Regulatory Requirements for Medical Devices and IVDs in India

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Lecture – 6
Technical Personnel: Manufacture of Medical Devices and IVDs

Welcome to Regulatory Requirement for Medical Devices and In-Vitro Diagnostics in India lecture 6. Lecture 6 that is Technical Personnel Manufacture of Medical Devices and in-vitro diagnostics. Why technical personnel is required for manufacturing of medical devices or in-vitro diagnostics or any of the product which relates to the medical devices. So, you understand that key drugs and medical devices can be highly complicated product; it is not simple as other products are. And their manufacturing activities require extraordinary skill and technical knowledge and only technical person can develop and manufacture such type of complex product.

So, technical knowledge is very important as far as manufacturing of the medical devices and in-vitro diagnostic is concerned. If we do not have the technical expertise in the manufacturing of particular devices, nobody we will foresee or identify the defects before they are released for use. And the material or the devices can cause hazardous to the human being. So, technical person can be identify and answer the question on the product and high skill is required for evaluating the products before they release into the market.

So, medical devices who will be the technical person, who will be the technical competent person that provision have already been made in the Medical Device Rule 2017. For manufacturing of medical devices, the person having adequate experience and qualification; what will be the qualification? The clearly mention in the rule 20, the manufacturer of the medical devices and in-vitro diagnostic should appoint competent technical staff; having qualification in engineering in the field of electrical mechanicals, bio medicals, pharmacies, biochemistries with adequate experience of minimum 2 years in the particular field. This is the qualification mentioned in the medical device rule 2017 for the manufacturing of the medical devices and in-vitro diagnostics.

Another qualification diploma in engineering, diploma in electrical, diploma in mechanical, diploma in biomedicals or the pharmacy with 4 years of experience in the particular field. So, this minimum qualification is already defined in the medical device rule 2017. So, this minimum qualification with minimum experience, person can only be responsible for manufacturing of medical devices and in-vitro diagnostic or he will responsible for manufacturing. Under his supervision of this competent technical person, the manufacturing activity or the quality control activities of the medical device and in-vitro diagnostic will be carried out at the premises.

So, this is the brief about the technical qualification of the personnel engaged in the manufacturing of medical devices and in vitro diagnostic; its clearly defined in the rule. So, the manufacturer can appoint suitable competent technical staff for manufacturing of their medical devices or in-vitro diagnostics and the qualification. Whatever, the qualification mentioned in the rules I have already explained; that has to be fulfilled by the person engaged in the manufacturing and quality control of the medical devices and in-vitro diagnostics.

So, this is the generally, general brief about the technical personnel and their requirement and the qualification and experience. Dear friends, the details of this lecture 6 that will be given by the Mister. Malay Mitra former Deputy Drug Controller, CDSCO. He will have lot of expertise in the regulation of the medical devices. So, he will explain all the details of the technical personnel; why it is required, where the expertise is required, what will be the training to the technical staff engage in the manufacturing of the medical devices and in-vitro diagnostics? So, please concentrate on the lecture, detail lecture which will be given by the Mister. Malay Mitra. And if you have any doubt please come back to us; we will try to clear that doubts further. Thank you very much.

Hi, in this particular presentation we are going to talk about the Technical Personnel and with reference to manpower required in the Manufacture of Medical Device.

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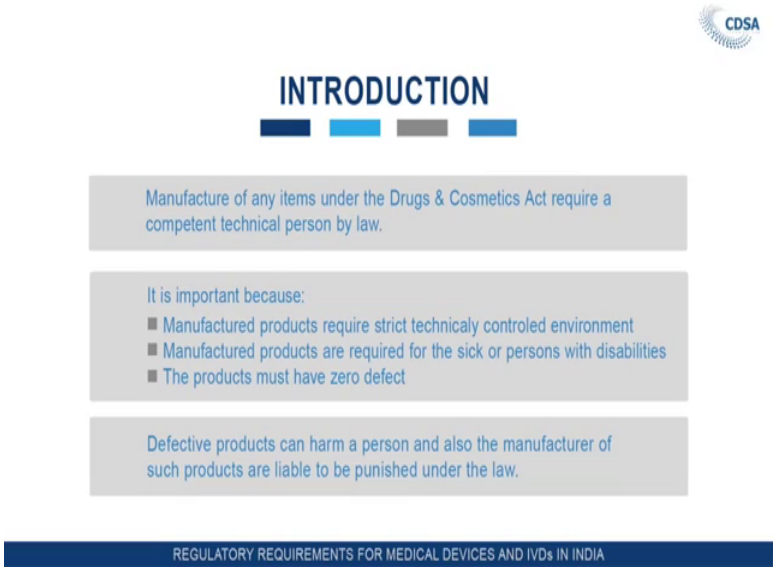

Introduction; it is very important to know that manufacture of any item under the drug and cosmetics act required a competent technical person by law. Products manufacturer controlled are based on science. The manufacture products are required for the sick or persons with disabilities; the production will be zero defect. Therefore, defective products can harm a person and also the manufacturer for such products are liable to be punished under law.

We understand by this four parameters that anything which is manufactured under drag and cosmetics act. Whether it is a drug, whether it is a medical device, whether it is a cosmetic they require technical persons of high caliber to manufacture that. And also the people who manufactured them the manpower are also of to be a special nature.

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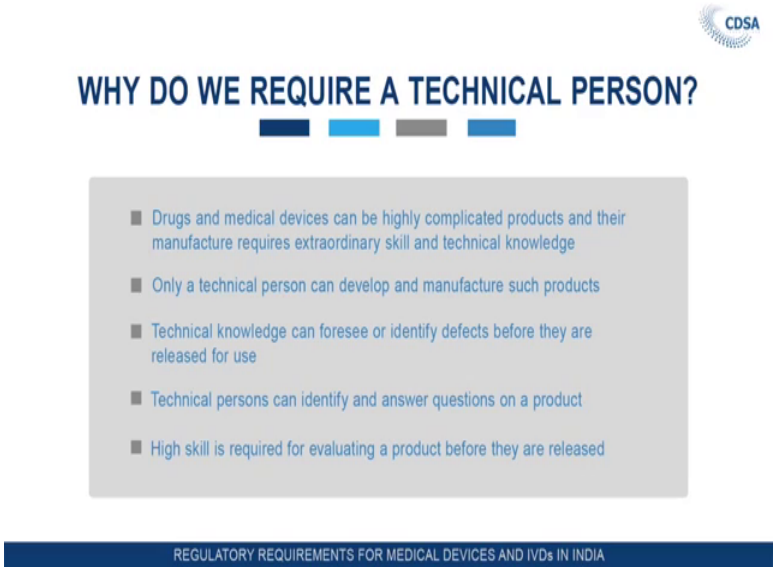

Now, why do we require a technical person to manufacture a medical device? Drugs and medical devices are highly complicated products and their manufacture requires extraordinary skill and technical knowledge. Anybody who is not technically qualified or competent enough cannot manufacture a drug or a medical device. Only a technical person can developed and then manufactures are that. Remember, a product which is a drug or a medical device have been designed and developed before their commercial production by highly technical scientists and people who have knowledge on those products. Therefore, the manufacture of these products also require highly technical personnel.

Technical knowledge can foresee or identify defects before they are released for use; that means, while if we manufactured, you can understand the defects that may developed between the time of manufacture and stop those products from being going to the market. Technical persons can identify and answer questions on a product. So, therefore, if there is a market complaint or a regulator ask a question on the product, the technical person should be able to answer those questions scientifically and explain to them.

