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

Prof. Arun B. Ramteke
Department of Biotechnology
Indian Institute of Technology, Madras

Lecture – 15
Clinical Trail Related Guidelines (NDCT Rules)

Hello everybody, today lecture is lecture 15 it is about the Clinical Trial Related Guidelines available in the country.

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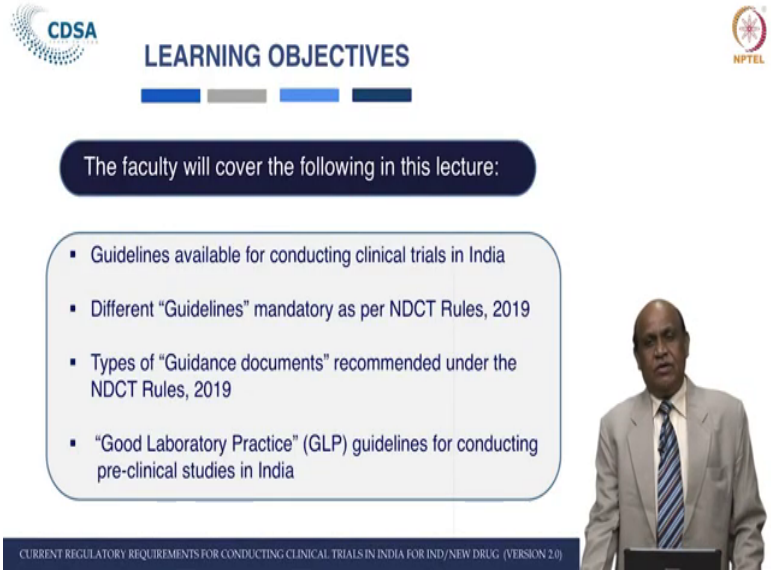

As you know every rules has to be explained properly that is why the there is a guidelines available which have we shows the details about the rules related to the clinical trials. So, guidelines help to understand the rules better and it gives the detailed procedures and rules related to clinical trials definitely. So, in India there is a few guidelines available to understand

the rule better rules are the mandatory in nature, but guidelines are not mandatory, it is a guidance to the applicant or to the stakeholders to perform their duty properly.

So, clinical trial if the main aim is to protect the patient safety and wellbeing so, what will we learn in this lecture? Lecture 15 that is; what are the guidelines available for conducting the clinical trial in India? We will learn about the different guidelines mandatory as per NDCT rules we will also learn about the types of guidelines available under the NDCT rules, 2019.

And there are also the guidelines for good laboratory practice is mandatory for conducting the pre-clinical studies that is animal studies and laboratory studies should be conducted as per the procedure in described in the good laboratory practice guidelines.

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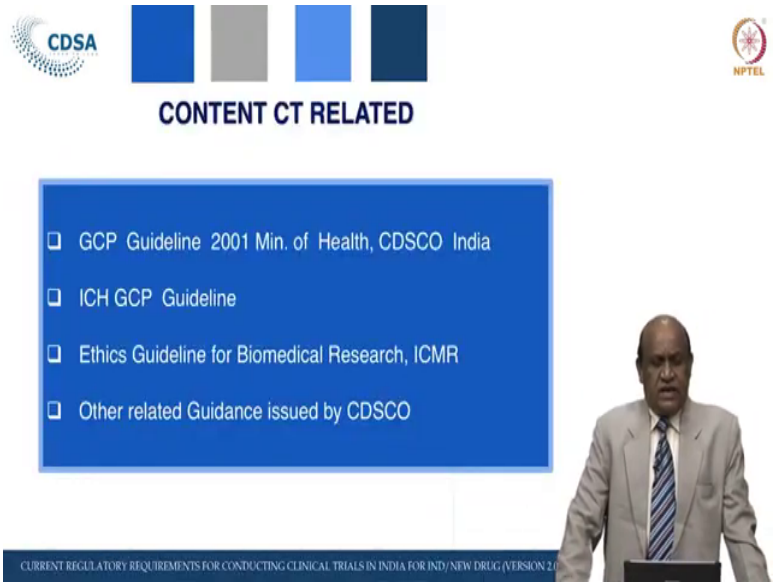

These are the slides which shows the guidelines available in India GCP Good Clinical Practice guidelines is available since 2001 made by the Ministry of Health and Regulatory Authority in India.

