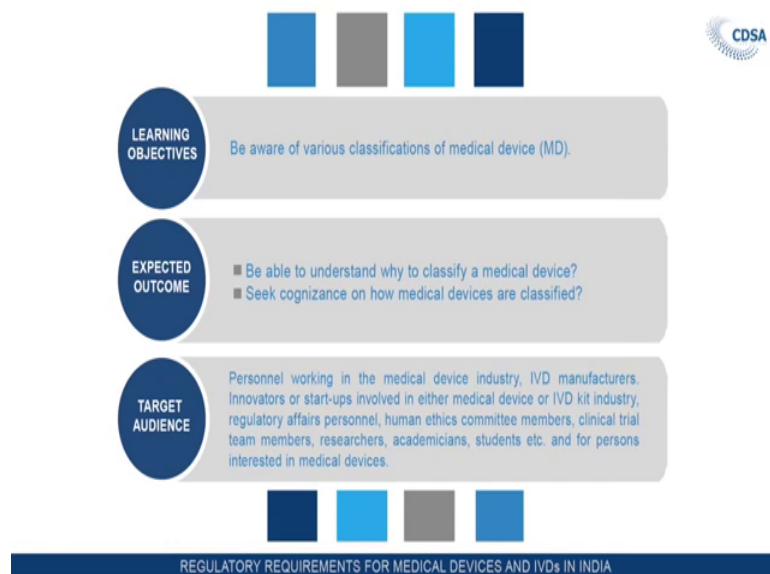


Regulatory Requirements for Medical Devices and IVDs in India
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Department of Biotechnology, Ministry of Science and Technology
Department of Higher, Ministry of human Resources Development
Government of India

Lecture –5
Classification of Medical

Hello, welcome to the training for training module Regulatory Requirements for Medical Devices and IVD in which the diagnostic kits in India. This presentation will actually give you, how to classify of medical devices? And what is classification of a medical device? This is a series of lectures 10, lectures on medical devices and IVDs. And we shall learn about classifications from this presentation.

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The objectives of this particular presentation is to be aware of various classification of medical devices. Outcome is able to understand and understand, why to classify medical device? Seek cognizance on how medical devices are classified? And target audience is personnel working in the medical device industry, IVD manufactures, innovators or start-ups involved in either medical devices or IVD kit industry, regulatory affairs personnel, human ethics committee members, clinical trial team members, researchers etcetera. And for the person is generally interested in medical devices. Anybody can go through this courses and learn about classification of medical devices.

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WHAT WILL WE LEARN IN LECTURE 3A?

Why classify?	Basic principles for classification	Risk based classification
Classification	How to classify?	Helpful documents

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

What will be learn in this lecture? Why classify? Classification is the main heading, risk based classification, machine learning model in vitro diagnostics is part of the classification. How to classify?

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DIFFERENCE BETWEEN DRUGS AND MEDICAL DEVICES

We have already learnt this in our lecture 1, let us revise this once again as it is important to understand the difference between drugs and medical devices to know the relevance of classification.

Though both drugs and medical devices are an important component of healthcare and are used for humans and animals for bringing them to normal state, their basic action and composition are different.


This is the basic reason why medical devices can not be considered as drugs.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Helpful and helpful documents; before you start representation on classification in medical devices; we have to understand the difference between drugs and medical devices.

Before, we going for the classification, it is very very important to know why drugs and medical devices are different. If drugs and medical devices are not different, we did not have gone for classification on medical devices. But rather used drugs in the sense that drugs are categorized. Though both drugs and medical devices form an important component of health care and are used for humans and animals for bringing them to normal state, the basic action and composition are different. This is the basic reason why medical devices cannot considered as drugs and must be classified. In the next slide we shall see, how they are different in different parameters.

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DIFFERENCE BETWEEN DRUGS AND MEDICAL DEVICES

Drug	Medical device
Based on chemistry & pharmacology	Based on engineering
Safety and efficacy	Safety and performance
Clinical trials	Clinical evaluation
GMP (Good Manufacturing Practice)	QMS (Quality Management System)
Local and systemic toxicity	Biocompatibility
Long product life cycle	Short product life cycle
Drug Interactions	Device malfunction
Large Population	Limited population

Further reading: http://www.globalmedicaltechnologyalliance.org/wp-content/uploads/GMTA_Differences_Between_Devices_IVD_Drugs_RevFINAL_17July12-pdf-pdf.pdf

