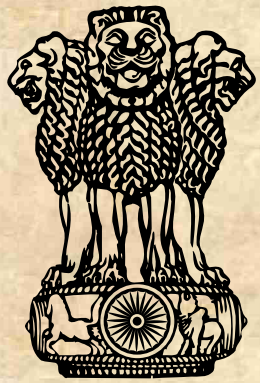
GOVERNMENT OF INDIA

Ministry of Health & Family Welfare



सत्यमेव जयते

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Induction Programme For Assistant Drugs Inspectors

Oct 05, 2015 to Dec 31, 2015

विद्या ददाति विनयं विनयाद्याति 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.

"Learning gives creativity,
Creativity leads to thinking,
Thinking provides knowledge,
Knowledge makes you great."

-Abdul Kalam

Human Resource Management in CDSCO.....

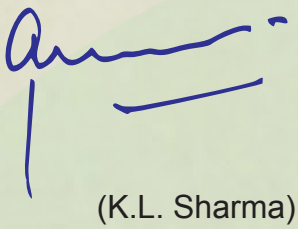
Human resources are one of the most critical elements in any endeavor and provision of health services is no exception. Keeping in view the commitment of the Government for providing optimal health care to all its citizens, a multi-pronged approach is being adopted to address health related concerns.

One of the important 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.

The role of the CDSCO, the organ of the Central Government in the process, is like a nervous system in a body. In fact, vibrancy and effectiveness of CDSCO not only acts as the role model for State regulators but also helps in provision of better health care services throughout the world in the reach of our pharma sector.

Keeping the above in view and as part of the massive organizational strengthening, the Government has decided to initiate a massive programme for development of human resources for the CDSCO and the States through appropriate training modules for different levels of induction and refresher courses. The present programme is the first one in the series for the enforcement staff. Earlier, a course has been conducted for Drug Analysts of all States. There are many more programmes that are being planned for the regulatory and laboratory staff and also for the Industry including e-learning modules.

Physical exercise and Yoga will be an integral part of all such programmes. 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.



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

Development of Human Resources for Efficient Drugs and Medical Devices Regulation.....

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 technology. 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 organisation 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 Assistant Drugs Inspectors 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 Information technology fundamentals to ensure efficient implementation of organization wide e-Governance programme. 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.

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 Drug 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 bring 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:

1. Efficient regulatory operations including procedural efficiency to ensure consistency, predictability, adaptability, timeliness and quality in the review process.

2. Robust scientific review of the applications to ensure Safety, Efficacy and Quality of products.

3. 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), Navasheva, Hyderabad.
- **Central Drugs Laboratories:** Mumbai, Chennai, Guwahati, Chandigarh, Kolkata, Hyderabad and Kasauli.

Every accomplishment starts with the decision to try.

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

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 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 zonal and sub-zonal offices of CDSCO

TECHNICAL

- 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 manufacturer for sale of drugs /cosmetics.
- 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 ensuring that imported drugs comply with the provisions of Chapter III of the Drugs and Cosmetic Act and Rules thereunder and Drugs and Magic Remedies (Objectionable Advertisements) Act and Rules and Narcotic Drugs and Psychotropic Substances Act and 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 thereunder.
- 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 permited 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.

Functions of State Drug 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 Drugs Testing Laboratories.
- Investigation and prosecution in case of violations under the Drugs and Cosmetics Act and Rules.

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

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 System 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.

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 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 a 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 working in CDSCO will undergo basic and advanced training programs.

Training Needs Analysis

Major focus of the training will be on following major areas:

1. Technical and Regulatory
2. Legal and Administrative
3. Managerial and Ethical
4. 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,
- Pharmacovigillance
- 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, Antimicrobial resistance etc.
- Advances in biotechnology and immunology
- Drug discovery and development
- International regulatory framework including WHO

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 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

CDSCO will update training needs through training need analysis with professional inputs.

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

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 Act, Narcotic and Psychotropic Substances Act, etc., Basic introduction to GMP, GLP,GCP, etc., IT skills, 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.

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 faculty would comprise:

1. Retired /Current Drug Regulatory personnel.
2. Experts from outside for Personality development.
3. Officials from CBI, IB, Legal Department.
4. Subject experts from academic institutions (NIPER, IIT, IISc, etc.
5. Subject experts professionals from Industry (GMP, GCP, GLP etc.).
6. Experts from international organizations including WHO etc.
7. Retired/Current senior Government officials.