There are international guidelines on good clinical practice mainly the ICH guidelines and there are ethics committee , guidelines for biomedical research mainly to rules and regulation about the ethics committee procedures and how to conduct the meetings and how to approve the clinical trial protocols of human involving human and there are some other related guidelines issued by the CDSCO.

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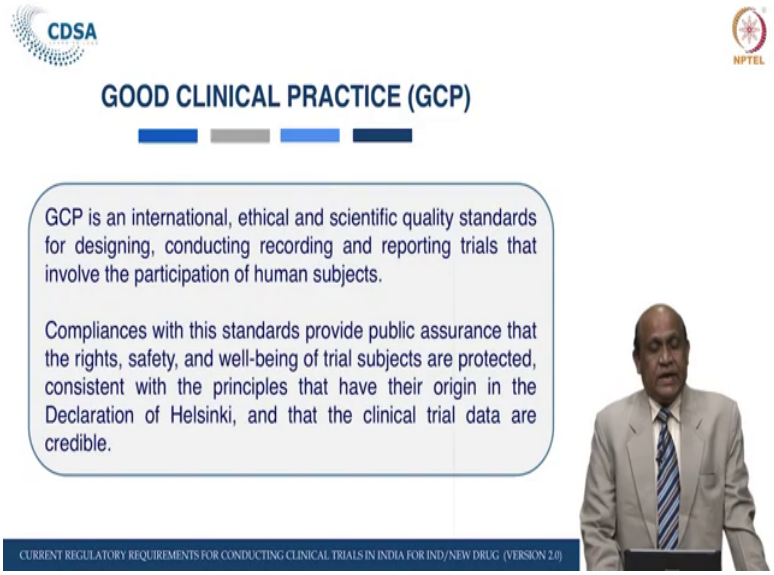

So, GCP Good Clinical Practice guidelines is an international, ethical and scientific quality standards for designing, conducting, conducting the trials recording and reporting the trials that involve the participation of the human subjects.

Compliances with this standards provide public assurance that right, safety and well-being of the trial subject are protected, consistency with principles that have their origin as per the Declaration of Helsinki and that the clinical trial data are credible. These are the principle of the GCP.

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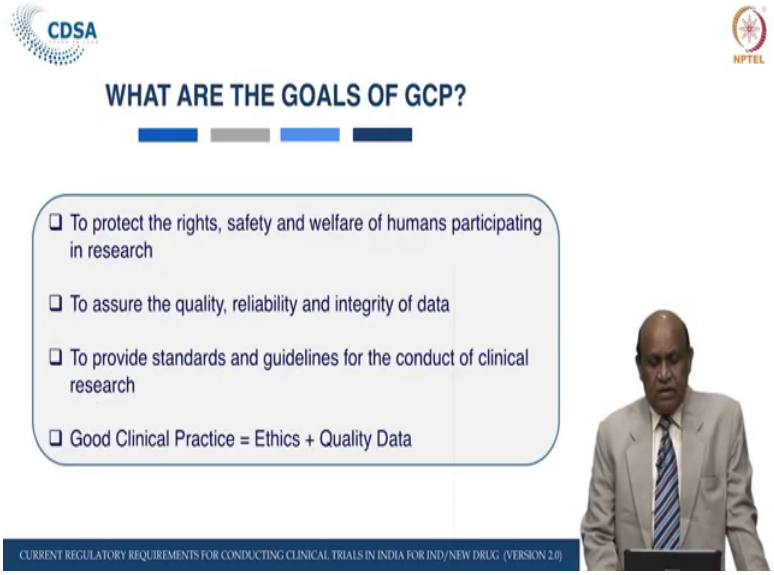

What are the goals of the GCP? that is to protect the right, safety and well-being of the human participants in the trials to assure the quality, reliability and integrity of the data collected in

the trial also to provide the standard and guidelines to conduct the clinical trials as well as clinical research that is; GCP is equal to ethics plus the quality data.

