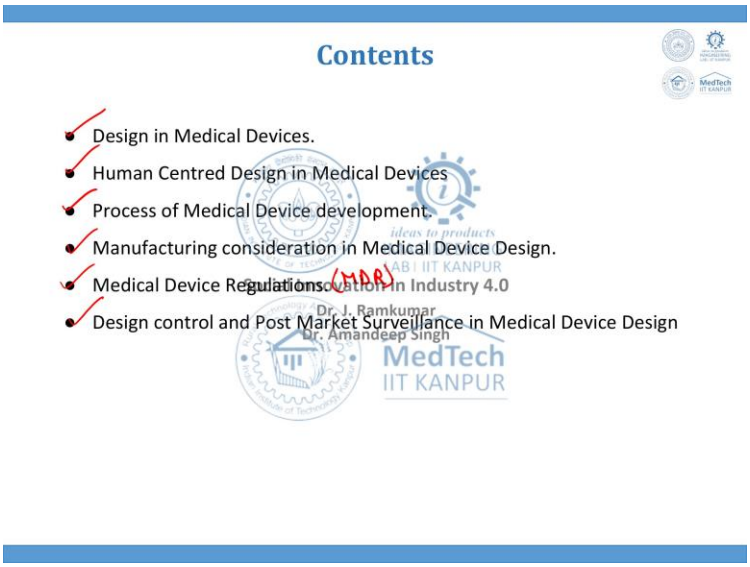
Social Innovation in Industry 4.0
Professor J. Ramkumar
Professor Amandeep Singh
Department of Mechanical Engineering and Design
Indian Institute of Technology, Kanpur
Lecture 34
Design and Social Innovation in Medical Devices (Part 1 of 2)

Welcome back to the course on Social Innovation in Industry 4.0. We have discussed multiple different topics in the course and what was promised as well was to discuss about the Social Innovation in Medical Devices and in agricultural devices or in agriculture. So, this week would be focused on Design and Development and Social Innovation aspects in Medical Devices and in Agriculture. Let me start with the lecture on Design in Medical Devices.

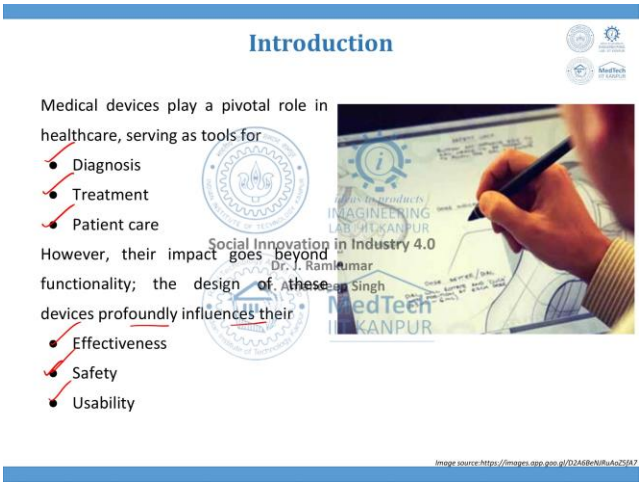


The Contents of the lecture would go from discussing the design in Medical Devices to simple Definition of what are the Specificities of Design when we talk about Medical Devices.

Then, Human Centered Design in Medical Devices because whenever we are trying to talk about Medical Devices, we are majorly talking about either someone is using that, the professionals, doctors, nurses are going to use the Medical Devices, or the patients upon whom the Medical Devices are to be used. For example, the thermometer etcetera the patients use for themselves itself, that is also Medical Device that tells us the temperature of the body. There are classification of Medical Devices. Class 1, 2, 3.

International classifications are there, India classifications are also there. Class is A, B, C, D depending upon the risk that is associated with the medical device. That is thermometer is a medical device where least risk is there, that does not go inside the body, no blood is taken out. And, there are certain medical devices that goes inside the body, like for example, the needles or surgical needles or so, this goes inside the body. So, there are different classifications of them and also Human Centered Design in Medical Devices is important.

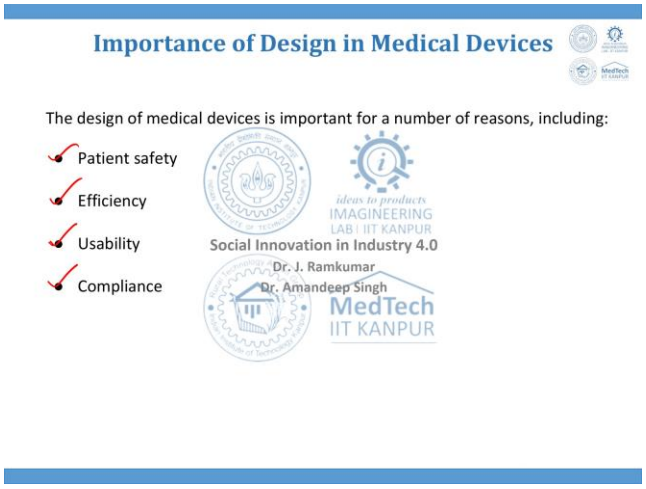
Process of Medical Device Development, this would also be discussed. Manufacturing Considerations in Medical Device Design. MDR which is Medical Device Regulation. MDR files, MDR regulations are there that also we will try to see what are these. Design Control and Post Market Surveillance in Medical Device Design would also be discussed in this lecture.



Number one Introduction Medical Devices play a pivotal role in healthcare, serving as tool for diagnosis, treatment and patient care. Diagnosis means we are just collecting the data for identifying or to know about what is the disease. For example, getting the temperature itself, taking the heartbeat, taking the blood pressure readings or so, this is all diagnosis. More deep diagnosis could be, we are trying to have a CT scan, we are trying to have an MRI, those are also diagnostics only. Treatment is whenever diagnostics leads to a prescription that is based upon the data that is available.

We apply analytics over it, the doctors apply their experience over it. So, whenever the prescription is given, either through the prescribed system by the software itself or the doctors with their own experience try to prescribe that is known as therapeutic treatment. So, this treatment is there. Patient care is always part of it whenever we design Medical Devices. However, their impact goes beyond functionality.

The design of these Medical Devices profoundly influences their effectiveness, safety and usability. So, these are the 3 key terms that we will discuss in the forthcoming slides in the lecture. Effectiveness and usability are two different terms. Safety is always associated whenever we are talking about medical devices, because medical devices are designed based upon a quality management system, that is we will try to discuss like ISO 13485 which is a quality management system that pertains to keeping the record of who is the person who has designed, who is the person who have performed certain operations on designing these medical devices, who has designed it, what are the materials used, where the materials come from, is the biocompatibility of the material correct or not, all these things are kept into account, so as to record that what is the risk if something fails. Based upon this the safety is always taken into account.

