

INAUGURAL NOTE

Second Induction Training Course

The first Induction Training Course was successfully organized by Central Drugs Standard Control Organization (CDSCO) in coordination with Indian Pharmacopoeia Commission (IPC) during 15th July'2013 to 2nd August'2013 at Indian Pharmacopoeia Commission, Raj Nagar, Ghaziabad.

Now, the second Induction Training Course (as Annexed program schedule) was inaugurated on 2nd Sept'2013 by lighting of lamp by Sh. S.K. Srivastava, Additional Secretary & Financial Advisor, Ministry of Health & Family Welfare, Govt. of India and welcome address by Dr. G.N. Singh, Drugs Controller General (India). The Drugs Controller General (India) has expressed his views that the newly recruited Drugs Inspectors should be trained on Quality Control of Drugs and its associated regulations with an objective of better regulations and monitoring of quality & safety of drugs.



Lighting of lamp by Sh. S.K. Srivastava, Additional Secretary & Financial Advisor, Ministry of Health & Family Welfare, Govt. of India



Lighting of lamp by Dr. G.N. Singh, Drugs Controller General (India)



The Additional Secretary & Financial Advisor expressed his views about the induction training course for newly recruited drugs inspectors that the drugs regulatory activities are essential part for public which contributes to good health. He has mentioned that the drugs inspectors represent the image of entire department and playing a powerful role under the provision of Drugs & Cosmetics Act and Rules. He also mentioned that the drugs inspectors

should be proud that the Government has given the platform for performance which should be executed with honesty and should honour the assigned responsibilities.

People will be benefited by supplies of good quality medicines and Sh. S.K. Srivastava has emphasized to focus and ascertain the quality of pharmaceutical products across the country. He also expressed that even during crises situation, the drug industry is still stable as we are importing 10 billion dollars of pharma products against greater export of 13 to 14 billion dollars.

He advised the drugs inspectors to ask questions without any fear and make the sessions live, interactive and be attentive in the class. He also advised that each drugs inspector should be allowed to speak during the session which will help in personality development by the way of presentation. Sh. S.K. Srivastava guided the participants by citing examples and mentioned **KNOWLEDGE IS POWER** and is helpful tool for strengthening the department with ultimate aim of helping the community by quality products availability to the common mass.

At the end of the session Sh. S.K. Srivastava shower his blessing to young Drugs Inspectors for all success, good & enjoyable carrier.

The inaugural session was concluded with positive remarks of Dr. K. Bangarurajan, Dy. Drugs Controller (India).



New training hall facility created at Indian Pharmacopeia Commission was inaugurated by Sh. S.K. Srivastava, Additional Secretary and Financial Advisor.



Sh. S.K. Srivastava & Dr. G.N. Singh at new training hall



View of new Training Hall

**Induction Training Course for Drugs Inspectors of CDSCO (Second Batch)
at Indian Pharmacopoeia Commission, Ghaziabad
2nd to 20th September'2013**

Date	Time	Registration	
Day 1 02.09.2013 (Monday)	09:00am-09:30am		
	09:30am-10:15am	Pre-Assessment	Smt. Rubina Bose, ADC(I), CDSCO, HQ Dr. Ajay Sachan, ADC(I), CDSCO (NZ)
	10:15am-10:45am	Tea Break	
	10:45am-12:00pm	Inauguration <ul style="list-style-type: none"> • Lighting of Lamp • Welcome address • Address by Chief Guest • Vote of thanks • Group Photograph 	Dr. G.N. Singh, Drugs Controller General (India) Sh. S.K. Srivastava, Additional Secretary & Financial Advisor Dr. K. Bangarurajan, DDC(I)
Moderator Dr. S.E. Reddy	TECHNICAL SESSION		
		Topic	Name of the speaker(s)
	12:00pm-1:30pm	Over view of Indian Regulatory System	Dr. S.E. Reddy, DDC(I), CDSCO, HQ
	1:30pm-2:00pm	Lunch Break	
	2:00pm-3:00pm	Role of Drugs Inspector under Drugs and Cosmetics Act and Rules	Dr. A. Ramkishan, ADC(I), CDSCO, Ahmedabad
	3:00pm-4:00pm	Inspection of Drugs Sales Premises, Samples Collection, Handling and Reporting	Dr. K. Bangarurajan, DDC(I), CDSCO, NZ
	4:00pm-4:30pm	Tea Break	
	4:30pm-5:30pm	Investigation of Spurious and Not of Standard Quality (NSQ) drugs	Dr. K. Bangarurajan, DDC(I), CDSCO, NZ
	5:30pm-6:00pm	Open House Discussion	
Day 2 03.09.2013	9:30am-11:00am	WHO Certification Scheme	Sh. Naresh Sharma, ADC(I), CDSCO, CHD.


