

**Regulatory Requirements for Medical Devices including In Vitro Diagnostics in
India (Version 2.0)
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**Lecture – L7
Quality Assurance and Quality Management System**

Dear friends, welcome to Regulatory Requirement for Medical Devices and In Vitro Diagnostics in India, lecture 7. Lecture 7 that is Quality Assurance and Quality Management System. What is the Quality Management System (QMS)? What is the Quality Assurance (QA) and Quality Control (QC) of the medical devices, you will understand in this lecture. This lecture will be given by Mr. Malay Mitra, former Deputy Drugs Controller who have lot of exposure and experience in the regulation of the medical devices and in vitro diagnostics. In this lecture, you will also understand where the provisions of the quality management system has been given in the medical device regulation.

In the previous lecture, we have discuss that the quality management system (QMS), Medical Device Rule 2017, fifth Schedule has been prescribed, fifth schedule has given the details of the quality management system for manufacturing of in vitro diagnostics and medical devices in the country. This quality management system, which is in the line of the internationally accepted quality management system as per ISO 13485 that has been prescribed with certain modification.

What modification we have included in the fifth schedule of the medical device regulation to have the harmonized or clarity on the Device Master File (DMF) and the Plant Master File (PMF), what will be the details of the requirement. All clearly prescribed in the fifth schedule that is the one of the additional part which have been included in the fifth schedule. So, the manufacturer, indigenous manufacturer of the medical devices, manufacture of the medical devices which are presently regulated has to confirm the requirement of the quality management system as prescribed in the fifth schedule of the Medical Device Rule 2017.

So, why this quality management system has been incorporated, why not the quality management system? Because the quality management system have 4 different

management system? Because the quality management system have four different major component. What will be the component for the quality management system? GMP is one of the part of the quality management system.

In the GMP, there is a interaction between the development of the medical devices and GMP, but there is no interaction between design of the medical devices and the Good Manufacturing Practices (GMP). And also if you see the quality risk management of the medical devices, the minimum ,there is a minimum interaction between the risk management of the medical devices and the GMP. However, in the quality management system there is a interaction between the design of the medical devices, development of the medical devices with the quality risk of the medical devices and also GMP.


GMP also included in the quality management system (QMS). So, the detail of the quality management system that you will understand in this lecture.why GMP was replaced with the QMS. The reason also you will understand in the forth coming that lecture which will be given by Mr.Malay Mitra. And also during the presentation you will understand what are the Quality Control (QC) parameter for the medical devices and in vitro diagnostics, what is the difference of quality control and quality assurance. So, all those topic you will understand in the lecture this detail lecture which will be given by Mr.Malay Mitra, Deputy Drugs Controller.

So, concentrate on the lecture and enjoy the lecture. If you have any doubt you ask, we will try to clarify that information further in future.

Thank you very much.

Today, we are going to go through the quality assurance (QA) and quality management system (QMS) under the new regulations of medical devices. This is part of the series of presentations on medical devices and this forms the bedrock of the manufacturing of medical devices. This forms part of the ISO 13485 which is universally accepted and applied on medical devices all over the world.

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WHAT IS QUALITY ASSURANCE?

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WHO says quality assurance (QA) is a wide ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals, quality assurance can be divided into four major areas: quality control, production, distribution, and inspections.

This can be applied to devices also.

Every aspect of the manufacturing system is controlled at every step in a QA process in such a manner so that the final product confirms to the requirement.

QA system covers design and development, manufacturing procedures, packaging, manpower, training, testing, release, documents and its control and any other activity related to the whole process of manufacturing.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, before we proceed further, let us first understand what is Quality Assurance (QA). WHO definition of quality assurance is, it is a wide ranging concept covering all matters that individually or collectively influence the quality of a product. With regard to pharmaceuticals quality assurance can be divided into 4 major areas that is quality control, production, distribution and inspection. This can be de applied to devices also because all this 4 parameters in the manufacture of a medical device drug are also applied to medical devices.

In applying QA system, every aspect the manufacturing system is controlled at every step in such a manner, so that the final product confirms to requirement. Quality assurance system covers design and development, manufacturing procedures, packaging, manpower, training, release, testing, documents and its control, and in any other activity related to the whole process of manufacturing. What it means is that the QA system is a all encompassing system which covers everything in the manufacture of a medical device, right from the time the raw material enters the plant and it is released as a finished product to go into the market. Even the distribution is covered under QMS system.

it covers. What does it cover? The quality assurance cover the design of the medical device, its developmental stage before its product wise approved for manufacture, the

manufacturing procedure, the packaging containers, the manpower the people that are working in the plant, the its covered by that training of the manpower, testing, etc.

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IS QUALITY ASSURANCE THE SAME AS QUALITY CONTROL?

Quality control (QC) is part of quality management system that fulfills certain requirements of quality assurance system.

While quality assurance (QA) ensures and control the whole process, quality control does the task of inspection and testing.

It is therefore clear that both QA and QC forms part of the quality management system.

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Is quality assurance the same as quality control? This is one of the very major confusions in the mind of people who are working in the manufacturing of drugs and medical devices. Is quality assurance the same as quality control? Let us see.

Quality control is part of quality management system that fulfils certain requirements of quality assurance system. It means that quality management system has called various verticles one of which is quality control system part of it is quality control system. And along with quality control stable other important parameters the QMS becomes a whole. While Quality Assurance (QA) ensures and controls the whole process, quality control does the task of inspection and testing. It is therefore clear the quality control forms part of the QA system. Quality assurance ensure the control of the whole process, the whole plant, whole everything, while quality control inspects a particular area and the finish product under the quality management system (QMS).

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QUALITY MANAGEMENT SYSTEM

Its frequently queried, if the product is tested at the end of production, why control the whole process?

