Preparation for PIC/S accession Challenges and Prospects

April 13, 2012 (Friday)

Pharmaceuticals and Medical Devices Agency
(PMDA)
Office of GMP/QMS Inspection
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PIC/S加盟の必要性

Why is PIC/S accession necessary?

1．使用者の保護（国民の安心・安全の確保）

Due regard to public health

2．リソースの有効活用

Utilization of resources

3．日本の製薬業界の地位確保・サポート

Secure the position of Japanese pharmaceutical Products

GMP調査体制
GMP Inspection System

厚生労働省医薬食品局
Pharmaceutical and Food Safety Bureau, MHLW
（manufacturing license, marketing license, marketing authorization, administrative order, pharmacovigilance, license withdrawal, seizure, penalty, etc.）

control over inspectorates, ultimate responsibility

PMDA is partially vested with authority of MHLW(assessment , GMP inspection, information gathering)

Prefectures are vested with part of MHLW's authority to have local autonomy.

医薬品医療機器総合機構
PMDA

Inspectorate

47都道府県
Prefectures

47 Inspectorates

PMDAと都道府県の比較

PMDA and Prefectures

●Inspection areas

460 Sites

		Domestic sites	Foreign sites
Drugs	New drugs, Biologics Radiopharmaceuticals, etc.	PMDA	PMDA
	Other drugs	Prefectures	PMDA

