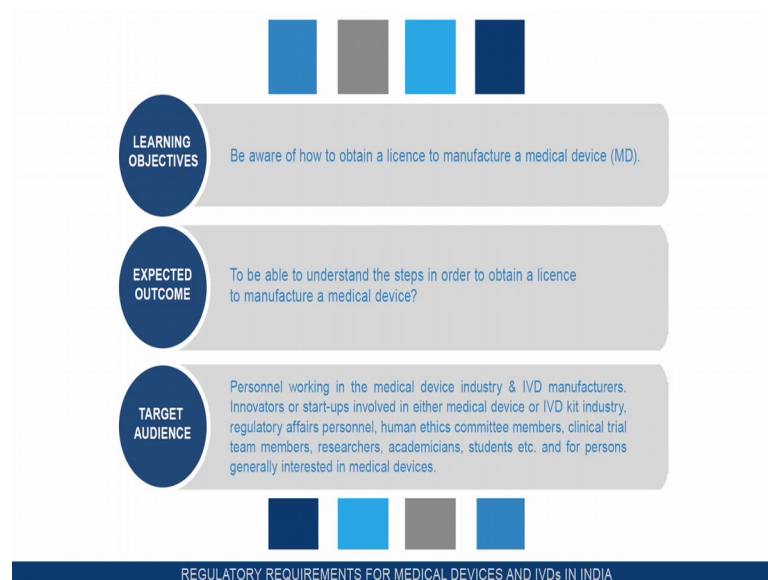


Regulatory Requirements for Medical Devices and IVDs in India
Prof. Aseem Sahu
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Department of Higher, Ministry of human Resources Development, Government of India

Lecture – 10
How to Obtain a Licence to Manufacture a Medical Device?

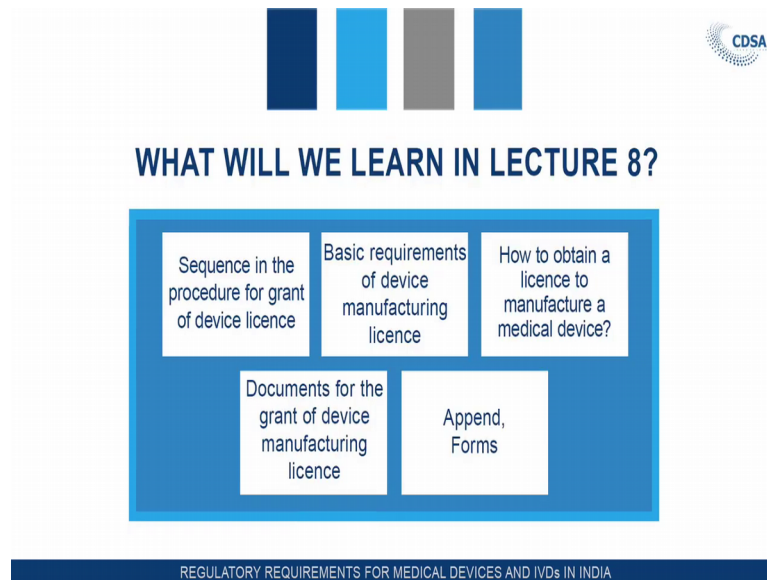
Welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India lecture 8 that is How to Obtain a Licence to Manufacture a Medical Devices and In Vitro Diagnostics?

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Now, learning objective of this lecture be aware of how to obtain a licence to manufacture medical devices and in vitro diagnostics. Expected outcome able to understand the steps need to obtain a licence to manufacture a devices or in vitro diagnostics. Target audience personnel working in the medical device industry in vitro diagnostic manufacturers, innovator, startups involved in either medical devices or in vitro diagnostic kit industry. Regulatory affairs personal, human ethics committee member, clinical trial team member, researcher, academician, students and the person generally interested in medical devices.

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What will we learn in the lecture 8? We will learn how to obtain a licence to manufacture in medical devices and in vitro diagnostics. The sequence in the procedure for grant of device licence. Basic requirement of manufacturing licence forms. What are the forms applicable for grant of manufacturing licence? Technical documents; technical documents required for grant of manufacturing licence. So, how to obtain a licence to manufacture in medical devices?

(Refer Slide Time: 01:40)



Any product that is controlled by Drugs and Cosmetic Act and Rules, as a drug, need a licence to manufacture. Why licence is required? Because to keep a control on the product to maintain the product efficacy safety and the quality.

To avoid duplicate and therefore, harmful product away. Keep track of the products moving in the market. Keep consistence in the manufacturing of the product. To have all those criteria the licence is required and through the licence we can control this.

(Refer Slide Time: 02:13)

The slide features a title in bold blue text: "HOW TO OBTAIN A LICENCE TO MANUFACTURE A MEDICAL DEVICE?". Below the title is a decorative bar with four colored segments: dark blue, light blue, grey, and medium blue. A CDSA logo is in the top right corner. The main text reads: "Now that we know medical devices are 'drugs', we need to obtain a license to manufacture them." Below this is a dark blue button with the text "Let us now unravel the following aspects:". Underneath are four light grey buttons with blue text: "Who issues the licence?", "To obtain a licence who do you approach?", "What is the procedure followed to obtain a licence?", and "To obtain a licence how do you approach?". At the bottom is a dark blue footer bar with the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA".

HOW TO OBTAIN A LICENCE TO MANUFACTURE A MEDICAL DEVICE?

Now that we know medical devices are 'drugs', we need to obtain a license to manufacture them.

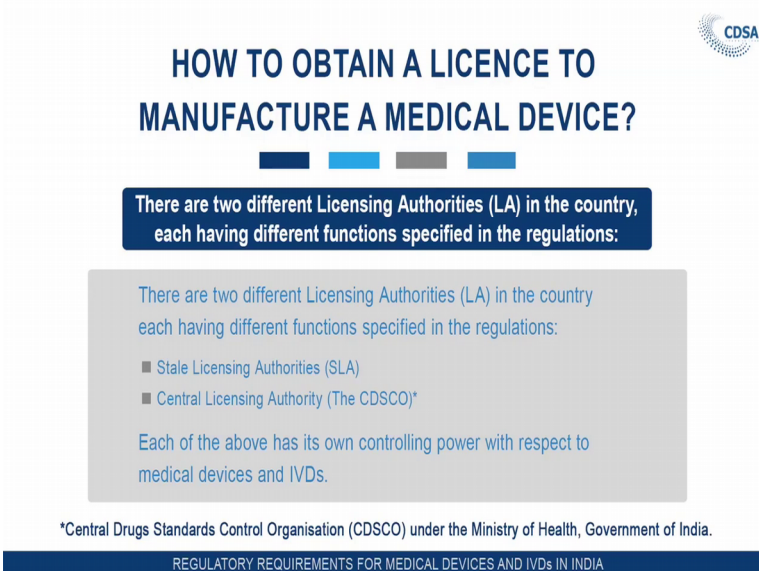
Let us now unravel the following aspects:

- Who issues the licence?
- To obtain a licence who do you approach?
- What is the procedure followed to obtain a licence?
- To obtain a licence how do you approach?

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

How to obtain a licence to manufacture medical devices? Now that we know medical devices are drug and the drugs which are regulated under the Drugs and Cosmetic Act and Rules, there under licence is required. Let us now unravel the following aspects; who issues the licence? To obtain a licence who do you approach? How is the procedure to obtain a licence or to obtain a licence how do you approach?

(Refer Slide Time: 02:41)



HOW TO OBTAIN A LICENCE TO MANUFACTURE A MEDICAL DEVICE?

There are two different Licensing Authorities (LA) in the country, each having different functions specified in the regulations:

- State Licensing Authorities (SLA)
- Central Licensing Authority (The CDSCO)*


Each of the above has its own controlling power with respect to medical devices and IVDs.

*Central Drugs Standards Control Organisation (CDSCO) under the Ministry of Health, Government of India.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

No in the Medical Device Rules we have discuss the authorities, authority is responsible for grant of manufacturing licence. The State Licensing Authority and the Central Licensing Authority two authorities they are responsible for grant of manufacturing licence of the medical devices and in vitro diagnostics. The controlling power of each authority has been prescribed in the medical device rule 2017.

