Overview of Inspection Process

Office of Manufacturing Quality for Drugs
Pharmaceuticals and Medical Devices Agency

GMP Inspection System

Pharmaceutical Safety and Environmental Health 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.

PMDA

Inspectorate

Prefectures

47 Inspectorates

Area of responsibility
PMDA and prefectural government

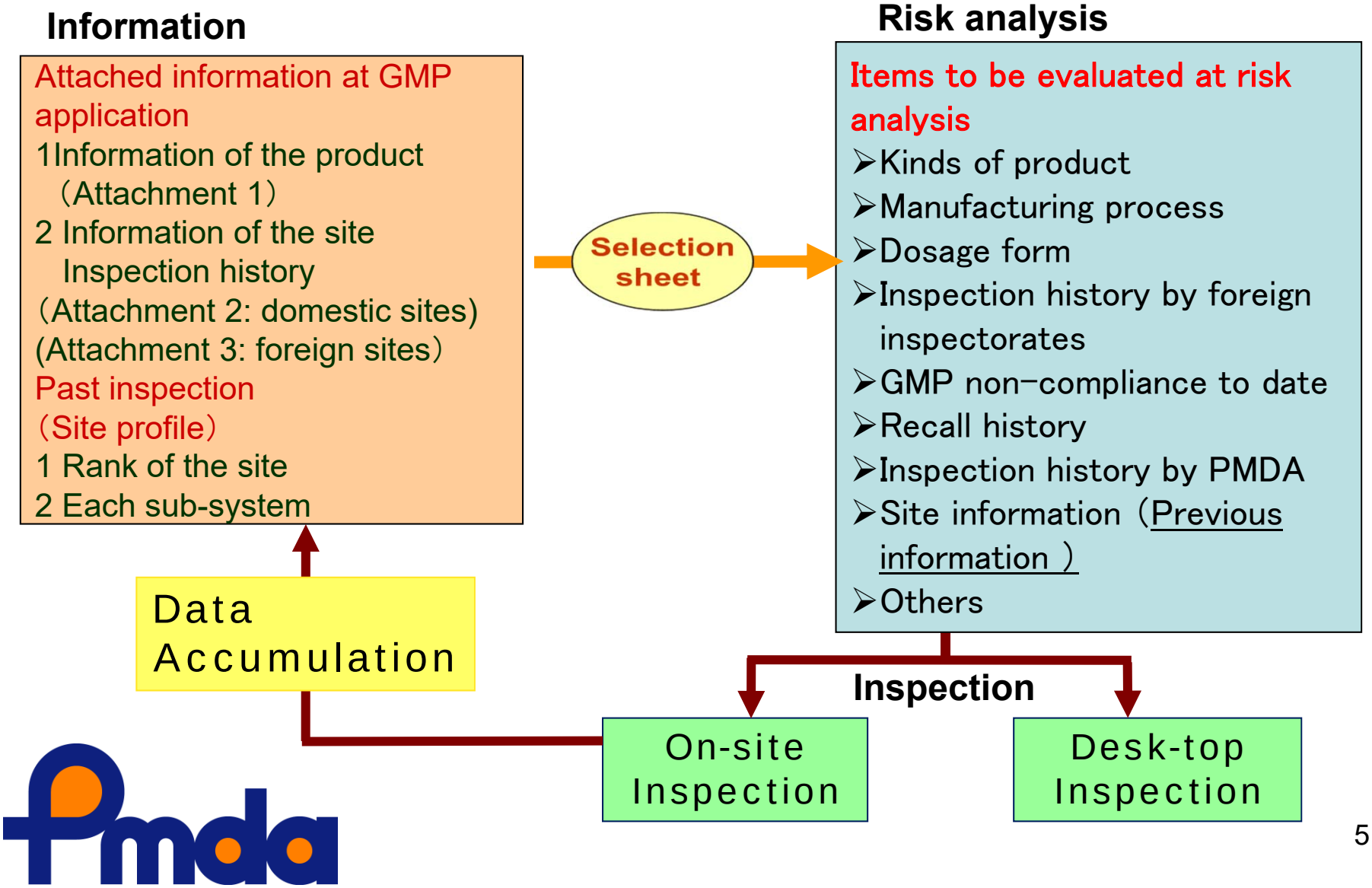
	Domestic Site	Foreign Site
New Drugs, Biological Products, Radio Pharmaceuticals, Regenerative medicinal products	PMDA	PMDA
Other Drugs	Pref. Gov.	PMDA

