# Revision of Pharmaceutical Affairs Law

Ministry of Health, Labour and Welfare

Pharmaceutical and Medical Devices Agency

# PAL Revision: 3 Major Objectives

- Substantial Revision of Medical Devices Regulation
- Consolidation of Safety Measures for Biological Products
- Revision of Approval System and Enhancement of Post-marketing Safety Measures

# PAL Reform (Review of Classifications and Safety Measures Concerning Medical Devices)

| International Classification | Current status and Proposed revision / Classification of medical devices according to risk |
|---|---|
| **Class A** | Medical devices that are believed to pose **extremely low risk to the human body** even if they fail<br>**Examples:** In vitro diagnostic devices, steel supplies, x-ray film, dental prosthetic supplies |
| **Class B** | Medical devices that are believed to pose **low risk to the human body** even if they fail<br>**Examples:** MRI, electromanometers, electronic endoscopes, digestive catheters, ultrasonic diagnostic equipment, and dental alloys |
| **Class C** | Medical devices that are believed to pose **medium risk to the human body** if they fail<br>**Examples:** dialyzers, artificial bones, respirators, and balloon catheters |
| **Class D** | Medical devices that are highly invasive upon the patient and may **directly endanger the patient's life (high risk)** if they fail<br>**Examples:** pacemakers, artificial heart valves, and stents |

| EU system outline | | FDA system outline |
|---|---|---|
| Notified Body's audit is not required | | PMA or 510k is not required |
| Notified Body's audit is required | On-site inspection only | PMA or 510k is required |
| | Document review is required | |

**Current Pharmaceutical Affairs Law**

| Manufacturing regulations / Distribution Regulations | |
|---|---|
| Pre-distribution Notification is not required | Approval of manufacturing is not necessary |
| Pre-distribution notification is required | Minister's approval for manufacturing |

**Proposed Revision**

| Classification name | Risk | Marketing regulations / Distribution regulations |
|---|---|---|
| General Medical Device | Extremely low | Pre-distribution Notification is not required<br>Approval for marketing authorization is not required |
| Controlled Medical Device | Low | Pre-distriburion notification is required*<br>Introduction of third-party certification system |
| Specially Controlled Medical Device | Middle | Introduction of license system for distribution |
| | High | Minister's approval for marketing authorization |

**Note:** The products shown as examples will be classified, in principle, based on GHTF recommendations. Minister of Health, Labour and Welfare to classify products according to recommendation of the Pharmaceutical Affairs and Food Sanitation Council. Although some medical devices are rented, and since rentals are handled in the same way as sales under the Pharmaceutical Affairs Law's regulations, they are omitted from this table.

* Specially Designated Maintenance Required Medical Device, even those that are classified as low risk, require a license for distribution as do high-risk medical

# *Medical Device New Approval Process*

**Applicant**

(Marketing Authorization Holder)

**Facilities**

(Manufactures)

**Approval Application Form**

- Product Name, Generic name
- Intended Use
- Material
- Product Specification
- Usage Method
- Manufacturing & QC Info.
- Storage Condition, Life time

+ STED and Data subsets

①Application

⑤Approval (MHLW)

ISO13485

④Site Inspection /Document Review

Local Agency for Domestic, Class III

⑥Follow-up Inspection After Approval

Periodic Inspection ISO13485

New Independent Administrative Agency

②Document Review

Review of Conformity for Essential Principles

STED (Summary)

**Attached data subsets**

A Development History, Overseas Usage Condition
B Manufacture and QC Data
C Safety Data
D Stability, Life time
E Performance
F Risk Analysis
G Clinical Data

