

Post market surveillance/vigilance in Japan -Industry perspective-



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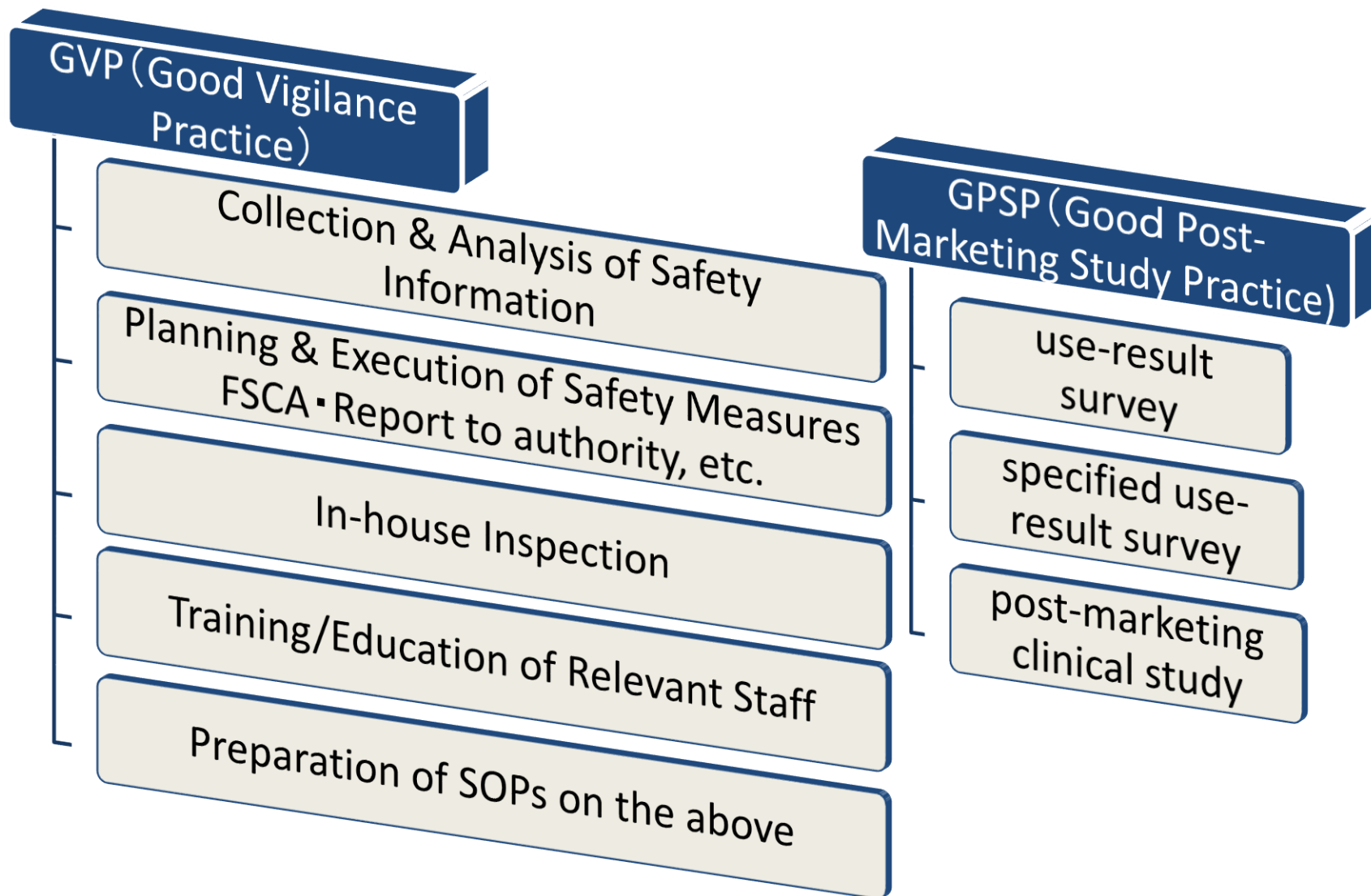
28 August, 2018

Disclaimers

- *Translation note*
 - *English and Japanese are not a perfect match*
- *The contents of this presentation represent the view of the speaker and do not necessarily represent the policies of the affiliation of the speaker*



