Report: 'One Day Seminar on Medical Devices: Current Needs and Solutions'

Date: 14th November 2017, Gandhinagar

NIPER-Ahmedabad organized an 'One Day Seminar on Medical Devices: Current Needs and Solutions' on 14th November 2017, whichstarted with a warm welcome to all the delegates, speakers, panellists and audiences who came from various parts of the country to discuss, nurture and accelerate one of the hottest field in healthcare *"The Medical Devices".*

The event inaugurated by the dignitaries with formal nodes of traditional culture by lighting of lamp by **Dr.Kirit Solanki**(MP-Ahmedabad-West),**Dr. V.M. Katoch**(Former, Dir. Gen., ICMR, New Delhi)**,Prof. Kiran Kalia**(Director, NIPER-Ahmedabad),**and Dr. Arvind Patel**(Chairman, Sahjanand Laser Technology, Gandhinagar) and other invited guests that marked the start of this one-day seminar.

The lamp lighting was followed by a welcome speech byProf. Kiran Kalia, who resourcefully enlightened the audience vis-à-vison medical devices fieldthatcurrently contributes to approximately 50% of industries in Gujarat. She updated the audiences about the history pertaining to the initiation of medical devices program in NIPER-Ahmedabad, andenvisionedthat she is confident that this unique program offered by NIPER-Ahmedabad will definitely mark significant impetus towards the growth of this field in India. She wishfully narrated about the importance of bridging the gap between the academicians, researchers, and industry for development of innovative medical devices.

Prof.Kalia explained that the objective of this seminar was to bring entire fraternity of medical devices under one umbrella to facilitate collaborations beyond boundaries and limitations. She proudly dedicated this platform where cross professional amalgamation of professionals from pharmaceuticals, clinical, engineering, physics industries, regulatory and many more diverse fields is anticipated to take place to facilitate progress in this field towards gaining more and more recognition. She also revealed that the seminar was focused mainly on medical devices related to cardiovascular and orthopedic domains and expressed anticipation that this seminar will help develop a proper ecosystem tofetch translational development in the field of medical devices to assist in inventively realize the 'make-in-India' vision of our Prime minister Shri Narendra Modi.

Followed by the speech of Prof. Kiran Kalia, Dr. Arvind Patel gave a brief introduction about the need of medical devices and how researchers and industry can work together to make better and more efficient devices. He also gave a small glimpse in of journey of Sahajanand. He conveyed the seminar participants his very best wishes and encouraged everyone to best utilize this unique platform to discuss and translate their ideas and inventions.

The next speaker in this series was**Dr. V.M. Katoch,** who started his speech with how our Prime Minister Narendra Modi explained the necessity of medical devices in India and importance of his 'Make in India' vision. He suggested that the industries should spend on research and development of medical devices as much as the revenue spent on development of drugs. He also mentioned that medical devices are a largely overlooked industry; and suggested that some measure should be taken to rectify the existing situation. He also mentioned that for better healthcare there is a need to combine medical devices and drug. He also emphasized on the importance of institutions like NIPER-Ahmedabad which may tremendously help in the growth of medical devices industry and provide the country with young enthusiastic researchers who will help in the betterment of the field. He thanked Prof. Kiran Kalia for inviting him to this seminar and wished everyone the best out of it!.

Dr.Kirit Solanki was the next to sharehiswisdom with the audience with his pearls of wise words. He started his speech with praising NIPER-Ahmedabad for gaining the excellence and reputation in such a short span of time. He then talked about importance of medical devices in India and shared his experience from his medicine practicing days. He also praised Prof. Kiran Kalia and congratulated her for hosting this seminar which will help young researchers as well as established medical practitioners to establishworthy collaborations. He also said that the seed that this seminar will sow today will grow as a massive tree which will help in innovation and development of medical devices which will help revolutionize the Indian medical device industry. He also talked about how this industry is about knowledge, research, innovation and medical devices. He also commented how medical devices has made critical operations easy to perform. He advised all the people present to have a common platform and regular meetings with doctors and people from industry to understand what they need and brainstorm on how to achieve it.