High skill is required for evaluating a product before it they are released; that is your final release either it is testing or evaluation of a product has to be done by a person, who has a extremely high knowledge of the product. Mentioned in regulation; let us go to the regulations to see where manpower is mentioned.

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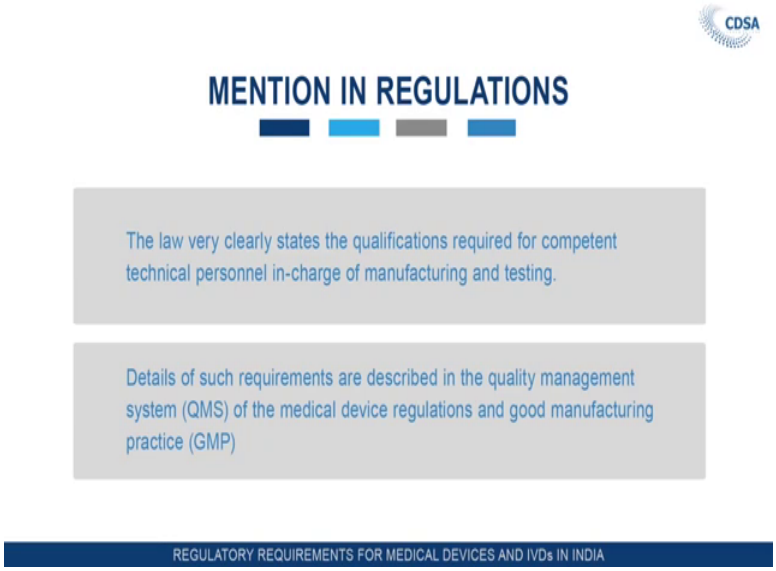

The law clearly states that the qualification required for competent technical personnel in charge of manufacturing and testing. Details of such requirements are described in the quality management system of the medical device regulations and also in the GMP. Now, wherever there is a mention of a manpower whether it is a workman, worker or a technical person, that particular area has to be stressed very clearly and understood.

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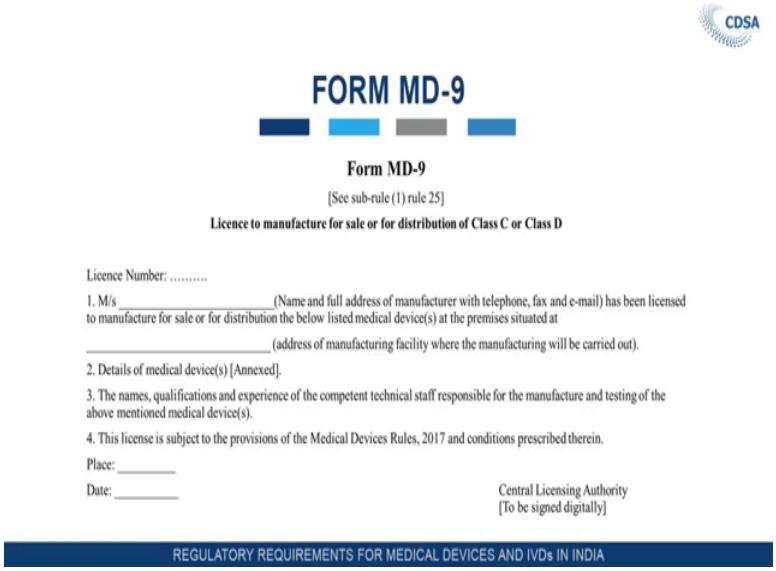

Let us start from the very beginning. This is the license to manufacture for sale or for distribution of Class C or D device. This is form MD-9, under which a personnel has to

apply for a manufacturing license. If you see the point number 3, in the license it says the names qualification and experience of competent technical staff responsible for the manufacture of and testing out the above mentioned medical device. Therefore, you have to submit to the regulatory authority. The technical persons, who are required to manufacture those products and also test them, this is as per law.

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Now, let us come to chapter IV of the Regulations Manufacture of Medical Devices for Sale or Distribution 22, requirement for grant of manufacturing license or loan license. While making application of grant or license or loan license under Rule 20 or 21, the applicant shall meet the following requirements namely.

The manufacturing site shall comply with the requirements of the quality management system as specified under the 5th schedule. Appoint competent technical staff under whose direction and supervision, the manufacturing activity of the medical device shall be undertaken. And such staff shall possess the following educational qualification and experience.

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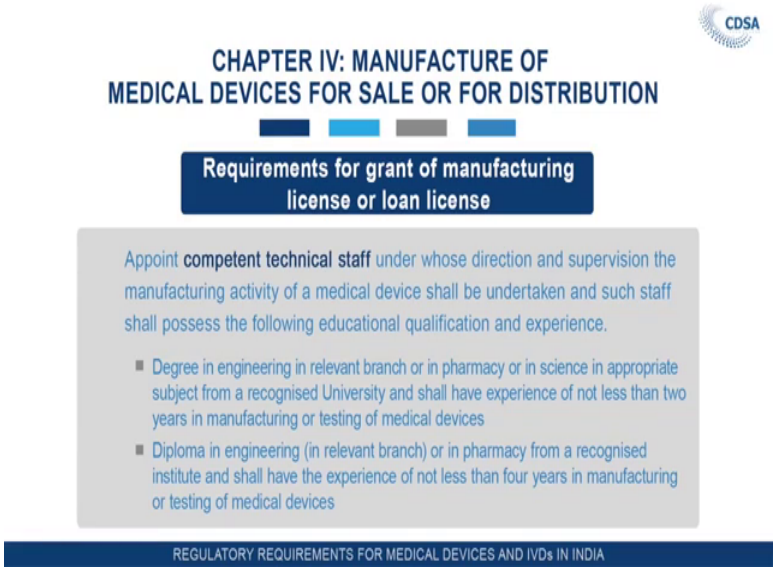

So, in Rule 22, roman two the tip appointment of technical competence staff has been made mandatory with the qualification experience as follows. They should have a degree in engineering in relevant branch or in pharmacy or in science in appropriate subject from recognized university and shall have experience of not less than two years in the manufacture and testing of medical device. Or diploma in engineering in relevant branch or in pharmacy from a recognized institute and shall have relevant experience of not less than four years in the manufacturing or testing of medical device.

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And three, appoint competent technical stuff with degrees or diploma in engineering in the relevant branch or in pharmacy or in science and relevant subject and having experience of not less than 2 years in testing of medical device under whose jurisdiction and supervision, the testing activity over medical device shall we undertaken.

Now, over here; it is very useful to note that the asas, the para asas degree in engineering in relevant branch or in pharmacy or in science in appropriate subject. Therefore, the subjects are not mentioned. You can pick a person of a particular subject, which is relevant to the particular medical device; it can be anything. Next slide will explain to better.

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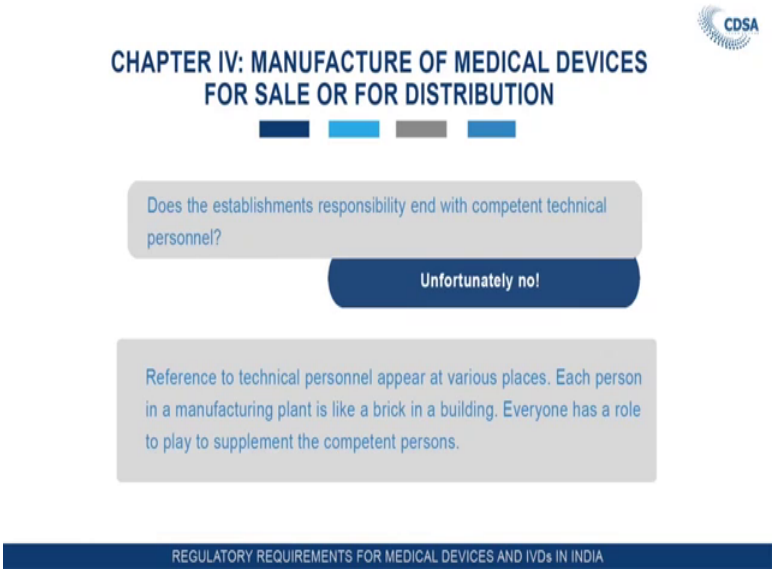

Does the established establishment responsibility end with the component technical personnel? Unfortunately, no; reference to technical personnel appear at various places. Each personnel element manufacturing plant is like a brick in a building. Everyone has a role to play to supplement in a competent person.

