Current Regulatory Requirements for Conducting Clinical Trials in India for IND/New Drug Version 2.0

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Lecture – 14
Requirements for import/ manufacture of new drug/ IND for conducting clinical trials in India

[FL]. Welcome to this online course Current Regulatory Requirements for Conducting Clinical Trials in India for investigational New Drug and New Drug Version 2. Today, I will take you through the lecture number 12. The lecture 12 has been divided into two parts, the lecture 12 A, which is the requirements for import of manufactured, import manufacture of new drug, investigational new drug for conducting clinical trials in India. And next to this is lecture 12 B; which is the requirements for import manufacture of new drug investigational new drug in India.

So, when we say new drug and when we say investigational new drug, by this time you must have learned gone through all the lectures, various lectures where there is a definition of the new drug and where there is definition of clinical trial as well as there is a definition of investigational new drug. But for the purpose of recapitulation I would like to mention that when we say investigational new drug it means our different it means a drug which is never has been manufactured in the globe.

So, we have define this investigational new drug in the current New Drugs and Clinical Trials Rules 2019. Which says that; it is a new chemical entity or a biological entity or a substance which has never been approved as drug in any country. So, that is very important; that means, it has never been used as a drug in any country and when we say it is a new drug, it is possible that it has been used as a new drug as a drug in other country. But it is a new drug in India, because it has been not tried or tested in the Indian population.

So, we have to be, we have to clearly understand what is a new drug and what is a investigational new drug. Also when we say new chemical entity; we can also just for your

information it can be a substance switches already existing, but its therapeutic efficacy has never been claimed.

So it can be an a substance which has never been published or which has never been used as a drug in the country. So, that is the difference when we say a chemical entity a new chemical entity. So, investigational new drug is a new chemical entity or a biological entity and when we say it is a chemical entity, it means that a substance or a chemical which has never been used as a drug in the country or anywhere in, but when we use the word investigational it means it has never been used anywhere in the world. So, now we start though this lecture; let us see what we learn in this lecture.

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The learning objectives, what are the current regulatory rules as per the New Drug and Clinical Trial Rules 2019. You know that when this New Drug and Clinical Trial Rules was published, it was published in March 2019 and has been implemented from that time.

In this rule, in this New Drug and Clinical Trial Rules; we in this particular lecture we are going to cover the manufacture import of new drug or investigational new drug for conducting clinical trials in the country. And the same conditions are existing for the bioavailability and bioequivalence studies or for the purpose of test and analysis.

So, you will see in the coming slides always we write clinical trial or bioavailability or a bioequivalence study or test and analysis. So, I would not be repeating the word bio availability bioequivalence or test and analysis and I would restrict my lecture or my presentation on the clinical trial. But it is the same requirements for the new drugs in this new drug and clinical trial rules. And also we will cover the manufacturer of unapproved API, Active Pharmaceutical Ingredient, for the development of new drug investigational new drug for clinical trial.

So what is this unapproved active pharmaceutical ingredient? It same that it has never been, it has never been approved or that means; has been permitted or licensed, we use the word licensing in the India. So, we say it has never been approved for as a drug in the country by the regulatory authority. So, you must be knowing who is the regulatory authority, the Central Licensing Authority, who is responsible for permitting clinical trial of new drugs in the country for permitting any manufacture or import of new drugs in the country besides many other functions and central licensing authorities central drug standard control organization.

And in this lecture we have the various conditions of permissions which are granted by CDSCO that is the Central Licensing Authority for conduct of clinical trial with a new drug or with an investigational new drug.

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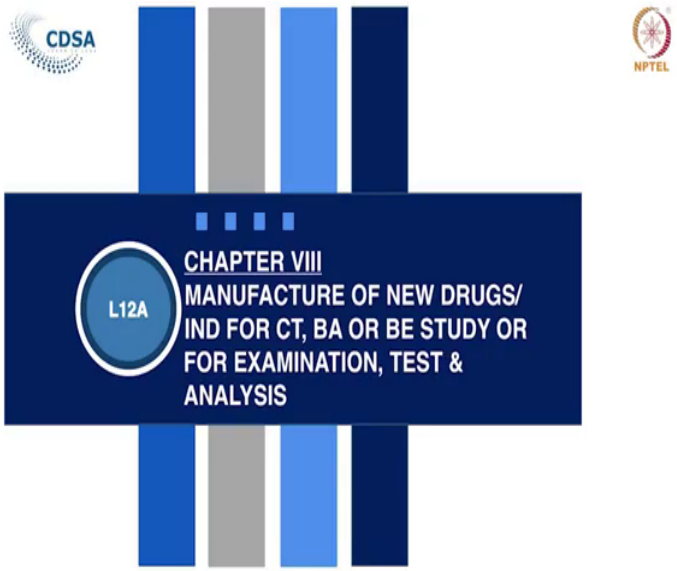

So, the first part as I said 12 A, it is chapter 8 in the new drug and clinical trial rules which says the manufacture of new drugs and investigational new drug for the conduct of clinical trial.

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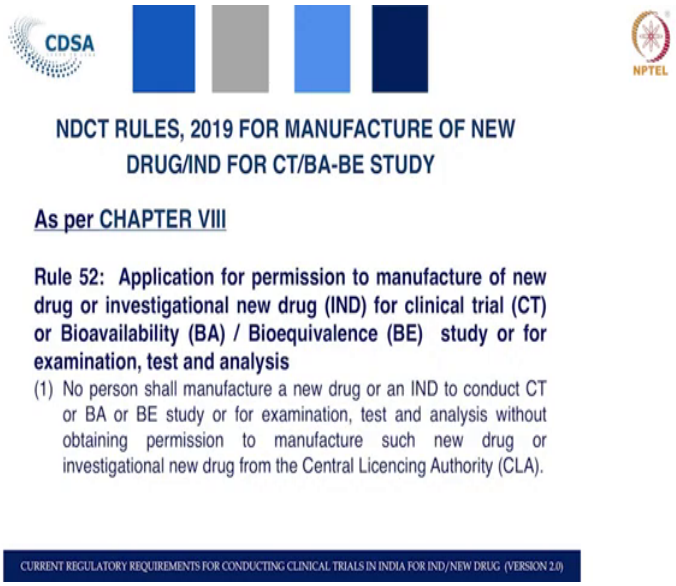

As per the chapter 8, you will see there are rules from rules 52, 2 rules 66. The rules cover all the requirements of manufacture of new drugs and investigational new drug in the country for the purpose of conducting clinical trial. So, starting with rule 52, what it says? It says the application process. So, what is that application process? As it is says that, you cannot manufacture any new drug or investigational new drug in the country for a for a clinical trial unless you are permitted by CDSCO, the Central Licensing Authorities.

So, no person can manufacture any new drug in the country without the permission of the regulatory authority that is Central Licensing Authority.

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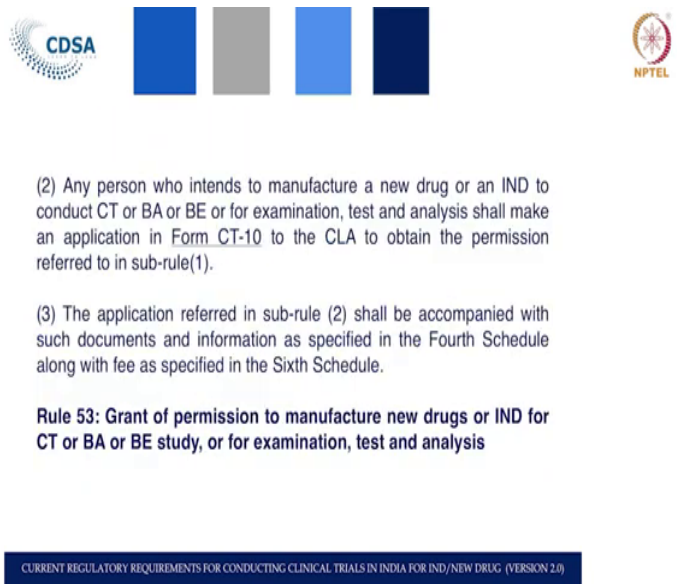

Also, what is the form for that there is a form which is called CT-10 and as per these form; any person who intends to manufacture this new drug or investigational new drug they have to apply in this specific form which is called CT-10 to the Central Licensing Authority.

In this form, there are also that various requirements the documents which is to be submitted and the fees to be paid for this for the application for the new drug or the investigational new drug for the conduct of clinical trial. So, what is there in this? If you see the 4th schedule which is also a schedule in the new drugs and the clinical trial rules, it gives the detailed requirements the documentations requirements for submission along with this form CT-10 and the fees are all specified in the 6th schedule for your information that always the fees for such application is 5000 per product.

And then the grant of permission to manufacture this new drugs or investigational new drugs is given in under rule 53. And the how what is the process we go to the next? It says that after the submission of all the documentation requirement and application in CT-10 along with the fees the licensing authorities CLA the reviewers in the CLA, scrutinize the information and the documentation furnished with the application and if required they may issue a query, further query to this over they may approve the applications if satisfied with the submission requirements.

In all cases, it has to be very clearly remembered that if you see the CT-10 form, the various requirements are very clearly mentioned and complete application form is very important for getting the you know the that is the most important part that you submit all information in a complete documentation and with the complete form online processing for further processing of such applications and you know that we are the CDSCO is online for has an online system for receiving such application.

In this application form, the various documentations for examples, if you see any of the form; you will see that the name of the drug or the code name for a drug if it is an investigational new drug, these are some examples which I am trying to share with you. So, there can be composition, dosage from, indication, therapeutic category. So, these are the things which are the common content of such forms also the manufacturer manufacturing address and also you have the annexures where you have to submit additional information related to this particular applications and your drug.