In Quality Management System (QMS), QA during manufacturing ensures that each step, each component, each procedure is under documented control to conform to the requirements.

Final testing at the time of release can only ensure the conformance of the product to physical parameters only.

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It is frequently queried if the product is tested at the end of production, why control the whole process? This is a very common question. I manufacture a medical device in my plant and at the end of the day will manufactured and packed, I send it to my laboratory for a complete testing of the medical device and it complies to the standards required. So why do I required QA system at all? This was very common in the earlier days. However, it was seen that the medical device failed while in use and therefore, it was ensured that quality assurance during manufacturing ensures that each step, each component, each procedure is under documented control to confirm to the requirements.

Final testing at the time of release can only ensure the conformance of the product the physical parameters. What it means is that quality assurance during manufacture ensure the each step, remember each step means manufacturing is a combination of different steps in the whole process. So, each step, each process is controlled and is controlled by people who are trained for that process and whatever they are doing is written down and documented. And therefore, what happens is that you built in quality right from the very beginning to the end.

So, in case your QMS is very very strong you may not require to test the final product at the end of the day, and it happens quite often when the product is very costly product. You cannot test it by destroying it; you have to put quality into it, for the final product that goes out conforms your requirement.

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SCHEDULE M III

Schedule M III, good manufacturing practice (GMP) for medical devices was effective under the Drugs & Cosmetics Rules 1945 as long as the Medical Device Rules, 2017 was non-existent. It helped the manufacturers as a guide in the earlier regulations.

The relevant areas of the Schedule M III has been incorporated in the Fifth Schedule (quality management system) of the Medical Device Rules, 2017, which is effective from 01.01.2018.

Therefore, this schedule is infructuous now.

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Now, a bit of Schedule M III: Schedule M III GMP for medical devices was effective under the drug and cosmetic rules 1945 as long as the medical device rule 2017 was non-existent. It helped the manufacturers as a guide in the earlier regulations. So, till 2017 end, all manufacturers were following schedule M III as a good manufacturing practice document. That document was a simplistic document and it gives you yes and no's in manufacturing what you have to do what you have not do. But it was not a comprehensive multi management system as required under 13485 ISO which is applicable all over the world.

So, for all manufacturers to follow 13485, so that we are in sync with the rest of the world this ISO has been adopted by the new regulation, the relevant areas of schedule M III. However, has been incorporated in the QMS system. So, you are not missing out on anything without the schedule M III not being there, but you are adding value to the schedule M III by way of accepting schedule ISO 13485.

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ISO 13485

ISO 13485 is not the only document required in QMS of medical devices. There are other ISO guidelines, namely:

- ISO 14971: 2007- This is an international standard (medical devices- application of risk management to medical devices) was issued in 2007
- ISO 10993-1: 2009- Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process

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Now, ISO 13485 is a mother document. You have to follow 13485 if you want to manufacture medical device. BIS has also got a equivalent ISO 13485 which is it has adopted in Toto.

Now, what are the other ISO required under this umbrella 13485? You require ISO 14971 which is an international standard that ISO issued in 2007. The title is medical devices application of risk management system. So, risk management is covered under this ISO 14971. In case you have to you encounter a risk in the in the whole process, this will apply and guide you to manage that risk. ISO 10993 is the biological evaluation medical device. If the medical device has to be evaluated biologically, then this ISO is required to be applied over there.

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ISO 13485

ISO 13485 is not the only document required in QMS of medical devices. There are other ISO guidelines, namely:

- IEC 62366-1: 2015, medical devices- Part 1: Application of usability engineering to medical devices
- ISO has issued ISO/TR 14969: 2004, medical devices- Quality management systems- Guidance on the application of ISO 13485:2003

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IEC 62366 is applicability of usability of engineering to medical devices that this is basically engineering a portion of the ISO under the ISO 13485.

ISO also has issued, ISO 14969, 2004, medical devices quality management system guidance. Now, this ISO is guidance to the application of 13485. So, if you want to apply 13485 into your system in a plant, you have to go through this ISO to understand how to apply that. So, it is become very user friendly ISO in case you want to apply 13485.

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ISO 13485

ISO 13485 is not the only document required in QMS of medical devices. There are other ISO guidelines, namely:

- ISO 14971: 2007- This is an international standard (medical devices- application of risk management to medical devices) was issued in 2007
- ISO 10993-1: 2009- Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process

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We will however, confine ourselves to ISO 13485 which is a Quality Management System(QMS) because going into all these ISOs at a go will it is not possible in one presentation, it will require days and days of understanding and presentations.

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QUALITY MANAGEMENT SYSTEM
(DERIVED FROM ISO 13485)

CDSA

Fifth Schedule
[See rule 20(3), 20(5), 20(8), 22(i)]
Quality Management System for medical devices and *in vitro*
diagnostic medical devices

The fifth schedule of the Medical Device Rules 2017 describes in detail
the quality management system that has to be followed by a medical
device establishment.