And here, in comes the importance of anybody who is working in a plant. It can be a technical person down to the shop level worker.

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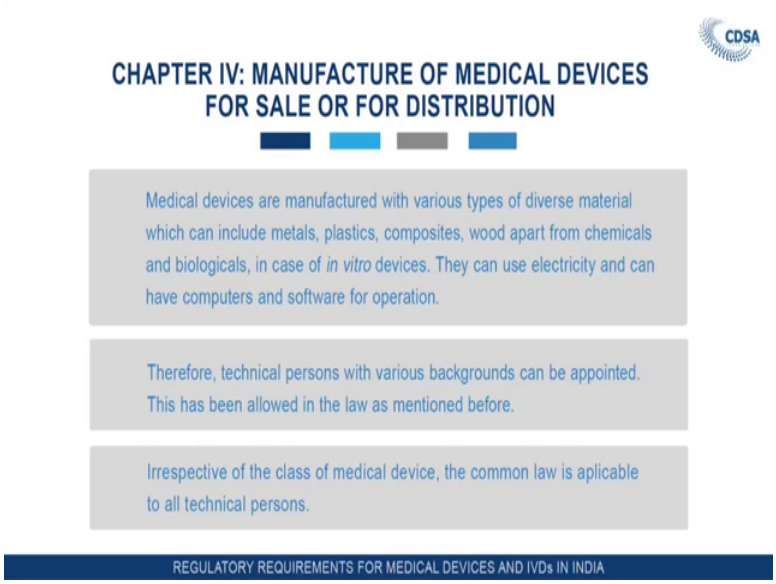

Medical devices are manufactured with various types of diverse material which can include metals, plastics, composites, wood apart from chemicals and biologics, in case of in vitro devices. Therefore, that in the earlier slide; so, mention in appropriate subject; it comes into play over here. They can use electricity for use and kind of computers and software flow operation. So, you can require a computer engineer also. Therefore, technical person with various backgrounds can be appointed. This has been allowed in the law as mentioned before. Irrespective of the class of medical device, the common law is applied for technical persons.

So, even if in manufacture a class A device or a D device high risk device, the law is common to all. You can appoint anybody with a particular appropriate knowledge of the device or the subject and the regulator will allow that person to work and manufacture that product.

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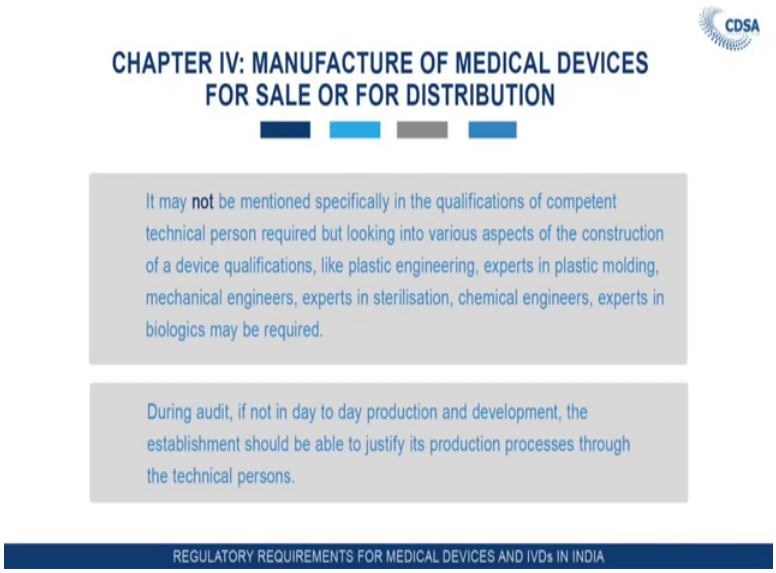

It may not be mentioned specifically in the qualifications of the component technical personnel required, but looking into various aspects of instructional of medical device qualification, like plastic engineers, engineering experts in plastic molding, mechanical engineers, experts in sterilization, chemical engineers, experts in biologics may be required. During audit, if not in day to day production and development, the establishment should be able to justify its production processes through the technical persons.

So, you see it is drug that, this is another definition between drug and a medical device. Drug requires the person, who has experience the manufacturer and formulations; which are chemical entities and do not require diverse engineering backgrounds like in medical devices. Medical devices are manufactured from device, diverse medical, diverse materials though you require diverse backgrounds.

So, in case of drugs, it is a manufacturing process is a process which is required is common to all products; whether it is a paracetamol tablet or a highly important antibiotic. The manufacturing process requires it some similarities. Therefore, a common educational qualification can help in those cases, but not in case of medical devices.

Let us go to the Site Master File or Plant Master File, where it mentions personnel.

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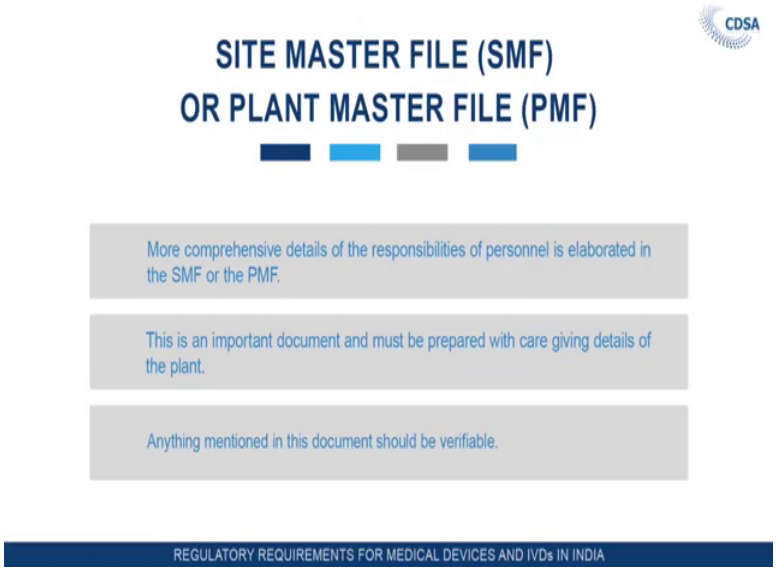

More comprehensive details of the responsibilities of personnel is elaborated in Site Master File or Plant Master File. This is an important document has been prepared with care giving details of the plant. Anything mentioned in the document should be verifiable; that means, anything you place in the Plant Master File and Site Master File should you should be able to explain that in reality in the plant where it exists.