And the documentation requirements which is in the 4th schedule which has a detailed information about the drug as well. So, you have a chemistry manufacturing control information which is as per the 4th schedule and the 4th schedule will referred to the second schedule which has a very detailed requirements. So, you have to go through this schedule to understand what are the regulatory requirements, but these are all related to the manufacturing of the drugs, the chemical testing and analysis of the drug, whatever information you which you have about the drugs at present.

So, once you submit, once it is reviewed and if it is satisfied the regulatory authorities satisfied with your applications, then they may give you a permission under form CT-11 and there is a timeline for all review and issuance of permission which is 90 working days. But in case, they are not satisfied with the applications and it is understood that the documentation and the supportive requirements cannot fulfill at present, then with the reasons recorded in writing we may the CDSCO may reject application which is made under rule 52.

In case, if CLA finds that there are some deficiencies in the application and the same maybe rectified in that case they can issue a query to the applicant with the deficiencies with a specified timeline.

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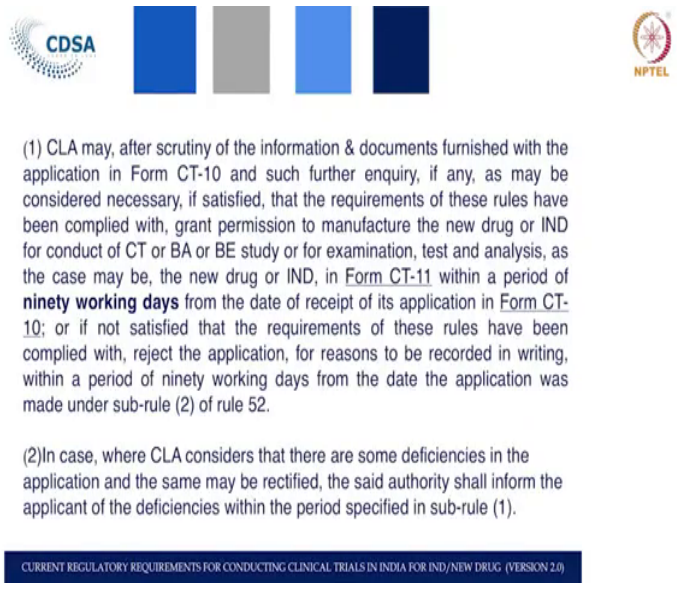

So, once the query is received by the applicant why then the deficiencies may be rectified and they can submit the deficiencies to the CLA, Central Licensing Authority within the period

specified and when such deficiencies are rectified within the period, then in that case again the CLA shall scrutinize such application and you satisfied can grant permission to manufacture for conduct a clinical trial.

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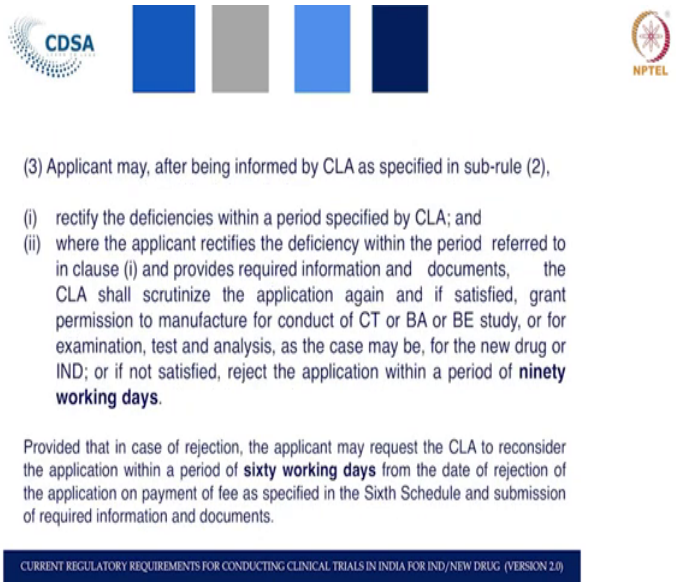

However, they can also reject the application. So, it depends on whether you had submission further submission is complete or it is incomplete or whether the data is not enough to satisfy the permission. Now, in that case; however, there is always in the, as you see that in the regulatory requirements when you have a application format, a grant of permission format, a conditions of permissions, as well as you have a mechanism of appeal.

So, in case of rejection; the applicant can farther come back to CLA with the specific fees, but it is also its a fees which is specified in the 6th schedule is a 2000 and with the fee they can

come back to reconsider the application within a period of 60 working days if they want to still go with their application and after that which can be again verified.

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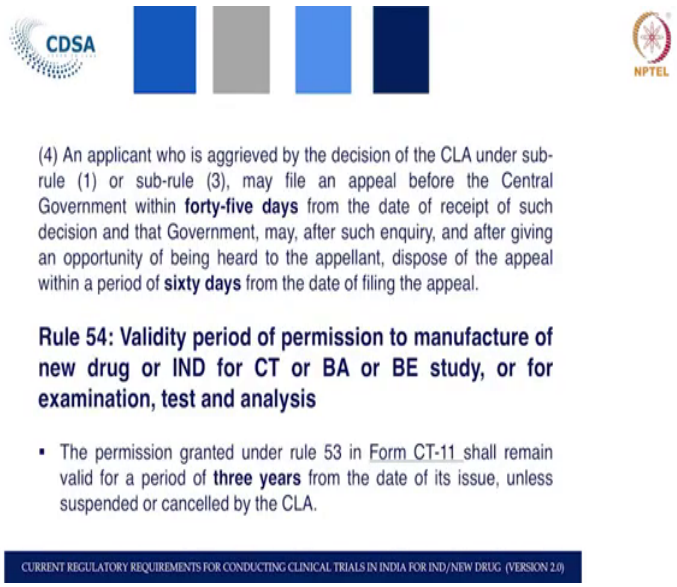

However, when the application is further rejected by CLA and the applicant is not satisfied they can also appeal before the central government with in 45 working days, 45 days from the date of receipt of such decision and the central government after giving a opportunity of hearing to the applicant may dispose of the applications again within a period of 60 days. So, there is a complete mechanism of appeal for your application.

Next, is the rule 54, which talks about the validity of the license which is three years from the date of its issue. Unless it is suspended or canceled by the Central Licensing Authority before. In some substances and which can be an exceptional circumstances, there can be a lot of cases where the applicant comes back that they are not able to start the clinical trial manufacture the

drug due to various reasons and if the CLA is satisfied with the reasons given by the applicant or in case of some exigency as well.

The CLA may extend the period of permission for a period further period of 1 year. So, that is the validity of the license. Now, what is there in the condition of permission? That is the rule 55 which says the condition of permission. In this permission, the grant of permission is subject to the various conditions, what is there? The first thing is most important is that when they manufactured that new drug they shall ensure when applicant has get a permission to manufacture a new drug, they will make use of the new drug only for the purpose of clinical trial and no part of it can be sold in the market or supplied to any other person or agency or an institution or organization.

Whatever work if you start with it, whatever you have mentioned in your application format and whatever permission has been given to you by CLA has to be complied with strictly by the applicant. So, that is the regulatory requirements. In this permission, it is said that; once you manufactured the drugs, the permission will define you the quantity to be manufactured. So, it can be manufactured only in small quantities and when you manufacture it has to be manufactured in a good manufacturing practices condition in a we call it a GMP environment observing the principles of GMP.

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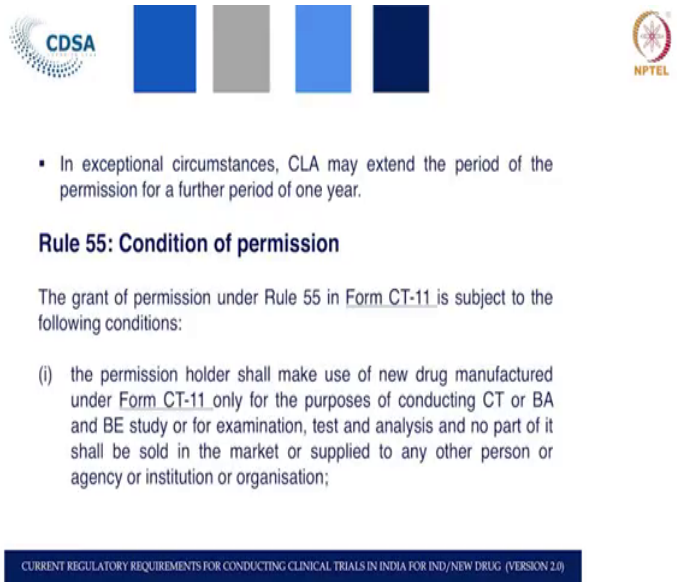

First is that you manufacture a specific quantity and second is that you manufacture it in a good manufacturing practices environment observing all principles of GMP. The permission holder shall keep a record. So, it is most important that as much you manufacture you have to maintain the record and the recording format is also specified in this four forms, but how you have to keep a record. So, the records of the new drugs and to whom it has been supplied for the clinical trial also that.

When such drug has expired or the shelf life has expired you have to specify your shelf life for the drug as per the study which you have done for that drug. So, if you see the CMC data which we call the chemistry manufacturing control data which is given in details in the second schedule, you will understand what are the different data requirements which are to be gradually fulfill for such drug.

So once you take a permission for test and analysis, you manufactured the drug, you prepared the various documentation, the manufacturing, the testing, the stability study, the validation part as much as possible at that particular quantity. So, these are the data we which you gradually start preparing for your drug and then you come back to the regulatory agency for the application is not it.

