
# Training Module

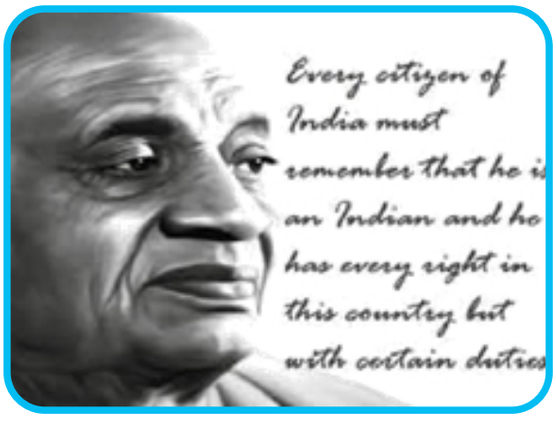
## Induction Training Programme for Assistant Drugs Inspectors

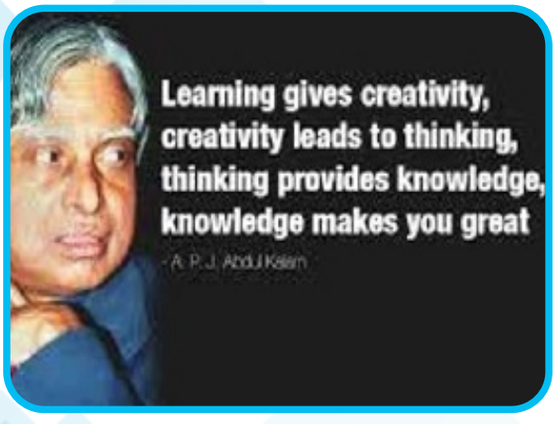
**8th March, 2017 to 7th June, 2017**

**Central Drugs Standard Control Organization**
**Ministry of Health and Family Welfare**
**Government of India**

विद्या ददाति विनयं वियाद्यति पात्रताम्।
पात्रत्वाद्धनमाप्रोति धनाद्धर्म ततः सुखम्।।

Education gives Humility; Humility gives Character;
from Character one gets Wealth;
from Wealth one gets Righteous (dharmam) life;
from Righteousness one gets Happiness

# Mission

To safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices

# Vision

To Protect and Promote public health in India

# Values

To achieve the mission and mandate of the CDSCO we will strive to act with transparency, accountability, punctuality, courtesy, openness, responsiveness, professionalism, impartiality, consistency, integrity and truthfulness.

# Enforcement for developing Quality of drugs

The Indian Pharmaceutical Industry is one of the most vibrant sectors of Indian economy. The total size of the Indian Pharmaceutical Industry is about Rs 2 lakh crore, out of which exports account for nearly 55%. To ensure the quality, safety and efficacy of medicines both for domestic use and for exports, the regulatory system is required to be strengthened. As the number of drugs and their volume, increases, the issue of quality will assume paramount importance. Across the globe, countries are adopting rigorous drugs quality control systems and enforcement mechanisms to avoid sub-standard/spurious drugs in their respective markets.

Though, the Drugs and Cosmetics Act has been in force for the past several decades, the level of enforcement in many parts of the country has been far from satisfactory. The non-uniformity in the interpretation of the provisions of laws and their implementation and the varying levels of competence of regulatory officials were the main reasons for this less than satisfactory performance.

The problems in the regulatory system in the country were primarily due to inadequate or weak drug control infrastructure at the State and Central level, inadequate testing facilities, shortage of drug inspectors, non-uniformity of enforcement, lack of specially trained cadres for specific regulatory areas, non-existence of data bank and non-availability of accurate information.

The opportunities before the country are immense. We, however, need to re-orient our structures for achieving this. Human resources are one of the most critical elements in any endeavour and provision of health service is no exception.

One of the critical pillars of public health services is the access to medical products that conform to parameters of quality, safety, efficacy or performance along with their affordability. Making such quality medical products available is the responsibility of the drugs regulatory structures in the Centre and the States.

In the process, the role of the CDSCO, the organ of the central government is akin to the nervous system in a body. In fact, the vibrancy and effectiveness of CDSCO not only acts as the role model for the State regulators but also helps in provision of better healthcare services through out there world given the reach of our pharma sector .The CDSCO is responsible for standard setting and is evolving ways and means for removing inter-state disparities in regulation and inter lab differences in drug testing analysis.

Keeping this in view and as part of the massive organizational strengthening, the Government has initiated a comprehensive programme for development of human resources for the CDSCO and the States through appropriate training modules for different levels of induction, basic and advanced courses. Recently, a number of courses have been conducted for Drug Analysts of all States, month long training programme for Drugs Inspectors of State/UT & CDSCO and induction programme for Assistant Drugs Inspectors. There are many more programmes including e-learning modules that are being planned for the regulatory and laboratory staff and also for the Industry.

The Government will also be exploring the feasibility of accreditation of drug regulators and laboratory personnel at different levels. Physical exercise and Yoga is an integral part of all such programmes including the present one. I am sure, the participants would be able to benefit from the present programme and the knowledge gained by them could be fruitfully utilized for the benefit of the nation and the humanity at large.

**(K.L. Sharma)**
Joint Secretary to the Government of India

## Regulatory challengers…

The Pharmaceutical industry represents one of the India's strength. It has been growing at the rate of over 10-12% annually and, currently, occupies the third position in the world in terms of volume. The industry has wide ranging capabilities in the complex field of drug manufacturing and technologies. Indian Pharmaceutical Industry is supplying high standard quality medicines at affordable price, to the Indian and global population.

Indian pharma industry has an annual turnover of more than Rs 2 lakh crore. Exports contribute around Rs 1.2 lakh cr and more than 60% of exports are to the developed countries such as USA, EU, Australia, Japan, etc. Drugs produced in the country are exported to more than 205 countries/Economies of the world. Indian vaccines and bio-pharma products are exported to about 150 countries including international organization such as UNICEF.

The main objective of the CDSCO and State Drug Regulatory Authorities is to safeguard and enhance the public health by ensuring the safety, efficacy and quality of drugs, cosmetics and medical devices. As part of this endeavour and to provide best quality medicines, action needs to be taken to enforce the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945.