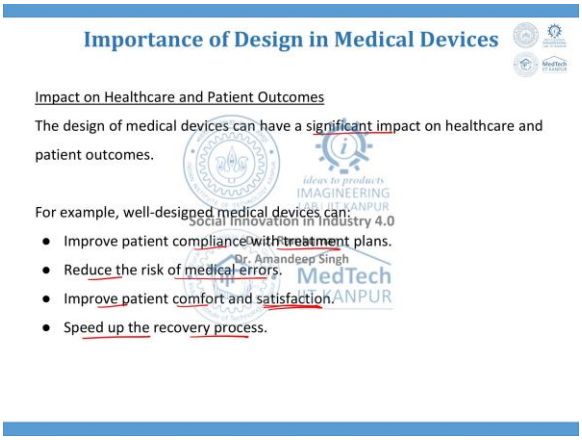


Now, Design of Medical Devices is important for a number of reasons. Number one is patient safety. When I say patient safety I mean to say here, a well-designed medical devices are safer for patients to use, that is safety becomes the concern here. Then, comes efficiency. Efficiency means the device should be efficient to be used.

When I say efficient the device should be able to save money or save time. Save time means if you get a blood pressure readings at home itself within less time, you do not have to go to the doctor, portable medical devices which are designed for this purpose, those save time. Efficiency means as early as possible if it gives the readings, for example MRI scan is there though the facilities are available separately at some places but immediately you get the print out of the different phases or different levels of your body part, whatever you are trying to get the diagnosis on. Usability is also important. Usability means the devices should be easier to use, so that the patient compliances and outcomes are improved.

Easier to use in a way all the time if only highly skilled people well-trained in using the devices are all required, so that also does not seems to be a very great design. Yes, certain medical devices or big machines are to be used by the experts only, but with a little training if the regular nurses could also use something that is a better design than what it can have been used only by super expert people. Then, comes compliances. Compliances means medical devices are more likely to comply with regulatory requirements. There are certain bodies who try to regularize, who try to take the results from the clinical test and try to approve, yes, this device could be used on the human body now.

So, different kinds of the sections are there, different kinds of the approvals are there, which try to provide us the regulatory compliances that are acceptable for the medical device to be finally used. We will talk about this in the forthcoming slides.

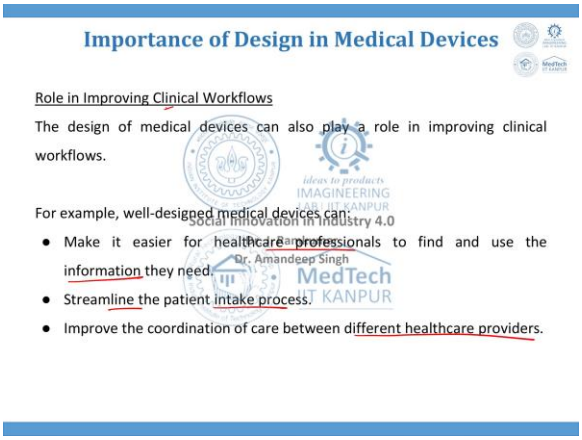


Next comes impact on healthcare and patient outcomes. The design of medical devices can have a significant impact on healthcare and patient outcomes. For example, well-designed medical devices can improve patient compliances with treatment plans.

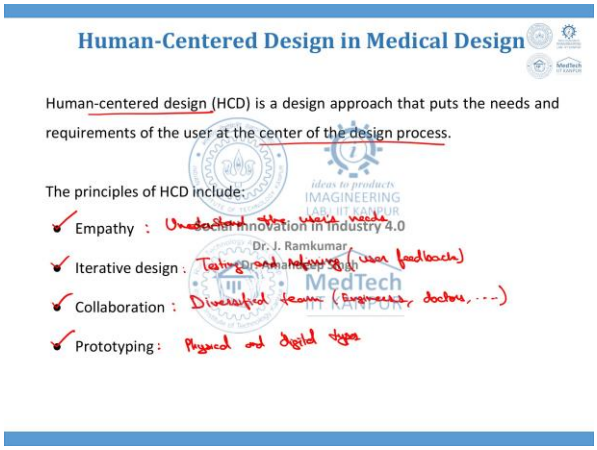
They can also reduce the risk of medical errors. They can improve patient comfort and satisfaction. Patient comfort and satisfaction is very important. Whenever we are trying to design a medical device, that device that is going to touch the patient, so, what has to be the design of that. For example, if you are just need to know the blood pressure of the system, just the belt design, the type of the flow that is to be chosen should be giving comfort to the patient.

Next is patient satisfaction. Satisfaction means the patient if also knows to some extent, okay, the result is coming correct, the device is using correctly, just also bring satisfaction. This speed up the recovery process because more closely we are able to use

the medical devices, and more quickly we get the results as well. So, recovery processes are also speeded up using some of the medical devices.



Role of medical devices in improving clinical workflows. The design of medical devices can also play a role in improving clinical workflows. For example, well-designed medical devices can make it easier for healthcare professional to find and use the information they need. Then, it also helps to streamline the patient intake process. Improvement in the coordination of care between different healthcare providers could also be given by designing good medical devices.



To design a medical device simply we have a Human-Centered Design Procedure, that is, the design approach that puts the needs and requirements of the user at the center of the design process.

We talked about design thinking in the previous lectures. Design thinking is, we try to do the empathy study. Then, we only try to do the defining, ideating, and everything is taken

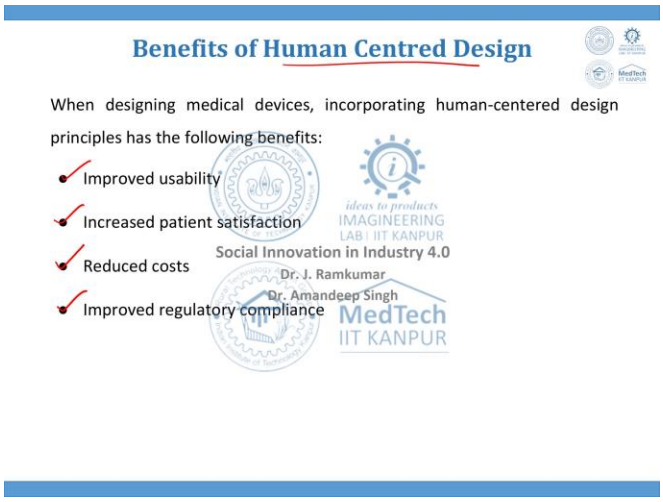
care later only here also, because human-centered design is there. Empathy study would also play a big role here, that is we try to understand the user needs. Then, it is an iterative design that is empathy study is only giving the initial data, we also try to keep testing and refining the design.

Now, this testing and refining is done based upon the user feedback. Collaboration is always part of the human-centered design because working with diverse team and stakeholders is always important. So, we say diversified team is there and collaboration between them is important. For example, one person who is going to only draw the design in the CAD (Computer Aided Design) program, another person who is going to actually use the medical devices on the patients. So, there is a big difference in this team.

These are two teams. The one person, who is just designing, is a mechanical engineer, who is only trying to put the systems, or the lines, or the graphs, everything into a 3D shape, and trying to give the shape to the design in the computer model only, another person is going to finally use. In between there are different levels of people who will try to convert that design into manufacturing design or manufacturing drawing or so. Then, that would be manufactured, material has to be complied. Another person may be the overall project manager would try to see, where the material is coming from, the availability and what is the life of the material, what should be the strength of certain parts of the components which are designed, those all are to be taken care of. So, therefore collaboration between diversified team starting from engineers, doctors, anyone could be part of it and so on.