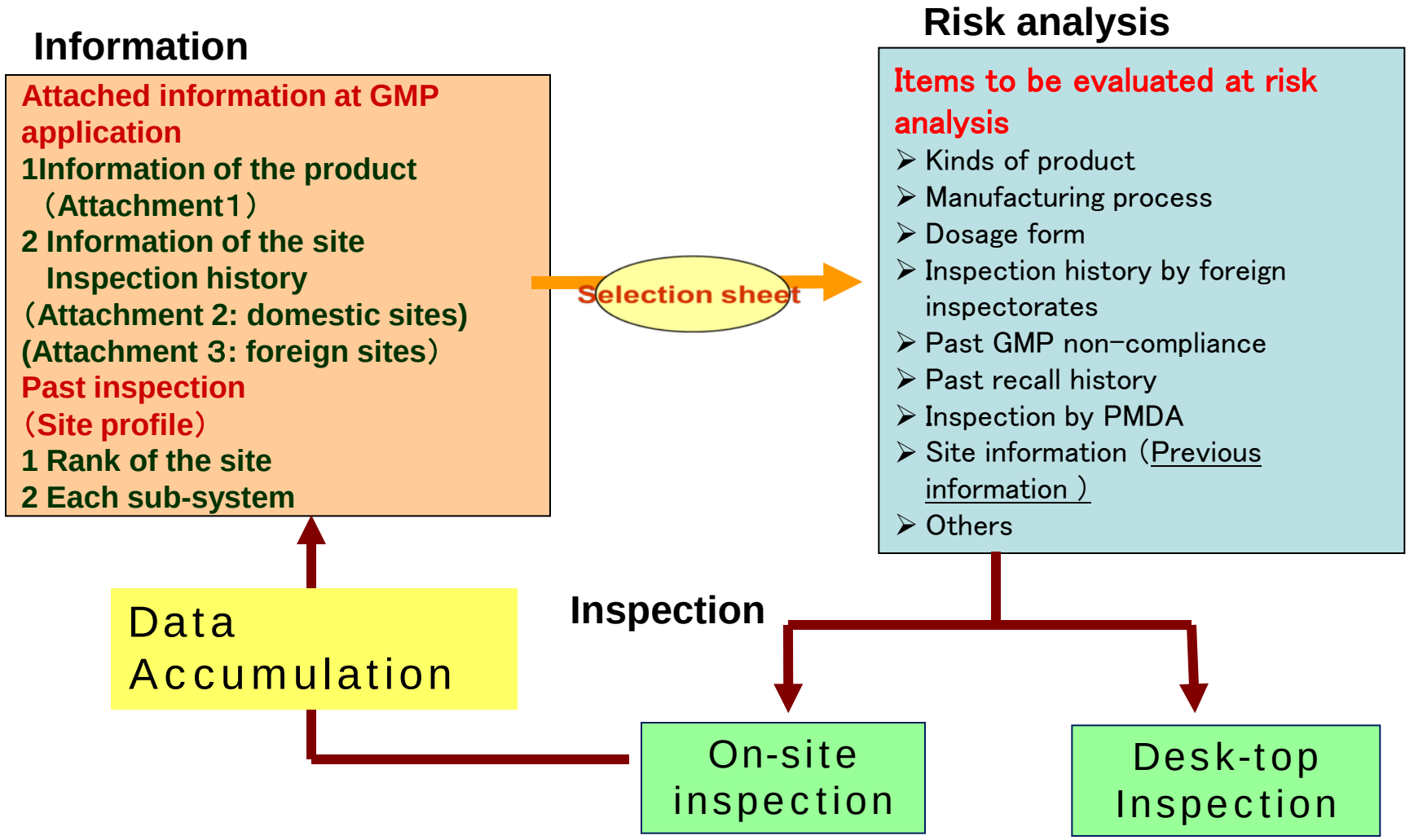
2000 Sites

●Number of GMP inspectors

	Mainly GMP	Mainly other operations
Prefectures	116	271
PMDA	24	2

As of December, 2011

PMDA:
Risk-based approach in selecting on-site inspection or desk-top inspection



GMPの国際整合化に向けての体制
Global Harmonization of GMP

Director-general, Pharmaceuticals and Food Safety Bureau of MHLW

GMP調査体制強化検討会
GMP Inspection System Review Committee
(Established in August, 2010)

●課題の抽出
To find issues to be attended

Study group for harmonization of GMP inspection method
(2009～2011)

●GMP調査機関の連携
Enhance cooperation among inspectorates

GMP Inspectorate Committee
(Established in July 2011)

Continue its activities

●GMPガイドラインの整合性
Harmonization of GMP Guidelines

Comparison and analysis of guidelines
(2010~2011)

Study group for harmonization of GMP guidelines on pharmaceuticals and excipients (2011~)

