CHAPTER-II

Roles and Responsibilities of the Regulatory authority

- Regulatory authorities are bodies having the power to regulate.
- In the ICH-GCP guideline the regulatory authorities includes the authorities that review submitted clinical data and those that conduct inspections.
- These bodies are sometimes referred to as competent authorities.
- The Drugs Controller General Of India (DCGI) or an office nominated by him is the regulatory authority for the purpose of carrying out Clinical Trials in India.

- The various roles and responsibilities of regulatory authorities are as follows:

1. Regulatory authorities are responsible to review clinical trials of both non-registered medicinal substances and new indications of registered medicinal substances.

2. Regulatory authorities has a statutory obligation to ensure that the drugs available in the country fulfils the necessary requirements for safety, quality and efficacy.

3. Regulatory authorities has the responsibility to close down an on going trial in the case there are serious breaches of Good Clinical Practice.

4. Regulatory authorities are responsible to implement a regulatory system where in all clinical trials to be conducted in the country have to register with them.

5. Regulatory authorities will have the overall responsibility to promote , ensure and monitor compliance by approved ethics committees in a country with relevant legislation, regulations and guidelines including guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in the country.

6. Regulatory authorities are responsible for effectively reviewing all the documents (containing both clinical and non clinical data) before giving permission for the marketing of a new drug in any country to ensure the efficacy and safety of the drug in humans.