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LICENSING AUTHORITIES WITH RESPECT TO THE TYPE OF MEDICAL DEVICES AND IVDS THAT THEY REGULATE

Device class activity	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

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

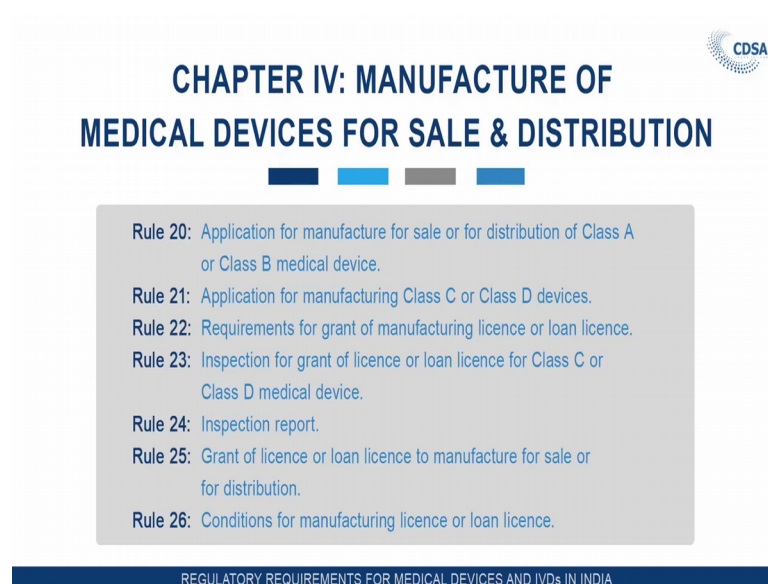
REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Also we have discuss that for which class of the medical devices, who are the authorities? For manufacturing State Licensing Authority is responsible for grant of

manufacturing licence for class A and class B devices. And the Central Licensing Authority that is CDSCO is responsible for grant of manufacturing licence of class C and class E devices.

In case of Qms verification, Qms audit for class A and class B we discussed many time that notified body is responsible for Qms verification of the class A and class B medical device manufacturing unit. And the Central Licensing Authority they are responsible for Qms inspection of class C and class D devices. Notified body who are the notified body is responsible for Qms verification of the class A and class B devices. The notified body which is registered with the Central Licensing Authority, they are only the responsible for Qms verification of the class A and class B devices.

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Now, the rules which rules deals with the grant of manufacturing licence of the medical devices and in vitro diagnostics. Which chapters have the provision for manufacturing of the medical devices? We have discussed in the Medical Device Rule 2017 where the total 12 chapters have been incorporated and 96 rules are there.

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CHAPTER IV: MANUFACTURE OF MEDICAL DEVICES FOR SALE & DISTRIBUTION

- Rule 27: Change in constitution
- Rule 28: Unannounced inspection by State Licensing Authority
- Rule 29: Validity of licence
- Rule 30: Suspension and cancellation of licence
- Rule 31: Test licence to manufacture for test, evaluation, clinical investigations, etc.
- Rule 32: Conditions of test licence to manufacture for test, evaluation, clinical investigations, etc.
- Rule 33: Cancellation of test licence to manufacture for test, evaluation, clinical investigations, etc.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, chapter 4 of the medical device rules gives the provisions for grant of manufacturing licence for medical devices and in vitro diagnostics under this chapters different rules are there for different purpose rule 20 to rule 33 have given for each of the different types of manufacturing licence we will discuss one by one this rules.

(Refer Slide Time: 04:58)

RULE 20

Application for manufacture for sale or for distribution of Class A or Class B medical device

Any person who intends to manufacture a Class A or Class B MD/IVD shall make an application (in Form MD-3) for grant of licence or (in Form MD-4) loan licence through an online portal to manufacture for sale to the State Licensing Authority.

The application shall be accompanied with a fee, as specified in the Second Schedule along with respective documents as specified in Part II of the Fourth Schedule.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Come to rule 20, the rule 20 that is application for manufacture of sale or for distribution of class A and class B medical devices. Under this rule any person who intends to manufacture a class A or class B medical devices or in vitro diagnostic, shall make

application in MD 3 for grant of licence or in MD 4 that is loan licence through an online portal to the Central Licensing Authority.

And when apply for grant of manufacturing licence or loan licence through this portal this licence will be diverted to the concerned State Licensing Authority who is responsible for grant of licence. The application shall be accompanied with a fees, as specified in the second schedule we have also discuss that what is second schedule?

Second schedules is the fees details of the fees required to be submitted for different activity. So, for manufacturing what rules required to be submitted for different types of classes it is prescribe in the second schedule. As per the second schedule the applicant has to submit the requisite fees and also the requisite document the technical document which is required to be submitted for grant of manufacturing licence that details has been given in the part II of the fourth schedule.

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The slide is titled 'RULE 20' and is part of a presentation from CDSA (Central Drug Standards Authority). It outlines the requirements for an application for manufacture for sale or for distribution of Class A or Class B medical devices. The slide is divided into two main sections: the first section states that the application must be accompanied by an undertaking to the effect that the requirements of QMS as specified in the Fifth Schedule have been complied with. The second section states that the State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a licence to manufacture Class A medical devices in Form MD-5 or loan licence in Form MD-6, within forty five days from the date. The slide is part of a larger presentation titled 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

RULE 20

Application for manufacture for sale or for distribution of Class A or Class B medical device

The application be accompanied with an undertaking to the effect that the requirements of QMS as specified in the Fifth Schedule have been complied with.

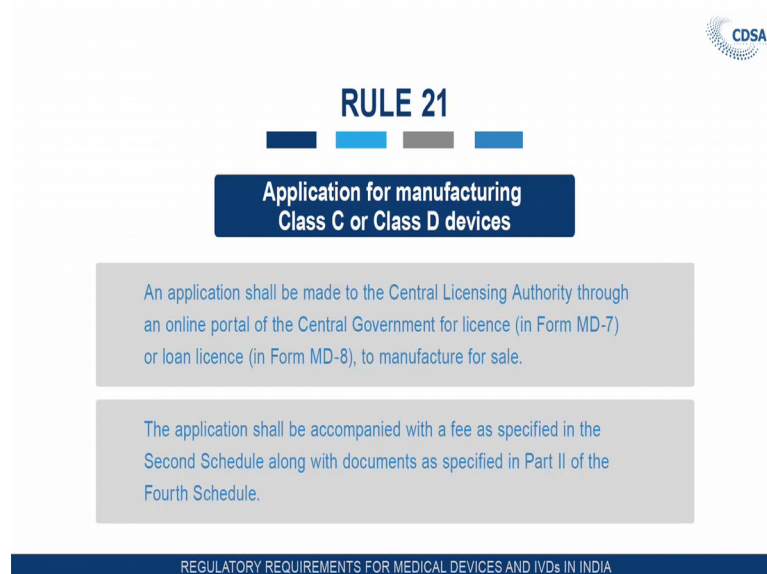
The State Licensing Authority shall, after scrutiny of documents and on being satisfied that the requirements of these rules have been complied with, grant a licence to manufacture Class A medical devices in Form MD-5 or loan licence in Form MD-6, within forty five days from the date.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The application shall be accompanied with an undertaking to effect that the requirement of quality management system as specified in the fifth schedule have been complied with. The applicant has to given the has to submit this undertaking (Refer Time: 06:40) they are fulfilling the requirement of quality management system as specified in the fifth schedule. The State Licensing Authority who is responsible for grant of manufacturing licence. Review the applications and after being satisfied the requirement under this rules

they will grant the licence to manufacture class A medical devices in MD 5 or loan licence in MD 6, within forty days from the date of receipt of the application.

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RULE 21

Application for manufacturing Class C or Class D devices

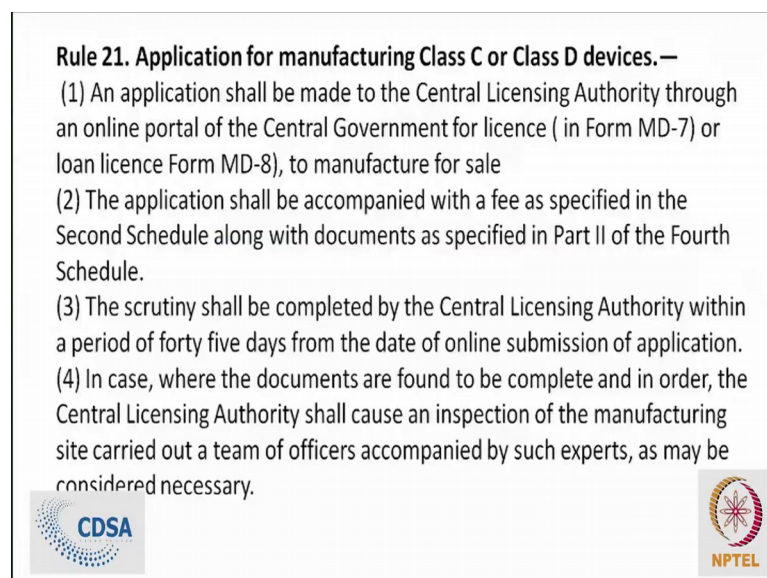
An application shall be made to the Central Licensing Authority through an online portal of the Central Government for licence (in Form MD-7) or loan licence (in Form MD-8), to manufacture for sale.

The application shall be accompanied with a fee as specified in the Second Schedule along with documents as specified in Part II of the Fourth Schedule.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 21 that is application for manufacturing of class C and class D devices. Here an application shall be made to the Central Licensing Authority through an online portal for grant of licence to manufacture or grant of loan licence, to manufacture the medical devices and in vitro diagnostics.