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

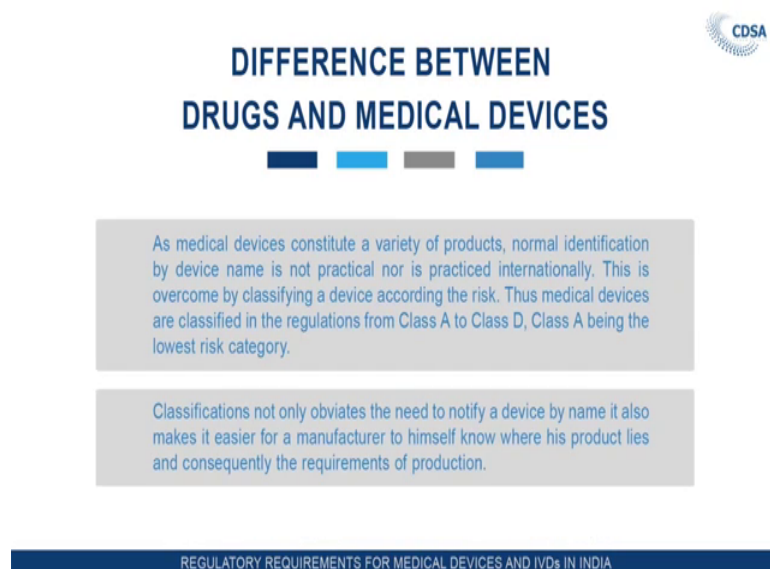
Difference between drugs and medical devices; on the left hand side you will see the parameters of drugs, on the right if parameters on devices. Drugs are based on chemistry and pharmacology. Devices are based on engineering. They are solid engineering products of plastic, metal or wood or whatever.

Drugs have safety and efficacy as their guiding criteria. They should be safe and efficacies. Medical devices are safety and performance, how they perform as a device in the human body. For drug, its clinical trials; for device it is clinical evaluation. For drug, it is GMP; for devices, it is quality management system. For drugs, local and systematic toxicity happens; for devices, its biocompatibility; whether the devices rejected by the human body or not or its compatibility to the human scale. For devices, local systematic

toxicity which are going to the systems and cost problems and sickness the human body. The drugs, they have a very very long product life cycle.

For devices, a very short product life cycle and device can change within a year or 6 months. For drugs, it is drug interactions for device, it is device malfunction. Drug, you can interact with a human body, device can malfunction and cause problems. Drug is used in very very large number of population; devices are used in a limited population. And that is the reason why devices have a short life cycle on so on.

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The slide features a title 'DIFFERENCE BETWEEN DRUGS AND MEDICAL DEVICES' in bold blue text, centered at the top. To the right of the title is the CDSA logo. Below the title are four colored bars (dark blue, light blue, grey, dark blue). The slide contains two text boxes: the top one explains that medical devices are classified by risk (Class A to Class D) because naming them is impractical, and the bottom one states that classification makes it easier for manufacturers to know their product's requirements.

**DIFFERENCE BETWEEN
DRUGS AND MEDICAL DEVICES**

As medical devices constitute a variety of products, normal identification by device name is not practical nor is practiced internationally. This is overcome by classifying a device according to the risk. Thus medical devices are classified in the regulations from Class A to Class D, Class A being the lowest risk category.

Classifications not only obviates the need to notify a device by name it also makes it easier for a manufacturer to himself know where his product lies and consequently the requirements of production.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

As medical device constitutes a variety of products. Normal identification by device name is not practical nor is practiced internationally. This is overcome by classifying a device according to the risk. Thus medical devices are classified in the regulations from class A to class D, class A being the lowest risk category.

Classification not only obviates the need to notify a device by name it also makes easier for a manufacturer to himself know where his product lies and consequently the requirements of production. A medical device, a common medical device can have say a hundred variant. So, therefore, it is better to have a device class for that variant rather than naming each hundred device by name.

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SOME EXAMPLES OF MEDICAL DEVICES



REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Some examples on medical devices to show that the range that medical devices constitute as a group; we have intra ocular lens which is main of polymer, plastic or P V P. We have got disposable hypodermic needles, syringes, part of it is metal, part of which is plastic; we have cardiac stent, which is made of again metals. We have automatic plants which can be plastics or stainless steel or any other metal, suitable metal.

So, this is a small range of in plan table medical device. Apart from this, you can have medical devices which are like instruments for blood chemistry; you can have devices which are actually in vitro diagnostic kits and various ranges. So, it is a huge complex complicated range of device. So, its not easy to gave name and use them, but have to classify them to show know, what class they fall into. Why classify a medical device? Now, that we already know drugs and medical devices are different are in different ways their control is also necessary to have to be different.

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The slide features a title at the top center: "WHY IS THERE A NEED TO CLASSIFY A MEDICAL DEVICE?". Below the title is a decorative horizontal bar with four colored segments: dark blue, light blue, grey, and medium blue. The CDSA logo is in the top right corner. The main content consists of four grey rectangular boxes, each containing a point. At the bottom, a dark blue footer bar contains the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA".

WHY IS THERE A NEED TO CLASSIFY A MEDICAL DEVICE?

- Now that we already know drugs and medical devices act in different ways, their control necessarily have to be different.
- Drugs are usually destructively tested on representative samples before release- mostly not possible for medical devices.
- Medical devices can vary in shape, size in usage virtually in unlimited ways- drugs act in definite well known ways.
- Medical devices can save a life and in its lowest avatar may not be used at all.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Drugs are usually destructively tested in representative samples before release; mostly not possible for medical devices. Let us develop this one. Drugs are usually destructively tested; that means, if I take a common drug say as an example paracetamol tablet its a batch of 1 lakh tablets. I usually takes a 100 tablets, send it to the lab; it is tested, destroy powder and it become unusable, but in medical devices most of the cases it is cannot be done. You cannot destroy medical device and test it.