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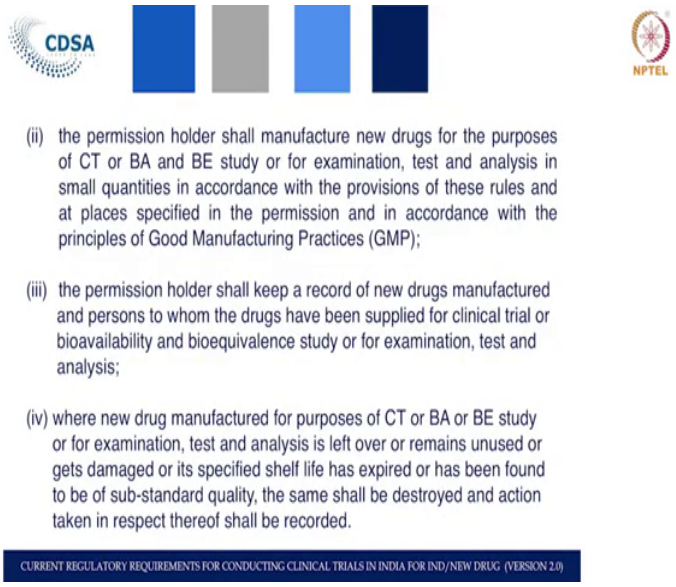

And then once you apply, you are get a permission for the clinical trial you start maintaining the records for everything. Now, if the drugs is not used then you have to keep a or if you find that how the drug failed. So, you have a test results and when you test it from time to time and the drug has failed, in that case that it has this has to be destroyed and whatever action you take you have to have an accountability for the same.

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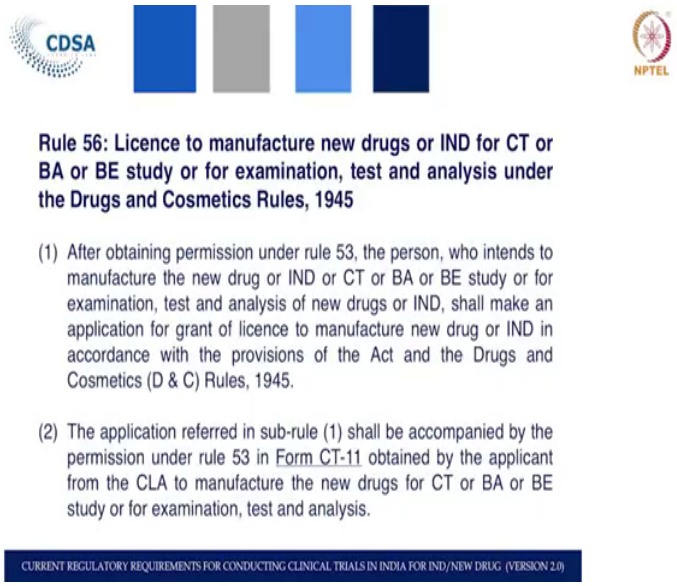

Next rule, which is rule 56 is the license to manufacture new drugs. In this license what we say that after from obtaining the permission and that the rule 53, the per person who intends to manufacture this new drug. So, you got a permission in CT-11 form from CLA. Now what you do? Now, you have to manufacture the new drugs in a particular manufacturing premises.

So, you go under the drugs and cosmetics act, there is an application which is an application form called form 30 where you applied to the concerned State Licensing Authority for manufacturing this new drug. So, you go to this state licensing authority with the permission of CT-11 and you get a permission in form 29 for manufacturing a new drug, for the purpose of clinical trial, for the purpose of test and analysis for the purpose of bioavailability or bioequivalence study. So, this is the application process after you get permission from CLA.

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We go to rule 57; where it is said that whenever you get such permissions, you are bound for inspection by the licensing authority. So whenever a license is issued under for a new drug for the conduct of clinical trial it is open for inspection by the CLA or by the State Licensing Authority who gives you now permission in form 29.

You know in case of the biological products, in case of some of the products where CDSCO or CLA is also a licensing approving authority along with the State Licensing Authority, there is a process of permission by the CLA along with State Licensing Authority which is the form 29. For example, biologicals for which includes the vaccines various are DNA products the monoclonal antibodies which includes large volume printers.

So, these are some of the products which are jointly licensed by SLA and CLA that is State Licensing Authority and the Central Licensing Authority. Now, so, you have the permission

you manufacture the drug and then it is the inspection which can be done at it is not a compulsory process it an mandatory process, but it is it can be done at any point of time.

And without any so it says that without prior notice or it may be with a notice to inspect such premises and then investigate the investigation is conducted and they investigate how you manufacture, how you store, how you record, how you use the drug in the clinical trial.

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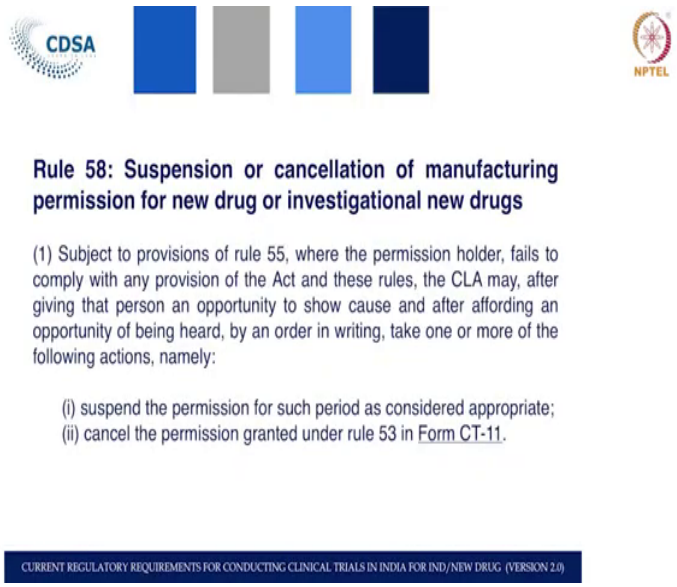

We come to rule 58, which is a regulatory process. In case you fail to comply with the conditions, the applicant fails to comply with the conditions of the licenses, then the CLA can take a action. But before taking action, they we have to there is a process that a show cause notices issued and after affording then there is an opportunity which is been given to the applicant for giving a response to the show cause notice and then they can suspend such permission or cancel the permission which is granted for inform CT-11.

So, this is a regulatory process. So, because. So, it cannot be. So, you know whatever conditions particularly, which is important how you manufacture, how you record the entire your drug. How you record the content of the drug whom you have given, whom you have used, how it has been used, how you have stored, that is very important for conducting the clinical trial in compliance with the GMP requirements in compliance with the requirements of the New Drug and Clinical Trial Rules.

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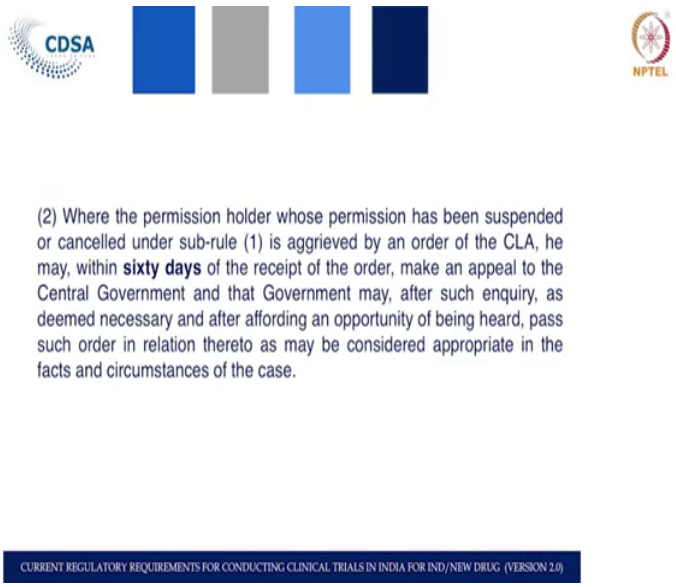

Now, again there is a process of appeal. So, if there is a license or a permission which has been suspended or canceled as in the previous page you have seen. In that case, they can also again appeal to the central government within the period of 60 days of the receipt of the order and after the central government being heard, they can after giving an opportunity of being heard,

they can pass an order which may be considered appropriate in facts and circumstances of the case.

So, it will be examined by the central government at that level and you can be given again a further they can continue with the order of CDSCO or they can ask the CLA to reconsider your application.

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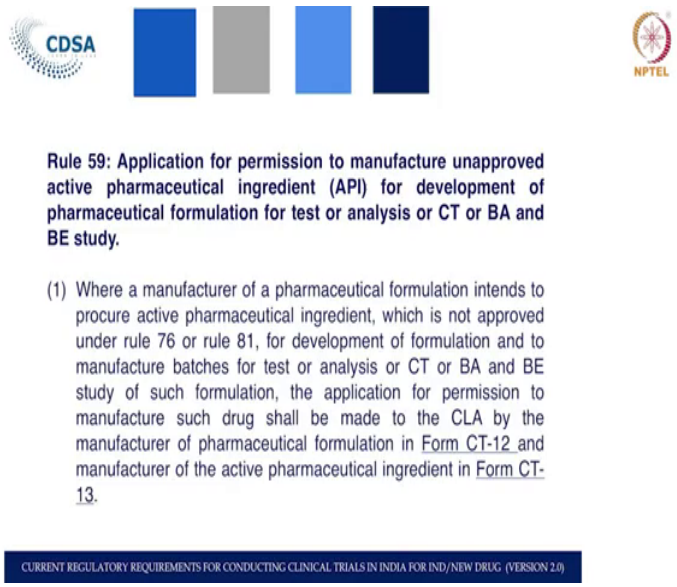

So this is the regulatory process. We come to rule 59, which is an application for permission to manufacture unapproved active pharmaceutical ingredient for the development of the pharmaceutical formulation for clinical trial, for test analysis or BA, BE study.

Now, why do we need this particular rule for application, for permission to manufacture the unapproved active pharmaceutical ingredient. This is because if you see a manufacturer; a

manufacturer normally of a formulation manufacturer we have who has the manufacturing permission to manufacture a dosage form and we also have the manufacturer who are manufacturer of active pharmaceutical ingredient.