In India good clinical practice guidelines issued by the Ministry of Health and CDSCO in 2000 December 2001, there are also the good laboratory practice guidelines issued by the CDSCO in 2005. And there is draft guidelines requirement of chemical and pharmaceutical information including the stability studies data before approval of the clinical trial or bioequivalence studies, in India it is posted on the CDSCO website on December, 2011.

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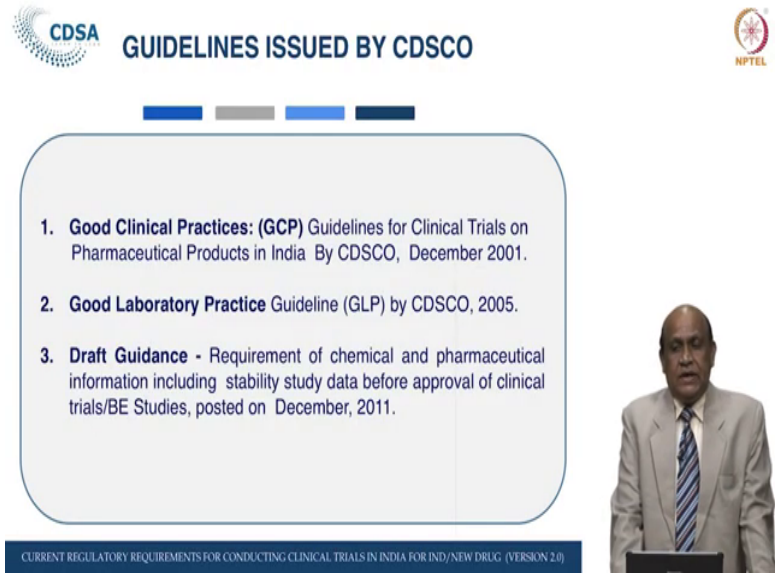

Some guidelines also issued by the CDSCO which are available at CDSCO website that is; a draft guidelines requirement of chemical and pharmaceutical information stability data in December, 2011.

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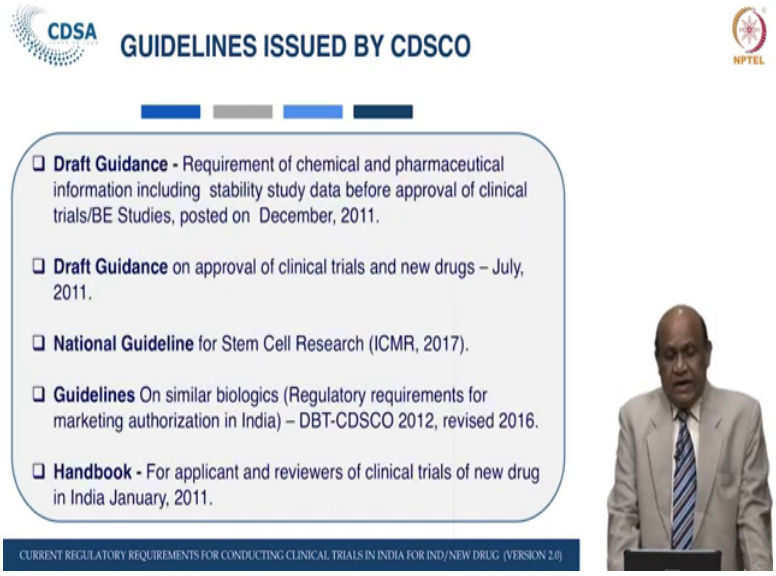

Draft guidelines for approval of clinical trial process of new drugs in July 2011. There are other guidelines like; national guidelines stem cell research issued by the ICMR guidelines on similar biologics that is; bio-similar is also available on the CDSCO and DBT website issued in 2012 and it is also revised in 2016 there is a handbook also available from the CDSCO website that is for the application and application and how to review the protocol clinical trial protocol of new drugs available at a CDSCO website in that is; available since January 2011.