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Rule 21. Application for manufacturing Class C or Class D devices.—

(1) An application shall be made to the Central Licensing Authority through an online portal of the Central Government for licence (in Form MD-7) or loan licence Form MD-8), to manufacture for sale

(2) The application shall be accompanied with a fee as specified in the Second Schedule along with documents as specified in Part II of the Fourth Schedule.

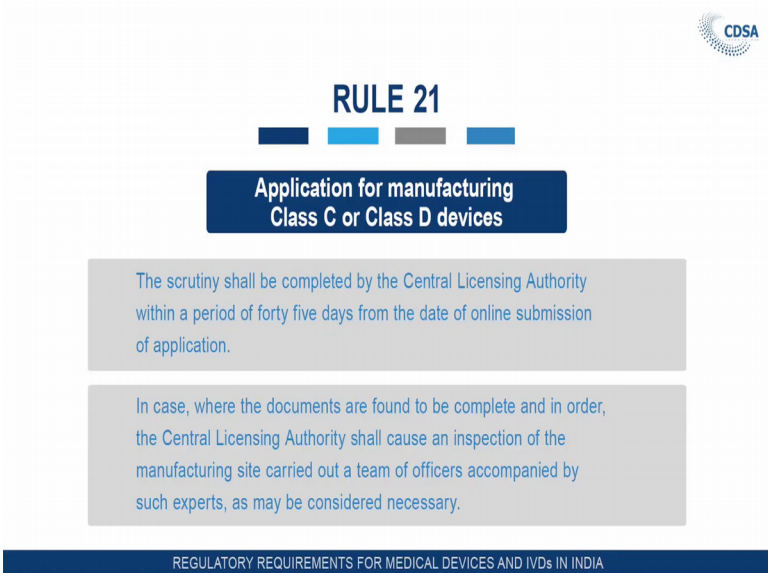
(3) The scrutiny shall be completed by the Central Licensing Authority within a period of forty five days from the date of online submission of application.

(4) In case, where the documents are found to be complete and in order, the Central Licensing Authority shall cause an inspection of the manufacturing site carried out a team of officers accompanied by such experts, as may be considered necessary.

CDSA NPTEL

The application shall be accompanied with the fees, fees as a specified in the second schedule and also the technical documents as a specified in the part II of the fourth schedule.

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RULE 21

Application for manufacturing Class C or Class D devices

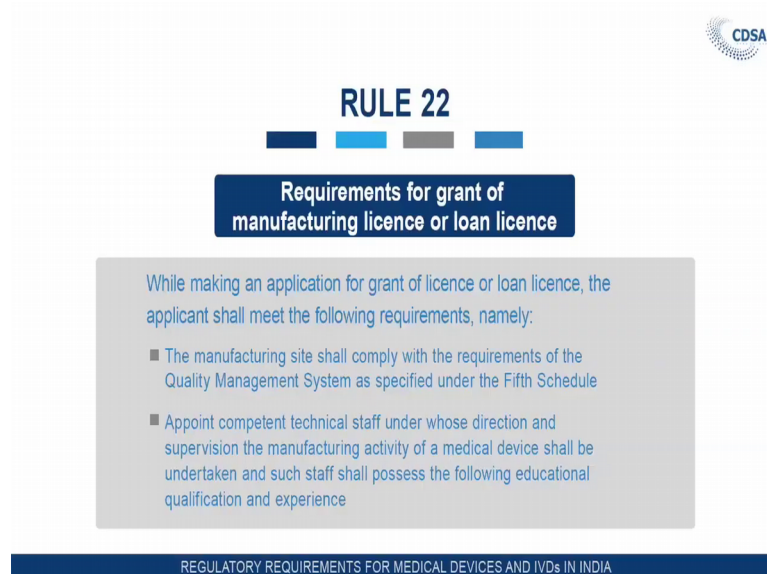
The scrutiny shall be completed by the Central Licensing Authority within a period of forty five days from the date of online submission of application.

In case, where the documents are found to be complete and in order, the Central Licensing Authority shall cause an inspection of the manufacturing site carried out a team of officers accompanied by such experts, as may be considered necessary.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The scrutiny shall be completed by the Central Licensing Authority within a period of forty five days through online only. And where the documents are found to be complete and in order the Central Licensing Authority shall cause an infection inspection of the manufacturing site. The inspection will be carried out by a team of the officer accompanied by an expert if necessary the experts maybe co opted for integration of for inspection of the manufacturing site of the class C or class D devices.

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RULE 22

Requirements for grant of manufacturing licence or loan licence

While making an application for grant of licence or loan licence, the applicant shall meet the following requirements, namely:

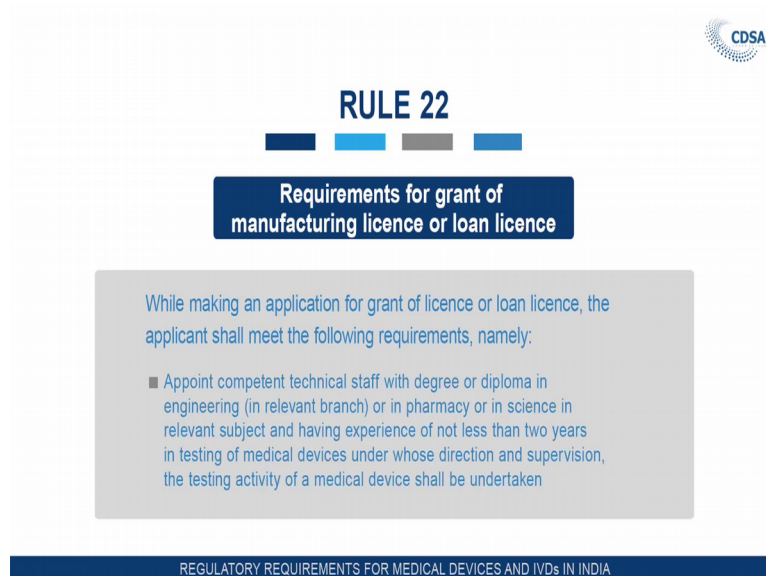
- The manufacturing site shall comply with the requirements of the Quality Management System as specified under the Fifth Schedule
- Appoint competent technical staff under whose direction and supervision the manufacturing activity of a medical device shall be undertaken and such staff shall possess the following educational qualification and experience

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 22, that is the requirement for grant of manufacturing licence or loan licence. While making the application for grant of licence or loan licence, applicant shall meet the following requirements, what are those requirement? The site shall comply with the requirement of the quality management system and undertaking in this regard as to be submitted by the applicant.

The manufacturer has to appoint competent technical staff under whose direction and supervision. The manufacturing activity of the medical devices shall be undertaken and such staff shall possess the requisite qualification as a specified with the medical device rule 2017.

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RULE 22

Requirements for grant of manufacturing licence or loan licence

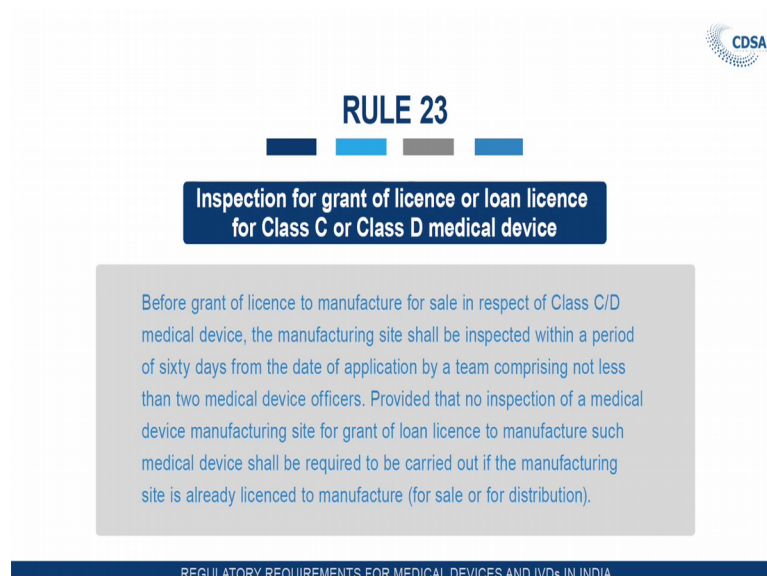
While making an application for grant of licence or loan licence, the applicant shall meet the following requirements, namely:

- Appoint competent technical staff with degree or diploma in engineering (in relevant branch) or in pharmacy or in science in relevant subject and having experience of not less than two years in testing of medical devices under whose direction and supervision, the testing activity of a medical device shall be undertaken

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The person should have bachelor degree in engineering or the pharmacy of the relevant field with minimum 2 years of experience that is given in the medical device rule 2017. Also the manufacturer has to appoint competent technical staff with degree in diploma or engineering or in the pharmacy or science or in relevant areas with the experience of two years in the testing of the medical devices. And in vitro diagnostic was direction and supervision the testing activity of the premises is carried out.

