Social Innovation in Industry 4.0
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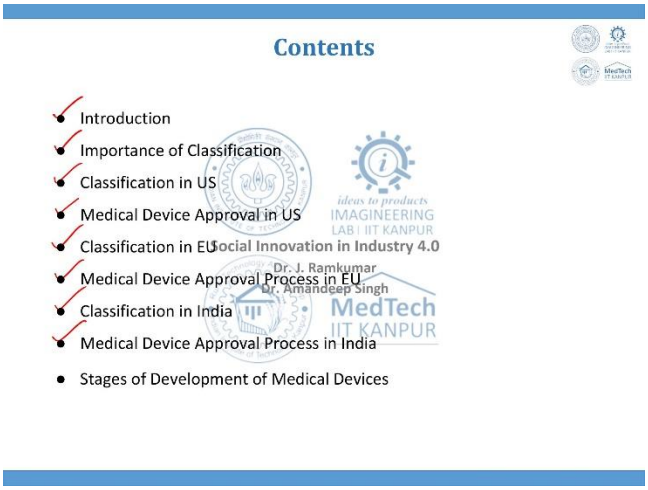
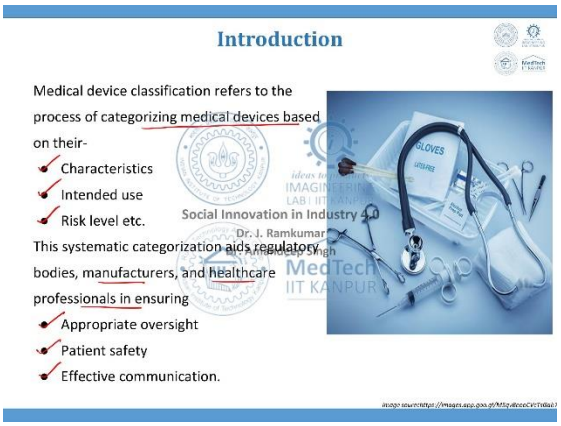
Lecture 36
Classification and Regulatory Process of Medical Devices

Welcome back to the course on Social Innovation in Industry 4.0. I have discussed the design of medical devices in this week. I have talked about the Classification and Regulatory Process of Medical Devices in the previous lectures. For this little more detail is given in this lecture.

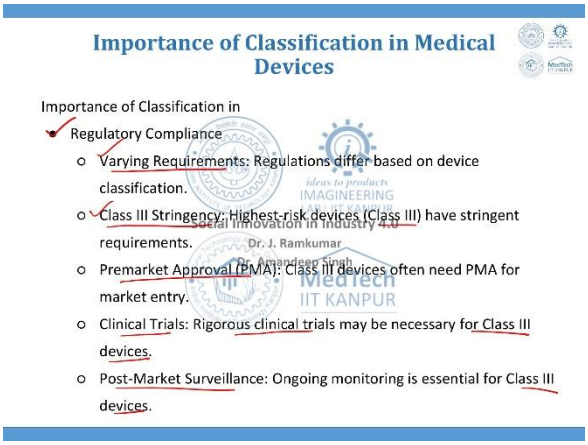


This lecture, we start with Introduction to what classification is, we are trying to cover or we are trying to talk about, and Importance of Classification.

Classification in the different parts of the world, for example Classification in the US and Medical Device Approval required in this country. Then, European Classification and Approval Process in this country. Then, in India, what is the Classification of the Devices and what is the approval process. This will be quickly discussed in this lecture. In stages of development will be discussed in this lecture.



Medical device classification refers to the process of categorizing medical devices based on their characteristics, intended use, risk level. This is only the recap of what we have discussed in the previous lectures. This systematic categorization aids regulatory bodies, manufacturers and healthcare professionals in ensuring appropriate oversight, patient safety, and effective communication. This is all largely discussed in the last two lectures.



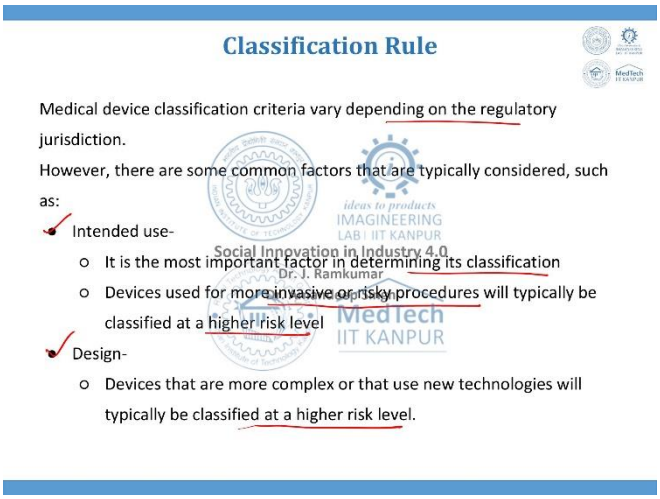
Now, the importance of classification is in regulatory compliances, that is, varying requirements are there. And, class 3 stringency is more important to be taken care of when we are trying to talk about medical devices in the US. Premarket approval that is PMA required clinical trials and post-market surveillance are to be taken care of. Varying requirements means the regulations differ based on the medical devices or the country. These are the variations. Class 3 stringency means high-risk devices, that is the class 3 devices have stringent requirements.

Then, premarket approval, that is the class 3 devices often need premarket approval for market entry without the approval, without the proper clinical tests and everything, we cannot even enter the market. Regressed clinical trials may be necessary for class 3 devices that we will try to see.

And, ongoing monitoring is essential for high risk devices, which is class 3 devices, the classification that we are trying to talk about here in this lecture.

Patient safety is also an importance of classification because patient safety to ensure the safety in clinical trials and enhance confidence, classification ensures devices meet safety standards, class 3 devices require trials to prove safety and efficacy, proper classification instills trust in device safety.

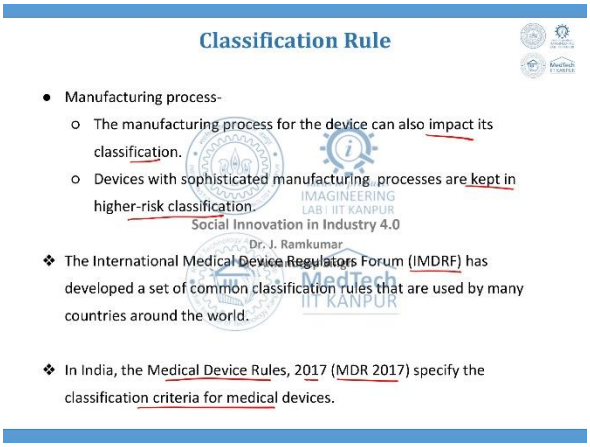
Market access, impact on access that is the classification affects market entry in various countries. Additional approvals that are class 3 devices might be needing extra approvals of certain markets. International trade, it is accurate classification aids global market expansion as well.



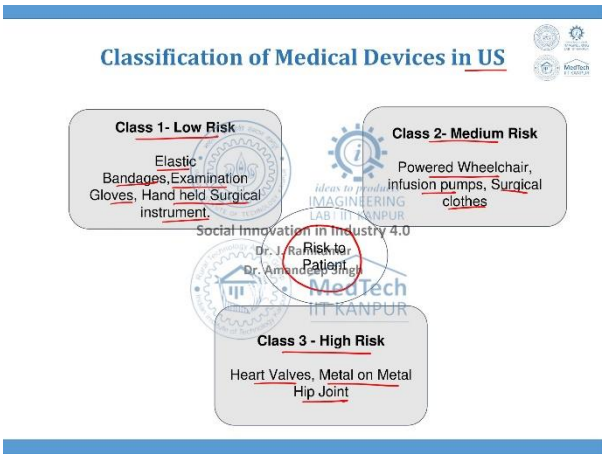
The general rule here is that medical device classification criteria vary depending on the regulated jurisdiction. However, these are some factors which are given here, which are typically considered, that is intended use of the product, the design of the product, manufacturing process and so on. Intended use means it is the most important factor in determining the classification.

The device used for more invasive or risky procedures will typically be classified as a high risk device or it will be classified at a high risk level. Invasive use means the device that goes inside the body, the needle goes inside the body, it has to puncture your skin and go inside that is an invasive use.