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Guidance for industry also available on submission of clinical trial application and evaluating safety and efficacy of the product. It is also gives the details about the requirement for permission of new drug approval post approval changes of biological products like and it contains the quality, safety and efficacy documents. Preparation of qualitative information for drug submission also available in the guidelines there is also the guidelines on the approval of new biotechnological drugs and biological products available at the CDSCO website that is www dot cdsco dot gov dot in.

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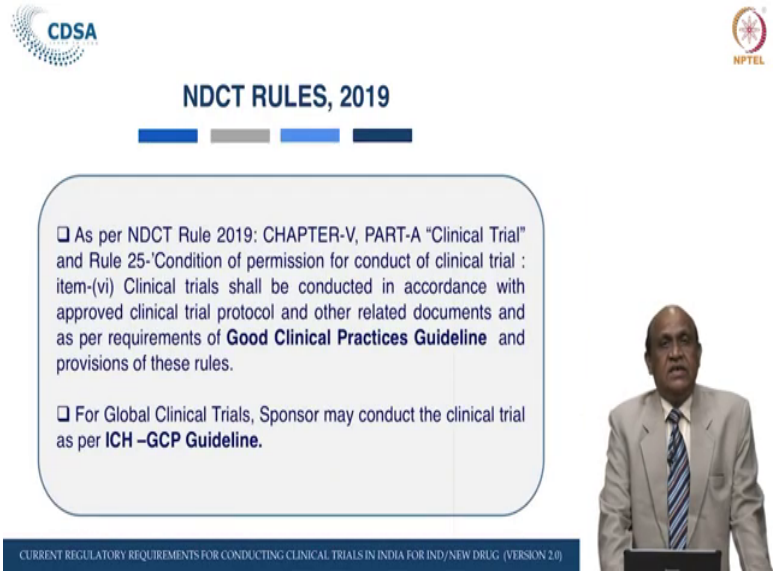

So, as per the recent NDCT rules 2019: in chapter 5, part-A which contained the "clinical trial" rules 25. They are condition of permission for conducting the clinical trials in the country this also shows the clinical trials shall be conducted in accordance with the approval approved clinical trial protocol by the regulatory authority and other related documents as required as per the GCP guidelines. For global clinical trials one has to submit the information as per the ICH guidelines ICH GCP guidelines for conducting the clinical trial in India.

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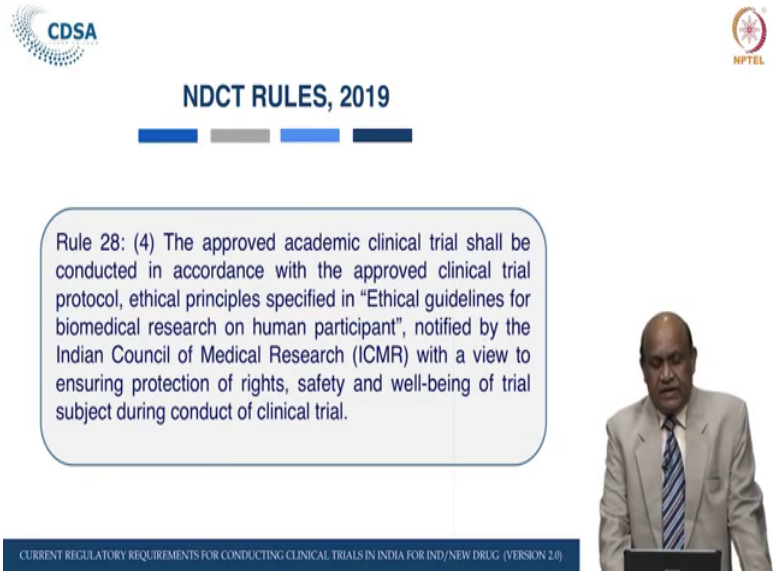

As per the rule 28 4 The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethics principle specified in the ethical guidelines biomedical research of ICMR with a view to ensuring the protection rights and safety health as well as well-being of the trial subjects during the conduct of the clinical trial in the country.