Then, comes prototyping. Prototyping means building and testing physical or maybe digital prototypes to get the feedback from the users. Physical prototyping, we will try to discuss about rapid prototyping or rapid manufacturing or additive manufacturing techniques in the next week of this course, where we will see, how these days quickly if you have something on your mind you can scan it and try to get a 3D print out of it and try to just have a feel this product would look like this. Finally, even the product that is to be used by the patient compatible materials, biomaterial could also be 3D printed. So, that is done through additive manufacturing or rapid prototyping nowadays. So, prototyping means to design the prototype, the prototype could be physical, it could be digital.

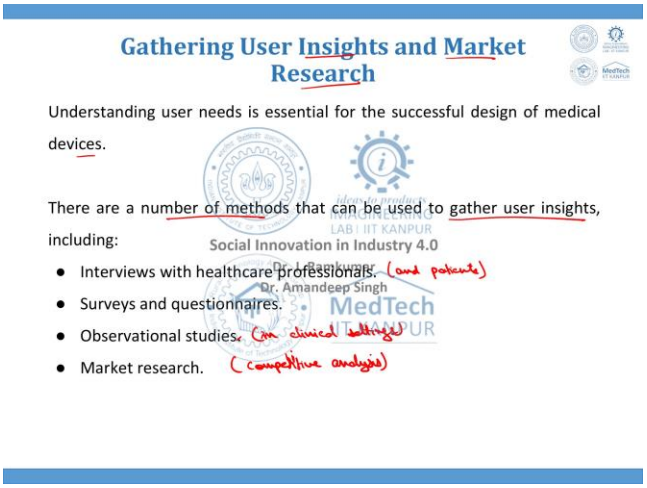
Physical is, finally, it is to be used by the user. Digital means, in a digital form what does it look like, this is one, or either it could be even a software that we are designing, that digital prototype can be also used for finally testing before it is finally used by the patients. I would put here physical and digital types.



Next comes, benefits from the human-centered design. When designing medical devices, incorporating human-centered design principle has following benefits.

These benefits are, number one is improved usability that is human-centered design can lead to improve usability of medical devices which can make them easier to use and it becomes more safe for the patients. Then, we have increased patient satisfaction as I just mentioned in the previous slides as well. Human-centered design can lead to increase patient satisfaction because it can improve patient compliance and patient outcomes. Costs are also reduced. The costs are reduced because human-centered design helps to identify and fix usability problems early in the design process because the design process includes empathy as well.

So, iterations numbers are reduced if the number of iterations are reduced, design time is reduced, the total design and development time if it is reduced, that means the costing is reduced. Then, comes improved regulatory compliances. The regulatory compliances that means to ensure the medical devices complied with regulatory requirements. These things are kept in mind in the beginning itself. So, there are certain benefits of having human-centered design.



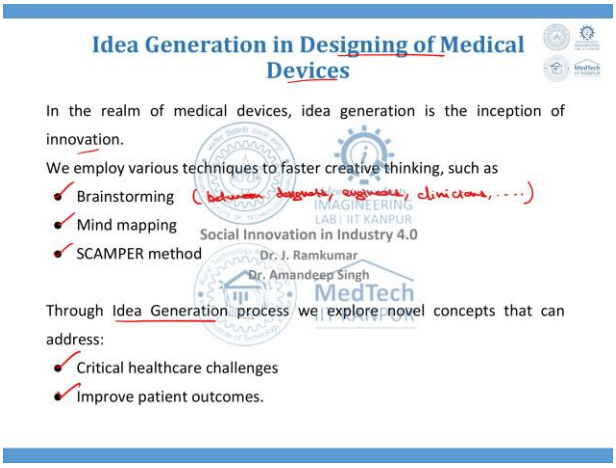
Next is Gathering User Insights and Market Research. Understanding user needs is essential for successful design of medical devices. There are a number of methods that can be used to gather user insights, which include interviews with healthcare professionals. Not only healthcare professionals, we can also have interviews with patients as well.

Then, surveys and questionnaires. So, these are the ways to collect the data. The direct interview method, the telephonic contact method, the in-person interview method, then surveys and questionnaires which are well used before as well, so, we curate it for our own specific need. Then, we try to use them for the specific requirement or the medical device that we are trying to work upon, and the geographical area that we have selected, demographics that we have selected, the kind of the customer segment that we have selected. Maybe we are designing something for kids only, so, we can interview the parents that what do the kids require. And, we can directly even interview the kids only, the patients are also interviewed only.

So, these questionnaires surveys do help in that. Then, is observational studies. Observational studies means in the settings which are controlled, that is, I would put here, in clinical settings. In clinical settings that is, within the control environment the observations are done to see, whether a device is working well or not. Then, market research is also one of the methods to get user insights, that is, we try to get the competitive analysis.

Market research means, if I am trying to design a separate product to understand maybe the impulse of the human. Similar products are those available in the market, if those are available, are those available in the local market in my country, if those are available in a country, for example, in an European country or maybe US, what is the price? So, what is the value proposition that we are trying to offer to my customers or my clients or my patients or doctors within my country itself. So, that could be one of the analysis, that is

the competitive analysis. So, market research also becomes a major method when we are trying to gather the data for designing the medical devices.

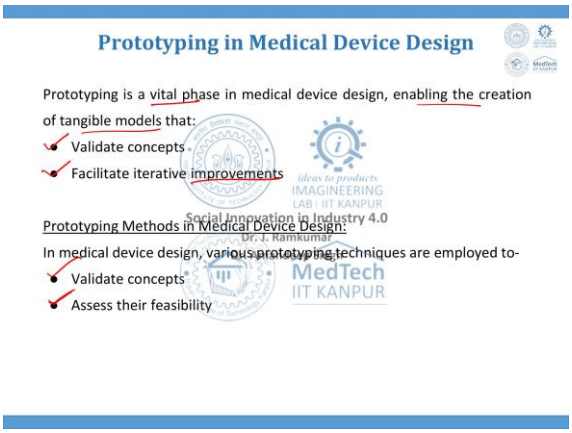


Then, Idea Generation in Designing Medical Devices is similar to as we discussed the idea generation in the design thinking process so well.

In the realm of medical devices, idea generation is the inception of innovation. We employ various techniques to faster creative thinking. These creativity techniques are generally brainstorming, mind mapping, and scamper methods. All of these methods are just to create ideas. Brainstorming could be either facilitated by a central person, or it could be within the team itself that each one of them is putting their idea and one person just noting down, the certain methods are there.

So, brainstorming, this is generally between designers, engineers, clinicians and so on. Any of the stakeholders could be part of it. Mind mapping is when we are trying to understand what is the thought or perception in the mind of the person who is going to use this product. So, this mind mapping techniques are also kind of an empathy study only, when we are trying to get the ideas for my product.