On-site inspection vs. desk-top inspection

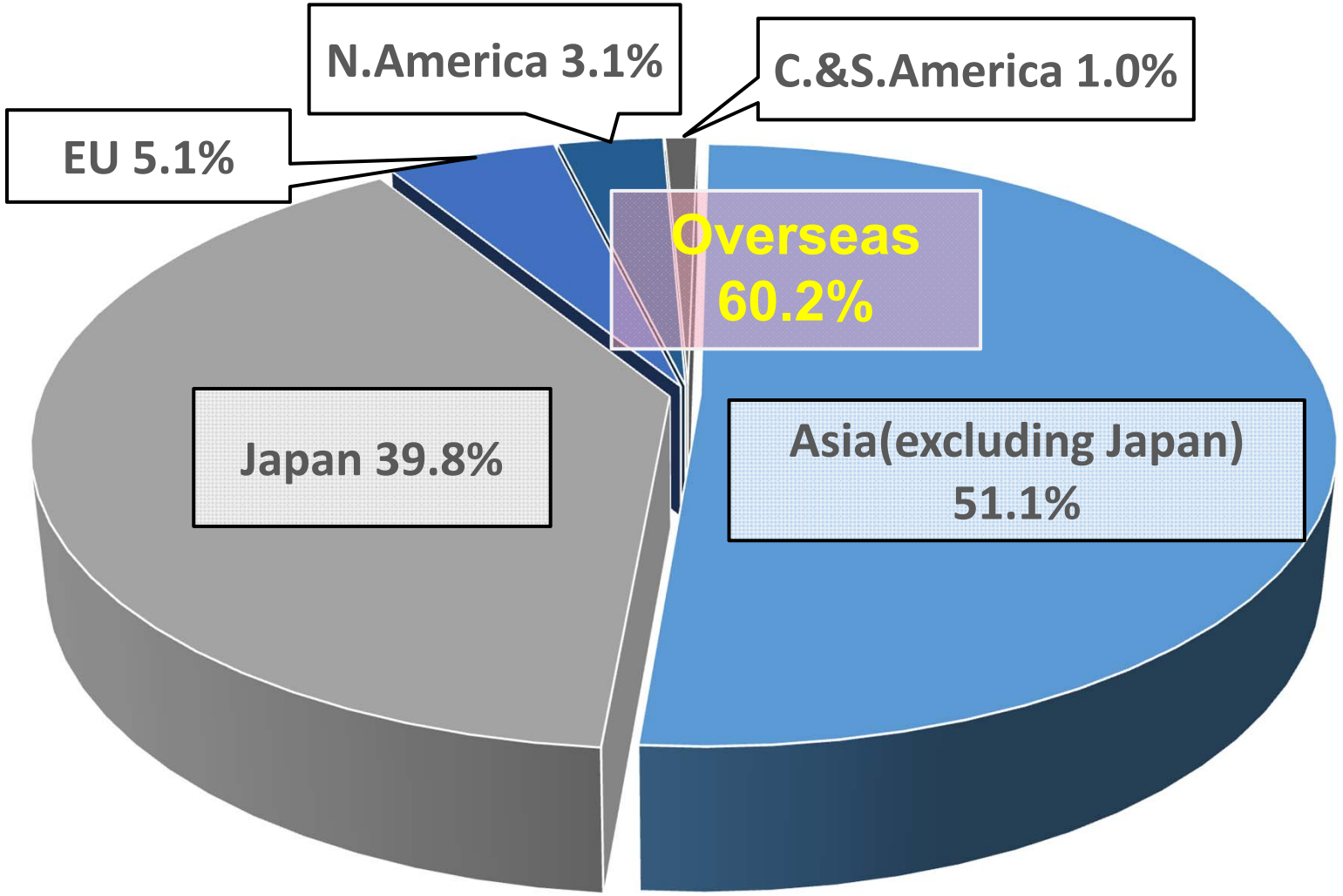
Due to limited resources, desk-top inspections are carried out for low risk products or sites.

A decision of “on-site” or “desk-top” is made for each of the Application for GMP Inspection through the risk assessment process.