The present training programme, has been conceived with the objective of imparting fundamental skills and knowledge in areas relating to investigation and prosecution. This training programme will also ensure effective and uniform enforcement across the country. I am sure, all participants will avail this opportunity and would make best use of the knowledge and skills of eminent speakers who would be interacting with them during the training programmes. It would also be possibly to evaluate practices followed in different states and identify best practices for replication everywhere.

It is considered that there is a huge gap in the regulatory science, practices and knowledge which needs to be bridged. Keeping in view the size and potential of our industry including India's status as the Pharmacy of the World, the skill sets possessed by our regulators need to be up-scaled substantially. There is a need for keeping pace with the technical and scientific advancements in the Pharmaceutical/Biological/Medical Devices industry among professionals and it is sought to be realized through continuous and organized training programmes.

**(Dr. G.N. Singh)**
Drugs Controller General (India)

## Drug Regulatory System in India

Various regulatory aspects related to import, manufacture, sale and advertisements related to drugs are covered by the Drugs & Cosmetics Act, 1940, the Drugs & Cosmetics Rules 1945, the Pharmacy Act 1948 and the Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954.

The Drugs and Cosmetics Act, 1940 is a central legislation, which regulates the import, manufacture, distribution and sale of drugs and cosmetics in the country. The main objective of the Act is to ensure that the medicines are safe efficacious and conform to prescribed quality standards and the cosmetics marketed are safe for use. The Drugs Act was enacted in 1940 in pursuance of the recommendations of Chopra Committee constituted in 1930 by the Government of India. The Act received the assent of the Governor General on 10th April 1940 and thus became a statute. The Drugs Rules were promulgated in December 1945 and the enforcement of the statutes and Rules started in 1947. The Act has been amended several times and is now titled as Drugs and Cosmetics Act. The Rules have also been amended from time to time to meet the needs of the times and to make good any deficiencies noticed during the implementation. The very definition of 'Drug' under the Drugs & Cosmetics Act covers a wide variety of therapeutic substances, diagnostics and medical devices. It thus requires an adequate multidisciplinary expertise, which should be available with regulatory agencies, especially at the central level. Moreover, the standards of safety, efficacy and quality of therapeutic products are becoming ever demanding. Therefore, regulatory capacity has to become world class. Under the Constitution of India, 'Drugs' being a concurrent subject, the responsibility of enforcing various provisions of the Act vests with the Central Government and the State/UT Governments. The roles of Central & State Governments are well defined.

## About CDSCO

Central Drugs Standard Control Organization (CDSCO) exercises regulatory control over the quality of drugs, cosmetics and notified medical devices in the country. It is the National Drug Regulatory Authority of the Government of India and is responsible for laying down the standards for Drugs, approval for Clinical Trials, control over quality of imported Drugs, coordination of activities of State Drugs Control Organizations and providing expert advice with a view to bring about uniformity in the enforcement of the Drugs and Cosmetics Act as well as granting and renewal of licenses for specified critical categories of Drugs such as blood and blood products, I.V. Fluids, Vaccine and Sera, r-DNA products and Medical devices. The Government of India is currently engaged in upgrading the quality of regulatory practices in the country and brings in a high degree of uniformity in these practices across the States.

One of the main interventions of the Central Government to achieve its Public Health objectives is to ensure that drugs available in the country are safe, efficacious and conform to prescribed quality standards.

A good regulatory system should help build a science based regulatory framework to support and promote Research and Development in country.

***The roles and responsibilities include:***

- Efficient regulatory operations including procedural efficiency to ensure consistency, predictability, adaptability, timeliness and quality in the review process.
- Robust scientific review of the applications to ensure Safety, Efficacy and Quality of products.
- Effective self-correction mechanism through audit and review of the processes to ensure

applicability and suitability of the regulatory framework.

- Strong stakeholder partnership bringing national and international academia, industry and regulators together on emerging regulatory topics will go a long way to ensure Patient safety, Drug's quality & Effectiveness, and growth of the industry.

## Offices of Drugs Controller General of India (CDSCO Offices /Labs)

| | |
|---|---|
| **CDSCO (HQ):** | New Delhi |
| **Zonal Offices:** | Mumbai, Ghaziabad, Chennai, Kolkata, Ahmedabad and Hyderabad |
| **Sub-Zonal Offices:** | Chandigarh, Bangalore, Jammu and Goa |
| **Port Offices:** | Ahmadabad, Kandla, Tuticorn, Bangalore, Goa, Chennai (Sea and Air), Delhi, Kochi, Kolkata (Sea and Air), Mumbai (Sea and Air) and Navasheva, Hyderabad |
| **Central Drugs Laboratories:** | Mumbai, Chennai, Guwahati, Chandigarh, Kolkata, Hyderabad and Kasauli. |

## Objectives of CDSCO

- To upgrade knowledge of regulators and to increase consumer awareness.
- To interact and cooperate with the State, Central Government, Union Territories and non-governmental voluntary organizations with a view to improve the quality of healthcare facilities.
- To inculcate a sense of dedication amongst regulators, assist them to improve their professional excellence, to improve their effectiveness enabling them to serve and safeguard the interest of the consumers.
- To promote and advance, in the interest of public, the art of science and pharmaceutical technology and to develop highest standards for Pharmaceutical and Medical Devices industry products with the use of technology.
- To offer better services to the public.
- To foster a science based, predictable and consistent regulatory framework to support and promote Research and Development in the country.

## Functions of the CDSCO (HQ)

- Laying down standards of Drugs, Cosmetics and Medical devices.
- Laying down regulatory measures, amendments to Acts and Rules.
- To grant Marketing Authorization of New drugs.
- To regulate clinical trials in India.
- To approve licenses to manufacture certain categories of drugs as Central License Approving Authority i.e. for Blood Banks, Medical Devices, r-DNA drugs, Large Volume Parenterals and Vaccines & Sera
- To regulate the standards of imported drugs.
- Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative

Committee (DCC).
- Pharmacovigillance Program of India.
- Coordinating activities of the State Drugs Control Organizations to achieve uniform administration of the Act and providing policy guidance.
- Guidance on technical matters\Participation in the WHO GMP certification scheme.
- Monitoring adverse drug reactions (ADR).
- Conducting training programs for regulatory officials and Government Analysts.