Overview of PMS

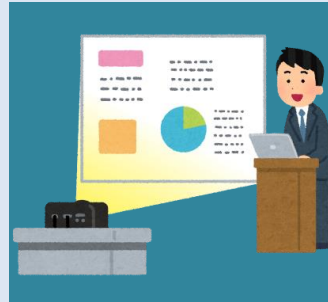


Collection of safety Information

Health Professional/
Medical institution



Academic society/
Literature/ Study



Government institution



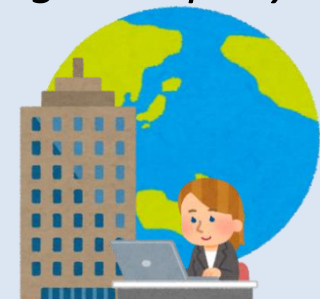
Other MAH, company



MAH



Foreign government/
Foreign company



Others



What information is necessary?

1. Medical Device Information

- ① Brand Name
- ② Device Identification Number
- ③ Usage of Device (Initial Use, the number of uses, beginning date of use)
- ④ Maintenance Condition if there is any problem with the medical device/ equipment.

2. Product Problem Information

- ① Date of Incident
- ② Reporter's Awareness Date
- ③ Details of Incident
- ④ Concomitant Medical Products (Including Pharmaceuticals)

3. Patient Information

- ① Initials, Age, Sex, Weight, Outcome
- ② Health damage, Patient's condition at the incident
- ③ Medical treatment after the incident

