Regulatory Requirements for Medical Devices and IVDs in India

Dr. Sucheta Banerjee Kurundkar
Director, Training (Project)
Clinical Development Services Agency, Government of India

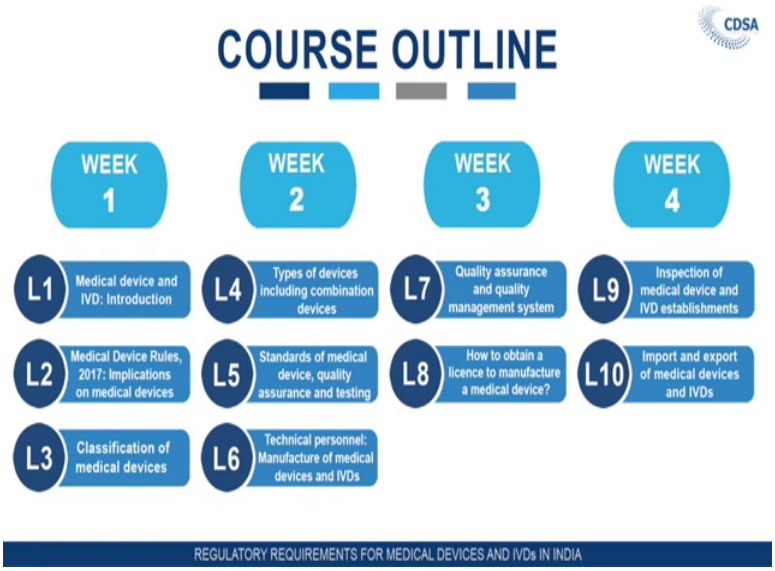
Lecture – 02
C2L00

[FL]. Welcome to our online course called Regulatory Requirements for Medical Devices and In Vitro Diagnostics in India. This online course is developed by CDSA with the help of various subject experts.

(Refer Slide Time: 00:30)

CDSA is Clinical Development Services Agency which is an extramural unit of Translation Health Science and Technology Institute under Department of Biotechnology, Ministry of Science and Technology, Government of India. This course is reviewed for its quality and content by the Indian drug regulators, the CDSCO - Central Drugs Standard Control Organization, which is under the Ministry of Health and Family Welfare, Government of India.

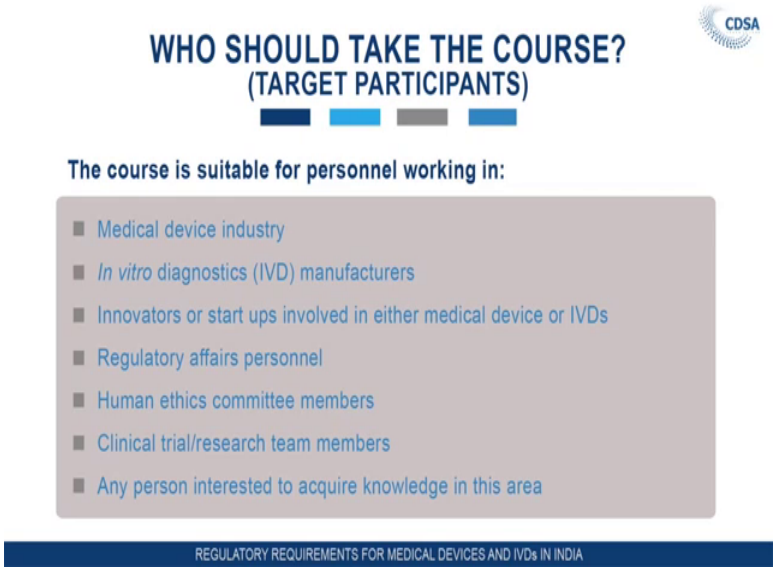
(Refer Slide Time: 01:06)



This online course is divided into 10 beautiful lectures and it is a 4 week course. The 10 lectures have a format of 3 lectures per week for week 1 and week 2; and two lectures per week for week 3 and week 4. The first lecture begins with an introduction which speaks about what is a medical device. The second lecture is extremely important, because it speaks about the new rules which is the medical device rules 2017, and its implication on the medical device. The third lecture is on classification of medical device. The fourth lecture which is speaks about the types of devices and it includes combination device. The lecture five is on standards of medical device quality assurance and testing.