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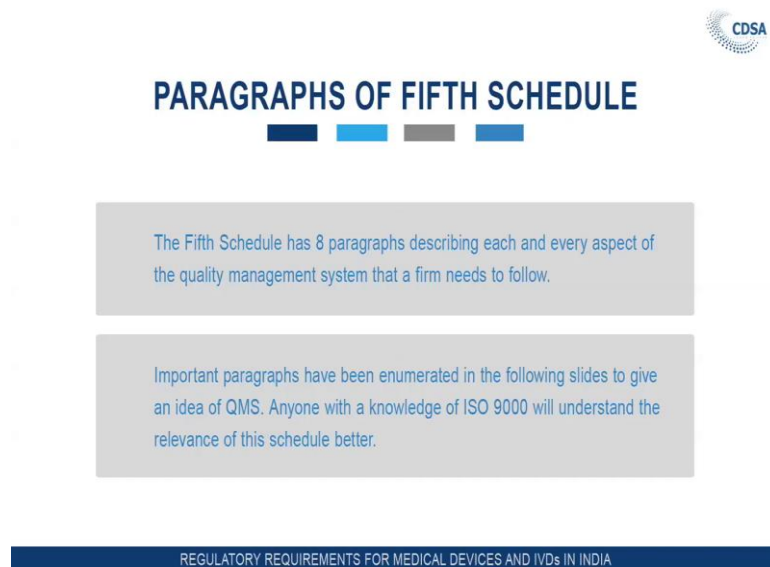
ISO 485 which is the mother for our quality management system is in the fifth schedule of quality management system for medical devices and in vitro diagnostic medical devices motion of the Medical Device Regulation 2017. The fifth schedule of the

Medical Device Rule 2017 describes in detail the quality management system that has to be followed by a medical device establishment.

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The Fifth Schedule has 8 paragraphs describing each and every aspect of the quality management system that a firm needs to follow.

Important paragraphs have been enumerated in the following slides to give an idea of QMS. Anybody having some interaction with the ISO 9000 will understand the relevance of the schedule.

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PARA 1 GENERAL REQUIREMENTS

Main focus: QMS is complementary to the technical requirement for products and do not replace them.

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Part 1, general requirement among other thing it is the QMS complementary to technical requirements for products and do not replace them. This is important. If you have technical requirements of a product they are not to be replaced with QMS. QMS will complement and help those technical requirement reach its ultimate goal.

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PARA 2 APPLICABILITY

The provisions of this schedule shall be applicable to manufacturers of finished devices, *in vitro* diagnostic medical devices, mechanical contraceptives (condoms, intrauterine devices, tubal rings), surgical dressings, surgical bandages, surgical staplers, surgical sutures and ligatures, blood and blood components collection bags with or without anticoagulants.



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Part 2 is applicability. The provisions of the schedule shall be applicable to manufacture of finished devices, *in vitro* diagnostic medical devices mechanical contraceptives, condoms, intrauterine devices, tubal rings, surgical dressing, surgical bandages, surgical

stapler, surgical sutures and ligatures, blood and blood component collection bags with or without anticoagulants. These items have been notified in the Drug and Cosmetics Act, and under the act and in case there are other items added under the act and notified they will also fall in this part to applicability portion.

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PARA 3: TERMS AND DEFINITIONS

This para gives the definition of certain terms which are as follows:

- 3.1 Active implantable medical device
 - 3.2 Active medical device
 - 3.3 Advisory notice
 - 3.4 Customer complaint
 - 3.5 Implantable medical device

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Terms and definitions (T&C), part 3 is the terms and definitions in the regulations. The para gives the definitions of certain devices which are as follows. 3.1 is active implantable medical device, 3.2 is active medical device, 3.3 is advisory notice, 3.4 is customer complaint, 3.5 is implantable medical device.

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PARA 3: TERMS AND DEFINITIONS

- **3.18** Validation means confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled
- **3.18.1** Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA


3.18 I have picked up the relevant paragraph. So, there are there may be a few paragraphs in between which are not as important as these, but if you go through these paras, you can understand those paras also.

3.18 is a very important para. Validation means confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistent to fulfil. That means, you may come across the word validation in this whole regulations here and there or not even here may be in other documents that you go through internationally. Now, what does validation mean? Validation means you confirm by examination and provisions of objective evidence that whatever you are doing in a particular manufacturing activity can be consistently fulfilled.

3.18.1 is the process validation which means establishing by objective evidence that a process consistently produces a result or product meaning its predetermined specifications. I am sure the language is very simple to understand, but in case you want to understand further from this I can explain that. Process validation is a system by which you have to divide; first of all you can divide the whole process A to Z into small segments. The each segment does its small work to change the raw material into the final product. Each of those segments have to be validated as a simple process, separate entity and the process.

Now, once you do that that process validation will prove or it will verify that the end result of that process is consistent batch after batch, product after product.

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PARA 3: TERMS AND DEFINITIONS

- **3.18.2** Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s)
- **3.19** Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

3.18.2, design validation means establishing by objective evidence that device of specifications conform with users need and intended uses. Design validation comes into place when you design a product; you have to design a product before it goes into commercial manufacturing. Therefore, when you are drawing board designing a product for a particular activity in the human body. You have to have this design qualification done and validate that whole design before you going for actual manufacturing.

3.19 is verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In this case, verifications means actually in a way in a simple language it is testing basically. We have to have objective evidence has specific requirement; that means, you have to verify that a particular item is 6 inches long at a particular process. It you have to verify that it is 6 inches long in that process which is been verified by process validation.

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PARA 4 QUALITY MANAGEMENT SYSTEM

- 4.1 General: The manufacturer shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this schedule. The manufacturer shall:
 - Identify the processes needed for the quality management system and their application throughout the organisation
 - Determine the sequence and interaction of these processes
 - Determine criteria and methods needed to ensure that both the operation and control of these processes are effective

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Para 4, quality management system: General, the manufacturer shall establish, document, implement and maintain a quality management system that and maintain its effectiveness in accordance with the requirement of this schedule. That means, he shall establish a QMS, he shall document everything that is done over there in the QMS and implement that in the plant to maintain the Quality Management System(QMS).


The manufacturer shall, I will define the process needed for quality management system and their application throughout the organisation. He has to identify the processes, the small process that I mentioned earlier those processes have to be identified by the management, and they have to be put forward for as a part of the validation system.

