GUIDANCE DOCUMENTS FOR REGULATORY SUBMISSIONS

In an effort to help stakeholders get over the regulatory complexities involved in their interactions with the Health Authorities, ministries or regulators, Indian Society for Clinical Research (ISCR) has attempted to provide a gist of the various process documents that are required for submission in the various categories of trials and what needs to be done / submitted, in a simple, easy to understand format.

DISCLAIMER

For document see below

Regulatory Requirements for Biotech products

There seems to be no explicit regulatory guidelines currently available for filing a CTA with Biotech products.
This implies that the current regulations governing CTA's in general will hold true for Biotech products as well.

However on the website of the Department of Biotechnology (Government of India) a Draft 'National Biotechnology Development Strategy' is posted. This document can be accessed using the following URL. This being a draft strategy, it is basically only in the form of recommendations. Further one can visit page numbers 18, 34, 41 and 42 of this document to get an idea of how the future regulatory framework for clinical trials is likely to emerge.
http://dbtindia.nic.in/biotechstrategy.htm

Also existing 'REGULATORY MECHANISMS FOR GMO AND PRODUCTS THEREOF' can be accessed from the following URL
http://dbtindia.nic.in/policy/polimain.html

For marketing authorisation (approval) of Biotech products, the recommendations and proposed classification of Biotech products alongwith the proposed regulatory flowchart is given in 'Notification regarding adoption of the recommendations of the task force on r-pharma under the chairmanship of Dr R A Mashelkar, DG-CSIR with effect from 1. 4. 2006' This notification can be accessed by the following URL.
http://envfor.nic.in:80/divisions/csurv/geac/rpharma_tf.pdf