## Broad functional activities and duties of the Zonal and Sub-zonal offices of CDSCO

- To participate in joint inspection for issuance / revalidation of Certificate of Pharmaceutical Products (COPPs) as per WHO certification scheme.
- To participate in joint inspection for grant/renewal of Blood Bank, LVP, r-DNA, Medical Devices, Vaccines and sera licenses under CLAA scheme.
- To participate in inspection of Clinical Trial facilities as directed by Drugs Controller General (India) from time to time.
- To carryout auditing/verification/post certification of manufacturers pertaining to preferred bidders.
- To carry out surprise checks/raids/ jointly and independently on the basis of complaints received under Whistle Blower scheme and also from other sources.
- To carry out joint inspection of Testing Laboratories for approval to carry out tests or analysis on drugs, cosmetics and raw materials used in the manufacturing of drugs /cosmetics for sale.
- Drawing drugs samples for testing at central laboratories, and carrying out investigation and launching prosecutions in cases where they do not conform to quality requirements.
- Deputation of drugs samplers to various places of suspicion and collect samples through them as surrogate patient from the sales premises by way of survey to monitor the quality of drugs.
- To pursue court cases pending in different courts in the zone.
- Preparation of Monthly / Quarterly / Annual Reports.
- Renewal of licenses for blood banks.
- No objection certificates for grant of licence to manufacture drugs for examination, test or analysis as provided under Rule 89 of the Drugs and Cosmetics Rules.
- No objection certificates for grant of permission for manufacture for export only of unapproved / approved new drugs and banned drugs.
- Permit import of small quantities of drugs for personal use under Form 12B of the Drugs and Cosmetics Rules.
- No objection certificates for grant of permission for import of dual use items not for medicinal use.
- Grant of license in Form-11.

## Functions of Central Drugs Laboratories

- Analytical quality control of imported drugs.
- Analytical quality control of drugs and cosmetics manufactured within the country.
- Test and analysis of new drugs referred by CDSCO, HQ.

## Functions of Port offices of CDSCO

- Scrutiny of Bills of entry with a view to ensure that imported drugs comply with the provisions of Chapter III of the Drugs & Cosmetic Act and Rules thereunder, Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules and Narcotic Drugs and Psychotropic Substances Act & Rules thereunder
- To check the shipping bills for export for statistical data and keep control under Narcotic Drugs and Psychotropic Substances Act & Rules and Drugs & Magic Remedies (Objectionable Advertisements) Act and the Rules there under.
- To ensure that no New Drug is imported into the country unless its import is permitted by the Central Licensing Authority under Rules 122 A & 30-AA.
- To ensure that small quantities of drugs imported for clinical trials or for personal use are duly permitted under Test License (11 or 11-A) or Permit License as (12 B) as the case may be.
- Maintenance of Statistics regarding import and export of drugs and cosmetics
- Coordination with Customs authorities.
- Coordination with States Drugs Controllers and Zonal Offices for post-import checks.
- Preparation of Monthly / Quarterly / Annual Reports
- To draw samples from import/export and re-import consignments.

## State Drugs Regulators

Under the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945, the manufacture, sale and distribution of drugs and cosmetics are regulated by the State Drugs Control Authorities appointed by the State Governments. Even sale of imported drugs after having been permitted by the CDSCO is monitored and regulated by State Drug Control Departments. Accordingly, the Drugs Control Departments of the States/ UTs play a vital role in implementing the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.

## Key functions of State Drugs Regulators

- Grant/renewal of Licenses for Manufacture, Sale and Distribution of Drugs, Cosmetics and Medical Devices
- Monitoring quality of Drugs and Cosmetics by drawing samples from the market and Evaluating its quality at their Drugs Testing Laboratories
- Investigations and prosecution in case of violations under the Drugs and Cosmetics Act and Rules.

## Role of Regulators in ensuring public health

Drugs and medical devices play a major role in the provision of health services to the public at large. The Quality, Safety and Efficacy of these medical products is, as such crucial for providing health services to the people at large keeping particularly in view, the growing incidence of antimicrobial resistance.

## A good drugs regulatory systems ensures

- Protecting public health through assured quality of drugs, medical devices and cosmetics
- Uniform and effective implementation of regulations
- Perform assigned functions efficiently and speedily.
- Development and deployment of qualified and trained professionals.
- Contemporary systems in place
- Availability of Data

## Values of Drug Regulatory System

- Professionalism through integrity, diligence, objectivity, excellence, commitment and consistency
- Accountability through open and transparent operations
- Achievement through professionalism and effective, efficient and timely work practices, which are focused on outcomes;
- Open and effective communication with all stakeholders

## Concern in Drug Regulatory System

The major concerns relating to drug regulatory systems are as below:

- Inadequate or weak drug control infrastructure at the State level.
- Inadequate drug testing facilities.
- Non-uniformity of enforcement of law and rules.
- Lack of training to regulatory officials.
- Lack of data base.
- Inadequate IT services.
- The need to ensure the quality, safety and efficacy of drugs both for the domestic consumers as well as for export purpose is paramount and if it is not ensured, it affects public health, national interest, and India's reputation in the world. The capacity and the strength of the technical manpower require to be augmented. It is decided to achieve an optimum system of regulation ensuring uniform enforcement of the laws across the country through a strengthened drug regulatory mechanism by the way of training.

## The Need for Training

Drugs regulatory system needs to keep itself abreast of the fast-changing scientific innovations, evolving international regulatory framework and other developments. The central role of the Indian Pharma industry and the globalization necessitate, that the regulatory framework has to constantly evolve by integrating new developments. It is, therefore imperative for the present and future drug control officials to continuously upgrade their skills and knowledge, and gain expertise in the variety of subjects to measure up to such functional requirements.

While the Government of India and the State Governments are recruiting a number of regulatory

personnel, the number of manufacturing establishments and distributors are also increasing every year. Therefore, the need of the hour is to train the regulatory officers to enable them to devise strategies for optimum utilization of available resources. Training that could constantly upgrade their technical, professional and other functional skills would play an important role in their professional growth and diligent execution of their responsibilities.

It is proposed to address the non-uniformity in the interpretation of the various provisions of the Drugs and Cosmetics Act and Rules and varying level of competence of the regulatory officials in its enforcement. It has been decided to impart specialized training to the Drugs Inspectors of CDSCO and States/UTs drugs control administration for uniform implementation of Drugs and Cosmetics Act and to strengthen enforcement activities across the country. The present course is one in the series of courses aimed at ensuring such uniformity.

