

Two Day Workshop on Internal Auditor – ISO 13485-2003 April 8th (Thursday), 9th (Friday) 2010

Course Description

ISO 13485-2003, Internal Auditor Workshop teaches the principles and practices of effective quality management systems for Medical Device Requirements and process audits in accordance with the ISO 13485 Standard and ISO 19011:2002, "Guidelines for Quality and/or Environmental Management Systems Auditing. "Students" will go through the entire audit process, from managing an audit program to reporting on audit results. Participants will gain necessary auditing skills through a balance of formal classroom tutorials, group workshops and open forum discussions.

Coverage

- Understand Quality Management Definitions, Concepts, and Guidelines
- Understand the Requirements of the ISO 13485-2003 Standard
- Apply ISO 19011:2002 Definitions, Concepts, and Guidelines
- Manage an Audit Program
- Initiate the Audit and Conducting Opening Meetings
- Understand Auditor Responsibilities
- Conduct On-site Audit Activities
- Communicate Effectively During the Audit
- Generate Audit Findings
- Prepare Audit Conclusions
- Conduct Closing Meetings
- Report Audit Results
- Conduct an Audit Follow-up

Who Should Attend

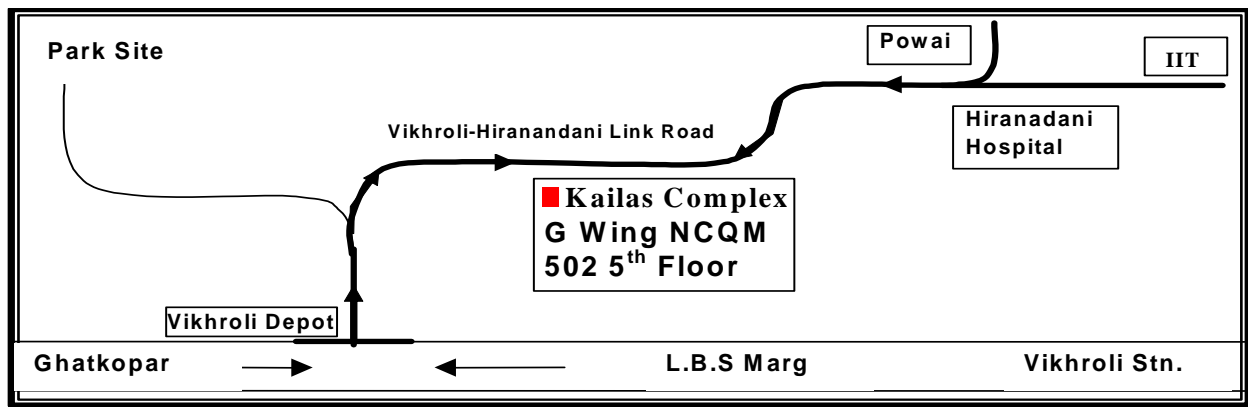
- Individuals interested in conducting internal and supplier audits
- Management Representatives
- Quality Directors, Managers, Engineers

TIMING : Registration: 09.00 hrs. (First Day)
Sessions : 09.15 hrs to 17.00 hrs

FEES : Rs. 5,000/- per participant
Rs. 4,500/- per participant
(For NCQM Members and group registration
of 3 or more participants)
Plus Service Tax 10.3%
Registration on first come first basis

(Fee include course material, cost of certificate, lunch, tea/coffee)

VENUE : NCQM Learning Centre, 5th Floor, G-502,
Kailas Industrial Complex, Parksite,
Vikhroli- Hiranandani Link Road,
Vikhroli (W)
Mumbai - 400079



REGISTRATION

Please send nominations accompanied by workshop fee in favour of **National Centre for Quality Management** by demand draft / Cheque payable at Mumbai, To,

Programme Co-ordinator

National Centre for Quality Management

G-501-503, 5th Floor, Kailas Industrial Complex, Parksite

Vikhroli – Hiranandani Link Road, Vikhroli (W), Mumbai – 400 079.

Tel.: 2517 0483 / 2517 0469 Fax: 2517 0144

Email: ncqm@vsnl.com ncqmmumbai@yahoo.co.in website: www.ncqm.com

Faculty Profile

Mr. Praful Mehta

Mr. Praful Mehta is M.S. in Chemistry, University of Bridgeport, CT.

Mr. Mehta directs and manages QMS and Quality Assurance for clients like, Kodak, B & L, J & J, BSC. He has performed more than 500 QMS audits to the applicable medical device standards such as ISO 13485, 21 CFR 820/FDA/GMP regulation and ISO 9001. He has assisted several companies in achieving their initial ISO certifications.

Mr. Mehta was responsible for developing, maintaining and auditing QMS to ISO 13485, FDA/cGMP, ISO 9001, ISO 17025, Canadian Medical Device Regulations and the European Medical Device Directive (MDD) for Johnson & Johnson, Kodak, Bausch & Lomb and other companies. He has 25 years of industry experience in the field of quality assurance in the medical device, pharmaceutical, photographic, chemical and electronic industries. Mr. Mehta has set-up supplier quality management (SQM) programs and has conducted numerous supplier audits for clients. He has lectured on quality management systems at the national and international levels in quality conferences, and he has authored the book, "ISO 9000 Questionnaire and Registration Guidelines" published through American Society for Quality (ASQ).

He is qualified to teach ISO 13485:2003 and ISO 9001:2008; Understanding, Implementing ISO System, IQA, Good Documentation Practice and the 5 day Lead Auditor Course.

He has trade Certifications in

- RAB Certified Lead Auditor, QMS-LA Q01758
- American Society for Quality Certified Quality Auditor
- American Society for Quality Certified Quality Engineer
- Six Sigma Black Belt Certification