The next on the itinerary was a keynote address by **Dr.V. M Katoch**who deliberated a talk on topic entitled "Current ecosystem in healthcare system prevalent in India". During this talk, he talked about current needs and their solutions regarding medical devices. He approached areas like the social readiness of medical devices, how health services in India can be made equitable and affordable and what government is spending on healthcare as opposed to an individual. He also talked about the needs like better institutions, better technologies, and better cost-effective solutions. He pointed out that still today 70 percent of Indians rely on private healthcare system for getting access to medicine under condition of emergencies. The level of health insurance scheme is only available to roughly 10 percent of Indians population, while a major proportion are still deprived of any healthcare benefits.

Shri Katochemphasized on creating benchmark in terms of providing availability and accessibility of medicine at doorsteps of patient. He was very hopeful that with recent advent in point of care technologies (POC)like sensors biomarkers nanotechnology-based inventions etc. could significantly bring a paradigm shift in how we perceive medical health ecosystem. He emphasized on a strong collaboration between academic institutions like NIPER with industry to propel India internationally in the area of medical device manufacturing. He also mentioned different medical devices needs for domains like infectious diseases, neonatal, perinatal and child care, woman-related issues and many more. He also enlightened the audiences about the grants given by DST for projects related to Medical Devices. He encouraged the scientists, industrialists, clinicians to enter into more rigorous research through inter-disciplinary collaborations between different institutions, industries, and agencies. He also highlighted about open source discovery program of ICMR, and other funding schemes of DRDO, DBT, DST which focuses on translational research and funds innovations with positive outcomes. He was very hopeful that the major bottleneck is our psyche and that is what is holding us back and needs to be overcome to put India on world map. He also mentioned the crucial role NIPER-A could play by acting as interlinking point of contact for different stakeholders and could be the Chintanshibir for deliberation of several ideas which could change medical devices scene in India.

Dr.JawaharJethwa, an Orthopaedic surgeon from Ahmedabad spoke about different medical devices that are needed by orthopedic surgeons in day to day life. He began his talk with Need of a biomedical engineer and severe dearth of suitable candidate. He emphasized on calling industry experts for sharing their knowledge so that students are aware of recent changes in industry. He pointed that in the area of orthopedic, implants, joint replacement components, Orthobiologics all have a huge market but unfortunately most of these are imported. Dr.Jethwa also mentioned about the importance of surface properties of implants and specific design which are crucial for medical device functioning.

Shri Jethwaalso shared his personal experience about how many problems faced by him during surgeries has made him innovate bydesigning specific devices to suit his needs. He was quite hopeful that future devices will be designed using computer simulation like finite element analysis which will reduce the risk of failure in long run. He ended his talk with some suggestions including having a cadaveric biomechanical testing facility tie-up and platforms similar to TED talks where like-minded people can come together and share their views and institute like NIPER can serve as platforms for advancing medical devices discovery in India. He mentioned some recent technologies that have revolutionized the field of medicine. He showed videos of how an effective medical device can help in changing life of a patient with deformed legs. He also said that the motivation to change a patient's life is the major key to work in the direction. In the end, he again emphasized the importance of collaborations of industry and research institutes.

Dr. Anil Jainfrom SAL Hospital as cardiologist talked about the cardiac surgery perspective in Indianscenario. He started his speech with a special attention to the need of improving quality of cardiac medical devices in India and the emerging need of a medical devices approving authority in India. He mentioned that medical devices have the capability and capacity to generate huge revenues and thus are huge returns on investment. He mentioned that with increasing accessibility of healthcare awareness about medical device is also increasing. With the increasing number of cardiovascular ailments affecting Indian population, cardiovascular stents and related medical devices are the need of the hour. They have now become more relevant as per latest WHO report which forecasted that 50 percent of cardiovascular

patient burden will be in India. He pointed out the shortcomings of the government in providing proper funds in development of medical devices.

