IJARSCT
ISSN (Online) 2581-9429
International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
Impact Factor: 7.301
Volume 3, Issue 1, December 2023

A Review on CDSCO: Central Drug Standard Control Organisation

Achal Ramteke, M. Bilal Sufi, Rajlaxmi Deolekar, Chelsi Pathik
New Montfort Institute of Pharmacy, Ashti, Wardha, Maharashtra.
ramtekeachal13@gmail.com

Abstract: *India has been a hub for managing various multi centre trials the central drug standard control organisation (CDSCO), headed by the drug controller general of India (DCGI), drowsing the regulationfor the manage of clinical trials in India the conduct of trails, regulations in India and quality of data generated may be the source for this evolution it is crucial that now all clinical trials conducted in India should as per the international conference of harmonization good clinical practice guidelines (ICH- GCP) for clinical trials and follow the newly amended schedule Y of the drugs and cosmetic Act.*

Keywords: zonal offices, authority, functions, duties, laboratory

I. INTRODUCTION

The Central Drug Standard Control Organisation (CDSCO) regulates drugs cosmetic diagnostic and device in India. It is headed by drug controller general of India (DCGI), responsible for safely, efficiency and quality standard for pharmaceutical and medical device and publisher of the Indian pharmacopoeia. The CDSCO works with the World Health Organisation to promote Good Manufacturing Practice (GMP) and international regulatory harmony.

Zonal office:
Total zonal office of CDSCO are 6 in India which are located in different state of India
Mumbai
Kolkata
Chennai
Ghaziabad
Ahmedabad
Hyderabad

Sub Zonal office:
Sub Zonal office are 3 in India which are located in 3 different regions of India
Chandigarh
Jammu
Bangalore

Laboratories:
Laboratories of CDSCO in India are 6 which are located as follows
CDL - Kolkata
CDL - Kasauli
CDTL - Hyderabad
CDTL - Chennai
RDTL - Chandigarh
RDTL – Guwahati

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Function of CDSCO:

Approval of new drug:

Substance which comes under the definition of new drug as per drug and cosmetic Act only approvedby CDSCO.

Approval of clinical trials:

Only CDSCO is authorised under the drug and cosmetic Act to approve clinical trials in IndiaApplicant has to submit an application having all the details about investigational drugs.

Licence and registration for import of drugs.

Amendment of drug and cosmetic Act 1940 and rules 1945.

Banning of drugs and cosmetic.

License and registration for export of drugs.

The role of Central Government:

Government is the agency or instrumentality through which the will of the state is formulated, expressed and realized government have three important organs in performing their roles these are:

- the executive
- the judiciary
- the legislature.

Function of state licensing authority:

The concerned state licensing authority is headed by state drug controller.

The state drug controller deals with licensing of manufacturing and sales premises both of drugs andcosmetic.

In the 7th schedule of the constitution there are three list

- union list
- state list
- concurrent list.

Responsibilities of state authority:

Manufacturing, sales, distribution of drug licensing drug testing laboratories. Approval drug formulation of manufacture.

Carrying out pre- and post- licensing inspection.

Overseeing the manufacturing process for drugs manufactured by respective state unit and those markedin the state.

Drug Controller General of India (DCGI):

He/she is responsible for approval of new drug, medical device and clinical trials to be conducted inIndia

He is appointed by the central government under the state drug control organisation will be functioning.

The DCGI (drug control of India) is advised by the drug technical advisory board (DTAB) and the drug consultative committee (DCC).

Procedure of Drug Inspection:

For taking samples of drug for analysis and their dispatch to the government analysis: when theinspector takes any samples of drug or cosmetic shall.

- Intimate the purpose to a person from whom, he takes the samples, in writing in a prescribed from
- Tender fair price of the sample and obtain acknowledgement thereof if price is refused, by suchperson, he has to tender receipt thereof in prescribed from.

Duties of Drug Inspector or Premises Licensed for sale:

Duties in relation to sale of drug and cosmetics

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- To inspect twice a year all establishment licenced for sale of drug in the area assigned to him andto check that whether to conditions of licence are being observed or not
- To maintain the record relating to all inspection and action taken by him and to submit copies ofsuch records to the controlling authority.

The function of the laboratory include:

- Analysis of drug and pharmaceuticals, cosmetic and medical device manufactured in the country
- Analysis of imports drugs and cosmetic samples entering through the port office of CDSCO
- Analysis of drugs and pharmaceuticals formulation received as survey samples from central drug standard control organisation and it's zonal offices.

II. CONCLUSION

Clinical investors and regulatory bodies a critical role in ensuring high quality studies a clinical trials should be planned and conducted by trained investors it is crucial to maintain highest standards and asany arrangements may jeopardize public confidence the participation in clinical trials and may basicallyaffect the accessibility of safe and effective product the recent regulatory amendment call for a fresh breath of air in the clinical research industry gripped by ethical matter and non-transparency

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