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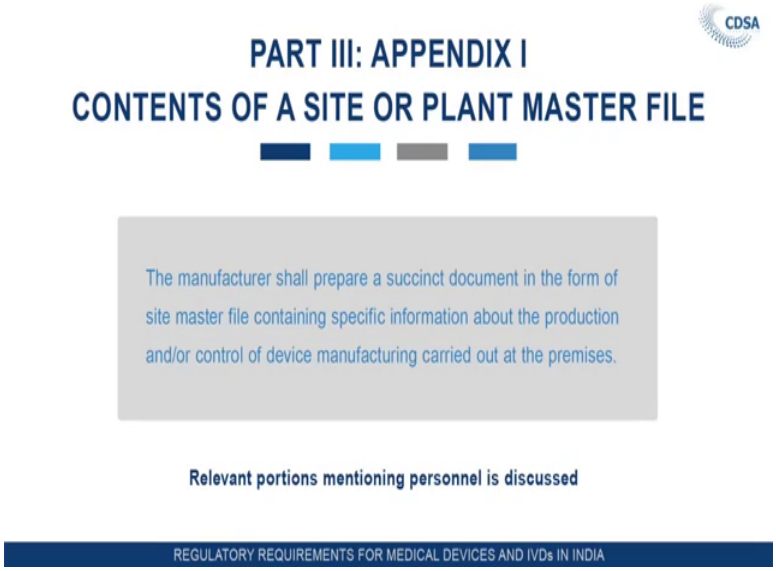

Part III Appendix I Contents of the Site or Plant Master File. The manufacturer shall prepare a succinct document in the form of site master file containing specific

information about the production air or control of device manufacturing carrying out at the premises. Relevant portions mentioning personnel is discussed here. So, if you go through the appendix I, you will find personnel being mentioned at various places.

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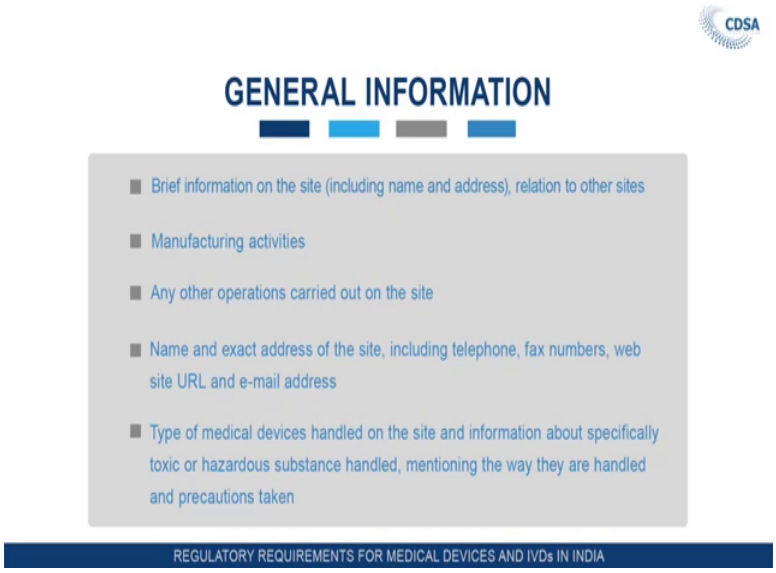

Part I is general information, brief formation on the site including name and address, relation to the sites, manufacturing activities, any other operations carried out, name and exact address of the site including telephone or fax number, type of medical devices handled on the site and information of the specificity toxicity or hazardous substances handled, mentioning the way they are handled and precautions taken; short description of the site including location, immediate environment etcetera.

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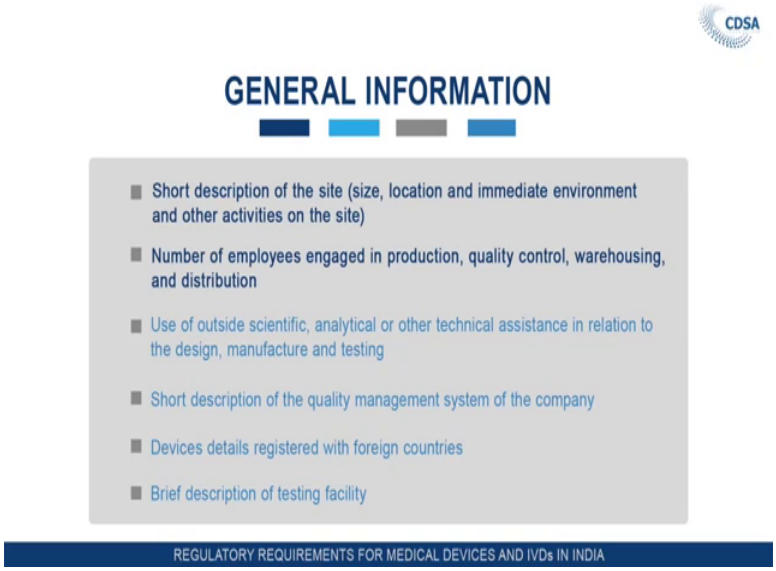

Now, number of employees engaged in production, quality control and warehousing and distribution. This is extremely essential, if you read with above paras type of medical device handled short description site. They should match with the number of employees engaged in the production, quality control, warehousing and distribution. Use of outside scientific, analytical or other technical assistance, in relation to the design, manufacturing and testing; now, this is also very important because this also gives references to technical personnel.

If you test the product in your own laboratory, if you have technical personnel appropriate to the testing of that particular medical device in your own laboratory. If you test it outside, if you take outside technical assistance; then, that has also be mentioned and that technical assistance outside technical, which is laboratory basically should also have technical personnel appropriate for testing the particular medical device. Then, we come to short description of the quality management system, the company device details etcetera etcetera.

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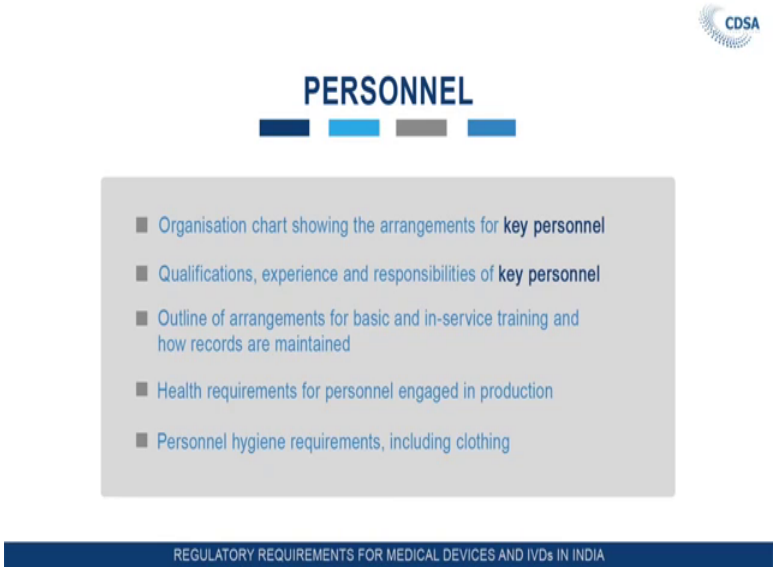

Personnel, organization chart showing the arrangement for key personnel, qualification, experience and responsibility of key personnel, outline of arrangements of basic and in-service training and how records are maintained, health requirements for personnel engaged in production personnel hygiene requirements, including clothing.

Now, in this personnel, this mentioned in the first roman I and roman II, key personnel the rules the regulation the middle device does not define key personnel, very clearly. So, I have taken the definition from some other source; which will come to a subsequent slide. It is a very important to mention over here that personnel hygiene requirements and health requirements are also very important for personnel; whether technical and non technical working in the plant. They have to undergo personnel hygiene requirements and have to have proper clothing that is uniform, which is non contaminating and they should be medically examined as per the periods mentioned in the law.

