

Government of India

Ministry of Health & Family Welfare

TRAINING MODULE



सत्यमेव जयते

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Month Long Residential Training Programme

for Drugs Inspectors of States/UTs and CDSCO

Jan 04, 2016 to Feb 3, 2016

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

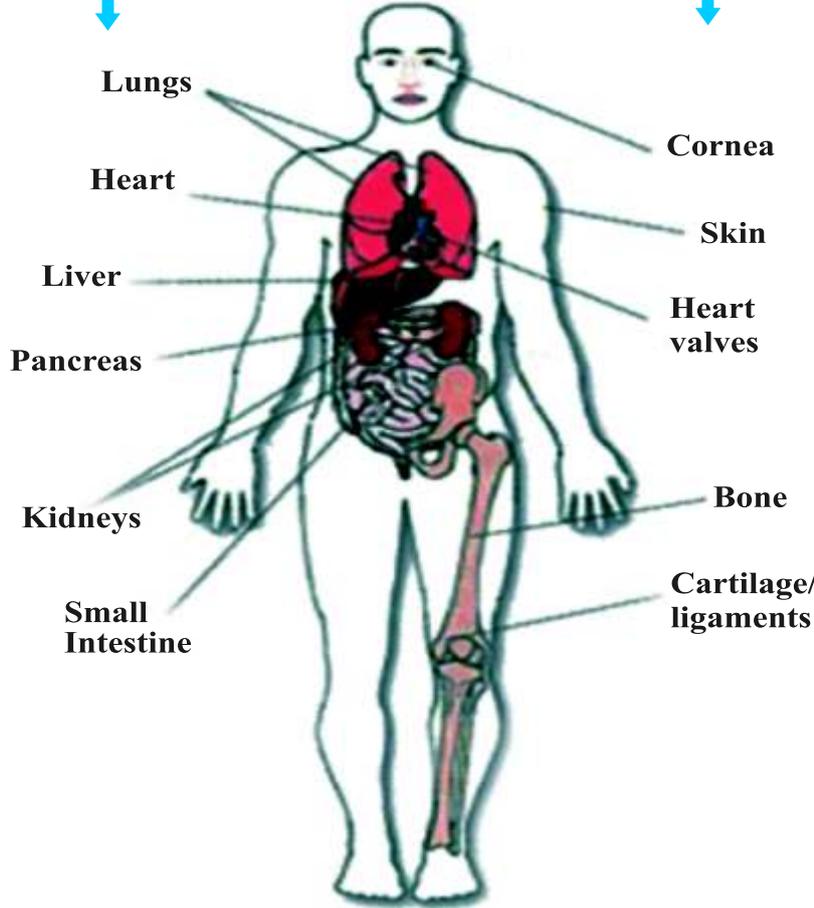
अंग दान . जीवन दान

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

ORGANS



TISSUES

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

विद्या ददाति विनयं वियाद्याति पात्रताम् ।
पात्रत्वाद्धनमाप्नोति धनाद्धर्मं 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**

एकता के बिना जनशक्ति शक्ति नहीं है जबतक उसे ठीक तरह से
सामंजस्य में न लाया जाए और एकजुट ना किया जाए,
और तब यह आध्यात्मिक शक्ति बन जाती है.

**Manpower without Unity is not a strength
unless it is harmonised and united properly,
then it becomes a spiritual power.**

Vallabhbhai Patel
वल्लभभाई पटेल

Developing Human Resources..

India is the pharmacy of the world and we are proud of that fact. However, in order to retain that position, we need to transform our production, quality control, assurance related activities and also other processes across all manufacturing units. A key requirement for this would be to upgrade our regulatory structures and practices so that there is no compromise on quality. This is particularly more so in areas of medical devices, where India could become the manufacturing hub for the world. Similarly, in biologicals and other emerging areas and clinical research/trials also, the potential is unprecedented.

As such, 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 endeavor and provision of health services is no exception. Keeping in view the commitment of the Government for providing optimal healthcare to all its citizens, a multi-pronged approach would be necessary to address health related concerns.

One of the critical pillars of public health services is the access to medical products that conform to the 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 State regulators but also helps in provision of better healthcare services throughout the world given the reach of our pharma sector. The CDSCO is responsible for standard setting and is striving to develop a uniform system of regulatory practices and evolving ways and means for removing inter-state disparities in regulation and inter-lab differences in drug testing and 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 and induction programme for Assistant Drugs Inspectors. Courses have also been conducted for accreditation of all drug testing Laboratories in the Centre and States by NABL and ISO certification of regulatory offices. 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 emphasis of the Government on training and development will set in motion a life long process of learning benefitting the humanity at large.