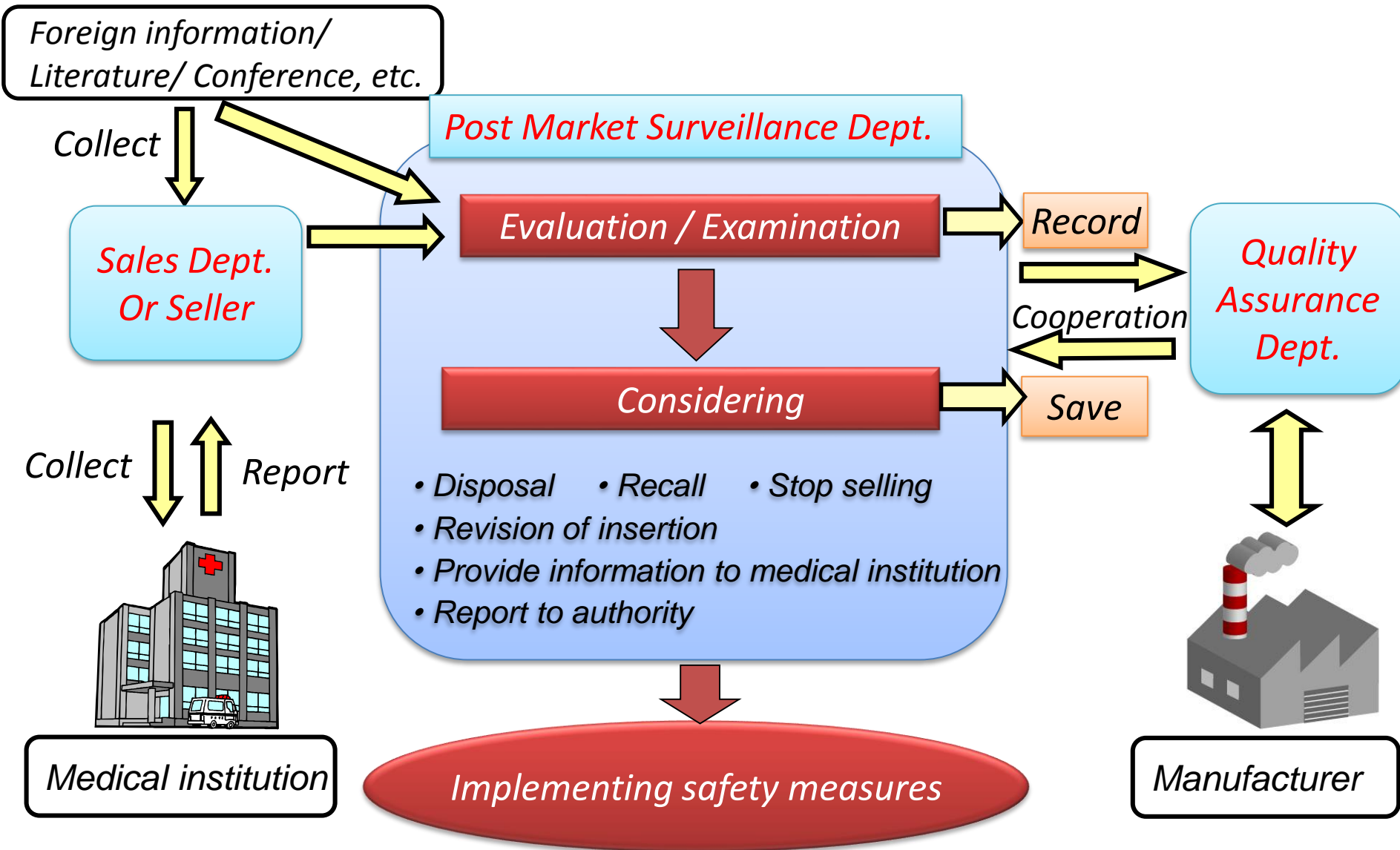
4. Detailed adverse event

- ① Operation/ usage status when it occurred.
- ② Whether the operator checked the package inserts/ manuals or not.
- ③ Whether the operator complied with the package inserts/ manuals or not.
- ④ Whether the operator checked and complied with other safety information or not.
- ⑤ Was the intended use appropriate? Was the device within the expiration date?
- ⑥ If it is a controlled medical device requiring special maintenance, were daily inspection and maintenance appropriate?

Prompt and accurate information collecting is required !



Implementation of safety measures



Report to Authority

- ✓ **Adverse event report**

Case report on adverse event in domestic cases and foreign cases related to medical devices.

- ✓ **Infectious disease report**

Case report on infections caused by use of biological products.

Report to Authority

✓ **Report of FSCA outside JAPAN**

*Report on FSCA of the device and foreign medical device**

✓ **Research Report**

Information from academic meeting and journals both domestic and foreign that shows serious adverse events or deaths may occur or occurrence trends have changed markedly by using the device is subject to report .