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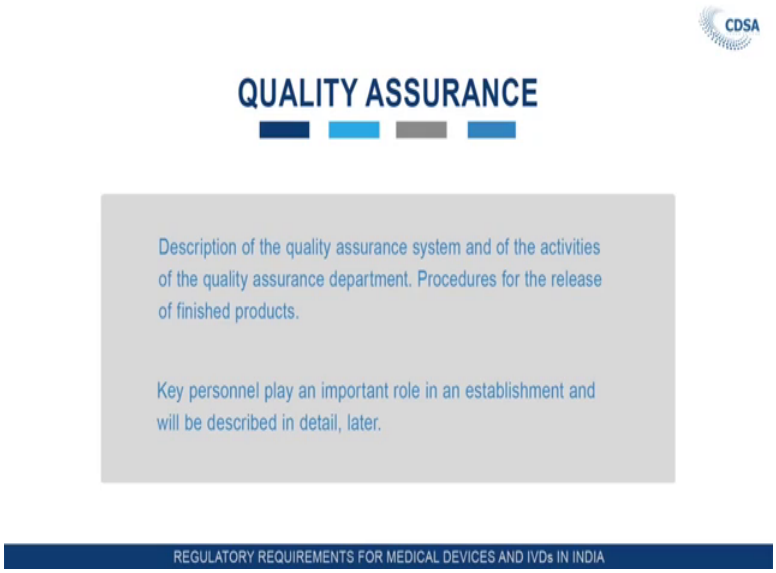

Quality assurance, description the quality assurance system and of the activities of quality assurance department, procedures for the release of finished product, key personnel play an important role in an establishment and have been described later. The below description of key personnel; now, I have come to the key personnel description.

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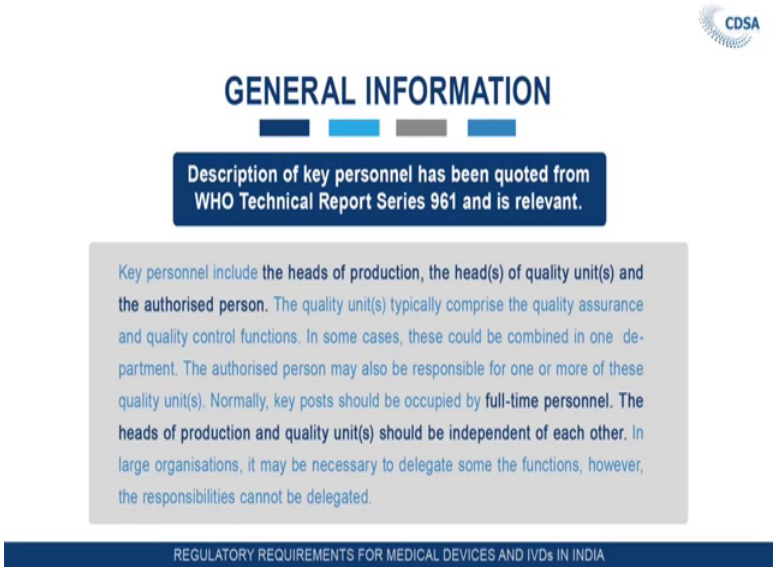

Key personnel has been quoted from WHO Technical Report Series 961 and is extremely relevant and applicable here also.

Key personnel as per the WHO definition is include the head of production, head of quality control and the authorized person. The quality units typically comprised of the quality assurance and quality control functions. In some cases these could be combined in one department. The authorized person may also be responsible for one or more of these quality units. Normally, key personnel should be occupied by full time personnel, heads of production and quality units and should be independent of each other. So, in large organizations, it may be necessary to delegate some of the functions, however, the responsibilities cannot be delegated.

So, key persons are who are the key persons? Normally, head of the production, head of the quality, quality units and the authorized persons; who is authorized person? I will come to that later on. The heads of production and quality units generally have some shared and jointly exercise responsibilities relating to quality. These may include depending on national regulations; that means, if the countries law defines something that will overrule this. The head of production has the following responsibilities mainly.

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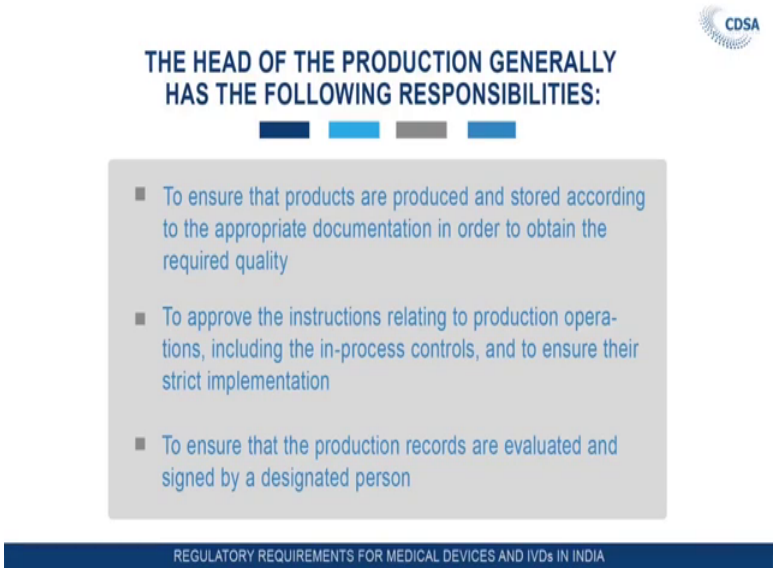

To ensure that the products are manufactured and produced stored according to the appropriate documentation in order to obtain the required quality. To approve the instructions related to production operations, including the in-process controls and to ensure their strict implementation. To ensure that the production records are evaluated and signed by a designated person.

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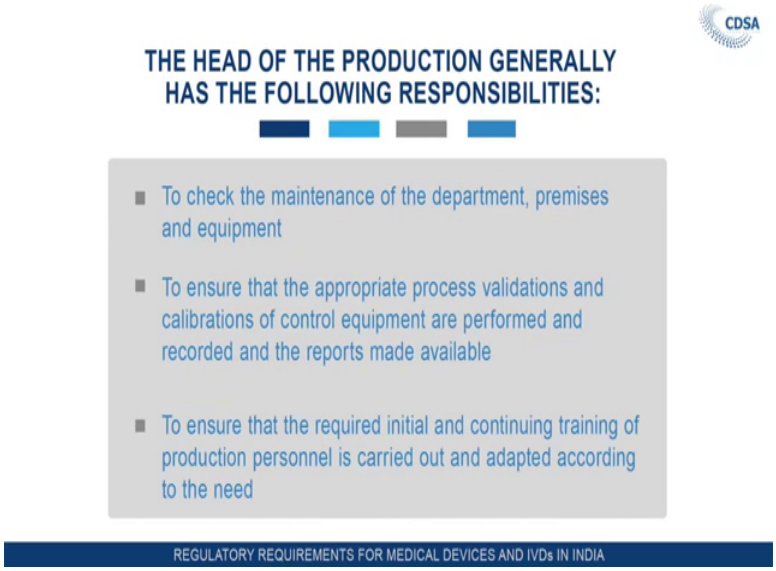

To check the maintenance of the department, premises and equipment. To ensure that the appropriate process validations and calibrations of control equipment are performed and recorded and the reports made available. To ensure that the required initial and continuing training program for training a production person is carried out and adopted according to need. Needless to add that these responsibilities are sometimes delegated to persons below the per head of the production; however, the production head is responsible at the end of the day.

