INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

QUALITY MANTRA

January 2020

Special Issue : ISO 13485

QCI/NABCB Launches Accreditation scheme ISO 13485 International Standard For Medical Devices

Inhouse Magazine For Internal Circulation

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Message from the Desk of CMD

Let's begin by expressing our gratitude. You made our 2019 great by being with us and thank you for same. There is a lot to look forward as we step into a new year – a new decade from quality control to total quality solutions, business development to business continuity while ensuring global issues of environment and occupational safety.

Our organization has entered in 21st year of operation in India and overseas. The last two decade has witnessed good growth and development and has successfully accomplished number of small, medium and large project in Oil & Gas sector industry. The certification activity has been progressing smoothly sustained by maintaining existing clientele with marginal increase. Our main focus has always been to maintain good quality. ICS Group Company added new products and services looking into market requirements. The new products and services covered are as follows:

New Products:

- ISO 13485: Certification of Medical Devices
- FSSAI: Food Safety and Standard Authority of India for the food business operators audit
- ZED: Zero Defect and Zero Effect Rating & Certification

New Business:

- Medical Tourism
- AusAdhA: Medical Devices & Materials
- Nonsense Multimedia Zone

The world economy has slowdown that also affected Indian economy. Politically stable central government has been taking many steps to give thrust to improve the economy. Although opposition parties have been non cooperative for government initiatives of economic policies, to bring the business environment suitable for new Entrepreneurs for SME sectors. We have joined hands with the Government to support the number of initiatives like:

- Make in India
- Skill India Mission
- Skill Development Program
- Education for girls
- ZED
- Rationalization of GST
- Reduction of Income tax rate
- Loan for SME
- New Start up India / Entrepreneurs
- Swachh Bharat
- PPP – Public Private Participation
- Social Security Program
- Pradhan Mantri Jan Dhan Yojana
- PM Kisan Schemes – Insurance for farmers
- Solar Power
- Defense – Open manufacturing policy

All above initiative should give boost to our country's economy in the year 2020.
Thanks to all our business associate, friends and ICS family for a successful year 2019.
Wishing you all the Best & Success with Wellness of Individual Citizen and Nation.

Dr. Sundar Kataria
Chairman & Managing Director
International Certification Services Pvt. Ltd.

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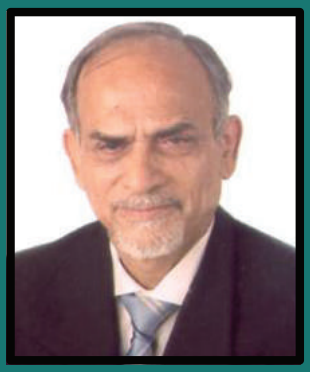
ISO 13485 : Management System for Medical Devices



Dr. Sundar Kataria
Chairman & Managing Director

Today, India is on the world map that provides with world class health services towards wellness of the human. The medical services are well regulated by the Government Acts and Regulations that covers wide spectrum of services covering clinics, hospitals, drugs and medicines, medical professional. However, it lackes proper control of the medical devices.

Government of India under ministry of Health and Family Welfare first time brought, the new rule for Medical Devices, 2017 (2) and made effective from 1st Jan, 2018.

The success of the medical treatment, its effectiveness and efficiency will be based mainly on many factors right from diagnosis, pathological investigation & testing, consultation, treatment, hospital (OPT, IPT, OT and operation, pre & post operation care) drugs / medicines, medical devices and services including competence of medical professionals (doctors, nurses, technicians and bio medical professionals) etc.

Medical treatment success rate mainly depends upon the quality of the medical devices those are used by the medical sector industry.

In the past, the quality of medical devices were in questions and we have to depend upon import from abroad.

Today,India manufacture & wide ranges of medical devices; however we need to adopt modern management system and advance technology to provide quality products to enhance its performance during life cycle.

International Certification Services provides broad portfolio of services to the medical industries for the certification.

Our services include issue certificates and independent Inspection & Laboratory testing as notified body duly accredited, and recognized by QCI/NABCB.

ISO 13485 is the answer to the proven international, harmonized management system to ensure the medical devices are safe, good consistant quality, good performance to ensure life cycle.