So, it is not possible always that the same manufacturer may also it is possible sometimes such the same manufacturer may have both the facilities at the same place, like an API manufacturing facility as well as formulation manufacturing facility. But in most cases they would be at a different site.

So that is the reason we had to create two forms; the form CT-12, for the permission to manufacture, pharmaceutical formulation and CT-13 for the manufacturer of the active pharmaceutical ingredients. So, who so ever is the manufacturer and who is proposing to manufacture an unapproved active pharmaceutical integrated has to applying the CT from 13. And if you go through this forms, as I told in the previous slides, all cases the content is same.

So, everything is that you take a talk about the drug or a code number, your site, your address, your constitution, because you need a you have to be a you those are legal documents and then you have the documents which are mentioned under annexure and what are the other documents which you need to submit.

So, these are all that same, the 4th schedule which includes the documentation requirements wherever applicable, as per as applicable for your this particular submission and as well as the fees and the fees are in all cases very same for this new drug for the purpose of clinical trial, it is always 5000 for per product. And also when you have an rejection for your application and you go for an appeal there is a fees of 2000 for per product.

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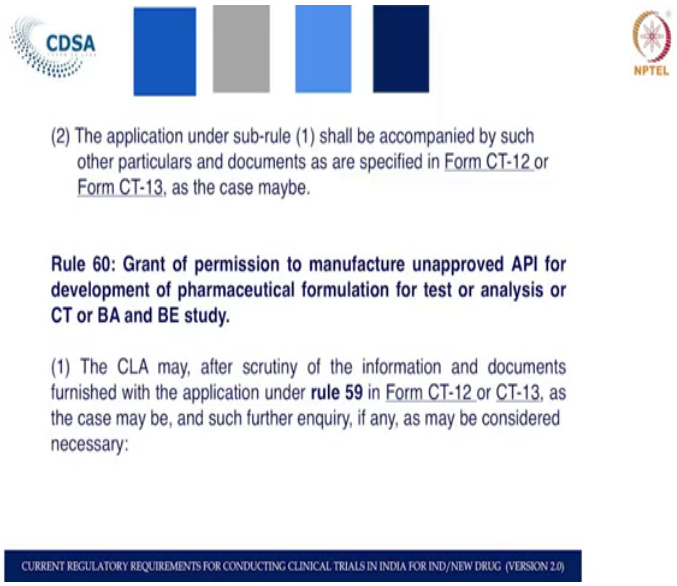

The documentation as I said these are specified as along with this form CT-12 or CT 13, the permission is granted under rule 60 and which is fact the same the after the scrutiny of your information, if it is satisfied then they can be a query or if there is a if it is not satisfied there can be a query, you should to the applicant and in case it is satisfied then permission is issued.

When satisfied the permission is issued in form CT 15, for the manufacturer of the unapproved API and in the permission for a manufacturer of the pharmaceutical formulation is issued in CT 14 and for the for the development of the pharmaceutical formulation. And there are also as I said always the timeline is specified is the 90 working days.

And in all cases when there is a rejection, if the satisfy the documentation submission and not satisfied and the reviewers and CLA is has a reason to believe that this applications requirements are not fulfilled and cannot be fulfilled then this such applications can be also

rejected with the results to be recorded in writing within a period of 90 working days. And in case there are that the deficiencies can be rectified then we issue the query is issued to the applicant for submission of the documents as per the deficiencies identified.

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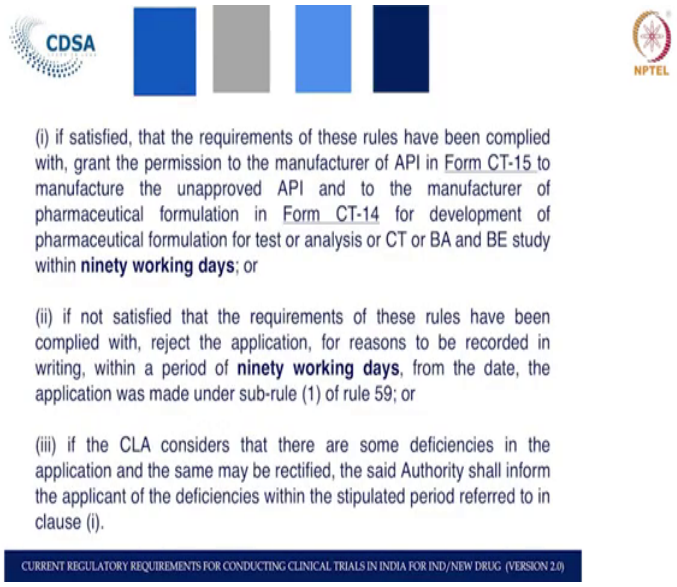

The applicant is after rectifying the deficiencies, once this submit back to CLA the permission is again that is being scrutinized by the Central Licensing Authority and for the API, the permission is granted in CT 15 and for the finished formulation, the permission is granted in CT 14 within the specific period of ninety working days or if it is not then it is again it can be rejected also within the same timeline of 19, ninety working days. And these are all counted from the date of where this application has been submitted the response has been submitted, also there is an appeal mechanism, if it is rejected in that case you can come back to CLA with the within a period of sixty days.

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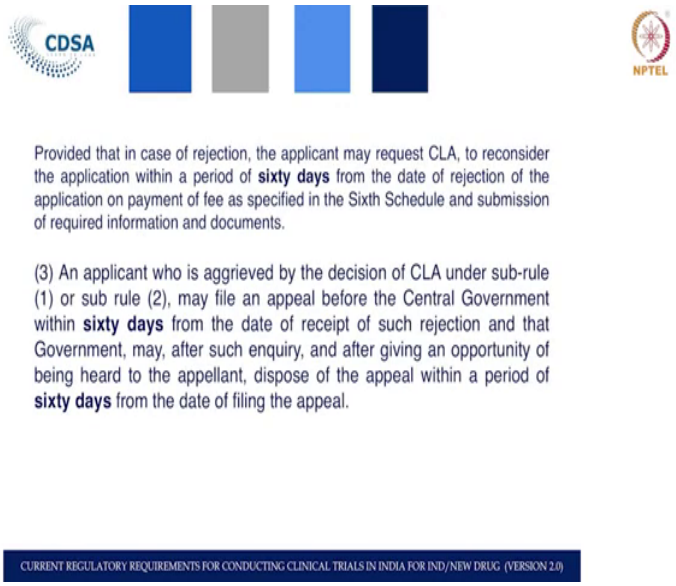

And if you are not satisfied with the decision of the central licensing authority, it can be gone to the Central Government with an appeal within a period of sixty days which can be again reconsidered. So, this is the process you will see throughout these particular sides. Now, for the rule 61, we come to the rule 61, validity period of permission is always 3 years and also where it is not satisfied where CLA is not satisfied.

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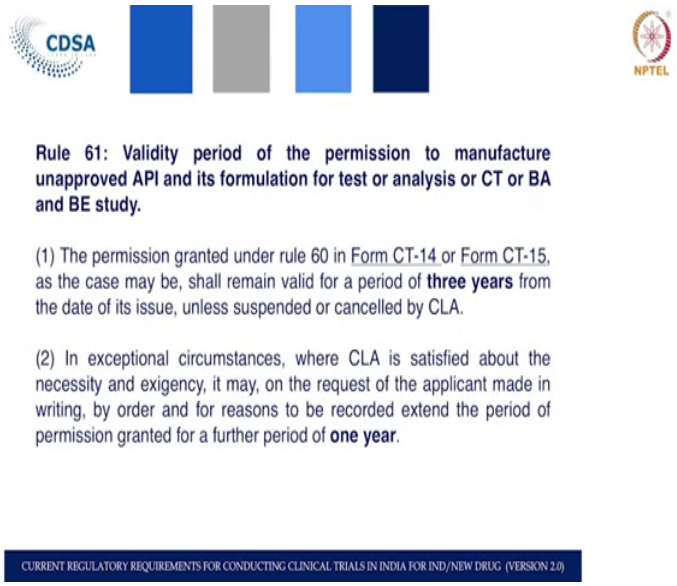

The permission is granted under rule 60 in form CT 14 or CT 15 and shall remain valid always for 3 years and in exceptional circumstances the permission can be extended up to 1 year when there is a particular reasons like it is always as I said that there was a problem. So, you have it has to be the applicant who has to justify for asking for an extension.

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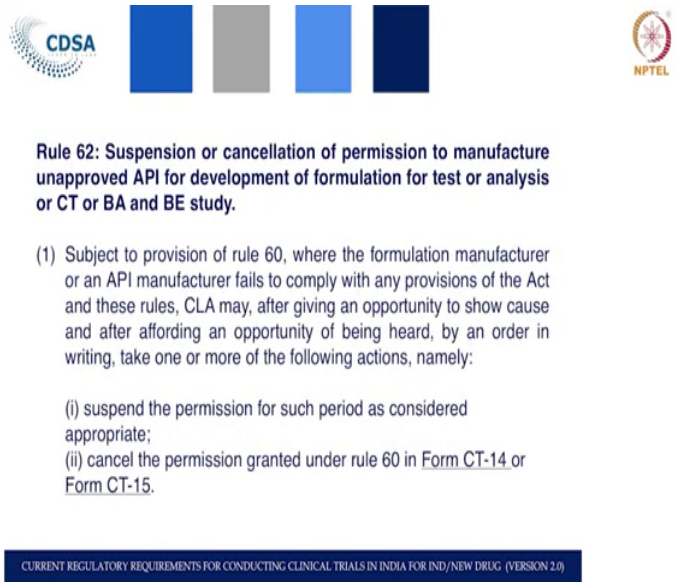

And the same process which is followed for the new drug it is also for the same for the unapproved API or for the finished formulation that once the permission is given if it is not if it can be suspended or canceled in case there are reasons to believe and in case, suppose there is an inspection of the facility and there are found there it is found that there are conditions of the license are not fulfilled then there can be a suspension or cancellation of the license.