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RULE 23

Inspection for grant of licence or loan licence for Class C or Class D medical device

Before grant of licence to manufacture for sale in respect of Class C/D medical device, the manufacturing site shall be inspected within a period of sixty days from the date of application by a team comprising not less than two medical device officers. Provided that no inspection of a medical device manufacturing site for grant of loan licence to manufacture such medical device shall be required to be carried out if the manufacturing site is already licenced to manufacture (for sale or for distribution).

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 23; that is inspection of grant of licence or loan licence for class C and class D devices. Before grant of licence to manufacture for sale in distribution of the medical devices, in respect of class C and class D. The manufacturing site shall be inspected within a period of sixteen days the time line has been given in the medical device rule and this inspection will be carried out by a team comprising of not less than two medical device officer.

However, no inspection for the medical device manufacturing site for grant of loan licence is required. If the manufacturing site is already licence to manufacture such medical devices for sale and distribution. This provision we have paid to avoid unnecessary repetition of the inspection. If the facilities already inspected earlier and they have complied with the Qms as specified in the fifth schedule at the time of grant of no licence by the uniform, no further inspection generally required to be carried out.

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The slide features the CDSA logo in the top right corner. The title 'RULE 24' is centered in a large, bold, blue font, with a decorative bar of four colored segments (dark blue, light blue, grey, and dark blue) below it. Underneath this is a dark blue rectangular box containing the text 'Inspection report' in white. The main content is a light grey box with a blue border, containing a paragraph of text. At the bottom, a dark blue footer bar contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA' in white.

RULE 24

Inspection report

After completion of inspection, the inspection team shall forward a descriptive report containing findings on each aspect of inspection along with the recommendations to the Central Licensing Authority, through online portal and forward a copy of the same to the applicant.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The inspection report after completion of the inspection, the inspection team shall forward the descriptive report containing the findings of the inspection and their recommendation they have to submit to the Central Licensing Authority through online portal and also forward a copy of the same to the applicant.

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The slide features the CDSA logo in the top right corner. The title 'RULE 25' is centered at the top. Below it is a blue box with the text 'Grant of licence or loan licence to manufacture for sale or for distribution'. Two text boxes follow: the first explains the conditions for granting a licence or loan licence, and the second specifies requirements for investigational and new in vitro diagnostic medical devices. A footer bar at the bottom reads 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

RULE 25

Grant of licence or loan licence to manufacture for sale or for distribution

If the Central Licensing Authority, after receipt of the report is satisfied that the requirements of these rules have been complied, that authority shall grant a licence in Form MD-9, or loan licence in Form MD-10 or may reject the application for reasons to be recorded in writing, within a period of forty five days from the date the inspection report has been received.

In case of investigational medical device or new in vitro diagnostic medical device, the applicant shall obtain prior permission in Form MD-27 or Form MD-29 from the Central Licensing Authority and no licence to manufacture any class of such medical device shall be granted without such permission.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 25, that is the grant of licence or loan licence to manufacture for sale or distribution of medical devices. If the Central Licensing Authority, after receipt of the satisfied report and the document as required under forth schedule of the medical device rule 2017. If the documents and inspection reports for satisfactory by the Central Licensing Authority. The licence shall be granted inform MD 9 or the loan licence in form MD 10.

The Central Licensing Authority may also reject the application for the reason to be recorded in writing within a of forty five days, from the date of inspection of the report. If certain measure non compliances were observed by the Central Licensing Authority. In case of the investigational medical devices or new in vitro medical devices, the applicant shall obtain prior permission in form 27 or form 29 from the Central Licensing Authority and no licence to manufacture any class of such devices shall be granted without such permission.

The applicant as to establish the safety and performance of the devices which falls under the investigational medical devices or if it is a new in vitro diagnostic. After obtaining the permission they will applied to the Central Licensing Authority for grant of manufacturing licence or loan licence in form MD 9 or MD 10.

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RULE 26

Conditions for manufacturing licence or loan licence

After grant of licence or loan licence in Form MD-5, Form MD-6, Form MD-9 or MD-10, as the case may be, the licence holder shall comply with all the conditions.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now rule 26, rule 26 gives the conditions of the licence, manufacturing licence or loan licence. After grant of the licence or the loan licence in form 5 or form MD 6 or form MD 9 or form MD 10, as may be case the licence holder shall comply with the conditions.

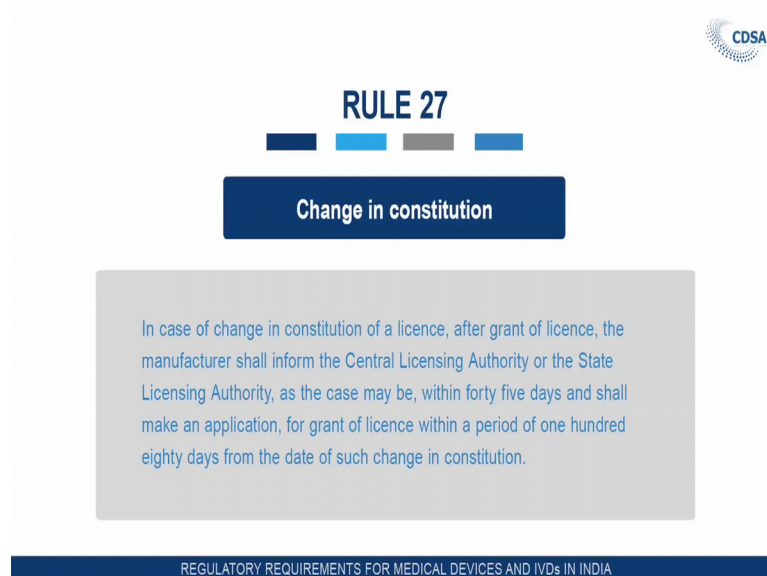
The conditions of the licences is mention in the rule 26 certain condition like the licence holder as to produce the licence before the medical device officer or the Central Licensing Authority. In case they wish to examine their licence for any reason they approve inform to the licensing authority, in case of any changes in the premises, in the facility, in the quality control of the manufacturing of the medical devices they have to inform to the licensing authority within a stipulated timeline for any change in the constitution of the firm.

They have to inform the licensing authority about any adverse event observed by them on their product manufactured by the manufacturer for marketing into the country they have to also inform any major changes in the manufacturing of the medical devices. If there is change in the intended use of the devices or if there is a change in the sterilization process of the devices or there is if there is a change in the material of construction of the devices.

All those changes which falls under the major category of the major changes as specified in the schedules they have to intimate to the Central Licensing Authority or the State

Licensing Authority. And for the major changes they need to obtain the prior approval, for minor changes only they have to inform by way of the notification.

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RULE 27

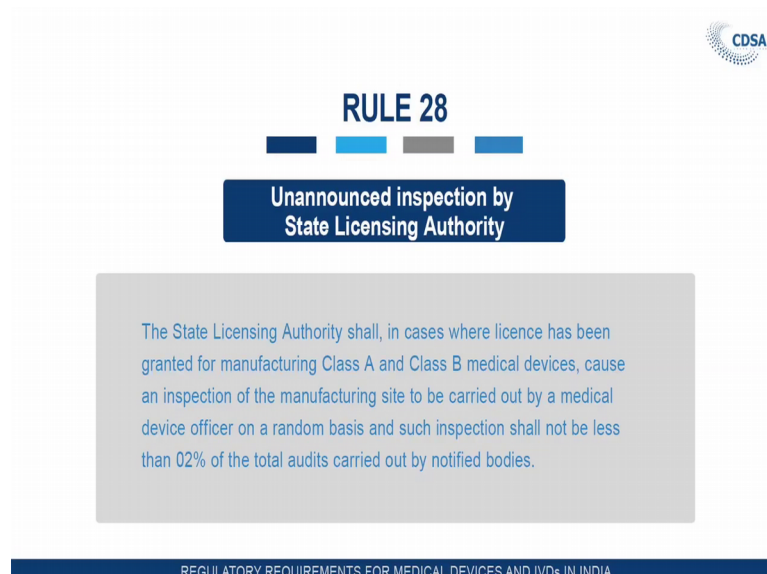
Change in constitution

In case of change in constitution of a licence, after grant of licence, the manufacturer shall inform the Central Licensing Authority or the State Licensing Authority, as the case may be, within forty five days and shall make an application, for grant of licence within a period of one hundred eighty days from the date of such change in constitution.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 27, that is change in the constitution. In case of change in the constitution of the licensing, after grant of the licence the manufacturer inform the Central Licensing or the State Licensing Authority, as the case may be within forty five days and shall make a application, for grant of licence within period of one eighty days from the date of such changes and in such cases a fresh licence is required to be obtained.

