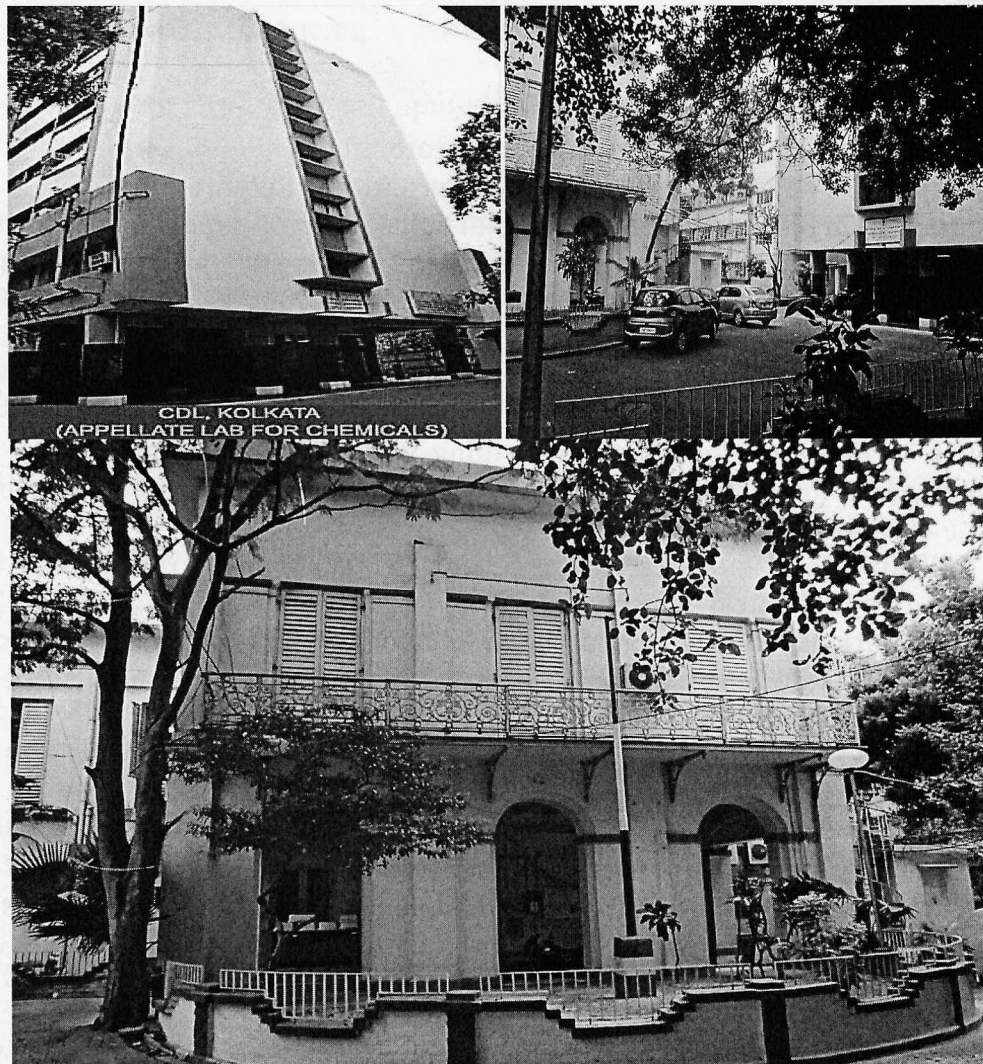


CENTRAL DRUGS LABORATORY, KOLKATA

The National Appellate Drug Control Laboratory of India



1. INTRODUCTION/BACKGROUND:

Central Drugs Laboratory is a National Appellate Laboratory of the Government of India for the quality control of Drugs, Pharmaceuticals, Cosmetics, Medical devices as per Drugs & Cosmetics Act 1940 and Rules thereunder. This is the oldest statutory quality control Laboratory under the CDSCO, functions under DGHS, Ministry of Health and Family Welfare of the Government of India. This laboratory is NABL accredited in the field of Chemical, Biological and Mechanical (Medical devices & Cosmetics).

2. MISSION

- a) Conversion of CDL to a "State of Art" Laboratory.
- b) Infrastructure development to comply International Requirement.
- c) Augmentation of instrumental testing facility and development of laboratory to test all parameters of Drugs, Cosmetics & Medical Devices as per National & International Standards.

3. VISION

- a. To be recognized globally for providing world class testing facilities for safeguarding human and animal health by establishing and reviewing quality objective at various levels of the organization.
- b. To safeguard and enhance public health by quality and excellence in testing of drugs, cosmetics and medical devices.
- c. To be a part of modern regulatory system in India to protect public health by ensuring provision of safe, effective and quality drugs and pharmaceuticals based on scientific excellence accountable to both, the Government and the public.