## Training Needs Analysis

Training will be imparted in following major areas:

- Technical
- Legal
- Managerial
- IT and Communication skills

## Technical Needs

- Quality audits and inspections – Planning, Procedures, Report writing
- Quality Standards of Drugs, Cosmetic and Medical Devices
- International regulatory framework
- Investigation techniques
- Cyber Crime

## Legal Needs

- In-depth knowledge of drug laws – Drugs and Cosmetics Act and Rules, Narcotic and Psychotropic Substances Act, Drugs Price Control Order, Drugs and Magic Remedies (Objectionable Advertisements) Act, Intellectual Property Rights, Patent Act
- Principles of jurisprudence, and Principles of natural justice
- Principles of interpretation
- Applicability of Code of Criminal Procedure Code in investigations and trials under drug laws
- Fundamentals of Evidence Act
- Investigation techniques including gathering of intelligence and making proper use of such intelligence
- Launching of Prosecutions

## Managerial Needs

- These will encompasses a series of activities relating to different aspects of management.

## IT and Communication Skills

Effective discharge of regulatory functions requires high degree of skills in:

- Computer & Information Technology
- Oral & Written Communication
- Listening Skills and
- Body Language

## Other areas of training programme will include

- Theories of morale and motivation
- Conflict management
- Interpersonal skills
- Team building / Leadership
- Resource Management
- Office administration
- Problem solving
- Giving and rec eiving feedback

## Training Action Plan for Assistant Drugs Inspector

| Duration | Areas to be covered |
|---|---|
| 3 months | Regulatory framework in India i.e. Drugs and Cosmetics Act and Rules, Drugs and Magic Remedies (Objectionable Advertisements) Act , Narcotic and Psychotropic Substances Act, etc., Basic introduction to GMP, GLP,GCP, etc., IT |

## Venue of Training Programme of Assistant Drugs Inspector

**NATIONAL INSTITUTE OF BIOLOGICALS**
(Ministry of Health & Family Welfare)
Government of India, Plot No. A-32, Sector-62,
Institutional Area, NOIDA-201309, Uttar Pradesh

## Training Resource Personnel

To begin with, CDSCO, will engage faculty drawn from regulatory agencies, administrative and police services, pharmaceutical industry, management institutes and colleges and also training modules adopted by other regulators. The facility would comprise:

- Retired /Current Drug Regulatory personnel
- Experts from outside for Personality development
- Officials from CBI, IB, Legal department / Police .
- Subject experts from academic institutions (NIPER,IIT,IIS etc)
- Subject expert professionals from industry (GMP,GCP,GLP etc.)
- Experts from international organizations like USFDA & WHO etc.
- Retired/Current senior Government officials.

In this batch there are total 45 participants. Entire batch is divided into five subgroups named as follows.

**Group 1:** Ganga
**Group 2:** Yamuna
**Group 3:** Narmada
**Group 4:** Krishna
**Group 5:** Kaveri

- To bring clarity in the course content, Day-wise agenda is provided in this booklet indicating, topics, and speaker's name and detailed activities of that day.
- There will be evaluation test on every Monday for the previous week modules. The test will be conducted in the class room itself.
- Each of the groups will select its group representative for each week and there will be no repetition of the group representative till the turn of everyone is over.
- One of the groups has to provide its feedback and suggestions at the end of the day. Feedback will be shared with the entire batch and with the organizer. Feedback may include suggestions for the improvement of the activities, class room training, code of conduct, etc.
- There will be a Syndicate activity on every Friday in Session-3 and Session-4. The topics for the syndicate will be decided in starting of the week. In this activity each group will need to analyze an identified problem, carry out a summary of existing literature, discuss the issue within the group and present the outcomes that may include but will not limited to Power point presentation, Case Studies related to the topics from the training modules or any other activity related to course which will be followed by a Group Discussion.
- There will be a performance evaluation of the syndicate activity of each group.
- At the completion of 2 months of class room training 46 Assistant Drugs Inspectors will be divided into 3 groups and will undergo field training at specified locations as per schedule indicated below:

| Location | Duration | | |
|---|---|---|---|
| | 08.05.2017 to 17.05.2017 | 18.05.2017 to 27.05.2017 | 28.05.2017 to 07.06.2017 |
| IPC, Ghaziabad | Group-I | Group-II | Group-III |
| CDSCO, North Zone | Group-II | Group-III | Group-I |
| IGI, Airport, New Delhi | Group-III | Group-I | Group-II |

**Note:** Each participant will be required to write a project report on the knowledge gained & its application in Training Programme.

At the end of the training, each participant will be required to appear in a written examination, qualifying in which would be mandatory criteria for assessment is as follows:

| Test / Activity | Percentage |
|---|---|
| Monday Tests | 15 % |
| Syndicate Work | 5% |
| Yoga /Physical activity | 3% |
| Punctuality / Behaviour / Attire / Aptitude | 3% |
| Communication / Presentation Skills | 7% |
| Report writing | 7% |
| Written Examination | 60% |
| Total | 100% |

**Note:** Qualifying Marks for written examination shall be 70 %

- Three best prizes will be given suitable prizes

## Inaugural Session

**Date: 08.03.2017**

| From (hrs) | To (hrs) | Topic | Speaker |
|---|---|---|---|
| 09:00 | 09:30 | Registration of Participants | |
| 9:30 | 9:40 | Welcome Address | Dr. S. Eswara Reddy, JDC (I), CDSCO |
| 9:40 | 9:50 | Inaugural Address | Dr. G. N. Singh, DCG (I) |
| 9:50 | 10:00 | Inaugural Address | Dr. Surinder Singh, Director NIB, Noida |
| 10:00 | 10:20 | Key note Address | Sh. K. L. Sharma, JS (R), Government of India |
| 10:20 | 10:30 | Vote of Thanks | Sh. Sunil Kulshrestha ADC(I), CDSCO(HQ) |
| 10:30 | 11:00 | Photo Session followed by High Tea break | |
| 11:00 | 11:30 | Participant introduction House-keeping announcement, general guidance of training programme | By coordinators |
| 11:30 | 13:00 | Pre-assessment Test | |
| 14:15 | 17:45 | Background, objective and expected outcomes of training and functions of ADI & Need for Drug Regulation in India | Sh. Arvind Kukrety DDC(I), CDSCO Ahmedabad |

| Session wise Schedule from Day-2 onwards | | |
|---|---|---|
| **Begin** | **End** | **Activity/ Sessions** |
| 6:00 | 7:00 | Yoga |
| 9:30 | 11:00 | Session-I |
| 11:00 | 11:30 | Tea break |
| 11:30 | 13:00 | Session-II |
| 13:00 | 14:00 | Lunch Break |
| 14:00 | 14:15 | Warm up |
| 14:15 | 15:45 | Session-III |
| 15:45 | 14:15 | Tea break |
| 14:15 | 17:45 | Session-IV |
| 17:45 | 18:00 | Evaluation of the day by one of the groups |

