Regulatory Requirements for Medical Devices and IVDs in India

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Lecture - 01
C2 Introduction Assorted Interviews

Greetings from Central Drug Standard Control Organization, friends as you know medical devices plays very important role in the public healthcare system. Most of medical devices especially very high end medical devices we are importing from other countries. To promote indigenous manufacturing of medical devices in India and also to promote innovation in medical devices, the Government of India has published medical device rules 2017.

The salient features of medical device rules are these rules are based on the risk based classification of medical devices. These rules are clearly specified the standards required for approval of medical devices in India. The medical device 2017 rules prescribes various regulatory requirements for manufacturing, import and to conduct clinical investigations in India.

These rules are framed with intention to harmonize our regulations on par with the any international standard. The Central Drug Standard Control Organization has conducted various training program to the indigenous manufacturers and drug regulators. But this

online training course will help many stakeholders to understand about the regulatory requirements to manufacture medical devices and IVDs in India. This course is developed by the CDSA, THSTI and the DBT in consultation with the standard drug control organization.

As you know knowledge is free and we believe that anyone can learn anytime and anywhere. This course is well designed and it is very user friendly. In this course, the regulatory requirements for medical devices and IVDs are shown in a very effective manner, and to understand this regulations by all the stakeholders for to promoting the indigenous production of medical devices and also innovation in India.

This course is offered free of cost through NPTEL, IIT Madras. And those candidates willing to apply for certification in the same course a proctor online examination will be conducted for these candidates for their registration. I request that you give feedback, so that we get better and better in future. This is a great way forward, I wish all my viewers a happy learning. Thank you very much.

Greetings from Central Drug Standard Control Organization; CDSCO, medical device and IVDs are posing enormous opportunities to explore and expand. We encounter many innovators, small and medium entrepreneurs, MS MES who are working in this area especially scientists from IITs, NCL venture centre, C camp incubators, THSTI innovators who are working in this area, but are not much aware of the regulatory pathway. We felt that an online course might be able to meet the unmet need. I had then suggested the course two regulatory requirements for medical devices and IVDS in India to CDSA.

And I am happy that they were able to convert them to an online course today. It is not easy for CDSCO as regulators to sit and write a course, review and approve. It is a human intensive and very demanding job. Me and my team, especially Dr. Sable and others had been working hard to ensure that such efforts meet a fruitful closure. I hope you will understand and appreciate this gesture from regulators and government to help in demystifying the regulatory knowledge, so that discoveries from bench to bedside are realized faster. I will be happy to see that you take this course and share your thoughts and comments with us. We will try and incorporate feedback, so that we continually improve and work towards greater public good. Enjoy the course and [FL].

This online training course is initiated first time in the country by CDSA with object to understand existing medical device regulation in the country. The stakeholder will acquire knowledge on requirements of import, manufacture, clinical investigation, sale and distribution of medical devices and in vitro diagnostic. I had been closely involved in review of the content of the course, and also associated with CDSA to ensure that only right information to the stakeholder without causing any confusion shall be reached.

I must congratulate CDSA on behalf of the CDSCO for taking this initiative. It is my pleasure to be a part of this online course. Friends, in India medical devices and in vitro diagnostic are a new area. The Ministry of Health, Government of India as well as CDSA has taken various measures to make medical device regulation at par with the globally accepted regulation and boost the medical device sector in the country. We hope that this course will be useful for having update information on regulation of medical device in the country. Please share your feedback with us. We would certainly like to undertake changes once we know what you would like to know more or in the different areas. I and my team at CDSCO wish you happy learning. Thank you.

Greetings from CDSA and CDSCO, I welcome all of you to this online course on current regulatory requirement on medical devices. Dear friends as you know the healthcare industry in India has been one of the country's largest economic sector with regard to both employment and revenue. Pharmaceuticals and medical devices plays a major role and the medical device market in India has seen rapid growth in recent years.

Dear friend, medical device is the emerging field and currently it is counted among the top 20 global device market. It is also fourth largest medical device market in Asia. To meet the requirement of medical device practices and to further streamline regulatory pathways, Ministry of Health and Family Welfare has published medical device rules 2017 which is effective from 1st January 2018. To have the current knowledge and correct understanding of these medical devices rule, there is an imperative need to have a seminar workshop and courses on these rules, but all the time to conduct seminars and workshop is not possible. Keeping in mind this aspect and at the right time CDSA in collaboration with CDSCO has developed an online course on current liability requirement on medical device.

I think this is the first course on regulatory requirement on medical device developed by CDSA and in collaboration with CDSCO. I and my seniors have reviewed this course for its correctness as per medical device rule 2017. I found the course is really amazing, it has been nicely designed very meticulously reviewed by all the senior staffs, so that only right and precise information reach to learners.

Dear friend, I wish a happy learning to all of you. You will definitely enjoy the course and you will definitely upgrade, update your knowledge with respect to the medical device, rules and regulation to meet your expectation. Do not forget to give your valuable feedback, so that we can make further improvement to meet your expectation. Thank you and all the best.