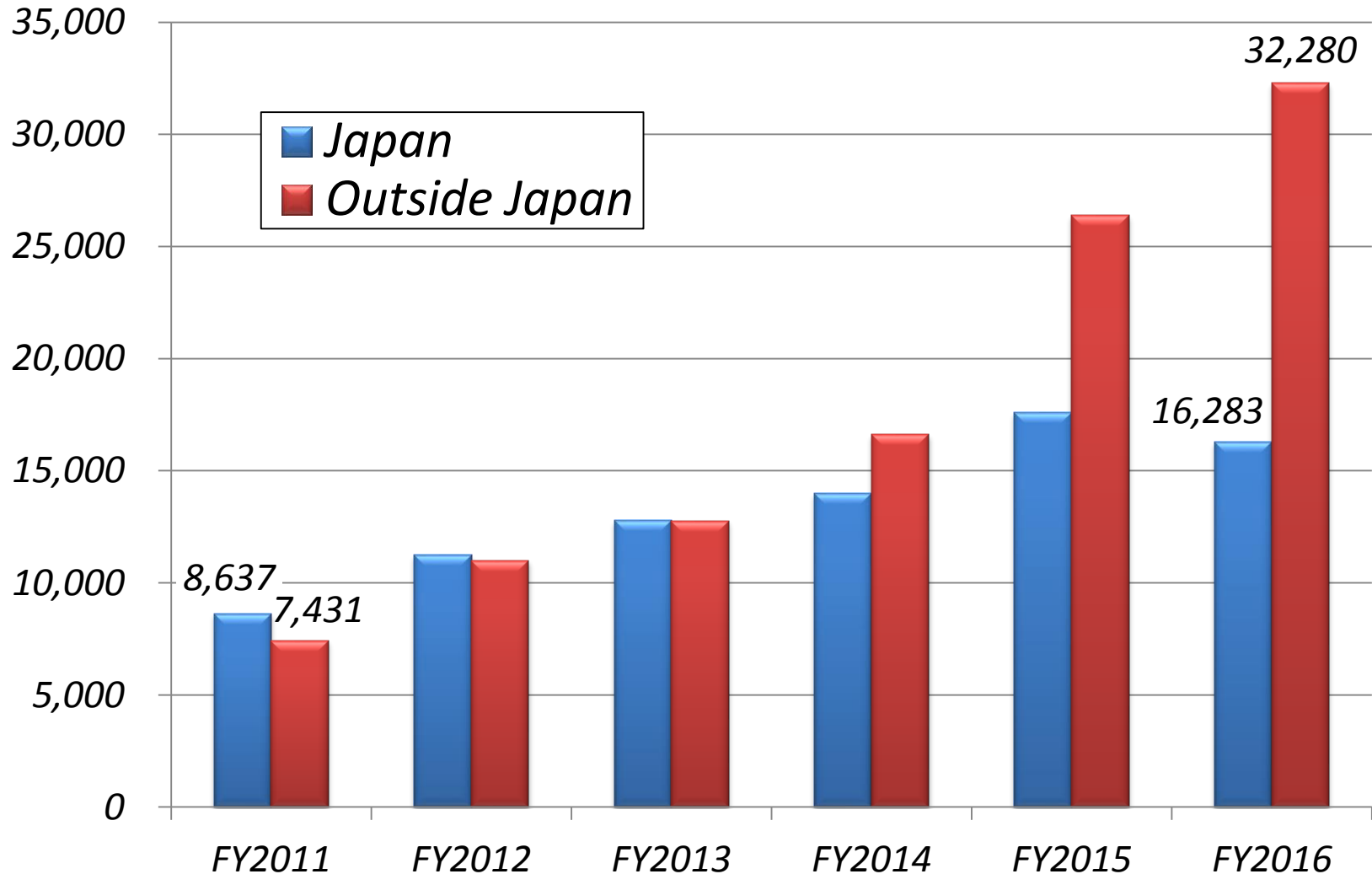
** foreign medical device:*

It has identity with domestic distribution items and medical devices used in