Before that our show cause is given to the applicant to give reply to this and once the reply is found not satisfactory then such suspension or cancellation of permission is being done.

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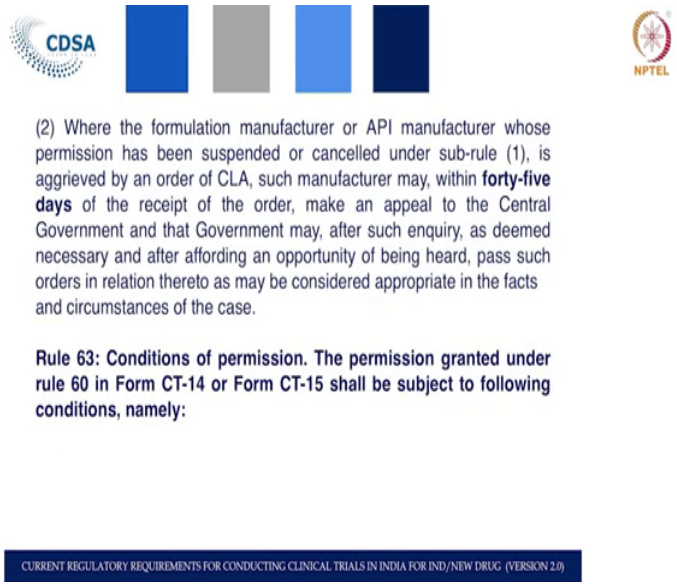

As said earlier, wherever there is such permission or an such suspension or cancellation is not found, is found not acceptable then they can; obviously, go to the central government within forty five days to make an appeal and for reconsideration.

Conditions of permissions in CT 14 and CT 15 are given under rule 63 as per that the API should be manufactured or the finished formulation should be manufactured. We say the pharmaceutical formulation should be manufactured under the principles of GMP, it should not be sold anywhere in the market other than the image purpose which is mentioned that whether it is for clinical trial where you have to maintain a complete record wherever the drug is used and also in cases fit is for the BA BE study.

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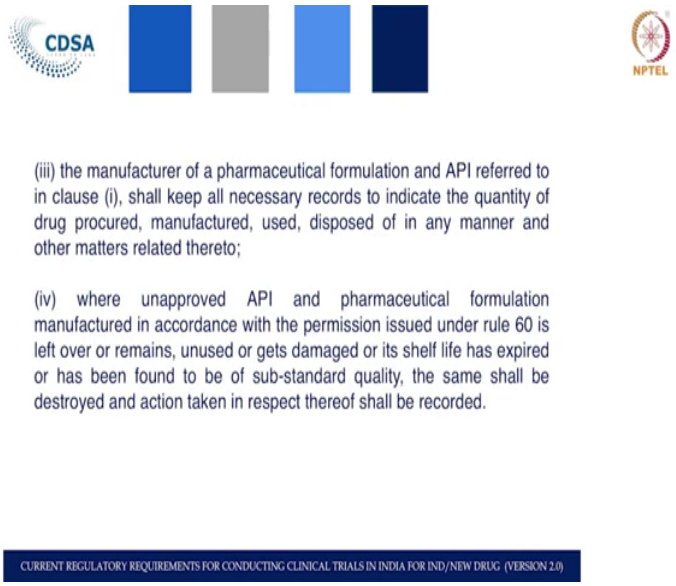

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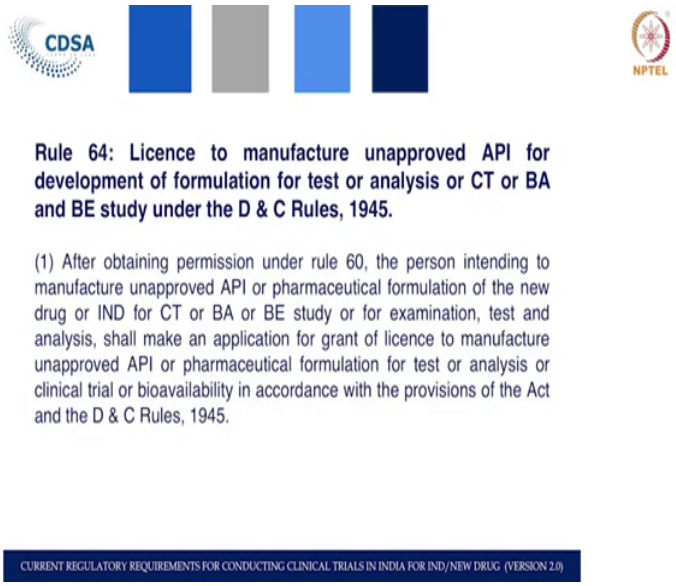

So, all cases that record has to be complete. And wherever in case the drug is already has expired or it has across the shelf life which has mentioned or it remained unused or there is a leftover that also it cannot be used anywhere or it cannot be given to any organization or institution it has to be destroyed and the records to be maintained.

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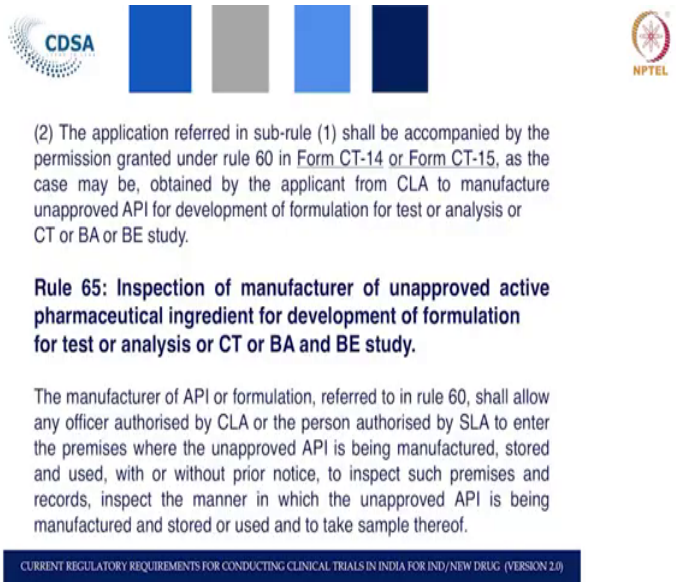

Further to this as I was as we have seen in the previously that once you get a permission from the CLA as like the CT-11 and CT-12 form applications of CT-11 form applications in CT-10 and getting a permission under CT-11. And similarly applications and permissions you receive under CT-14 and CT-15. After with this permission, you have to now apply under the drugs and cosmetics act with the same license that is which we call which is under the drugs and cosmetics act form 30 to the respective State Licensing Authority for manufacture of the drugs and you get a permission in form 29 to manufacture the drug.

So this permission has to be obtain after you get the permission to manufacture the drug from CLA. Once this permission is obtained then you can you are permitted to manufacture the drug and as was also explained earlier, you have the specific rule in 65 for the inspection whenever required by the state or the central licensing authority or it can be a joint inspection

always and it is always open for inspection and there can be a notice for an for such inspection or there may not be a notice.

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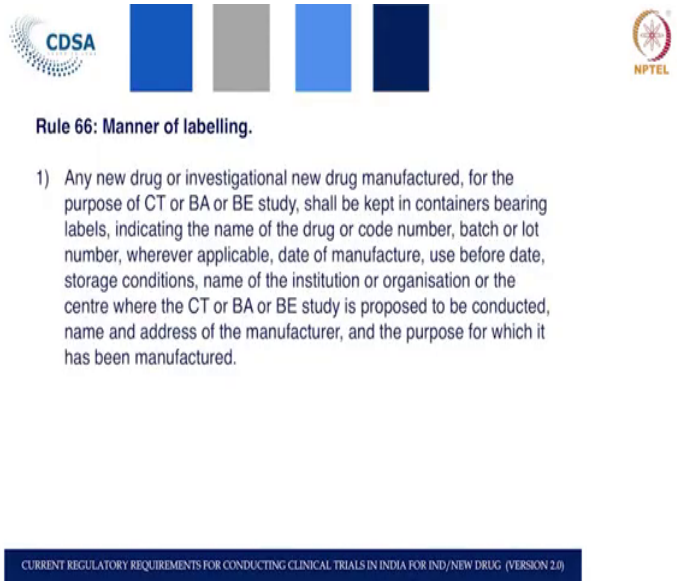

Also, this coming to the next slides which is rule 66 which is we feel this is the most important the manner of labeling it is important to label the drug using the code number or the name if there is a name for the drug, you may have a code number for an investigational new drug wherever applicable, you have to put the batch number or the lot number, date of manufacturer use before date storage conditions, name of the institution or organization where you are going to conduct the study and also you have to mention that the purpose for that drug.

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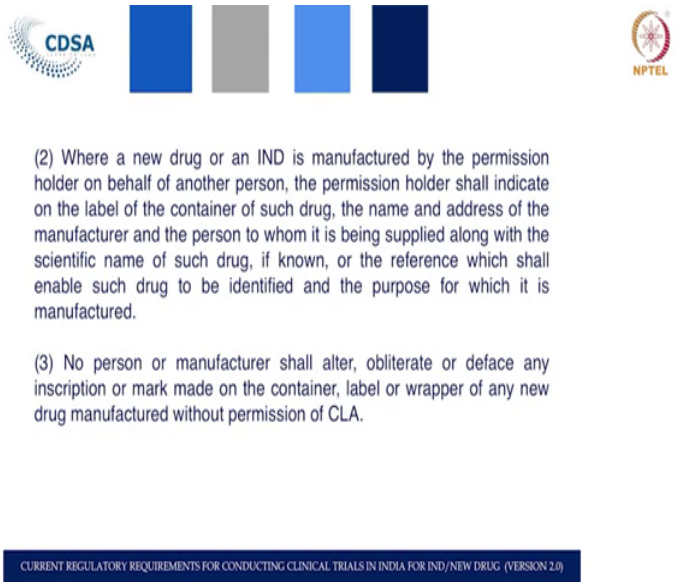

So, it is very important what we call this in a clinical trial definitely, we say that it is for the purpose of clinical trial or for the it is a new drug for the purpose of BA BE study. It is a new drug for the purpose of test or analysis wherever you give and we mentioned also we can use the word invest as an IP, I mean the investigational product ok. So, this is the, this is what we are learnt in this slides from rule 53 to rule 66 for manufacture of the new drug for the purpose of clinical trial.

