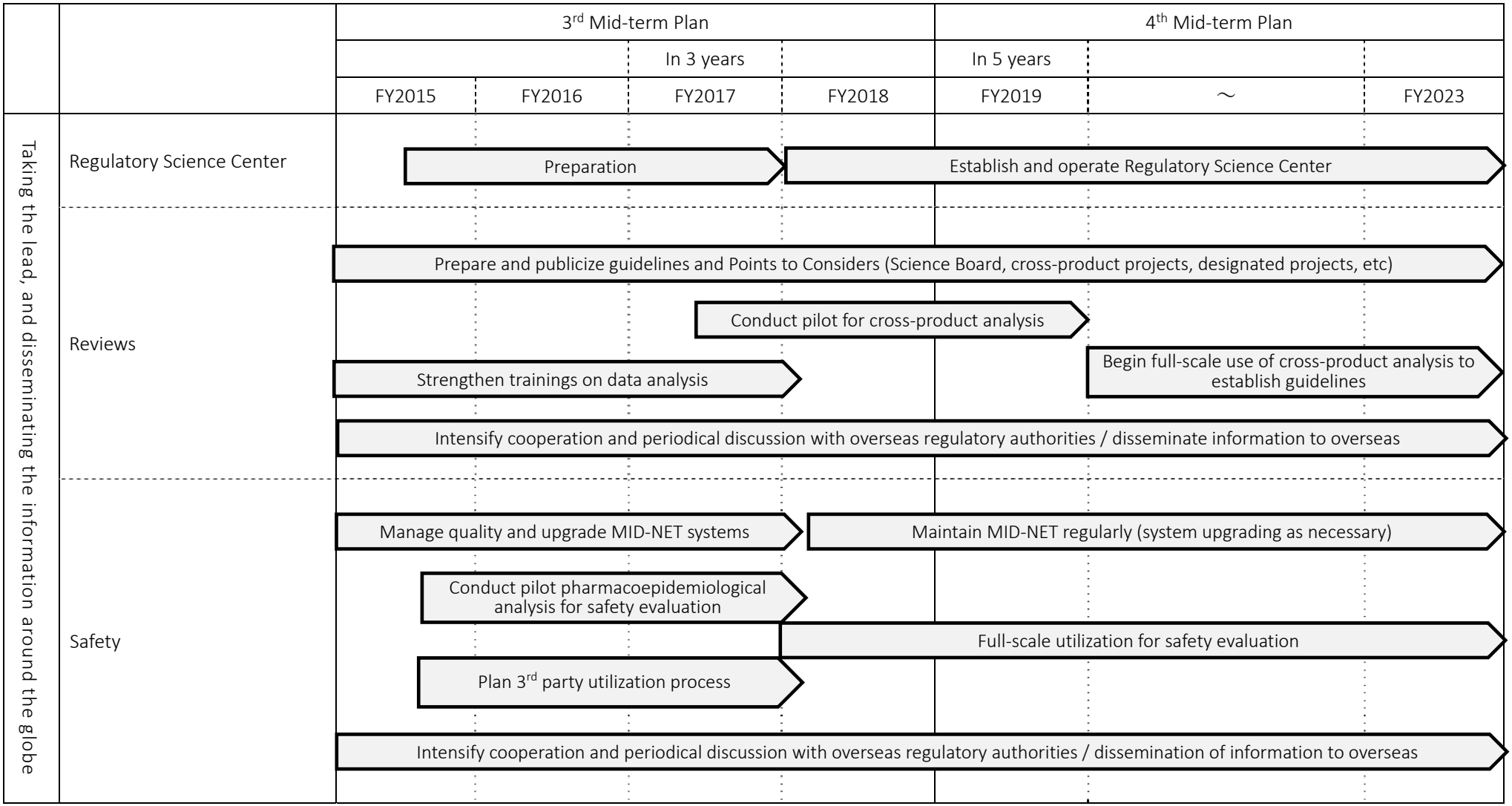
Creating a solid foundation for international operations in order to achieve the above vision

In order to implement the above International Strategic Plan, PMDA will strive to place emphasis on cultivation of human resources, and strengthening of translation work, information dissemination, and information analysis.

