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## Management

We all know that systems engineering has a major role to play in business and defense industries, but has it ever occurred to you that system engineering is also a major player in the healthcare sector? On March 24, 2014, Mr. Dr. Steven W. Badelt of Suttons Creek Inc., a seasoned expert in product development, engineering management, business development, and systems engineering, spoke on ‘ Systems Engineering in Healthcare.’ Dr. Steven has an MS in Biomedical Engineering from UCLA, and a PhD in Neuro-engineering from UCLA. Dr. Steven has also won several awards in writing business plans, research, and leadership. Today, Dr. Steven leads the Biomedical and Healthcare Working Group (BHWG) for the International Council on Systems Engineering (INCOSE) in southern California.
After starting his career in particle physics and x-ray optics, it was obvious that Dr. Steven would shift his loyalty from industry-specific systems engineering, to medical care. Dr. Steven has worked on the application of real-time signal processing and pharmacokinetics to induce and sustain barbiturate coma. This may sound confusing to many of us who are not familiar with Medtech, but what is of relevance to us is that, there is a strong demand for Systems Engineers in the field of medical technology. Dr. Steven moved from lab-to-practice to development of PI for pre-clinical implants, and then to market research in the neuro-modulation space. Since then, Dr. Steven has worked on automated systems for product hyper-customization, low-power wireless communications for on-body personal health, auto-injectors, networked medical devices, in-home health monitors, wearable infusion pumps, and disposable injection systems. Dr. Steven revealed that the medical technology (Medtech) industry was new, and that a huge market remained untapped. Opportunities in the Medtech industry remains high, as the industry remains fragmented, and there is scope for development of multiple varied technologies. For Systems Engineers, Medtech offered huge scope in research and development of new technologies, and, it made it even more attractive as it did not follow the standard defense acquisition models. Systems Engineers could innovate and develop technologies that enhanced healthcare. In order to market the product in the U. S, one would need pre-market notification, device listing, good manufacturing practices (GMP), record keeping, controls, performance standards, and investigational device exemption use under approved for use with institutional review boards. However, Systems Engineers, who plan to enter the Medtech industry, must keep in mind that their technology should be for the benefit of medical sciences and human healthcare, therefore, patient safety is uncompromised. They must ensure that they adhere to risk management activities such as, identifying, analyzing, controlling, and monitoring their product right through their research and development process. Therefore, it is advisable that brainstorming exercises are mandated at each level of development, and risk analysis goes through a rigorous and structured process. It is advisable to look through running risk logs, similar physical models, histories of design changes, trade-off studies, interface matrices, functional blocks, and quality functional checks. Remember, one needs to study each step of a case scenario in detail, explore all possible alternative flows that can be used for each step, generate a list of all possible risk items from the cases, counter-check these with all previous FMEA items and observation data, and finally, tick-off all the identified risk items to the risk analysis process.
Reflecting on Dr. Steven’s lecture, I have understood that there is a huge scope for systems engineering in the field of healthcare. While risks remain, the healthcare industry does give opportunity for Systems Engineers like me, to explore new technologies that can assist in healthcare. I will ensure that I follow Dr. Steven’s advise of concentrating on the rules of risk management and develop technologies that do not, in any way, cause healthcare issues.
I personally felt that Dr. Steven gave a great insight into the possibilities of imbibing systems engineering practices in Medtech. The presentation was effective, and influenced me to such an extent that, I too plan to enter the highly opportunistic field of medical technology.