Design, Technology and Innovation
Prof. B. Ravi
IDC School of Design
Indian Institute Technology Bombay

Lecture-17
Systemic Approach to Biomed Innovations Part 1

Welcome to this session. We are here to share our experience and some stories about medical device innovation.

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In particular, we will answer 4 questions. Why do we need new medical devices? Number 1. Number 2: How can we develop and commercialize those devices? Specifically in an academic setting, students and faculty and so on. The third thing is: Are there any examples of indigenous medical devices which have actually reached the market? And fourth is: What are the best practices? Some tips to create many success stories in this field. These 4 we will answer.

Let me start with this slide which shows that Indians are innovative. You have to just go on to Google and say 'India and Jugaad'.

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And you will find many, many examples of Indians being very innovative. Whether it is shaving without a mirror, peeling onions without getting tears. Whether it is making *Lassi* in the washing machines or whether it is putting tractors as bullock carts. And one more innovation, which is the Jaipur leg. One Common Factor in all innovations is that there are no engineers involved. Even the first picture is the brother of an engineer, not an engineer.

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So if there are no engineers involved and there is a raw innovation capability in the Indian public, how come, that today when we go to market and look for some mass produced technology products, there is not a single Indian company to be looked to be found worldwide. We may find some Indian companies selling in India, but can you find Indian Products across the world?

Consumer goods, mobile phones, TV's, defence, transport, industrial machinery and medical devices? Very, very few. At this point of time we are just importing, importing and importing. The reasons for that are that it is not so easy to take an idea from a research lab into industry through the commercialization pathways.

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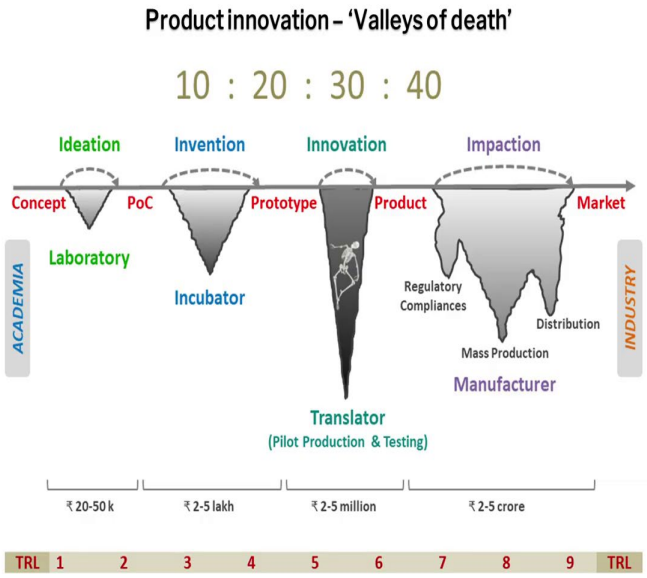

We say that there are 4 valleys of death. The first valley of death is just your idea in the head, putting it on the table in the form of a proof of concept. It could be just a plain paper and some threads and tubes, things like that. If you cross this value of the death, the next one is to create a prototype. That is also not so difficult to do in research labs because it is some 3D printing, maybe it is some PCB, maybe it is even a breadboard. You can do these things in labs these days.

The problem is taking the prototype into the market through a product. Converting a prototype into a product is not easy. Neither academics know the game nor industries what should take a risk into that. Ok? There is a body of knowledge which is required to convert prototypes into a product which neither the academics nor the industry have. But if you somehow cross the third valley of death. The rest of the game is very well known to industries. How to get government permissions? How do you raise money? How to get land? Hire people, right equipment, distribution sales, they know the game.

Why is this not happening? One other reason is not happening is that academics think that if they got an idea, and maybe made a PoC (Proof of Concept), or maybe made a prototype, maybe wrote a paper or in the great case, published a patent, they think that the job is over. They think that half the job is over. It is not really so. Actually it is the other way around that idea generation is very easy. You and me can sit for the next half an hour and generate 30 ideas just like that, but taking ideas all the way to commercialization is actually very difficult.