PMDA's Risk-based Approach in Selecting "on-site" or "desk-top" Inspection

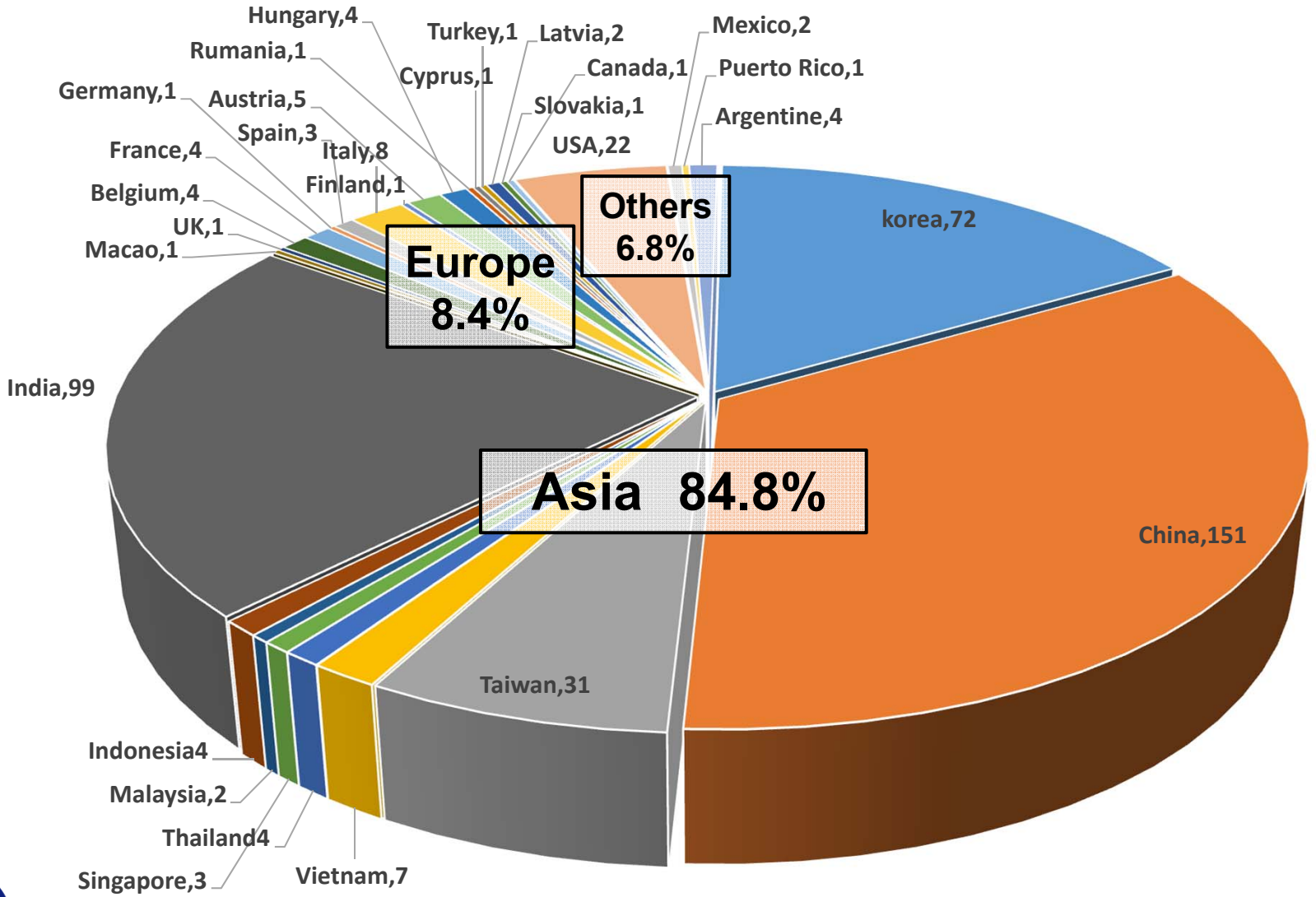


On-site GMP inspections by PMDA



(Sum of Apr. 2014–Mar. 2019)

Overseas on-site GMP inspections by PMDA



(Sum of Apr.2014-Mar.2019)

How to perform on-site inspection to overseas sites?

- Method is the same as domestic site inspection
- Two inspectors attended per inspection in general
- Accompanied by interpreters
- Duration : 3 to 4 days
- Notice: 3 – 6 weeks before the inspection
- Submission of data/ information (see slide 5) required prior to the inspection
- The inspection focuses on the points which are determined beforehand via discussions among inspectors with submitted data/ information.

Overview of on-site inspections by PMDA

PMDA internal assessment data: Rating manufacturing sites

Based on results of on-site inspection (assessment), manufacturing sites are rated as S, A, B, C, or D (Degrees and numbers of defects, and assessment by sub-system are totaled for overall rating).

D : Manufacturers in non-compliance with GMP

C : Manufacturers in compliance with GMP but need to be given continuous instructions

Main area	Number of on-site inspections Apr. 2014–Mar. 2019	Grade of manufacturing site		Total	% of C and D
		C	D		
Asia (excluding Japan)	374	108	7	115	31%
EU	37	5	0	5	14%
North America	7	1	0	1	14%
Central and South America	23	5	0	5	22%
Japan	291	103	4	107	37%

Grade of each S, A, B or C is *"in compliance"*.

- The percentage of sites rated C and D is higher in Asia (excluding Japan).