He also talked about the need for the Indian industries to develop cost-effective and readily available cardiac care devices which will be clinically tested and will bring help counteract overpriced healthcare system in India.He direly felt the need for having a clinical study relating the effects of tobacco consumption on cardiovascular complications. He mentioned about huge business opportunity in designing medical devices as most of the current devices are imported. Innovations is also hindered owing to regulatory norms which are acting as huge roadblocks.

Following this session, **Dr. Sanjeev Bhatt** (VP, Merrill Life Science) delivered a talk on topic entitled "Contributing to Growth in India's Healthcare Scenario- Meril Life Sciences". During his talk, Dr. Bhatt mentioned that for developing newer technologies, it is required to spend significant time in serious fundamental research activities. The research should be focused. The R&D facility should be equipped with latest technologies. In the medical device research, all expect to get high-quality device at less cost. Meril Life Science is a global medical device company, the core objective of which is to design, manufacture and distribute clinically relevant, state-of-the-art and best in class medical devices to alleviate human suffering. Their broad operational canvas includes diagnostic, surgical treatment, orthopedic and cardiovascular diseases. They engage in grooming the talent in the medical device sector. Regular education and training programme is required to the manufacturing persons. The researcher should focus on strong R&D, manufacturing and committed to bring innovation.

Shri Bhatt mentioned that the academic Institute like NIPER-A are amongst the unique type of academic institutions that produces expert researcher in the field of medical device. They are also cultivating technology to address unmet medical need. Commitment to large-scale manufacturing is important. They have been awarded with best medical technology company in India. He mentioned that smokers are more prone to coronary blockage and therefore, may need to treat with stent in later stage. He described that in case of aortic stenosis in elderly and other cases where operation is technically not possible, alternate therapy is the only solution and people have to depend on advanced medical devices. He pointed out the advantages of

newer medical devices such as Freedom Knee/Destiknee that can save bone, save procedure time and have high flexibility. Meril have more than 100 different product lines, business in 100 countries and above 4000 employees. They are also engaged in fundamental research to develop newer medical devices. He listed how Meril Life Science is contributing to improve India's healthcare landscape. He talked about recent technologies developed like Aortic Stenosis and freedom knee and how they have helped many patients. He also mentioned about the shortcomings that they as an industry faced during their research and how they had to outsource their animal studies abroad because they were unable to find any institutions in India. This example portrayed the dire need of institutions and labs that are needed to be set up in India for the development of medical devices. He ended his talk with emphasis on practicing with stronger rigor. He encouraged all students to explore the vast ocean of possibilities that lie ahead in terms of exploring newer medical devices.

This talk was followed by lunch, which was enjoyed as well as a resourceful interaction session wherein all participants interacted and exchanged their ideas as well as thoughts.

After lunch, the session started with a lecture by **Mr. JayeshPatil** who mainly focused on the difference in scenario regarding the healthcare industry in India and USA. He pointed out the gaps that are present in India regarding healthcare and how there is a dire need of improvement in the sector. He pointed out that there should be a balance between the cost and the quality and that we should not blindly follow and adopt norms created by the western world. As there no proper research and industries in India, we import 75% of the medical devices used and out which, 30% are imported from USA. He updated that currently there is a big mismatch between the demand and the supply to the Indian industry, which needs to be addressed in due course of time.

