Indian Drugs/Biologics Regulations

Four Essential Elements of Regulations

- There is a OR multiple Regulatory Authority/ies
- There are National Laws
- There are different entities to be approved- Drugs, Biologics, Recombinant biologics, Cell-based therapies, Devices etc.
- These entities are at different levels/stages of development for approvals-Importation, Pre-clinical, Phase I/II/III or Indigenously developed
Laws on Biologics Regulation in India

Multiple

- The Drugs & Cosmetics Act, 1940
- Schedule Y introduced under Drugs & Cosmetics Act, 1940 in 1988 (Amended version, 2005)
- The Environmental Protection Law, 1986
- The Bio-safety Regulations, 1989
- The Patents Law, 1970 (The Patents Amendment Act, 2005)
Regulatory Authority/ies

**Multiple**

- The Drugs Controller General of India (DCGI) under the Ministry of Health & Family Welfare
- The Department of Biotechnology under the Ministry of Science and Technology
- The Ministry of Environment and Forests
- The Controller General of Patents, Designs, Trademarks under the Ministry of Commerce and Industry
- Now proposed National Biotechnology Regulatory Authority
The Drugs & Cosmetics Act, 1940

Schedule Y

Refers to requirements and guidelines to be followed in order to attain permission of:

- Importing
- and/or
- Manufacturing New Drugs to market
- or
- To undertake clinical trials in India.
Essentials of Schedule Y

- Depends on the status of drug in the country of origin
- Approved Drugs/Biologics-Phase III
- Not Approved Drug-One Phase earlier
- New Discovered Drugs in other countries- Phase I not permitted; hence Safety data needed
- Trials permitted for drugs of special relevance
Essentials of Bio-safety Laws

- Applicable to all r-DNA products
- Three-tier bio-safety system before clinical trials
  1. IBSC (At the Institute Level)
  2. RCGM (At the D/O Biotechnology level)
  3. GEAC (At the M/O Environment)
- Approval for Human trials given by the DCGI
Drivers of making Laws

- Domestic needs-(Cost-Effective)
- Economic needs- (To capture non-regulated OR semi-regulated markets by making Generics & Bio-similars)
- Political situation-(Adopting Process Patent)
- Providing impetus to technological development (Adopting Process Patent)
- Promoting inventive activities in the country (Adopting Process Patent)
- International obligations on Trade matters (WTO) (Adopting Product Patent)
- Harmonization of International standards for Quality(ICH-GCP)
What is there in Cancer Biologics?

- Cancer Vaccines-Prophylactic (Hep-B, HPV, H. pylori)
- Cancer Immuno-modulators (bCG, M. indicus pranii)
- Cancer therapeutics (Predominantly Bio-similars)
- Stem Cell therapy-????
- Other cell-based therapies (DC-based)
- Devices????