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RULE 28

Unannounced inspection by State Licensing Authority

The State Licensing Authority shall, in cases where licence has been granted for manufacturing Class A and Class B medical devices, cause an inspection of the manufacturing site to be carried out by a medical device officer on a random basis and such inspection shall not be less than 02% of the total audits carried out by notified bodies.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 28, that is unannounced inspection by the State Licensing Authority. As we have discussed earlier for the Qms verification of the class A and class B devices the State Licensing Authority shall be responsible for grant of manufacturing licence or grant of loan licence based on the Qms audit carried out by the notified body. So, under this rule that provision has been made the State Licensing Authority shall carry out the inspection of 2 percent of the site which have been frequented by the notified body for granted manufacturing licence.

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RULE 29

Validity of licence

A licence or loan licence issued in Form MD-5, Form MD-6, Form MD-9 or Form MD- 10 shall remain valid in perpetuity, subject to payment of licence retention fee as specified in the Second Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by Licensing Authority.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 29, that is the validity of the licence. A licence or loan licence issued in form MD 5, form MD 6, form MD 9 or form MD 10 shall remain valid in perpetuity, we have discussed earlier also many times. Subject to the payment of the retention fees as specified in the second schedule. At the interval of every five years from the date of its issue, then their licence will be considered in perpetuity. Till the suspension or cancellation of the licence by the licensing authority or till the withdrawn by the licensee.

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RULE 30

Suspension and cancellation of licence

Where the licence contravenes any provision of the act and these rules, the Licensing Authority, shall, after giving the licence an opportunity to show cause as to why such an order should not be passed, shall by an order and for reasons to be recorded in writing, suspend it for such period as it considers necessary either wholly or in respect of any of the medical device or cancel the licence or loan licence.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The suspension and cancellation of the licence under rule 30, that provision has been made. Where the licensee contravene any provisions of the act and these rules, the licensing authority shall after giving so cause as to why such an order should not be passed, shall by an order or for the reason to be recorded in writing, suspend it for such a period as it consider necessary either wholly or in respect of the medical devices or cancel the licence or the loan licence.

The suspension and cancellation of the licence provision have been made under this rules. Before cancellation of suspension the licensing authority shall so cause the licensee and if the proper justification is not there licensing authority may cancel or suspend the licence for the particular reason.

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RULE 31

Test licence to manufacture for test, evaluation, clinical investigations, etc.

- Small quantity of Class A/B/C/D of medical devices may be manufactured for the purpose of clinical investigations etc. or which an application shall be made in Form MD-12 to the Central Licensing Authority and shall be accompanied with a fee as specified in the Second Schedule.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 31, the provision for grant of test licence to manufacture, medical devices or in vitro diagnostics for test and evolution or clinical investigation. For a small quantity of class A class B class C and class D devices the manufacture shall obtain test licence to manufacture the test batches for the purpose of test analysis for the purpose of evaluation, for the purpose of clinical investigation or for the purpose of demonstration.

Under this test licence they will manufacture the test batches they will generate the certain data, they will generate the qc data, they will generate the safety data, they will generate the efficacy data and the data they will submit for grant of manufacturing of the particular medical devices. That provision has been made earlier this licence was issued by the State Licensing Authority. Now the Central Licensing Authority is responsible for grant of test licence for all classes of the medical devices.

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CDSA

RULE 31

Test licence to manufacture for test, evaluation, clinical investigations, etc.

- The application made shall also be accompanied with the following documents, namely:
 - Brief description of the medical device including intended use, material of construction, design and an undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices
 - List of equipment, instruments
 - List of qualified personnel

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

While submitting the application the applicant has to submit the certain formation. They have to submit the brief description of the medical devices it is intended use, material of construction, device, undertaking stating that the required facility including the equipment, instrument and the personnel have been provided to the manufacture of such medical devices. Whatever the list of the equipment or instrument is there they have to give that, they have to submit the details of the list of the qualified person, they have to submit the details of the qc parameter of that medical devices or then vitro diagnostic to be manufactured for text and analysis.

They have to submit the test method; they have to submit the specification of the product, they have to submit the layout plan of the facility all those information the applicant has to submit it along with the requisite fees to the Central Licensing Authority. And the Central Licensing Authority will grant the test licence for the purpose of test and analysis of the product.

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**BASIC REQUIREMENTS FOR APPLYING
MANUFACTURING LICENCE**

Requirements for a licence:

- Premises as per the requirement of the MDR 2017
- Equipment required for the devices to be manufactured
- Technical manpower as mentioned in the regulations
- Documentation required for activities (SOP, procedures etc.)
- Laboratory and instruments for the testing of devices and material

All the above are inspected and scrutinised during the inspection

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now basic requirement for applying the manufacturing licence. While applying the licence to the concerned State Licensing Authority or the Central Licensing Authority the manufacturer they have to fulfill the requirement as mentioned in the Medical Device Rule 2017. The facility should be in the line of quality management system as prescribe in the fifth schedule of the Medical Device Rule 2017. The equipments required for manufacturing of the particular devices to be manufactured.

The technical manpower, the documentation of the activities all the SOPs, work in sections, procedures they have to set up the laboratory and instruments for testing of the devices and materials. All these facility are to be inspected and a scrutinized during the inspection of the firm by the licensing authority or by the notified body. Then what technical document required to be submitted at the time of submission of the application? The details of the technical documents has been given in the forth schedule of the Medical Device Rule 2017.

(Refer Slide Time: 20:59)

TECHNICAL DOCUMENTS

Requirements

- Device description, intended use of the device, specification including variants and accessories
- Material of construction
- Working principle & use of a novel technology (if any)
- Labels, package inserts (IFU, etc.), user manual, wherever applicable
- Summary of any reported Serious Adverse Events (SAE) in India and action taken by the manufacturer

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

And many times also we have discussed the same the documents that required to be submitted with respect to the manufacturing of the in vitro diagnostics or medical devices. The device description, intended use of the devices, specification including the variant and accessory. Material of construction, what is the material of construction of the devices? Working principles and use of the novel technology if any. The labels of the devices, package inserts, IFU, user manual, wherever applicable that information they required to be submitted. The summary of any reported serious adverse event in India and action taken by the manufacturer.

(Refer Slide Time: 21:43)

TECHNICAL DOCUMENTS

Requirements

- Analytical performance summary including sensitivity and specificity (for IVDs)
- Site or plant master file
- Device master file as specified in Appendix II for medical devices, or Appendix III for IVD
- Constitution details of the firm

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Analytical performance summary including the sensitivity and specificity that is required for the in vitro diagnostics. The site master file or plant master file that is given in the part III of the forth schedule. Device master file as specified in appendix II of the medical devices or appendix III for the in vitro diagnostics constitution details of the firm.

(Refer Slide Time: 22:07)



The essential principle checklist for demonstrating and demonstrating confirmatory to the essential principles for safety and performance of the medical devices. Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provision of quality management system as specified in the Medical Device Rule 2017 fifth schedule.

And for in vitro diagnostic performance evaluation report is also required to be submitted. Now fees and forms for the medical devices relevant form. We have all already discusses that here the forms.

(Refer Slide Time: 22:43)

The slide features the CDSA logo in the top right corner. The title 'FEES AND FORMS FOR MANUFACTURING LICENCE' is centered at the top. Below the title is a progress bar with four segments, the second of which is highlighted in blue. A dark blue box labeled 'Legal documents:' is positioned below the progress bar. Underneath this box is a light grey box containing the text 'Forms for medical device (MD)/in vitro diagnostics (IVD)' followed by a bulleted list of four items: MD-3 (Application for manufacture licence - Class A & B), MD-4 (Application for loan licence - Class A & B), MD-7 (Application for manufacture licence - Class C & D), and MD-8 (Application for loan licence - Class C & D). At the bottom of the slide is a dark blue footer bar with the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

FEES AND FORMS FOR MANUFACTURING LICENCE

Legal documents:

Forms for medical device (MD)/in vitro diagnostics (IVD)

- MD-3 (Application for manufacture licence - Class A & B)
- MD-4 (Application for loan licence - Class A & B)
- MD-7 (Application for manufacture licence - Class C & D)
- MD-8 (Application for loan licence - Class C & D)

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

For grant of manufacturing of class A class B class C and class D devices. MD 3 that is the application for manufacturing licence for class A and class B devices. MD 4 that is the loan licence application for class A and class B devices. MD 7 that is the application for grant of manufacturing licence for class C and class D devices.