B, determination determine the sequence and interaction of these processes; that means, one process, process a will precede process b and process b will precede process c, you cannot have process a and then process f and come back to process b. The sequence have to established and the interaction of these processor one process will follow the next process the sequence and the interaction these processes have to be established.

Determined criteria and methods need to assure that both the operation and control of this f processes are effective. You have to have a criteria and a system by which you have to ensure that both the operations and control, operations means you are doing it regularly a process and control mean that that regular process that you having doing is

controlled by way of a method. So, these have to be effective and the management has to establish.

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PARA 4 QUALITY MANAGEMENT SYSTEM

- 4.1 General: The manufacturer shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this schedule. The manufacturer shall:
 - Ensure the availability of resources and information necessary to support the operation and monitoring of these processes
 - Monitor, measure and analyse these processes
 - Implement actions necessary to achieve planned results and maintain the effectiveness of these processes

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

D, ensure the availability of resources and information necessary to support and the operation and monitoring these process. Remember resources means not only money, resources means manpower, resources mean machinery, resources means any other thing is required to monitor of the process. So, the management should ensure the availability of everything that is required to ensure the QMS system.

Management should monitor, measure and analyze these processes. You have seen that this is this is part of the validation and verification process. Implement actions necessary to achieve planned results and maintain the effectiveness of these processes. Implement actions necessary to achieve planned results; that means, in case if a result that you are getting is not what you have required then to implement the change that method, so that the end result remains the same year after year, month after month.

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PARA 4 QUALITY MANAGEMENT SYSTEM

These processes shall be managed by the manufacturer in accordance with the requirements of this schedule. Where a manufacturer chooses to outsource any process that affects product conformity with requirements, the manufacturer shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE: Processes needed for the quality management system referred to above shall include processes for management activities, provision of resources, product realisation and measurement.

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These processes shall be managed by the manufacturer in accordance with the requirements of the schedule. Where a manufacturer chooses to outsource any process that affects product conformity with requirements the manufacturer shall ensure control over such processes. Control of such outsourced process shall be identified within the quality management system.

Note is that processes needed for the quality management system referred to above shall include process of management activities, provision of resources, product realization and measurement.

Second line is very important. It says that when a manufacturer chooses to outsource any process that affects the product conformity with requirement. That means, I manufacture a medical device a part of it or a component of it is been manufactured by somebody else under my contract. Now, in that case I am responsible for the QMS of that contract manufacturer's process also. So, I have I am have added responsibility for that.

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The slide features the CDSA logo in the top right corner. The main title is 'PARA 4.2 DOCUMENTATION REQUIREMENTS' in bold blue text, with a decorative bar of four colored segments (dark blue, light blue, grey, dark blue) below it. A dark blue box contains the sub-section title '4.2.1 General'. Below this, a light grey box contains a bulleted list of requirements. At the bottom, a dark blue bar contains the text 'REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA'.

- The quality management system documentation shall include:
 - Documented statements of a quality policy and quality objectives
 - A quality manual
 - Documented procedures required by this schedule
 - Documents needed by the manufacturer to ensure the effective planning, operation and control of its processes
 - Records required by this schedule

Part 4.2 is documentation requirement. This is extremely important, extremely important. Generally is a quality management system documentation shall include, documented statements of quality policy and quality objectives, a quality manual, documented procedures required by the schedule, document needed by the to ensure the effective planning operation and control processes requires, records required by this schedule.

Remember, a document which is not just statement of quality and quality objective that is of course, over there we find them framed and put on the walls in the company that is very important to remind the people working over there the quality policy and the systems. However, each activity that is carried out in the plant, each when I say each activity I mean each activity right from the way the personnel or recruited, trained, put into operation how a switch in a machineries operated all these have to be documented and each one of the action that is taken care of is again documented that process has been done.


So, documentation is extremely important objective of QMS. In case of documentation the benefits are that in case something goes wrong somewhere we can trace the source of that problem with the help of documents. Documents are interlinked and you can go down to the source of the problem and rectify that.

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PARA 5.2: CUSTOMER FOCUS

Top management of the manufacturer shall ensure that customer requirements are determined and met.



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Customer focus: This is we know need to emphasize that customer requirements are determined and are met management of the manufacturers are ensure. That means, if I manufacture something, a pen or whatever, it has to be to the satisfaction of the ultimate end user who is the customer. So, our production should be customer focused.

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PARA 5.3 QUALITY POLICY

- Top management of the manufacturer shall ensure that the quality policy:
 - Is appropriate to the purpose of the manufacturing facility
 - Includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system
 - Provides a framework for establishing and reviewing quality objectives
 - Is communicated and understood within the manufacturer's organisation
 - Is reviewed for continuing suitability

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

5.3 is Quality Policy (QP): what is the quality policy of a plant? Quality policy is top management of the manufacturer shall ensure that the quality policy is appropriate to the purpose of the manufacturing facility. You cannot have a quality policy of something

else applied to your plant, it should be appropriate to the purpose of the manufacturing the timed way. Include a commitment to comply with the management requirements and to maintain the effectiveness of quality management system. Provides a framework for establishing and reviewing quality objectives, is communicated and understood within the manufacturer's organisation and is reviewed for continuing suitability. These each of these lines are self-exploratory and they do not need to be elaborated further.

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PARA 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

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 organisation. Top management of the manufacturer shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

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Responsibility authority and communication, 5.5.1: responsibility and authority, top management of the manufacturer shall ensure that the responsibilities and authorities are defined, documented and communicated within the manufacturing organisation. Top management of the manufacturer shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

We must ensure, we must emphasize over here other that in this case the ISO or QMS has roped in the top management of the company, the Directors or whoever the owners. They are also responsible for quality. It is not only the shop floor people or the technical people. The top management shall ensure the necessary resources and facilities are provided and they shall be held responsible if it is not there.