Hello everybody, my name is Arun Kumar Ramteke; I am a retired joint drug controller CDSCO, I retired in 2011. And since then I am working as a consultant at clinical development service agency which is the department of biotechnology. And we have developed this course; online course for the stakeholders mostly on the regulatory requirement for conducting the clinical trial in India. So, hope you will learn something from this course, and we will help in the learning.

Hello guys my name is Malay Mitra; I am ex-deputy drugs controller of CDSCO, headquarters New Delhi. I have been involved in medical devices regulations right from the time it started. And after my retirement 2011, I have been involved in various aspects of medical devices with the industry as well as the regulators that is my intro. Now, what about the course that you are available to see now, the course is actually designed there are two courses course 1 and course 2. I have been dealing with course 2, it will comprise of different presentations, each presentation will be actually giving you in depth analysis and details of medical devices in all that aspects right from what is a medical device to how it is regulated, how it is sold, and how is it imported and how it is how it is exported. So, the introductory lecture that I am going to give which will be the best lecture and following those lectures you have to go through the other 11 lectures to understand in a better manner what is a medical device, and how it is controlled in this country.

When we do research we all often come up with ideas that we think require a lot of dissemination. Particularly, if you are developing tools and technologies, you would

want them to have application to a wider population. This can be tremendously exciting, but people get frustrated and falter along the way because they do not have a clear idea of the way forward. When it comes to developing medical devices as well as in vitro diagnostics, sometimes regulatory pathways can be quite challenging.

The clinical development services agency of the Translational Health Science and Technology Institute has developed content for a course that will teach you about the regulatory requirements of in vitro diagnostics and medical devices in India. This is essential learning for anyone who is seeking to develop such products in India. The course content was developed by experts in the field in India and has been reviewed by the CDSCO which has just brought out its new guidelines.

The new guidelines from the basis of this course, but as we must remember guidelines are all frequently renewed as requirement change over time and content may need to be updated. Therefore, we hope that you will enjoy the experience of this online course. We will use it to the full and also provide feedback on way you think there might be gaps or new material might be required. We will also play our part by updating this course as and when required. I hope you will enjoy the experience of learning along with us here.

Warmest greetings from the Translational Health Science and Technology Institute, it gives us great pleasure to welcome you for this online course on regulatory requirements for medical devices and in vitro diagnostics in India. A critical lacuna amongst our physicians, engineers and scientists has been the gap in knowledge on regulatory requirements for taking their products to the market. We believe that this course will be an important step to bridge this gap, and encourage young innovators through the various phases of their product development. CDSA has worked with subject experts and mainly the drug regulators from CDSCO who have reviewed the technical content of this course and recorded many lectures.

It is one of the first courses of its kind and CDSA has worked very hard to make it informative and novel. CDSA was conceived to address important unmet need in clinical research in the country, and being involved with CDSA from the beginning, it gives me immense happiness that this course has been initiated. We believe that this course will go onto becoming a very successful program. I hope you enjoy this course, and we will greatly appreciate a critical feedback to make it better. Thank you.

In India we have been talking about Make in India, developing lots of devices in India for Indian patients, having quality control of devices which are imported from different countries and sold in India, people often question about the quality, people question about how the process of import and export is done. And the regulation about the devices in India is fast changing. There are a set of devices which have been notified and these notified devices are also included in Drugs and Cosmetic Act. And therefore, the regulation which is employed in drugs and cosmetic also is implied.

However, there are several devices which are not notified are in the process of notification. What is the rule what is the regulatory position of how we introduce them into the market, what is the type of clinical trial, validation, proof of concept is to be done, how many number of patients in which this have to be tested, where this have to be tested, what is the performance evaluation, what is the percent validity and reliability and efficacy which should be acceptable before the market authorization can be granted, these are the frequent questions which are faced by the physicians, the regulators also and the public.

India is promoting through startups giving them funds DVT, DST, ICMR, SMSC, they are giving funds for creating a startups for creating manufacturing these devices. And these startup companies incidentally they know how to make it, but there we have to be told what regulatory process they are going to be involved in or they will be facing. And this course I am sure coming from straight from the regulators giving simple examples will solve their problems. Therefore, when they start up the journey, they are fully aware of the regulatory requirements and therefore their journey will be simple, will be accurate and will be fruitful. And this will help the lots of devices of quality origin coming to India for better health care system. Thank you very much.

[FL], greetings from CDSA and welcome to the joy of learning, this gives me great pleasure to welcome you on board to our online course regulatory requirements for medical devices and IVDs in India. We hope you have a good experience that exceeds your expectation and enjoy the whole course. Your interactions and feedback in this course is extremely important to us. It would help us to improve and fill in the gaps if any. Our team has worked hard to make this possible for you. With your inputs, we will be able to make it a still better. We are always available to help you, in all aspects of

learning, follow up, sported support and examination. So, please do not hesitate to contact us. We will be happy to help you and resolve your queries.

Thank you.