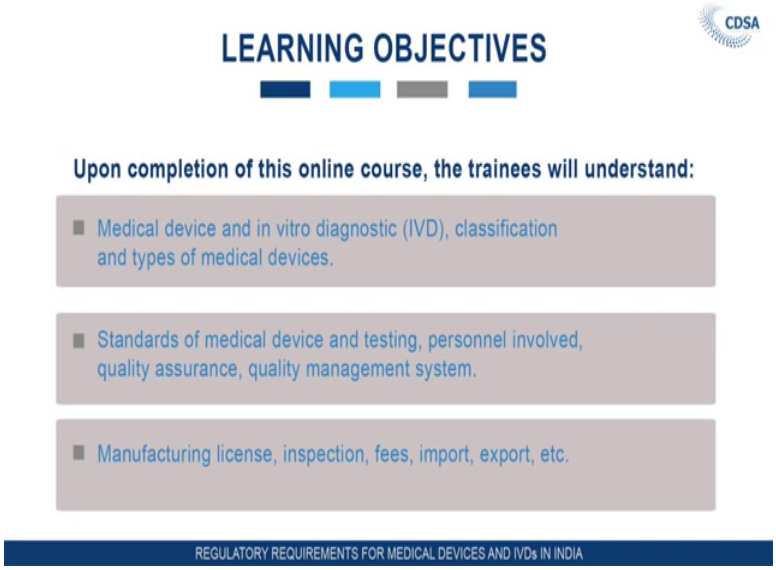
Lecture 6 speaks about the technical personnel who are involved in the manufacture of medical devices in India. The week 3 begins with lecture 7 which speaks about QA and QMS, Quality Assurance and Quality Management System. The week 3 has a lecture called lecture 8 which is about how to obtain a license to manufacture a medical device in India. The lecture 9 speaks about the inspection of medical devices and the IVD establishments. The lecture 10 is the last lecture of this online course and it speaks about the import and export of medical devices in India.

(Refer Slide Time: 02:44)



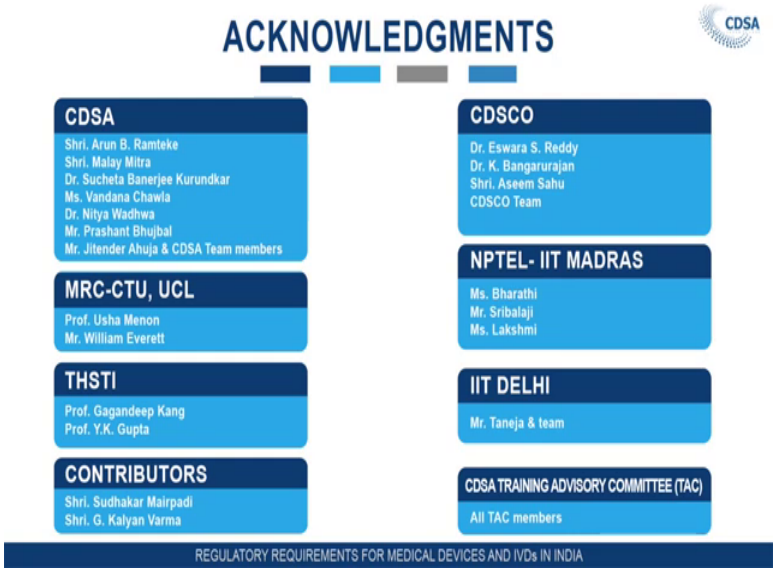
Now, who should take this course? This course is suitable for any person who is interested to acquire a knowledge in this area. They can be from the medical device industry; they can be from in vitro diagnostics; the manufacturers, the innovators, the startups various regulatory affairs personnel who are dealing with medical device and IVDs. The human ethics committee members who review protocols which are related to medical devices, any clinical trial or research members involved in medical device industry or any other person as I mentioned is interested to take or have an understanding about this area of medical device and IVDs in India.

(Refer Slide Time: 03:22)



Once you complete the course, you will have a brief overview about what is a medical device and in vitro diagnostics, what are their classifications, what are the different types of medical devices like combination devices. Our learning objectives also include that you will seek in cognizance about what are the various standards of medical device and testing. You will understand who are the personnel involved, specifically the technical personnel involved in the manufacture of medical device. The quality assurance and the quality management system involved here; the manufacturing license, the inspection, the fees, the import and export. This course was in fact, suggested by the Indian drug regulator CDSCO.