The Government of India has also made mandatory requirements for the manufacturing to get their organisation certified for ISO 13485, international standard - Management System for Medical Devices.

Another step ahead by our pragmatic Quality Council of India also launched the ISO 13485 accreditation scheme last year to facilitate and ensure effectiveness of the certification in India.

The ISO 13485, International Standard requirements specifies the organisation need to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Organization involving product life cycle fully and/or partially including design and development, production, storage and distribution, installation or servicing of a medical devices including associated articles (technical support). This standard is not limited for the manufacturers but also used by the suppliers or external parties. The standard's all clauses are fully applicable unless regulatory requirements permits exclusion. Organisation shall also prove supplementary information for the medical devices.

- Uses of medical devices.
- Modification of the medical devices.
- Return of the medical devices.
- Destruction of medical devices.

The medical devices covers instruments and apparatus, equipment, machine, appliance, implant, regents for in-vitro uses, software and material etc. Those are used for following medical purposes.

- Diagnosis, presentation, monitory treatment or alleviation of diseases.
- Investigation, replacement, modification or support of the anatomy or physiology process.
- Control of conception.
- diagnosis,manufacturing, treatment, alleviation of or conception for an injury.
- supporting and sustaining life.
- providing information by measures of in vitro examination of specimen drived from human body.

The other products also include :

- Disinfector substance.
- devices incorporating animal or human tissues.
- aid for person with disabilities.
- devices for in - vitro fertilization or assisted reproduction technologies.

The main objective of the standard is to facilitate the manufacturer to have a harmonized medical devices regulation and guidelines.

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Benefits of ISO 13485

- Improve your company's credibility and image
- Improve customer satisfaction
- Improve your processes
- Improve decision-making
- Create a culture of continual improvement
- Better employee engagement

Earlier this month, the Ministry of Health and Family Welfare issued a draft notification where it said it planned to define all medical devices (including software, equipment, accessories and contraceptives) in accordance with the Drugs and Cosmetics Act and the apex drug controller, effective December 1st, 2018.

REVAMP PLAN

- **Health ministry has issued draft notification to define** all medical devices under Drugs and Cosmetics Act.
- **This is part of a broader move to regulate all devices** for safety, performance, and quality.
- **CDSCO to regulate medical devices for now;** it has sought additional manpower of 700.
- **Matter has in-principle approval** from DTAB; needs Cabinet nod.
- **Autonomous body in line** with FSSAI in the works.
- **Size of the domestic medical devices industry** is roughly Rs.90,000 crore.
- **In FY19, India imported devices** worth Rs.38,800 crore.

How to go about ISO 13485

- Safety and quality are non-negotiables in the medical devices industry.
- Regulatory requirements are increasingly stringent throughout every step of a product's life cycle including service and delivery.
- Increasingly, organizations in the industry are expected to demonstrate their quality management processes and ensure best practice in everything they do.

How to go about certification

We at International Certification Services will be pleased to extend our Certificationt services :

Contact us

Website : www.icsasian.com
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Phone No : 022-42200900