Non-invasive use means the device that remains outside the body, like the shoe design that I showed you, like the fundoscope that I showed you, those are all non-invasive, those are medical devices, those are the diagnostic devices or in-use devices in a medical uses as well, but do not go inside the body. Design devices that are more complex or that use new technologies will typically be classified at high risk level devices because for the new technologies the risk is not yet explored.



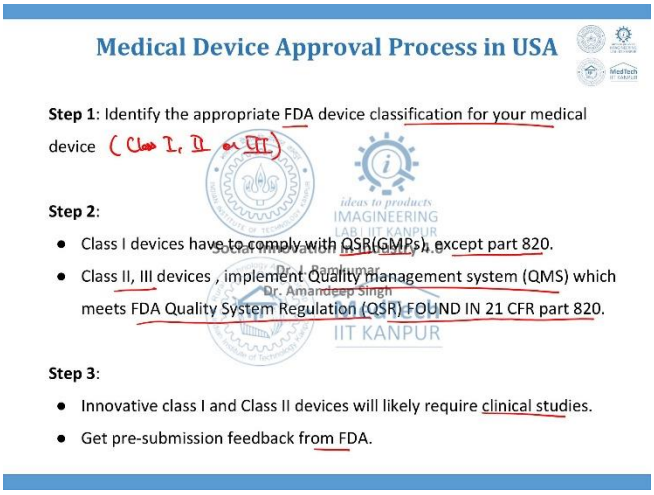
Then, manufacturing processes, the manufacturing process for the device can also impact its classification if the manufacturing process is very sophisticated. The devices are kept at a high risk classification. The International Medical Device Regulation Forum, that is IMDRF, has developed a set of common classification rules that are used by many countries around the world. In India, MDR that I talked about Medical Device Rule 2017 specify the classification criteria for medical devices.



Classification of medical devices in the US is based upon the major 3 classifications here. Class 1 is the low risk medical device and class 3 is the high risk. In between we have medium risk.

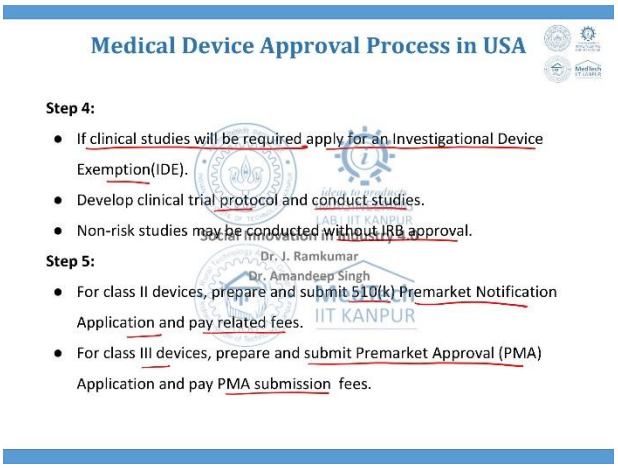
In class 1, certain examples are the elastic bandages that remain outside your skin, examination gloves, simply the gloves used in medical examinations, those are also non-invasive at all, handheld surgical instruments which are non-invasive are also low risk devices only. Then, high risk devices at the heart walls, maternal metal hip joints, these are prone to high risk because they

go inside the body. In-between we have medium risk devices which fall in class 2, which have certain examples, such as power wheelchair, infusion pumps and surgical clothes also. So, it depends upon what is the risk to the patient in using upon them the medical device. Medical device approval process in the US is in such a way that certain steps are there. There are mentioned 10 steps of this classification

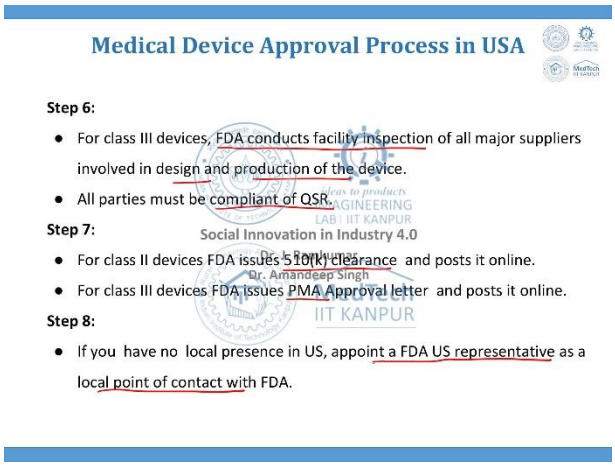


Step 1 is identifying the appropriate FDA device classification for your medical device, that is, the FDA gives us the classification that, whether we are trying to classify it in class 1, 2 or 3. Step 2 is the class 1 devices have to comply with QSR, GMP that is only Good Medical Practices except part 820.

This is mentioned in the Quality System Regulation of the Good Medical Practices in the US, QSR is Quality System Regulation. Class 2 and 3 devices implement the Quality Management System, that is the QMS, such as ISO 13485 which meets FDA Quality System Regulation. QSR was found in 21 CFR part 820. Step 3 is innovative class 1 and class 3 devices will likely require clinical studies. So, we get pre-submission feedback from FDA here, pre-submission feedback because the class is getting higher and feedback from FDA is taken here.



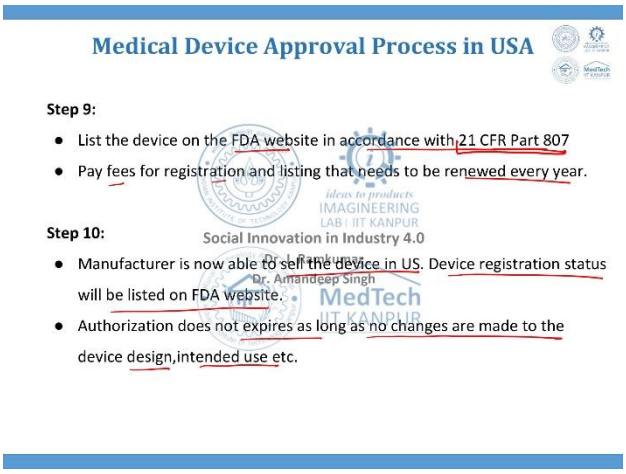
The step 4 includes applying for the IDE, that is Investigational Device Exemption, if clinical studies are required. Then, develop clinical trial protocol and conduct studies, this is within step 4 that is, if it is required, we need to draft the trial protocols. Non-risk studies may be conducted without the IRB approval. Step 5 includes for class 2 devices and class 3 devices, for class 2 devices, we need to prepare 510K. That is 510K they call, which is a premarket notification application and we need to pay related fees For class 3 devices, we need to prepare and submit Pre-Market Approval, that is PMA application and pay PMA submission fees.



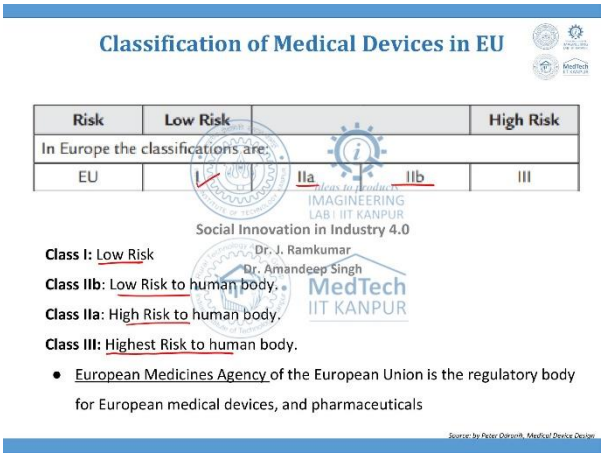
For step 6, class 3 devices include facility inspection as well. So, here FDA conducts facility inspection for all major suppliers involved in design and production of the device. All parties must be compliant of the QSR, so that means the vendors who are supplying the material should also have their own Quality Management Systems in place. Step 7 includes the clearance from 510K, that is for the class 2 devices and for class 3 the pre-medical improvement, that is also given by FDA in a letter, and this is all posted online, this is all 2 differences between class 2 and

class 3 here.

So, if we have no local presence in the country United States, we need to appoint a FDA US representative. This comes as a step 8, because this person becomes a local point of contact with FDA.