4. OUR QUALITY POLICY

Central Drugs Laboratory, Kolkata is the National Statutory laboratory of Govt. of India for quality control of drugs and cosmetics established under the Drugs and Cosmetics Act, 1940. It is the only "National Appellate Authority" in matters of disputes related to quality of drugs.

The Laboratory is fully committed to:

- (a) Implement, maintain and continually improve its effectiveness of the management system as per ISO/IEC 17025:2017 & NABL, Drugs & Cosmetics Act 1940 & Customers to attain the optimum proficiency, Competency and impartial testing of Drugs and pharmaceuticals as per Standard method for total satisfaction of Customers.
- b) Maintain impartiality and confidentiality in test results on identifying relevant risks.
- (b) Develop and supply of Reference Standards/materials conforming to I.P. to maintain uniform standards.
- (c) Impart training on the management system requirements to its staff to familiar themselves with the quality management requirements as well as customer's requirements.
- (d) Impart training on the analysis of Drugs and Pharmaceuticals to States/Central Govt. analysts to improve their competence and compliance to analytical test procedures.

5. IMPORTANT FUNCTIONS OF CENTRAL DRUGS LABORATORY, KOLKATA:

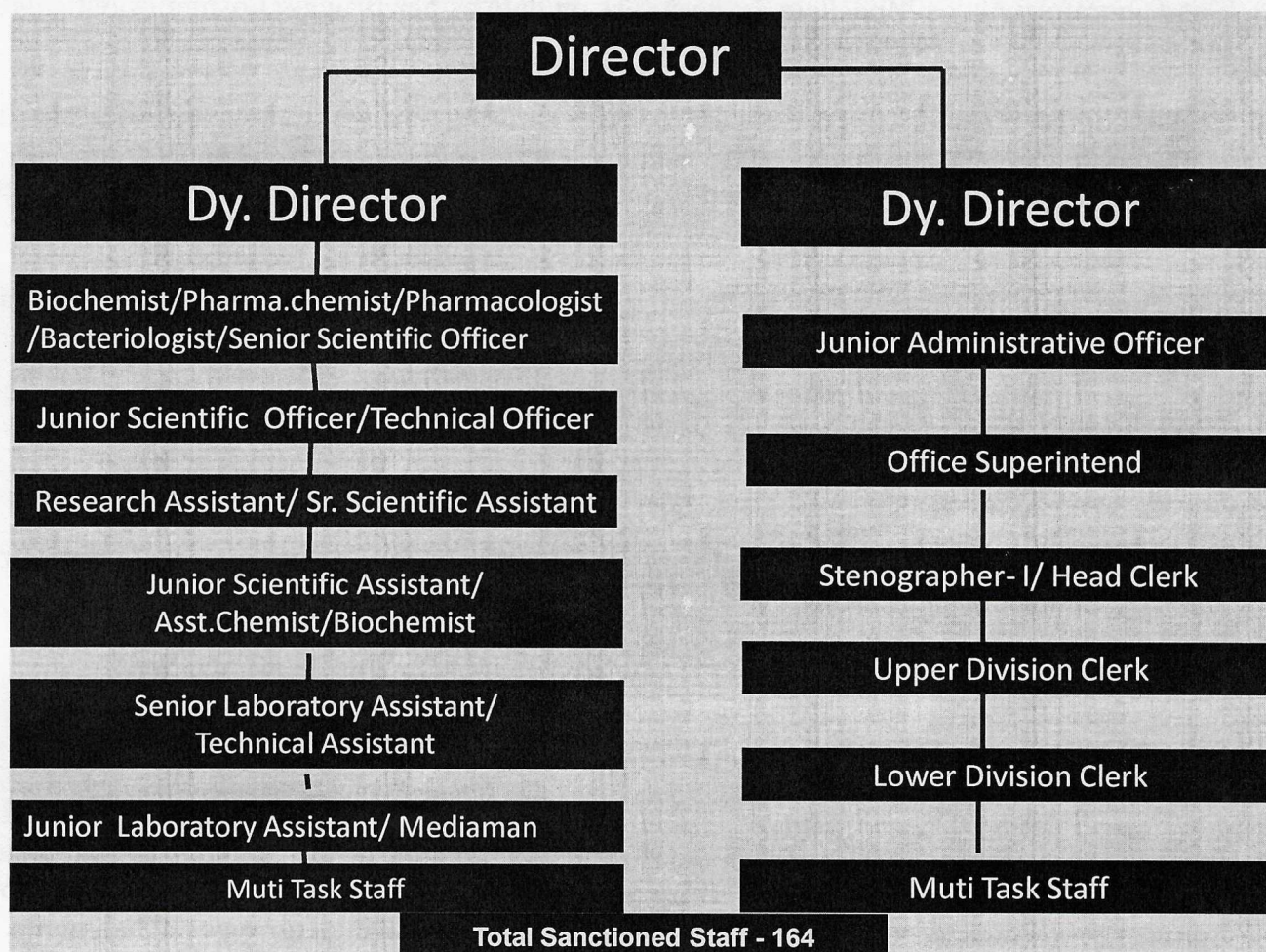
- a) Function as Analytical & quality control Laboratory for Drugs, Cosmetics & Medical Devices manufactured in the country on behalf of the Central and State Drugs Control Administration.
- b) This Laboratory Act as "*Appellate Authority*" as on date as per Drugs & Cosmetics Act' 1940 in the matter of dispute relating to quality of Drugs.
- c) Quality Control of majority of the imported Drugs entering through the various ports in India.
- d) Central Drugs Laboratory is recognized Laboratory by WHO in the country for the "Proficiency Testing" of Drug samples conducted in worldwide.
- e) Imparting Training to Drug Analyst deputed by the Central and State, and other Government laboratories and WHO nominated Analysts.
- f) To advice the CDSCO in respect of quality and toxicity of drugs awaiting for License.
- g) To undertake analytical research on standardization and methodology of Drugs.
- h) Analysis of Drugs received as National Survey of Quality of Essential Drugs from Central Drugs Standard Control Organization.
- i) Testing of samples received under AEFI (Adverse Events Following Immunization).
- j) Collection, storage of International Primary Reference Standard Preparations of Drugs and Pharmaceuticals substances.
- k) Preparations of National Reference Standard and maintenance of such standards. Maintenance of Microbial Cultures useful in the drug analysis Distribution of standards and Microbial Cultures to various Central and State laboratories and Drug manufacturing establishments.