foreign countries.



Adverse event reports

Total submitted number



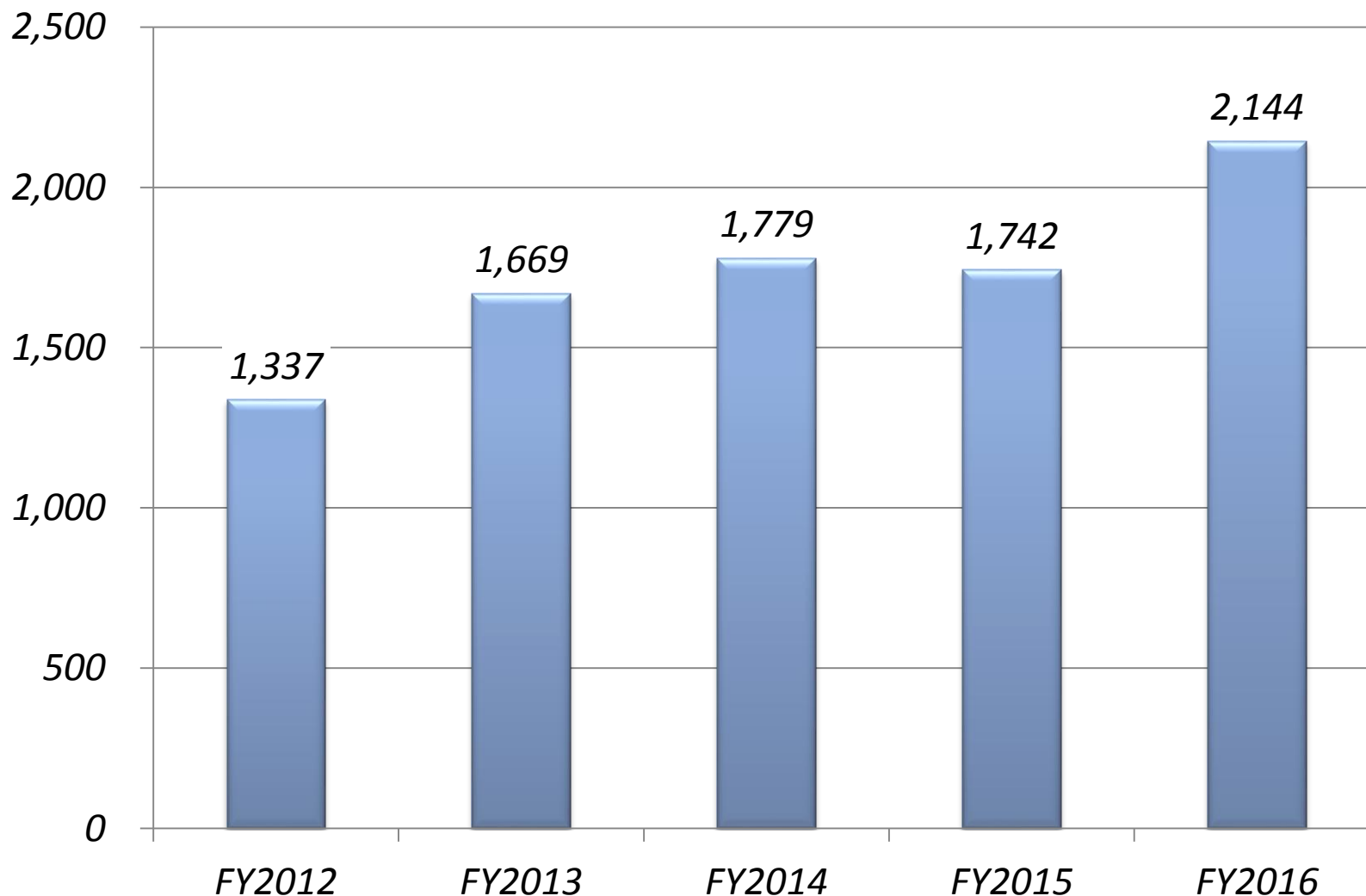
Source: PMDA Annual Report, etc.