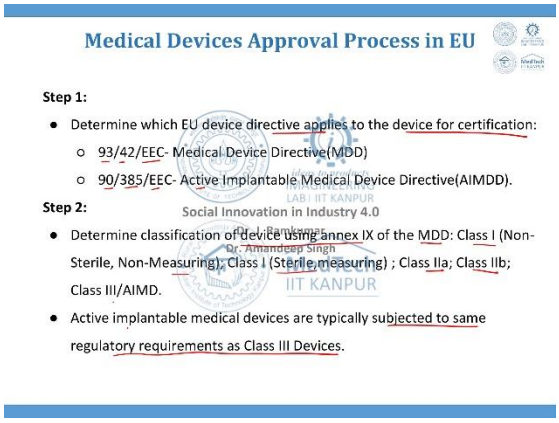
Step 9 is we list the device on the FDA website in accordance with 21 CFR part 807, we pay fees for registration and listing that needs to be renewed every year this 21 CFR part 807, this means, it is an establishment registration and device listing for manufacturers and initial importers of devices. Step 10 is now for the manufacturers, manufacturers are now able to sell the device in the US, device registration status will be conducted on FDA website, authorization does not expire as long as no changes are made to the device design, that is intended use etc. Now, these steps are all listed here.



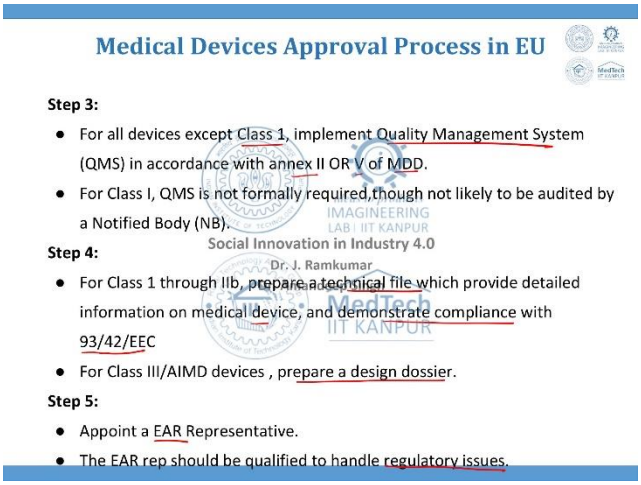
There are certain medical approval steps or the classification in Europe as well, which is almost similar to that is there in the US. Europe also the classification is class 1, 2 and 3.Only the class

2, they have divided into 2 parts, that is 2A and 2B. Again in Europe, class 1 is a medical device that is pertaining to low risk. The highest risk is given to the class 3 devices. In between we have low risk to the human body and high risk to the human body, that is, it is lesser than the very high risk, those are also given in class 2.

Now, the European Medicines Agency, that is EMA of the European Union, is the regulatory body for European Medical Devices and pharmaceuticals. They also have certain steps for approval.

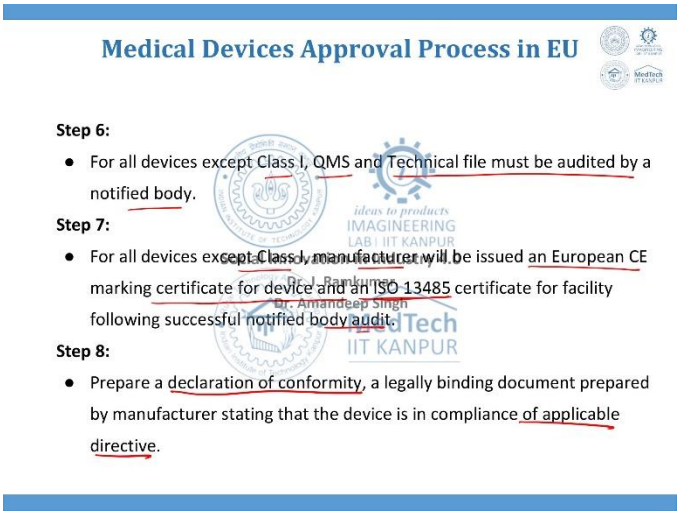


Step 1 is to determine which EU device directive applies to the device for certification that is 9342 EEC Medical Device Directive (MDD), or 9385 EEC Active Implantable Medical Device Directive (AIMDD), which one is applying that is to be identified, then step 2 is to determine classification of device using an action 9 of MDD. Class 1 is non-sterile, non-measuring, class 1 sterile and measuring class 2A class 2B, class 3 and so on. Then, active implantable medical devices are typically subjected to the same regulatory requirements as class 3 devices. Active implantable means anything that goes as an implant inside the body that is put in the class 3 devices, in general.

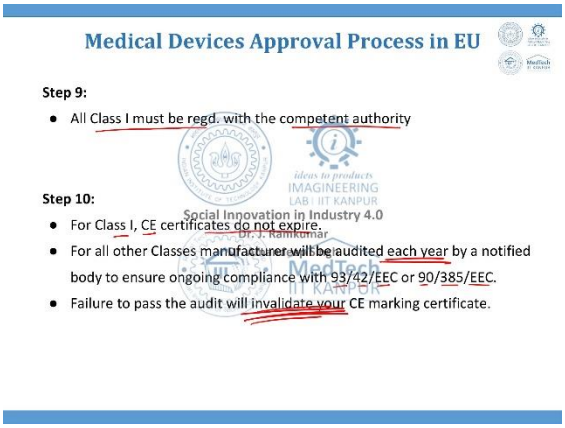


Here also, we have 10 steps only, step 3 is for all devices except class 1, implement QMS in a context with an extra 2 or 5 of MDD. For class 1 since QMS is not formally required, though not likely to be audited by the notified body, so it can go directly without even going through the QMS requirements.

Step 4 is for class 1 through 2B. It is needed to prepare a technical file which provides detailed information on medical devices and demonstrates compliance with 9342 EEC. For class 3 or AIMD devices preparation of a design dossier is must. Step 5 is again for the people who are not from Europe or so, they need to appoint an European representative EAR. EAR is a European Authorized Representative. So, EAR representatives should be qualified to handle regulatory issues.



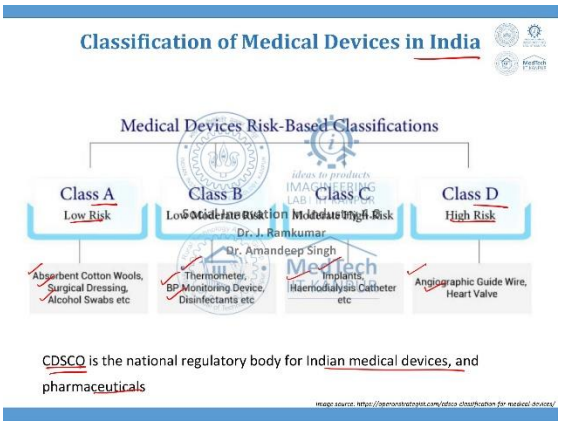
Step 6 is for all devices except class 1 where QMS and technical file must be audited by the notified body. For all devices except class 1, manufacturers will be issued an European CE marking certificate for device and an ISO 13485 certificate for facility following successful notified body audit. Step 8 is to prepare a declaration of conformity that is a legally binding document which is prepared by the manufacturer stating that the devices are in compliance of applicable directive. So, this is a certification or declaration or undertaking taken from the manufacturer.



Step 9 is, all class 1 devices should be registered with competent authorities and step 10 is for class 1 CE certificates, do not expire. For all other classes, manufacturers will be audited each year by a notified body to ensure ongoing compliance with 9342 EEC or 90385 ECC. Failure to pass an audit will invalidate your CE marking certificate, that is each year an audit happens for the high risk kind of the medical devices in manufacturing and the audit gives the non-conformances, if those are there.

Non-conformances all the time are not just to fail or invalidate your CE marking certificate. Non-conformances could be major or minor. If those are minor, minor are just taken care of there itself. Sometimes, small things are okay, the document number is not correct or so, these are all small minor.

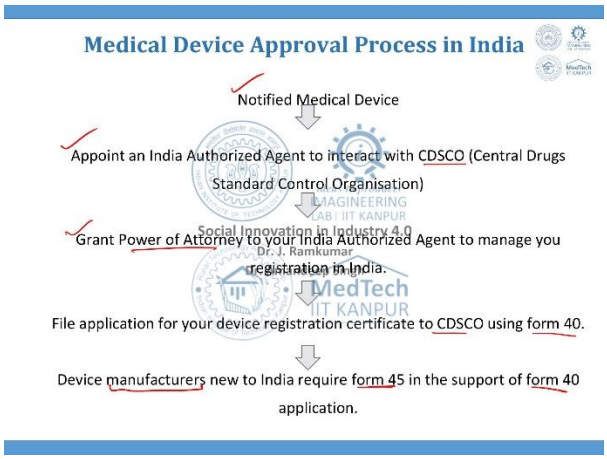
If the major non-conformances do come, 1 or 2 non-conformances are also sometimes acceptable, depends upon the kind of the severity of the non-conformance that is given. If the similar non-conformance repeats the next year, then invalidation generally happens. So, this is how the audits happen.



