Pharma Regulations & Guidelines-India

(1). Regulations & Guidelines:

CDSCO	**Central Drugs Standard Control Organization (CDSCO),** Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India.
NPPA	**Drugs (Price Control) Order 1995** and other orders enforced by **National Pharmaceutical Pricing Authority (NPPA),** Government of India. View the list of drugs under price control here.....
D & C Act, 1940	**The Drugs & Cosmetics Act, 1940** regulates the import, manufacture, distribution and sale of drugs in India.
Schedule M	**Schedule M** of the D&C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.
Schedule T	**Schedule T** of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.
Schedule Y	The clinical trials legislative requirements are guided by specifications of **Schedule Y** of The D&C Act.
GCP guidelines	**The Ministry of Health,** along with **Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR)** has come out with draft guidelines for research in human subjects. These **GCP guidelines** are essentially based on Declaration of Helsinki, WHO guidelines and ICH requirements for good clinical practice.
The Pharmacy Act,1948	**The Pharmacy Act, 1948** is meant to regulate the profession of Pharmacy in India.
The Drugs and Magic Remedies (Objectionable	**The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954** provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities.

Advertisement) Act, 1954	
The Narcotic Drugs and Psychotropic Substances Act, 1985	**The Narcotic Drugs and Psychotropic Substances Act, 1985** is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

(2). Links to important international guidelines and regulatory bodies:

WHO (Medicines)	**WHO guidelines** on medicines policy, intellectual property rights, financing & supply management, quality & safety, selection & rational use of medicines, technical co-operation and traditional medicines.
WHO sites	**WHO guidelines** on all areas relevant to health of people all over.
ICH	**International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH)** guidelines defining quality, safety, efficacy & related aspects for developing and registering new medicinal products in Europe, Japan and the United States
OECD	**Organization for Economic Collaboration and Development**including 30 member countries covers economic and social issues in areas of health care.
EMEA	**European Medicines Agency (EMEA),** a decentralised body of the European Union headquartered in London, prescribes guidelines for inspections and general reporting and all aspects of human & veterinary medicines in the European Union.
US FDA	Regulations, guidelines, notifications, news and communications from US **Food and Drug Administration.**
TGA	Specifications regulating medicines, medical devices, blood, tissues & chemicals, issued by **Therapeutic Goods Administration,** the Australian regulatory body.
South Africa	**The department of Health, South Africa.**
WTO	News, resources, documents and publications of the **World Trade Organization (WTO),** the global international organization dealing with the rules of trade between nations.

Codex Alimentarius	Collection of international food standards and guidelines for processed, semi–processed and raw foods, adopted by the **Codex Alimentarius Commission under the Joint FAO / WHO Food Standards Programme.**
MHRA	News, warnings, information and publications of **Medicines and Healthcare products Regulatory Agency (MHRA),** responsible for ensuring efficacy and safety of medicines and medical devices in the **UK.**
Health Canada	Advisories, warnings, recalls, reports, publications, activities, legislations and guidelines from **Health Canada,** the Federal Department responsible for health related issues in Canada.
Thai FDA	**Thai Food and Drug Administration** laws and regulations with respect to drugs, food, cosmetics and narcotics.
HSA, Singapore	**Health Sciences Authority (HSA), the regulatory body of Singapore.**
DOH, Philippines	**The Department of Health, Philippines.**
Medsafe, New Zealand	**Medsafe,** New Zealand Medicines and Medical Devices Safety Authority.
NPCB, Malaysia	Regulatory information, news and publications of **National Pharmaceutical Control Bureau, Malaysia.**
DGMP, Belgium	Guidelines and useful information to ensure safety, efficacy and quality of medicines, issued by **Directorate-General Medicinal Products, Belgium.**
BfArM, Germany	Licensing and registration guidelines for medicinal products laid down by **Federal Institute for Drugs and Medical Devices, Germany**
Swiss Medic	**Swiss regulatory agency** for therapeutic products.
MPA, Sweden	Regulatory and surveillance guidelines issued by **Medical Products Agency, Sweden.**
NAFDAC, Nigeria	News, regulations and guidelines issued by **The National agency for Food Administration and Control (NAFDAC), Nigeria.**

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