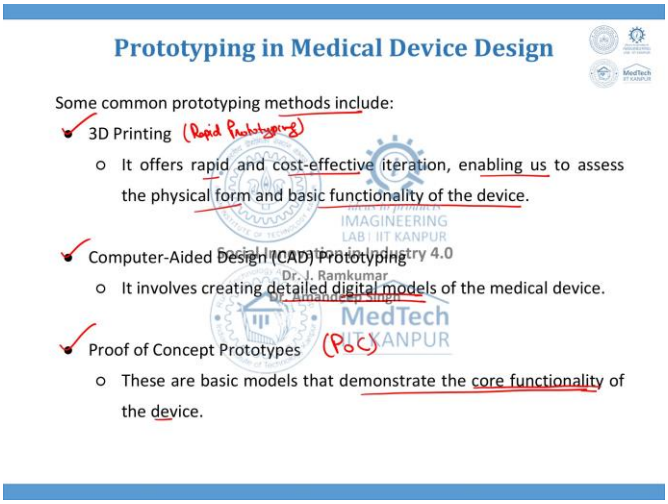
Then is scamper method. This is also discussed previously by professor Ramkumar only, so I will miss it here. So, through idea generation process we explore novel concepts that can be addressed. So, novel concepts, that is, critical healthcare challenges are taken care of, and improved patient outcomes is also one of the important factors.



Prototyping in Medical Devices is a vital phase, in which the device that is going to be designed or developed, which is going to enable the creation of tangible models. So, we need to validate these models and we need to facilitate iterative improvements.

There are multiple steps in medical device development. Two of the major parts where we try to just test or review our designs are known as verification and validation. I will try to discuss about them later in the forthcoming slides as well. Verification is just trying to see whatever dimensions we have given whatever shape we have given is correct or not. Validation is finally testing with the patient but whatever we have designed is giving the planned output or not.

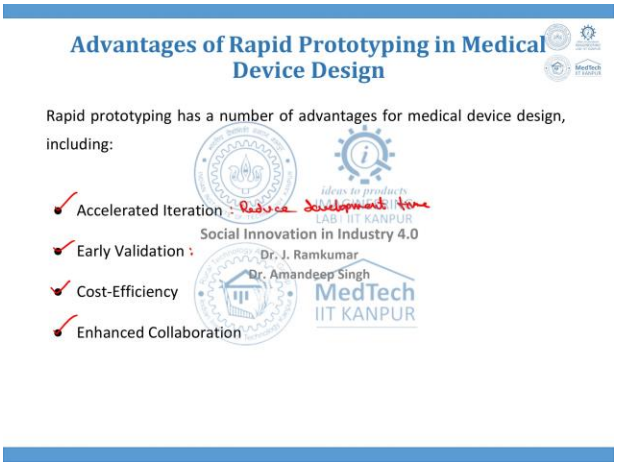
So this is validate the concepts. So, then facilitate iterative improvements and facilitate mean iterative improvement after validation. suppose, if something is to be changed later that change how closely, we can implement. that iterative improvements are to be used upon. Prototyping methods in medical device is designed. In medical device design, various prototyping techniques are employed to validate the concepts and to assess their feasibility.



So, some of the common methods here include, Number one is 3D printing which we will discuss in the forthcoming lecture. This is rapid prototyping. Rapidly we try to just scan something or just try to design it on the computer, and try to get a print out of that and we get a 3D model, and try to have a feel of the size, shape and what the product would look like. It offers rapid and cost-effective iteration, enabling us to assess the physical form and basic functionality of the device.

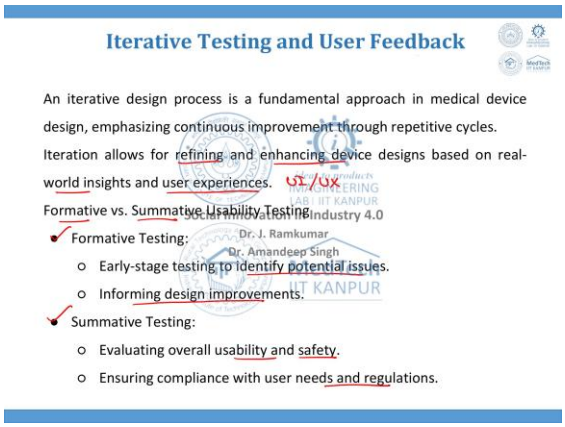
Then is computer-aided design prototyping. Simply only having a digital design or digital models of medical devices. Just to present the photographs to maybe funding partner or collaborators or certain stakeholders, that device would something look like this if it is applied on a patient, maybe that photographs could also be developed. Photographic, when I say these are the CAD models (Computer- Aided Models), where digital model of the product is generated. So, proof of concept prototypes. Proof of concept prototypes here there are basic models that demonstrate the core functionality of the device, that is here only not the snaps but core functionality of the model is also presented.

So, this could be a 3D printed prototype only, where core functionality that this product would try to solve the problem more easy. I will come to an example that I have to show you certain proof of concepts which were designed at Medtech IIT Kanpur as well. So, proof of concept prototypes are also known as POC prototypes serve to verify that the fundamental features and mechanisms of the work as intended for the device is okay. However, the CAD design or CAD prototyping facilitates in virtual testing or maybe visualization or offering insights into potential improvements as well. So, proof of concept is a bigger or the more advanced version than the other two above.



Rapid prototyping has a number of advantages for medical device design, which includes accelerated iteration. The iteration is accelerated that means rapid prototyping expedites the design refinement and reduce the development time. Then, early validation, because we are trying to enable early testing and we are trying to uncover the flaws, and we are also enhancing the user interaction. So, early validation happens. Then, cost-efficiency, that is, the issues are identified in the prototyping phase and this minimizes the cost and any changes that could come later are identified as early as possible.

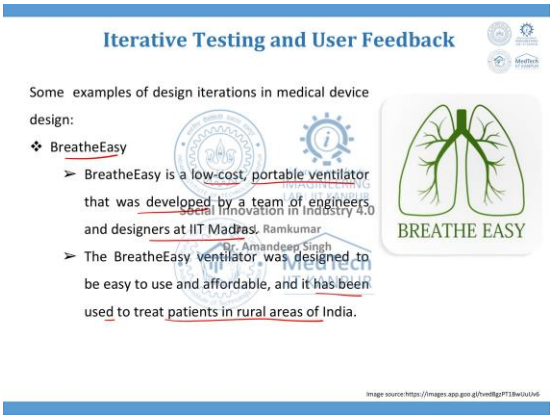
Then, we have enhanced collaboration. Enhanced collaboration means tangible prototypes facilitate effective communication among cross functional teams. So, collaboration is enhanced because the teams are cross functional, as I said it could be an engineer, it could be doctor, it could be in between simply the CAD model or so. So, collaboration between them is enhanced.



Then is Iterative Testing and User Feedback. An iterative design process is a fundamental approach in medical device design, emphasizing continuous improvement through repetitive cycles.