**Note:** Evaluation test will be conducted on every Monday from 08:30 AM to 09:30 AM

| Session | Topic | Speaker |
|---|---|---|
| **09 March 2017 (Thursday)** | | |
| 1 | Genesis of Drug Regulation | Dr. S.Eswara Reddy JDC(I) |
| 2 | Overview of Indian Drug Regulatory System | |
| 3 | Issues and Challenges in Drug Regulation | |
| 4 | Proposed amendment in Drugs & Cosmetics Act and Rules | |
| **10 March 2017 (Friday)** | | |
| 1 | Structure, function and role of CDSCO | Dr. V.G. Somani JDC(I) |
| 2 | Functions of State Licensing Authority | |
| 3 | Computer Classes | Subject Experts |
| 4 | | |
| **11 March 2017 (Saturday)** | | |
| 1 | Administration Matter | Subject Experts |
| 2 | | |
| 3 | Syndicate activity | By Participants |
| 4 | | |
| **12 March 2017 (Sunday)** | | |
| **13 March 2017 (Monday) holiday** | | |
| **14 March 2017 (Tuesday)** | | |
| 1 | Definition of drug, cosmetic, manufacture, spurious, adulterated and misbranded drugs | Dr. R. Chandrashekar DDC(I), CDSCO(HQ) |
| 2 | Role of Statutory Bodies: DTAB, DCC & CDL | |
| 3 | Introduction of Indian Pharma Industry | Mr. D.G. Shah. IPA |
| 4 | Role of Indian pharma industry in meeting health care need | Dr. Ajay Sharma, Director, Research & Government Affairs, OPPI |
| **15 March 2017 (Wednesday)** | | |
| 1 | Power and duties of Licensing Authority, Controlling Authority and Drugs Inspector | Mrs. A. Visala DDC(I), CDSCO(HQ) |
| 2 | Offences and Penalties in the Drugs & Cosmetics Act | |
| 3 | Procedure of Banning of Drugs | Mr. A. K. Pradhan DDC(I), CDSCO, Ghaziabad |
| 4 | National list of essential Drugs in India | |
| **16 March 2017 (Thursday)** | | |
| 1 | Overview of CLAA Scheme | Sh.Manivannan DDC(I) CDSCO, Chennai |
| 2 | Overview of WHO-GMP Certification Scheme | |
| 3 | Overview of Indian Pharmacopoeia | Dr. P L Sahu Sr. PScO, IPC Ghaziabad |
| 4 | Role of Indian Pharmacopoeia Commission | |
| **17 March 2017 (Friday)** | | |
| 1 | An introduction to Drugs and Magic Remedies (Objectionable Advertisements) Act | Sh. Nilesh Gandhi Asst Commissioner, FDA Maharashtra |
| 2 | | |
| 3 | Computer Classes | Subject Experts |
| 4 | | |

| | | |
|---|---|---|
| **18 March 2017 (Saturday)** | | |
| **1** | Administration Matter | Subject Experts |
| **2** | | |
| **3** | Syndicate activity | By Participants |
| **4** | | |
| **19 March 2017 (Sunday)** | | |
| **20 March 2017 (Monday)** | | |
| **1** | Right to Information Act | Sh. S.R. Dhaleta<br>Former J.S. Ministry of Law & Justice |
| **2** | | |
| **3** | Overview of DPCO and Essential Commodity Act | Representative from DPCO |
| **4** | | |
| **21 March 2017 (Tuesday)** | | |
| **1** | Relevant provisions under CrPC applicable during the investigation/raid | Mr. Rishikant<br>Legal Advisor |
| **2** | Relevant provisions under IPC applicable during investigation/raid | |
| **3** | Overview of Prevention of Corruption | Sh. V.P. Arya<br>Former Sr. Supt., CBI |
| **4** | | |
| **22 March 2017 (Wednesday)** | | |
| **1** | Intelligence gathering and verification of complaints / information | Expert from CBI |
| **2** | Methodology of processing of complaints and category of complaints | Expert from CBI |
| **3** | General procedures and precautions to be followed during investigation/raid. | Expert from CBI |
| **4** | Search and Seizure for material evidence of electronic evidence and cyber crime | Expert from CBI |
| **23 March 2017 (Thursday)** | | |
| **1** | Interpretation of definition of drug, cosmetics, manufacture, spurious, adulterated and misbranded drugs and Cosmetics (Case study). | Sh. O.S. Sadhwani<br>Joint Commissioner,<br>FDA Maharashtra |
| **2** | | |
| **3** | Offences and Penalties under the Drugs and Cosmetics Act and Rules | Sh. K.R. Chawla, ADC,<br>NCT of Delhi |
| **4** | | |
| **24 March 2017 (Friday)** | | |
| **1** | Narcotic Drugs and Psychotropic Substances Act | Narcotics Control Bureau |
| **2** | Time Management/Stress Management during investigation/raid | Ms. Soni Sharma<br>IMT, Ghaziabad |
| **3** | Computer Classes | Subject Expert |
| **4** | | |
| **25 March 2017 (Saturday)** | | |
| **1** | Administration Matter | Subject Experts |
| **2** | | |
| **3** | Syndicate activity | By Participants |
| **4** | | |