(Tuesday) Moderator Sh. Naresh Sharma	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Administrative matter – Classification Conduct and Appeal, Conduct Rules	Sh. Sachinder Sharma, Administrative Trainer
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Principles of Vaccines manufacturing and Good Manufacturing Practices	Sh. MM Javadekar, Addl. Director-QA, Serum Institute of India, Pune
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Good Manufacturing Practices	Sh. ArvindKukrety, ADC(I), CDSCO, HQ
	5:30pm-6:00pm	Open House Discussion	
Day 3 04.09.2013 (Wednesday) Moderator Dr. Ajay Sachan	9:30am-11:00am	Microbiological Testing Procedure & BET	Sh. Shikher Sharma, Asst. Manager (Microbiologist) Unichem Labs.
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Right to Information Act 2005	Dr. A.N. Chakraborty, Administrative Trainer
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Stability Testing Part I	Dr. Saranjit Singh, Dean, NIPER
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Stability Testing Part II	Dr. Saranjit Singh, Dean, NIPER
	5:30pm-6:00pm	Open House Discussion	
Day 4 05.09.2013 (Thursday) Moderator Dr. Raman	9:30am-11:00am	Analytical Method Validation (AMV) with special emphasis on HPLC and GC with Head Space	Sh. Sanjay Kumar, Sr. Manager (Quality), Unichem Labs.
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Cleaning Validation	Dr. Tapan Kumar Panda, Manager (Technology Transfer), Dr. Reddy's Laboratories Ltd.
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Good Laboratory Practices	Dr. R.A. Singh, Director, RDTL, Chandigarh
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Case Study by Regulatory Authority (Dr. Ajay Sachan, ADC(I), CDSCO (North Zone))	
	5:30pm-6:00pm	Open House Discussion	
Day 5	9:30am-	Building Plan and Layout	Sh. Ravi Saxena,

06.09.2013 (Friday) Moderator Dr. Ajay Sachan	11:00am	Design	Managing Director, cGMPPharma'n'Plans Pvt. Ltd.
	11:00am- 11:30am	Tea Break	
	11:30am- 1:00pm	Clean Room Concept & HVAC System	Sh. Ravi Saxena, Managing Director, cGMPPharma'n'Plans Pvt. Ltd.
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Process & Equipment Validation	Dr. M. Damodharen, Ranbaxy Laboratories Ltd.
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Documentation (SMF, SOP, MFR, BPR etc)	Sh. Vijay Sharma, Sr. Manager, QA Ranbaxy Laboratories Ltd.
	5:30pm-6:00pm	Open House Discussion	
Day 6 07.09.2013 (Saturday) Moderator Sh. Ankit Sharma & Sh. Naresh Sharma	Factory Visit and Stay at NIPER		
Day 7 08.09.2013 (Sunday)	Off Day		
Day 8 09.09.2013 (Monday) Moderator Sh. Ankit Sharma & Sh. Naresh Sharma	Factory Visit and Back to Ghaziabad		
Day 9 10.09.2013 (Tuesday) Moderator Sh. R. Chandra Shekhar	9:30am- 11:00am	Inspections of Blood Bank – Schedule F Part XII B	Dr. R. Chandra Shekhar, DDC(I), CDSCO, HQ
	11:00am- 11:30am	Tea Break	
	11:30am- 1:00pm	Donor Room Procedure in Blood Bank	Dr. R.N. Makroo, Director, Transfusion Medicine, Apollo Hospital, Delhi
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Testing Procedure in Blood Bank	Dr. Vimarsh Raina, Director, Transfusion Medicine & Pathology, The Medicity Hospital, Gurgaon
	3:30pm-4:00pm	Tea Break	

	4:00pm-5:30pm	Blood Components Preparation, Storage & Testing	Dr. MrinaliniChatruvedi, Medical Director, Cryo Bank International, Gurgaon
	5:30pm-6:00pm	Open House Discussion	
<p>Day 10 11.09.2013 (Wednesday)</p> <p>Moderator Dr. K. Bangaru Rajan</p>	9:30am-11:00am	Behavioral Aspects	Dr. DevArora, Centre for Management Development, Modi Nagar
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Communication Skills	Ms. Ina Singh, Language /PD Trainer & Placement Coordinator Vishveshwarya Group of Institutions, Ghaziabad
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Intelligence gathering	Sh. V.P. Arya, CBI
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Launching of prosecution, CRPC and Evidence Act	Sh. Rishikant, Legal Advisor & Sh. R. Chandra Shekhar, DDC(I), HQ
	5:30pm-6:00pm	Open House Discussion	
<p>Day 11 12.09.2013 (Thursday)</p> <p>Moderator Smt. Rubina Bose</p>	9:30am-11:00am	Schedule M WHO GMP	Smt. Rubina Bose, ADC(I), CDSCO, HQ
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Quality by Design (QbD)	Dr. Bhupinder Singh Bhoop, Prof. & Dean, Punjab University
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Vaccine Regulation – Overview & NRA Assessment	Dr. V.G. Somani, JDC(I), CDSCO, WZ
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	How to carry out inspection of vaccine units	Dr. V.G. Somani, JDC(I), CDSCO, WZ
	5:30pm-6:00pm	Open House Discussion	
<p>Day 12 13.09.2013 (Friday)</p> <p>Moderator Sh. A.K. Pradhan</p>	9:30am-11:00am	Experience /Case Studies on Good Clinical Practices	Dr. Ketan Parikh, Mumbai
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Good Clinical Practices	Dr.UrmilaThatte, Mumbai
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:00pm	Bio-Availability / Bio-Equivalence	Sh. P.B.N. Prasad, DDC(I), CDSCO, SZ