Until academics realise the importance of commercialization, this is not going to happen. it is not even 10, 20, 30, 40, it is actually in the order of magnitude. You can build a prototype, PoC for a few thousand rupees, prototype for a few tens of thousands of rupees, and it keeps on growing 10 times and 10 times as you go to the next stages of the product life cycle. So, it is not easy, it is expensive.

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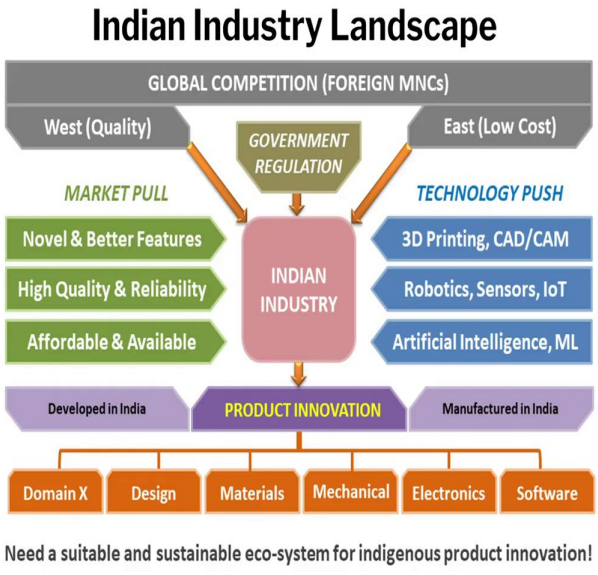

So what is the status of the Indian industry today? I am sure reading papers that Indian industries are not doing so well. Sector after sector is either collapsing, or not doing very well, you must be hearing that. The reason is that at this point of time we are neither able to compete with the quality of western countries, nor can you compete with the Eastern countries: China, Vietnam, Thailand increasing. Even in Bangladesh, they are a much better manufacturers of textiles now, number 2, right after China. Ok?

So we are not able to compete when it comes to cost because of the Eastern countries, and Government regulations is, of course, always a bottleneck. Although they are trying to do ease of business. So the only way to do so is innovation and there are some drivers there. Because customers are not loyal. Today you buy a Samsung phone, tomorrow you have some other company offering better features in less price. Are you going to be loyal to Samsung? Most probably not. Maybe there are some die hard fans of Apple but that's about it.

So, we can say that maybe we lost the game, but having said that there is a silver lining in the horizon, in the sense that there is this whole host of new technologies. Whether it is 3D printing, and CAD/CAM, whether it is sensors and the Internet of Things, whether it is medical imaging or imaging in general, image processing, artificial intelligence and machine learning, these are giving us a chance to rethink, reinvent products from scratch.

To give better features and better quality and lower cost and so on. So, the only way ahead actually is innovation. But please, as I keep mentioning all the time, innovation is not specifically a specific discipline. You cannot say that a product is mechanical or electrical or electronics and software, we need all the branches. And the domain discipline, if the product is for medical, we need doctors in the game. If the product is for agriculture, we need farmers in the room.

So we need to have domain expertise also. Ok, so having understood the whole reason for all that: Do we have the ecosystem for innovation in India this point of time? If not, how do you go about building the ecosystem? That is the question we want to answer.

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So, let me say that if you want to pick and choose which areas you want to start the innovation game rolling, to build the ecosystem, and young people actually have come up with consultation from all the countries and everyone else, politicians: Seeing the world at this point of time need to focus on 17 sustainable development goals. These actually give us a very good starting point, and a lot of young people are actually concerned and thinking about carriers in these domains.

If you think about these 17 SDG (Sustainable Development Goals) as a starting point, Where do we pick and choose? And I would like to say that, let us think about Healthcare as a starting point. Because ‘Healthcare’ and ‘Innovation’ and ‘Life on Land’ is 3 out of 17 and I will give 4 reasons for doing that.