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PARA 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

5.5.2 Management representative:

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:

- Ensuring that processes needed for the quality management system are established, implemented and maintained
- Reporting to top management on the performance of the quality management system and any need for improvement

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Management Representative: who is a management representative? This is a management representative you can find in ISO 9000; also now this is replica of that only.

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority to that include, ensuring that a process needed for the quality management system are established implemented and maintained. Reporting to top management on the performance of the quality management system and any need for improvement and ensuring the promotion of awareness of regulatory and customer requirement for the manufacturing organisation. That means, top management shall appoint a member of management; that means, top management system Directors who will appoint a person as a management their representative for overseeing the whole process of QMS. He shall be responsible for as a communicating link between the top management and the plant to pass on the messages and improve things.

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PARA 5.6 MANAGEMENT REVIEW

4.2.1 General

Top management shall review the organisation's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained.

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Management review: General, top management shall review the organisations quality management system, at planned intervals, to ensure its continuing suitabilities, adequacy and effectiveness. This is also the responsibility given to the top management. The top management cannot say that since I am a top management I am a director of the company or we are the directors of the company, so we are not responsible for this. They are fully responsible as per this para 5.6.1.

This review shall include assessing opportunities for improvement and the need for changes to the quality management system including the quality policy and quality objective. Records from management review shall be maintained. It does not mean that the top management can be an expert or should be an expert in a particular medical device. He has to sit down with the management representative and the technical persons and discuss and decide for going forward further.

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PARA 6.2 HUMAN RESOURCES

6.2.1 General:

Personnel 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, shall undergo medical examination including eye examination, and shall be free from communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof.

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Human resources: General, human resources means people working in the plant. Anybody, it can be the guard of the gate to the technical person who is actually overseeing the production. Personnel 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. These are all simple easy to understand sentences. Prior to employment, all personnel shall 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.

Personnel performing work affecting the first line affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. Now, as I gave the example of a gate the guard over there may allow a truck containing material to come inside the plant after examining the suitable suitability of documents to show that the plant requires that and then verify, then allow. So, everybody that is working in a plant has some sort of responsibility under the QMS and he has to follow that.

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PARA 6.2 HUMAN RESOURCES

6.2.2 Competence, awareness and training:

The manufacturer shall:

- Determine the necessary competence for personnel performing work affecting product quality,
- Provide training or take other actions to satisfy these needs
- Evaluate the effectiveness of the actions taken

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

6.2.2, competence, awareness and training: the manufacturer shall determine the necessary competence for personnel performing work affecting product quality. Provide training or take other actions to satisfy these needs. Evaluate the effectiveness of the actions taken, Ensure that its personnel or aware of the relevance and importance of the activities and how they contribute to the achievement of the quality objective. Maintain appropriate records of education training skills are required experience and establish documented procedures for identifying training needs and ensure that all personnel trained and adequately perform the assigned (Refer Time: 29:24). These all these provisions were there in schedule M III in a different language.

So, this is not something new for any manufacturer. Training is very important and we know that training is actually improves quality, so they have to be trained. The evaluation of the training has to be done of the people who are taking the training, then they should be made aware of what they are doing. These are all records that have to be maintained of the training. These all are schedule M III, but in this it is a language of ISO basically which explains them.

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PARA 6.3 INFRASTRUCTURE

The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- Buildings, workspace and associated utilities
- Process equipment (both hardware and software)
- Supporting services (such as transport or communication).
The manufacturer shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained



REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Infrastructure, we come to the breaker mortar now. The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to the product requirement infrastructure includes, as applicable. Buildings, workspace and associated utilities, Process equipment both hardware and software and supporting services such as transport or communication. The manufacturer shall establish documented requirement for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality, Record of such maintenance shall be maintained.

Now, this is very easy to understand. When they say that infrastructure means building workplace and associated utilities, it does not simply mean that you should have a building or workplace. Building and workplace are again controlled by different paragraph, what kind of building you require, what is infrastructure you require, the workplace, process equipment those are covered elsewhere. But this actually tells you that all these have to be controlled under the infrastructure 6.3.

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PARA 6.4 WORK ENVIRONMENT

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements. Following requirements shall apply, namely:

- The manufacturer shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product
- If work environment conditions can have an adverse effect on product quality, the manufacturer shall establish documented requirements as per Annexure- 'A' of this schedule for the work environment conditions and documented procedures or work instructions to monitor and control these work environment condition

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Working environment: the organisation shall determine and manage the work environment needed to achieve conformity to product requirements. So, the environment that is used for the manufacture of these products should conform to the product requirement. Remember, the product should not conform to the environment, but the environment should be design for whatever the product a finally is. Following requirement shall be shall apply,namely.

The manufacturer shall establish document requirements for health, cleanliness and clothing of all personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product. That means in simple language, if an operation requires that the personnel shall wear gloves and full body suit that is part of it. If they required to wash their hands and feet before entering an area, that forms part of the environment. B says if work environment conditions can have an adverse effect on the product quality the manufacturer shall establish documented provision requirement as per annexure 'A' which is later on of the schedule for the work environment conditions and documented procedures for work instructions to monitor and control these work environment condition.

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PARA 6.4 WORK ENVIRONMENT

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements. Following requirements shall apply, namely:

- The manufacturer shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained and supervised by a trained person
- If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The manufacturer shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained and supervised by trained personnel. What does it mean? What does the c mean? c simply means in our Layman's term, that who are required to work temporarily means either they are temporarily appointed or for short term basis to work in that environment or if I take it to a different level all together if a machine in a special environment is broken down and the maintenance people have to enter that premises he works there as temporarily. So, he shall be trained for that environment properly.