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

Regulatory challengers...

Indian Pharmaceutical Industry is one of the most vibrant sectors of Indian economy. It is also one of the largest and most advanced among the developing countries. 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 Indian and global population.

Indian pharma industry has an annual turnover of more than Rs. 2 lakh crore and is growing at the rate of 12-14% per annum. 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. India ranks 3rd largest in the world in terms of volume of production and 10th in terms of value. Drugs produced in the country are exported to more than 205 countries / Economies of the world, including USA and European Union. Indian vaccines and bio-pharma products are exported to about 150 countries including international organization like UNICEF.

The main objective of the CDSCO and State Drug Regulatory Authorities is to safeguard and enhance the public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices. The training programme for the Drugs Regulatory Officials has been conceived with the objective of imparting fundamental skills and knowledge in all aspects of Drugs Regulatory System in India and also to acquaint the officials with international regulatory practices. The training programme also aims to establish strong regulatory advancement to ensure effective and uniform enforcement across the nation. 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 training programme.

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)



सत्यमेव जयते

CDSCO

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.

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 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.

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

- **CDSCO, HQ at New Delhi**
- **Zonal Offices:** Mumbai, Ghaziabad, Chennai, Kolkata, Ahmedabad and Hyderabad
- **Sub Zonal Offices:** Chandigarh, Bangalore, Jammu and Goa
- **Port Offices:** Ahmedabad, 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, Head Quarter

- Laying down standards of drugs, cosmetics, diagnostics and 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

Be congruent, be authentic, be your true self

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).
- Pharmacovigilance 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 Rules.
- No objection certificates for grant of permission for manufacture for export only of unapproved / approved new drugs and banned drugs.

An obstacle is often a stepping stone

- 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 and Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules & 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 Drugs 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 function of State Drugs Regulators are list below:

- Grant/renewal of Licenses for Manufacture, Sale and Distribution of Drugs, Cosmetics and Medical Devices

Wake up every morning with the thought that something wonderful is about to happen

- 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.

Roles 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

Zeal without knowledge is fire without light

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 meet with such functional requirements.

On one hand, the Government of India and the State Governments are recruiting a number of regulatory personnel and on the other hand, 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 develop an extensive training programmes for various regulatory officials covering all areas of functions of CDSCO including deputing the inspectors in various zonal offices, port, sub-zonal offices for receiving practical experiences, hands-on training in the various regulatory functions of CDSCO. It has also been decided that all regulatory personnel will undergo basic and advanced training programs.

Training Needs Analysis

Training will be imparted in following major areas:

- Technical
- Legal
- Managerial
- IT and Communication skills

Technical Needs

- Good Manufacturing Practices
- Good Laboratory Practices
- Good Clinical Practices
- Good Distribution and Storage Practices
- Principles of product development and pre-formulation studies
- New Drug Approval Process

- Clinical Trials Including BA/BE studies,
- Pharmacovigilance
- Quality audits and inspections – Planning, Procedures, Report writing
- Quality assurance and safety aspects in blood and blood products
- Special feature of manufacture and quality assurance in Vaccines and Sera, r-DNA products, Active Pharmaceutical Ingredients, Medical Devices, Stem Cells, Monoclonal Antibodies etc.
- Advances in biotechnology & immunology
- Drug discovery and development
- International regulatory framework

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 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 encompass a series of activities relating to management of 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 receiving feedback

The CDSCO will update training needs through Training Need Analysis with the professional inputs.

Training Action Plan for Drugs Inspector

Duration	Areas to be covered
• 1 months	Regulatory framework in India i.e. Drugs and Cosmetics Act and Rules, Drugs and Magic Remedies Act, Narcotic and Psychotropic Substances Act etc., Basic introduction to GMP, GLP,GCP etc. and communication skills.

Training Venue



NATIONAL INSTITUTE OF BIOLOGICALS

(Ministry of Health & Family Welfare)

Government of India Plot No. A-32, Sector-62, Institutional Area,NOIDA-201 309 (U.P.), INDIA.

Quality is not an act, it is a habit

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
- Subject experts from academic institutions (NIPER, IIT, IIScetc.)
- Subject experts from Industry (GMP, GCP, GLP etc.)
- Experts from international organizations like WHO etc.
- Retired/Current senior Government officials
- Industry professionals.