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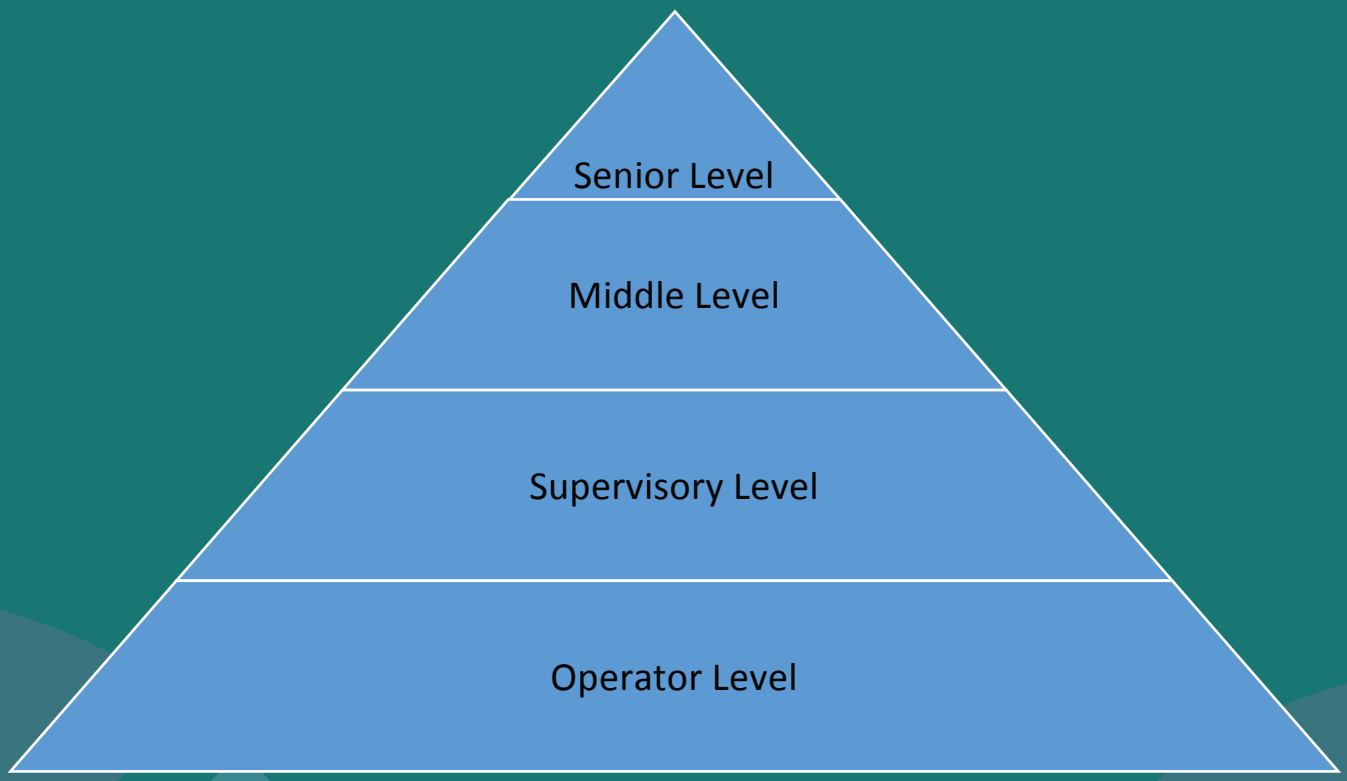
People Development

What is People Development?

People are considered as family member / asset of any organization / human resource of an organization. People development covers activities that identify & develop talents, build human capital and facilitate career propagation, enhance the quality of life and contribute to the realization of their dreams and aspirations. The human resource pyramid is depicted below:



Objective

Coordinated activities of identifying the knowledge and skill gap, imparting the same, enhancing desired attributes that are necessary to perform one or more role based tasks, and the evaluation that the desired competencies have been achieved for all the employees.

Benefits for Organization

- Increased productivity and adherence to quality standards.
- Economy of Operation: Skill people avoid accident, wastage of material and reduce cost of production.
- Coordination among team create improved employee satisfaction and morale.
- Reduced employee turnover.
- Multitasking of operators across areas.
- Encourage innovation and creativity.

Skill Matrix Production/Quality/HR/Management/Procurement/Audit												
SR No	Employee Name	Designation	Product Knowledge	Process Knowledge	Operation Skill	Mould set up skill	Inspection skill	Instrument Handling	Quality System	55/Visual Control	Average	No. of training reqd
1	Name 1	Engineer	4	4	4	4	4	4	4	4	4.0	0
2	Name 2	Supervisor	4	3	3	3	3	4	3	2	3.1	2
3	Name 3	Supervisor	4	4	4	4	4	4	4	4	4.0	0
4	Name 4	Supervisor	4	4	4	4	3	4	2	4	3.6	2
5	Name 5	Operator	2	3	3	3	2	3	2	3	2.6	3
6	Name 6	Operator	2	2	3	2	3	2	2	3	2.4	5
7	Name 7	Operator	3	4	3	3	2	3	3	2	2.9	2
8	Name 8	Operator	3	2	2	2	3	3	3	3	2.6	3
9	Name 9	Operator	3	2	2	2	1	2	2	3	2.1	2
10	Name 10	Operator	3	2	1	1	2	1	3	2	1.9	3
11	Name 11	Operator	3	3	2	N/A	N/A	2	2	1	2.2	2
12	Name 12	Operator	3	1	2	N/A	N/A	1	2	1	1.7	2
Note : 1 mean Training (0.5)												
Average Score	1	2	3	4								
	Trainee	Can work under supervision	Trained	Ability to coach								
	Company Policy	Every employee should gradually move to score 3 in atleast 5 skills										
	Prepared By :								Approved By			
	Date								Date			

