Function of various Regulatory Authorities of India

Review Committee for Genetic Modification RCGM: The function of this committee is to frame the regulations for the institutions involved in rDNA research activities and

i. to review the on-going researches involving hazardous microorganisms,
ii. to visit the experimental site and ensure that the trial is being carried out as per the guidelines,
iii. to advice the custom authority on import of microorganism and G.M. products.

Principal Investigator (PI): The principal investigator of the company is primarily responsible for ensuring compliance with biosafety standards. The PI functions as a project manager as well as a researcher, communicating with the IBSC and bearing responsibility for training and supervising personnel. His functions include:

i. to make an initial determination of the required levels of physical and biological containment in accordance with the DBT guidelines.
ii. to submit the initial research protocol and any subsequent changes (such as changes in the source of DNA or host vector system) to the IBSC for review and approval.
iii. to ensure that no work is initiated until the research project has been approved by the IBSC and has met all requirements of DBT guidelines.
iv. remain in communication with the IBSC throughout the conduct of the project.
v. to ensure the safe conduct of the rDNA experiments in his laboratory.
vi. to make available the protocols that describe the potential biohazards and the precautions to be taken to all laboratory staff.
vii. to instruct laboratory staff about the practices and techniques required to ensure safety, and the procedures for dealing with accidents including the reasons and provisions for any precautionary medical practices advised or requested (e.g. vaccinations or serum collection).
viii. to supervise the performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
ix. to undertake corrective measures promptly for any work errors and conditions that may result in the release of recombinant DNA materials.

Institutional Biosafety Committee (IBSC): IBSC is the nodal point of interaction within a commercial organisation/applicant company involved in rDNA research for the implementation of rDNA guidelines.
IBSC has to furnish half yearly reports on the ongoing projects in the organization to RCGM regarding the observance of the safety guidelines including accidents, risks and deviations, if any. IBSC functions include:

i. to bring out manuals of guidelines specifying producers for regulatory process on GMOs in research, use and applications including industry with a view to ensure environmental safety.
ii. to review all ongoing r-DNA projects involving high risk category and controlled field experiments.
iii. to lay down producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications.
iv. to permit experiments with category III risks and above with appropriate containment.
v. to authorize imports of GMOs/ transgenes for research purposes.

vi. to authorize field experiments in 20 acres in multi-locations in one crop season with up to one acre at one site.
vii. to generate relevant data on transgenic materials in appropriate systems.
viii. to undertake visits of sites of experimental facilities periodically, where projects with biohazard potentials are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.
ix. to adopting emergency plans.

Recombinant DNA Advisory Committee (RDAC): The main function of the committee is to review the developments in Biotechnology at the national and international levels and to recommend the appropriate safety regulations for India in rDNA research works i.e r-DNA guideline.

State Biotechnology Coordination Committee (SBCC): The function of this committee is mainly to

i. to inspect, investigate and has the power to take punitive action in case of violations of statutory provisions through the State Pollution Control Board or the Directorate of Health etc.
ii. to review periodically the safety and control measures in various institutions handling GMOs.
iii. to act as nodal agency at State level to assess the damage, if any, due to release of GMOs and to take on site control measures.

The Committee coordinates the activities related to GMOs in the State with the Central Ministries. This committee also nominates State Government representatives in the activities requiring field inspection of activities concerning GMOs.

Genetic Engineering Approval Committee (GEAC): The main function of this committee is to approve or deny various activities. In the cases of large-scale field trials, deregulation and commercialization, a permission of GEAC constituted under the MoEF is required in addition to the DBT approval process.

Precisely, approval of the GEAC is required from the environmental angle on:

i. Import, export, transport, manufacture, process, selling of any microorganisms or genetically engineered substances or cells including food stuffs and additives that contain products derived by gene therapy.
ii. Discharge of genetically engineered/classified organisms/cells from Laboratory, hospitals and related areas into environment.
iii. Large-scale use of genetically engineered organisms/classified microorganisms in industrial production and applications. Production can only be commenced after obtaining such approval.
iv. Deliberate release of genetically engineered organisms.

Indian Council for Medical Research (ICMR): is the apex body in India for the formulation, coordination and promotion of biomedical research. Clinical trial to be performed needs to be carried out under the various guidelines set up by ICMR. These guidelines and relevant information is provided at the following web link:

- Biomedical ethics - human experimentation (web link)
- Biomedical ethics- Laboratory animal welfare (web link)