| | | |
|---|---|---|
| **26 March 2017 (Sunday)** | | |
| **27 March 2017 (Monday)** | | |
| **1** | Drug discovery | Dr. Ajith V. Kamath<br>Head, External R&D Innovation, India Worldwide Research & Development Pfizer Inc |
| **2** | Pre-clinical study | |
| **3** | Evaluation of Animal Toxicity data & Prevention of Cruelty to animal Act and role of CPCSEA | Dr. Vyas Shingatgeri<br>Director,<br>M/s Sun Pharma |
| **4** | | |
| **28 March 2017 (Tuesday)** | | |
| **1** | Phases of Clinical trials | Mr. A.K. Pradhan<br>DDC(I), CDSCO, Ghaziabad |
| **2** | Overview of Clinical Trial- Regulations | |
| **3** | An introduction to GCP | |
| **4** | IEC, Registration and role of Ethics Committee | |
| **29 March 2017 (Wednesday)** | | |
| **1** | Clinical trial design, method of randomization and role of Biostatistician | Dr. Bikash Medhi<br>Professor, PGIMER, Chandigarh |
| **2** | Evaluation of Clinical Trial data | |
| **3** | Conduct of GCP inspection | |
| **4** | Clinical Trial inspection checklist and common observations | |
| **30 March 2017 (Thursday)** | | |
| **1** | Marketing Authorization process of New Drugs, Investigational New Drugs, Fixed Dose Combination and Subsequent New Drugs | Mr. R. Chandrashekhar<br>DDC(I), CDSCO(HQ) |
| **2** | | |
| **3** | Various Committees and their role in New Drugs Approval Process | |
| **4** | Evaluation of CMC Data | Sh. P.B. N Prasad<br>DDC (I), CDSCO, Hyderabad |
| **31 March 2017 (Friday)** | | |
| **1** | Clinical data evaluation with case study for Marketing Authorization of New Drugs | Dr. Suresh Menon<br>Regulatory Head,M/s Novartis |
| **2** | Post Marketing Surveillance and its monitoring | |
| **3** | Computer Classes | Subject Expert |
| **4** | | |
| **01 April 2017 (Saturday)** | | |
| **1** | Administrative matters | Subject Expert |
| **2** | | |
| **3** | Syndicate Activity | By Participants |
| **4** | | |
| **02 April 2017 (Sunday)** | | |
| **03 April 2017 (Monday)** | | |
| **1** | Serious Adverse Effect (SAE) in Clinical Trial and reporting | Mrs. A. Visala<br>DDC(I), CDSCO(HQ) |
| **2** | Causality assessment of SAE and compensation | |
| **3** | Regulation provisions for grant of manufacturing licence | Sh. K. Bangarurajan<br>DDC(I), CDSCO, Mumbai |
| **4** | Schedule-M and its Objectives and Components | |

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|---|---|---|
| **04 April 2017 (Tuesday) Holiday** | | |
| **05 April 2017 (Wednesday)** | | |
| **1** | Role of Quality Control and Quality Assurance division in Pharmaceutical Industry | Sh. Prashant Dixit<br>General Manager,<br>M/s Actavis Pharma |
| **2** | | |
| **3** | GMP- Active Pharmaceuticals | Sh. Biju Philip<br>Vice President,<br>M/s Actavis Pharma |
| **4** | GMP- Oral Solid Dosage Form | |
| **06 April 2017 (Thursday)** | | |
| **1** | GMP- Sterile Products | Subject Expert |
| **2** | | |
| **3** | GMP-Oral Liquid and External Preparation | Subject Expert |
| **4** | GMP-Metered Dose Inhalers | Sh. Kiran Rote,<br>M/s Cipla |
| **07 April 2017 (Friday)** | | |
| **1** | Aseptic Processing Techniques | Representative from Hospira |
| **2** | Simulation Studies- Media Fill | |
| **3** | Computer Classes | Subject Expert |
| **4** | | |
| **08 April 2017 (Saturday)** | | |
| **1** | Language (Grammar & its usage) & Noting, Drafting | Subject Expert |
| **2** | | |
| **3** | Syndicate Activity | By Participants |
| **4** | | |
| **09 April 2017 (Sunday)** | | |
| **10 April 2017 (Monday)** | | |
| **1** | Qualification and Validation Principles | Dr. V.V. Dikshit<br>Vice President-Facilities<br>Maintenance Engineering,<br>M/s Dr. Reddy's |
| **2** | HVAC Qualification and Validation Principles | |
| **3** | Cleaning Validation | Sh. Sanjay S. Shetgar<br>Vice President Quality,<br>Dr. Reddy's/Sh. Sanjay Rajpal Sharma, Dr. Reddy's |
| **4** | Water System in Pharmaceutical Industry | |
| **11 April 2017 (Monday)** | | |
| **1** | Validation of Sterilization Products | Sh. Amit Dixit<br>M/s Sun Pharma |
| **2** | Basic Concept of Quality Risk Management | |
| **3** | Concept and Definition of OOS, Change Control, and Self Inspection | Sh. Deep Chandra Upadhyay<br>M/s Glenmark |
| **4** | Risk based inspection of manufacturing premises | |
| **12 April 2017 (Wednesday)** | | |
| **1** | Inspection - planning, preparation, collection of evidences | Dr. S. Manivannan<br>DDC(I), CDSCO, Chennai |
| **2** | GMP inspection checklist | |
| **3** | Inspection report preparation | Mr. Arvind Kukrety<br>DDC(I), CDSCO, Hyderabad |
| **4** | Non Compliance observed during GMP audit | |