The Japan Federation of Medical Devices Associations

JFMDA

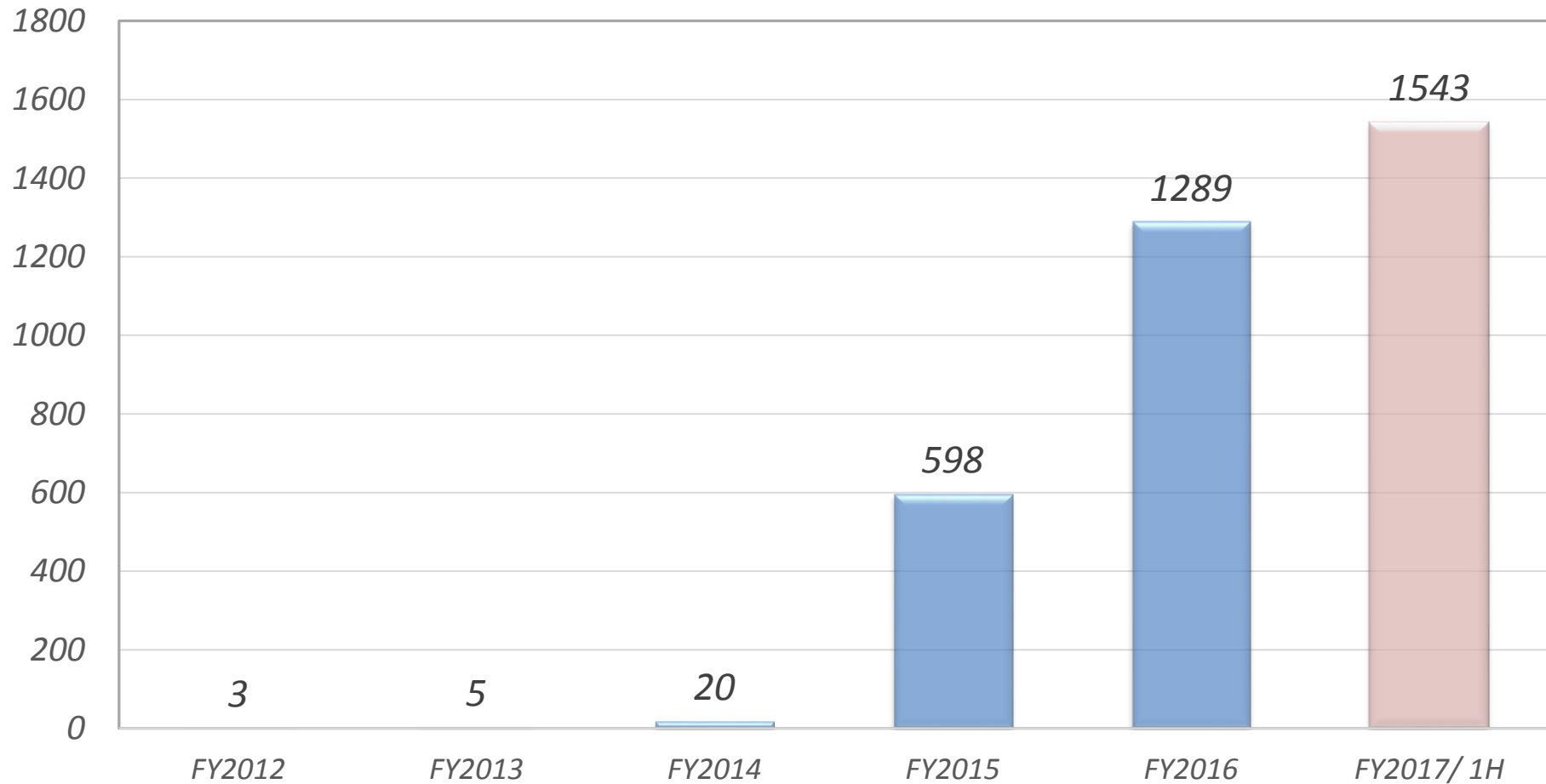
Reports of FSCA outside JAPAN

Total submitted number

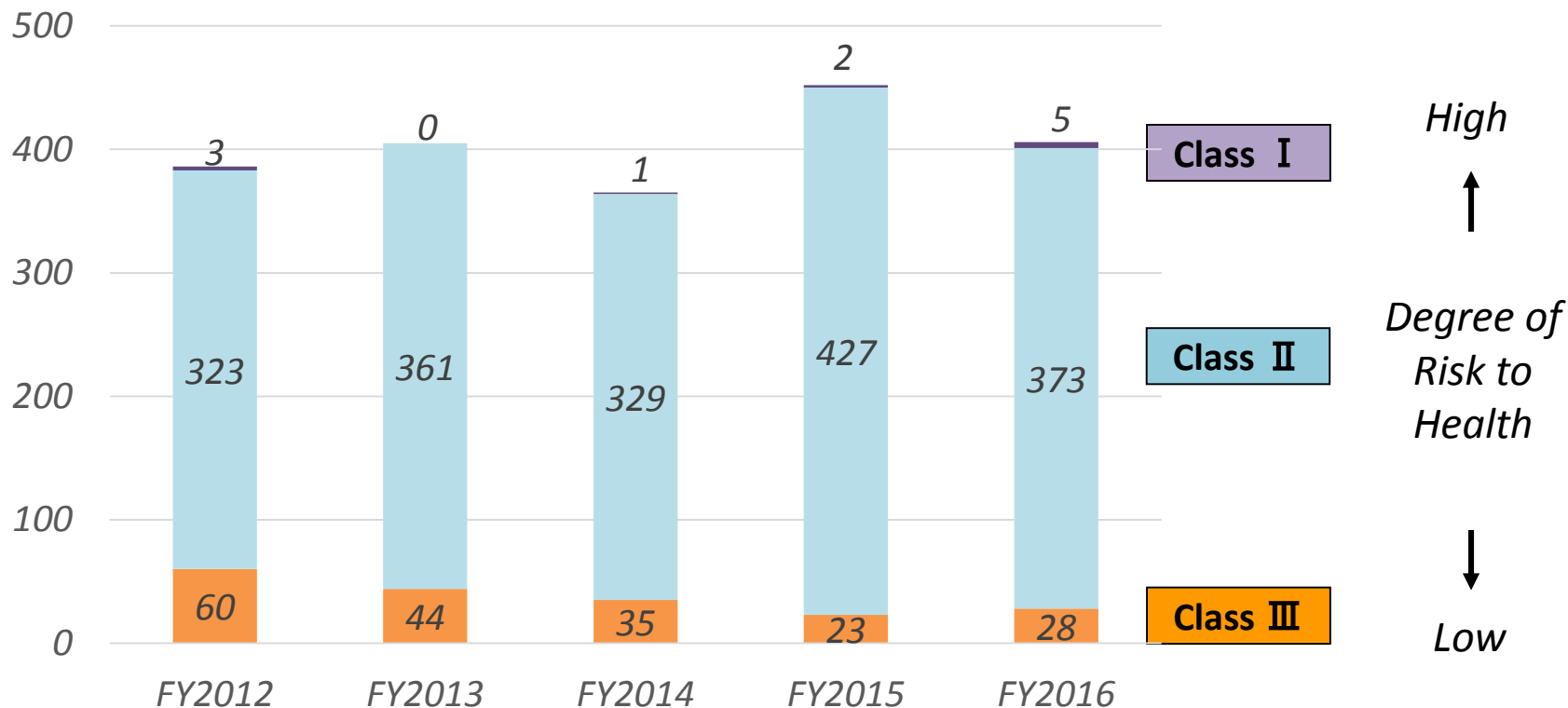


Research reports

Total submitted number



Recall



Class I: A situation where there is a reasonable chance that a product will cause serious health problems or death.

Class II: A situation where a product may cause a temporary or reversible health problem or where there is a slight chance that it will cause serious health problems or death.