Guidelines for the Basic Residential Training Program for newly recruited Assistant Drugs Inspectors of CDSCO at NIB, Noida w.e.f. 05.10.15 to 31.12.2015

- The batch will comprise of 30 participants. Entire batch will be divided in to 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 has been 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 in activities, class room training, code of conduct, etc.
- Commencing from the second week, there will be a syndicate activity on every Friday in Session-3 and Session-4. The topics for the syndicate will be decided during the first week of training. In this activity, each group will need to analyze an identified problem, carry out a survey of the existing literature, discuss the issue within the group and present the outcomes that may include but will not be limited to power point presentation, case studies related to the topic or any other activity related to course which will be followed by a question and answer session.
- The syndicate activity of each group will be evaluated.
- At the completion of 2 months of class room training, 30 Assistant Drugs Inspectors will be divided into 3 groups and will undergo field training at specified locations as per schedule indicated below.

Duration Location	01.12.2015 to10.12.2015	11.12.2015 to 20.12.2015	21.12.2015 to 25.12.2015
IPC, Ghaziabad	Group-1	Group-3	Group-2
CDSCO, North Zone	Group 2	Group-1	Group-3
IGI Airport	Group-3	Group 2	Group-1

Note: All participants will visit identified industries from 26.12.2015 to 30.12.2015.

- Each participant will be required to write a report on the work undertaken at IPC and IGI airport office and field visit and clearly identify the differences in the working of Central Government labs and private labs and suggest learnings from such visits.
- 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 will be as below:

Test / Activity	Percentage distribution
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%

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

Registration and Inauguration

October 04, 2015

Venue: National Institute of Biologicals, Plot No. A-32, Sector-62, Institutional Area, NOIDA

From (hrs)	To (hrs)	Subject	Speakers
1630	1730	Registration of participants: Participants will register and enroll for the training.	
1730	1740	Welcome Address	Dr. V. G. Somani, JDC (I)
1740	1800	Inaugural Address	Dr. S. E. Reddy, JDC (I)
1800	1820	Inaugural Address	Dr. G. N. Singh, Drugs Controller General (I)
1820	1840	Inaugural Address	Dr. G. R. Soni, Deputy Director QC, NIB Noida
1840	1900	Keynote Address	Shri K. L. Sharma, Joint Secretary (R)
1900	1910	Vote of Thanks	Ms. Rubina Bose, DDC (I)
1910	2100	Photo Session followed by Dinner	

Training Sessions from October 5, 2015 Onwards

From (hrs)	To (hrs)	Activity / Sessions
0600	0700	Yoga and Meditation
0900	0930	Evaluation Test (Only on Monday)
0930	1100	Session - 1
1100	1130	Tea Break
1130	1300	Session - 2
1300	1400	Lunch Break
1400	1415	Warm up
1415	1545	**Session- 3
1545	1615	Tea Break
1615	1745	**Session- 4
1745	1800	Evaluation of the Day by one of the groups

Note:

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

Session wise Schedule from Day-2 onwards

Session	Topic	Speaker
05 October 2015, Monday		
1	Participant introduction House-keeping announcement, general guidance of training programme	Mr. Sunil Kulshrestha, ADC(I) Mr. kailash Malik (DI)
2	Pre-assessment	
3	Background, objective and expected outcomes of training and functions of ADI	Mr. Arvind Kukrety, DDC (I)
4	Need for Drug Regulation in India	
06 October 2015, Tuesday		
1	Genesis of Drug Regulation	Dr. S.E. 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	
07 October 2015, Wednesday		
1	Structure, function and role of CDSCO	Mr. R. Chandrashekar, DDC(I)
2	Functions of State Licensing Authority	
3	Introduction of Indian Pharma industry	Mr. D.G. Shah. IPA
4	Role of Indian pharma industry in meeting health care need	Mr. Tabrez Ahmed, Secretary General, OPPI
08 October 2015, Thursday		
1	Definition of Drug, Cosmetic, manufacture, spurious, adulterated and misbranded	Dr. D. Roy, Ex. CDSCO
2	Role of Statutory Bodies: DTAB, DCC & CDL	Dr. V.G. Somani, JDC(I)
3	Power and duties of Licensing Authority, Controlling Authority and Drugs Inspector	Mrs. A. Visala, DDC(I)
4	Offences and Penalties in the Drugs & Cosmetics Act	