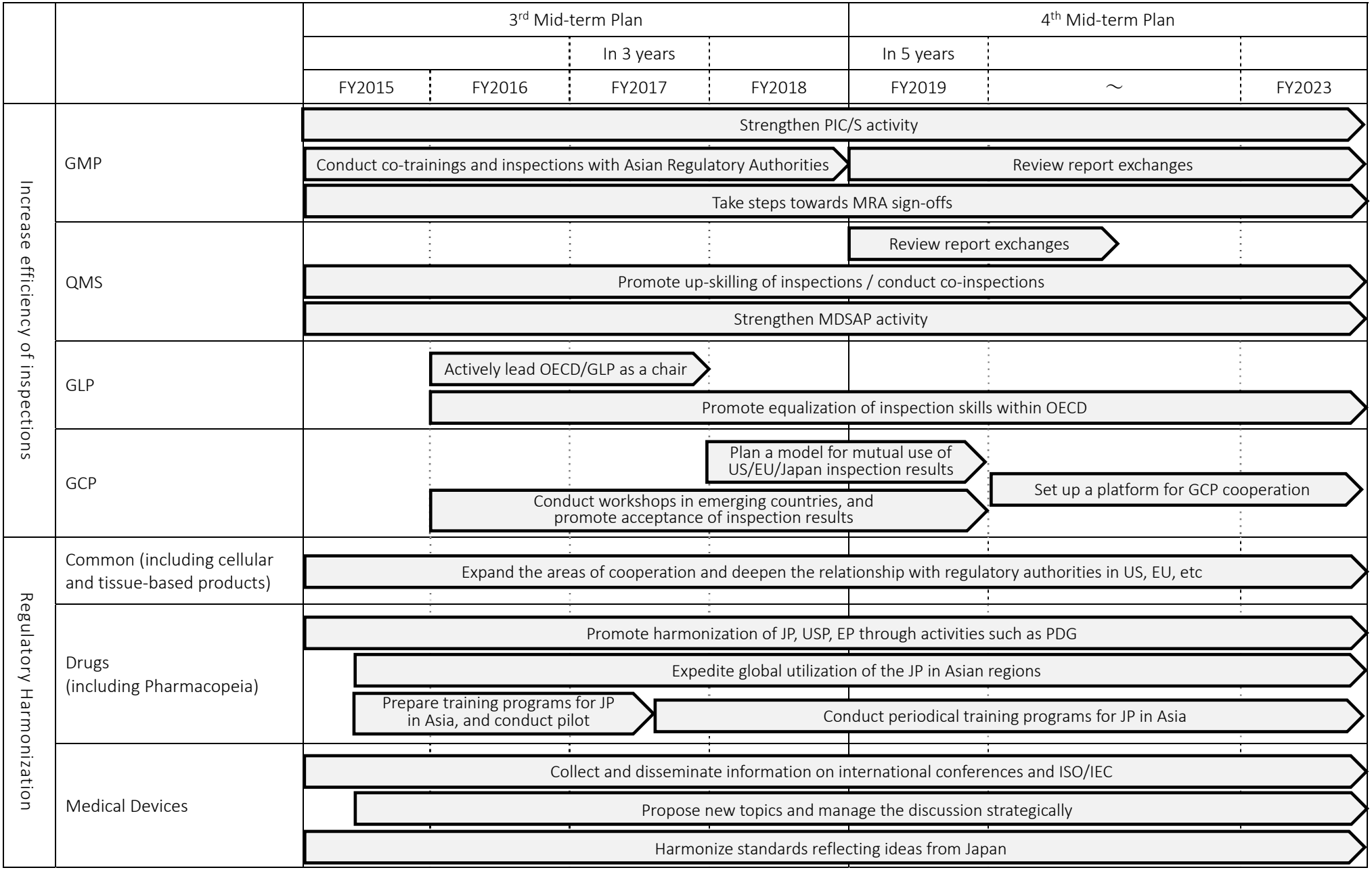
Progress management based on the Roadmap

The Roadmap to achieve the key strategy in each Vision has been set forth as attached.
It should be noted that roadmaps for multi-lateral activities have not been prepared since they should be formulated within each activity by the participants, and not solely by PMDA.