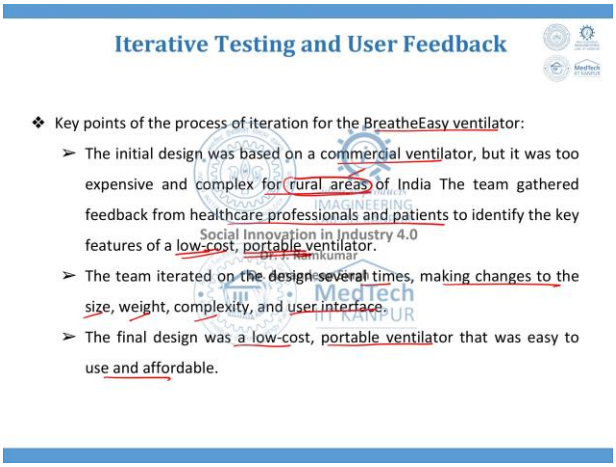
Iteration allows for refining and enhancing device design based on real-world insights and user experiences. So, UI and UX (User Interface and User Experience) are the major concerns. When we are trying to have the testing of the prototype that we have developed. So, it could be formative or summative. Formative versus summative usability testing, how is it compared? Formative testing is something where early-stage testing is taken care to identify a potential issues.

It is informing design improvements only. Summative testing is one where evaluating of overall usability and safety is concerned about. Now, ensuring compliance with user needs and regulation is taken care in the summative testing.



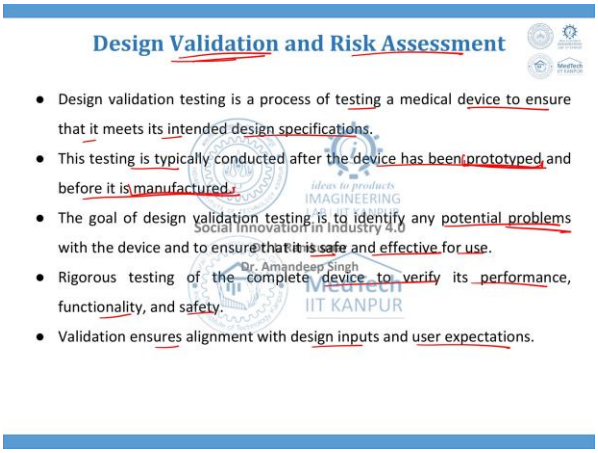
Now, let us take an example for this. For example, this is a product BreatheEasy in which portable ventilator was developed which was of low cost.

It was developed by a team of engineers and designers at IIT Madras. The BreatheEasy ventilator was designed to be easy to use and affordable, and it has been used to treat patients in rural areas of country.



Key points of the process of iteration for BreatheEasy ventilator design are mentioned here. The initial design was based upon a commercial ventilator, but it was too expensive and complex for rural areas. The team gathered feedback from healthcare professionals and patients to identify the key features of a low-cost, and portable ventilator. These two were the key value propositions which they were trying to offer to the rural areas.

The team iterated on the design several times, making changes to the size, weight, complexity, and user interface. And, the final design that was obtained was of a low-cost, portable ventilator that was easy to use and affordable.



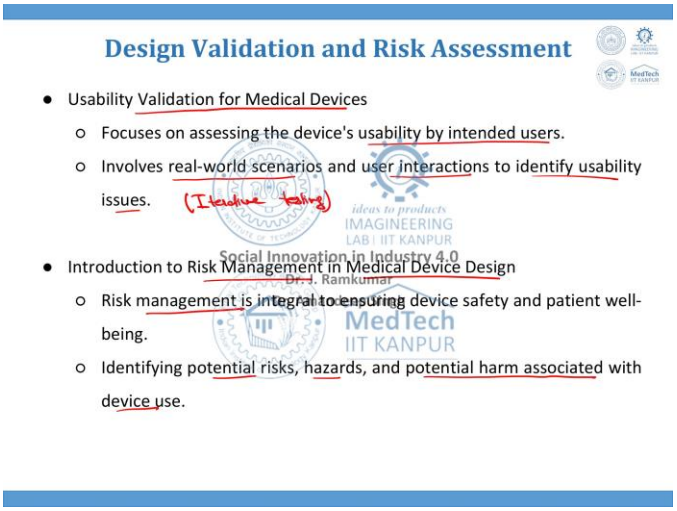
Next point is Design Validation and Risk Assessment. Design validation as I said is something that we finally take to the patient, and try to validate at whatever the outcomes were planned are coming accordingly or not.

So, what was scheduled and what is actual. What was planned and what is actual, these are all compared and risk assessment is also taken care here. The design validation testing is a process of testing a medical device to ensure that it meets its intended design specifications. This testing is typically conducted after the device has been prototyped and before it is manufactured. So, between prototyping and manufacturing, prototyping means we try to develop a few number of the prototypes only.

A full-fledged manufacturing setup is not made. For example, for the finally compliance testing or clinical testing five numbers are required. Let me say oxygen concentrator, oxygen concentrator is to be tested for its flow ability, its capacity and the kind of the pressure it is provided for the oxygen, different parameters are set. Only five pieces of this whole oxygen concentrator machines are developed to finally test it at the laboratories which give us the approval. This is all a prototyping.

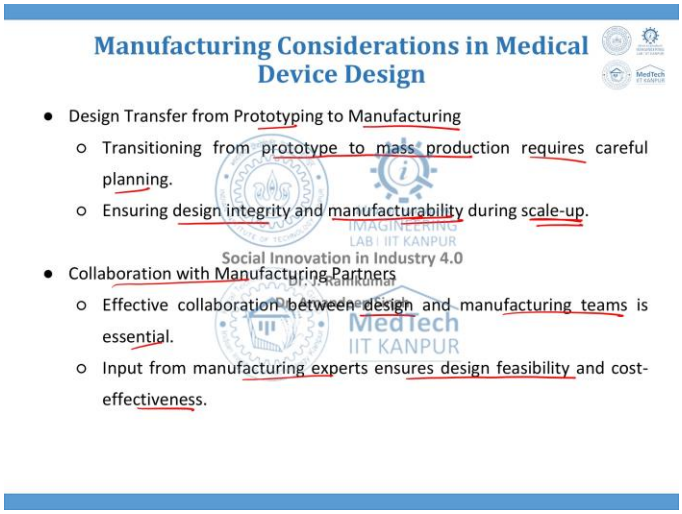
Once it is approved, then a full-fledged manufacturing setup could be made, where it could be maybe 500, 5000, 50,000 pieces could be manufactured, and the machines could be set in a different kind of the flows, maybe a process flow or a product flow machines could be set.

So, in between the prototyping and manufacturing this validation happens. Yes, the product is validated and it is approved by the testing agencies. The goal of design validation testing is to identify any potential problems with the device and to ensure that it is safe and effective for use. This is the major concern in that design validation. Regressed testing of the complete device to verify its performance, functionality, and safety is taken care. Validation ensures alignment with design inputs and user expectations.



Now, in design validation and risk assessment there are certain points which are taken care of, for example usability validation for medical devices. This focuses on assessing the devices usability by intended users. And, it involves real-world scenarios and user interactions to identify usability issues. Now, iterative testing to refine user interfaces, or ergonomics, or overall user experience are always applied.

I would just write it here iterative testing. It is we keep on getting different feedback from the patients, the doctors who are going to use the medical device and these iterations of the improvements to happen. Now, introduction to risk management in medical device design. Risk management because medical device is always based upon the risk whenever those are designed as I said. Risk management is integral to ensuring device safety and patient well-being. Identifying potential risks, hazards, potential harm associated with device use is an important factor, and risk assessment informs design decisions and also the mitigations.