Class III: A situation where a product is not likely to cause any health problem or injury.

Safety measures for DES impressed on MAH

- ✓ Holding seminars for proper use and sales are limited to participating medical institutions only
- ✓ Maintenance of explanatory documents for patients
- ✓ Rapid report of stent thrombosis cases
- ✓ Report of **all cases of death**
- ✓ Collaboration with antiplatelet manufacturer / distributor
- ✓ Follow up of domestic trial cases (up to 5 years) , etc.

Additionally... **PMS (Use-result survey)**

Five-year follow-up survey on over **2000 cases**

Although the sales have already ended, the survey continues.



- ✓ A new system for PMS has been introduced
- ✓ Effective utilization of registry's clinical outcome

Package inserts

■ PMD Act Article 63-2 (Matters to be indicated in Package Inserts)

The package inserts of a medical device shall indicate the following matters **based on the findings obtained from the latest papers and others pertaining to such medical device.**



Prepared by MAH

2017年3月作成(第1版)

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管理販売権等 株式会社アセリヤード (販売コード: 70328001)

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A4 size paper
Generally
up to 8 pages



Information provided
to users

Contents of package inserts

1. Date of preparation/ revision
2. Approval number
3. Commodity classification number/ brand name
4. Name of product
5. Warnings
6. Contraindication/ prohibition
7. Composition and product description
8. Intended use/ effect
9. Method of operation/ use
10. Precautions concerning use
11. Clinical studies
12. Storage method/ Shelf life
13. Precautions concerning handling
14. Matters concerning maintenance and inspection
15. Scope of approval
16. References and request for literature should be made
17. The name and address of the MAH/ manufacturer

Necessary to
pay special
attention

Excluded
patients/
usage



Precautions necessary for use and handling

1. *Precaution for use (Careful administration)*
2. *Important precaution*
3. *Interaction*
 - (1) *Contraindications for co-administration*
 - (2) *Precautions for co-administration*
4. *Malfunction/ Adverse event*
 - (1) *Serious malfunction/ adverse event*
 - (2) *other malfunction/ adverse event*
5. *Geriatric use*
6. *Use during pregnancy, delivery or lactation and pediatric use*
7. *Impact on the clinical test results*
8. *Excessive use*
9. *Other precautions*



Package inserts on PMDA-Website

The screenshot shows the PMDA website's medical device information search interface. The PMDA logo and name in Japanese and English are at the top. The main heading is '医療機器 情報検索' (Medical Device Information Search). A red dashed box with the text 'Medical device information search' points to this heading. Below the heading, there is a search form. A red dashed box with the text 'Examine the package insert of a medical device' points to the search form area. The search form includes a dropdown menu for '表示件数を選ぶ' (Select number of items to display) set to '10件', a blue '検索' (Search) button, and a red dashed box with the text 'Search' pointing to the button. Below the search button is a '検索条件消去' (Clear search conditions) button. The search form also includes a section titled '医療機器の添付文書等を調べる' (Check medical device package inserts, etc.) with a note: '※添付文書が公開されている品目について、その記載内容から検索を行い、検索された、医療機器に関連する文書を一覧表形式で表示します。' (For items with attached documents published, search from the content and display related documents in a list table format). Below this note is a text input field for '一般的名称・販売名（医療機器の名称）' (General name/sale name (Medical device name)). A red speech bubble with the text 'Enter search term' points to this input field. To the right of the search form, there is a '特定' (Specified) section with a note: '※「特外のきま検索' (Note: 'Special search').