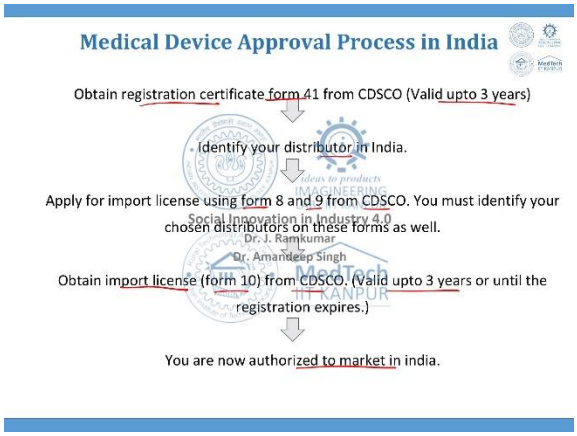
In India now, medical devices are classified based upon the risk again from the categories A to D. Category A is low risk, D is the highest risk. In between we have classification class B and class C which are low moderate and moderate high risks respectively.

In low risk medical devices certain examples which are given here are absorbent cotton wools, surgical dressing, alcohol swabs, etcetera. In low moderate risks thermometers, BP monitoring devices, disinfectants etcetera. As I said, the thermometer could fall in a low risk, but here in India it is following in the low moderate risk kind of the category where the thermometer goes inside your mouth. So, this is a low moderate risk. Then, moderate high risk is in plants or hemodialysis catheters.

For very high risk or high risk classification angiographic guide wire or heart valve are the examples. So, CDSCO is a national regulatory body which was discussed in the previous lectures, for Indian medical devices and pharmaceuticals.



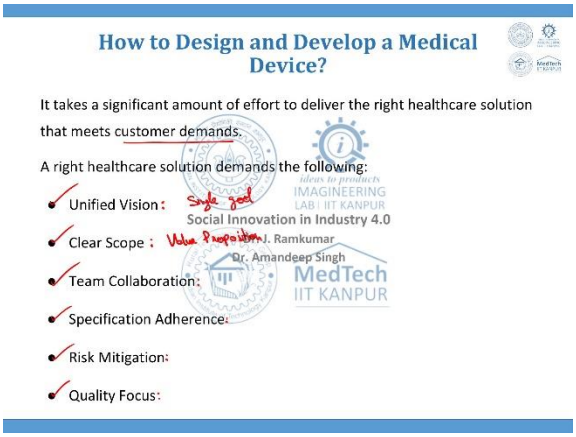
Medical device approval process in India is simply we get notified the medical device. Then, we appoint an India authorized agent to interact with CDSCO, then we grant Power Of Attorney, that is POA, to your India authorized agent to manage your registration in India. File application for your device registration certificate to CDSCO using Form 40. Then, this Form 40 and Form 45 are both required for the manufacturers who are new to India.



Next is Form 41 is required, which is to obtain a registration certificate that is valid for 3 years. Then, identify your distributor in India, apply for import license using Form 8 and 9 from CDSCO. One must identify your chosen distributors on these forms as well. Then, we need to obtain an import license that is Form 10 from CDSCO which is also valid for 3 years or until the registration expires. You are now authorized to market in India. This is a simple listed steps in India to market our product or to launch our product in India. Anyone from outside the country can also launch, only they have to fill the specified forms here. For example, Form 45 in support of Form 40, if the person is not from the Indian background.

India's new medical device regulations include MDR 2017, which came into effect on 1st January 2018 and will be applicable to medical device and in-vitro diagnostic medical devices. The Ministry of Health and Family Welfare has come up with this. Application for a license to manufacture for distribution of medical devices of any class can be found completed and submitted on the Ministry of Health and Family Welfare online portal.

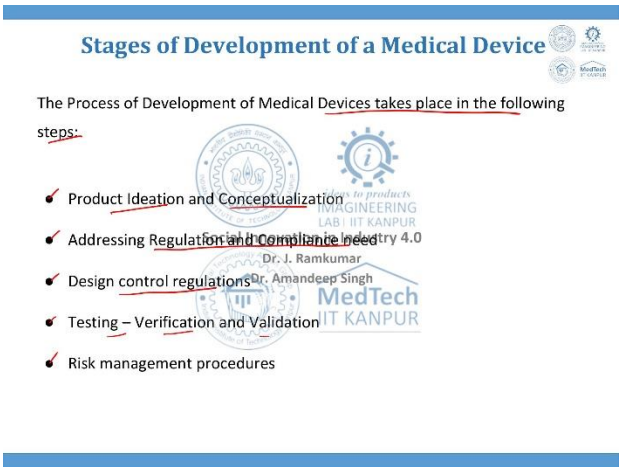
For any medical device which is manufactured in India, it is mandatory to have a CDSCO medical device manufacturing license. For class A and B medical devices manufacturing licenses will be issued from state licensing authorities. For this, the manufacturing license is effective for class A and B from 1st of October to 2022 that is now effective. But for the classes C and D, medical devices manufacturing licenses will be issued from the CLA's only central licensing authorities. So, the CDSCO manufacturing license will be effective for all non notified class C and D from 1st of October 2023.



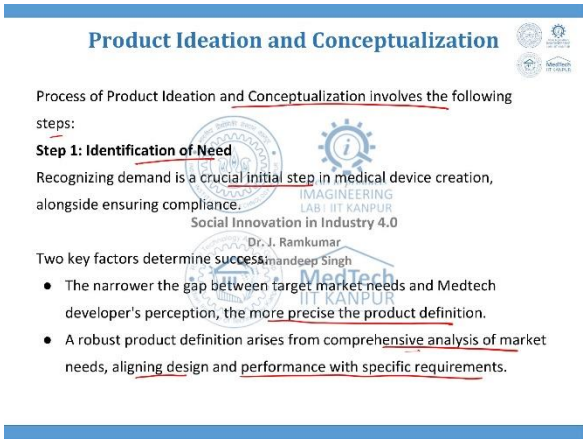
How to Design and Develop a Medical Device? It takes a significant amount of effort to deliver the right healthcare solution that meets customer demands. A right healthcare solution demands the following unified vision, clear scope, team collaboration, specification adherence, risk mitigation and quality focus. When I say unified vision, this means alignment is crucial for effective healthcare solutions. That vision has to be unified and all the stakeholders should have a single goal, that is vision has to be unified. Then clear scope, a well defined scope starts with understanding the end users needs. For instance, in MedTech IIT Kanpur, the scope of the design is only developing a prototype.

If the scope is to manufacture it as well, that is a different level of scope. And also, what need or what value proposition we are trying to hit, that becomes a part of the scope. Team collaboration, team collaboration means collective efforts of all the stakeholders of the design process drive towards successful outcomes. Specification adherence, which means specifications that stem from product definition should be adhered to. Risk mitigation which is the core in the medical device design because risk mitigation simultaneously managing and mitigating potential risks is to be taken care of.

Focusing on quality, that is maintaining high quality standards throughout the design, throughout the development, and the use that is being catered to. Stages of Development of a Medical Device.



The process of development of medical devices takes place in the following steps. We will try to discuss these steps in the forthcoming slides, which are product ideation and conceptualization, addressing regulation compliance needs, design control regulation, testing that is verification and validation, risk management procedures.

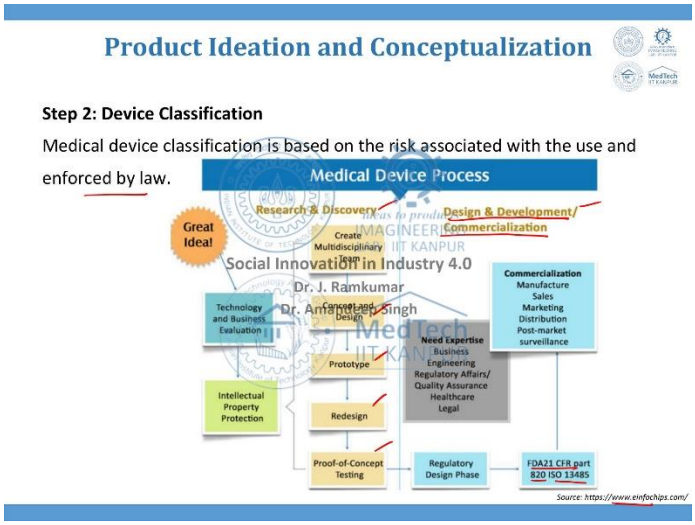


First step is the product ideation and conceptualization. Now MedTech innovation, MedTech innovation starts with analyzing and identifying the market, the need of which is untapped or unmet or there is a more efficient way to address those particular needs.