So, therefore, it has to be actually put in a class of high risk or low risk to see. And accordingly, build the quality management system for the device. So, that the product is actually representing that design of that device. Medical device can vary in shape and size usually virtually in unlimited ways; drugs act in definite well known ways. Drugs for instance, a tablet we know it what will be the shape, size.

There are fixed parameters for testing of a tablet. In case of medical devices, a same device, a device which is used say for in a plant can vary a shapes and sizes. So, we focus more on the material of construction of the medical device rather than what it is state away. Medical device can save a life and in its lowest avatar may not be used at all.

So, very simple, medical devices for instance, for cardiac stent can save a life; however, as in the lowest possible class A you may not use a medical device at all in case you require it. So, it is optional whether use it or not in the lowest case of medical device.

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WHY IS THERE A NEED TO CLASSIFY A MEDICAL DEVICE?



Basic principle of classification of medical device is risk based.

Low risk  High risk

All medical devices are not placed in the same basket of risk.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, it is huge range. Basic principle of classification of medical devices risk based we know earlier low risk to high risk. Lowest risk, medical devices are simple items like a walking stick, spectacles or for instance, say hospital bed, on a bed panel whatever. And the high risk of course, we know can be IVDs, for HIV etcetera and cardiac stents and brain implants.

All medical devices are not placed in the same basket of risk. Over here, may I mention the classification that a same medical device. Class, it is dependent on the usage of the medical devices. Same medical device can be used in high risk class also and low risk class also. See, this classification.

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RISK BASED CLASSIFICATION

Medical devices are classified in the regulations based on the classification rules specified in the First Schedule of the drafted rules.

Following are the risk classes and the classification criteria based on the severity of risk associated with the medical device.

Risk Criteria	Risk Class
Low	Class A
Low-moderate	Class B
Moderate-high	Class C
High	Class D

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Medical devices are classified by the regulations based on classification rules divide in the first schedule of the drafted rules. I wants a drafted over here because rules already been published. Following are the risk classes and the classification criteria based on the severity of risk associated with the medical device. Risk criteria, low risk class A, low moderate class B, moderate high is class C and very high risk medical devices are class D.

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REGULATORY AUTHORITIES RESPONSIBILITY IN INDIA

Device Class	Class A	Class B	Class C	Class D
Import	CDSCO	CDSCO	CDSCO	CDSCO
Manufacture	*SLA	SLA	CDSCO	CDSCO
Permission to conduct clinical investigation	Permission from CDSCO			
Sale	SLA			
Qms verification by	*Notified bodies	Notified bodies	CLA	CLA

*Voluntary only (in case the manufacturer wants to export)

Note: Notified bodies shall be registered with CDSCO and shall be audited by CDSCO.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Regulatory authorities responsible in India; now, we have got in this particular slide the device classification and the regulatory authority who are responsible for certain actions on those medical devices. For import all classes, class A, B, C and D; import is the CDSCO of the regulatory authority. That is a central government, central drug control. For manufacturer, class A and class B are controlled by the State Licensing Authorities; class C and class D are controlled by the CDSCO. Permission to conduct clinical investigation is central government again. Sale is controlled by the state government; Qms verification is done for class A and B by notified bodies; class C and D by the central government.

Now, whether you need a license or not for class A medical device depends whether you want to export a medical device or not; you may get a license, but notified you may carry out your own classification and own Qms. If you want to, if you do not want to export it, but if you want to export it; you have to carry out Qms verification by a notified body. Notified bodies shall be registered with CDSCO and shall be audited by the Special Notification Authority.

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REGULATORY AUTHORITIES ACROSS THE GLOBE

RISK LEVEL	INDIA*	GHTF	AUSTRALIA	CANADA	EU	JAPAN	USA
Low	A	A	I	I	I	General	I
Low-moderate	B	B	Ila	II	Ila	Controlled	II
Moderate-high	C	C	Ilb	III	Ilb		
High	D	D	III	IV	III	Highly controlled	III

* Probably the best possible system for India

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

This is a chart just to give an example of how classification is done worldwide. We have got India and GHTF in the first 2 columns ABCD. If the classification done by the GHTF that the Global Harmonization Task Force and we have adopted that in India and notified our medical devices as A, B, C and D. In Australia, it is class I, class Ila, class Ilb, class

III corresponding to each of the classes to GHTF. In Canada, it is I, II, III and IV. Similarly, with GHTF in EU it is same as Australia as I, IIa, IIb, III. In Japan of course, now this is different, embed different. In Japan, low risk are general medical devices; low moderate risk are controlled moderate devices and moderate high and high are put in to a (Refer Time: 12:38) highly controlled devices.

In the US again there is a difference, the low risk devices are class I GHTF of class I is the lower risk devices class I. Class II devices constitute low moderate and high mod part of high moderate medical devices and class III are high highly risky medical devices. So, this in general there is a difference in Japan and US, but still we have the same low high and low moderate high and very high risk medical devices categorized image of the countries.

