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Market Authorisation Approval Pathway for Medical Devices in Brazil & Japan

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Abstract

Pharmaceutical product (Medical Devices) is an expensive and time consuming process to launch the product from the early to promoting stage. This method is involved with a number of heavy research and increase in work. The implementation of this method should be guided in accordance with the connected administrative prerequisites which helps to set time aside and sale of products to the public. These requests will help to improve exercise and also helps you to manufacture a product that follows the impact focused administrative requirements, i.e., a quality product that is safe and effective for its intended use. Eventhough the fact that data on the administrative prerequisites (e.g., regulations, supervisory reports) entire human resources products, developments are actively accessible, exploring the administrative system is not so simple when handling with multiple tasks. The main key point is to help the administrative understanding that oversees product advancement and affirm the administrative recognition. It may be utilized very well as an initiation stage to guide you in building up your product. On building of a systemic process for collation, analysis, documentation, dissemination, updating & re-validation of information data created for easy & effective LCM & regulatory compliances. It helps business people a guide to follow.

Key words: Regulatory Requirements, Navigation, Regulations & Medical Devices.

I. OBJECTIVES:

- To build a navigation pathway on how to access key regulatory information for biologicals during lifecycle management in Brazil the form of factsheet that can be used as a ready reckoner.
- To collate data for better analysis & understanding on trend followed in Brazil.
- To recommend on building of a systemic process for collation, analysis, documentation, dissemination, updating & re-validation of information data created for easy & effective LCM & regulatory compliances.

II. DISCUSSION

a. Overview

Table 1: Introduction to Brazil

Country	**Brazil**
Capital	**Brasilia**
Currency	**Brazilian real**
Language	**Portuguese**
Regulatory Authority	**ANVISA (Agência Nacional de Vigilância Sanitária)**
Country Flag	

b. Regulatory Factsheet for Medical Device in Brazil

REGULATORY FACTSHEET	
Medical Devices	
PRODUCT	Medical Devices
COUNTRY	Brazil
REGULATORY AGENCY	ANVISA
TYPE OFAPPLICATION	Market Authorisation Approval (MAA)

INTRODUCTION

Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices

Providing information by means of in vitro examination of specimens derived from the human body[1].

ANVISA categorizes Medical Devices into four types:

- medical equipments,
- materials for health use,
- orthopaedic implants and
- in vitro diagnostics.

REGULATIONS

Table 2: Regulations for CFDA

Sl No.	Categorizes	Regulations
01.	Medical equipments	Resolution RDC 185/2001 and RDC 211/2018
02.	Materials for health use	Resolution RDC 185/2001 and RDC 211/2018
03.	Orthopaedic implants	Resolution RDC 185/2001 and RDC 211/2018
	In vitro diagnostics	Resolution RDC 36/2015 and RDC 211/2018

CLASSIFICATION:

Table 3: Classification of Medical Devices-Brazil

Class	Risk	
Class I	Low risk	do not expire, but they might be cancelled upon request, in case of reassessment, in the impossibility of solving irregularities, or when fraud is detected
Class II	Low-moderate risk	
Class III	Moderate to high risk	Pre-market approvals for products categorized as Risk Class III and IV are valid for ten years from the date of their publication in the Brazilian Official Gazette, and may be renewed for equal and successive periods.
Class IV	High risk	

Timelines:

Class	Timeline	Validity
Class I	1-3 months	Does not expire
Class II	1-3 months	Does not expire
Class III	8-15 months	10 years
Class IV	8-15 months	10 years

APPROVAL PROCEDURE [2]:

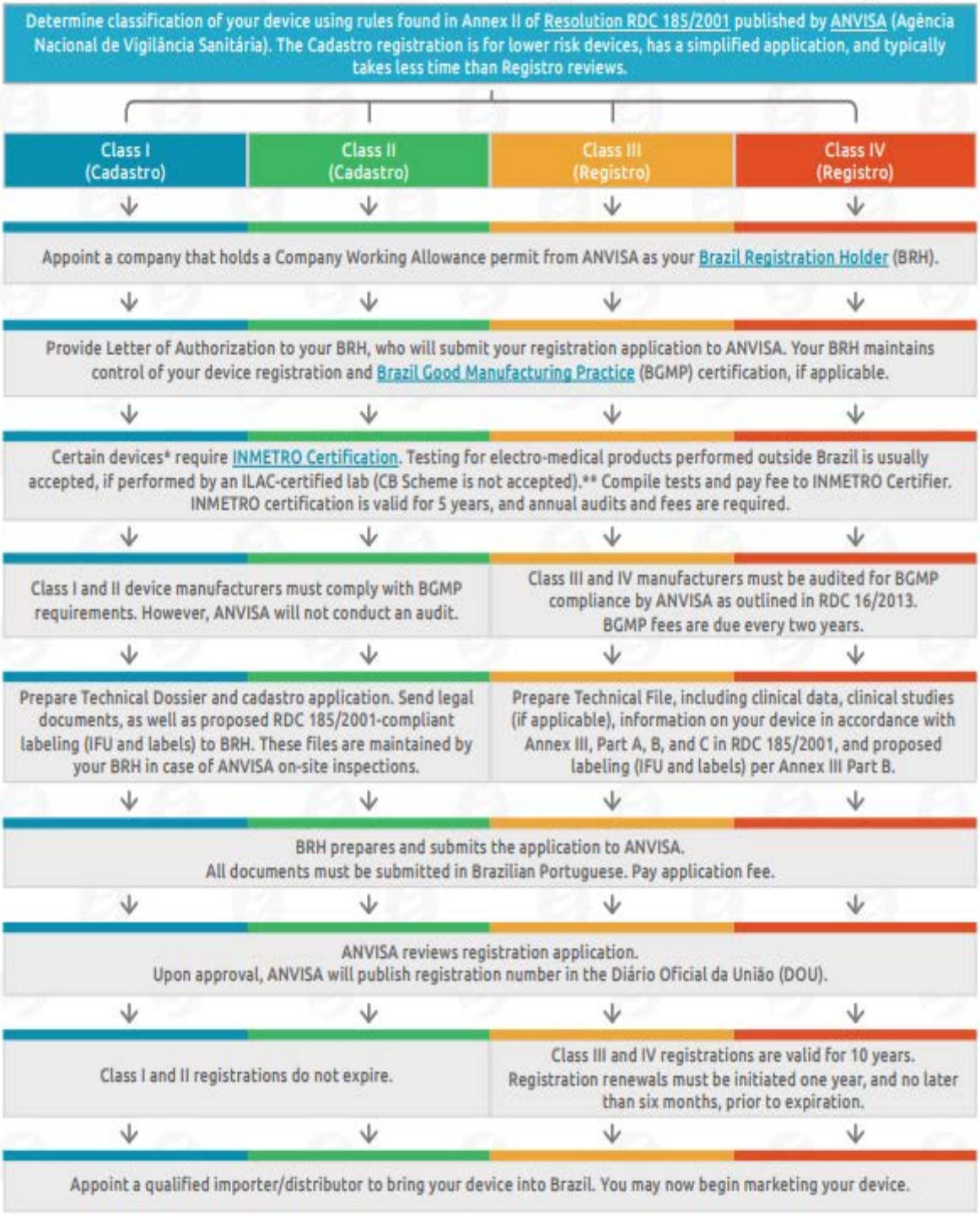
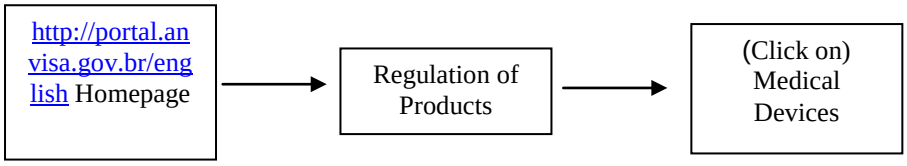


Figure 1: Approval Procedure for MAA Medical Devices- Brazil

SUBMISSION PATHWAY:



LINK: http://portal.anvisa.gov.br/medical-devices

NAVIGATION PATHWAY[3]