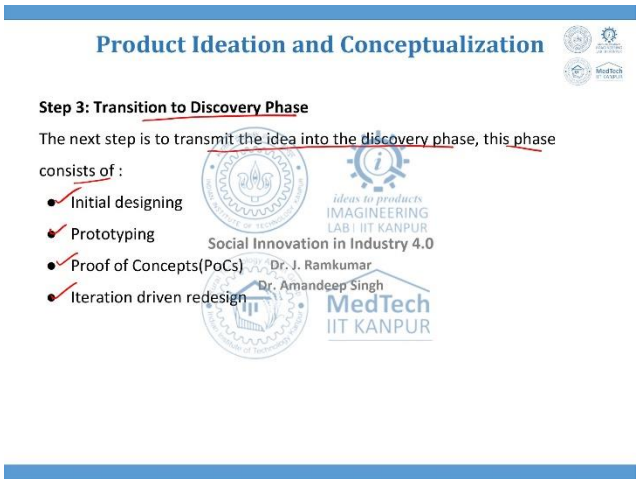
These needs could be anything that delivers the solutions. The solutions could be a new or a better way of monitoring health and enhanced care delivery solutions, devices or technologies to deliver better administration or anything that supports health and human life. For example, a smart watch or a device such as a health tracker, that tracks what? It could track the steps taken, calories burnt, this is a health tracker device. So, there could be many other points. Like, it monitors one sleeping habit, it monitors what routine you are trying to follow. So, it gives you a fair idea about your daily routine, which helps you to improve your health or lifestyle.

This kind of solution could be termed as a vitamin. While a device that addresses a problem, such as an insulin pump, is a painkiller. So, these devices are helping you to get rid of the many pills that otherwise you need to take. So, here the process of product ideation and conceptualization involves the following steps. There are three major steps, the first step is identification of need. Recognizing demand is a crucial initial step in medical device creation, alongside ensuring compliance. Two key factors that determine success are the narrower the gap between the target market needs and MedTech developers perception, the more precise the product definition.24:05

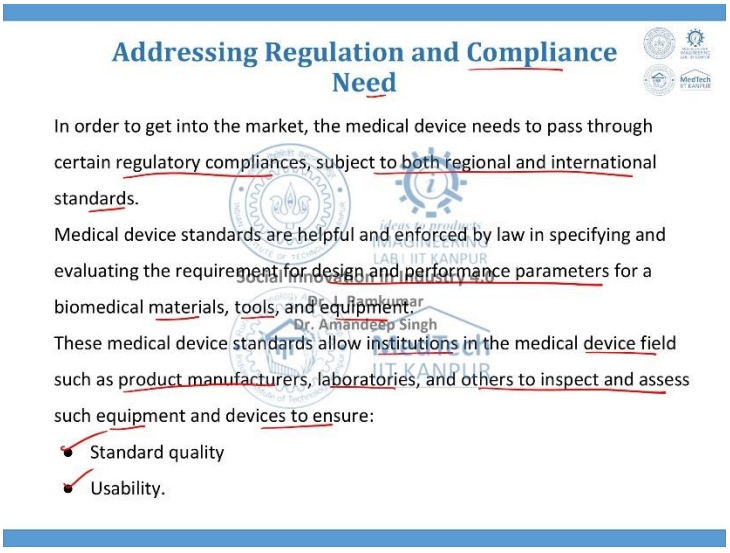
Just keep it in mind, the robust product definition arises from comprehensive analysis of the market and aligning design and performance with specification requirements. So, medical device product definition involves articulating design and intended performance to fulfill a particular requirement for which device classification was discussed.



Medical device classification is based on the risk associated with the use and it is enforced by law. So, medical device processes could be any research and discovery design and development commercialization. There are many parts of it, how do we create a team for medical design and how do we try to concept and design prototype redesign proof of concept. This is taken from a reference, and here you can see the FDA 21 CFR all 820 ISO and 13485 compliances are given which are to be taken care of when we are trying to work upon the design and development of the medical device or the commercialization of medical device in a different part of the world.

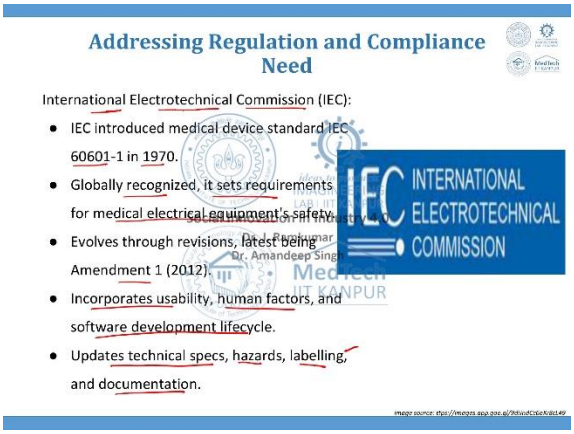


Step 3 is transition to discovery phase. Here, the next step is to transmit the idea into the discovery phase. This phase consists of initial designing, prototyping, proof of concept and iteration driven redesign, these were all discussed in the previous lectures.



Now, the next point is addressing regulation and compliance needs. In order to get into the market the medical device needs to pass through certain regulatory compliances subject to both regional and international standards. Medical devices standards are helpful and enforced by law in specifying and evaluating the requirements for design and performance parameters for biomedical materials, tools and equipment.

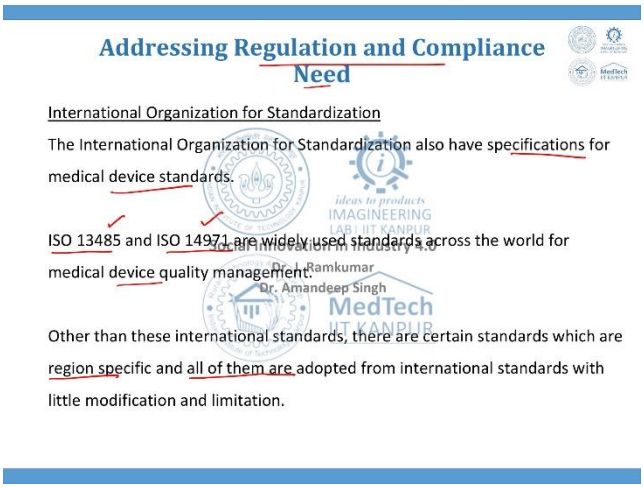
These medical device standards allow institutions in the medical device field such as product manufacturers laboratories and others to inspect and assess such equipment and devices to ensure standard quality and usability.



Now, when we are talking about the regulation the International Electrotechnical Commission introduced medical device standard IEC 606011 in 1970. It is globally recognized and it sets requirements for medical electrical equipment safety. It evolves to revisions latest being amendment 1 2012 which means the electrical noise that is coming out of the device.

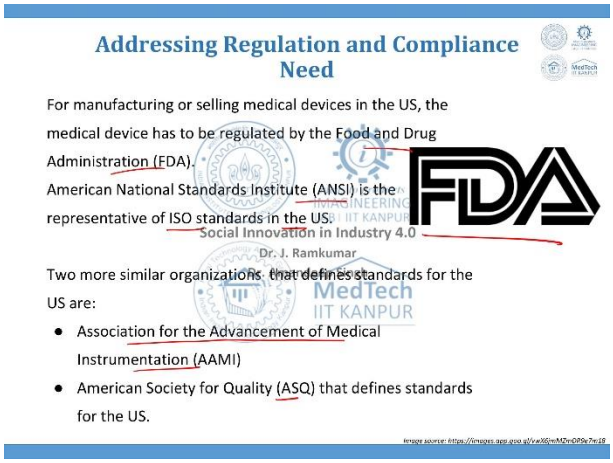
For example, even if I am using the mobile phone, if I am using the Wi-Fi router in this room. So, they are also emitting some electrical signals these signals should not harm the human body these are the general compliances and for medical devices, if you are using something that is using electrical energy and also being used on a body that also should not emit any of the electrical signals or noises that is the electromagnetic compliances or electromagnetic interferences with the body should be such a way that it should not harm the body.