Mr. BhavdeepDoshi, The Director (Marketing and Sales), Envision Scientific delivered a speech on "Key Challenges & Solutions In Development Of Cardiovascular Devices". Mr. Doshistated that there is always a scope in the improvement in research not only in developing newer medical devices but also in solve the problems of existing technologies. Though stent is now available for correcting the cardiovascular problems, but lot of difficulties still exist in it which need to be corrected. So, the terminology 'innovation' is also applicable for this type of

research. Diabetic patient can be treated using specialized medical device. Drug-coated medical devices have been developed to treat diabetes which is effective for 180 days. For better outcome in the field of medical device innovation, government, industry and academic research institution need to work together. Newer techniques are emerging day by day all over the world in the field of medical device. Discovery of new medical devices is a long process. It was brought in the notice of the audiences that Envision Scientific developed the new medical device 'Nano late' which is a drug-coated balloon catheter to deliver Litmusanalog. Phospholipid-based carrier system has been used as a carrier for this molecule. This technology can be useful in different complicated conditions like cardiovascular problem, renal transplantation etc. The key challenges in medical device discovery include lack of proper analysis facility, preclinical laboratories, and government guidelines. Lack of funding in research and inadequate IPR protection guideline are also amongst the major issues. He pointed out that collaboration and development of product through PPP model can be a solution. Again, the acceptability of India based innovative medical device product is quite low.

He expressed that the absence of indigenous quality certification is also an issue. The cost of the medical device manufactured in India becomes high due to inadequate test facility and unavailability of raw materials. For raw materials industry has to pay more than 20% customs duty which makes the medical device product costly. As a solution, Indian government should ease the policy for doing business in this field. Government should provide fund for medical device research. Indian medical devices are now becoming competitive in global market. Shri BhavdeepDoshi talked about the key challenges and solutions in development of CVS devices. He mentioned some drawbacks of the cardiac implants focusing mainly on cardiac stents. He also directed the attention to the importance of IPR in the current scenario of medical devices. He also said that how Envision Scientific has 25 patents. He mainly talked about their drug-eluting stents which remains intact in the body for up to 3 years in contrast to others which start degrading within a month. He talked about the challenges he faced in the studies pertaining to testing and analysis, preclinical labs, grants and guidelines and knowledge regarding IPR.

Shri PratapPokale(Director (QA & RA), Advance MedTech Solutions Pvt. Ltd.) gave an exceptional speech on topic "Title of speech: Making medical devices in India – Drivers & Challenges". Mr. Pokale pointed out that about 38 crores of Indian people stay in urban areas whereas, 83 crores are in rural areas. He mentioned that India is amongst the top 20 medical device markets in the world. But, Indian medical device market is largely import dependent. About 70% of medical devices used in India are imported from the other countries. Mr. Pokale started with the reasons why medical devices in India is optimum for better manufacturing which is the cost, availability of talent, strong technology and the positive push from the government. He classified the challenges faced into 3A's i.e. affordability, accessibility, and acceptance. He also talked about the benefits of medical devices innovation and how it will help in the betterment of the country. According to him, lack of clear regulation in India is a major problem for the medical device manufacturer. NIPER through setting up the medical device section playing important role in creating talent in this particular field. NIPER can support the R&D activities of industries to solve the problems arises in the development of medical devices.

He expressed that the CAMTech Innovation Platform is addressing a critical gap in the MedTech ecosystem by providing expertise, resources and targeted support to global health innovators. The government has proposed a new bill for medical device in 2013. Indian government also taking initiative to increase the research funding in the field of medical device. The challenges associated with the development of newer medical device include affordability for the associated cost, accessibility of the testing facility, acceptability of the Indian products etc. As a solution, government should increase the research fund to the researcher of this field. Collaboration of research industry with academic institution can solve the problem of testing. Again, creating awareness through government or NGO can be useful to increase the use of the medical devices manufactured in India. There is also a need to set up proper regulations and guidelines related to medical devices and their IPR protection.Understanding of the need of local market by the manufacturing industries is also important. He also mentioned that India has a huge quality talent pool with which the medical device field can move forward in a faster rate if more rigorous multidisciplinary training is provided to them. According to him, Indian medical device

technology is evolving very fast and India has a huge potential in future to become a center for medical device manufacturing.