If appropriate, general special arrangement shall be established and documented for the control of contaminated or potentially contaminated products in order to prevent contamination of the product, the work environment or personnel. So, if a product has to be sterile, we have to have documented and established control of such product manufacturing. Special arrangement means it should have a clean room, clean air supply and all those stuff. So, the product personnel as well as the product is saved from contamination.

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PARA 6.4 WORK ENVIRONMENT

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements. Following requirements shall apply, namely:

- All personnel shall bear clean body covering appropriate to their duties. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production, laboratory and storage areas.

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All personnel shall bear clean body appropriate to their duties. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production laboratory. So, this is part of the line 3 which very clearly says these things.

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7.2.3 CUSTOMER COMMUNICATION

The manufacturer shall determine and implement effective arrangements for communicating with customers in relation to:

- Product information
- Enquiries, contracts or order handling, including amendments
- Customer feedback, including customer complaints and
- Advisory notices

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Customer communication: the manufacturer shall determine and implement effective arrangements for communicating with the customer in relation to; product information, enquiries, contract or other order handling, including amendments, customer feedback including customer complaints and advisory notes. So, a manufacturer is not only the

product of the manufacturer should not only be oriented towards the physician or the personnel who is going to apply those products on a human body, but even the customer himself. In case, it is a patient the patient has to have the product information too.

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7.4 PURCHASING

7.4.1 Purchasing process:

The manufacturer organisation shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product. The manufacturer shall evaluate and select suppliers based on their ability to supply product in accordance with the manufacturer's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

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Purchasing process, 7.4.1: the manufacturer organisation shall establish documented procedures to ensure that purchased product conforms to specified purchase requirement. The type and extent and control applied to the supplier and the purchase product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. The manufacturer shall evaluate and select suppliers based on their ability. This paragraph basically is vendor evaluation in a common GMP terms.

Whenever you want to purchase a particular item from outside you have to evaluate that product that you are purchasing is confirming to your final product and it is useful in that case. The vendor there is supplying to you is conforms to quality management system and he is able to supply you with that product of consistent quality time after time. So, its vendor selection, evaluation and revaluation shall be carried out.

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7.4 PURCHASING

7.4.3 Verification of purchased product:

The manufacturer shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the manufacturer intends to perform verification at the supplier's premises, the manufacturer shall state the intended verification arrangements and method of product release in the purchasing information. Records of the verification shall be maintained.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Verification of purchased product: this is basically in common terms is this is testing of the raw materials purchased, but in this case in medical devices it may well go beyond the verification that is required for drugs. The manufacturer shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. You may have to visit the vendor's premises to inspect it or carry out anything else to ensure that the purchase product meets the specified purchase requirements. You have certain criteria for that purchase product and by way of any means including inspection you have to ensure that the manufacturer of that product can supply you that product as per your requirements.

Where the manufacturer intends to perform verification at the supplier's premises, the manufacturer shall state the intended verification arrangements and methods of product release in the manufacturing ,purchasing information. Records of the verification shall be maintained. That means, you are also responsible for the products quality at the suppliers premises also.

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Paragraph related to GMP. Now, GMP forms a part of QMS. So, these are some of the paragraph which are actually related to GMP. Some of the paragraph that I mentioned earlier also conforms to GMP requirements. These are specific that I picked up for our understanding.


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Production and service provisions: 7.5.1, Control of production and service provisions. 7.5.1.1, under this para say, general requirement, the manufacturer shall plan and carry out production and service provision under controlled conditions. Controlled conditions

shall include as applicable wherever required. The availability of information that describes the characteristic of the product. The availability of documented procedures, documented requirements work instructions and reference material and reference measurement procedures are necessary.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 Control of production and service provision:

- **General requirements-** The manufacturer shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:
 - The use of suitable equipment
 - The availability and use of monitoring and measuring devices
 - The implementation of monitoring and measurement

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The use of suitable equipment, use the availability and use of monitoring and measurement devices. So, this is the general requirement of a manufacturing process as required.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION


7.5.1 Control of production and service provision:

- **General requirements-** The manufacturer shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:
 - The implementation of release, delivery and post-delivery activities
 - The implementation of defined operations for labeling and packaging

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Followed by the implementation of monitoring and measuring equipment is the implementation of release delivery and post delivery activities. That means, not only you release the product and deliver it, even post delivery activities you have to implement as per the requirement of that particular product. The package, the implementation of define operations for labeling and packaging.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 Control of production and service provision:

The manufacturer shall establish and maintain a record for each batch of medical device or *in vitro* diagnostic medical devices that provides traceability and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The manufacturer shall establish and maintain a record of each batch of medical device or in vitro diagnostic medical devices that provides traceability and identifies the amount, manufactured and amount approved for distribution. The batch record shall be verified and approved.

The last para is very important and so well known in the manufacturing circles of pharma. We have to have a batch record; that means, we are manufacturing in a batch of say 20 products, 20 medical devices; then that 20 batch record shall be there giving all details of that the raw material, the manufacturing process, the release distribution, documents etc. and these shall be verified by somebody over the personnel who is preparing these and approved.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1.2 Control of production and service provision-specific requirements

- **Cleanliness of product and contamination control:**
The manufacturer shall establish documented requirements for cleanliness of product, if:
 - Product is cleaned by the manufacturer prior to sterilisation or its use
 - Product is supplied non-sterile to be subjected to a cleaning process prior to sterilisation or its use

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

7.5.1.2, control of production and service provisions specific requirements; point one of that is cleanliness of production contamination control. The manufacturer shall establish documented requirement for cleanliness of the product, if, product is cleaned by the manufacturer prior to sterilization or its use or product is supplied non-sterile to be the subjected to a cleaning process prior to sterilization or its use or product is supplied to be used non-sterile and its cleanliness is of significance in use or process agents are to be removed from the product during manufacture.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1.2 Control of production and service provision-specific requirements

- **Cleanliness of product and contamination control:**
The manufacturer shall establish documented requirements for cleanliness of product, if:
 - Product is supplied to be used non-sterile and its cleanliness is of significance in use
 - Process agents are to be removed from product during manufacture

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Now, this is something which we read between the lines actually. The product is to be cleaned we understand that it has to be cleaned. Now, the level of cleanliness depends on its use it can be manufacture by you, and say made sterile by sterilization process and packaged and sold. It can be sterilized before used by the user or it can be sold non-sterile too. Sometimes what happened is process agents are to be removed from the product.