Figure 2: MAA-Medical Devices Pathway- Brazil

c. Overview

Table 4: Introduction to Japan

Country	Japan
Capital	Tokyo
Currency	Japanese yen
Language	Japanese, English
Regulatory Authority	Pharmaceuticals & Medical Device Agency (PMDA)

d. Regulatory Factsheet for Medical Devices in Japan

REGULATORY FACTSHEET	
Medical Devices	
PRODUCT	Medical Devices
COUNTRY	Japan
REGULATORY AGENCY	Pharmaceuticals and Medical Devices Agency (PMDA)
TYPE OFAPPLICATION	Market Authorisation Approval (MAA)

INTRODUCTION

Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Control of conception,
- Disinfection of medical devices

Providing information by means of in vitro examination of specimens derived from the human body[4].

REGULATIONS

Table 5: Regulations for Medical Devices in Japan

Sl No	Documents	Published
01.	Japan MHLW Ord. 136 - QA Procedures for Device	9/2004
02.	Japan MHLW Ord. 169 - QMS Compliance	12/2004

GUIDANCE DOCUMENTS

Table 6: Guidance Documents for Medical Devices in Japan

Sl No.	Guidance Documents	Published
01.	Japan Guidance for Medical Device Applications 1 of 2	2/2005
02.	Japan Guidance for Medical Device Applications 2 of 2	2/2005
03.	Japan Handling Medical Device Foreign Clinical Data	3/1997
04.	Japan Medical Device Complaint Handling Process Chart	3/2005
05.	Japan QMS Inspection Process for Medical Devices and IVD	12/2010
06.	Japan STED Submission Preparation Handbook	2/2016

CLASSIFICATION: Medical devices in Japan are classified based on risk to the human body. The PMDA uses a tiered classification system for medical devices as shown below.

Table 7: Classification of Medical Devices-Japan

Class	Risk	
Class I	low risk	General medical devices
Class II	low/medium risk	Specified Controlled medical devices
Class II	medium risk	Controlled medical devices
Class III	medium/high risk	Highly Controlled medical device
Class IV	high risk	Highly Controlled medical devices