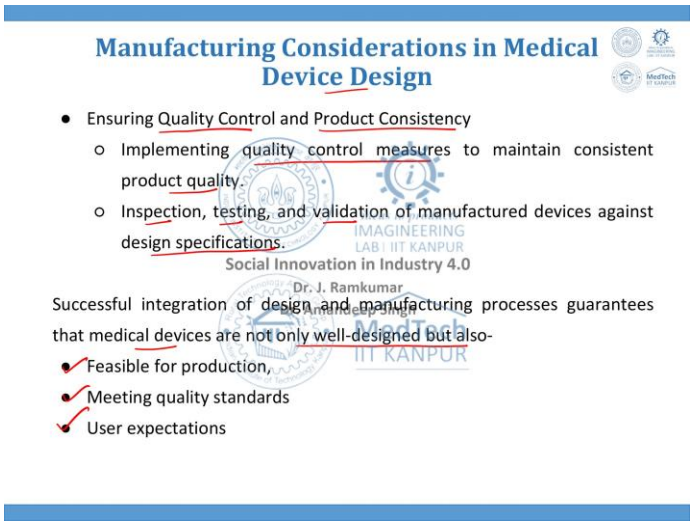
Then comes one of the Manufacturing Considerations in Medical Device Design that is design transform from prototyping to manufacturing. Prototype is now ready and it is to be transition to the manufacturing, before transition to the manufacturing approvals are taken care of. Now, transitioning from prototype to mass production requires careful planning, in which ensuring design integrity and manufacturability during scale up is also important. What is manufacturability? The product that is of a shape which is very difficult to design to intricate corners are there. Sometimes the manufacturability means it is not even easy to manufacture or the costing of this product would go too high.

Manufacturability is, how easy is it to manufacture this product based upon your available settings. Some products we might be able to design very greatly in the CAD, digital models are developed. Even 3D printed models are developed but when we try to

go for the mass production of them. So, then these mass production may be special purpose machines are required which are not available to close vicinity only. These machines may be for example in Kanpur, these machines are available may be in Bangalore only, or some machines are even available in US or may be some far countries.

So, then manufacturability is lesser here. Manufacturability is, how close, how fast, how cost-effective you can manufacture the product. So, manufacturability is also important to scale-up the product. Scale-up means we are scaling-up the numbers of the units which are to be manufactured. So, here addressing potential challenges in selecting materials, selecting different processes, or may be different production techniques, these are very important.

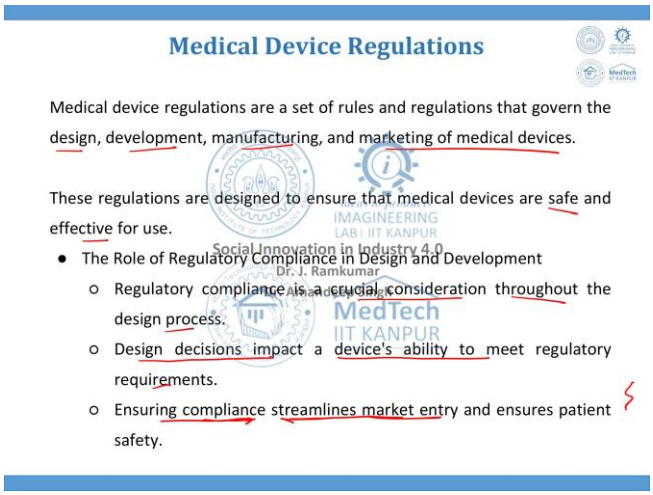
Collaboration with manufacturing partners. Effective collaboration between design and manufacturing teams is essential. Input from manufacturing experts ensures design feasibility and cost-effectiveness. Now, iterative feedback, I keep on telling this point time and again iterations and getting feedback, these loops are kept on coming time and again to optimize design for efficient production.



Also, in the manufacturing consideration in medical device design there comes the quality control and product consistency. When I say product quality control, implementing the quality control measures to maintain consistent product quality is taken care of, where inspection, testing, validation of manufacture devices against the design specifications is always taken care of.

Here, also continuous monitoring to prevent defects and to ensure compliance with the regulatory standards is taken care of. When I say continuous inspection or maintenance,

the maintenance here could be for the machines that you have used to manufacture the product, the maintenance could be preventive, it could be addictive, whatever it is, breakdown maintenance is always avoided because breakdown means the machine is completely come to stand-still, and you have to invest something on the machine to get the production restarted again, the production stops there. So, that is avoided, so maintenance part is also taken care of here. Successful integration of design and manufacturing processes guarantees that medical devices are not only well-designed but also they are feasible for production, they are meeting quality standards and they are meeting the user expectations.



Then, comes Medical Device Regulations. Medical device regulations or MDR are a set of rules and regulations that govern the design, development, manufacturing and marketing of medical devices. These regulations are designed to ensure that medical devices are safe and effective for use.

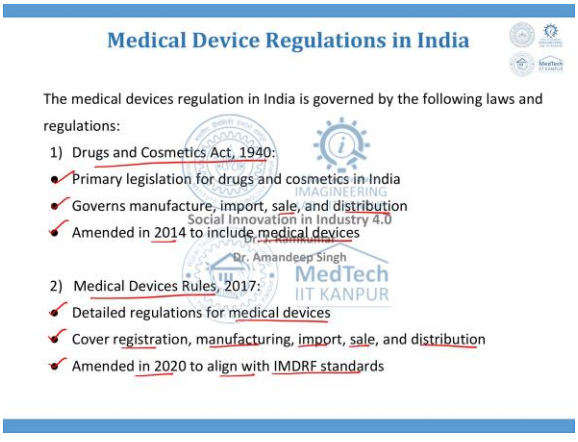
The role of regulatory compliance in design and development is that the regulatory compliance becomes crucial consideration throughout the design process and the decision the design that is design decisions impact a device's ability to meet regulatory requirements. Ensuring the compliance streamlines the market entry and ensures patient safety because whenever the products are taken to the patient, or the user, or maybe doctors are always having this information that the product is whether approved or not.

The product is approved by FDA, the CDSCO in India, the different approval agencies are there. So, whenever the compliance are complied to market entry is streamlined.

Now, different kind of the medical device regulations are there as I just said FDA (Food and Drug Administration). The regulatory requirements for medical devices vary from country to country. In US, FDA that is Food and Drug Administration regulates medical devices.

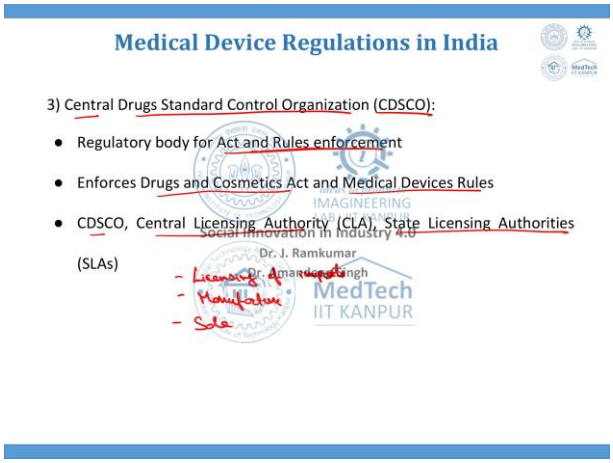
There are two kinds of the markthey give that are FDA cleared and FDA approved. This is required for the product to be completely safe, cleared mainly, it has only cleared the first level only. So, this FDA approved is the final approval that is given for the product to be used.