Role Mapping For Manufacturing Process									
Role	Position	AVP Operations	AGM Manufacturing	Works Manager	Production Manager	Assistant Manager	Line Supervisor	Line Operator	Administrative Executives
Plant development		√					×		×
Planning & Organization		√							×
Product/Process Training			√						
Corporate Management		√							
Key project Accountability		√		√				×	×
Training & Development (Process/Product Behaviour)						√			√
Process Expertise / Improvements			√			√			
Delivery Index Achievement/execution				√		√			
Quality Index Achievement			√	√				√	√
Customs & Factory Regulations							√		
Geneation Of MIS report & analysis								×	
Continual improvement in Plant		√		√					
Maintaining Factory stabdards & better work environment			√			√			√
Plant Layout		√							
Rejection Disposal Actions			√				×	×	×
Goal setting		√	√						
Mandatory Regulatory			√	√	√	√			√
New product development					√				
Risk Mitigation plan & execution									
Documentation & Execution			√		√				
Process Validation		√							
Symbol use Role:Yes	√								
Symbol USE Role: No	×								

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ICS

LEGAL AND REGULATORY REQUIREMENTS ENVIRONMENTAL MANAGEMENT SYSTEM , ISO 14001

Meeting environmental legislation is one of the most critical parts of the ISO 14001 standard. While the standard does not distinguish between different business sectors, it is easy to imagine the potential negative effects of the hazardous industry like Construction Industry, Power Plants, Oil and Gas, Chemical Plant failing to meet legal requirements and the resulting impact. Therefore, given the importance of meeting legislation, what steps can a company take to ensure that these requirements are met ahead of an certification audit/third and second party audits?

We need to prepare and have **ISO 14001 legislation checklist** as ready to achieve compliance for your company?

Environmental legislation: Standard Requirements

Clause 5 of the standard mentions that each company will have a requirements to fulfil its compliance obligations, and this is expanded upon in clause 6, which addresses “planning.” As seen in the article Compliance requirements according to ISO 14001:2015 - What has Changed?, legislation and the needs of the company’s interested parties can how be classified together as “compliance obligations.”

The Standards suggests every company should have access to obligations that effects it, determine how they might affect the EMS, and take them into account when planning activities.