(Refer Slide Time: 23:11)

This slide is identical in layout to the previous one, featuring the CDSA logo, the title 'FEES AND FORMS FOR MANUFACTURING LICENCE', a progress bar with the second segment highlighted, a 'Legal documents:' box, and a list of forms. The bulleted list in this slide includes: MD-5 (Manufacture licence - Class A & B), MD-6 (Loan licence - Class A & B), MD-9 (Manufacture licence - Class C & D), and MD-10 (Loan licence - Class C & D). The footer bar at the bottom contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

FEES AND FORMS FOR MANUFACTURING LICENCE

Legal documents:

Forms for medical device (MD)/in vitro diagnostics (IVD)

- MD-5 (Manufacture licence - Class A & B)
- MD-6 (Loan licence - Class A & B)
- MD-9 (Manufacture licence - Class C & D)
- MD-10 (Loan licence - Class C & D)

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

MD 8 application for loan licence class C and class D devices. MD 5 that is the manufacturing licence issued by the State Licensing Authority for class A and class B devices. MD 6 that is the loan licence issued by the State Licensing Authority for class A

and class B devices. MD 9 is the manufacturing licence issued by the Central licensing Authority for class C and class D devices. MD 10 that is the loan licence issued by the Central Licensing Authority for class C and class D devices.

(Refer Slide Time: 23:37)

The slide is titled "FEES AND FORMS FOR MANUFACTURING LICENCE" and features the CDSA logo in the top right corner. Below the title is a dark blue button labeled "Legal documents:". Underneath this is a light grey box containing the heading "Fees for MD/IVD:" followed by two bullet points: "■ Class A & B MD [For site: INR 5000 & INR 500 for each distinct MD]" and "■ Class C & D MD [For site: INR 50000 & INR 1000 for each distinct MD]". At the bottom of the slide is a dark blue footer bar with the text "REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA".

Class	Site Fee (INR)	Device Fee (INR)
Class A & B MD	5000	500
Class C & D MD	50000	1000

Fees for medical devices and in vitro diagnostic kits for class A and class B medical devices, site fees is 5000 and rupees 500 is distinct medical devices. For class C and class D medical devices and in vitro diagnostics, the site fees is 50000.

And the product fees, device fees for each distinct medical devices 1000 Indian rupees. This is a fees structure and the forms, application forms related to manufacture and loan licence for different class of the medical devices and the licence or loan licence for different class of the medical devices. Now the standards of the medical devices, what is standard is applied for the medical devices being manufactured by the manufacturers?

(Refer Slide Time: 24:25)



The slide features a title 'RULE 7: PRODUCT STANDARDS FOR MEDICAL DEVICE' in bold blue text, preceded by a CDSA logo. Below the title is a list of three bullet points: '■ BIS or those set by Central Government', '■ Failing (i) by International Organisation for Standardisation (ISO) or International Electro Technical Commission (IEC)', and '■ Failing both, manufacturers validated standards'. The slide is framed by a dark blue footer containing the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

RULE 7: PRODUCT STANDARDS FOR MEDICAL DEVICE

- BIS or those set by Central Government
- Failing (i) by International Organisation for Standardisation (ISO) or International Electro Technical Commission (IEC)
- Failing both, manufacturers validated standards

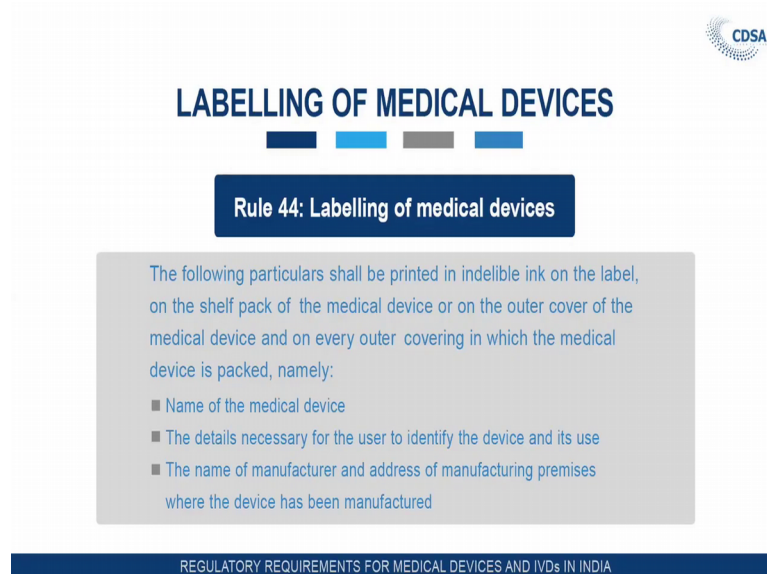
REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Rule 7, of the Medical Device Rule 2017 gives the provisions for product standard of the medical devices, as per rule 7 Bureau of Indian Standard or the standard set up by the Central Licensing Authority is applicable for the devices which is being manufactured in the country. If there is a no BIS standard or no standard approved by the Central Licensing Authority for the particular medical devices.

The other international standards ISO International Organization for Standardization or International Electro Technical Committee IEC standards is applicable for those devices. If there is no ISO or international standard is available, in such cases the manufacturers validated standards approved by the Central Licensing Authority is applicable.

So, the standard supply it for the devices that provision has been given in the rule 7 of the Medical Device Rule 2017. Now the labelling provision of the medical devices what labelling requirement has to be follow by the manufacturers also that is follow for the imported products.

(Refer Slide Time: 25:36)



The slide features a title 'LABELLING OF MEDICAL DEVICES' in bold blue text, preceded by four colored bars (dark blue, light blue, grey, and medium blue). Below the title is a dark blue box containing 'Rule 44: Labelling of medical devices'. A light grey box below this contains text about indelible ink printing and a bulleted list of requirements. The CDSA logo is in the top right corner, and a dark blue footer bar at the bottom contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

CDSA

LABELLING OF MEDICAL DEVICES

Rule 44: Labelling of medical devices

The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

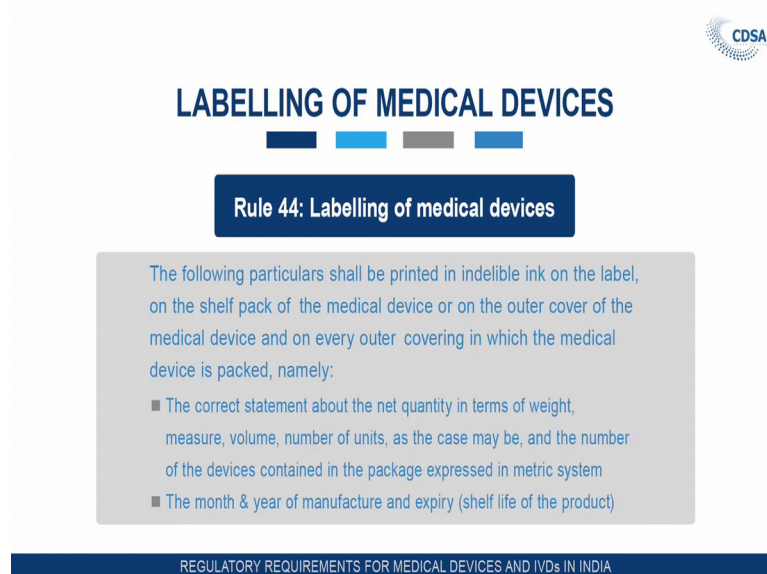
- Name of the medical device
- The details necessary for the user to identify the device and its use
- The name of manufacturer and address of manufacturing premises where the device has been manufactured

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, the labelling provision for the medical devices that is given in the chapter 6 and the rule 44 gives the details what labelling requirement is there for the medical devices and in vitro diagnostics.

Then formation shall be printed indelible ink on the label, on the shelf back of the medical devices or on the outer cover of the medical devices and on every outer covering in which the medical devices is packed. Then formation which are to be submitted are as under. The name of the medical devices that has to be mentioned on the label of the devices. The details necessary for the user to identify the devices and its use if it is there it has to be mention. The name of the manufacturer and address of the manufacturing premises where the device has been manufactured detail address has to be mentioned on the label.