So, FDA classifies devices into different classes based upon their level of risk. These are the levels of risk to the patient, and manufacturers must submit premarket submissions for review. Similarly, in European countries that is European Union medical devices bear CE marking, indicating compliance with the MDR or In Vitro Diagnostic Regulations as the IVDR. The CE marking demonstrates that the device meets the EU safety and performance requirements.

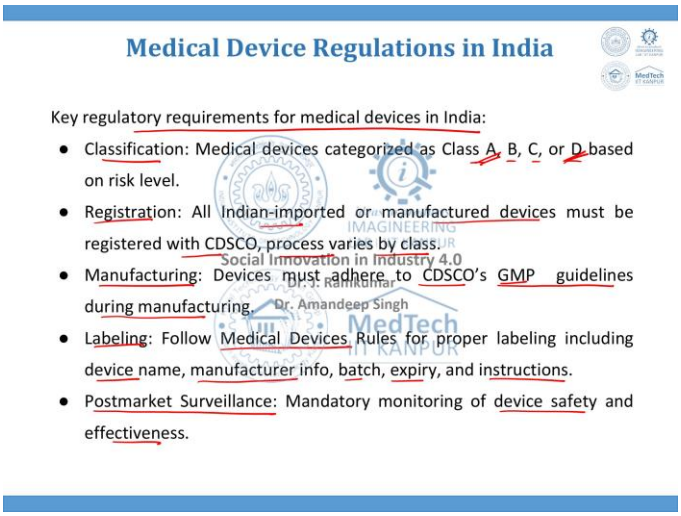


Similarly, we have an administration in India which is governed by the following laws. Drug and Cosmetics Act 1940, and we have MDR (Medical Devices Rule) 2017. This is a very important document here. The first one, Drugs and Cosmetics Act, it tells that the primary legislation for drugs and cosmetics in India is this only.

And, it governs manufacture, import, sale and distribution. It was amended in 2014 to include medical devices. Now, Medical Devices Rule that is MDR 2017 has a detailed regulation for medical devices, whenever a medical device company or medical prototyping company such as Medtech is a facility at IIT Kanpur, we need to keep the files of the MDR 2017 to understand okay, these are the rules that we are going to apply to maintain our ISO standards, that is 13485 ISO standard that is being maintained here at IIT Kanpur. So, this cover the registration, manufacturing, import, sale, and distribution of the medical devices, that we are trying to prototype here. This was also amended in 2022 aligned with IMDRF standards.



Next is CDSCO, that is Central Drug Standard Control Organization. This is a regulatory body for Act and Rules Enforcement. It enforces Drugs and Cosmetics Act and medical devices rules. CDSCO then we have Central Licensing Authorities and State Licensing Authorities, which are CLA and SLAs respectively are the one which try to keep control over the design and distribution of the medical devices. Their responsibilities are Licensing of imports, then manufacturing. It is mentioned already manufacturing and sale.



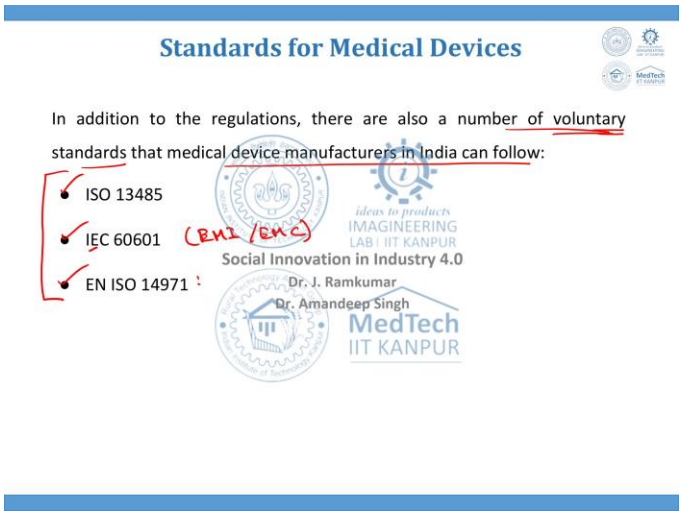
Generally, to design a medical device key regulatory requirements include classification, registration, manufacturing, labeling and post-market surveillance. What is classification? That is medical devices has to be classified or categorized into classes A, B, C and D. These are the classification based upon the risk, that is associated with the medical devices. For instance, class A is having a medical device that has a minimum risk as I talked about thermometer or may be tongue depressor or so.

As and when the risk keeps on increasing the class level keeps on increasing. For example, class D is a medical device with the highest risk where even a small failure in the medical device can even have a fatal failure as well. So, based upon different kinds of the risk associated, these classes are classified here. Next comes the registration. Registration that is all Indian-imported or manufactured devices must be registered with CDSCO, process varies by class.

That is the stringent requirements are therefore high risk, that is D. And, those are low for the class A devices which are low risk. Then manufacturing, devices must adhere to CDSCOs GMP guidelines, that is GMP are Good Medical Practices guidelines, these are taken care during manufacturing. Labelling, to follow medical devices rules for proper labelling. it includes device name, manufacturer information, badge, expiry, instructions.

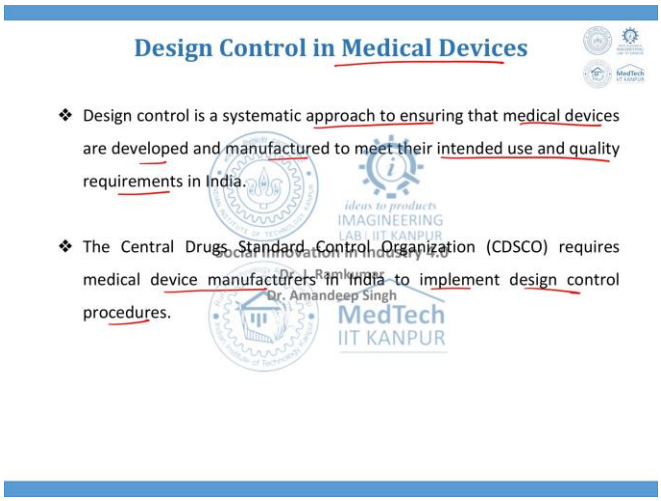
You can see if you pick any medical device these things are always there. Even the drugs that you purchase expiry date is given here and who has manufactured here. That is the person or the company who would be responsible in case of any failure that has to be labelled properly on the medical devices. Then, Post-market surveillance. Post-market

surveillance means mandatory monitoring of device safety and effectiveness, which include the data analysis on adverse events, the recall or complaints, post-market surveillance is always there. The medical devices which are replaced or medical devices for which complaints have come, and how quickly have you addressed the complaints these all data points are to be kept into the register.