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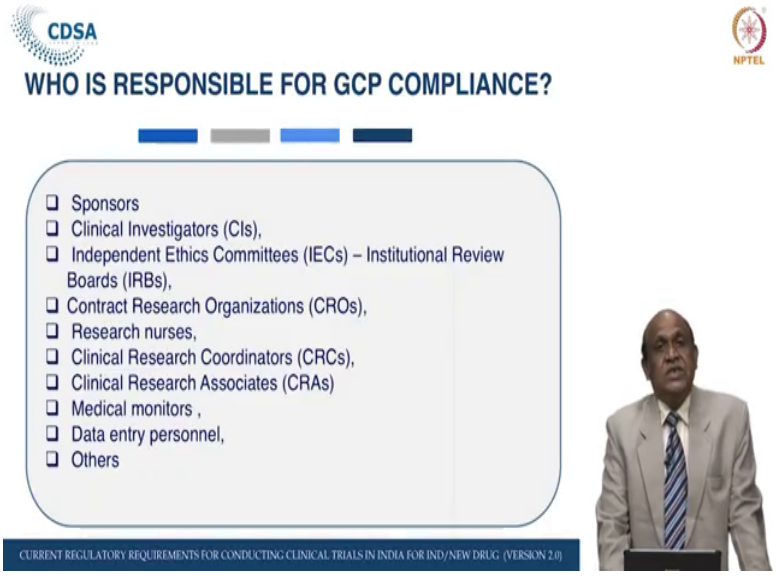

Who is a responsible for GCP compliance? These are the few stakeholders listed out here that is; sponsor, clinical investigator, independent ethics committee or institutional ethics committee, contact research organizations, research nurse, clinical research coordinators, clinical research association associated associates and medical monitoring and data entry personnel, etcetera are responsible for compliance of the GCP in the country.

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ICH, ICH is the International Conference of Harmonization of technical requirements for registration of pharmaceutical for human use it is a. Harmonization conference of the initially it was only the Europe, Japan and United State are members of the ICH to discuss the scientific and technical aspects of pharmaceutical product registration. International council of harmonization is a unique in the bringing, bringing together the regulatory authorities of and pharmaceutical industry to discuss the scientific and technical aspects of the drug registration in their countries.

Since it is inception in 1990 ICH has gradually evolved to respond to increasingly global phase of drug development ICH's is a mission to achieve greater harmonization worldwide to ensure that the safe, effective and high quality medicines are developed and registered in the most of the resource efficient manner.

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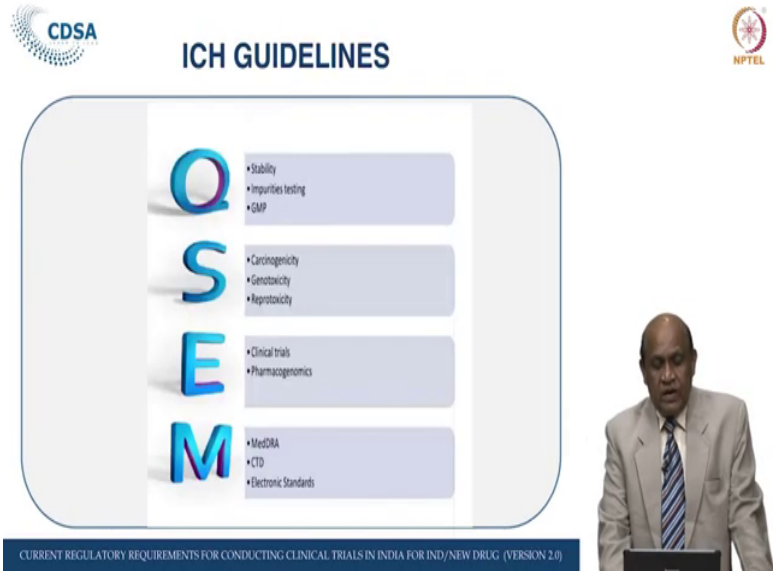