We have to mention here that in case a manufacturer India wants to export a medical device to say USA in spite of his classification done in India, he has to get its classification as and the manufacturing Qms as per the class II of the USA. How classification is done?

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The slide features the CDSA logo in the top right corner. The title 'HOW IS CLASSIFICATION DONE GLOBALLY?' is centered at the top. Below the title are four grey rectangular boxes, each containing a blue text point. At the bottom of the slide is a dark blue horizontal bar with white text.

- It is for the manufacturer to decide on the classification of a device.
- The regulator do not play a role in the classification at the time of submission.
- The regulator examines the device and decides and allows the product to be permitted.
- The classification can go up in case the regulator feels it deserves to be so.


REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

It is for the manufacturer to decide on the classification on device. The regulator will not tell a manufacturer, what is his class? He can guide him to the glass, but the manufacturer has to first decide, what is his class? Regulator does not play roll the

classification on time of submission. The regulator examines the device and decides and allows the product to be permitted to be manufactured or sold.

The classification can go up in case the regulators feel it deserves to be sold. So, in case a manufacturer applies for a class B device manufacture and the regulator feels that class C device the regulator can tell the manufacturer that your devices class C according to our assessment and it should not be placed in class B. So, initial assessment has to be done on the manufacture; the final decision with the regulators who can agree with a manufacturer classification or put a most engine classification.

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HOW IS CLASSIFICATION DONE GLOBALLY?

A system has been devised to decide on a devices classification to avoid any discrepancy. Classification rule- 'decision tree'.

This has been agreed by the industry and the regulators for a smooth and effective implementation.

Decision is based on the way a device is used.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

A system has been devised to decide on a devices classification to avoid any discrepancy. Classification rule is the decision tree basically. So, yes no correct type of decision tree, which the GHFT formulated very nicely. And through the tree, you can find out where you have medical device falls in the risk class. It has been agreed by the industry and the regulators for a smooth and effective implementation. Decision is based on the way a device is used basically.

(Refer Slide Time: 14:56)

REFERENCE TO CLASSIFICATION IN THE MEDICAL DEVICE RULES, 2017



First schedule

[See rule 4]

Parameters for classification of medical devices and *in vitro* diagnostic medical devices.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, let us come down to our regulation reference to classification of medical devices rule, 2017. First schedule, rule 4 parameters of classification of medical devices and *in vitro* diagnostic medical devices; I shall give it to head use of these, which gives a description in the actual rule. If you go through the actual rules in find out small description of that heading.

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BASIC PRINCIPLES FOR CLASSIFICATION



Application of the classification provisions shall be governed by the intended purpose of the device.

If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

Software, which drives a device or influences the use of a device, falls automatically in the same class.

If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Basic principle of classification; application of the classification provisions shall be governed by the intended purpose of the device. The device is intended to be used for a

risky procedure in the human body. Accordingly, the risk classification will decide the risk classification.

Two, if the device is intended to be used in combination with another device the classification rules shall apply again. So, if two medical devices are mixed together, you have to go for the classification rule and decide. We have to come to the classification rule later on. However, accessories are classified in their own rights separately from the device with which they are used. So, if there are two medical devices; one major medical device along with an accessory.

The accessory shall be classified in their own right compared to the main medical device which is used. At the end of the day; however, if they are used together in the human body then, the higher risk class will apply to both of them. If the class of device which is the main device is class C and the accessories class B then, both of them will be treated as class C in case it is used together. Software, which drives a device or influences the use of a device falls automatically in the same class as the (Refer Time: 16:39) device; that is very simple.

If the device is not intended to be used solely or principally in a specific part of the body; it must be considered and classified on the basis of the most critical specific use. If several rules apply to the same device based on the performance specified by the manufacturer. The strictest rules resulting in the higher classification shall apply. This is very simple if a device falls in this separate different categories low to high risk. The highest risk will apply to the device not the low risk. Now, how do you classify? These are the parameters of classification in a medical device.

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GENERAL PARAMETERS FOR CLASSIFICATION

- Non-invasive medical devices which come into contact with injured skin
- Non-invasive medical devices for channeling or storing substances
- Non-invasive medical devices for modifying compositions of substances
- Other non-invasive medical devices
- Invasive (body orifice) medical devices for transient use
- Invasive (body orifice) medical devices for short term use

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

And each of these parameters are described in short detail in the general cosmetic regulations which you can go through. And if there are queries regarding those, you can get back to a (Refer Time: 17:30) little bit apply tool. Now, what are the parameters? Number 1 is non-invasive medical devices which come into contact with the injured skin. So, these are medical devices which are non-invasive in the sense they do not enter the human body, but come into contact with a surface of the skin which is injured.

Number 2 is non-invasive medical devices for channeling or storing substances. Number 3 is non-invasive medical device for modifying composition of substances. Number 4 is other non-invasive medical devices which are usually class A devices. Number 5 is invasive body orifice medical devices for transient use. Next is a shorter use, third is a long term use.