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Reason number one is that, at this point of time medical devices are badly needed for taking care of both diagnosis and treatment of various diseases.

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How many diseases? 14,000 as per WHO (World Health Organisation). So you need a variety and an army of devices to diagnose, screen, monitor, treat, rehabilitate and assist patients.

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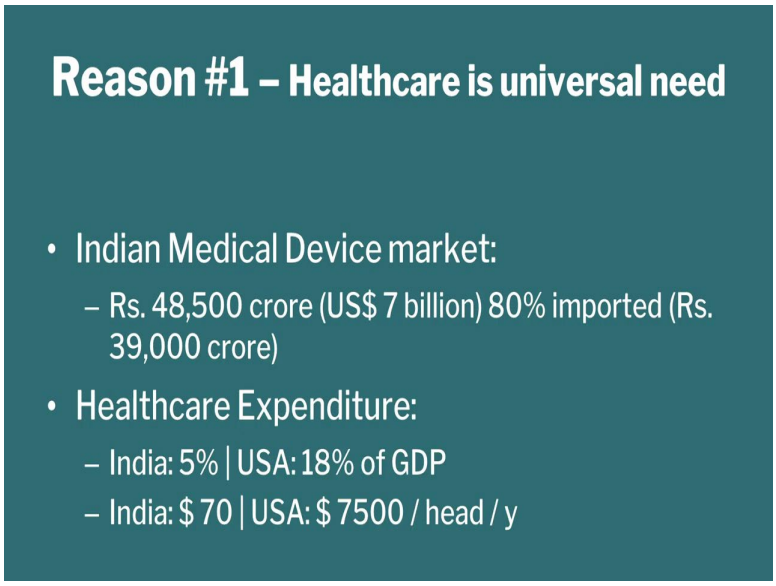

And what is the current scenario? The per capita expenditure on healthcare in India is less than 1% of that of the USA. And the USA is the world's, both, largest producer as well as consumer of medical devices. So even if you take a made in the USA device and give a 90% discount, it is still 10 times more expensive than what can be afforded by the average Indian population.

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Reason number 2 is that Healthcare has a great social impact.

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If you can lower the cost of not just the device but cost of treatment or diagnosis to let us say, 1% and it is feasible. If you can, someone lower the cost for one person, it is a great opportunity to reach out to a large number of the population at the bottom of the Pyramid. Those who are specially unprivileged, if they fall sick, they lose 1 days wages. If one days income is not there, one days food is not there on the table. So, they cannot afford to fall sick. We need to make sure that they do not fall sick or are diagnosed time.

As per some reports Healthcare has become the largest employer in the USA already. And Healthcare startups are number 2 among all startups in India at this point of time, right after E-Commerce. Even in SINE (Society for Innovation and Entrepreneurship), IIT Bombay, now, out of 20 companies. Apparently half are Healthcare startups. So, startups are giving a lot of employment opportunities aswell.

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The third reason is that at this point of time there are fantastic funding avenues available from various Governments bodies apart from NGOs and the private sector.

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If you just take one Government arm itself which is BIRAC (Biotechnology Industry Research Assistance Council), which is an arm of the Department of Biotechnology, which is an arm of the Ministry of Science and Technology, just one arm of an arm, you may say one finger of the Government,

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has so many schemes, I have listed only a few, including the famous BIG or Biotechnology Ignition Grant. A BIG grant of 50,000 rupees or 5 million rupees is given directly to an innovator or a startup company to start a company and take a product to market. Equity free, you can say, grant, and they are not going to take any shares in the company. It is a pure equity free grant.