6. ACTIVITIES & ACHIEVEMENTS:

Various category of Samples Tested in Central Drugs Laboratory, Kolkata viz Appellate Samples, Imported Samples, New Drugs, Statutory Drugs Samples. (Form- 18 as per Drugs & Cosmetics Act & Rules), National Survey on the Quality of Essential Drugs (NSQED), Zonal samples (CDSCO), Samples received from World Health Organization (WHO).

- a. Quick analysis of life saving drugs on all India basis received under National Survey of Quality of Essential Drug (NSQED) Programme from Zonal offices of the CDSCO.
- b. On National interest impurity of **NDMA (N-nitrosodimethylamine)** level in the Ranitidine API has been tested in collaboration with NIPER & IIT Bombay.
- c. Reference Standard /Working Standard distributed free of cost.
- d. Govt. Analyst participated for technical Audit on analysis of critical Control points on quality of drugs.
- e. Scientific Officer of Central Drugs Laboratory, Kolkata has been declared as Government Analyst for 16 different states to test some Complained/Complicated drugs samples received from viz. Andhra Pradesh, Bihar, Himachal Pradesh, Orissa, Madhya Pradesh, Jharkhand, Rajasthan and Uttar Pradesh etc. Accordingly the samples are tested and reported

7. ORGANOGRAM CHART FOR CDL, KOLKATA



Total Sanctioned Strength 164 officials, as on date 83 officials are on role.

8. TOTAL FIFTEEN SPECIALIZED WINGS AND THE SUBJECT EXPERTS ARE WORKING UNDER THE RESPECTIVE WING VIZ

- i) Biochemistry Wing
- ii) Pharmacology Wing
- iii) Microbiology Wing
- iv) Toxicology Wing
- v) Medical Devices Wing
- vi) Cosmetics Wing,
- vii) Central Instrumentation Wing,
- viii) Pharmaceutical Chemistry Wing
- ix) NSQED Wing
- x) Reference Standard Wing
- xi) Pharmacognosy Wing
- xii) Animal House Wing
- xiii) Training Wing
- xiv) Library Wing
- xv) Administration & Store Wing

9. Contact Details :

- a) **The Director**
3, Kyd Street, Kolkata – 700 016 (W.B.)
- b) Telephone No. : (033) 2229 9380/2265 0897
- c) E.mail address: cdlkol@cdsco.nic.in

10. Details of Central Public Information Officer (CPIO):

- a) First Appellate Authority: Sri. C. Hariharan, Director-in-Charge
Tel. No. – (033) 2229 9380
- b) Dr. Dipak Shivaji Harel, Junior Scientific Officer – CPIO,
Tel. No. – (033) 2229 9021 (Ext- 113)