	3:00pm-3:30pm	Pharmacovigilance	Dr. V. Kalaiselvan, SSO, IPC
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Registration of Ethics Committee and SAE	Dr. Annam Vishala, DDC(I), CDSCO, HQ
	5:30pm-6:00pm	Open House Discussion	
Day 13 14.09.2013 (Saturday) Moderator Sh. DharmendraPandey & Sh. AbhishekChawla	Visit to Clinical Research Organisation and Blood Bank		
Day 14 15.09.2013 (Sunday)	Off Day		
Day 15 16.09.2013 (Monday) Moderator Dr. Robin Kumar	9:30am-11:00am	Water for Pharmaceutical Use	Sh. DipakSelot, Pharma Head, M/s Cipla, Baddi
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Risk Based Approaches – GMP	Dr. Ajay Prakash, Vice President (Technical), Win Medicare
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Quality Control of Vaccines	Sh. Anil Sood, Vice President (QC & QA), Panacea Biotec, Lalru, Punjab
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Schedule Y	Sh. A.K. Pradhan, DDC(I), CDSCO, HQ
	5:30pm-6:00pm	Open House Discussion	
Day 16 17.09.2013 (Tuesday) Moderator Dr. S.E. Reddy	9:30am-11:00am	Current Regulation on Medical Devices & IVD	Dr. S. Eswara Reddy, DDC(I), CDSCO, HQ
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	ISO-13485,	Sh. P. Manickam, M/s UL Pvt. Ltd.
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Requirement of Import Registration	Sh. S.P. Shani, DDC(I), CDSCO, HQ
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Functions of CDSCO Port Offices	Smt. SanthyGunashakaran, DDC(I), Chennai Port

	5:30pm-6:00pm	Open House Discussion	
Day 17 18.09.2013 (Wednesday)			
	9:30am-11:00am	Over view of Pharmacy Profession	Dr. P.C. Dandiya, Ph.D(Toronto), F.A.M.S., Emeritus Prof. & Advisor, Dr. Robert Helieg Library, SMS Medical College, Jaipur
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Introduction on Indian Pharmacopoeia & Indian Pharmacopoeia Commission, Ghaziabad	Dr. Raman Mohan Singh, Principal Scientific Officer & Dr. Jai Prakash, Principal, Principal Scientific Officer
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Hands on training at IPC lab- HPLC, GC, Kf, IR Spectrophotometer etc.	at IPC Lab, Ghaziabad
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Hands on training at IPC lab- HPLC, GC, Kf, IR Spectrophotometer etc.	at IPC Lab, Ghaziabad
	5:30pm-6:00pm	Open House Discussion	
Day 18 19.09.2013 (Thursday)			
Moderator Sh. Naresh Sharma	9:30am-10:15am	GMP Inspection (Checklist & Preparation of Report)	Sh. Naresh Sharma , ADC(I), CDSCO
	10:15am-11:00am	Good Laboratory Practices Inspection (Checklist & Preparation of Report)	Dr. Robin Kumar, SSO and Smt. MeenakshiDahiya, SSO, IPC, GZB
	11:00am-11:30am	Tea Break	
	11:30am-1:00pm	Good Clinical Practices Inspection (Checklist & Preparation of Report)	Sh. A.K. Pradhan, DDC(I), CDSCO, HQ
	1:00pm-2:00pm	Lunch Break	
	2:00pm-3:30pm	Case Study / Talk by State Drug Controllers Panel (Sh. NavneetMarwah, State Drug Controller, HP & Sh. SaleemValjee, Director, FDA, Goa	
	3:30pm-4:00pm	Tea Break	
	4:00pm-5:30pm	Blood Banks / Testing Laboratory Inspection (Checklist & Preparation of Report)	Sh. P.K. Jaggi, Former Head of Office, Delhi Drug Control Deptt.
	5:30pm-6:00pm	Open House Discussion	
Day 19 20.09.2013 (Friday)			
	9:30am-10:30am	Post-Assessment	Smt. Rubins Bose, ADC(I), CDSCO, HQ, Sh. Naresh Sharma, ADC(I), CDSCO & Dr. Ajay Sachan, ADC(I)

	10:30am-11:30am	Road Map for Indian Regulators	Dr. Surinder Singh, Director, NIB
	11:30am-12:00pm	<i>Tea Break</i>	
	12:00pm-1:30pm	Case Study / Talk by State Drug Controllers Panel (Dr. H.J. Khosia, Commissioner, FDA, Gujarat)	
	1:30pm-2:30pm	<i>Lunch Break</i>	
	2:30pm-4:00pm	Valedictory Session will be Chaired by Shri R.K. Jain, Additional Secretary & Director General (CGHS) Ministry of Health and Family Welfare	