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GENERAL PARAMETERS FOR CLASSIFICATION

- Invasive (body orifice) medical devices for long term use
- Invasive (body orifice) medical devices for connection to active medical devices
- Surgically invasive medical devices for transient use
- Surgically invasive medical devices for short term use
- Implantable medical devices and surgically invasive medical devices for long term use
- Active therapeutic medical devices for administering or exchanging energy

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

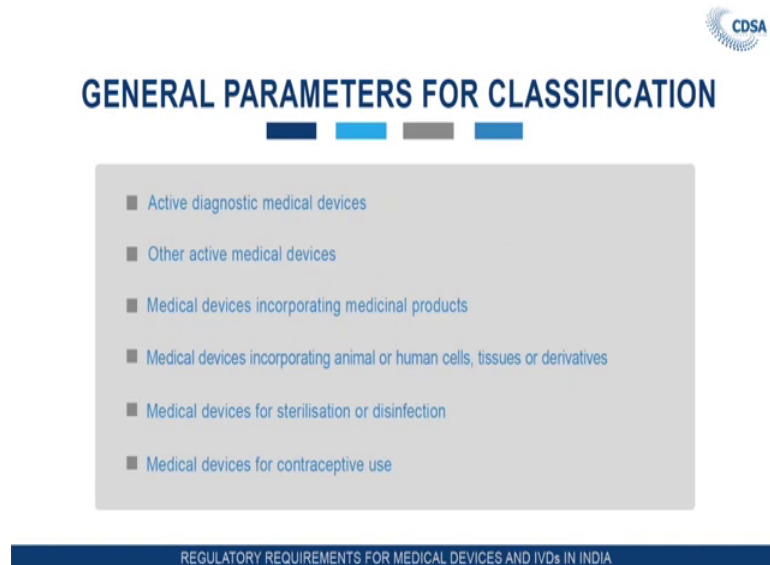
We can explain this very clearly with the help of an example. Invasive body use for transient use short not actually short term a medium term used; for instance, a catheters inserted in the human body for say 2 hours or 3 hours that is the transitive medical device in the body orifice.

The body orifice is invasive in the body orifice which punches the body orifice. A needle for short term use is your injection that will be which enters the body and remains the human body for a few seconds. And for long time use it can be use it for 15 days to 1 month or even more than that which goes it to human body. So, thee all three are define separately in the classification table. 8 is invasive body orifice medical device for connecting connection to an active medical device. Now, we have an active medical device which can be instrument, which uses are in city and active and that is connected to a human body through a body orifice. So, that becomes actually a invasive medical device for a different classification.

Surgically, invasive medical devices for transient use, short term use; the both are the surgically invasive means they have put into the human body for short term use and all long term use. Number 11 is a implantable medical devices as surgically invasive medical device for long term use. These are also for long term use you can see these medical devices being used in a continuous manner in ICUs in hospitals where, lot of devices going into the human body and remain there for long long time. So, those are

long term uses medical devices. Number 12 is an active medical devices for administering or exchanging energy.


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Number 13 is active diagnostic medical devices. This is the diagnostic part coming over here; which are also control another classification rules. Other active medical devices, medical device incorporating medicinal products which have combinational devices; there is separate presentation on that; medical devices incorporating animal or human cells, tissues of this derivatives. This is also combination medical device help them separately.

Medical devices for sterilization or disinfection, this is a bit odd man out over here. Because in India till recently, we used to consider sterilization or disinfection material to be drugs. For instance, in a common (Refer Time: 20:58) we can say Dettol or Savlon (Refer Time: 20:59) but the new regulations, they are medical devices; of course, internationally they are medical devices; so, two or three fall different category all together. And the next one is the medical devices for contraceptive use; that is your may be condoms copper T and all those things.

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GENERAL PARAMETERS FOR CLASSIFICATION

■ ■ ■ ■

A useful set of rules have been devised for classification of medical devices by GHTF.

Going step by step in the rules makes it easy for defining a device class.


This includes all aspects of devices like active device.

Suggested to further reading: <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n15-2006-guidance-classification-060627.pdf>

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

A useful set of rules have been devised for classification of medical devices by GHTF. You can go through GHTF website and find that out; its very simple, very easy; it gives step by step. How to make it easy for defining a device class? This includes all aspects of such devices like active devices etcetera etcetera. And I will get a link at the bottom which is for suggested to further GHTF PDF for that.

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GENERAL PARAMETERS FOR CLASSIFICATION

■ ■ ■ ■

The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

The risk presented by a device also depends, in part, on its intended user/users, its mode of operation, and/or technologies. In general, the classification rules are intended to accommodate new technologies.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The risk presented by a particular device depends substantially on its intended purpose and the effectiveness of the risk management techniques applied during design, manufacture and use.

So, the risk presented by device also depends, in part, on its intended users, its mode of operation and our technologies. In general the classification rules are intended to accommodate new technologies. So, classification rules are extremely essential and useful for classifying a device and without the classification rules you cannot classify a medical device at all. So, I suggest that you go to the classification rules in details to understand, how they are classified.