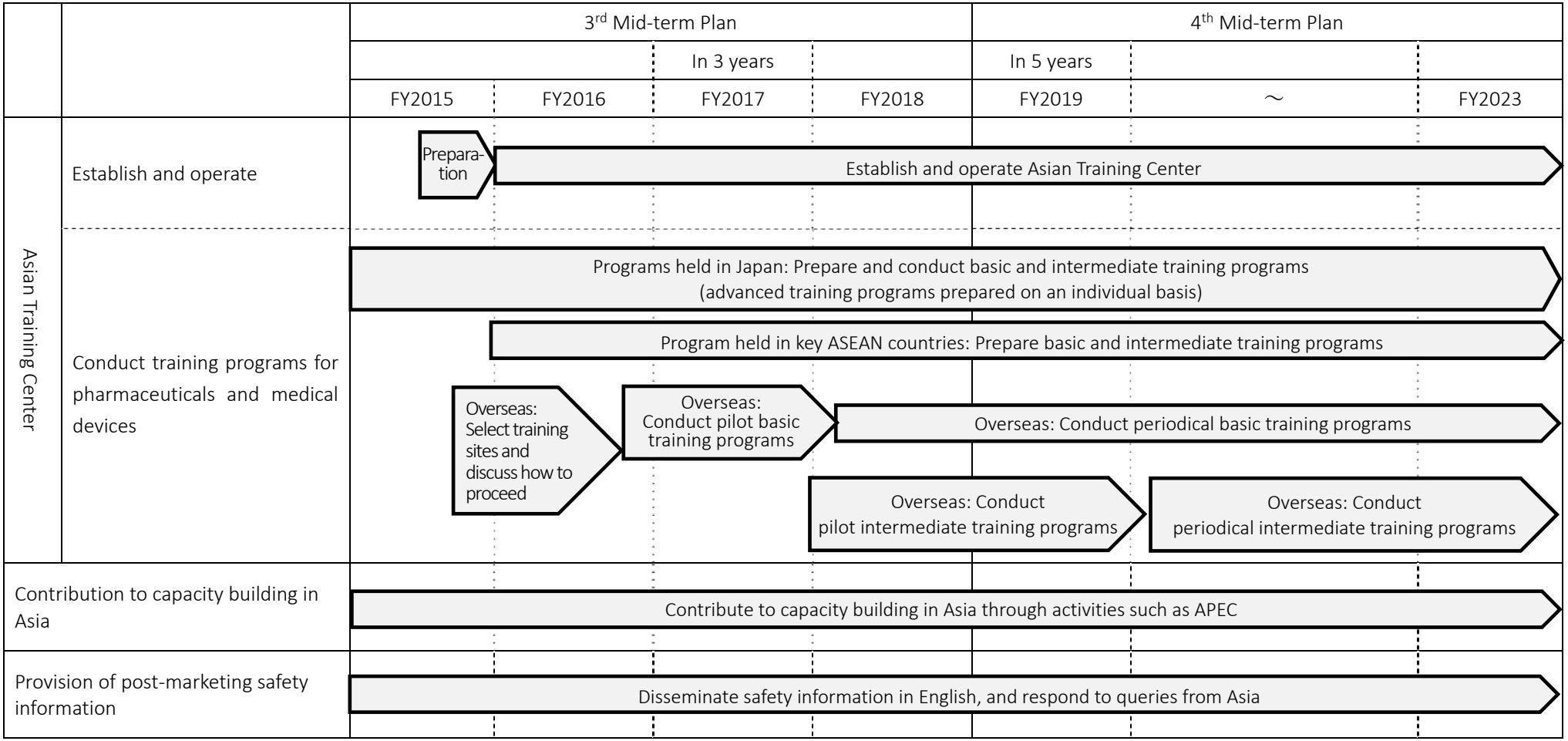
1. Key strategies under Vision I <To contribute to the world through regulatory innovation>



2. Key strategies under Vision II <To maximize the common health benefits to other countries/regions>



3. Key strategies under Vision III <To share the wisdom with other countries/regions>



Abbreviation	Explanation
APEC LSIF RHSC	Asia-Pacific Economic Cooperation Life Sciences Innovation Forum Regulatory Harmonization Steering Committee A committee that discusses regional convergence on regulatory approval procedures for medical products
ASEAN	Association of Southeast Asian Nations
BRICs	Brazil, Russia, India, and China
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GXP	Good XXX Practice (abbreviation consolidating GCP, GLP, GMP, etc.)
HBD	Harmonization by Doing By doing effort for medical device regulatory harmonization among academia, industry and regulators of the US and Japan
ICCR	International Cooperation on Cosmetics Regulation A voluntary international group of cosmetics regulatory authorities with the aims of global consumer protection and minimization of international trade barriers
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use A conference consisting mainly of the regulatory authorities and the pharmaceutical trade associations from the US/EU/Japan, intending to promote harmonization in the requirements for product registration
ICMRA	International Coalition of Medicines Regulatory Authorities A voluntary organization of regulators' executives for providing strategic coordination and leadership
IEC	International Electrotechnical Commission An organization for preparing and publishing International Standards for all electrical, electronic and related technologies
IGDRP	International Generic Drug Regulators Program A program to promote collaboration and convergence of generic drug regulators
IMDRF	International Medical Device Regulators Forum A forum consisting of medical device regulators to accelerate international medical device regulatory harmonization and convergence
ISO	International Organization for Standardization An independent, non-governmental membership organization that develops international standards
MDSAP	Medical Device Single Audit Program A QMS audit program conducted by an recognized auditing organization to satisfy the needs of multiple regulatory jurisdictions in a single audit
OECD	Organization for Economic Co-operation and Development
PDG	Pharmacopoeial Discussion Group A group working on pharmacopoeial harmonization (JP/USP/EP) of general chapters and excipient monographs
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme A group for providing an active and constructive co-operation in the field of GMP and mutual training of GMP inspectors
QMS	Quality Management System
Self-CARER	Self-Medication Collaborative ASIAN Regulator Expert Roundtable A forum designed to promote collaboration within Asian OTC pharmaceutical regulator experts
U.S. FDA	United States Food and Drug Administration