Steps for compliance with ISO 14001 legal requirements

Compliance obligations: Above are mandatory requirements

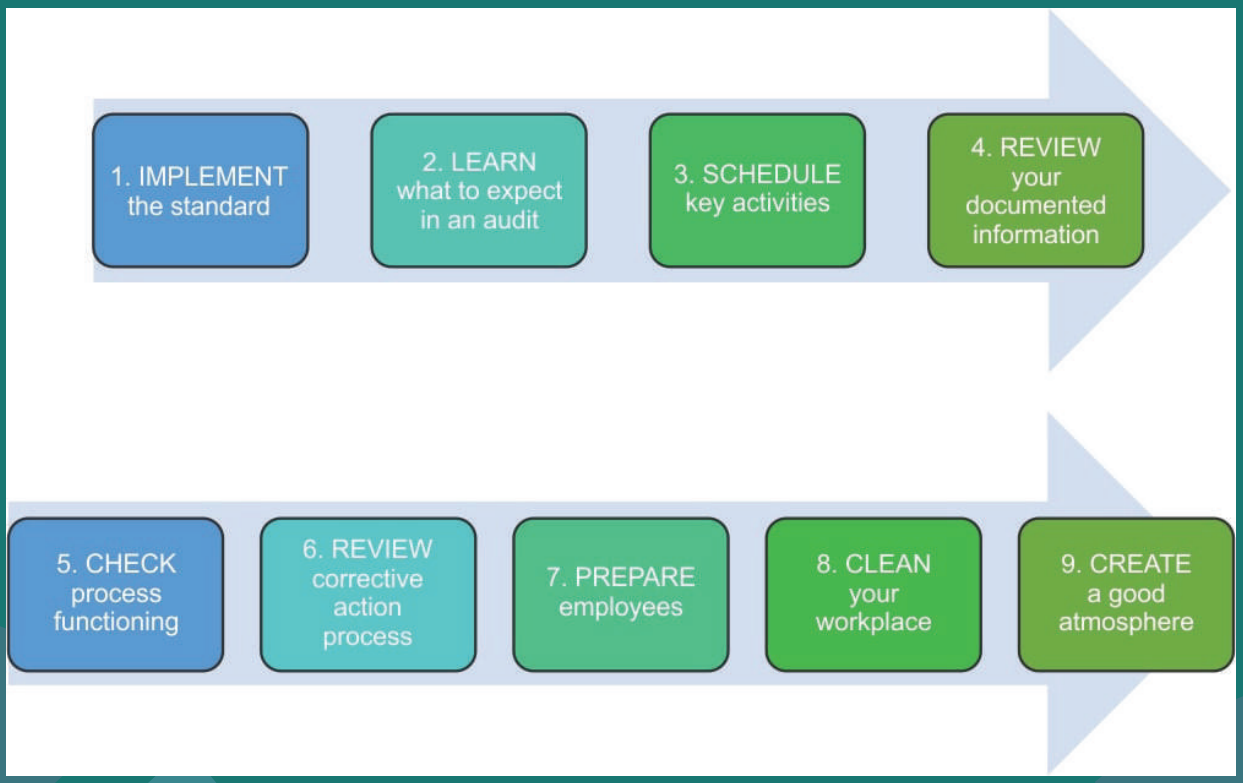
Since, we understand that legislation and the needs of interested parties are classified together, we can decide where to documents this, how to verify it and how to review it's effectiveness. It makes sense to consider the following questions:

- What channels can be identified and used to ensure relevant legislation is identified?
- Who is responsible for this within the organization?
- Are all stakeholder requirements considered? Do we need input from different internal departments and defined external partners to achieve this?
- How is internal and external communication managed? Do employees and other stakeholders need to be informed of changes to ensure processes and behaviors are adjusted accordingly? Is training a requirements to meet the terms of any changes?
- Is there independent third party checking that all the correct compliance obligations have been identified and maintained.

The most important thing is that you can now create a checklist that ensures these tasks are allocated, carried out, and recorded in a manner that makes it possible to review their effectiveness.

An external certification audit, second and third party is one method of "independent checking" that many business choose to use.

How to prepare for ISO 14001:2015 certification audit



Legislation requirements being mandatory and critical part of the audit scope, complying with legislation can help meet business objectives, avoid costly financial penalties and, our business reputation remains intact. Consolidating the legislation changes, responsibilities, dates of change and actions required to communicate to stakeholders can help achieve this efficiently.

For example, if your electronics business must conform to RoHS legislation (Restriction of Hazardous Substances), you may have to prove your compliance at least twice yearly. In this case, if we have the legislation issue on our checklist (compliance to RoHS legislation), and your compliance requirements, we should ensure our checklist prompts the responsible person to review the status and make necessary changes every three months, and/on one month before the compliance dates.

Satisfied Stakeholders

ISO 14001: The benefits to customers : As we examined the many positive factors that adoption of the standard can bring to our customer base. Ensuring that our compliance obligations are organized, visible, responsibilities allocated and the whole process documented can bring another benefit to our customers, and a checklist is an excellent method of achieving this. Satisfying a Certification Body auditor and customer including and business-critical to the environment.

