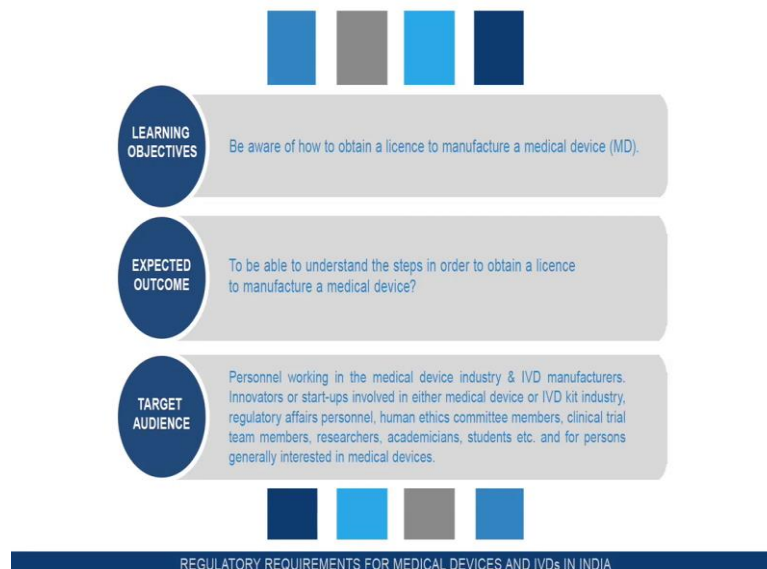


Regulatory Requirements for Medical Devices including In Vitro Diagnostics in India (Version 2.0)
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Lecture – L8
How to Obtain a Licence to Manufacture a Medical Devices?


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 personnel, human ethics committee member, clinical trial team member, researcher, academician, the students and the persons generally interested in medical devices.

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WHAT WILL WE LEARN IN LECTURE 8?

Sequence in the procedure for grant of device licence	Basic requirements of device manufacturing licence	How to obtain a licence to manufacture a medical device?
Documents for the grant of device manufacturing licence	Append, Forms	

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

What will we learn in the lecture 8? We will learn how to obtain a licence to manufacture a 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.

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HOW TO OBTAIN A LICENCE TO MANUFACTURE A MEDICAL DEVICE?

Any product that is controlled by the Drugs & Cosmetics Act and Rules, as drugs, need a licence to manufacture.

This is necessary keeping in mind to:

- Keep a control on the product
- Maintain the products efficacy, safety and quality
- To avoid duplicate and therefore harmful products away
- Keep track of products moving in the market
- Keep consistence in the manufacturing of the products

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

So, how to obtain a licence to manufacture a medical devices? 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 these.

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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 thereunder licence is required. Let us now unveil 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?

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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:

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

Now, in the medical device rules we have discussed the authorities; authorities responsible for grant of manufacturing licence, the State Licensing Authority (SLA) and the Central Licensing Authority (CLA), 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 described 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 discussed that for which class of the medical devices, who are the authorities. For manufacturing State Licensing Authority (SLA) is responsible for grant

of manufacturing licence for class A and class B devices, and the Central Licensing Authority(CLA) that is CDSCO is responsible for grant of manufacturing licence of class C and class D 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 (CLA) they are responsible for QMS inspection of class C and class D devices.

Notified body, who are the notified bodies responsible for QMS verification of the class A and class B devices? The notified body which is registered with the Central Licensing Authority (CLA), they are only the responsible for QMS verification of the class A and class B devices.

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CHAPTER IV: MANUFACTURE OF MEDICAL DEVICES FOR SALE & DISTRIBUTION



- Rule 20: Application for manufacture for sale or for distribution of Class A or Class B medical device.
- Rule 21: Application for manufacturing Class C or Class D devices.
- Rule 22: Requirements for grant of manufacturing licence or loan licence.
- Rule 23: Inspection for grant of licence or loan licence for Class C or Class D medical device.
- Rule 24: Inspection report.
- Rule 25: Grant of licence or loan licence to manufacture for sale or for distribution.
- Rule 26: Conditions for manufacturing licence or loan licence.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

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 discuss 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 four 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 I have given for each of the different types of manufacturing licence, we will discuss one by one this rule.