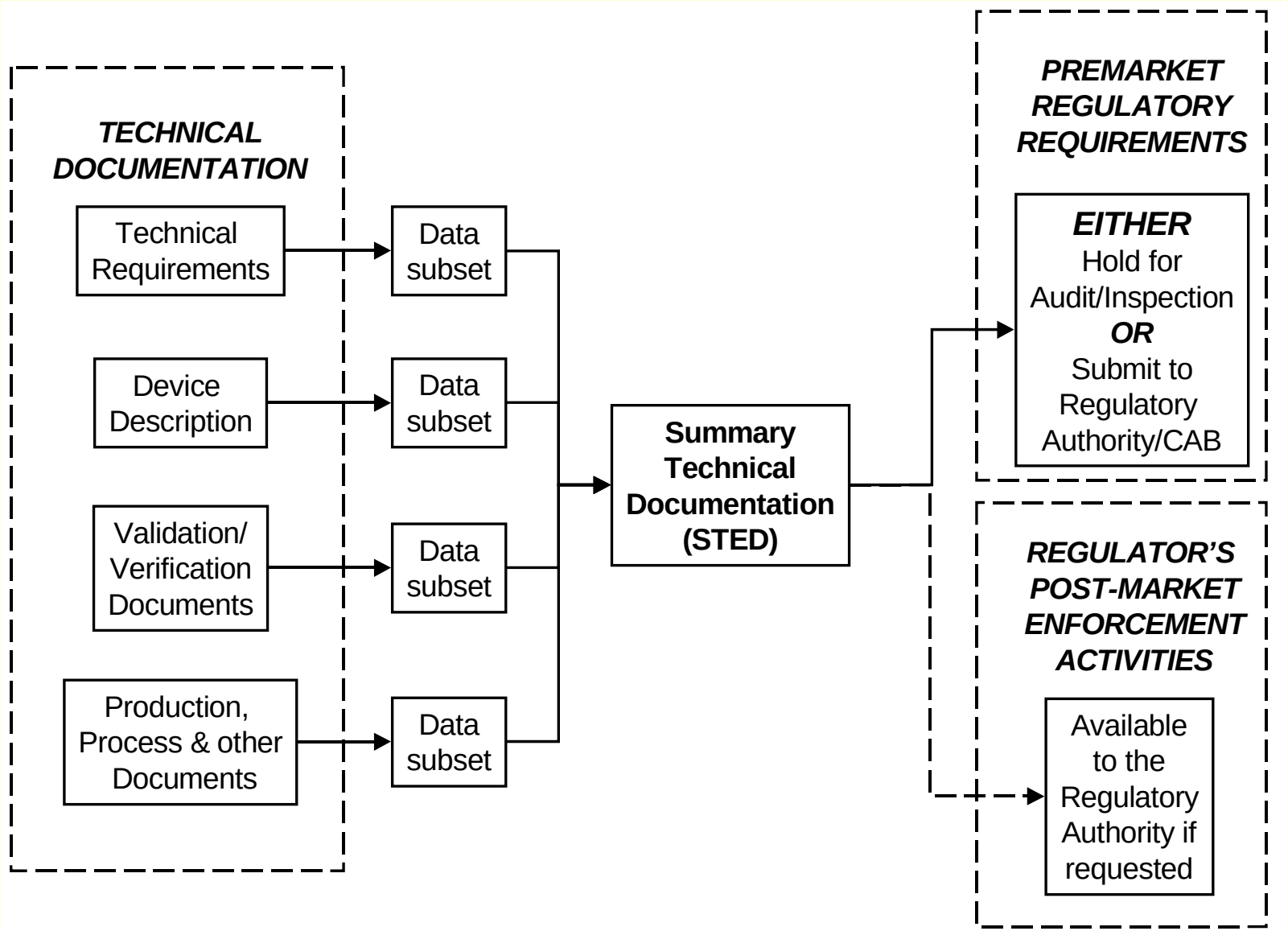
③Reliability Review

Site Inspection /Document Review for Reliability of Data subsets and conformity for GLP and GCP

# Basic Concept how to use STED

- After introduction of GHTF Essential Principles for regulation, MHLW have a plan to use ＳＴＥＤ as format of summary of data subsets attached Approval application form

- Implementation pilot project of STED from Feb. 2002
  （accept STED as format of summary of data subsets phase）
- Plan of fully Implementation of STED from 2005




**SOURCE AND APPLICATION OF THE STED**

# Direction toward Amendment of Approval Application

## Current Pharmaceutical Affairs Law

(1) **Application Form**

- Configuration, structure and dimensions
- Material
- Performance, intended use, indications or effects
- Operation method
- Manufacturing method
- Life time
- Standards and test methods

Device identification

(2) **Outline of Attached Documents**

(Summary of attached documents)

(3) **Attached Documents**

Origin and development story, Physicochemical properties, Data on standards and test methods, Stability, Safety, Performance, Clinical evidence

Evaluation of effectiveness and safety for medical device

## Revised Pharmaceutical Affairs Law

(1) **Application Form**

- Configuration, structure and mechanism
- Material
- Intended use, indications or effects
- Operation method
- Manufacturing and quality control method
- Life time
- Device specifications

Device identification

(2) **STED**

- Essential Principles and applicable standards
- Device description
- Documents for demonstrating conformity to relevant Essential Principles
- Labeling
- Risk analysis
- Manufacturing information

Effectiveness and safety of medical device are evaluated based on demonstration of conformity to relevant Essential Principles

(3) **Attached Documents**

# PMDA

PMDEC
Division 4
(Medical Devices)

PMDEC
Division 1 2 3
(Drugs)

New Organization for Pharmaceutical and Medical Device Agency (PMDA)

Japanese Association for the Advancement of Medical Equipment (JAAME)

Organization of Pharmaceutical and Safety Research (OPSR)