So, there are certain compliances for this as well. It incorporates usability, human factors, and software development life cycle. It updates technical specifications, hazards, labeling and documentation. Gambling means whatever the range of the electrical signal it would emit that also is labeled here.



Again, further, in addressing regulation and compliances need international organization for standardization has given specifications for medical device standards, that is the ISO system which I discussed in the previous lectures 13485 and ISO 14971. This is for medical devices, this is for manufacturing of medical devices.

These are widely used standards across the world for medical device quality management. These are QMS systems anyway. Other than these international standards there are certain standards which are region specific and all of them are adopted from the international standards with little modification and limitation.

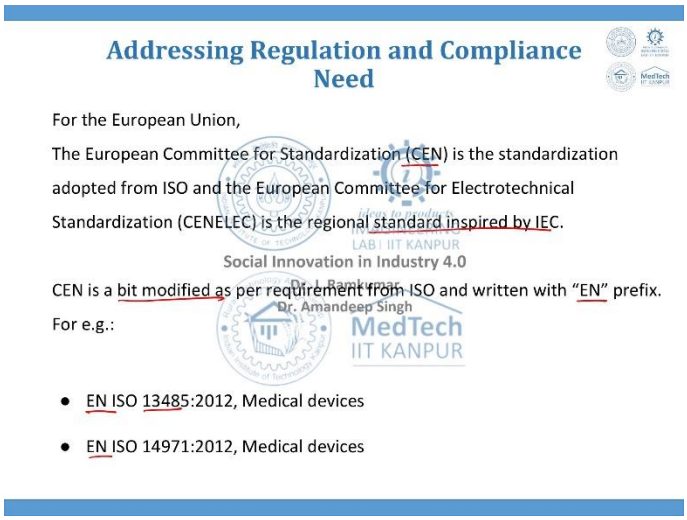


The certain international standards as I mentioned FDA is one that is Food and Drug Administration, American National Standards, ANSA is other that is representative of ISO standards in US to more similar organization that define standards for USR Association for the

Advancement of Medical Instrumentation that is the AAMI and ASQ which is American Society for Quality that define standards for the US.

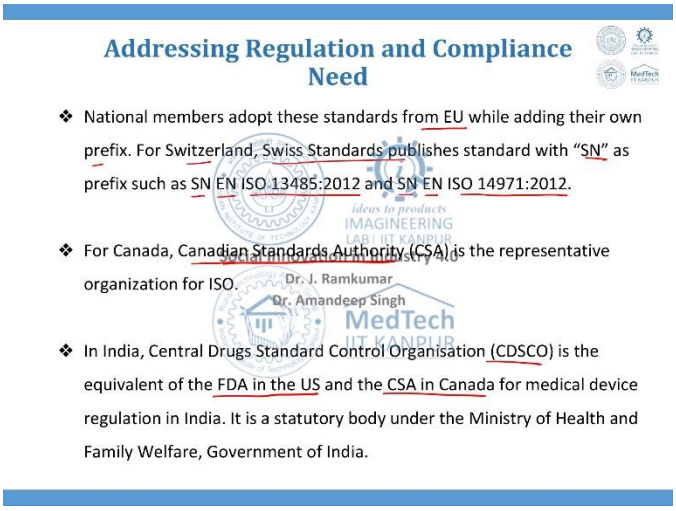
Now, FDA has its own set of procedures for risk management derived from both international and region standards which include the ISO systems that is ISO 14971, 2007 medical devices which is application of risk management to medical devices and ANSI, AAMI, ISO 14971, 2007 that is R2010 medical device application of risk management to medical devices.

In the case of the quality management standard it does not follow the international or regional version of ISO 1345 standard because FDA has different guidelines for quality management in medical devices for the US market.



For the European Union the European Committee for Standardization CEN is a standardization adopted from ISO and the European Committee for Electrotechnical Standardization, that is CENELEC is the regional standard inspired by IEC. Now CEN is a bit modified as per

requirement from ISO and written with EN specific that is EN is European. EN ISO 1345 medical device, EN ISO 14971, 2012 medical devices. So, these are both European standards.

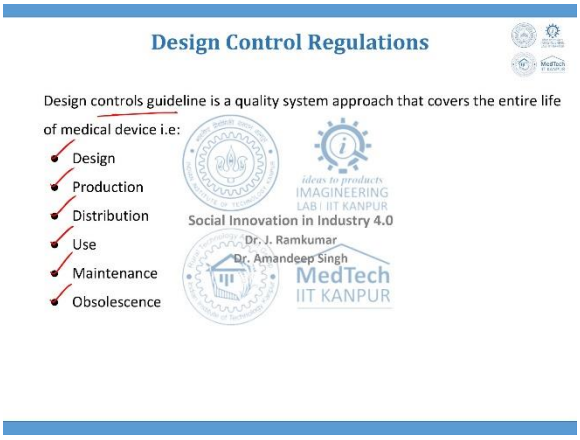


National members adopted these standards from the Europe while adding their own prefix Switzerland, Swiss standards, publicity standards, SNS prefix SNEN ISO 1345, 2012 or SNEN ISO 14971, 2012 where SN is for the Switzerland for its own country they have the local standard here.

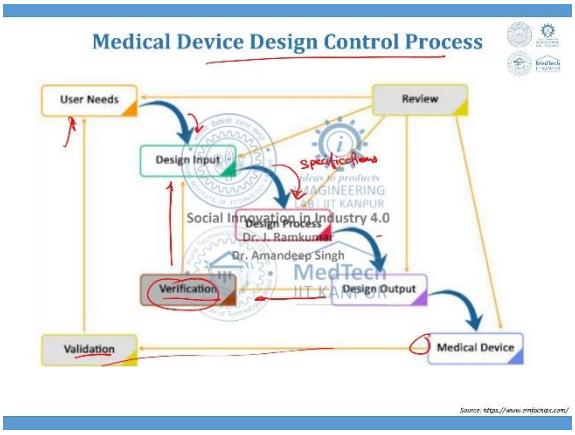
For Canada these are the standard developed by its own authority known as CSA that is Canadian Standard Authority which is a representative organization for ISO. In India as it is mentioned Central Drug Standard Control Organization, CDSCO is the equivalent of FDA in the US and CSA in Canada for medical device regulation in India. It is a statutory body under the Ministry of Health and Family Welfare, Government of India.

Medical devices manufacturers need to follow design control guidelines since the regulatory bodies want to ensure that medical devices are safe for potential users before manufacturers start to market their devices.

In US design controls are defined under FDA 21 CFR 820.30 which has a similar intent to section 7.3 that is design and development described under the guidelines of ISO 13485. To successfully implement design control of medical devices professionals with both technical and non-technical background such as business, administration, life science, engineering, computer science and arts are all required. So here for the design control regulations there are certain guidelines which are given by different parts of the stakeholder, different parts of the designer or different fields as mentioned here. They help in the design control.

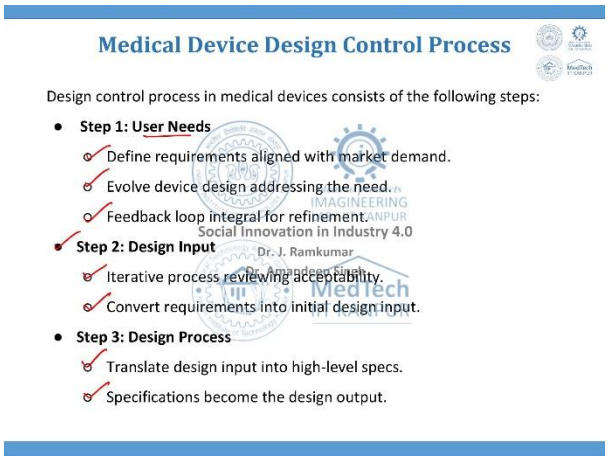


Design control guideline is a quality system approach that covers the entire life of the medical device that is the design, production, distribution, then use by the doctors or whoever is using it, then maintaining it and obsolescence. If it is obsolescence then disposal or after use part is also covered here.