Even in case of this labeling where it is someone else is manufacturing. So, it has to be clearly mentioned that where it when you are going to, to whom you are going to supply. So, if the manufacturer is different and the recipient who is going to conduct a clinical trial is different, it should be clearly mentioned in the label. And this is very important, no person or manufacturer

should ever be appealed it is not permitted to alter or obliterate or deface any inscription or mark made on the container labeled or wrapper of a new drug manufactured once.

So, you have to submit you know your label to the CLA before you start manufacturing the drug and putting a label. So, it cannot be done anything which you have mentioned in your application you are going to mention on your label that cannot be changed without the permission of the Central Licensing Authority.

So it is said that labeling is very important because, label shows that what is the drug anything and it is most important to have a proper label on any a new drug or investigational new drug.

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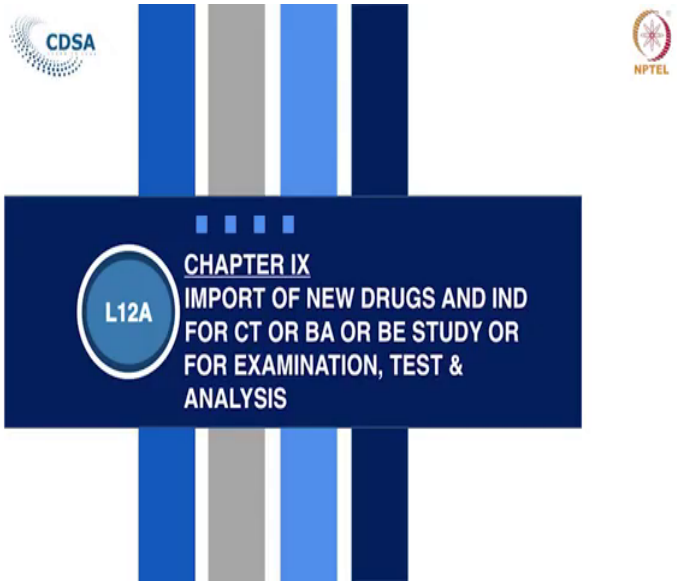

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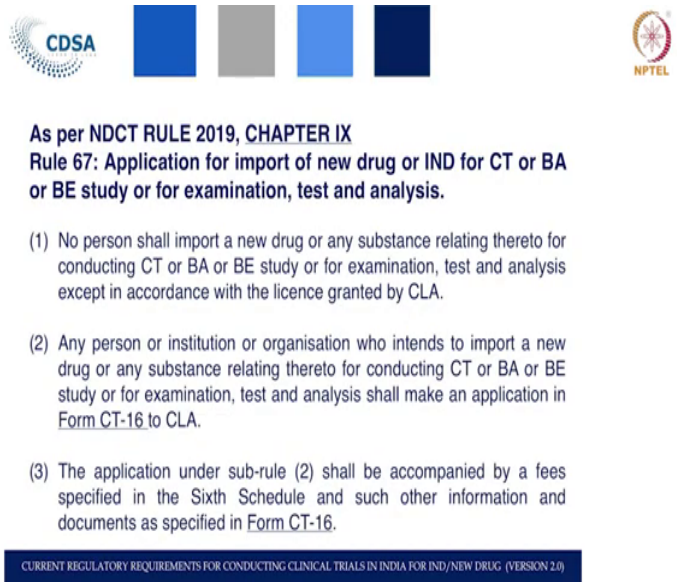

So, we finished the first part of this chapter 12 A and then we have the next part of the chapter 12 A which is chapter 9 and it deals with the import of the new drugs and the investigational new drug for clinical trial or as I said it can be BA BE study or for the examination test and analysis.

So, one was the first part was the manufacture and the second was that if you if the applicant proposed to import the drug for the purpose of conduct of clinical trial. As per this clinical trial rules, as per the chapter 9, that is starts with the rule 67 and goes up to rule 73 up to the manner of labeling as well.

So it starts how do you apply, so the application form in this case is form CT-16. And as was the conditions in the manufacturing case also in the conditions of import, you cannot import any new drug or any substance for conducting clinical trial unless you have obtain permission

from the CLA. So, you make the application in CT-16 for such important drug with the same fees which is proposed which is given in the 6th schedule 5000 per product and also with the documents which is mentioned in the 4th schedule.

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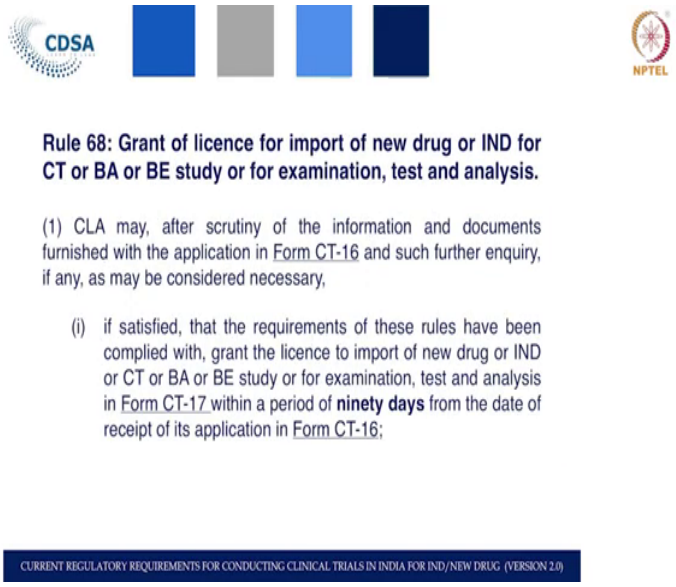

So, you get the permission is received in CT 17 and the timeline is said about ninety working days. So, either your applications after scrutinization will be accepted and a permission will be issued or otherwise the applications may be rejected. And in case there are deficiencies and the and it is understood by or it is failed by the CLA that the deficiencies can be rectified our deficiencies will be issued to the applicant within a specific timeline to comply with.

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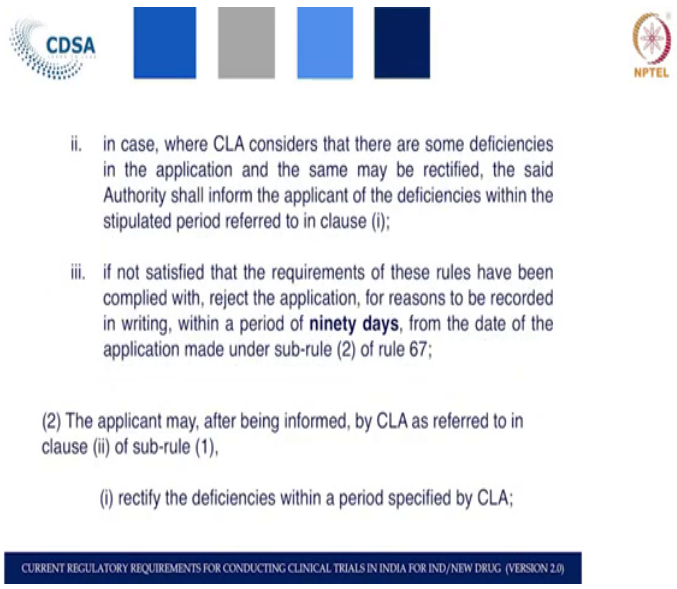

Once the compliance is made by the applicant then again within the timeline then the permission can be issued. So, that is the process which goes on for a manufacture or for an import.

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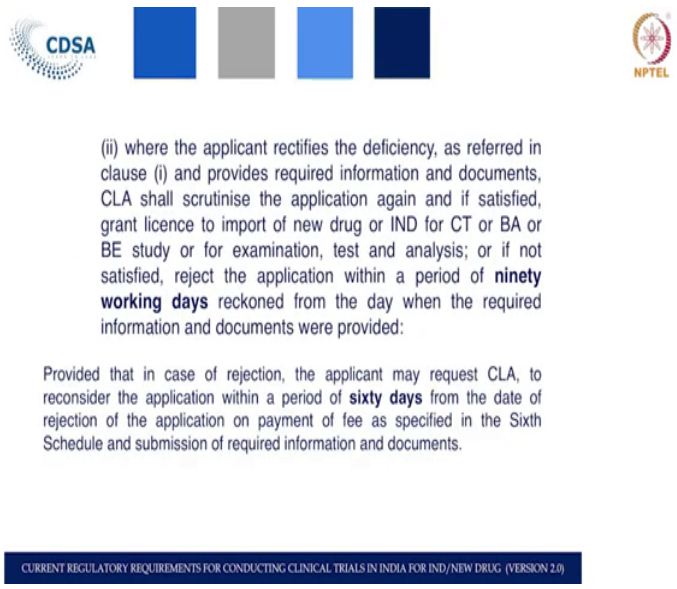

In all case, the type line of ninety days to be observed. And deficiencies once rectified is submitted to CLA, then the permission can be further issued as same as in case of the manufacture is also in the same case of import if the applicant is not contended or if the applicant is not a is aggrieved with the decision of the Central Licensing Authority they can appeal to the central government within sixty days and within the sixty working days the Central Government will be disposing off.