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|---|---|---|
| **13 April 2017 (Thursday)** | | |
| 1 | Good Laboratory Practices- Schedule L1 of Drugs & Cosmetic Rules, 1945 | Dr. R.A. Singh<br>Director, RDTL, Chandigarh |
| 2 | | |
| 3 | Development of analytical methods | Manish Kumar Dare<br>M/s Jubiliant |
| 4 | | |
| **14 April 2017 (Friday) Holiday** | | |
| **15 April 2017 (Saturday)** | | |
| 1 | Language (Grammar & its usage) & Noting, Drafting | Subject Expert |
| 2 | | |
| 3 | Syndicate Activity | By Participants |
| 4 | | |
| **16 April 2017 (Sunday)** | | |
| **17 April 2017 (Monday)** | | |
| 1 | Validation of analytical methods | Md. Sadakat<br>M/s Akums Drugs |
| 2 | | |
| 3 | Microbiological testing procedure | Sh. K.B. Satpute<br>M/s Serum Institute |
| 4 | BET & Sterility Validation | |
| **18 April 2017 (Tuesday)** | | |
| 1 | Inspection of laboratory checklist | Dr. Raman Mohan Singh<br>Director, CDTL, Mumbai |
| 2 | Noncompliance observed during GLP audit | |
| 3 | Behavioural aspects in effective leadership | Ms. Soni Sharma |
| 4 | Personality development & Communication skills | |
| **19 April 2017 (Wednesday)** | | |
| 1 | Basic principles of stability of drugs | Dr. Saranjit Singh<br>NIPER, Mohali |
| 2 | Stability studies of pharmaceutical products | |
| 3 | Stability studies of biological products | |
| 4 | Stability studies of biological products | |
| **20 April 2017 (Thursday)** | | |
| 1 | Regulatory requirement for the functioning and operation of a blood bank and preparation of blood components | Sh. P.K. Jaggi<br>Former ADC, NCT OF Delhi |
| 2 | | |
| 3 | Inspection of blood banks | Dr. Kabita Chatterji<br>M.B.B.S. MD (Pathology), Blood Bank, AIIMS |
| 4 | | |
| **21 April 2017 (Friday)** | | |
| 1 | Import & Registration of drugs and Import of drugs under dual use/test licence/ personal use | Mrs. Rubina Bose<br>DDC(I), CDSCO(HQ) |
| 2 | | |
| 3 | Computer classes | Subject Expert |
| 4 | | |
| **22 April2017 (Saturday)** | | |
| 1 | Language (Grammar & its usage) & Noting, Drafting | Subject Expert |
| 2 | | |
| 3 | Syndicate Activity | By Participants |
| 4 | | |

| | | |
|---|---|---|
| **23 April2017 (Sunday)** | | |
| **24 April 2017 (Monday)** | | |
| **1** | Import & Registration of cosmetics | Sh. Sudipta Dey<br>DDC(I), CDSCO(HQ) |
| **2** | Requirement for approval of LVP | Sh. Sanjeev Kumar<br>DDC(I), CDSCO, Indore |
| **3** | Veterinary Drugs & Misuse of drugs in animals | |
| **4** | BA/BE Export NOC | Dr. A. Ramkishan<br>DDC(I), CDSCO(HQ) |
| **25 April 2017 (Tuesday)** | | |
| **1** | Biological products – Vaccine basics | Sh. Anil Sood,<br>M/s Panacea Biotech |
| **2** | Basics of Recombinant Technology - Science and challenges | |
| **3** | Stem Cells, Regenerative Medicines | Representative from AIIMS |
| **4** | Monoclonal Antibodies | Dr. Sanjeev Kumar<br>M/s Zydus Cadila |
| **26 April 2017 (Wednesday)** | | |
| **1** | Evaluation of preclinical and clinical data of biological products | Sh. S.P. Shani<br>DDC(I). CDSCO Kolkata |
| **2** | | |
| **3** | Evaluation of CMC Module III of CTD | Smt.Swati Srivastava<br>DDC(I), CDSCO(HQ) |
| **4** | AEFI with respect to vaccines | |
| **27 April 2017 (Thursday)** | | |
| **1** | Marketing Authorization of biological products | Dr. A Ramakishan<br>DDC (I) |
| **2** | | |
| **3** | Manufacturing process and Process flow of vaccine and formulation | Sh. Sunil Goel<br>Deputy Director, M/s Serum Institute of India |
| **4** | Quality Control of vaccines | |
| **28 April 2017 (Friday)** | | |
| **1** | Procedure for Post approval changes of Biologicals | Smt. Rubina Bose<br>DDC(I), CDSCO(HQ) |
| **2** | NRA Assessment of vaccines | |
| **3** | Computer classes | Subject Experts |
| **4** | | |
| **29 April 2017 (Saturday)** | | |
| **1** | Language (Grammar & its usage) & Noting, Drafting | Subject Expert |
| **2** | | |
| **3** | Syndicate Activity | By Participants |
| **4** | | |
| **30 April 2017 (Sunday)** | | |
| **01 May 2017 (Monday)** | | |
| **1** | Current Regulation on Medical Devices & IVD, Drugs Vs Devices | Dr. S. Eswara Reddy<br>JDC(I) |
| **2** | Proposed Regulation on Medical Devices | |
| **3** | Biocompatibility study | Sh. Sharad Shukla<br>Manager, M/s Johnson & Johnson |
| **4** | Classification of Medical Devices and Diagnostics | Sh. R. Asok Kumar<br>Vice President |

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|---|---|---|
| **02 May 2017 (Tuesday)** | | |
| **1** | Clinical Investigation | Mrs. Sumati Randeo<br>M/s Abott |
| **2** | ISO-13485 | Dr. K. Shiv Kumar<br>M/s. Stretegy |
| **3** | Standards of Medical Devices | Sh. Sudhakar Mairpady |
| **4** | Import & Registration of Medical Devices | Mr. Aseem Sahu<br>DDC(I), CDSCO(HQ) |
| **03 May 2017 (Wednesday)** | | |
| **1** | Inspection of drugs sales premises, samples collection, handling and reporting | Sh. K. Rajabhanu,<br>ADC, Andhra Pradesh |
| **2** | Investigation of Spurious and Not of Standard Quality (NSQ) drugs, Procedure for launching prosecution | |
| **3** | Good Distribution Practices | Mrs. Rubina Bose<br>DDC(I), CDSCO(HQ) |
| **4** | | |
| **04 May 2017 (Thursday)** | | |
| **1** | Pharmacovigilance Programme in India | Dr. Kalaiselvan<br>IPC, Ghaziabad |
| **2** | Materiovigilance Programme in India | |
| **3** | Haemovigilance Programme in India | Dr. Akanksha Bisht<br>Scientist Grade-III, NIB, Noida |
| **4** | Role of PHARMEXCIL | Representative from<br>Pharmexcil |
| **05 May 2017 (Friday)** | | |
| **1** | Neutral drug Code/Special code, Written Confirmation and export NOC | Dr. R. Chandra Shekhar<br>DDC(I), CDSCO(HQ) |
| **2** | | |
| **3** | Computer classes | Subject Experts |
| **4** | | |
| **06 May 2017 (Saturday)** | | |
| **1** | Language (Grammar & its usage) & Noting, Drafting | Subject Expert |
| **2** | | |
| **3** | Syndicate Activity | By Participants |
| **4** | | |
| **07 May 2017 (Sunday)** | | |
| **08 May 2017 (Monday)** | | |
| | **Visit to IPC, Ghaziabad**<br>**Visit to CDSCO Zonal Office, Ghaziabad**<br>**Visit to IGI Airport, New Delhi** | **Group 1 & 3**<br>**Group 2 & 5**<br>**Group 4 & 6** |

