



**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 6th JANUARY TO 10TH JANUARY, 2014

The workshop on “**IN-HOUSE LEAD AUDITOR COURSE ON QUALITY MANAGEMENT SYSTEM AS PER IS/ISO 9001:2008**” was organized by Quality Assurance Division of CDSCO 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 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
Faculties from BIS			
1.	Mr. T. Venkataraman	Faculty	BIS
2.	Mr. Praveen Pasricha	Faculty	BIS
Participants from CDSCO			
1.	Dr. V. G. Somani	Joint Drugs Controller (India)	CDSCO, HQ
2.	Dr. S. Eswara Reddy	Deputy Drugs Controller (India)	CDSCO, HQ
3.	Mr. A. C. S. Rao	Deputy Drugs Controller (India)	CDSCO, Hyderabad
4.	Mr. R. Chandrashekar	Deputy Drugs Controller (India)	CDSCO, HQ
5.	Mr. P.B.N. Prasad	Deputy Drugs Controller (India)	CDSCO, SZ
6.	Ms. Shanthi Gunashekaran	Deputy Drugs Controller (India)	CDSCO, CDTL, Chennai
7.	Dr. G. Nageswara Rao	Assistant Drugs Controller (India)	CDSCO, Ahmedabad
8.	Mr. A.Senkathir	Assistant Drugs Controller (India)	CDSCO, Air Port Office, Chennai
9.	Mr. B. Kumar	Assistant Drugs Controller (India)	CDSCO, Sea Port Office, Chennai

Sr. No.	Name of the Participant	Office Address	Designation
10.	Ms. Kavita Sharma	Assistant Drugs Controller (India)	CDSCO, HQ
11.	Mr. Sunil Kulshrestha	Assistant Drugs Controller (India)	CDSCO, HQ
12.	Mr. Naresh Sharma	Assistant Drugs Controller (India)	CDSCO, Chandigarh
13.	Dr. Ajay Sachan	Assistant Drugs Controller (India)	CDSCO, NZ
14.	Mr. Arup Kumar Chatterjee	Assistant Drugs Controller (India)	CDSCO, EZ
15.	Mr. Gaurav Kumar	Assistant Drugs Controller (India)	CDSCO, HQ
16.	Ms. Jayant Kumar	Assistant Drugs Controller (India)	CDSCO, WZ
17.	Mr. Suresh Kumar Kalwaniya	Drugs Inspector	CDSCO, HQ
18.	Ms. Sidharth Sahai Malhotra	Drugs Inspector	CDSCO, HQ
19.	Dr. V. Kasi Sankar	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**

6th January to 10th January, 2014

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



Ms. Anita Veigas
Technical Officer, IGI, Port

Dr. S.E Reddy
DGCI, CS&CO (HQ)

Senkathir
CS&CO (HQ), New Delhi

Sh. Sunil Kulshrestha
ADCI, CS&CO (HQ), New Delhi

Sh. B.Kumar

Official Inauguration and opening and address of the workshop was made by Dr. V. G. Somani , Joint Drugs Controller (India)



Photo Session with all the Faculties & Participants



Introduction and Programme of the day, workshop methodology and planned activities were explained by Mr. T. Venkataraman to the participants.

THE DEFINITION OF QUALITY

“The degree to which a set of inherent characteristics fulfils requirements”

ISO 9000:2005

- Fitness for Use J. M. Juran
- Conformance to Requirements Philip Crosby
- Fitness for Purpose William Edwards Deming
- providing a product that does not come back from customer

LEAD AUDITOR ISO 9001:2008

REV : 03



Mr. T. Venkataraman
BIS, Faculty

Sh. G. Nageshwar
BIS, COO, M...

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

to 10th January, 2014

Commission, Malaviya Smriti Bhawan, D.D.U. Marg
New Delhi - 110002



All the participants took keen interest in the various presentation and Case Studies.

Central Drug
Ministry Of Health & Family Welfare
Government Of India

6th January to 10th January

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New Delhi - 110002



Dr. V.G. Somani
JDC(I), COSCO, West Zone

Xalta



Sh. Mohtra
New Delhi

Sh. Suresh Kumar Kalwaniya
Drug Inspector, CDSCO (HQ) New Delhi

Sh. Jay...
ADC(I), CD...





Sh
Sharma
Chandigarh



Sh P.B.N Prasad
DDC(I), CDSCO, South Zone



Sh

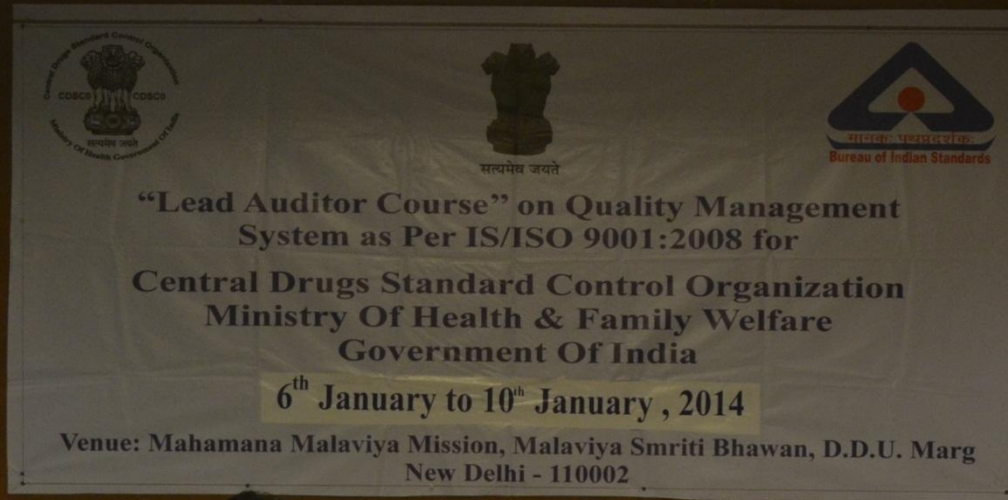


C.S. Rao
CO, Hyderabad



Dr. S.E Reddy
DAC(I), CDSCO (HQ)





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 amongst the participants during the workshop on Practical sessions of Mock audit.



Post assessment of the participants on the fifth day.



Evaluation of the training and its usefulness was done by Dr. V. G. Somani, Joint Drugs Controller (India) to Dr. G.N. Singh, Drugs Controller General (India) on the final day of training



The action plan for ISO certificate and the steps for implementation were explained by Mr. T. Venkataraman (faculty from BIS).

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 senior level and mid level officers who are the heads of the zone/sub-zones/ports offices 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.



Dr. G.N. Singh, Drugs Controller General (India) addressed the participants during the closing ceremony of workshop.



The five day programme was concluded with promising vote of thanks from Drugs Controller General (India)