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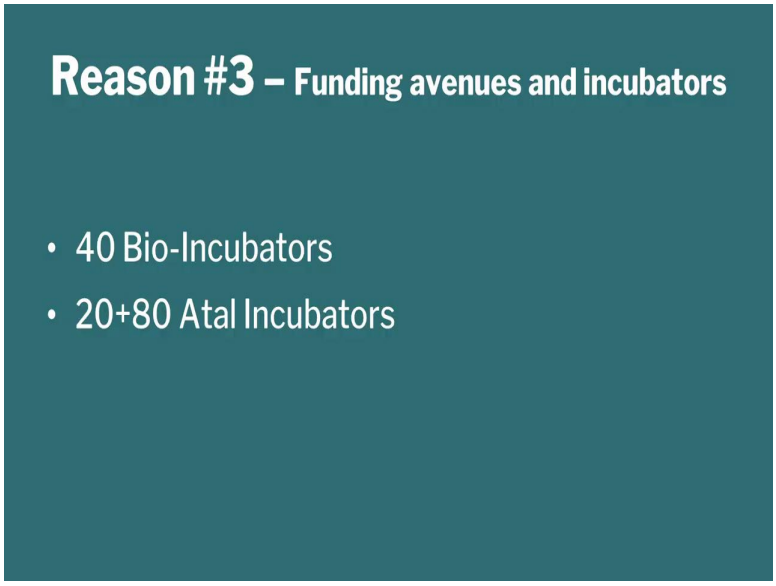

And of course there are a large number of Bio-Incubators and Atal-Incubators where you can actually go and start this company.

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Reason number 4 as I saved for the best which is: You cannot do innovation unless you do collaboration, and you cannot do collaboration unless you go out of your comfort zones. Ok? And at this point of time, bio combined with any domain, you cross bio with any domain, as you can see here, Bio-physics, Bio-electronics, Bio-materials and Bio-technology itself has several colours. Ok? Not only potential for research but also potential for practical applications.

And nothing like biomedical because if you want to collaborate and go out of comfort zones, the test of that is can you ask stupid questions to each other. You cannot have ego there. It is easier to let go of ego when you are trying to solve the problem of someone in pain or someone suffering. So, it is easy to collaborate in the Healthcare domain, coming across various disciplines because of this factor of social impact it has got.

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Let me come to what we are doing at BETIC (Biomedical Engineering and Technology Innovation Centre). So, BETIC is the lab inside IIT Bombay. It is a R&D project funded by the State Government of Maharashtra and Central Government of India, Department Science and Technology. And we started with a very simple thing.

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We said let us just bring the stakeholders together. What stakeholders? Doctors, researchers, entrepreneurs and Investors. These are the 4 critical stakeholders for medical device innovation and commercialization. Simply just we said, let us get them together and magic will start. So what we have inside the lab are several different small cells, you can say.

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Medical device innovation facilities - Virtual prototyping

We have one cell for generating ideas where the doctors meet us, we have one cell for doing CAD and simulation, one cell for doing plastic prototyping,

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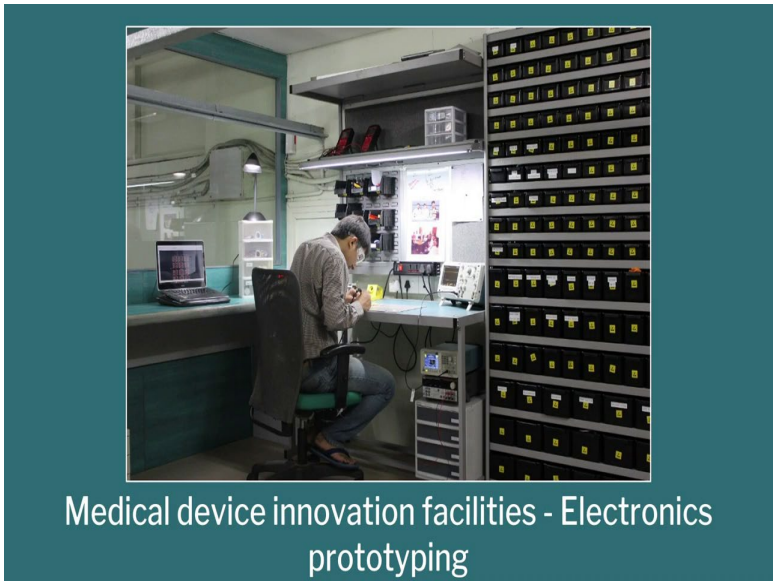