In case of, I can give you a very simple example of a process agents. In case of ethylene oxide sterilization, we find that the ethylene oxide gas is use for sterilization of certain items like syringes or tyvek paper, packed products. Now, in case you want to sell that product we must ensure that ethylene oxide is zero in the product after its sterilized. So, anything that is used in the process has to be removed which we are not required in the final product.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1.2 Installation activities:


If appropriate, the manufacturer shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device or *in vitro* diagnostic medical devices. If the agreed customer requirements allow installation to be performed other than by manufacturer or its authorised agent, the manufacturer shall provide documented requirements for installation and verification. Records of installation and verification performed by the manufacturer or its authorised agent shall be maintained.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Installation activities: if appropriate, the manufacturer shall establish documented requirement which contain acceptance criteria for installing and verifying the installation of the medical device in or in vitro diagnostic medical device. If the agreed customer requirement allow installations to be performed other than by the manufacturer authorized agent, the manufacturer shall provide documented requirements for installation and verification. Records of installation verification performed by the manufacturer or its authorized agent shall be maintained.

Now, we are the bit confused in this, we all are because how do install a medical device this is not for the medical devices which are notified at the moment. These are for both medical devices which are large, for instance MRI machine or X-ray machine, which are actually installed in a manufacturing premises. In such cases the manufacturer shall provide the necessary know how and the man pot install that the premises. If they cannot they must provide the necessary documents for a third party to install that machine in the premises.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.1.3 Particular requirements for sterile medical devices:

The manufacturer shall maintain records of the process parameters for the sterilisation process which was used for each sterilisation batch. Sterilisation records shall be traceable to each production batch of medical device.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Particular requirements for sterile medical devices: this is very important because lot of medical devices in the market which are high end class D risky medical devices are sold sterile. These medical devices either usually go into the human body for use or cultural the human body for use.

The manufacturer shall maintain records of the process parameters for sterilization process which was used for each sterilization batch. Sterilization records shall be traceable to each product batch of the production batch of the medical device. This is very simple. We know that whenever you have to sterilize something the parameters of the sterilization are to be maintained, what kind of sterilization with a steam, dry heat, ethylene oxide or gamma radiation. Each batch that goes through it has to be documented and recorded in the manufacturing records.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.2 Validation of processes for production and service provision:

7.5.2.1 General:

The manufacturer shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Validation shall demonstrate the ability of these processes to achieve planned results.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

7.5.2, validation of process for production and service provision. We had a glimpse of validation earlier. Now, in this it is much more in detail. 7.5.2.1 says in general, the manufacturer shall validate any process or production and service provision where the resulting output cannot be verified by the subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Validation shall demonstrate the ability of these processes to achieve planned result.

There are lot of medical devices, we know very well that what are medical devices they are which cannot be the usage of that product cannot be validated by way of end product testing, at the end of the production cycle. So, in that case, the manufacturer has to validate each process that is going on in the manufacturing that which is of course, designed carefully for that particular process. So, that at the end of the day even if the product is not tested it complies with your standards.

Manufacturer shall establish documented procedures for the evaluation validation of the application of computer software and changes to the such software. Now, in this case it is a computer software validation in you know, devices that are notified at the moment do not require any computer or software for their running. These are required in high end medical devices which are actually of the range of say MRI, X-ray machines and all those equipment which require a software for its running in application, so that software or computer system has to validated again.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.2.2 Particular requirements for sterile medical devices:

The manufacturer shall establish documented procedures for the validation of sterilisation processes. Sterilisation processes shall be validated prior to initial use. The records of validation of each sterilisation process shall be maintained.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Particular requirements for sterile medical devices, it is it is 7.5.2.2 is extension of 7.5.2. Manufacturer shall establish documented procedures for the validation of sterilization process. Sterilization process shall be validated prior to initial use. The records of validation of each sterilization process shall be maintained. We already saw that as a batch we saw that that each batch, as to be validated in this case each production cycle of a sterilization process has to be again validated and recorded.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.3.2 Traceability:

7.5.3.2.1 General:

The manufacturer shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required. Where traceability is a requirement, the manufacturer shall control and record the unique identification of the product.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Traceability: 7.5.3.2.1 is general. The manufacturer shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required. Where traceability is requirement the manufacturer shall control and record the Unique Identification (UID) of the product.

That means, what happens is once the product goes on the market in use and it means it malfunctions, we have to back trace from the product to the manufacturer, to the production cycle to the batch. So, this is actually traceability. And in case of intra plant traceability we can trace a particular process to a batch to a person who made that who activated that process and who responsible. So, traceability of an action in a manufacturing plant is extremely important to troubleshoot problems later on.

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PARA 7.5 PRODUCTION AND SERVICE PROVISION

7.5.3.2 Traceability:

7.5.3.2.1: The manufacturer shall require that its agents or distributors maintain records of the distribution of active implantable medical devices and implantable medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Manufacturer shall require that it is agent or distributions maintain record of the distribution of active implantable medical device and implantable medical device to allow traceability and that such record are available for inspection. Records of the name address of the shipping package consignee shall also be maintained. So, it is a comprehensive record keeping of the whole product.