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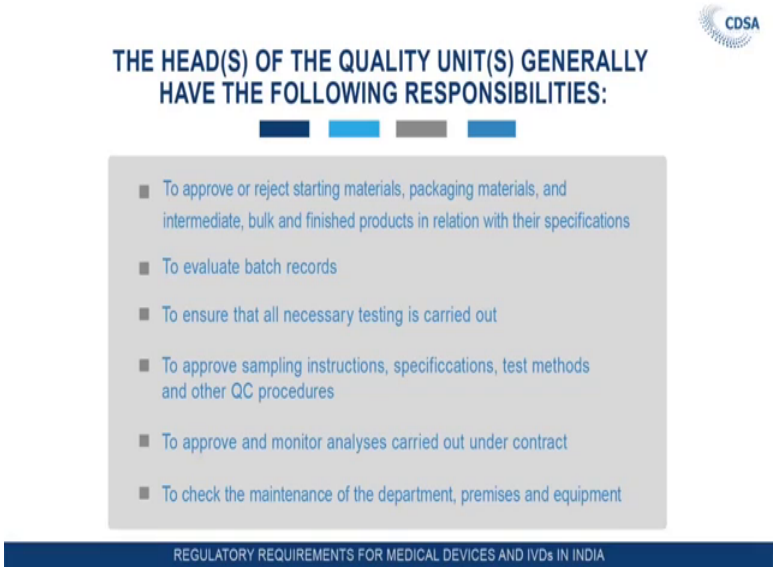

The head of quality chemistries, quality control and quality assurance came together have the following responsibilities. To approve or reject starting material, packaging material and intermediate, bulk finished products in production in relation with their specifications. To evaluate production records, to ensure that all necessary testing is carried out. To approve sampling constructions, specifications, test methods and the quality control procedures. To approve and monitor analyses carried out under a contract; to check the maintenance of the department, premises and equipment.

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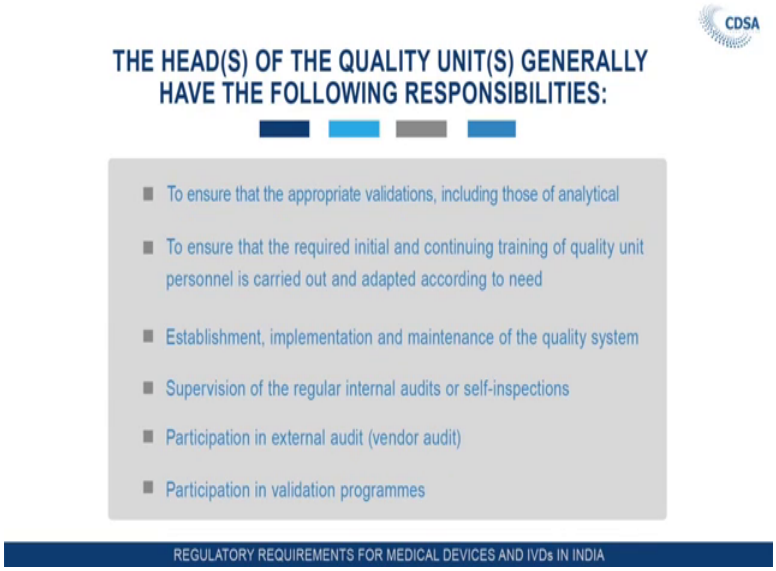

To ensure that the appropriate validations, including those of analytical procedures and calibrations of control equipments are carried out; to ensure that the required initial and continued training of quality unit personnel is carried out and adopted according to a need. Establishment, implementation and maintenance of quality system, supervision of regular internal audits or self inspections, participation of external audit that is the vendor audit, participation in validation programs.

This is the requirement generally that the head of quality units have that quality management system. Apart from what has been discussed the OMS mentioned personnel and their implant responsibilities at various places. Passing mention of, these are mentioned in the following slides to get an overview of the importance of manpower. QMS is an addition to the drug and cosmetics rules with the introduction of the medical devices as a controlled item.

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QMS was not there earlier, but now it has been introduced. 5th schedule, Rule 20 3, 20 5, 20 8 and 22 i, Quality management system for medical devices and in vitro diagnosis devices; this is in the medical device regulations 5th schedule.

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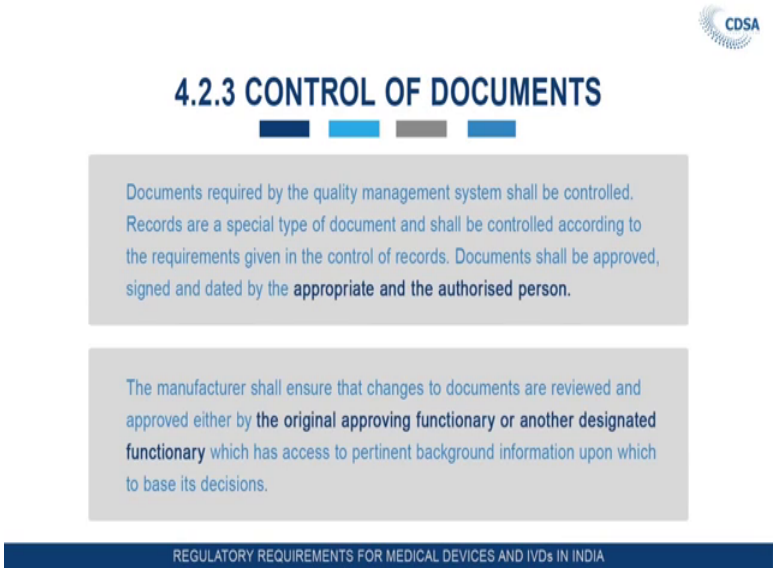

4.2.3 Control of Documents, documents required by quality management system shall be controlled. Records are specially, are a special type of document and shall be controlled according to the requirements given in the control of records. Document shall be approved, signed and dated by the appropriate and the authorized person. Now, here

comes your technical personnel; then, we have got the and end we have got the manufacturer shall ensure that changes to documents are reviewed and approved either by the original approving functionary or another designated functionary which is access to pertinent background information upon which to base its decisions.

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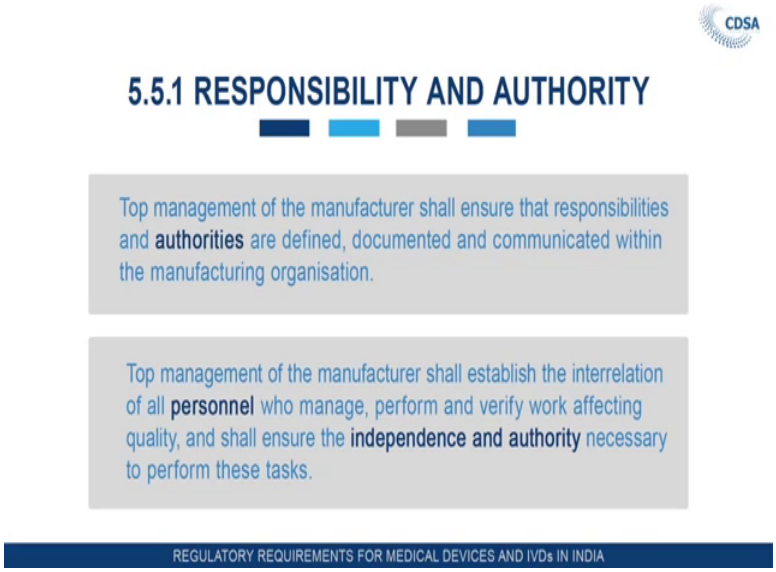

5.5.1 Responsibility and Authority, top management of the manufacturer shall ensure that responsibilities and authorities are defined, documented and communicated within the manufacturing organization. Top management other manufactures shall establish the inter relation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.