## List of Participants

| S.No | Name | S.No | Name |
|---|---|---|---|
| 1 | Ms. Afrin Siddique | 24 | Dr. Midhun Kumar Duddu |
| 2 | Mr. Animesh Kumar | 25 | Mr. Nagendra Kumar |
| 3 | Mr. Andhavarapu Santosh Kumar | 26 | Mr. Nitish Kumar |
| 4 | Ms. Aswini M. | 27 | Ms. Pavani Killamsetty |
| 5 | Mr. Banoth Venkateswarlu | 28 | Mr. Prashanth Kumar Killi |
| 6 | Mr. Bihari Lal Ahirwar | 29 | Mr. Rajiv Kumar |
| 7 | Ms. Bodapati Kamala | 30 | Ms. Ranjitha Nayak |
| 8 | Ms. Boyina Anusha | 31 | Ms. Renuka Pothu |
| 9 | Mr. Budhabhaskar Gotru | 32 | Ms. Sana |
| 10 | Ms. Bulusu Sai Gayatri | 33 | Mr. Santha Vardhan Malapolu |
| 11 | Ms. Gajji Manasa | 34 | Mr. Saurabh Sahu |
| 12 | Ms. Gannamani Swathi | 35 | Mr. Shabari Girinath K |
| 13 | Ms. Gunja Chaturvedi | 36 | Ms. Smitha Somashekar |
| 14 | Ms. Ippili Rekha | 37 | Ms. Sowmya Katreddy |
| 15 | Ms. Kamatam Thulasi Lakshmi | 38 | Mr. Sravan Kumar Muppu |
| 16 | Ms. Kelothu Danthi Bai | 39 | Mr. Sumanta Kumar Ghosh |
| 17 | Ms. Koppula Tejaswini | 40 | Ms. Swapna Gandham |
| 18 | Ms. Kothamangala Bhavani | 41 | Ms. Teku Rajya Lakshmi |
| 19 | Mr. Krishnagopal Das | 42 | Ms. Thottempuri Priyanka |
| 20 | Mr. Lohithasu Duppala | 43 | Ms. Veena Vijan |
| 21 | Mr. M. Sundara Karthikeyan | 44 | Ms. Vejendla Manasa Rojamble |
| 22 | Ms. Maloth Padma Kumari | 45 | Mr. Velisetti Vijaya Kumar |
| 23 | Ms. Meena Devi M | 46 | Mr. Venkateshwarlu R. |

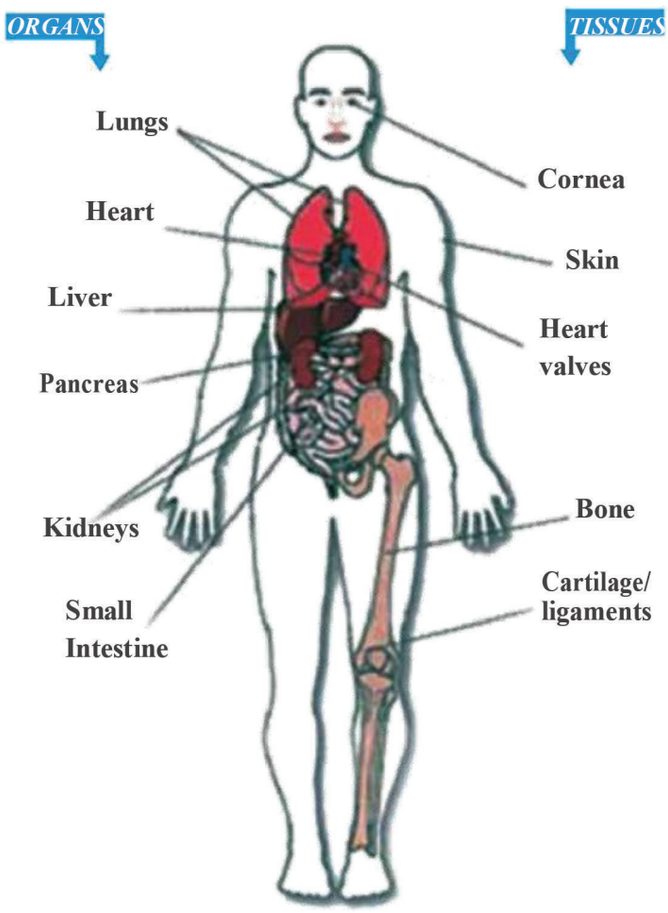
है एक ऐसा काम, जो नहीं कर सकते स्वयं भगवान !!!
स्वेच्छा से अंगदान..जो कर सकता है सिर्फ एक नेक इंसान!!!

# अंग दान . जीवन दान

## PROMOTION OF ORGAN DONATION

There is a huge mismatch between the demand for and supply of human organs. While the estimated annual requirement for kidney, heart and liver donations is around 2,80,000, only around 7515 transplants are performed throughout the country annually. Most such transplants are with organs from live donors. In case of cornea, about 25000 transplants are done every year against the requirement of 1 lakh.

### Organs & Tissues that can be donated




Organ donation rate in India is approximately 0.33 per million population; whereas it is 35 per million population in Spain.

Nearly, 1.38 lakh deaths occur annually due to road accidents in India. most of those involved in such fatal accidents are potential organ donors. Cadaveric transplant can be done from "brain stem dead" persons before heart stops beating or after circulatory death after heart beating stops. Lives of a large number of patients suffering from end stage organ failure can be saved through cadaveric retrieval of organs. Donation of organs can mitigate the sufferings of many. Let's resolve to promote awareness about organ donation and make it a national mission.

**Let us not take our Organs to heaven. Heaven knows we need them here to save lives of needy.**

**Donate Organs……Save Lives**

**Website: www.notto.nic.in** **Helpline No- 1800-11-4770**

Notes

ऊँ सर्वे भवन्तु सुखिनः सर्वे सन्तु निरामयाः।
सर्वे भद्रणिपश्यन्तु मा कश्चिदुःख भाग भवेत्।।

# CDSCO (HQ), New Delhi


**Central Drugs Standard Control Organization**

**Ministry of Health and Family Welfare**

**FDA Bhawan, Kotla Road, New delhi -110002**