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The slide features the CDSA logo in the top right corner. The main title is 'GENERAL PARAMETERS FOR CLASSIFICATION', centered and underlined with four colored bars (dark blue, light blue, grey, dark blue). Below the title are two grey text boxes. The first box contains the text: 'It is essential that medical devices be classified for proper control. Regulating medical devices by name is risky and cumbersome for both the regulator and the industry.' The second box contains: 'Classification of medical device is an international norm being gradually accepted by all nations.' At the bottom, a dark blue footer bar contains the text: 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

It is essential the medical devices be classified for proper control. Regulating medical devices by name is risky and cumbersome for both the regulator and the industry. Classification on medical device is an international norm gradually accepted by all nations. So, classification of medical devices is not country specific its internationally accepted.

So, any medical device which is a class A medical device, D medical device sold in one country. We know what class is? What the risk associated with that in any other country also? So, instead of having a name of the medical device and its use; classification gives the general picture of the type of medical device it is.

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HEALTH CANADA DOCUMENTS

Useful guide for industry

Regulators guide

Starting reference point

Can merge with existing guidelines

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, I here at the end, I would like you to; I suggest you to go through this documentary as a documents available in the world also. In other regulatory (Refer Time: 23:12) Australia has got also. Where health Canada has certain documents which is very very useful for the industry and anybody who likes to know odd classification classified medical devices. As a starting point you can uses can merge with a existing guideline (Refer Time: 23:27)

(Refer Slide Time: 23:28)

HEALTH CANADA DOCUMENTS

GUIDANCE DOCUMENT

Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs)

Published by authority of the
Minister of Health


Date Adopted	2015/04/23
Effective Date	2015/06/12

Health Products and Food Branch

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

to go through the classification rules and then, fall into the particular bracket which make and combustion.

(Refer Slide Time: 24:16)



RECAP

- 1** Which Class of medical devices the riskiest of all?

Class D medical devices are the riskiest while Class A are least risky.
- 2** Are medical devices tested destructively?

Medical devices are usually not destructively tested but quality is built into them.
- 3** What is the equivalent of GMP used in the manufacture of medical devices?

QMS or quality management system is used in place of GMP in the manufacture of medical devices.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, some of the question and answer over are over here, very simple one; however, you will be getting much more question and answers. You have to submit later on for assessment. Thank you very much; this is the end of that.

Welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India. This is add on lecture 2, 3; that is the Classification of the Medical Devices. This lecture already we have discuss in detail, previously. So, this is continuation to the earlier lecture which we have discuss in detail.

(Refer Slide Time: 25:06)



TOPICS COVERED IN LECTURE 3B

- Why the classification of device is required?
- What is risk based classification?
- How classification is done globally?
- Principles for classification of medical device & diagnostic
- Chart for how classification is done in major countries
- Responsibilities of authorities under MDR, 2017

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

In this lecture we have discussed that, why the classification of the devices is required? We have also discuss that, what is the risk based classification? How the classification is done globally? What criteria for classification of the medical devices in different countries?

The principles for classification of medical devices and diagnostics, we have also discuss that; also we have discuss the classification of the major country. What classification they have made and how they have done that classification?

We have discussed that classification of the GHTF, classification of Health Canada. We have discuss the classification of PMDA that is Japan; we have also discussed the classification of the Australia, TG Australia. We have also discussed the classification of the USFDA. And also in our country, what classification we have made? That we have discussed in the earlier lecture 3 classification of the medical devices; also in that lecture we have covered the responsibility of the authorities under the Medical Device Rules, 2017.

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RESPONSIBILITIES OF REGULATORY AUTHORITIES

Device Class	Class A	Class B	Class C	Class D
Import	CDSCO	CDSCO	CDSCO	CDSCO
Manufacture	SLA	SLA	CDSCO	CDSCO
Permission to conduct clinical investigation	Permission from CDSCO			
Sale	SLA			
Qms verification by	Notified bodies	Notified bodies	CLA	CLA
<small>Note: Notified bodies shall be registered with CDSCO and shall be audited by CDSCO.</small>				

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The responsibility of the authorities that is given in the medical device rule based on the risk of the classes. We discuss that class A and class B devices that is the low risk devices. The responsibility for different activity had been described in the Medical Device Rules, 2017. We have discuss earlier that Kimpo, responsibility lies with the Central Licensing Authority that is CDSCO; manufacture, for grant of manufacturing licence the responsibility has been given to State Licensing Authority for class A and class B devices; for Central Licensing Authority class C and class D. The permission to conduct the clinical investigation, permission from CDSCO is required.

CDSCO is the Central Licensing Authority. So, permission for all classes of the devices, if clinical investigation or clinical evaluation is required to be obtained the licenses permission is issued by the Central Licensing Authority. Responsibility of the sale and distribution of the medical devices and in vitro diagnostic; responsibilities given to the State Licensing Authority; Qms verification for class A and class B devices; the provisions for audit of notified body has been made. Notified body will audit the promises of the class A and class B medical devices. They will confirm the quality management system as prescribed in the fifth schedule of the medical device rule.


It is mandatory for all type, all class A and class B devices; Qms compliance by notified body is mandatory; however, for class A devices the prior audit or inspection by the notified body has not required. Was the licence is submitted to the State Licensing

Authority? The State Licensing Authority is responsible for grant of manufacturing license; however, the Qms audit and verification will be carried out by the notified body.