Now, the first part of it, the top management of the manufacturer shall ensure that responsibilities and the authorities as defined, documented this, will be based on the key personnels work actually, which we; I have mentioned from the WHO definitions. Similarly, the second part that is the top management of the manufacturer shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, will be based on a table to show which personnel is related to which person and who manages what?

So that, no person is independently working on his own thought process, but he is guided and controlled by his co workers everywhere, throughout the manufacturing process.

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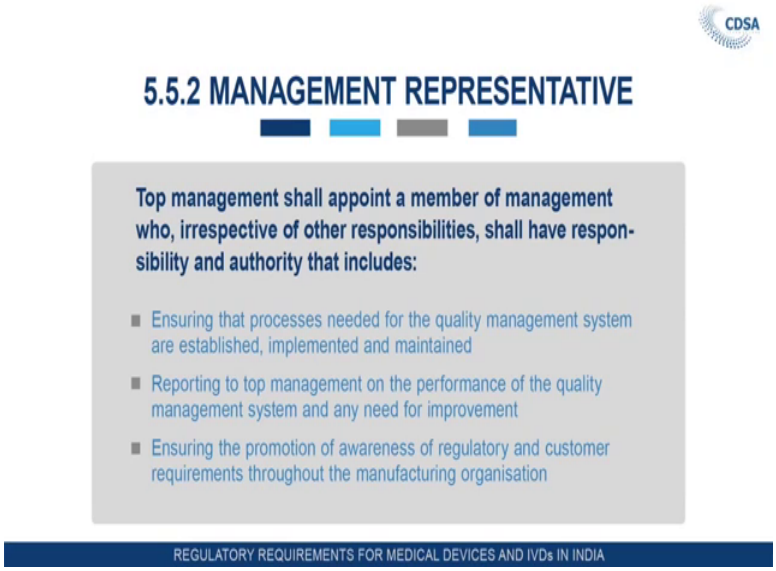

5.5.2 is Management Representative.Top management shall appoint a member of the management who, irrespective other responsibilities, shall have responsibilities and authority that include. Ensuring that the processes needed for quality management system are established, implemented and maintained; resort, reporting to top management on the performance of the quality management system and any need for the improvement and ensuring the promotion of awareness of regulatory and customer requirements throughout the manufacturing organization.

So, this manufacturing, management representative is the personnel from the top management, who will ensure that the quality management system is working properly. He may not be an expert in all these things, but he should be able to understand, what is required and he is reported to by the other members of the manufacturing and other technical personnel for their needs and their requirements. And if required, if it is not, he is not able to address those, he shall report these to the top management for compliance.

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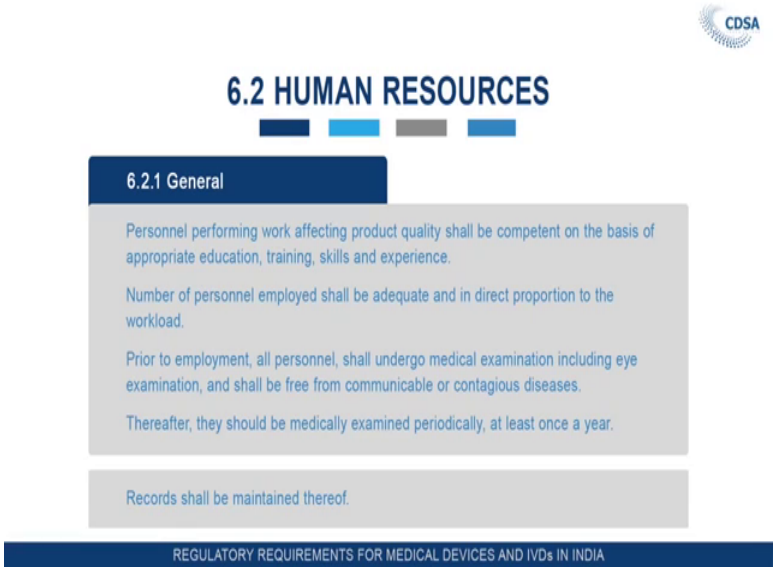

Human Resource General; now, we come back to some personnel portion of the QMS. Personnel work performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. Number of personnel employed shall be adequate and in direct proportion to the workload. Prior to employment all personnel, should undergo medical examination including eye examination and shall be free from communicable or contagious diseases.

Thereafter, they shall be medically examined periodically, at least once a year. Records shall be maintained thereof. Therefore, we see from this slide that all personnel who are appointed in a manufacturing plant of a medical device should have appropriate education, training, skills and experience. Now, even a personnel who is working in a sorting area; for sorting finished medical devices should have appropriate training and skills in that area. If not, he should be trained according to the QMS.

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Competence 6.2.2 Competence, Awareness and training, the manufacturer shall determine the necessary competence for personnel performing work affecting product quality. So, a person who is not competent to do a work shall not be put into that work, but should be put in some other work where, he is competent; provide training to us to or take other action to satisfy these needs; evaluate the effectiveness of the actions taken.

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Ensure that is person are aware of the relevance and importance of the achieve activities and how they contribute to the achievement of the quality objectives.

This means that, a personnel who is working in a area, in a manufacturing plant if he is not told the reasons for his action and he does it mechanically, he will not achieve the competence that is required. He should be explained and told, why that person is doing the particular work in a particular manner?

Maintain appropriate records of education training, skills and experience and established documented procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. This training is very very important in QMS and this training should be important to not only workmen and middle level workers, but also to competent technical staff now and then.

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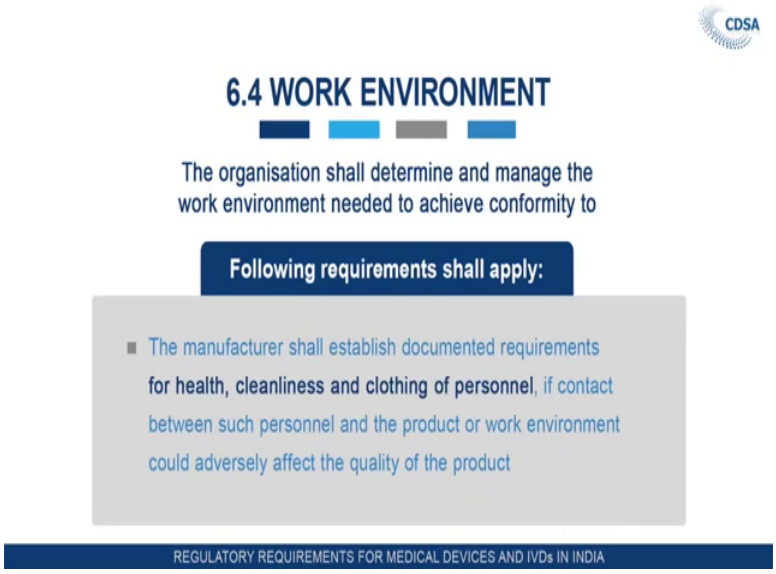

Work Environment; the organization shall determined and manage the work environment needed to achieve conformity to product requirement. Following the requirement shall apply namely. The manufacture shall establish documented requirements for health, cleanliness and clothing a personnel very important personnel, cannot enter the premises in the clothes that he is wearing from outside. He should change it to factory clothing, he should be clean, he should be told to maintain a good degree of personnel hygiene.