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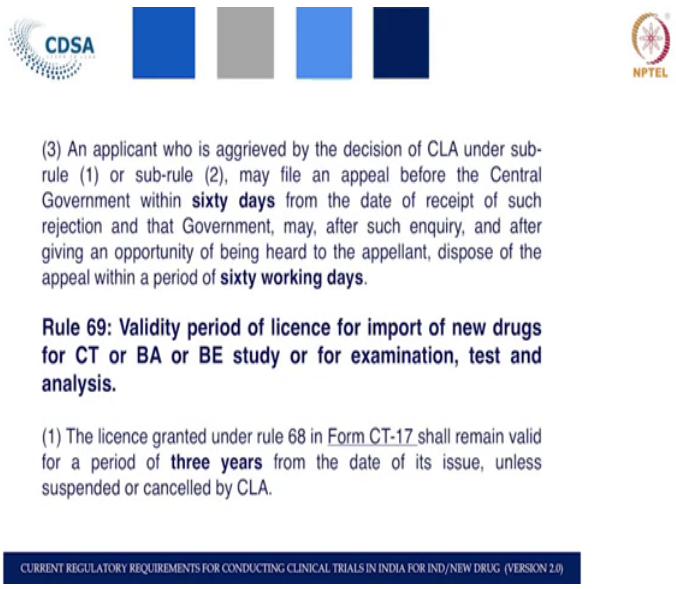

So, as the new drugs and the clinical trial rules has specifically mentioned all timelines, all mechanism, all process for an application and how the applicant has to go stepwise. Regarding the documentation also as it was told it is a just another recapitulation which is being made for you that the documentation requirements for any new drug for the purpose of the clinical trial you have to always refer to the 4th schedule and when you see the forth schedule, you will see the second schedule.

And the second schedule mentions the detailed documentation requirements and one by one for the different type of drugs and for the drugs and how the documentation of what are the requirements. So, basically, whatever information you have about your drug which you are under development you have to furnish, the forms are very simple and it can be; it can be the minimum information in which you have to start.

But it is very important that you mention clearly about your organization, about your constitution, about the manufacturer, about the manufacturing site address, the drug, the composition, the therapeutic category, all such informations and there are annexures with each form which is to be fulfilled. So, coming to the validity it is the same the three years and it can be also extended.

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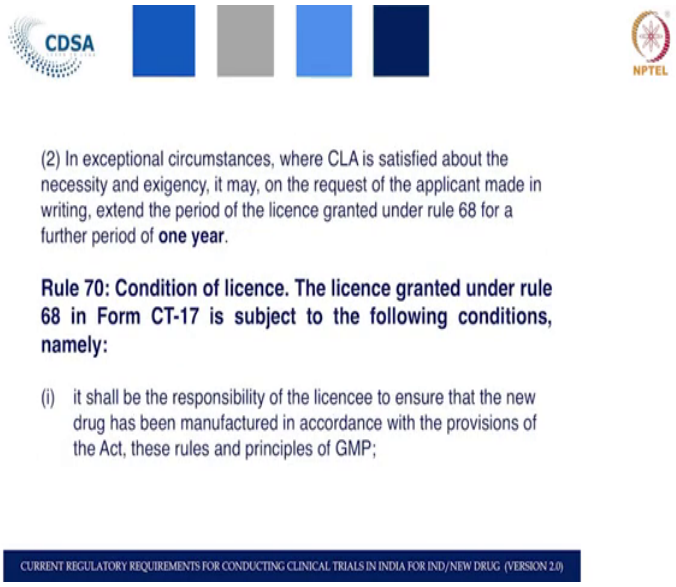

Where in the exceptional circumstances at circumstances, when you say that there is a results and you can satisfy then in the request of the applicants such license granted can be extended further to one year. The conditions of the license is also the same under the rule 70 that it should be that the drug which is being manufactured this it should be manufactured in accordance with the principles of GMP.

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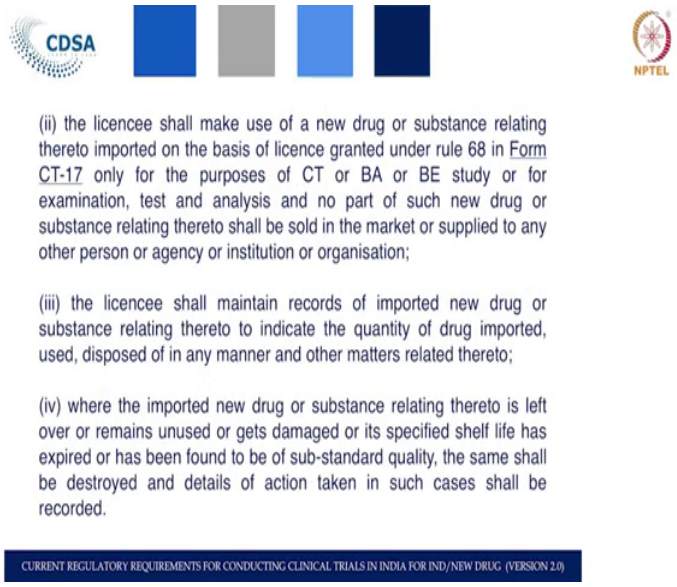

In all cases, it cannot be given to any person to anybody in the market or supply to any other person or agency other than the one which is specified in the permission, the quantity will be specified in the permission how much you are permitted to import the records of all such important drug shall be maintained by the applicant and it can it has to be how you are disposing of everything has to be completely maintained and when there is a damage or unused drug this also if you destroy the drugs the records to be maintained.

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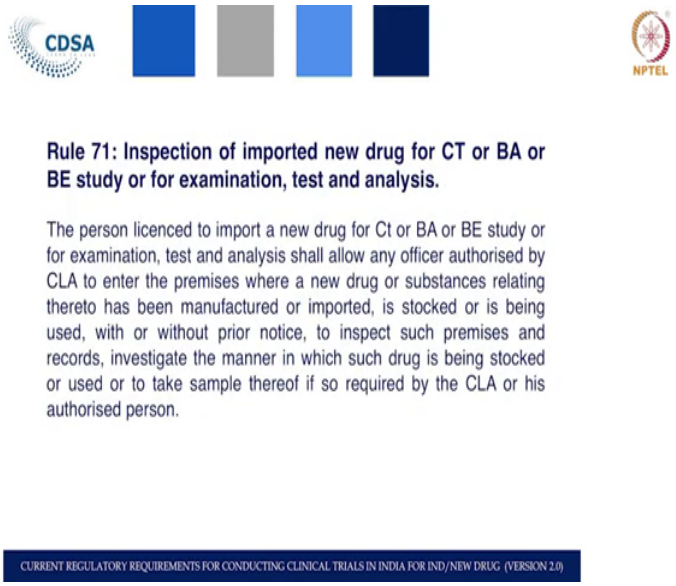

Also in case of such imported drug when you wherever it is stored in that case and you know the imported drug for storing such imported drug normally a premise has to be licensed for storing such imported drug even for the purpose of clinical trials. And such storage also will be mentioned in the permission and under the rule 71, the inspection is to be allowed and the same way without prior notice with or without prior notice it has to be it will it can be verified by the licensing authority it can be ct CLA or it can be SLA.

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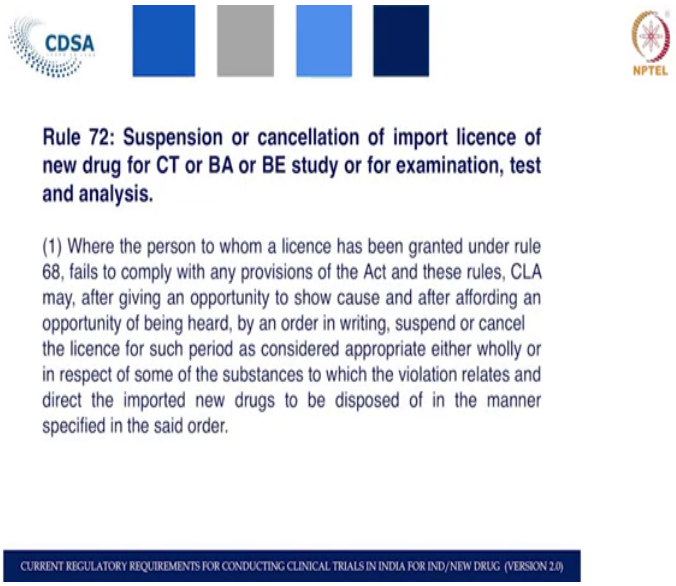

Also, there is the scope of suspension and cancellation under rule 72, in case there is a cancellation or suspension and it is aggrieved by the order of CLA, the person it cannot go back go to go to the central government within 45 days for reconsideration and also there appeal reconsider within 60 working days.

The manner of labeling as I was already told under the previous slides the same you have to indicate the name of the drug or the code number batch or lot number date of manufacturer use, before date storage conditions, which is most important because if you do not store the drug in a proper conditions you have not conduct a stability study for the drug which has been manufactured and which has been proved to be stable in a particular storage conditions, then such drug when given to the patient or in a clinical trial becomes of no use.

So, because of the in proper storage and if there is a degradation of the drug due to improper storage, the that the purpose is not fulfilled. So your purpose of conducting the clinical trial to test the efficacy of the drug, the safety and the efficacy of the drug will fail. So, it is very important that the storage conditions to be maintained and in all cases, again and again for all the slides in all the cases we have seen it is always mentioned that it has to be manufactured observing the good manufacturing practices principles.

So, that when further this drug is taken up in the further stage if it has proved to be safe and efficacious for the clinical in the clinical trial for a particular disease conditions.