(Refer Slide Time: 04:05)



I am thankful to Dr. K. Bangarurajan who has suggested this course to be undertaken by CDSA, and this course was really really a great way of learning for us. So, I thank my entire team who had made this possible. To begin with this course was initially written by Shri. A B. Ramteke who is the former joint drugs controller at CDSCO. And then it was later on added by Shri. Malay Mitraji who is the former deputy drugs controller at CDSCO. My CDSA team Ms. Vandana Chawla, Dr. Nitya Wadhwa, Mr. Prashant Bhujbal, Mr. Jitendra Ahuja, Mr. Wazahath Ali Khan and the entire CDSA team.

When this course was conceived we had recorded the sessions and we found that it required a lot of professional outlook. And I am thankful to Prof. Usha Menon from MRC-CTU, University of College of London who gave a professional outlook and made

this online course more interesting and an attractive. Thank you Prof. Menon; I am also thankful to William Everett from UCL.

I thank the THSTI admin, it is led by Prof. Gagandeep Kang who is the executive director. I also thank Prof. Y. K. Gupta, the chairman of the training advisory committee of CDSA for this support and believe in us. There were many people who have contributed to this course, in specially in the content area I am thankful to Shri. Sudhakar Mairpadi and Mr. Kalian Varma. This course called regulatory requirements for medical devices and IVDs in India is incomplete without the regulators.

So, I thank immensely to the entire CDSCO team led by Dr. S. Eshwara Reddy, The Drugs Controller General of India for his support and constant encouragement to make this possible. I am thankful again to Dr. K. Bangarurajan who has been a strong support in making this possible; every time we had faced problem, he had come to rescue.

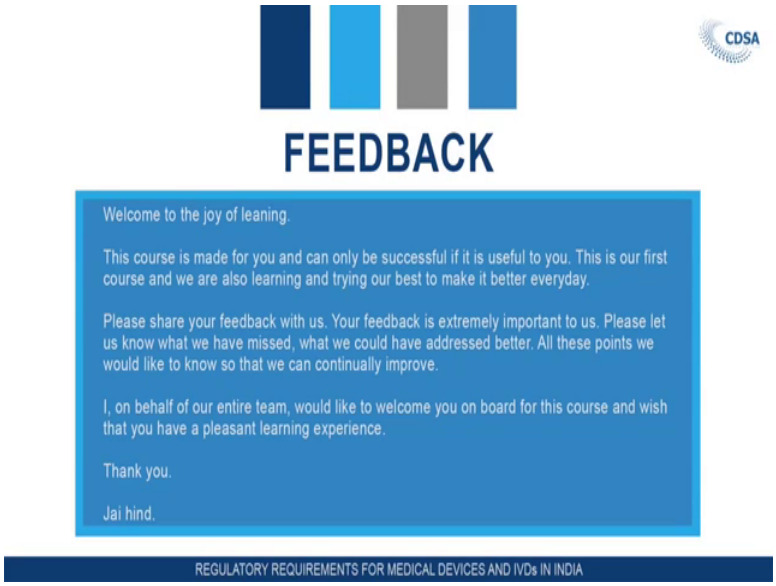
This course was not possible without strong and I think a lot of efforts by Shri. Aseem Sahuji the deputy drugs controller at CDSCO, now heading the north zone. And he has put his lot of efforts and time and attention; and has reviewed each and every slide, ladies and gentlemen, so that only correct information reaches you. In spite of his very hectic schedule, he ensured working day and night with me that the correct information reaches you in a very simple and lucid form. And he in fact, has reviewed approved and recorded the lectures here. So, I thank Shri. Aseem Sahuji and the entire CDSCO team for their support to make this possible.

This course was a distant dream without the IT and led by NPTEL. So, I am thankful to NPTEL, IIT Madras team led by Ms. Bharathi, Mr. Sribalaji and Ms. Lakshmi. Majority of our recordings are done at IIT, Delhi; and it is tough for us for a new people like us to understand the entire business of online course and recording.

I am immensely thankful to Shri Tanejaji and his entire IIT Delhi studio team for their support and cooperation to make this possible. I am also thankful to all the training advisory committee members of CDSA who had a belief that a small team of CDSA comprising of only two three members can make this dream possible.

So, ladies and gentlemen, my dear friends welcome to the joy of learning. This course is made for you and can only be successful if it is useful to you.

(Refer Slide Time: 07:56)



Your feedback is extremely important to us. Please let us know what we have missed, what we could have addressed them better, all the points will help us to continually improve and make the next version of this course more user friendly and effective.

I on behalf of my entire team welcome you once again onboard to this course, and wish you all a very happy learning.

Thank you and [FL].