Medical device information search

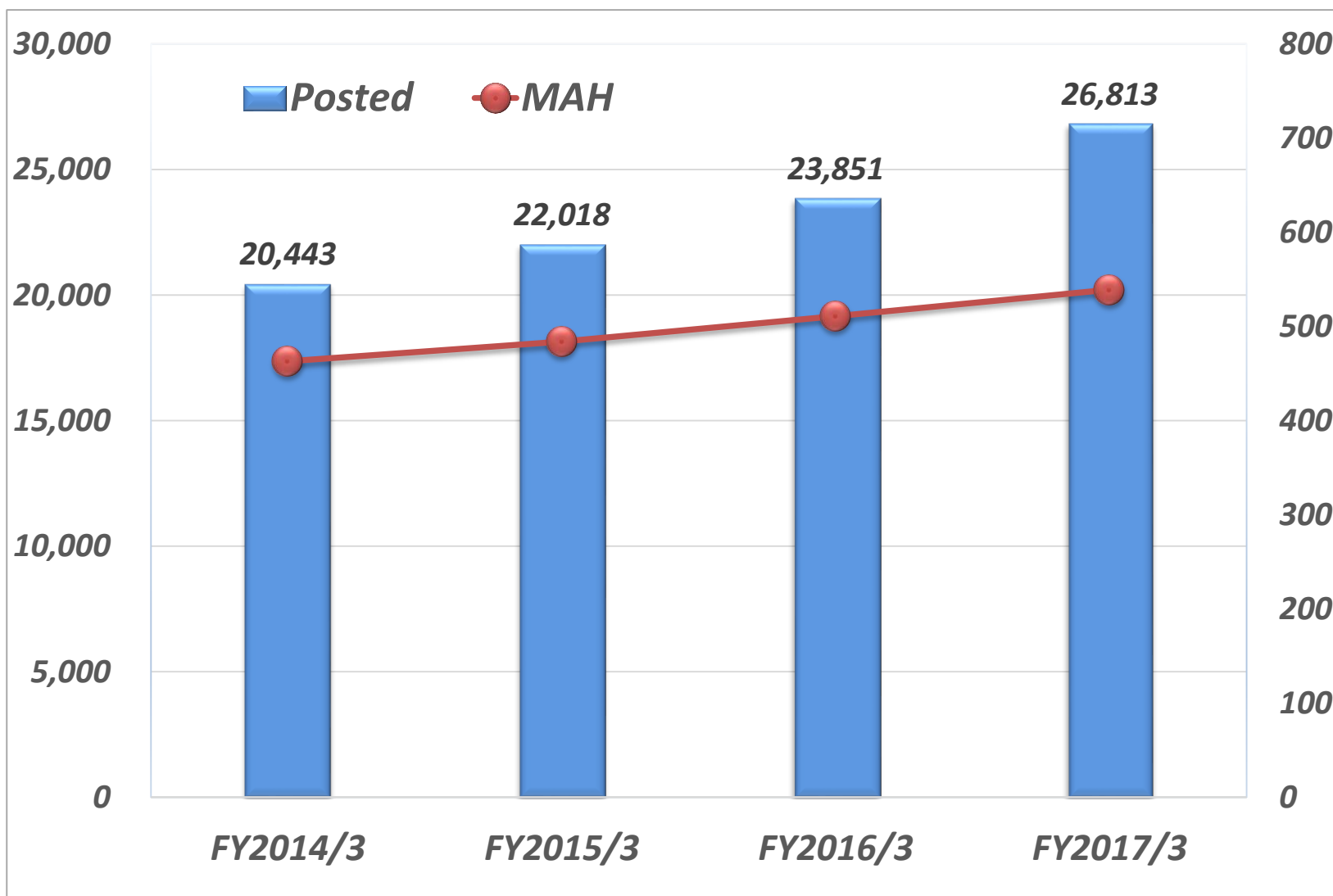
Examine the package insert of a medical device

Search

Enter search term

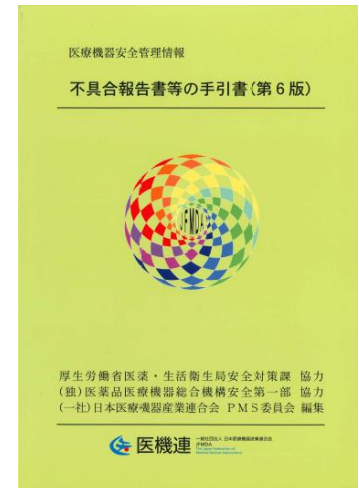
- ✓ For User: quick search and check is available
- ✓ For MAH: Prompt provision of revised contents is possible

Package inserts on PMDA-Website



Activities of JFMDA PMS committee

- Regular meetings with regulatory authority
- Safety management workshops
- Preparation of guidance
 - ✓ Reports to regulatory authority
 - ✓ Preparation of Package insert
- Preparation and maintenance of terminologies for categorized Adverse Event Reporting
- **Collaboration with regulatory authorities**



Summary

- ✓ *Companies are conducting PSV based on GVP and GPSP.*
- ✓ *Information collection from foreign countries are requested, and the number of reports to the administration is increasing*
- ✓ *Matters in the package insert are specified in detail by notification etc.*
- ✓ *The upload of the package insert on the website of PMDA is useful.*
- ✓ *Industry and regulatory authorities are collaborating for patient's safety.*



***Thank you for your
attention!***