These are the 4 main requirements as per the ICH guidelines that is; Q is for quality which contain the stability, impurity testings and good manufacturing practice. S is a safety that is in like; a pre-clinical annual talks, carcinogenicity, genotoxicity and reprotoxicity. E is the efficacy that is; done in the form of clinical trial and pharmacogenomics and M is the management that is medical DRA, CDT, electronic standards are given in the details about this in the ICH guidelines.

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GCP is a international quality standard we already known that ICH also saying the same thing. Main goal of the ICH is harmonization of technical products and standards, to improve the quality of the medicine. In 1997, the FDA endorsed the GCP guidelines developed by the ICH. After that it goes various revisions and last revision was done in 2016 ICH guidelines have been adopted into law in various other countries.

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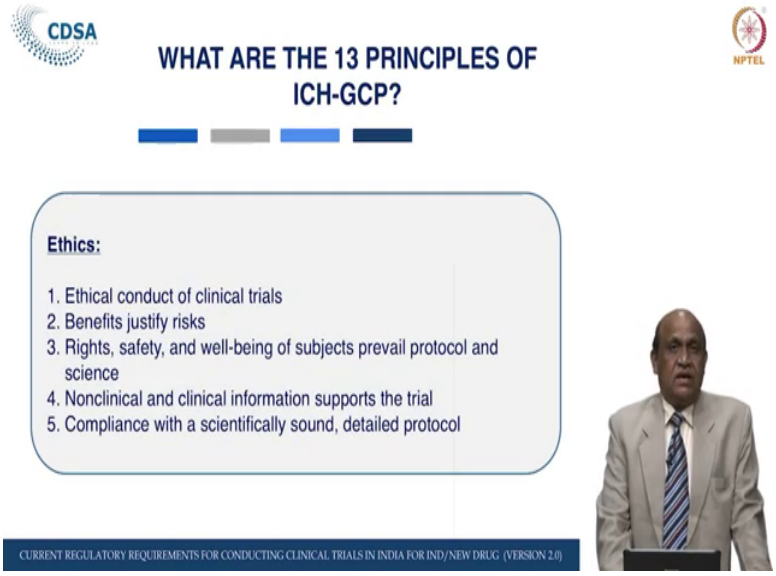

There are about 13 principle recommended by the ICH GCP; one is, under the ethics there is a ethical conduct of the; ethical conduct of the clinical trials. Benefits for justification of justify the risk and benefits. Right, safety and well-being subject will be prevailed and non clinical and clinical information support the trial, compliance with the scientifically sound and details protocol.

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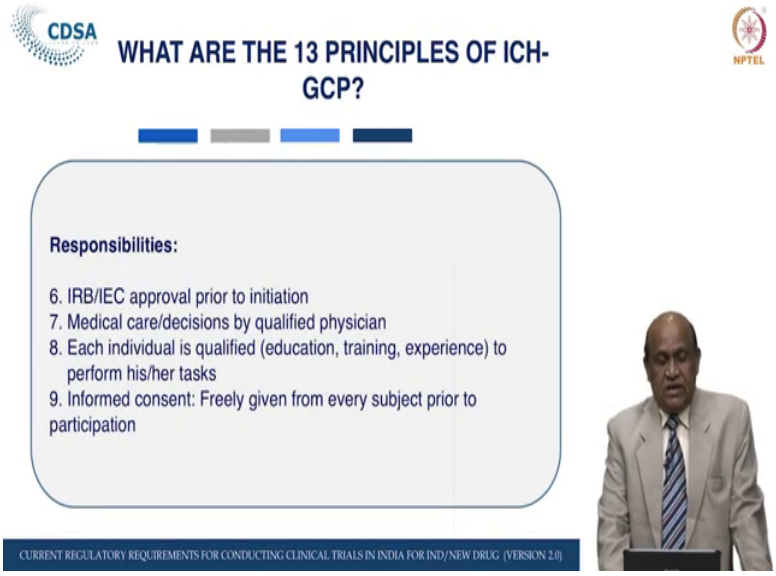