If you want to shine like a sun, first burn like a sun

Session	Topic	Speaker
09 October 2015, Friday		
1	Procedure of Banning of Drugs	Mr. A. K. Pradhan, DDC(I)
2	National list of essential Drugs in India	
3	Syndicate Activity	By Participants
4		
10 October 2015, Saturday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & Usage), Noting and Drafting	
4		
11 October 2015, Sunday (Holiday)		
12 October 2015, Monday		
1	Overview of CLAA Scheme	Mr. P.B.N. Prasad
2	Overview of WHO-GMP Certification Scheme	
3	Overview of Indian Pharmacopoeia	Expert from IPC
4	Role of Indian Pharmacopoeia Commission	
13 October 2015, Tuesday		
1	An introduction to Drugs & Magic Remedies Act	Mr. K. Bangarurajan, DDC(I)
2	Overview of DPCO and Essential Commodity Act	
3	Right to information Act	Dr. A. N. Chakraboty
4		

Perseverance is failing 19 times and succeeding the 20th

Session	Topic	Speaker
14 October 2015, Wednesday		
1	Overview of Prevention of Corruption Act	Mr. V. P. Arya Ex. CBI
2	Narcotic Drugs and Psychotropic Substances Act	Representative from Narcotics Control Bureau
3	Overview of Code of Criminal Procedure and Indian Penal Code	Mr. Rishikant, Legal Advisor
4	Indian Penal Code - Case Studies	
15 October 2015, Thursday		
1	Administrative matters	Mr. Sachinder Sharma
2		
3	Overview of Evidence Act	Expert from Intelligence Bureau
4	Cyber Crime Investigation	Expert from CBI
16 October 2015, Friday		
1	Intelligence gathering in respect of counterfeit drug manufactures and conducting secret/ discreet verification	Expert from CBI
2	National & International Drugs Trafficking Scenario-An overview	Expert from CBI
3	Syndicate Activity	By Participants
4		
17 October 2015, Saturday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & Usage), Noting and Drafting	
4		
18 October 2015, Sunday (Holiday)		

Session	Topic	Speaker
19 October 2015, Monday		
1	Drug discovery	Industry Expert
2	Pre-clinical study	Dr. Dilip Roy, Panacea
3	Evaluation of Animal Toxicity data	Expert from ITRC / Industry
4	Prevention of Cruelty to animal Act and role of CPCSEA	
20 October 2015, Tuesday		
1	Phases of Clinical trials	Mr. A.K. Pradhan, DDC(I)
2	Overview of Clinical Trial- Regulations	
3	An introduction to GCP	Mrs. A. Visala, DDC(I)
4	IEC, Registration and role of Ethics Committee	
21 October 2015, Wednesday		
1	Clinical trial design, method of randomization and role of Biostatistician	Dr. Bikas Medhi
2	Evaluation of Clinical Trial data	
3	Serious Adverse Effect (SAE) in Clinical Trial and reporting	Mrs. A. Visala, DDC(I)
4	Causality assessment of SAE and compensation	
22 October 2015, Thursday (Holiday)		
23 October 2015, Friday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & Usage), Noting and Drafting	
4		
24 October 2015, Saturday (Holiday)		
25 October 2015, Sunday (Holiday)		

Session	Topic	Speaker
26 October 2015, Monday		
1	Marketing Authorization process of New Drugs, Investigational New Drugs, Fixed Dose Combination and Subsequent New Drugs	Dr. V. G. Somani, JDC (I)
2		
3	Various Committees and their role in New Drugs Approval Process	
4	Evaluation of CMC Data	
27 October 2015, Tuesday		
1	Clinical data evaluation with case study for Marketing Authorization of New Drugs	Industry Expert
2	Post Marketing Surveillance and its monitoring	
3	Conduct of GCP inspection	
4	Clinical Trial inspection checklist and common observations	
28 October 2015, Wednesday		
1	Provisions relating to grant of manufacturing licence	Mrs. Rubina Bose, DDC(I)
2	Schedule-M- Objectives and Components	
3	Role of Quality Control and Quality Assurance division in Pharmaceutical Industry	Representative from Glenmark Ltd.
4	GMP- Oral Solid Dosage Form	
29 October 2015, Thursday		
1	GMP- Sterile Products	Representative from Hospira Ltd.
2	GMP- Active Pharmaceuticals	
3	GMP-Metered dose inhalers	Representative from Cipla Ltd.
4	GMP-Oral Liquid and External Preparation	