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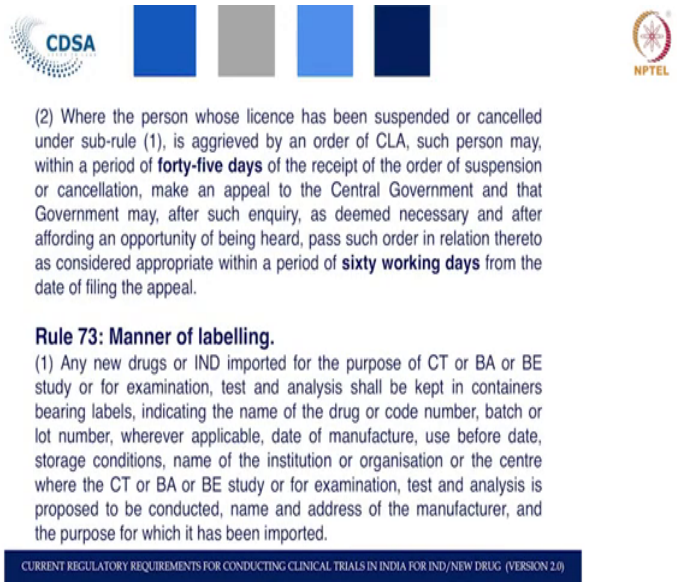

That case the manufacturing can be you know, there can be easily technology you know the same technology, the same manner can be used for manufacturing the drug. So, it is very important, how you develop your drug what is your manufacturing process how you stabilize

your drug and then finally, you put it into the storage conditions and you test the drug and you are going to use it into that patient. So, the label is important, the storage is important, organization and institution where the studies proposed is important and you also say the purpose of the drug.

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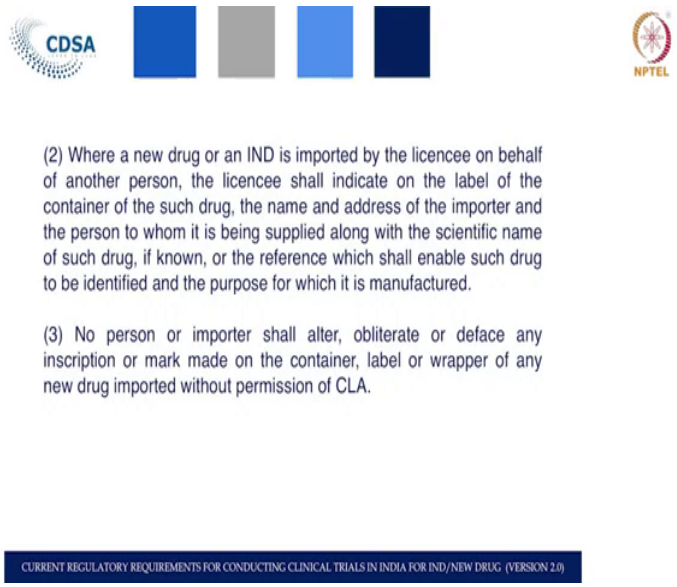

And if it is imported by some another person on behalf of another. So, everything should be very clearly mentioned in the label and nobody can alter or change the label which is a offense under the new drug in the clinical trial rule.

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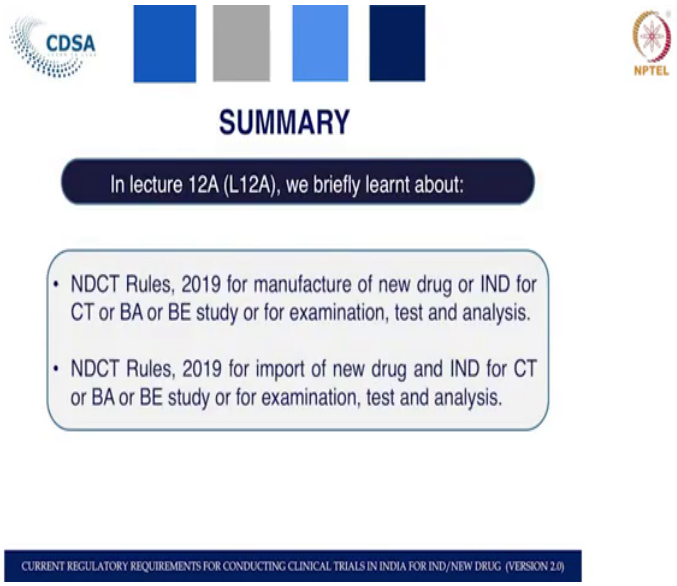

So, in this lecture 12 A, what we learnt? We learnt about the New Drug Clinical Trial Rules 2019 where it is mentioned the chapter 8 and chapter 9 talking about the manufacture of the new drug or investigational New Drug for a Clinical Trial and which is same also for conducting a bioavailability and bioequivalence study or for doing examination test and analysis. Because, you first of all need to know that the dragons of good quality.

So, you need an examination test and analysis. So, and also the various requirements and conditions and where conditions are if conditions are not fulfilled. So, that is the, in case of the import of the new drug for the purpose of clinical trial. New drug and investigational new drug for clinical trial.

So, in this chapter 12 A, we briefly learnt about the New Drug Clinical Trial Rules for manufacture of new drug or investigational new drug for clinical trial or a BA BE study of

examination test and analysis and also the rules for import of the new drug and investigational new drug for clinical trial or BA BE study or for the purpose of examination test and analysis.

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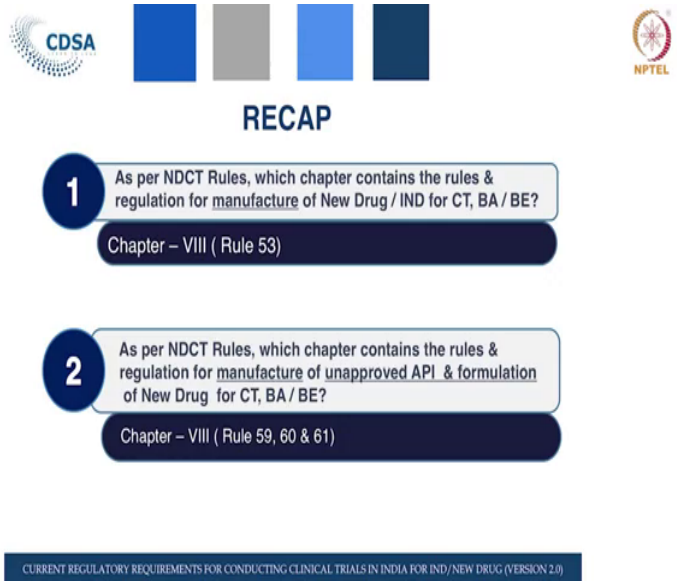

So, let us recapitulate, let us have some question answers. Are you ready? It is very easy is not it, the chapter is very easy. It is so, same for all the regulations you have learn the same thing, but you need to know where it is written, how you have to interpret and how you are going to act on that. So, what is there? As per the new drug clinical trial rules which chapter contains the rules and regulation for manufacture of new drug, investigational new drug for clinical trials for BA BE study. Can you please give me the answer? Do you have the answer with you?

We have just learnt. It is very easy chapter 8, rules and the rules are also you always have to refer to the rules? The rules 52 and 53. We go to next question as per new drug clinical trial

rules which chapter contains the rules and regulation for manufacture of unapproved API and formulation of New Drug for Clinical Trial, already written the answer is not it? Very easy. Shall I see the answer?

Let us see chapter 8, same chapter we have only gone through one of the chapter, chapter 8, but the rules are different, rule 59, 60 and 61 and it is very important to understand the rules because as I said again and again you should always refer back to the rules and read the content to understand what is the conditions you should comply with.

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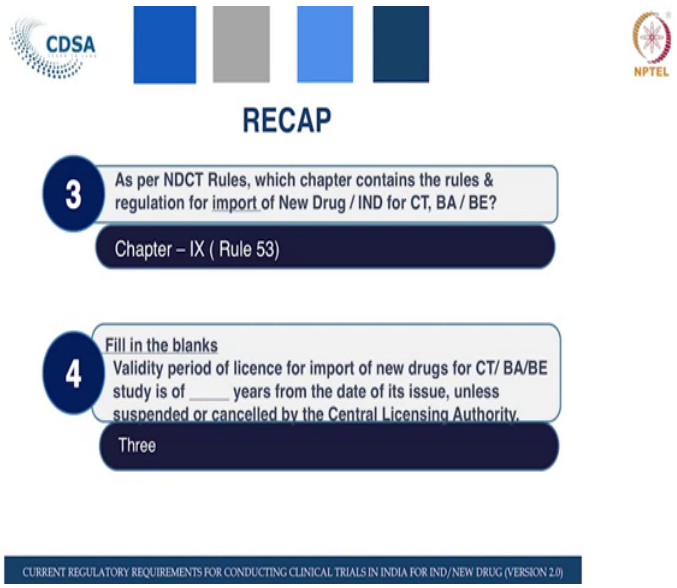

Question number 3; as per new drug clinical trial rules, which chapter contains the rules and regulation for import of new drug investigational new drug for clinical trial or BA BE study or for the purpose of test and analysis. Are you correct? Have you written the answer clearly? I

hope you have not repeated the same answer let us see what is the answer, chapter 9, but you have to mention the rules, the rules 67, 68, 69 and 70.

Let us do a small fill in the blanks, validity period of license for import of New Drugs for Clinical Trial BA BE study is of dash years from the date of its issue unless suspended or cancelled by the Central Licensing Authority. By the time I write you have written the answer is not it. So, let us see the answer I know everybody has written it correctly. That is 3 years always in all cases whether it is manufacture or whether it is import of drugs.

So, we have completed the lecture, are you hope you have all enjoyed this lecture. If you have any comments feedback and suggestions, we will be happy to address then and please write to us for your comments feedback suggestions thank you very much and all best wishes to you.