The next speaker was **Mr. JigneshUteshiya**(Director, UteshiyaMedi Care) on topic entitled "Current needs and solutions in orthopedic implant industry". He said that quality-based competition should be preferred as related to price-related competition. He shared that industrialists face lot of challenges while opening a medical device industry. First of all is the mindset of the common people towards the Indian products. It is difficult to convince Indian customers to go for a medical device that has been manufactured in India. The brand value of Indian medical device product is not satisfactory. He mentioned that market competition should be based on quality instead of price. He also said that brand value of Indian products has increased tremendously globally. He mentioned that a new medical device park in Telangana is equipped with all the facilities that are needed by the medical device industry. He talked about the current challenges faced by the industry like investments, lack of R&D and matching pace with the fast-changing industry and he suggested that to overcome that a better synergy is required between institutes, industry and surgeons and some clear-cut guidelines for the industry. He pointed out that different kinds of research are going on for the orthopedic implants. Current focus is on bone graft and bone cement.

Shri Jignesh suggested to set up industries with medical device park, similar to technology park. Gujrat already have some similar type of park. He discussed the need of the integrated facility such as testing facility, prototyping laboratories, and warehouse for raw materials, sterilization and packing facilities for a medical device industry. He also discussed the importance of support from the academicians through collaborative research. He discussed on the advancement of different materials used for the preparation of medical devices. He also discussed on the new technologies adopted by medical device industries. He pointed out that the major challenges lies with the medical device industry are procurement of machinery and raw materials as well as the certification of finished product. According to him, medical device is a fast-changing industry and adopting advanced raw materials, newer technologies and newer designs following revised market requirements. The requirement of collaboration between industry and academic sector has been pointed out as the key factor for success of the research in this field. As per him, for

better growth, government need to focus to this field, approval process should be faster and clear guidelines should be provided for their approval.

All the talks were followed by a panel discussion chaired by **Dr.V Nagarajan** (MD MNAMS DM DSc-Neurology; Dsc, Sr. consultant Neurologist) and co-chaired by **Dr.Vinay Kumar** where the dignitaries from the industry and academia sat on the panel and had a fruitful discussion regarding the topics discussed in the sessions conducted earlier. The panel discussion composed of other executive members including Dr. Vinay Kumar (Greens Surgicals Pvt. Ltd.), Mr. BhavdeepDoshi (Envision Scientific Pvt. Ltd.); Mr. PratapPokale (Advance MedTech Solutions Pvt. Ltd.); Mr. JigneshUteshiya (Uteshiya Ltd.); Mr. Siddharth Jain (CEO and Chief Regulatory AdvisorSymbiorph Clinical Trialogy); Dr. DL Pandya (Medical Plastics Data Service); Dr. Rajesh Shah (Sahjanand Laser Technologies Pvt. Ltd); Mr. ChetankumarHalani (CTquest LLP).

The panel members exceptionally boosted and facilitated the discussion session. They also answered several questions as asked regarding the industry by the students present in the audience.

The seminar ended with a monologue by Dr.Pallab Bhattacharya who thanked all the chief guest, keynote speakers, the dignitaries and the panel members **Mr. Rajat Patel, Mr. Siddharth Jain, Dr. DL Pandya, Dr. Rajesh Shah, Mr. Kaushik Pal and Mr. ChetankumarHalani.** The whole NIPER-A family lead by Prof. Kiran Kaliaalso expressed deep gratitude towards Honourable Minister of state Shri Mansukh Bhai Mandaviaji for his kind consent to be a part of today's conference. However, due to some unavoidable circumstances, he could not make it. In the vote of thanks, it was expressed that the moral attendance and support has always been a main pillar towards successful initiation as well as execution of scholarly activities and progress at NIPER-Ahmedabad. Finally, the conference concluded with uniform commitment of all attendees to motivate Medical Devices research in India, by enhanced participations led by the leads they obtained from this conference at NIPER-A.