So, for class A medical devices, the Qms verification will be done after issuance of the import license; sorry, after issuance of the manufacturing license and class B devices prior audit is required. Before grant of the license Qms audit is to be carried out. Timeline has been clearly prescribed in the rules, the satisfactory compliance of the Qms requirement and other relevant document as we have discussed in the previous lectures.

These State Licensing Authority shall grant manufacturing license to the manufacturer for manufacturing of class A and Class B devices. So, the Qms verification is mandatory for class A and class B devices; it is not a optional. For class C and class D, Qms verification will be done by the Central Licensing Authority and based on the satisfactory report and other required, other requisite information review by the Central Licensing Authority found satisfactory. Then license will be granted. So, this is the responsibility given in the Medical Device Rules, 2017 for State Licensing Authority and for the Central Licensing Authority.

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MEDICAL DEVICE RULES, 2017

Rule 4 under Chapter II of MDR, 2017 has provision for classification of medical devices:

- Medical devices other than *in vitro* diagnostic medical devices shall be classified on the basis of parameters specified in Part I of the first schedule, in the following classes, namely:
 - Low risk- Class A
 - Low moderate risk- Class B
 - Moderate high risk- Class C
 - High risk- Class D

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, in the classification of the medical devices although, this part we have discuss in earlier lecture, but under Medical Device Rule, 2017 the provision for classification of the medical devices has been made in chapter 2. We have also discuss in the previous slides and previous lecture also; the medical device rules have 12 chapters and 8

schedules; out of 12 the chapter 2 which has the, chapter 2 gives the provision for classification of the medical devices.

Under chapter 2, rule 4 that gives the provision for classification under this rule medical devices other than in vitro diagnostic shall be classified on the basis of parameter is specified in part I of the first schedule. The classification shall be done based on the risk. And following classes that is low risk to high risk classes; devices has to be done by the Centre Licensing Authority, where the low risk devices that is class A devices; low to moderate risk devices that is classified as a B class, class B devices moderate to high risk class C. High risk devices will be classified as a class D devices.

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MEDICAL DEVICE RULES, 2017

Rule 4 under chapter II of MDR, 2017 has provision for classification of medical devices:

- *In vitro* diagnostic medical devices shall be classified on the basis of parameters specified in Part II of the first schedule, in the following classes, namely:
 - Low risk- Class A
 - Low moderate risk- Class B
 - Moderate high risk- Class C
 - High risk- Class D
- The Central Licensing Authority shall classify medical devices referred in rule 2, based on the intended use of the device and other parameters specified in the first schedule.
- Based on the classification, class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organisation.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

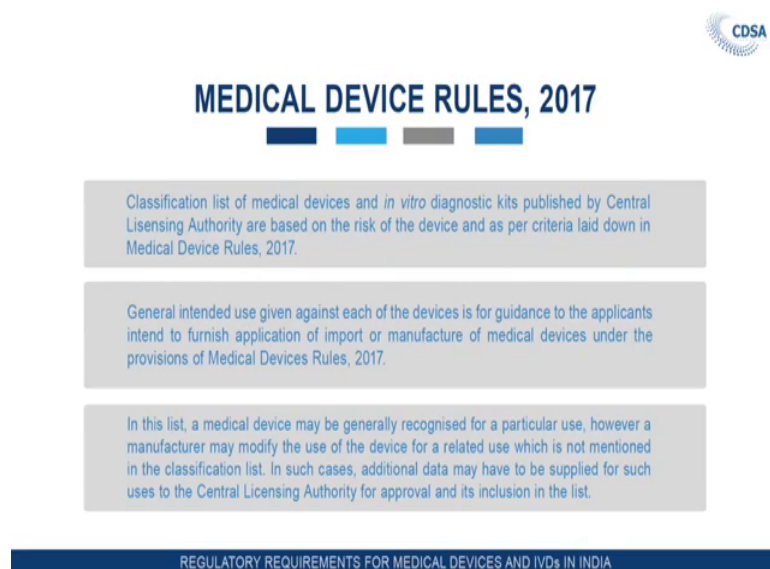
Likewise, in vitro diagnostic kits shall also be classified on the basis of parameter is specified in part II of the first schedule. In the following classes, low risk to high risk classes, low risk class A devices; low to moderate class B devices; moderate to high risk class C; high risk to high risk devices class D devices. So, this provision have been made in the Medical Device Rule, 2017 and the Central Licensing Authority shall classify the medical devices refer to in rule 2.

Rule 2, where the medical devices which are regulated under the Medical Device Rule, 2017 has been given. So, the medical devices which are presently regulated under the Medical Device Rule, 2017 shall be classified by the Center Licensing Authority based on the intended use of the devices, their potential risk and other parameters specified in

the first schedule. Schedule also we have discuss in the earlier lectures; first schedules gives the details criteria, parameters principles of the classification.

Part I of the first schedule gives the details, detail parameter and criteria for classification of the medical devices. Part II of the first schedule gives the principles and criteria for classification of the in vitro diagnostic kits. Based on the classification as per the first schedule of the medical device rule, Central Licensing Authority self published the classification list for the manufacturers, for the importers.