国際整合化に向けての課題
Issues to be attended

1．GMP調査当局（PMDAと都道府県の品質システムの整備

Improvement of quality system at GMP inspectorates and enhance cooperation

2．個々のGMP調査員の質の確保

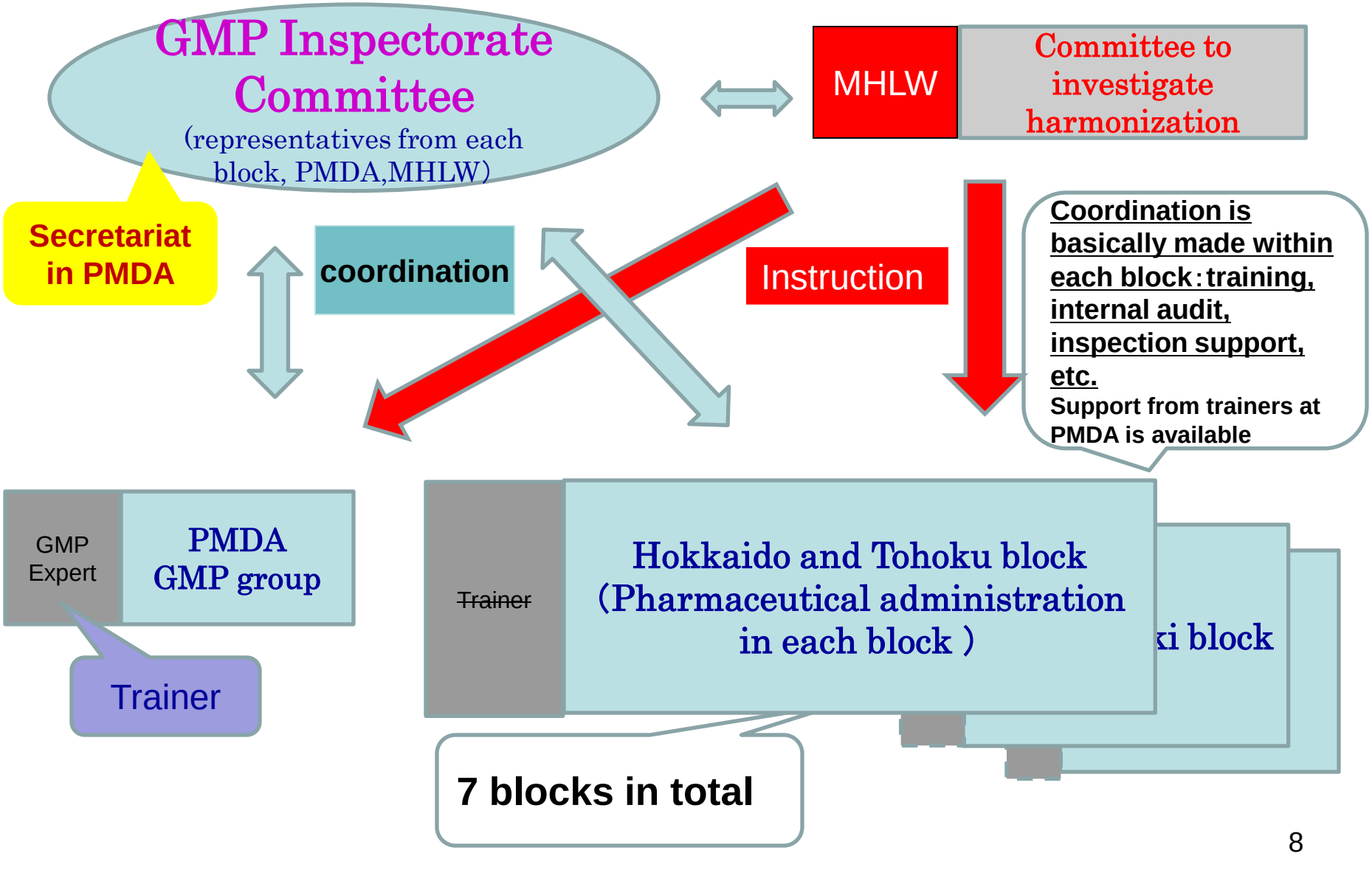
Ensure qualification of each inspector

3．国内GMP関連規制とPIC/S　GMPガイドの同等性確保

Ensure equivalence between Japanese GMP related regulations and PIC/S GMP Guide

GMP調査当局会議

Establishment of GMP Inspectorate Committee



GMP調査当局会議の活動
Activities of GMP Inspectorate Committee

1．品質システムの共通化
Common quality system among inspectorates（Revision of SOP, Internal audit, etc.）

2．GMPガイドラインの継続的なアップデート
Continuous updates on GMP Guidelines

3．継続的なトレーニングの立案、教育資料提供
Development of training plan, sharing of the training materials

4．国際整合性に関する情報入手と提供
Information acquisition and information sharing on global harmonization

5．全体会議の開催と密接な連携・情報交換
Holding of meeting among all the blocks for communication and information exchange

6．指導内容に係る調査権者と業界双方の受付と解決
Consultation for inspectorates and industries

調査要領の改訂
Recent revision of the Inspection Manual

・調査要領の改訂

Revision of Inspection Manual
(Notification from the director of Compliance and Narcotics Division, Pharmaceuticals and Food Safety Bureau, MHLW February16, 2012)

48調査権者の一体化と調査の質向上を目的

To improve quality of GMP inspection in Japan by 48 inspectorates

＜主な改訂点　Major revision points＞

・品質マニュアルの制定

Establishment of Quality Manual to create common quality system at each inspectorate