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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, 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 (CLA) and when applied for grant of manufacturing licence or loan licence through this portal this licence will be diverted to the concerned State Licensing Authority (SLA) who is responsible for grant of licence.

The application shall be accompanied with fees, as specified in the Second Schedule we have also discussed that what is Second Schedule, Second Schedule 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 prescribed 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 detail has been given in the part two of the fourth schedule.

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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 submit this undertaking they are fulfilling the requirement of Quality Management System (QMS) as specified in the fifth schedule.

The State Licensing Authority (SLA) who is responsible for grant of manufacturing licence review the applications and after being satisfied with 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 40 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 (CLA) 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.



The application shall be accompanied with the fees. Fees as I specified in the Second Schedule and also the technical documents as I 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 (CLA) within a period of 45 days through online only and where the documents are found to be complete and in order the Central Licensing Authority (CLA) shall cause an 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 investigation 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 requirements? The site shall comply with the requirement of the Quality Management System (QMS) and undertaking in this regard has 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 in 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 2 years in the testing of the medical devices and in vitro diagnostic, whose 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 16 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 (MDO).

However, no inspection for the medical device manufacturing site for grant of loan licence is required if the manufacturing site is already licensed 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 loan licence by the firm no further inspection generally required to be carried out.

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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 (CLA), through online portal and also forward a copy of the same to the applicant.

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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 (CLA), 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 (CLA) the license shall be granted in form MD 9 or the loan licence in form MD 10.

The Central Licensing Authority (CLA) may also reject the application for the reason to be recorded in writing within a of 45 days from the date of inspection of the report, if certain major non compliances were observed by the Central Licensing Authority (CLA).

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 (CLA) And no licence to manufacture any class of such devices shall be granted without such permission.

The applicant has 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 apply to the Central Licensing Authority (CLA) 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 licenses is mentioned in the rule 26 certain condition, like the license holder has to produce the licence before the medical device officer or the Central Licensing Authority (CLA) in case they wish to examine their licence for any reason.

They have to 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 for marketing into the country. They have to also inform any major changes in the manufacturing of the medical devices.

If there is a 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 category of the major changes as specified in the schedules, they have to intimate to the Central Licensing Authority (CLA) or the State Licensing Authority (SLA) 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 (SLA) as the case may be within 45 days and shall make a application for grant of licence within period of 180 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 (SLA) . As we have discuss earlier for the QMS verification of the class A and class B devices, the State Licensing Authority (SLA) 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 (SLA) shall carried out the inspection of 2 percent of the site which have been recommended 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 5 years from the date of it issued. Then their licence will be considered in perpetuity till the suspension or cancellation of the licence by the licensing authority or till 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 show 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 rule. Before cancellation of suspension the licensing authority shall show 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, these licence was issued by the State Licensing Authority (SLA), now the Central Licensing Authority (CLA) is responsible for grant of test licence for all classes of the medical devices.

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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 information. They have to submit the brief description of the medical devices, its 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 the in vitro diagnostics to be manufactured for test and analysis. They have to submit the test methods, 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 (CLA).

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Basic Requirements For Applying Manufacturing License

Requirements for a license:

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

All the above are inspected and scrutinized during the

CDSA NPTEL

And the Central Licensing Authority (CLA) 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

CDSA NPTEL

Now, basic requirement for applying the manufacturing licence. While applying the licence to the concerned State Licensing Authority (SLA) or the Central Licensing Authority (CLA) 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 prescribed 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, working 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 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?

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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

The details of the technical documents has been given in the forth schedule of the medical device rule 2017, 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 accessories.

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 (SAE) in India and action taken by the manufacturer.

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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 3 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.

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TECHNICAL DOCUMENTS

Requirements

- Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the medical device
- Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the quality management system requirement (Fifth Schedule)
- PERs (for IVDs)

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The essential principle checklist for 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 (QMS) 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 already discussed that.

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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

Here the forms 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, MD 8 application for loan licence class C and class D devices.

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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 5 that is the manufacturing licence issued by the State Licensing Authority (SLA) 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 (CLA) for class C and class D devices. MD 10 that is the loan licence, issued by the Central Licensing Authority (CLA) for class C and class D devices.