(Refer Slide Time: 26:26)



The slide features the CDSA logo in the top right corner. The title 'LABELLING OF MEDICAL DEVICES' is centered at the top in a large, bold, blue font, with a decorative bar of four colored squares (dark blue, light blue, grey, and blue) below it. A dark blue box with white text contains 'Rule 44: Labelling of medical devices'. Below this, a light grey box contains the following text: 'The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:'. This is followed by a bulleted list: '■ The correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system' and '■ The month & year of manufacture and expiry (shelf life of the product)'. At the bottom, a dark blue bar contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

CDSA

LABELLING OF MEDICAL DEVICES

Rule 44: Labelling of medical devices

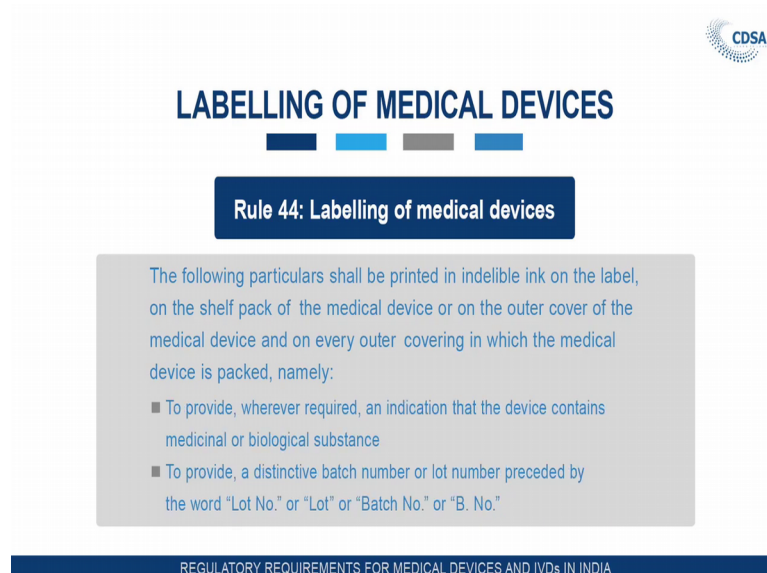
The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

- The correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in metric system
- The month & year of manufacture and expiry (shelf life of the product)

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The correct statement about the quantity in terms of weight, measures, volume, number of units wherever is applicable they have to mention in metric system. The month and year of the manufacture or expiry that is the shelf life of the product has to be mentioned on the label.

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The slide features the CDSA logo in the top right corner. The title 'LABELLING OF MEDICAL DEVICES' is centered at the top in a large, bold, blue font, with a decorative bar of four colored squares (dark blue, light blue, grey, and blue) below it. A dark blue box with white text contains 'Rule 44: Labelling of medical devices'. Below this, a light grey box contains the following text: 'The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:'. This is followed by a bulleted list: '■ To provide, wherever required, an indication that the device contains medicinal or biological substance' and '■ To provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No."'. At the bottom, a dark blue bar contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

CDSA

LABELLING OF MEDICAL DEVICES

Rule 44: Labelling of medical devices

The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

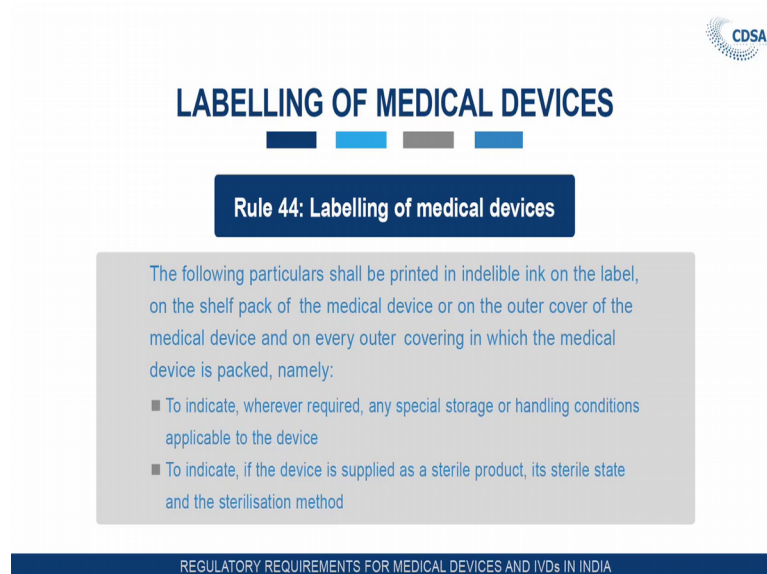
- To provide, wherever required, an indication that the device contains medicinal or biological substance
- To provide, a distinctive batch number or lot number preceded by the word "Lot No." or "Lot" or "Batch No." or "B. No."

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

To provide wherever required the indication that the device contain medicinal or biological substances if. So, then formation has to be mentioned on the label of the product. To provide, a distinct batch number or lot number preceded by lot number or lot

or batch number or B dot and no dot. This information they have to mention on the label of the product.

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CDSA

LABELLING OF MEDICAL DEVICES

Rule 44: Labelling of medical devices

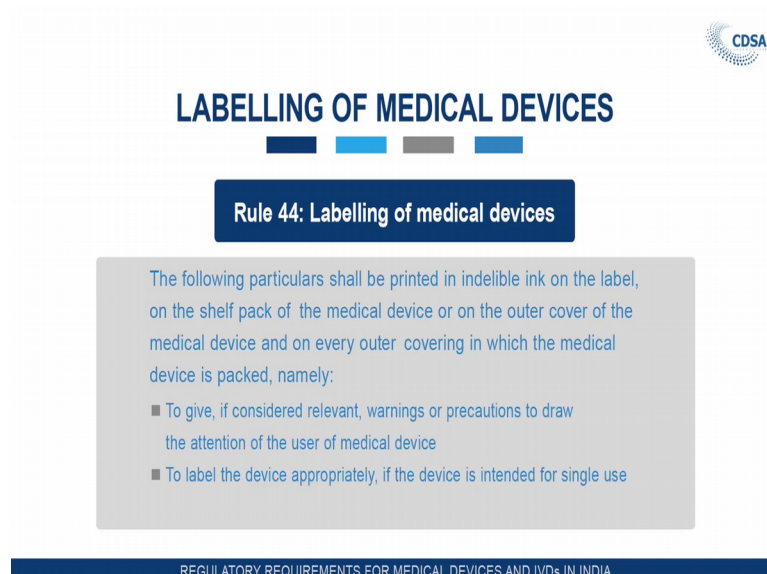
The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

- To indicate, wherever required, any special storage or handling conditions applicable to the device
- To indicate, if the device is supplied as a sterile product, its sterile state and the sterilisation method

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

If there any special storage or handling condition applicable for the devices that information also has to be mentioned on the label. If the device is supplied as a sterile if it is a sterile it is state and the sterilisation method has to be mentioned. Like if it is sterilised by EtO in the label the symbol or EtO that startup information has to be mention on the label of the product.

(Refer Slide Time: 27:35)



CDSA

LABELLING OF MEDICAL DEVICES

Rule 44: Labelling of medical devices

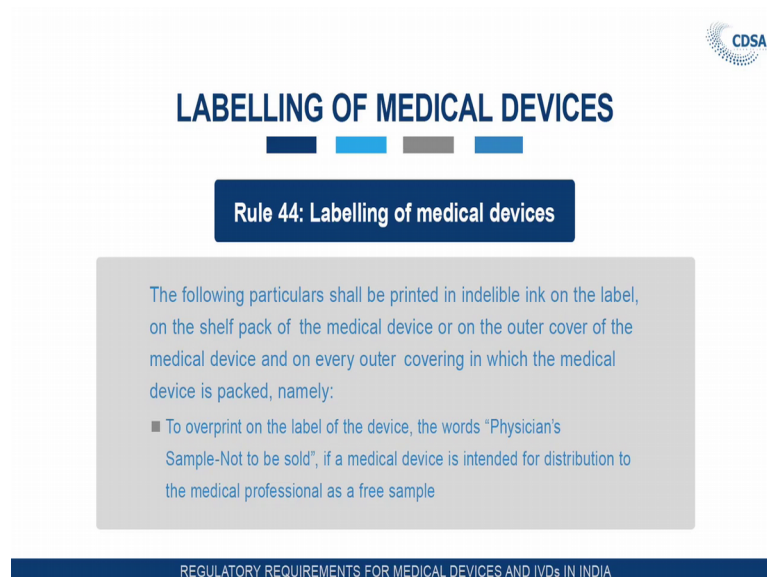
The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:


- To give, if considered relevant, warnings or precautions to draw the attention of the user of medical device
- To label the device appropriately, if the device is intended for single use

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Warning or precaution to draw the attention of the users of the medical devices, if the device required so that information also need to be mentioned on the label. If it is a single use devices that it has to be mentioned on the label of the product.

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LABELLING OF MEDICAL DEVICES

Rule 44: Labelling of medical devices

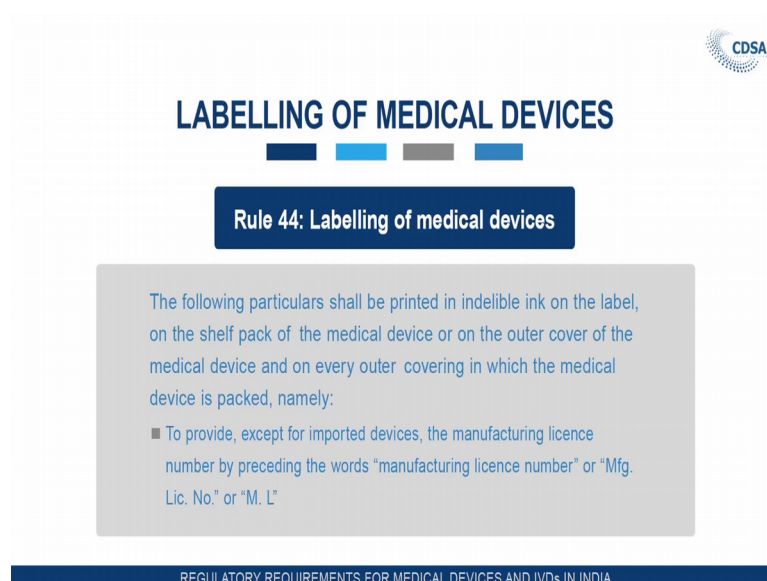
The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:


- To overprint on the label of the device, the words "Physician's Sample-Not to be sold", if a medical device is intended for distribution to the medical professional as a free sample

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

If the medical devices is intended for distribution to the medical professionals as a free samples; physician sample not to be sold that caption has to be capture on the label of the product. And other such information that required to be mentioned on the label of the medical devices.