Medical device innovation facilities - Electronics prototyping

one for electronics prototyping including electronics, CAD simulation and PCB milling,

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and one for metal 3D printing. Plus we also have access to testing labs across IIT and so on. That is at IIT Bombay.

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But BITEC is also in other Institutions. One partner is VNIT (Visvesvaraya National Institute of Technology) Nagpur where they have tissue engineering facilities. You can 3D print materials which are bone-like substitutes and we can use them to fill gaps in the human body, especially bone gaps. We also have a BITEC cell in college of engineering Pune, where they are focusing on 3D printing and electronics. And we have a Gait Lab, where we have cameras on the ceiling and on the floor by which, when you walk we can capture 3D moments, which can be used to create, we can say, a stick diagram or Forced Model Diagram of the human body.

The way you walk is a signature of not only your skeletal problem, but also it is a signature of your neurological problem. The walking signature can tell the doctor what you are suffering from. So, we have the lab for doing that also.

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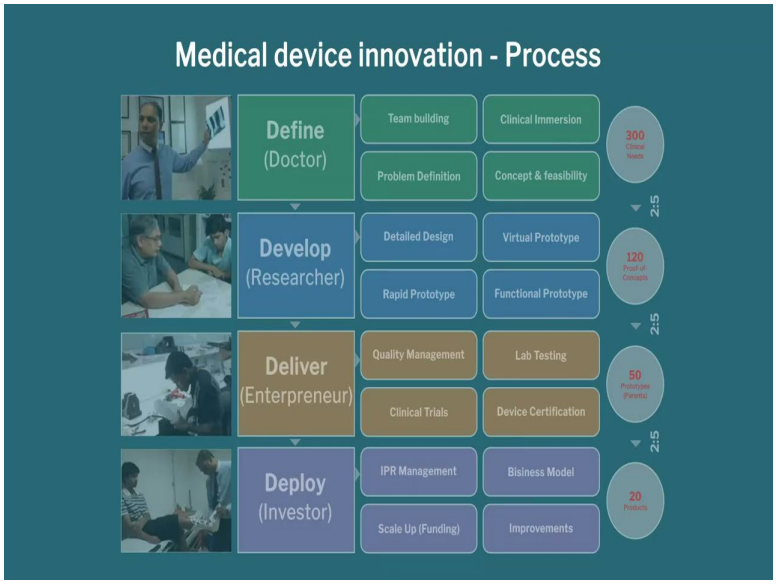

Then we have put a process in place for innovation, and this process if you can see has 4 major stages. Stage 1 is called ‘Define’, where doctors play a critical role. Stage 2 is called ‘Developed’ where researchers play a critical role. Stage 3 is called ‘Deliver’ a tested device where entrepreneurs play a role and Stage 4 is to ‘Deploy’ and practice, where investors are necessary. What we did was to divide each of the stages into 4 steps each so you have 16 steps.