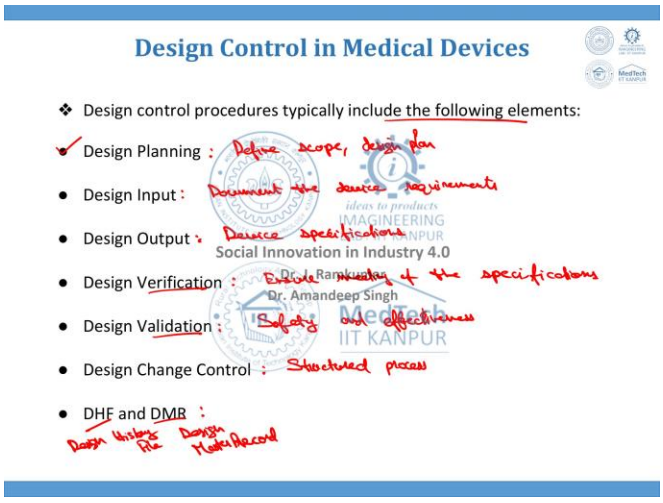
In addition to the regulations, there are also a number of voluntary standards that medical device manufacture in India can follow. Previous one, the CDSCO and other rules were the mandatory. Now this one, it is ISO standards ISO 13485, IEC 60601, EN ISO 14971 are for different kinds of the applications that we are trying to use. So, like, ISO 13485 are quality management system for medical device design, manufacturing, or servicing, or maybe even for prototyping as well, like MedTech IIT Kanpur doing prototyping only. Then, IEC is a safety performance requirement for the electrical equipment, that is, we have electromagnetic interference or electromagnetic compliances, which are to be taken care of for these IEC standards are taken or put there.

Then, we have ISO 14971 which are the risk management processes for management devices, these are all to be taken care of but these are voluntary as it is mentioned here. If we use these standards, the medical devices could be used or sold in different parts of the world, globally it could be sold. This is the call taken by the manufacturer or the designer where that what kind of standards, what kind of the stringent standard the person would like to follow or where the market is? So, accordingly these standards are followed.



Next comes Design Control in Medical Device. When I say design control, design control is systematic approach to ensure that medical devices are developed, and manufactured to meet their intended use and quality requirements in India.

The CDSCO requires medical device manufacturers in India to implement design control procedures. So, these design control procedures include many things, it could be planning, input, control, output those are mentioned in the next slide here.

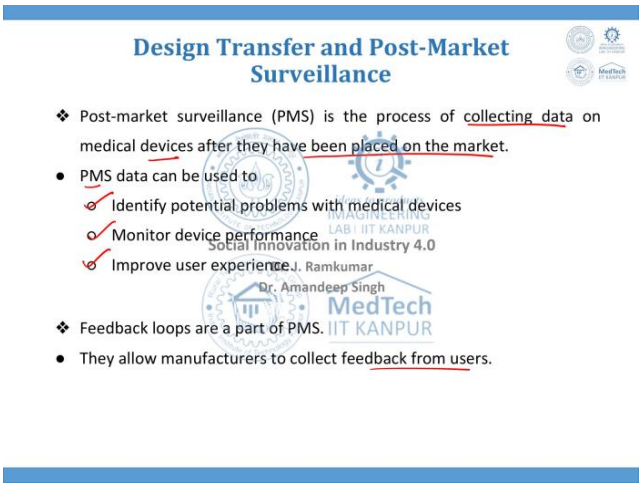


Design control procedures typically include the following elements. Design planning, design planning means we try to define scope, then we try to make design plan, identify

the stakeholders and so on. Design input, that is we try to gather and document device requirements, and whatever is considered by user and stakeholder those are all input here. Then comes design output, that is, we create a detailed device specifications which includes drawing and schematics or so.

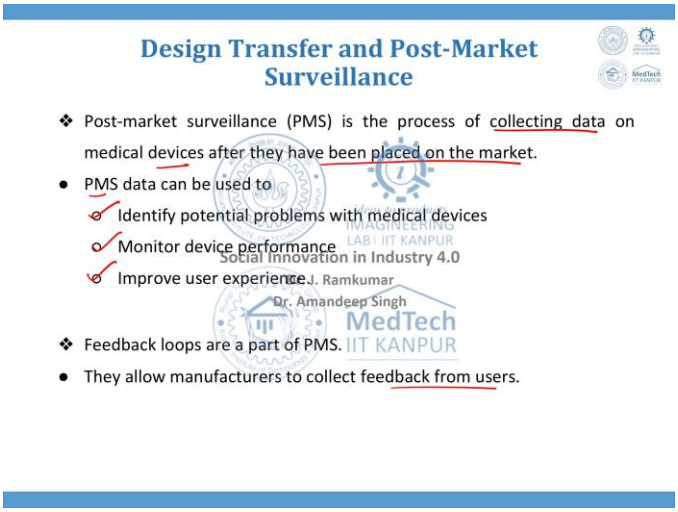
As I said, verification and validation are two different terms, first comes the verification and the verification is to ensure that the specifications are met, ensure meeting of the specifications. Design validation is, we will try to validate that in the intended environment for safety and effectiveness. Then comes, design change control that means wherever the design change has to be happened, it has to go through a structured process. Then, DHF and DMR, DHF is Design History File and DMR is Design Master Record.

To maintain DHF and DMR for documentation and compliance, it is important. DHF is a collection of document, that records the development of a medical device and DMR is a subset of the DHF in which the most critical design documents are kept.



Then, comes Design Transfer and Post-Market Surveillance. Design transfer is transferring from the design to the manufacturing team, when the design is approved we need to transfer. So, here design transfer is the process of transferring the design from the engineering team to the manufacturing team.

The design transfer process should include a detailed plan, clear communication and thorough documentation. It is important to involve all relevant stakeholders in the design transfer process which include the engineers who have designed who has given the design specifications for the prototype or the product finally that you like to manufacture later. The manufacturing personnel who are gonna actually manufacture because they know what setup is required or is available with them. Then, quality assurance personnel who would make sure that the regulatory requirements are well-met.



So, in design transfer and post-market surveillance, post-market surveillance is an important process. So, this is a process of collecting data on medical devices after they have been placed on the market. The post-market surveillance data can be used to identify potential problems with medical devices, monitor device performance, improve user experience.

Feedback loops are part of post-market surveillance. They allow manufacturers to collect feedback from users. So, both these that is the post-market surveillance and feedback loops which are itself part of PMS.

Both these ensure the safety and effectiveness of medical devices in the long term. To Summarize this lecture, design of medical devices is important process as it affects safety. Design of medical devices should always follow human-centered principles. The process of designing a medical devices include the following steps. That is, insights are gathered and market research is conducted, idea is generated, iterative testing and user feedbacks are taken, prototyping is done.

The designing process is bound by different regulations as I said ISO 13485 and so on. Different parts of the world have different kinds of the processes or different kinds of the standards. There are many international standards for medical devices which are to be complied to, that this is one of the international standard that is mentioned here. Design control and post-market surveillance are also very important. With this first lecture of this week is over we will try to discuss more on the design of the medical devices. And then, about the agricultural implements or agricultural equipment in this week. Thank you.