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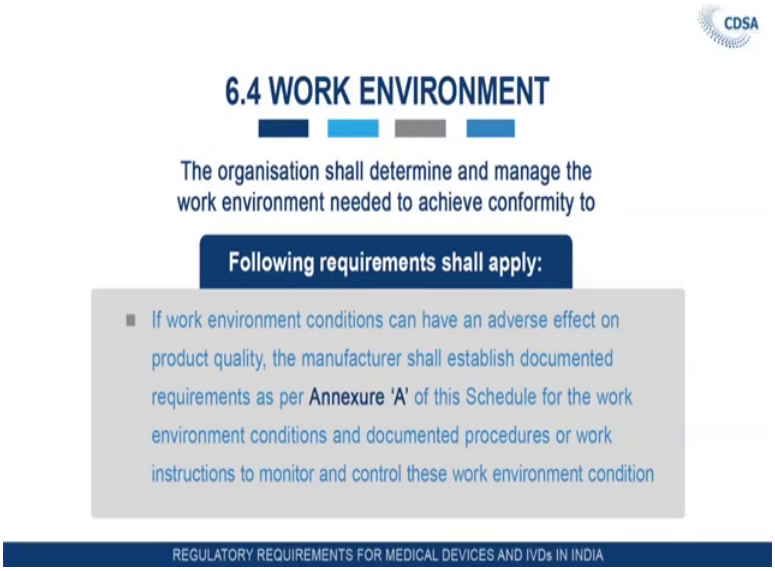

If work environment conditions can have an adverse effect on product quality, the manufacturer shall establish documented requirements as per Annexure A of the schedule for the work environment conditions and documented procedures of work instructions to monitor and control these work environmental conditions.

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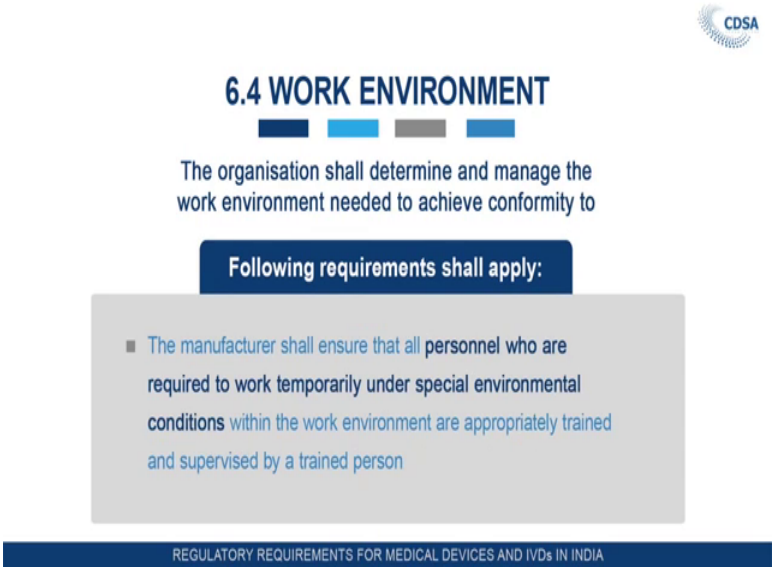

The manufactures shall ensure that all personnel who was required to work temporarily under special environment conditions within the work environment are appropriately trained and supervised by a trained personnel; that means, today these days firms employ

a temporary workers on a daily wage basis. These workers are the most dangerous workers as for as the environmental safety of product is concerned.

They are usually given to unskilled works likes stacking of ballots and unloading and unloading. But if they are required to be put in special areas where, a skill is required for working; they should be clearly trained and adjust to be able to work in those environments.

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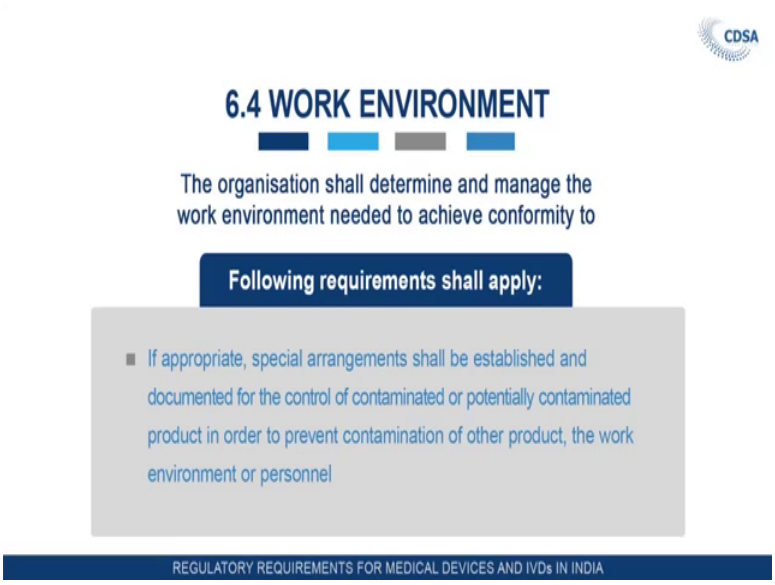

If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated products in order to prevent contamination of other products, the work environment or personnel.

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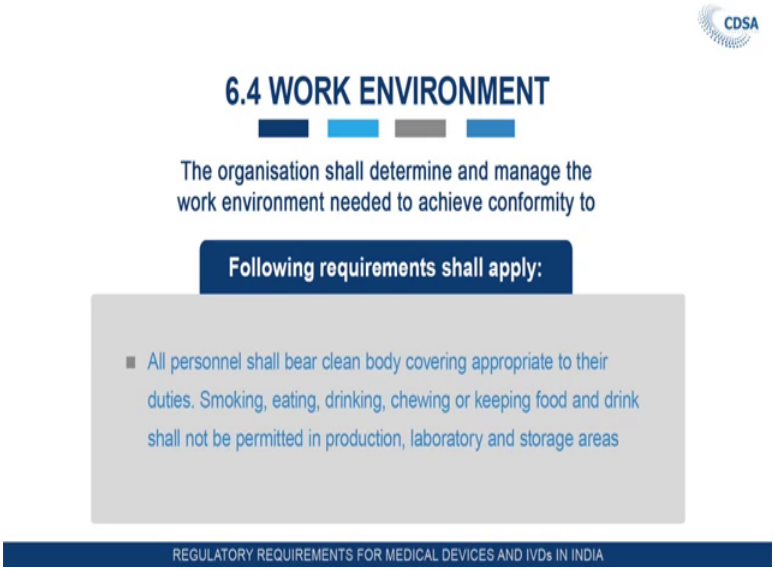

All personnel shall be air where, clean body covering appropriate to the ration. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production laboratory and storage areas. This is very very important as it is understood from the sentence itself.

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It is apparent that competent technical personnel and other personnel play a very vital role in the quality of a medical device. It is the collective responsibility of everyone to ensure that they carry out the assign responsibilities as to the procedures to get a required

product of appropriate quality. It is well known that quality management system ensures that quality is built into the product and that the final testing release does not guarantee performance. What it means, in nutshell is that you cannot test a medical device; some of the medical device can be tested destructively, but most cannot.

So, you like a drug; which is a sample is taken from the final lot and destructively tested; it does not affect the final quality of the product, but you can get a general idea of the quality of the product in that destructive testing. In case of medical devices, a product cannot be destructively tested. For instance, a manufacturer manufacturing say 20 stents per day; each stent costing around 20000 rupees.

You cannot expect a manufacturer to take one of those stents in their laboratory and one to the job. It will be like a number of more than one. To be taken to the laboratory and tested in a manner which can destroys the product. So, the quality has to built in the product and a major component for building that quality in the product is manpower, technical and otherwise.

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Now, some of the question and answers over are over here, very simple one; however, you will be getting much more question and answers, we have to submit later on for assessment.

Thank you very much.