Guidelines for One month Residential training for Drugs Inspectors of State and CDSCO at NIB, Noida w.e.f. 04.01.16 to 03.02.2016

- In this batch there are total 80 participants. Entire batch is divided in to eight subgroups named as follows.

Group 1: Ganga,

Group 2: Yamuna

Group 3: Narmada

Group 4: Krishna

Group 5: Kaveri

Group 6: Tapti

Group 7: Godavari

Group 8: Jhelum

- To bring clarity in the course content, Day-wise agenda is provided in this booklet indicating, topics, 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 Saturday 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

Perseverance is failing 19 times and succeeding the 20th

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 1 months of class room training, all participants Drugs Inspectors will be divided into 3 groups and will undergo field training at specified locations as per schedule indicated below.

Location	30.01.2016		01.02.2016	
	Morning	Afternoon	Morning	Afternoon
Industry-I	Group-1	Group 2	Group-3	
Industry-II	Group 2	Group-1		Group-3
Industry-III	Group-3		Group-1 and 2	

- **Note:** All participants will visit identified industries on 30.01.2016 and 01.02.2016.
- Each participant will be required to write a report on the work undertaken at NIB and field visit.
- 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 / Behavior / Attire / Aptitude	3%
Communication / Presentation Skills	7%
Report writing	7%
Written Examination	60%
Total	100%

- Qualifying Marks for the test shall be 70 %.
- Three Best trainees will be given suitable prizes.

Day – 04-January, 2016, Monday

From (hrs)	To (hrs)	Subject	Speakers
09:00	09:30	Registration of participants Participants will be registered and enrolled for the training.	
09:30	09:40	Welcome Address	Dr. S. Eswara Reddy, JDC(I), CDSCO
09:40	09:55	Inaugural Address	Dr. G. N. Singh, DCG (I)
09:55	10:05	Inaugural Address	Dr. Surinder Singh, Director NIB, Noida
10:05	10:20	Key note Address	Shri K. L. Sharma, JS (R) Government of India
10:20	10:30	Vote of Thanks	Dr. V. G. Somani, JDC(I), CDSCO
10:30	11:15	Photo Session followed by Tea break	
11:15	11:45	Introduction of the Participants	Dr. Naresh Sharma, ADC (I), CDSCO
11:45	1:00	Pre- Assessment	Dr. Naresh Sharma, ADC (I), CDSCO

Common Schedule from Day-2 Onwards

Begin	End	Activity / Sessions
6:30	7:30	Yoga and Meditation
9:30	11:00	Session – 1
11:00	11:30	Tea Break
11:30	13:00	Session – 2
13:00	14:00	Lunch Break
14:00	14:15	Warm up
14:15	15:45	*Session- 3
15:45	16:15	Tea Break
16:15	17:45	*Session- 4
17:45	18:00	Evaluation of the Day by one of the groups

Note:

-Evaluation Test will be conducted on every Monday from 9:00 to 9:30 hrs.

* On Every Friday, there will a Syndicate activity (defined in guidelines) in Session 3 and 4

A journey of thousand miles begins with a single step

Session wise Schedule from Day-1 onwards

Session	Topic	Speaker
04 January 2016 (Monday)		
3	Background, objective and expected outcomes of training.	Dr. S. Eswara Reddy, JDC(I), CDSCO
4	Issues and Challenges in Drug Regulation	Dr. S. Eswara Reddy, JDC(I), CDSCO
05 January 2016 (Tuesday)		
1	Role of Indian pharma industry in meeting health care need	Dr D. Roy, Ex DDCI(I), CDSCO
2	Role of Statutory Bodies: DTAB, DCC and CDL	
3 and 4	Statutory provisions and power for control of drugs including Offences and Penalties.	Smt. A. Visala, DDC(I), CDSCO
06 January 2016 (Wednesday)		
1	Procedure for Banning Drugs	Sh. A. K. Pradhan, DDC(I), CDSCO
2	National List of Essential Medicines in India	
3	An introduction to Drugs & Magic Remedies Act	Sh. K. Bangarurajan, DDC(I), CDSCO
4	Overview of DPCO and Essential Commodity Act	Representative from NPPA
07 January 2016 (Thursday)		
1	Overview of CLAA Scheme	Sh. P. B. N. Prasad, DDC(I), CDSCO
2	Overview of WHO-GMP Certification Scheme	
3	Overview of Indian Pharmacopoeia	Dr Jai Prakash, PSO, IPC
4	Role of Indian Pharmacopoeia Commission	
08 January 2016 (Friday)		
1	Right to information Act	Sh. A. N. Chakarborti, RTI Expert
2	Overview of administrative matters	Sh. PCP Mahapatra, AO, NIB
3	Overview of Evidence Act	Sh. Amzad Ali, APP, CBI
4	Cyber Crime Investigation	Sh. M.S.Chauhan, Inspector, CBI Academy
09 January 2016 (Saturday)		
1	Overview of Prevention of Corruption Act	Sh. V.P. Arya, Ex. Sr. Supdt, CBI
2	Narcotic Drugs and Psychotropic Substances Act	Sh. R.S. Joshi, Narcotics Control Bureau
3 and 4	Syndicate Activity by Participant	By Participants
10 January 2016 (Sunday)		