・調査員の資格要件

Establishment of qualification of inspectors to ensure inspection quality

・GMP調査当局会議の設立

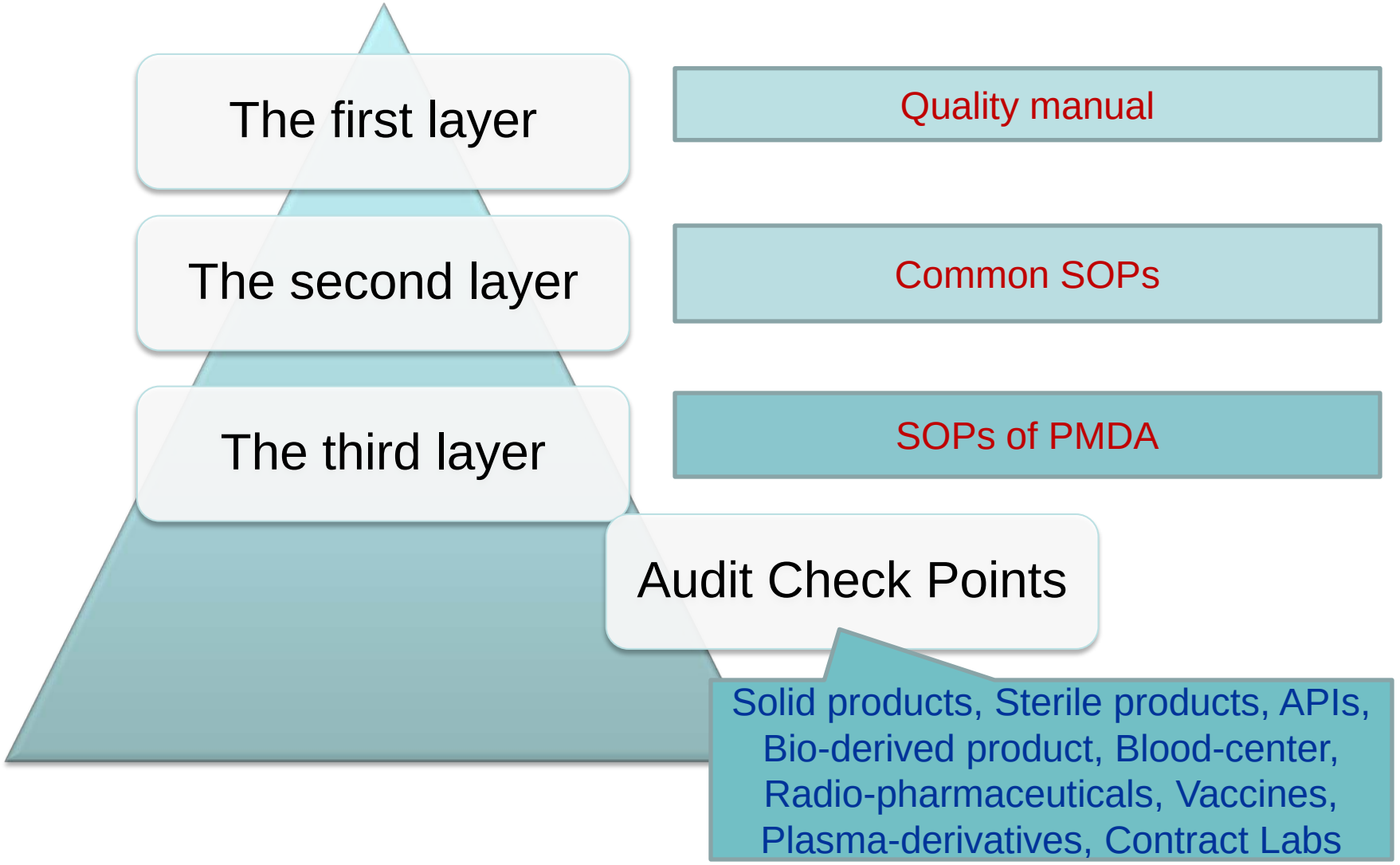
"GMP Inspectorate Committee" to be established for the maintenance of quality management system at each inspectorate and facilitation of communication among inspectorates

・公的試験検査機関の認定要件の規定

Qualification of official medicines control laboratory for the analysis of samples

PMDAの品質マネジメントシステム

Quality management system



進めている当局間の連携
Enhanced cooperation of inspectorates

◆ 国内の４８調査権者間　Cooperation among 48 inspectorates

〇当局会議の開催（年3-4回）

GMP Inspectorate Committee meeting (3-4 times a year)

〇情報交換（教育資料、手順書等）

Information Sharing (Training tool, SOPs etc.)

〇模擬査察、自己点検の実施

Mock inspection by each block, Internal Audit, etc.