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The slide features the CDSA logo in the top right corner. The main title is "MEDICAL DEVICE RULES, 2017" in bold blue text, centered. Below the title are four colored bars (dark blue, light blue, grey, dark blue). Three light grey text boxes are stacked vertically, each containing a paragraph of text. At the bottom, a dark blue bar contains the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA" in white capital letters.

Classification list of medical devices and *in vitro* diagnostic kits published by Central Licensing Authority are based on the risk of the device and as per criteria laid down in Medical Device Rules, 2017.

General intended use given against each of the devices is for guidance to the applicants intend to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017.

In this list, a medical device may be generally recognised for a particular use, however a manufacturer may modify the use of the device for a related use which is not mentioned in the classification list. In such cases, additional data may have to be supplied for such uses to the Central Licensing Authority for approval and its inclusion in the list.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

And based on the classification, the importer or manufacturer shall submit their application to the authority for grant of import or manufacturing licence for marketing their product into their country. We have also discussed that classification list of the medical devices and in vitro diagnostic kits have been published by, have been published and it is uploaded on the website of Central Licensing Authority that is CDSCO.

This classification list has been published based on the risk of the devices. This classification list is for guidance to the applicant intend to furnish, application to the Central Licensing Authority or the State Licensing Authority for import or manufacture of the medical devices under the provisions of Medical Device Rules, 2017.


In this list devices may be generally recognized for a particular use; however, the manufacture may modify the use of the devices. For the related use which is not mention

in the classification list in such cases additional data may have to be submitted to the Central Licensing Authority for consideration and approval. And once it is approved by the Central Licensing Authority it is included in the sad classification list.

So, this classification list whatever that Centre Licensing Authority that classification list is only applicable for the devices which has been classified under the classification list. And based on the classification of the medical devices the applicant shall be submitted application to the concerned authority for grant of import or manufacturing licence. So, here in India, this it is not the case the manufacture can classify their devices based on the criteria mention the medical device rules; to have the uniformity in throughout the country, this decision has been made by the ministry of Health and Family Welfare.

And to have the harmonized classification for the medical devices in the country, throughout the country this classification list has been published.

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MEDICAL DEVICE RULES, 2017

The component and accessories to a medical device or *in vitro* diagnostic medical devices has been classified separately. However, the component is classified generally and placed in the same class as the principle device.

It is also recognised that some of the medical devices or *in vitro* diagnostic medical devices may have **dual use** and they may be classified accordingly.


This list is **dynamic** and is subject to revision from time to time under the provisions of the Medical Device Rules, 2017.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

In this classification list also we have discussed the component and accessory to the medical devices or in vitro diagnostic kits has been classified separately; however, the component is classified generally and placed in the same class as the principal devices. It is also recognize that some of the medical devices and in vitro diagnostic may have dual use and they may be classified accordingly.

This list is dynamic. So, from time to time this based on the review of the documents. The Central Licensing Authority may review the classification list and make certain changes based on the documents, based on the evidence. And they can again publish; they can again update the classification list.

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MEDICAL DEVICE RULES, 2017

Classification List- (A) List of medical devices (MDs) under provisions of sub rule (1) Rule 4 of the Medical Devices Rules, 2017- Total 379 MDs.

Classification List- (B) List of *in vitro* diagnostics medical device under provisions of sub rule (2) Rule 4 of the Medical Devices Rules, 2017- Total 247 numbers.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

In the classification list published by the Central Licensing Authority, part I that is the classification of the medical devices have been made under this classification. So, for 379, different medical devices has been classified. 379 Medical Devices, which are presently regulated under the Medical Device Rules, 2017. These includes all the categories of the medical devices; which are presently under regulation.

In this detail list, we have discussed in the previous lecture. Classification list for *in vitro* diagnostic kits, the part B of the classification list gives the details about the classification of the *in vitro* diagnostics. And total 247 types of the *in vitro* diagnostic kits have been classified. So, this is all about the classification.

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SUMMARY

In Lecture 3 (L3B), we briefly learned about:

- Why the classification of device is required?
- Parameters of classification?
- Classification of major countries.
- Principles for classification of medical device & diagnostic.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, in the classification of the earlier lecture and this adobe lecture, we have discuss, why the classification of the device is required? Parameter for the classification? What classification have applicable in the major country; the principles of the classification in medical devices.

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SUMMARY

In Lecture 3 (L3B), we briefly learned about:

- Chart for how classification is done in major countries.
- Provision of classification of medical devices in MDR.
- Classification list published by CLA.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

How classification is done in other countries? Provisions of the classification of the medical devices in Medical Device Rule, 2017 and the classification list published by the Center Licensing Authority; so, by this way we have come to the conclusion. In this

classification based on the risk of the medical devices; their intended use have been done in India also. This classification is criteria is in the line of the globally accepted, criteria for classification of the medical devices and in vitro diagnostics. So, other chapter of the medical devices regulation we will cover in the next lecture; with this I would conclude this lecture.

Thank you very much.