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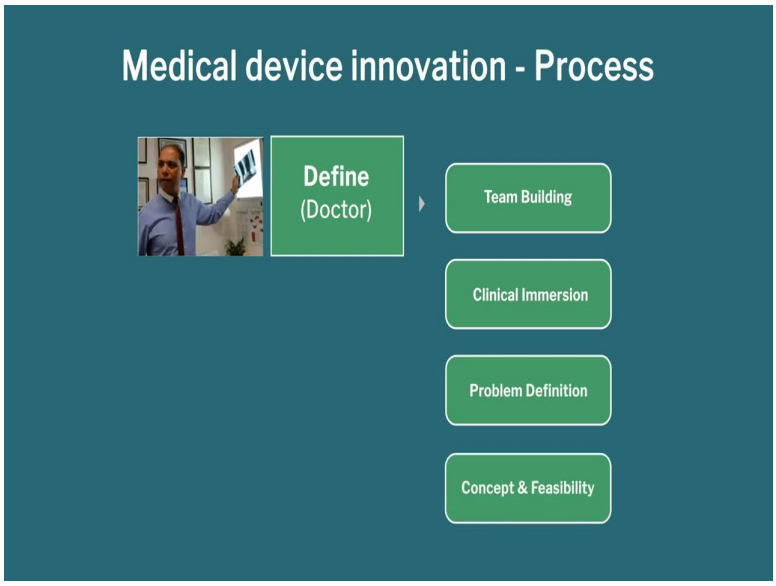

So the Define stage has 4 steps: Build a team, go and watch what is happening in hospitals, define the problem that you want to solve and then create a concept and then check the feasibility of the concept right at the early stages before you invest more effort and money into that.

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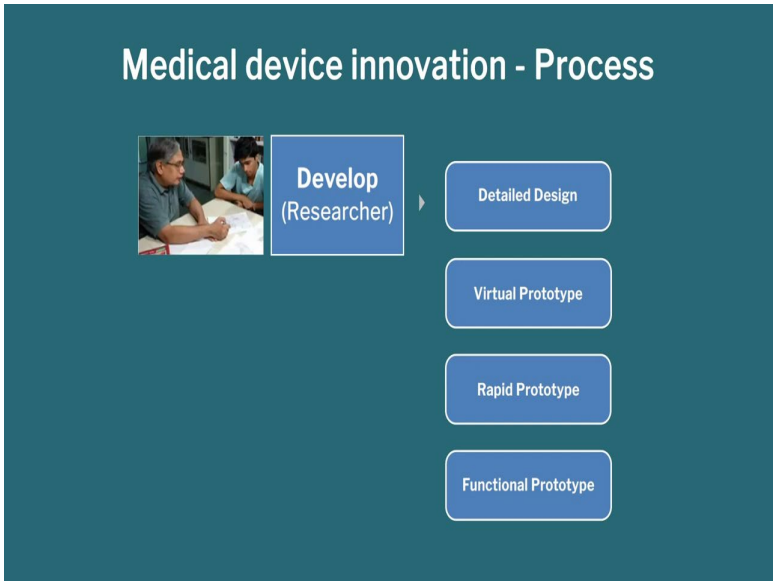

Then you get into the Development stage where you actually looking at the detailed design, Virtual CAD modelling, then Rapid Prototyping and Functional Prototyping.

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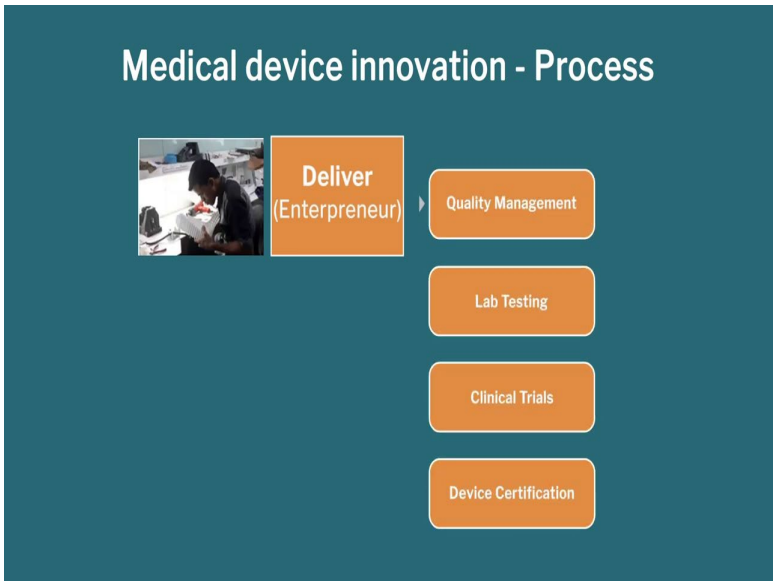