Under the responsibilities there is a IRB Institutional Review Board or IEC Institutional Ethics Committee approval for initiation of the trial, medical care or a decision by the qualified physician, each individual is qualified must be qualified that is why; by education as well as training and experience to perform her his or her tasks properly there is an informed consent informed consent should be freely given from every subject prior to participation.

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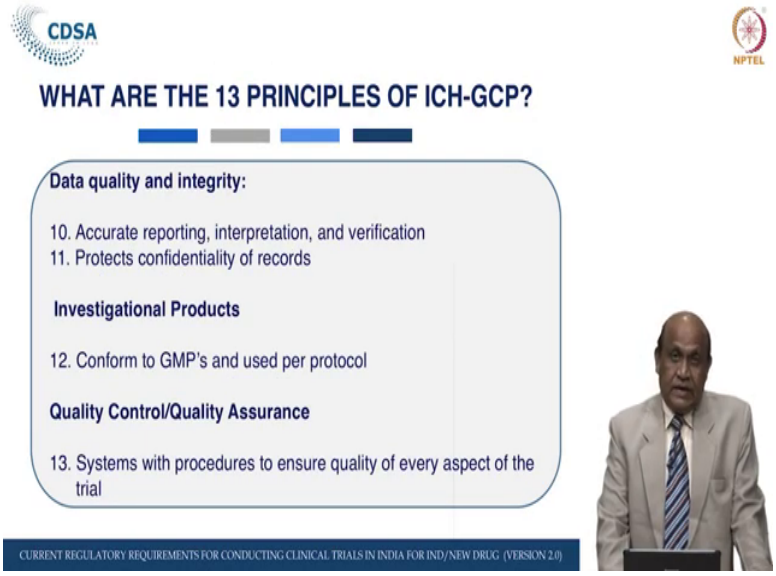

And under the data quality and integrity; it is also the accurate reporting, interpretation of the results verification and protects of the confidentiality in the records. Under the investigational product it should be as manufactured as per the GMP norms Good Manufacturing Practice norms and use as per the protocol. Quality control or quality assurance also there are systems available for the procedure to ensure the quality of every aspects of the trial.

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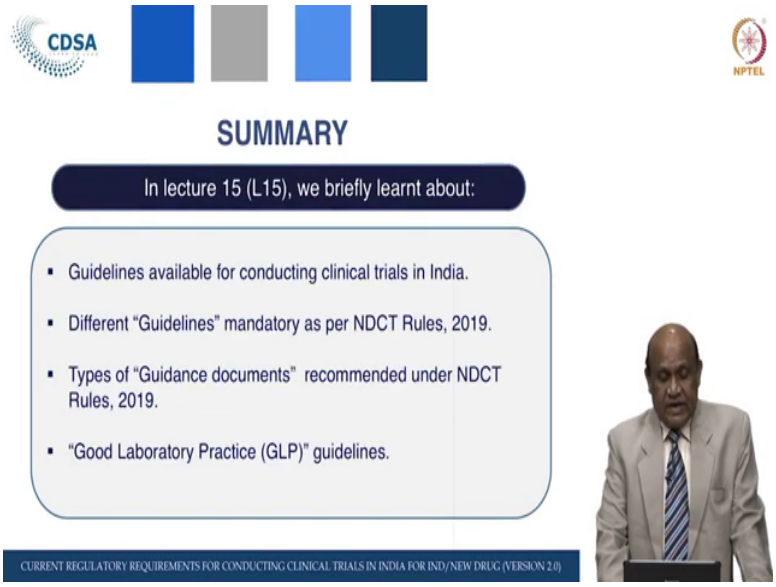

So, these are the brief about the guidelines use in the clinical trial conducting the clinical trials in the country.