TRAINING CALENDER

Training Calendar October 2019 to June 2020			
	Oct-19	Nov-19	Dec-19
Date of training	15th to 19th October 2019	12th to 16th November 2019	20th & 21st December 2019
Course Name	Lead Auditor Training - Quality Management System	Lead Auditor Training - Occupational Health & Safety Management System	Internal Auditor Training - Quality Management System
Location	Mumbai	Mumbai	Mumbai

	Jan-20	Feb-20	Mar-20
Date of training	20th & 21st January 2020	20th & 21st February 2020	27th & 28th March 2020
Course Name	Internal Auditor Training - Environmental Management System	Internal Auditor Training - Quality Management System	Internal Auditor Training - Occupational Health & Safety Management System
Location	Mumbai	Mumbai	Mumbai

	Apr-20	May-20	Jun-20
Date of training	24th & 25th April 2020	19th to 23rd May 2020	15th to 19th June 2020
Course Name	Internal Auditor Training - Environmental Management System	Lead Auditor Training - Quality Management System	Lead Auditor Training - Occupational Health & Safety Management System
Location	Mumbai	Mumbai	Mumbai

ONLINE TRAINING

AWARENESS	INTERNAL QUALITY AUDITOR	LEAD AUDITOR
➢ DTQM ➢ QMS ➢ EMS ➢ OHSAS 18001 ➢ ISO 45001 ➢ FSMS ➢ SA 8000 ➢ ISMS ➢ IMS ➢ Medical Devices 13485 ➢ 5S ➢ Solving Techniques ➢ Space Utilization ➢ Staff Utilization ➢ FSMS_Transition	➢ QMS ➢ EMS ➢ OHSAS 18001 ➢ ISO 45001 ➢ FSMS ➢ SA 8000 ➢ ISMS ➢ IMS ➢ 13485	➢ QMS ➢ EMS ➢ OHSAS 18001 ➢ ISO 45001

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Ganesh Festival

Ganesh Festival is the biggest occasion celebrated at large scale in all over mumbai, Maharashtra In respect of organization's culture, we celebrate ganesh festival at our ICS Mumbai - HO for 10 days and the glimpse of the celebrations is as follows.

Every year complete office is decorated by office staff based on different themes and this year's theme was origami.

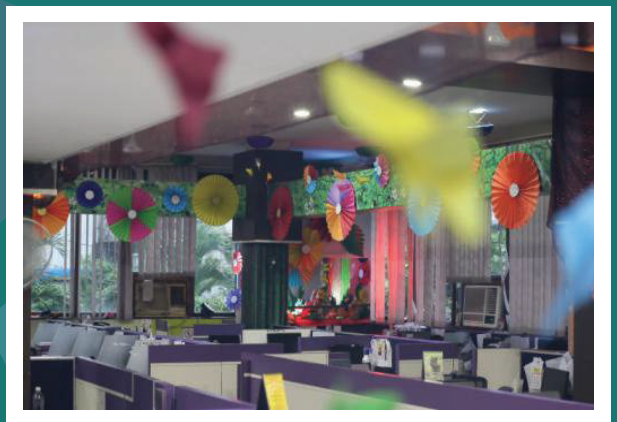
During this occasion the day at office starts with ganesh aarti, followed with Nasta (Break Fast), Prasad (Sweets) and Team Activity Games for all office staff being arranged by respective Department nominated for that particular day. Likewise all respective operating departments are nominated for all 10 days celebration.

This Celebration ends up with a Team competition and exciting winning prices like Department Trophy, Best Nasta and Prasad, Best Rangoli, Best Team, Best Traditional Dress.

At the end we have a grand celebration on the last day of Ganesh chaturti, wherein we invite family member of our HO staff, its a get together where families gets a chance to enjoy participate in group events, games and fun with their loved ones, followed with family lunch and sweets arranged by our management, this helps the families to understand our work culture also helps to know about our management and organization.

Such kind of celebrations at office levels helps us to motivate and appreciate our employees for active participation in terms of Team building activities to build positive attitude towards work, which is a part of employee engagement and welfare.

Finally, We take this opportunity to thank our management for support and every single personnel for actively participating in this course of event without keeping any personal interest and putting their extra efforts for the development and growth of our organization.



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INTERNATONAL CERTIFICATION SERVICE

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