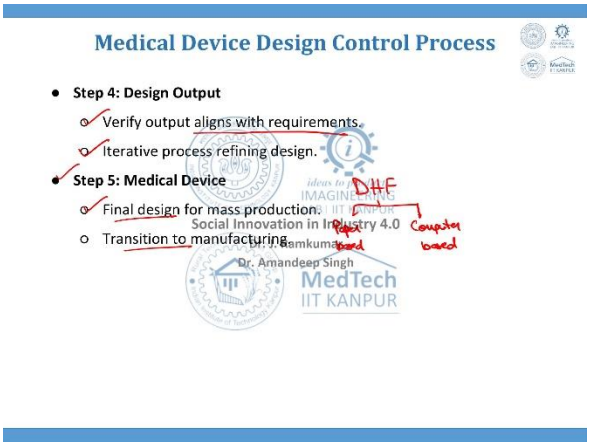


Here is a schematic that is given that how does the, here is a schematic that is given here which represents where does the verification and validation happens and what are the medical device design control process elements here. So here you can see review is happening at each point, user needs are there, it gives the design input, design input gives the design process, what design process it should be because the specification has been gotten from here.

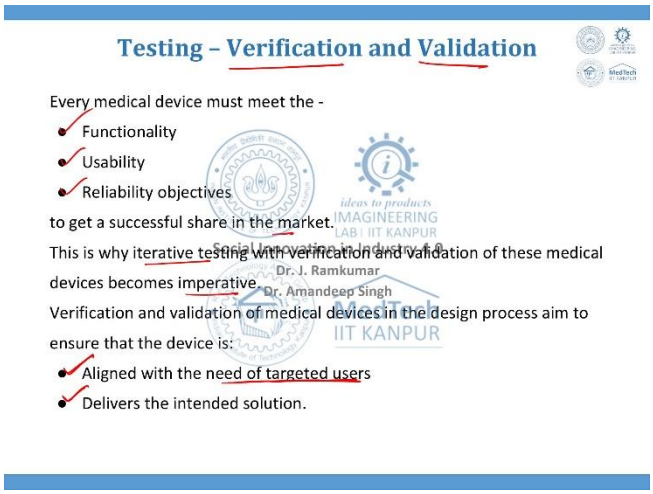
So, here the specifications have been gotten. From these specifications the design process is there, design process gives us the design output, design output gives us the medical device. Here you can see the design output is always verified with the design input. This is verification and the medical device is validated with the user need. This is how it goes, the difference between verification and validation. We will try to see it further. Let us see all these terms separately here.



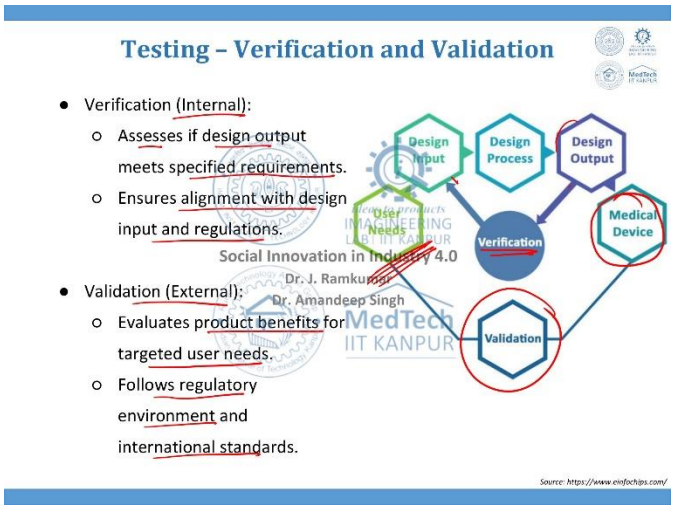
The step one is user needs which means we define the requirements aligned with the market demand then evolve device design addressing the need and feedback loop integral for refinement. Second step is design input which is an iterative process reviewing the acceptability or converting requirements into initial design input. Step three is the design process that is translating design input into high level specifications and these specifications become the design output.



Next comes the design output. The design output that is we verify the output whether it aligns with the requirements or not then iterative process of re-refining the design whenever or wherever necessary. Then finally step five is medical device that is what we have gotten as a final design for mass production then transition to the market. Design control regulation mandates the design history file as it was mentioned in the previous lectures. The design history file is one that records the linkages, changes and development processes. So, this DHF can be a paper based or software based design history file.

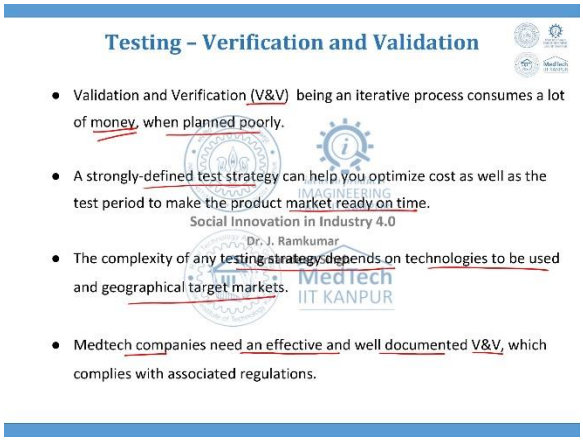


The testing that is verification and validation. Each and every medical device must meet the functionality, usability and reliability objectives. To get a successful share in the market. This is why iterative testing with verification and validation of these medical devices become imperative. Verification and validation of medical devices in the design process aim to ensure that the device is number one aligned with the need of the targeted users, number two it delivers the intended solution for which each medical device should comply or should be verified or validated.



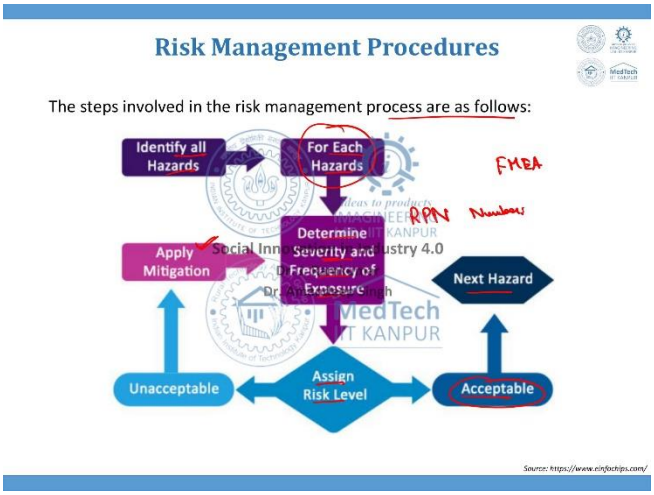
As it is mentioned before as well there is another schematic that tells that verification is between the design input and design output. Design output whatever we have got, for instance, if I have designed a medical device, if I have designed maybe a smart watch only as a medical device the size of the watch, the performance of the watch with respect to what is the input given and whether it is giving the right output the heart beat is being noted the pulse is being noted properly or not this is design output that is verified with the design input.

User need is to record or to monitor itself that is the medical device smart watch is validated with the user need whether actually the health is being monitored whether the graphics are giving the required user interface to the user properly or not this is validation. So, verification is internal validation is external, verification is when it assesses if design output meets the specified requirements or it ensures alignment with design input and regulation. However, validation is when it evaluates that product benefits for the targeted user needs or not it follows regulatory environment and international standards.



Both V & V that is validation and verification being an iterative process consumes a lot of money when planned poorly. So, that is why, the pre-planning or re-planning initially it is better to have a pilot run or maybe simulation in the beginning, it is better to fail a simulation than to fail an actual product though the investment in the simulation would be little high in the beginning but later when it is planned poorly a lot of money is consumed, it is mentioned.

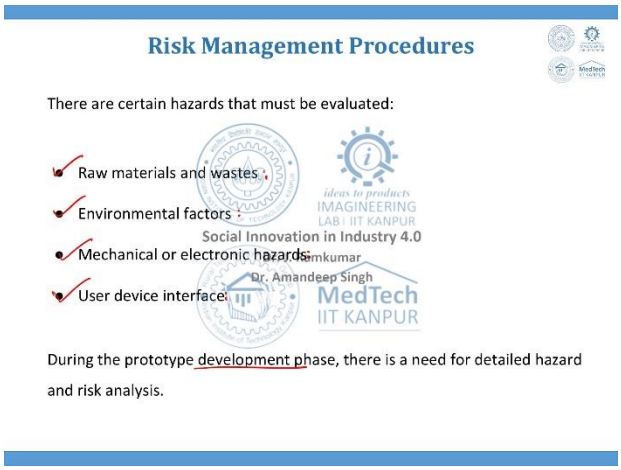
A strongly defined test strategy can help you optimize cost as well as the test period to make the product market ready on time. The complexity of any testing strategy depends on technologies to be used and geographical target markets. Product companies need an effective and well documented V and V that is verification and validation which complies with associated regulations.