11 January 2016 (Monday)		
1	Overview of Code of Criminal Procedure	Sh. Rishikant, Legal Advisor
2	Overview of Indian Penal Code	
3	Drug discovery, Pre-clinical study and Phases of Clinical trials and Regulation Overview	Dr. Ajith V. Kamath, Ph.D. Head, External R&D Innovation, Pfizer Inc.
4	Institutional Ethics Committee, Registration and role of Ethics Committee	Smt. A. Visala, DDC(I), CDSCO
12 January 2016 (Tuesday)		
1 2	Marketing Authorization process of New Drugs, Investigational New Drugs, Fixed Dose Combination and Subsequent New Drugs	Dr. VG Somani, JDC(I), CDSCO
3 4	Role of various Committees in New Drugs Approval Process	Sh. R. Chandra Shekhar, DDC(I), CDSCO
13 January 2016 (Wednesday)		
1	Post Marketing Surveillance and its monitoring	Dr Bikash Medhi, Professor, PGIMER
2	Conduct of GCP inspection	
3 4	Clinical Trial inspection checklist and common observations	Sh A. K. Pradhan, DDC(I), CDSCO
14 January 2016 (Thursday)		
1	Regulatory provisions for grant of manufacturing licence	Smt. Shanthi Gunashekharan
2	Schedule-M- Objectives and Components	
3	Role of Quality Control and Quality Assurance division in Pharmaceutical Industry	Sh. Ajay Prakash, Vice President M/s Win Medicare
4	GMP- Oral Solid Dosage Form	Sh Biju Philip, Vice President, Watson Pharma Pvt. Ltd., Mumbai
15 January 2016 (Friday)		
1	GMP- Sterile Products	Sh. Deepak Kasbi, Vice President- Corporate Quality, Lupin Limited, Mumbai
2	GMP- Active Pharmaceuticals	
3	GMP-Metered dose inhalers	Sh. Kiran Rote, Team Lead , pMDIs, Cipla Ltd.
4	GMP-Oral Liquid and External Preparation	
16 January 2016 (Saturday)		
1	Aseptic processing techniques	Representative from M/s Hospira Ltd.
2	Simulation studies- Media fill	
3 ans 4	Syndicate Activity (Clean room concept-HVAC & Environmental Monitoring & Trend Analysis)	By Participants
17 January 2016 (Sunday)		

18 January 2016 (Monday)		
1	Qualification and validation principles	Sh V.V. Dikshit, Vice President- Facilities, Maintenance (Engineering) Dr. Reddy's Laboratories Ltd.
2	Water System in Pharmaceutical industry	
3	Process Validation	Sh Sanjay Rajpal Sharma, Director- Validation, Dr. Reddy's Laboratories Ltd.
4	Cleaning Validation	Sh Sanjay S. Shetgar, Vice President-Quality Dr. Reddy's Laboratories Ltd.
19 January 2016 (Tuesday)		
1	Validation of Sterilization Products	Sh. Manoj Sagwekar, GM Quality Assurance Glenmark Pharmaceuticals Limited
2	Quality Risk Management - a conceptual framework	Sh. Hitesh Patel, Head Quality Assurance and Quality control, Cadila Healthcare Ltd.
3	Concept and Definition of Out of Specification, Change Control, and Self Inspection	Sh. Deep Chandra Upadhyay, GM Quality Assurance Glenmark Pharmaceuticals Limited
4	Risk based inspection of manufacturing premises	Sh. Ashish Dave, GM, Quality Assurance Glenmark Pharmaceuticals Limited
20 January 2016 (Wednesday)		
1	Inspection - Planning, Preparation, Collection of Evidences	Dr. A. Ramkishan, DDC(I), CDSCO
2	GMP inspection Checklist	
3	Inspection Report Preparation	Sh Arvind Kukrety, DDC(I), CDSCO
4	Non Compliance observed during GMP Audit	
21 January 2016 (Thursday)		
1	Good Laboratory Practices- Schedule L1 of Drugs & Cosmetic Rules, 1945	Dr. R.A. Singh, Director, RDTL
2	Development of Analytical Methods	Dr. Manish Kumar Dare, Head Analytical, Jubilant Generics Limited, Noida
3	Validation of Analytical Methods	
4	Microbiological Testing Procedure	Dr. Ajay Shankar Singh, Head of Analytical Development, Fresenius Kabi Oncology Limited, Gurgaon