◆グローバルな連携　Cooperation with other countries

〇EudraGMPの設置

Establishment of link with EudraGMP

Training • Training • Training

Training program scheduled in this year

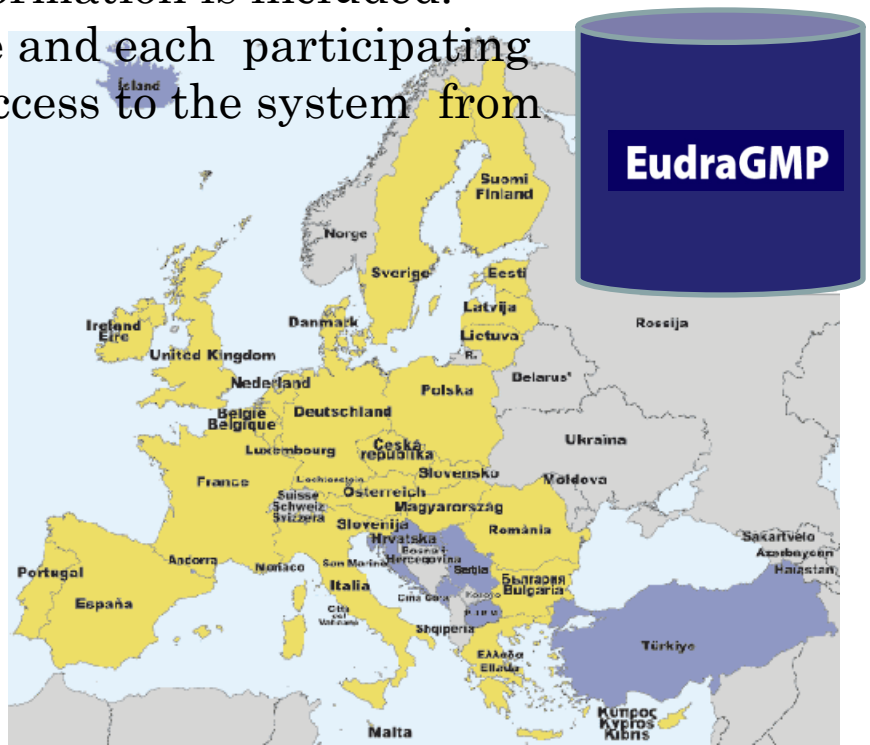
- Training program within each block
- Mock inspection within each block (several times/ year in each block)
- Mock inspection sponsored by MHLW
- Training by NIPH ※ (in Wako City)
- Training by PMDA（3days x 4 times/year, open to prefecture inspectors）
- On the job training ※※ (PMDA:2 months × 2 times)

※NIPH: National Institute of Public Health

※ ※Training of manufacturing control and QC at a manufacturing site.

Link with EudraGMP

・GMP related community database in EU
・100 NCAs(National Competent Authority) in EU countries (27 countries) and MRA partners with EU (8 countries) participated
・In put items:「GMP Compliance (manufacturing sites for which GMP certificate are issued)」、
and「Manufacturing & Importation Authorization (corresponding to drug manufacturing license in Japan)」
・Information of manufacturing sites outside EU is included including US, India, China, and Japan. Non compliance information is included.
・Host computer is located in EMA main office and each participating authority connected through EudraNet can access to the system from their terminal



Situation of attendance to the PIC/S meetings

Outline of the situation of past two years (open circle indicate plan)

●26－28 May, 2010　PIC/S Expert Circle on APIs 3rd meeting (Ireland)
●9 September, 2010　PIC/S Expert Circle on Quality Risk Management (Poland)
●28 September－1 October, 2010　PIC/S Expert Circle on Human Blood, Tissue and cells　(France)
●10－12 November, 2010　PIC/S Annual Seminar (Malaysia)
●31May －1 June, 2011　PIC/S 40th anniversary (Swiss)
●26－30 September, 2011　PIC/S Expert Circle on Human Blood, Tissue and cells (Estonia)
●12－14 October, 2011　PIC/S Expert Circle on API(Singapore)
●9－11 November, 2011　PIC/S Annual Seminar (South Africa)
○7－8 May, 2012 PIC/S Committee , 9－10 PDA-PIC/S Workshop（Swiss)
○17－19 September, 2012　PIC/S Expert Circle on API(US-FDA)
○1－2 October, 2012　PIC/S Committee ,3－5　PIC/S Seminar (Kyiv)
○15－19 October 2012　PIC/S Expert Circle on Human Blood, Tissue and cells (Singapore)

Application to PIC/S by Japan

- Application letter, Questionair, Audit Check List and 12 supporting documents were sent to PIC/S secretariat on March 9, 2012
- The secretariat informed this to all the participating countries on the same day.
- Rapporteur will be appointed during the PIC/S committee meeting on 7-8 May, 2012, and assessment for accession will be started.