



**Ministry of Health and Family welfare  
Government of India**

**WORKSHOP ON “IN-HOUSE LEAD AUDITOR COURSE  
ON QUALITY MANAGEMENT SYSTEM AS PER IS/ISO  
9001:2008”  
FOR  
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION OFFICERS  
FROM 2<sup>ND</sup> DECEMBER TO 6<sup>TH</sup> DECEMBER, 2013**

The workshop on “**IN-HOUSE LEAD AUDITOR COURSE ON QUALITY MANAGEMENT SYSTEM AS PER IS/ISO 9001:2008**” was held in collaboration with Bureau of Indian Standards to impart the knowledge of Quality Management System (QMS) to senior Officers of Central Drugs Standard Control Organization.

The participants for the workshop for Lead Auditor Course on the Quality Management system as per IS/ISO 9001:2008 are the Division head/ Zonal head who are Deputy Drugs Controller (I)/ Assistant Drugs Controller (I) and Seniors Drugs Inspectors working in various divisions, zones, subzones and ports who are responsible for the implementation of QMS in their own divisions, zones, subzones and ports.

The objective of this workshop is better and clear understanding of Quality Management System as per requirements of IS/ISO 9001:2008, to prepare a work plan for the implementation of QMS as per ISO 9001:2008 and to get certified as an ISO 9001:2008 organization.

# Agenda for the workshop

Day1	Day 2	Day 3	Day 4	Day 5
Opening, welcome and introduction	Program of the day	Program of the day	Internal Practice sessions of Mock inspection	Program of the day
Photo session Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break
History and Development of Quality	Quality Management System As Per IS/ISO 9001:2008	Introduction Planning of Audit	Audit Reporting and Auditing continual Improvement	Discussion, Clarification
Lunch Break	Lunch Break	Lunch Break	Lunch Break	Lunch Break
Establishment of Quality System	Exercise and Case Studies	Practical Audit	Registration and certificate of Audit	Post Workshop Assessment Test
Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break	Tea/Coffee Break
Exercise and Case Studies	Exercise and Case Studies	Exercise and Case Studies	Exercise and Case Studies	Closing of the Workshop

## List of Participants in the training on “In-house Lead Auditor Course On Quality Management System As Per IS/ISO 9001:2008”

Sr. No.	Name of the Participant	Designation	Office Address
<b>Faculties from BIS</b>			
1.	Mr. T. Venkataraman		BIS
2.	Mr. S. M. Tewari		BIS
<b>Participants from CDSCO</b>			
1.	Dr. K. Bangarurajan	Deputy Drugs Controller (India)	CDSCO, NZ
2.	Mr. S. Mukhopadhyay	Deputy Drugs Controller (India)	CDSCO, EZ
3.	Ms. Annam Visala	Deputy Drugs Controller (India)	CDSCO, HQ
4.	Mr. Aseem Sahu	Deputy Drugs Controller (India)	CDSCO, HQ
5.	Dr. A. Ramkishan	Deputy Drugs Controller (India)	CDSCO, HQ
6.	Ms. Rubina Bose	Assistant Drugs Controller (India)	CDSCO, HQ
7.	Dr. Ravi Kant Sharma	Assistant Drugs Controller (India)	CDSCO, HQ
8.	Mr. Sanjeev Kumar	Assistant Drugs Controller (India)	CDSCO, HQ
9.	Mr. Gulsan Taneja	Assistant Drugs Controller (India)	CDSCO, HQ

Sr. No.	Name of the Participant	Designation	Office Address
10.	Ms. Swati Srivastava	Assistant Drugs Controller (India)	CDSCO, HQ
11.	Mr. B.K. Samantaray	Assistant Drugs Controller (India)	CDSCO, Subzone Jammu
12.	Mr. Somnath Basu	Assistant Drugs Controller (India)	CDSCO, HQ
13.	Dr. Inderjeet Singh Hura	Assistant Drugs Controller (India)	CDSCO, HQ
14.	Mr. Jayant Gangakhedkar	Assistant Drugs Controller (India)	CDSCO, HQ
15.	Mr. Sunil M. Joshi	Assistant Drugs Controller (India)	CDSCO, HQ
16.	Ms. Shraddha Srivastava	Drugs Inspector	CDSCO, HQ
17.	Mr. Manish Singhal	Drugs Inspector	CDSCO, HQ
18.	Mr. Vinod Kumar	Drugs Inspector	CDSCO, HQ
19.	Ms. Nisha Sankhwar	Drugs Inspector	CDSCO, HQ
20.	Mr. Yogesh Shelar	Drugs Inspector	CDSCO, HQ



सत्यमेव जयते



**“Lead Auditor Course” on Quality Management  
System as Per IS/ISO 9001:2008 for  
Central Drugs Standard Control Organization  
Ministry Of Health & Family Welfare  
Government Of India**

**2<sup>nd</sup> December to 6<sup>th</sup> December , 2013**

**Venue: Mahamana Malaviya Mission, Malaviya Smriti Bhawan, D.D.U. Marg  
New Delhi - 110002**



**Official Inauguration and opening and address of the workshop was made by Dr. G.N. Singh , Drugs Controller General (India)**

Dr. G.N. Singh, Drugs Controller General (India) addressed the participants during the workshop on the objective and Expected outcome of the workshop. Dr. G.N. Singh, Drugs Controller General (India) mentioned the importance of Quality Management System (QMS), the role of each participants in the implementation of QMS and expectation of uniformity in the execution of regulatory system by entire CDSCO at all levels subsequent to the QMS training.

It was also emphasized by Drugs Controller General (India) that the ISO certification is the important performance indicator for CDSCO and QMS training for all Drugs Inspectors is the first step towards achieving the goal.

It was also mentioned that the performance of the all the participants with respect to the uniform implementation of QMS will be reviewed by the top management after 3 months to determine the effectiveness of the training.

# Photo Session with all the Faculties & Participants



06/12/2013



Introduction and Programme of the day, work shop Methodology and planned activities were explained by Mr. S. M. Tewari to the participants.



During workshop, the importance of Quality Management system was explained by Mr. T. Venkataraman to the participants.

All the participants took keen interest in the various presentations and Case Studies









Mr. Shashi Sivastava  
APCO, COSCO (INDIA) NEW DELHI

Mr. Karim Sharma  
APCO, COSCO IND.

Mr. Yashvir Shekar  
APCO, COSCO IND.

Smt. Nisha Sankhwar  
APCO, COSCO IND.

Smt. Rubina Bose  
APCO, COSCO (IND) NEW DELHI

06/12/2013



Group exercises were given during and after the presentation by the faculties to make learning interactive and interesting and easy to understand the concept of the presentation.



Discussion of the participants during the workshop on Practice sessions of Mock audit.

Post assessment for the participants for evaluation of the training on the fifth day.



The five day programme was concluded with vote of thanks from  
CDSCO