Session	Topic	Speaker
30 October 2015, Friday		
1	Aseptic processing techniques	Representative from Lupin Ltd
2	Simulation studies- Media fill	
3	Syndicate Activity (Clean room concept-HVAC & Environmental Monitoring & Trend Analysis)	By Participants
4		
31 October 2015, Saturday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & Usage), Noting and Drafting	
4		
01 November 2015, Sunday (Holiday)		
02 November 2015, Monday		
1	Qualification and validation principles	Representative from Sun Pharma Ltd.
2	Process Validation	
3	Cleaning Validation	Representative from Dr. Reddys Ltd.
4	Water System in Pharmaceutical industry	
03 November 2015, Tuesday		
1	Validation of Sterilization Products	Representative from Zydus Pharma Ltd.
2	Basic Concept of Quality Risk Management	
3	Concept and Definition of OOS, Change Control, and Self Inspection	Representative from Watson Pharma Ltd.
4	Risk based inspection of manufacturing premises	

Session	Topic	Speaker
04 November 2015, Wednesday		
1	Inspection - Planning, Preparation, Collection of Evidences	Dr. S. Manivannan, DDC(I)
2	GMP inspection Checklist	
3	Inspection Report Preparation	Mr. Arvind Kukrety, DDC(I)
4	Non Compliance observed during GMP Audit	
05 November 2015, Thursday		
1	Good Laboratory Practices- Schedule L1 of Drugs & Cosmetic Rules, 1945	Dr. R.A. Singh, Director, RDTL
2	Development of Analytical Methods	Representative from Jubilant Ltd.
3	Validation of Analytical Methods	
4	Micro Biological Testing Procedure	Representative from Fresenius Kabi Ltd.
06 November 2015, Friday		
1	Inspection of Laboratory Checklist	Director, CDTL, Chennai
2	Noncompliance observed during GLP Audit	
3	Syndicate Activity	By Participants
4		
07 November 2015, Saturday		
1	Biological Products – Vaccine Basics	Industry Expert
2	Basics of Recombinant Technology - Science and Challenges	
3	Stem Cells, Regenrative Medicines	Industry Expert
4	Monoclonal Antibodies	
08 November 2015, Sunday (Holiday)		

Session	Topic	Speaker
09 November 2015, Monday		
1	Evaluation of Preclinical and Clinical Data of Biological Products	Dr. A Ramakishan, DDC (I)
	Marketing Authorization of Biological Products	
3	Evaluation of CMC Module III of CTD	
4	AEFI with respect to vaccines	
10 November 2015, Tuesday		
1	Manufacturing Process and Process Flow of Vaccine and formulation	Industry Expert
2	Quality Control of Vaccines	
3	Procedure for Post approval changes of Biologicals	Mrs. Rubina Bose, DDC(I)
4	NRA Assessment of Vaccines	
11 November 2015, Wednesday (Deepavali Holiday)		
12 November 2015, Thursday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & usage) & Noting, Drafting	
4		
13 November 2015, Friday		
1	Regulatory requirement for the functioning and operation of a blood bank and preparation of blood components	Mr. Arvind Kukrety, DDC (I)
2	Inspection of Blood banks	
3	Syndicate Activity	By Participants
4		

Session	Topic	Speaker
14 November 2015, Saturday		
1	Import & Registration of Drugs and Import of Drugs under Dual Use/Test Licence/ Personal Use	Mrs. Shanthy Gunashekharan, DDC(I)
2	Import & Registration of Cosmetics	Mr. Sudipto Dey, DDC
3	Requirement for approval of LVP	Dr. A Ramakishan, DDC (I)
4	Veterinary Drugs & Misuse of Drugs in Animals	
15 November 2015, Sunday (Holiday)		
16 November 2015, Monday		
1	Basic Principles of Stability of Drugs	Dr. Saranjit Singh, NIPER
2	Stability studies of Pharmaceutical Products	
3	Stability studies of Biological Products	
4	Stability studies of Biological Products	
17 November 2015, Tuesday		
1	Current Regulation on Medical Devices & IVD, Drugs Vs Devices	Dr. S.E. Reddy, JDC(I)
2	Proposed Regulation on Medical Devices	
3	Biocompatibility Study	Representative from SCTIMST, Trivandrum, India
4	Classification of Medical Devices and Diagnostics	Industry Expert
18 November 2015, Wednesday		
1	Clinical Investigation of Medical Devices	Mrs. Sumati Randeo, Abott India Pvt.Ltd.
2	Overview of ISO-13485	Industry Representative
3	Standards of Medical Devices	Dr. Jitender Sharma, NHSRC, New Delhi
4	Import & Registration of Medical Devices	Mr. Aseem Sahu DDC (I)