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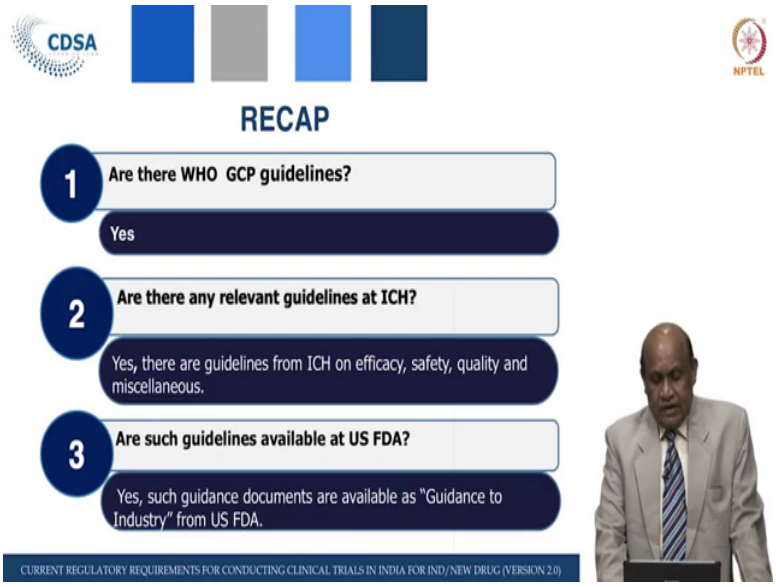

So, now we have come to the end just we will learn about the what we learned these are the few questions, which I put it on the slides are the who GCP guidelines- are there answer is yes, are there any relevant guidelines at ICH- yes, there are different guidelines on ICH efficacy, safety, and quality and management. Are such guidelines available in the US FDA- yes, US FDA has their own guidelines on good clinical practice which is available as a guidance to industry at US FDA site.

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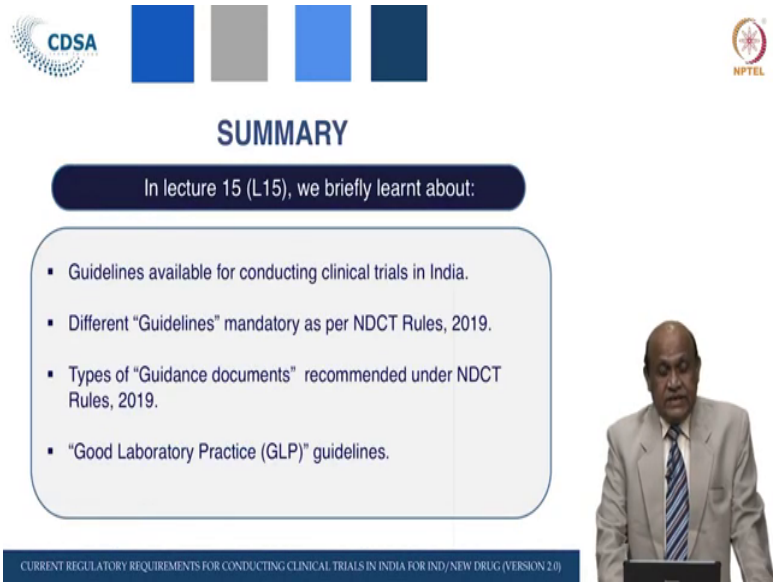

In summary of lecture 15 we briefly learned about the what are the guidance available for the conduct of clinical trial in India, we will also learn about the guidelines mandatory as per the NDCT rule 2019. We also learn about the types of guideline documents available and recommended by the NDCT rules and we also briefly about good laboratory practice guidelines available in the country.

Thank you very much.