APPROVAL PROCEDURE[5] **:**

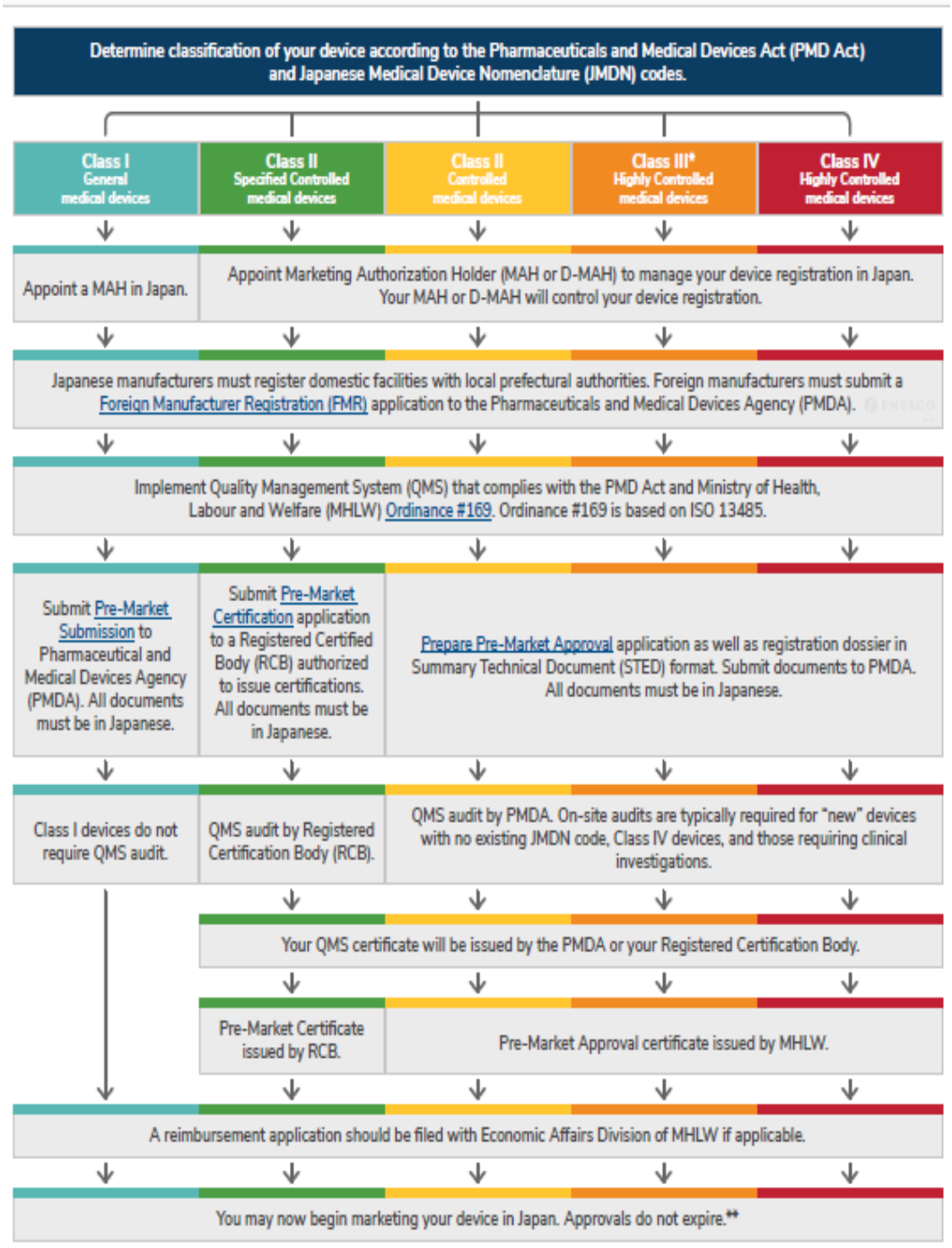
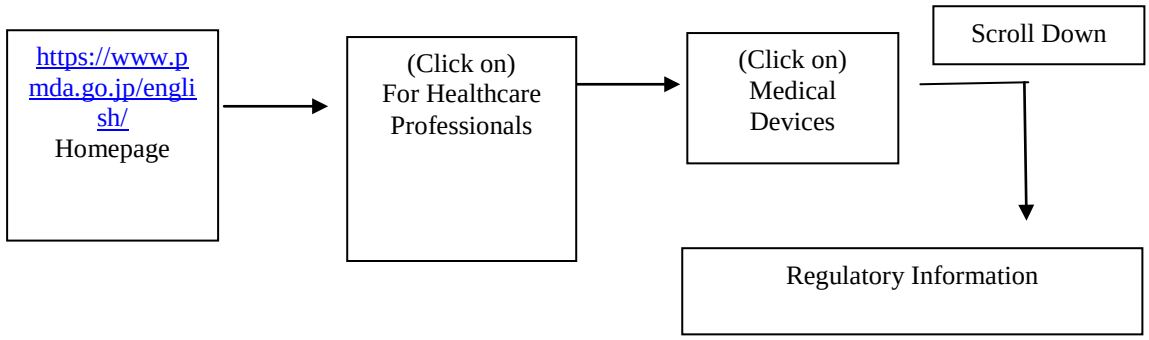


Figure 3: Approval Procedure for MAA Medical Devices- Japan

SUBMISSION PATHWAY:



LINK:
https://www.pmda.go.jp/english/review-services/reviews/approved information/devices/0002.html

NAVIGATION PATHWAY[6]

Figure 4: MAA-Medical Devices Pathway- Japan

III. CONCLUSION

- To establish Navigation Pathway on how to access key regulatory information for MAA of Medical Devices in Brazil & Japan.
- A detailed factsheet has been prepared to access the key regulatory information for aforementioned from the various regulatory website i.e., Brazil & Japan.
- The current study provides a detailed regulatory information of act/regulations, guidelines, approval procedure & their timelines for approval of medical devices in Brazil & Japan.

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