Then we have a Delivery stage where testing has to come into picture. This is where most of the academics give up. They think that Development is over, they can file a patent or publish a paper, our job is over, someone will take it forward. Usually no one takes it forward. You are the mother and father of the idea, so it is your responsibility to nurture the child beyond. Testing is one critical phase like that. So, you have to actually figure out, how to test in the lab?

How to test it in the, how to manage the quality systems before you do testing? What standards do you have to follow? Then lab testing, the, clinical trials, preclinical trials, main clinical trials and finally certification of the device. Unless certification, you cannot go forward into manufacturing.

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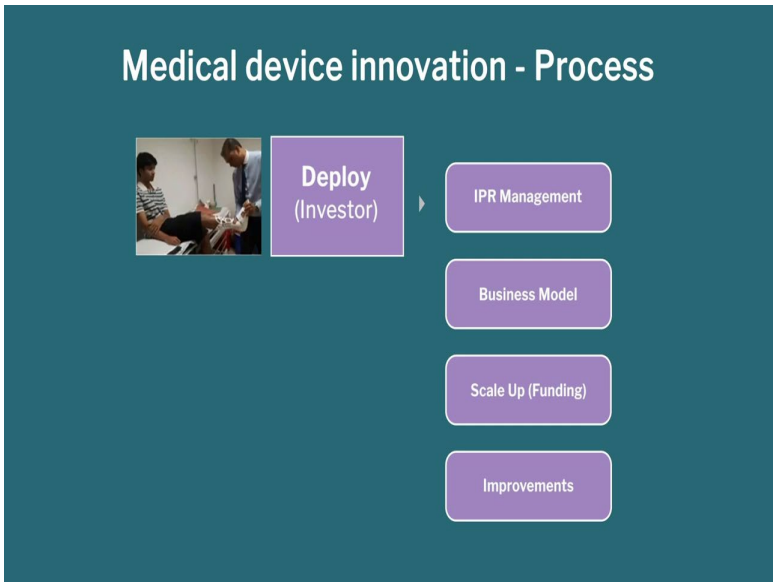

Then the last stage comes where you have to Deploy the device into the market. So here we have the IPR (Intellectual Property Rights). You have your, you have to create a business model. How are you going to sell the product? Through what channels? What is your supply chain? Distribution channels all those things. And then you look at where do you get the funding for initial, and then scaling up, sustaining the activities and life is not over.

Once you have version 1 in the market, you go and build version 2 and version 3 and so on. No one brings a perfect product which is stable forever. Now, usually people say that the innovation game is very risky. Ok? If you have to start with 10 ideas, you go for 1 prototype, out of 10 prototypes 1 becomes the product, 10 products go to market 1 will make it big, breaking even, for 10 which break even 1 will make fantastic or huge profits.

It is a 10,000 is to 1 success ratio. But be careful when people say that or you hear this type of statement. When we are talking about the idea stage I mentioned to you earlier that we can sit for 1 hour and can generate 100 years if you wish, now what is the cost per idea? Hardly anything. Maybe some tea and coffee. Out of 100 ideas we decide to take forward only one or two and that's a 90% failure rate. Does it sound like a good thing or a bad thing? It is a good thing. You have tried 100 with hardly any cost, throw away 98 and you are taking 2 forward.

So as you go forward in the life cycle of a product development, initially you can throw away a lot of ideas but it does not cost you anything or very little. But by the time we come to the final stages and the product is actually manufactured and put in the market, you better be very sure that it will break even at least, if not make you handsome profit. The actual success rate or actual failure rates are not as they say. The real cost of failure is not really that. Ok? If you do things in a systematic way.