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Dr. Suresh Nair is an alumnus of IIT Bombay, he co-founded Design Alpha with the support of Social Alpha. Design Alpha supports entrepreneurs working on products and technologies in the domains of health, environment, agriculture and education. In 2014 Dr. Suresh Nair was awarded The DST Lockheed Martin award and there are various other accolades he has received for his innovation.

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Design Principles to Build Healthcare Products

Healthcare products are intended to diagnose, treat, cure, or prevent a disease or other health condition. Even with over 100,000 different medical devices on the market today, the industry is growing every year, and numerous startups are focusing on this area. Due to the direct health and safety effects that these healthcare products have on the users, medical devices are subject to many regulations and must undergo extensive validation procedures, composed of checks, tests, analysis, and reviews before they are allowed in the market.

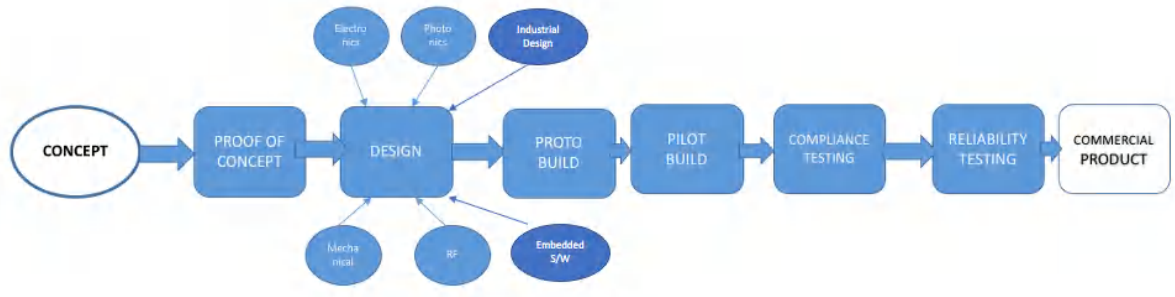
Proof of Concept

The foremost activity for any innovator is to prove to others and convince them that their idea works. It can be demonstrated using standard laboratory equipment like power supplies, signal generators, spectrum analysers, oscilloscopes, computers, and off shelf development kits.

Design

Requirements' formulation is one of the most vital aspects of the design process because it lays the foundation for the rest of the design. Once the idea is proven, the next step is to go for the design. First we come up with a Requirement Specification document. It will have overall system requirement specifications including, input/output, user interfaces, regulatory compliance, reliability, etc. It shall then be translated to mechanical, electronics, power, software requirements engineering specifications, with possible subsystem specifications. Design-to-cost is another essential factor to be seriously considered as a requirement specification. It invokes the designers to explore alternate technologies, methods to

The Concept to Product Development Life Cycle is schematically represented below.



achieve the function at optimum cost.

The design towards the first prototype needs to be very close to the final product, in terms of form and fit, aesthetics, ergonomics, and functionalities. The prototypes can be built using fast processes like 3D printing, vacuum casting, soft tooling, machining, rapid PCB fabrication, hand soldering, etc. Under prototypes, a few stages like Alpha and Beta prototypes are standard.

The alpha prototype shall be tested internally first and then handed over to potential users to get feedback. All these feedbacks shall be implemented in building the next prototype, called the Beta prototype. It can also be considered as a Minimum Viable Product (MVP).

Pilot Build

The pilot build has to be done once the design, process, iteration, all are set. It needs to be done in an ISO13485 certified manufacturing facility, where the final volume manufacturing will take place. The pilot volume can be a few tens, and the samples will be used for reliability and regulatory compliance testing. Thus, once the product successfully undergoes compliance testing, no further modification shall be permitted on either component or processes. Any such change will call for re-compliance.

Compliance testing

Compliance testing and approval are mostly considered to be a significant hurdle in healthcare device development. During the design process, whenever the components are selected, mechanical enclosure designs are done, PCB layout is performed, or interconnections are planned. Those are to

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