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FEES AND FORMS FOR MANUFACTURING LICENCE

Legal documents:

Fees for MD/IVD:

- Class A & B MD [For site: INR 5000 & INR 500 for each distinct MD]
- Class C & D MD [For site: INR 50000 & INR 1000 for each distinct MD]

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Fees for medical devices and in vitro diagnostic kits. For class A and class B medical devices, site fees is 5000 and rupees 500 each 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 the 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 standards applied for the medical devices being manufactured by the manufacturers?

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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 Standards(BIS) 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 (CLA) for the particular medical devices.

The other international standards ISO International Organization for Standardization or International Electro Technical Committee (IEC), 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 (CLA) is applicable. So, the standard applied 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 followed by the manufacturers, also that is followed for the imported products.

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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:

- 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 information shall be printed indelible ink on the label on the shelf pack 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 information 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 mentioned. 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.

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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:

- 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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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 information 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 ,NO. This information they have to mention 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 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 is 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 state and the sterilisation method has to be mentioned. Like, if it is sterilised by ETO in the label, the symbol or ETO that short up information 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 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 then 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 captured 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

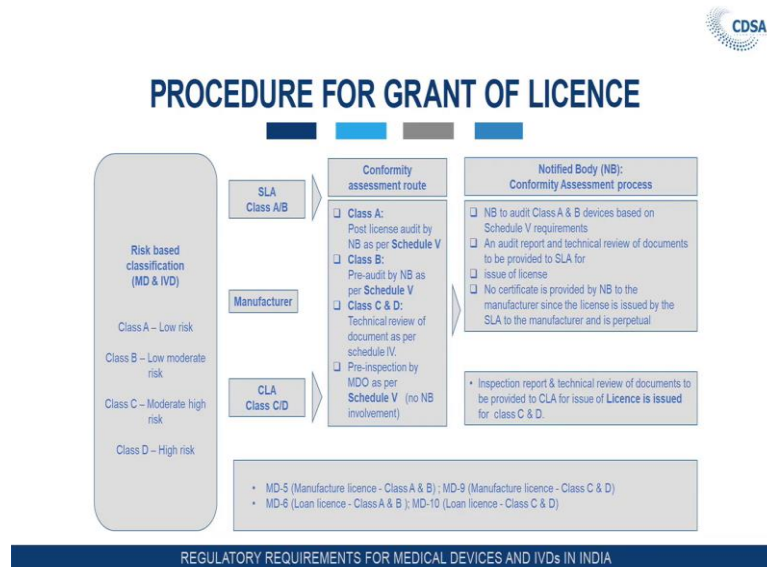
The following particulars shall be printed in indelible ink on the label, on the shelf pack of the medical device or on the outer cover of the medical device and on every outer covering in which the medical device is packed, namely:

- 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

Now, the what procedure followed for grant of manufacturing licence? This is the one slide where the sort of flowchart is there.

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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 (SLA) is responsible, for grant of manufacturing licence and the central 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 (SLA), and for C and D it is with the Central Licensing Authority (CLA).

The documents, the requisite fees and the application form that we have discussed, once it is submitted to the Central Licensing Authority (CLA) or the State Licensing Authority (SLA), 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 (QMS). For class C and class D, the Central Licensing Authority, the offices of the Central Licensing Authority (CLA) 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 (SLA) based on the audit report of the notified body and the technical documents submitted by the manufacturers of 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 (CLA), we have also discussed that that is in perpetual, there is a no validity provided the licensee shall submit a requisite fees of at the interval of every 5 years. So, this is the procedure for grant of licence.

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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

Now, forms we have discussed this is the one slide we have all the relevant form related to manufacturing of licence or 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 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.

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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 (CLA) in MD 23. Permission to conduct the clinical performance evaluation of new *in vitro* diagnostics MD 24, application and the permission is in MD 25.

Permission to manufacture 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 who 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 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 question answer session. So, we will take one- two questions whether you understand or not, have you aware of that or not.

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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 (SLA) and the Central Licensing Authority (CLA).

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.

So, thank you very much. And hope next chapter we will cover the remaining part of the medical device rule 2017.

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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, 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 license and the forms. So, I hope you understand the requirement for the grant of manufacturing license.

Thank you very much.