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LABELLING OF MEDICAL DEVICES

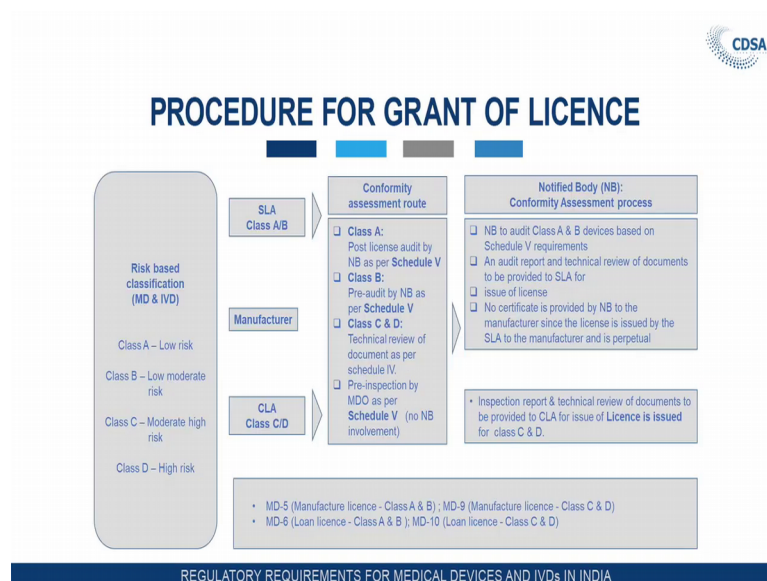
Rule 44: Labelling of medical devices

The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

- To provide, except for imported devices, the manufacturing licence number by preceding the words "manufacturing licence number" or "Mfg. Lic. No." or "M. L."

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

(Refer Slide Time: 28:13)



Now the what procedure followed for grant of manufacturing licence. This is the one slide where the short of flowchart is there. The risk based classification we have discussed that. Based on the risk of the classes medical devices and in vitro diagnostics have been classified as class A class B class C and class D devices.

And also we have discussed for class A devices State Licensing Authority is responsible for grant of manufacturing licence and the center licence is responsible class C and class D devices. The application for all the classes has to be submitted through the centre online portal and for A and B medical devices the application directly diverted to the concerned State Licensing Authority. And for C and D it is with the Central Licensing Authority. The documents, the requisite fees and the application form that we have discuss once it is submitted to the Central Licensing Authority or the State Licensing Authority as per the requirement of the Medical Device Rule 2017.

And if the document found satisfactory, the conformity assessment is to be carried out for class A and class B. The notified body will audit the site manufacturing site of class A and class B devices with respect to verifying the conformance of the quality management system. For class C and class D the Central Licensing Authority the offices of the Central Licensing Authority will be responsible for audit of inspection of the class C or class D devices with respect to conformance of the Qms.

After submitting the report if the report found satisfactory and the document technical document submitted by the firm is in order. The licensing authorities shall grant the licence to the manufacturer of the class C and class D devices. And the State Licensing Authority based on the audit report of the notified body and the technical documents submitted by the manufacturers by class A and class B.

They will consider their application for grant of manufacturing licence or grant of the loan licence. We have also discussed that MD 5 that is the manufacturing licence for class A and class B devices. MD 9 that is the manufacturing licence for class C and class D devices. MD 6 loan licence for class A and class B, MD 10 is the loan licence for class C and class D devices.

So, the licence issued by the Central Licensing Authority we have also discussed that that is in perpetual. There is a no validity provided the licensee so I will submit the requisite tradition fees of at the interval of at every 5 years. So, this is the procedure for grant of licence. Now forms we have discussed this is the one slides we are all the relevant form related to manufacturing of licence or by loan licence that is related to medical devices and in vitro diagnostic have been given. The licence to manufacture class A and class B devices application in MD 3 and the licence will issue.

(Refer Slide Time: 31:40)




APPENDIX FORMS

Topic	Application Licensing	
Licence to manufacture Class A or Class B medical device.	MD-3	MD-5
Loan licence to manufacture of Class A or Class B medical device.	MD-4	MD-6
Licence to manufacture for Sale of Class C or D.	MD-7	MD-9
Loan licence to manufacture for Sale of Class C or Class D.	MD-8	MD-10
Form in which the Audit or Inspection Book shall be maintained.	-	MD-11
Licence to manufacture medical device for purpose of clinical investigations, test.	MD-12	MD-13

In MD 5 loan licence for A and B, MD 4 is the application, MD 6 is licence for C and D application is MD 7. Licence in MD 9, loan licence for manufacture of the class C and

class D devices, application is MD 8, licence is MD 10. Forms in which the audit or inspection book shall be maintained by the licensee MD 11, licence to manufacture the medical devices for the purpose of test, evaluation or clinical investigation, application in MD 12, licence in MD 13.

(Refer Slide Time: 32:28)



APPENDIX FORMS

Topic	Application Licensing	
Permission to conduct clinical investigation of an investigational medical device.	MD-22	MD-23
Permission to conduct clinical performance evaluation of new <i>in vitro</i> diagnostic medical device.	MD-24	MD-25
Permission to manufacture for sale or for distribution of medical device which does not have predicate medical device.	MD-26	MD-27
Permission to manufacture for sale or for distribution of new <i>in vitro</i> diagnostic medical device.	MD-28	MD-29

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Permission to conduct the clinical investigation of the investigational devices, application in MD 22 and the permission is granted by the Central Licensing Authority in MD 23. Permission to conduct the clinical performance evaluation of new in vitro diagnostics MD 24, application and the permission is an MD 25. Permission to manufactured for sale or for distribution of the medical devices which does not have the predicate devices MD 26 is the application and the permission is MD 27. Permission to manufacture for sale or distribution of the new in vitro diagnostics application MD 28 and the permission is issued in MD 29.

These different forms have been described in the Medical Device Rule 2017. So, in this lecture we have covered what are the rules applicable for the grant of manufacturing licence? Who are the authorities responsible for grant of manufacturing licence for class A class B devices and over the authority responsible for manufacturing of class licence for class C or class D devices? We have also covered which rules, which chapters applicable for the medical devices. What is standard is required? What is the living

provision applicable for the medical devices and in vitro diagnostics? All that topics we have covered in this chapter.

So, if you have some more you required some more detail about the provisions of the medical device rule you go through the website of the CDSCO, where the medical device rule is there. And if you have any further doubts you want to see clarification you approach to us for further clarification. Now, just have some sort of question answer session. So, will take one two questions whether you understand or not have you aware of that or not.

(Refer Slide Time: 34:52)


RECAP

- 1 Name two different licensing authorities in the country?
State Licensing Authorities (SLA) and Central Licensing Authority (CDSCO)
- 2 Which form should be filled for seeking permission to conduct clinical investigation?
Form MD-23.
- 3 What is form MD-3?
Application for grant of licence to manufacture Class A or Class B device.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, name the two different licensing authority in the country which is responsible for grant of manufacturing licence we have discussed so many times that is State Licensing Authority and the Central Licensing Authority. Now, which forms is to be filled for permission to conduct the clinical investigation, the forms required to obtain the permission to conduct the clinical investigation it is MD 23. Now, what is MD 3? MD 3 is the licence to manufacture class A or class B medical devices it is not licence it is a application for grant of licence to manufacture class A and class B devices.

(Refer Slide Time: 36:01)



SUMMARY

In Lecture 8 (L8), we briefly learned about:

- How to obtain a licence to manufacture a medical device?
- Sequence in the procedure for grant of device license.
- Basic requirements of device manufacturing license.
- Documents for grant of device manufacturing licence.
- Appendix forms.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, thank you very much and hope next chapter we will cover the remaining part of the Medical Device Rule 2017. So, in summary the lecture we briefly learnt about the how to obtain the manufacturing licence. The sequence of the procedure of the grant of the manufacturing licence. Basic requirement for the manufacturing licence. Documents for grant of medical device manufacturing licence and the forms. So, I hope you understand the requirement for the grant of manufacturing licence.

Thank you very much.