You are never too old to set another goal or to dream a new dream

22 January 2016 (Friday)		
1	Inspection of Laboratory Checklist	Dr Raman Mohan Singh, Director, CDTL, Mumbai
2	Noncompliance observed during GLP Audit	
3	Syndicate Activity	By Participants
4		
23 January 2016 (Saturday)		
1	Biological Products – Vaccine Basics	Sh Anil Sood, Vice President (QC & QA), Panacea Biotec, Lalru, Punjab
2	Basics of Recombinant Technology - Science and Challenges	
3	Stem Cells, Regenrative Medicines	Dr. N. K. Mehra, National Chair & Former Dean, (Research) AIIMS, New Delhi
4	Monoclonal Antibodies	Dr. Sanjeev Kumar, Sr. Vice President, Zydus Cadila Healthcare Ltd.
24 January 2016 (Sunday)		
25 January 2016 (Monday)		
1	Current Regulation on Medical Devices & IVD, Difference between Drugs and Devices	Dr. S.Eswara Reddy, JDC(I) CDSCO
2	Proposed Regulation on Medical Devices	
3	Biocompatibility Study	Mr. Muraleedharan CV, Scientist G & Associate Head SCTIMST Trivandrum, India
4	Classification of Medical Devices and Diagnostics	Representative from Industry.
26 January 2016 (Tuesday)		
27 January 2016 (Wednesday)		
1	Manufacturing Process and Process Flow of Vaccine and formulation	Dr. Sunil Goel, Deputy Director of Quality Assurance Serum Institute of India
2	Quality Control of Vaccines	
3	Basic Principles of Stability of Drugs	Dr. Saranjit Singh, NIPER
4	Stability studies of Pharmaceutical Products	
28 January 2016 (Thursday)		
1	Regulatory requirement for the functioning and operation of a blood bank and preparation of blood components	Dr. S. Manivannan, DDC(I)
2	Inspection of Blood banks	
3	Quality control and quality assurance of blood and blood products.	Dr. R. N.Makroo, Dept.Transfusion Medicine, Apollo HospitalsDelhi
4	Import & Registration of drugs and functioning of port offices	Smt. Shanthi, Gunashekharan, DDC(I)
29 January 2016 (Friday)		
1	Inspection of Drugs Sales Premises, Samples Collection, Handling and Reporting	Dr. Jagashetty, Ex. Drugs Controller, Karnataka
2	Investigation of Spurious and Not of Standard Quality (NSQ) drugs, Procedure for launching prosecution	

3	Import & Registration of Medical Devices	Sh. Aseem Sahu, DDC (I)
4	Good Distribution Practices	Smt Rubina Bose, DDC(I)
30 January 2016 (Saturday)		
1	Industrial Visit	By Participants
31 January 2016 (Sunday)		
01 February 2016 (Monday)		
1	Industrial Visit	By Participants
02 February 2016 (Tuesday)		
1	Behavioral Aspects in Effective Leadership	Dr. Dev Arora
2	Personality Development & Communication Skills	Ms. Soni Sharma
3	Neutral drug Code/Special code, Written confirmation and export NOC	Sh. R. Chandra Shekhar, DDC(I), CDSCO
4	Role of PHARMEXCIL	Dr. P V Appaji, Director General, PHARMEXCIL.
03 February 2016 (Wednesday)		
1	Post Assessment	Programme Organiser
2	Roadmap for Indian Regulators	Dr. Surinder Singh, Director NIB, Noida
3	Overview of National Organ and Tissue Transplant Organisation (NOTTO)	Dr. Saudan Singh Director, NOTTO
4	(I) Valedictory Session	
	(II) Final Evaluation of the Training and Concluding Presentation	

Strength does not come from physical capacity. It comes from an indomitable will



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सर्वे भद्राणिपश्यन्तु मा कश्चिद्दुःख भाग भवेत् ॥



CDSCO, Head Quarter, New Delhi



सत्यमेव जयते

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
Ministry of Health & Family Welfare
FDA, Bhavan, Kotala Road, New Delhi - 110002