Next comes the risk management procedures. The steps involved in the risk management process are as follows. We identify all the hazards for each hazard. We determine the severity and frequency of exposure. The severity is known as RPN number which is a parameter in the FMEA analysis FMEA is failure modes and effects analysis RPN is risk priority number. Risk priority means what is the likelihood of the occurrence of the risk, likelihood of its detection and severity of the impact.

As it is mentioned frequency and severity all are given by this RPN number. So, this number is generated for each of the risk and we assign the risk level accordingly. So, if it is acceptable then we go to the next hazard because it is done for each of the hazards, and if it is not acceptable we try to go for the mitigation of the risk that is we try to reduce the may be the ranges which are given for the voltages or we try to improve the quality of the material.

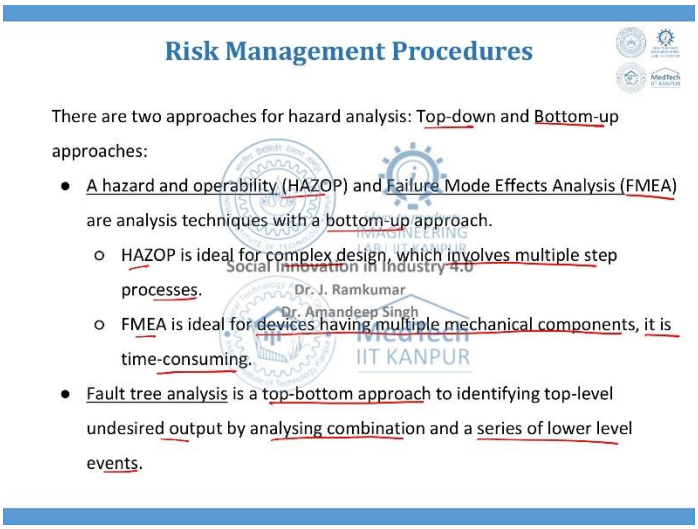
So, mitigation is applied and again we try to determine the RPN number. This is how the cycle keeps on running until and unless we get an acceptable RPN number for the specific hazard that we are trying to work upon.



So, there are certain hazards that must be evaluated, raw materials and wastes, environmental factors, mechanical or electronic hazards, user device interface. When I say raw material and waste it is about toxicity, flammability and reactivity of the material. When I say environmental factors, I am talking about sensitivity to temperature, sensitivity to humidity and many such things. When I say mechanical or electronic hazards, mechanical hazards could be any mechanical failure that happens, maybe because of the small screw which is not tightened properly, electronically the circuits might not be connected properly.

Then, user device interface, when I say user device interface the hazards which are associated with human factors such as ineffective delivery, then may be by drug administration or incorrect or incomplete information or control of life sustaining operations all of these are involved in user

device interface. So, during the prototype development phase there is a need for detailed hazard and risk analysis.



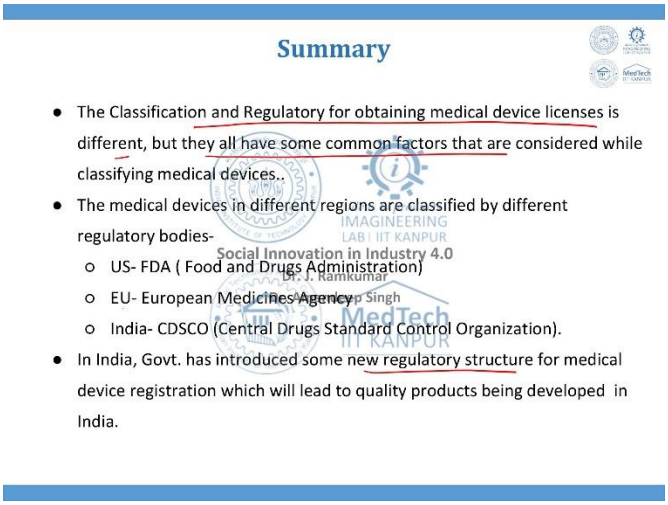
There are two approaches for hazard analysis top down and bottom up. A HAZOP or FMEA are two analysis techniques, a hazard and operability and failure mode effect analysis. So these are two techniques with a bottom up approach that is we try to identify the fault at the bottom and try to rise from there which were discussed in the previous weeks.

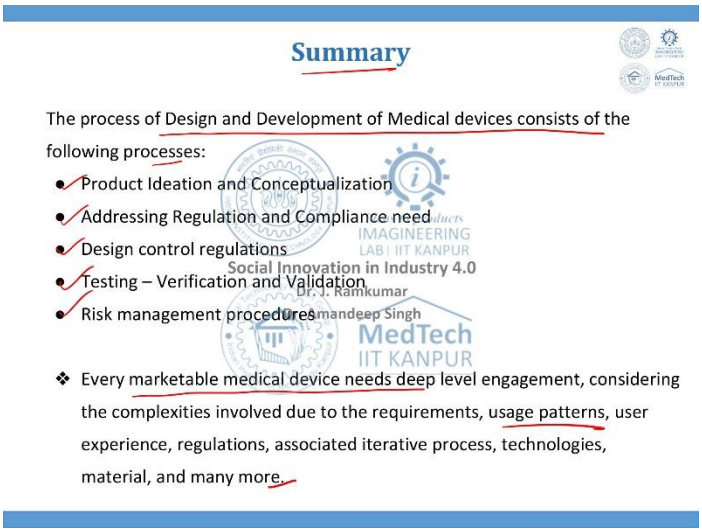
The bottom-up approach is here. HAZOP is ideal for complex design which involves multi-step processes. FMEA is ideal for devices having multiple mechanical components because for each of the components we can try to mitigate what kind of risks are there, we can try to change the component size, component material or so that the RPN number comes to the acceptable level and we try to then go to the next hazard.

So, it is time consuming because we keep on mitigating till the point we are getting the acceptable hazard level. Then comes the fault tree analysis which is a top-bottom approach to identify top level undesired output by analyzing combinations and a series of lower level events. Though we have discussed certain other bottom up and top down approaches in the previous lectures, those approaches could also be approximated for the medical device designs as well.

With this my discussion on medical devices design and development finishes here. Though there are many things that could be discussed, what is FMEA, what are the procedures to conduct FMEA, what kind of criteria could be used to put the numbers in RPM for the severity, for the likelihood, for the frequency of occurrence. So many things could be further discussed. You can

definitely refer to the books which are mentioned in the reference sections of these slides and you can read it further for the design and development of the medical devices. If you need to further really design medical devices then please try to read the standards that are ISO 13485 standard. This whole standard is available online and also the MDR 2017 book the medical device rule for India that also you can read. This would be helpful to you to design your medical device or anything that you will have to put in the market.





To summarize this lecture, the classification and regulatory for obtaining medical device licenses is different but they all have some common factors that are considered while classifying medical devices. The medical devices in different regions are classified by different regulatory bodies, for example in the US it is FDA, in Europe it is European Medical Agency, in India it is CDSCO. In India, the government has introduced some new regulatory structures which is MDR 2017 for medical device registration which will lead to quality products being developed in India. So, we

will try to see what is the design process for medical devices though the design process is already discussed by Professor Ram Kumar in general for any product in Social Innovation but for medical devices what is the design process because we are trying to more focus on the risk here.

The process of design and development of medical devices consist of the following processes, that is product ideation and conceptualization, addressing regulation and compliance needs, design control regulations, testing verification, evaluation, risk management procedures. Every marketable medical device needs deep level engagement considering the complexities involved due to the requirements, user spectrums, user experience, regulations, associated iterative process technologies, material and many more.

Next, I would like to discuss the design of agricultural machinery. Agricultural machinery does not have these stringent or deep compliances as there goes in the medical devices because the risks associated with the human body are not higher there but still those designs or what are the trends or changes which have come through the time in the past decade we will try to see them and the next week we will try to see the rapid prototyping or 3D printing as a part of our course. Thank you.