Session	Topic	Speaker
19 November 2015, Thursday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & Usage), Noting and Drafting	
4		
20 November 2015, Friday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & usage) & Noting, Drafting	
4		
21 November 2015, Saturday		
1	Computer Classes	Subject Expert
2		
3	Language (Grammar & usage) & Noting, Drafting	
4		
22 November 2015, Sunday (Holiday)		
23 November 2015, Monday		
1	Inspection of Drugs Sales Premises, Samples Collection, Handling and Reporting	Dr. Jagashetty, Ex. Drugs Controller, Karnatka
2	Investigation of Spurious and Not of Standard Quality (NSQ) drugs, Procedure for launching prosecution	
3	Good Distribution Practices	Mrs. Rubina Bose, DDC(I)
4		

Session	Topic	Speaker
24 November 2015, Tuesday		
1	PharmacovigilanceProgramme in India	Dr. Kalaiselvan (IPC)
2	HaemovigilanceProgramme in India	Dr. Akansha Bist
3	Materiovigilance Programme in India	Dr. Kalaiselvan (IPC)
4	Antimicrobial Resistance	Subject Expert
25 November 2015, Wednesday (Holiday)		
26 November 2015, Thursday		
1	Behavioural Aspects in Effective Leadership	Dr. Dev Arora
2	Personality Development & Communication Skills	Ms. Soni Sharma
3	Computer Classes	Subject Expert
4		
27 November 2015, Friday		
1	Language (Grammar & usage) & Noting, Drafting	Subject Expert
2		
3	Syndicate Activity	By Participants
4	Syndicate Activity	
28 November 2015, Saturday		
1	Neutral drug Code/Special code, Written confirmation and export NOC	Mr. R. Chandra Shekhar, DDC(I), CDSCO
2	BA/BE Approval – Site and Protocol	
3	Function of Port office of CDSCO	Mr. S.P. Shani, DDC (I)
4	Role of PHARMEXCIL	Dr. P V Appaji, Director General

Session	Topic	Speaker
29 November 2015, Sunday (Holiday)		
30 November 2015, Monday		
1	Post Assessment	Mr. Sunil Kulshrestha ADC (I)
2	Roadmap for Indian Regulators	Dr. Surinder Singh, Director NIB, Noida
3	Valedictory Session	Training Coordinators
4	Final Evaluation of the Training and Concluding Presentation	

Note:

1. Date of written examination will be intimated separately.
2. Computer and IT skills will also be evaluated separately.

Lists of Participants

S. No.	Name	S. No.	Name
1.	Ms. Ankur Sharma	17.	Mr. DevendraPratap Singh
2.	Mr. J. Ravi Kumar	18.	Mr. Kundan Kumar Keshari
3.	Ms. Kumari Sugandha	19.	Ms. Kamla
4.	Ms. Haritha Sameeraja Nagampalli	20.	Ms. RajeshwariKoruprolu
5.	Ms. Ranjita Nayak	21.	Ms. Lipika Roy
6.	Mr. Anjan Goud Pendem	22.	Ms. Vibha Sharma
7.	Ms. Sonali Suman	23.	Ms. Kavita
8.	Mr. Ramu Miryala	24.	Mr. K. R. Koteshwara Rao
9.	Mr. Ashish Bhavsar	25.	Ms. Jyotsna Mala Das
10.	Ms. Bindu Kumari	26.	Ms. Yamini Gaur
11.	Mr.Mangal Jyoti Das	27.	Ms. Sobha Deepthi Kompella
12.	Ms. Vandana Malviya	28.	Mr. Abhishek Kumar
13.	Ms. Ushmaleena Basumatary	29.	Mr. VeeraiahBanothu
14.	Ms. Monika Patanwar	30.	Mr. More ParthKishanlal
15.	Ms. R. Aarthy	31.	Ms. Afrin Siddiqui
16.	Ms. Saranya Bhoghadhi		

Happiness is when what you think, what you say, and what you do, are in harmony

ॐ सर्वे भवन्तु सुखिनः सर्वे सन्तु निरामयाः ।
सर्वे भद्रणिपश्यन्तु मा कश्चिद्दुःख भाग भवेत् ॥

Om - May all become Happy

May all be Healthy and free from illness

May all see what is auspicious

May no one suffer

CDSCO Head Quarter - New Delhi

Central Drugs Standard Control Organization
Director General of Health Services
Ministry of Health & Family Welfare
FDA, Bhavan, Kotla Road, New Delhi - 110002