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PARA 7.6 CONTROL OF MONITORING AND MEASURING DEVICE



The manufacturer shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. The manufacturer shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

7.6, Control monitoring and measuring devices: these are devices which actually control and record and measure unit quantities of anything. For instance, it can be temperature, pressure, related humidity or length, breadth which is which has a quantifiable value. The manufacturer shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of the product to determine requirements. The manufacturer shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

So, the monitoring and measurement requirements are controlled by monitoring and measurement equipments which are again dependent on what is the requirement of the product. The product requires a length of 6.5 inches, the instrument require for that measurement should be calibrated for that particular item now and then re-calibrated, so that anything that is going on in the plant which can be identified by a value has a machinery or equipment or instrument which is actually proper calibrated and used regularly.

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PARA 8.2.2 INTERNAL AUDIT

- The manufacturer shall conduct internal audits at planned intervals to determine whether the quality management system:
 - Conforms to the planned arrangements, to the requirements of this Schedule and to the quality management system requirements established by the manufacturer
 - Is effectively implemented and maintained

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Internal audit: now, what is an internal audit? The manufacturer shall conduct internal audits at planned intervals to determine whether the quality management system. Conforms to the planned arrangement, to the maintenance to the requirements of the schedule and to the quality management system requirements established by the manufacturer and is effectively implemented and maintained.

What is internal audit? Internal audit is basically a self infection of the plant by its own. Internal audit is different from external audit in which an external agency carries out an audit for a regulator, to carry out an inspection it is an external audit. But internal audits carry out, it is internal inspection sort of you can say in which selected personnel from the plant carry out the audit of the plant as per the requirement a thorough honest audit to find out the requirements that are actually falling out of specifications or improvement that are required to be done and records of such have to be maintained properly.

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PARA 8.2.2 INTERNAL AUDIT

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA


An audit programme shall be planned, now this is internal audit programme shall be planned taking into consideration the status and importance of the processes and areas to be audited, as well as the pre results of previous audits. That means, if this is a simple process you need not do the audit internal audit on the regular basis, but if it is a critical process that internal audit has to be done properly and documented.

The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure the objectivity and impartiality of the audit. I mean, it is needed to say that audit has to be extremely impartial. You cannot be partial to a particular area within the order because that particular area has one of the persons whom you like. So, it has to be impartial. And it is best to avoid auditing those areas by interested people of the plant, have neutral impartial people audit in those areas.

Auditors shall not audit their own work. Very important as I mention a laboratory audit cannot be done by personnel for the laboratory, it has to be from somebody other than the laboratory area. The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that the actions are taken without undue delay and eliminate detected conform conformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification result.

After an audit you have to prepare a non-conformity report or a audit report in which it has to be mentioned and highlighted the short comings and an action taken to be, time to be given and the conformities have to be the deficiencies have to be confirmed to the requirements within that particular time period.

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PARA 8.2.2 INTERNAL AUDIT

8.5.2 Corrective action:

The manufacturer shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.5.3 Preventive action:

The manufacturer shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Corrective action: Manufacturer shall take in take action to eliminate the cause of conformities in order to prevent recurrence. Corrective action shall be appropriate to the effective to the effects of non-conformities encountered. I explain in earlier also, corrective action is simply removing the defects and recording it.

Preventive action, the manufacturer determined action to eliminate the cause of the potential conformities in order to prevent their occurrence. Preventive action shall be appropriate to the effects of the potential problems. Preventive action is basically preventing maintenance is one can be preventive action likewise.

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ANNEXURE 'A' (REFER SUB-PARAGRAPH 6.4 (B))



Environmental requirement for medical devices and
in vitro diagnostic medical devices

Annexure A which forms part of the fifth schedule describes
the environmental class required for manufacturing
of different type of devices.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

Annexure A refer to sub paragraph 6.4 B. Environment requirement for medical devices and in vitro diagnostic medical devices. Annexure A which forms part of the fifth schedule describes the environmental class requirement for manufacturing of different type of devices. Now, we have different classification class A, B, C, D, E, particle count Grade A, Grade B, Grade C, the all this requirements will confirm to the requirement of your product.

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QUICK VIEW: FIFTH SCHEDULE OF MEDICAL DEVICES



The Fifth Schedule of the Medical Device Rules, which describes the Quality Management System has to be supplemented with various other objective documents which clearly gives absolute values.

Some of these documents can be detailed product specification, personnel, hygienic requirements, procedure for actual data collection and recording etc. These operations need to be authorised and validated as required under the QMS.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

The fifth schedule of Medical Device Rules, which describes the Quality Management System has to be supplemented with various other objective material which clearly gives absolute values.

Some of these documents can be detailed products specification, personnel, hygienic requirements, procedure for actual data collection and recording etcetera. The operation need to be authorized and validated as required under the QMS. That is the actual is quality management system.

If you have any queries you can get back to us and we shall make a every effort to answer your queries and remove your doubts.

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RECAP

- 1 Which ISO is applicable for medical device ?
ISO 13485.
- 2 In which year the relevant areas of the Schedule M III has been incorporated in the Quality Management System of the Medical Device Rules?
2017.
- 3 How many paragraphs are there in Fifth Schedule (with respect to quality management system that a firm needs)?
8 paragraphs.

REGULATORY REQUIREMENTS FOR MEDICAL DEVICES AND IVDs IN INDIA

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.

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RECAP

- 4 Under which paragraph of Fifth Schedule, corrective & preventive action are covered ?
8.5.2 & 8.5.3
- 5 Paragraph 7.5 of Fifth schedule of GMP is related to _____
Production and service provision.

Thank you very much.