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Experts recommend harmonising MedTech industry regulations, standards

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Health and Pharmaceutical Manufacturing & Medical Devices Committee, PHDCCI in association with Department of Pharmaceuticals, Ministry of Chemicals & Fertilisers, Govt of India recently organised the fourth series of Self Sufficiency in Medical Technology on Optimum Regulations, Quality Standards, Controls for MedTech on March 12, 2021.

The webinar was graced with the presence of Dr N Subramanian, Chair, Health Committee, PHDCCI & Director, Medical Services, Indraprastha Apollo Hospitals, Dr Sameer Gupta, Co-Chair, Health Committee, PHDCCI & Dr Harvinder Popli, Director, Delhi Pharmaceutical Science & Research University.

The session was moderated by Vivek Seigell, Assistant Secretary-General, PHDCCI. Anil Zainulbhai, Chairperson, Quality Council of India said QCI looks forward to collaborating and working together with CDSCO and BIS for further standardisation for the MedTech industry. He further mentioned QCI is currently focusing on moving faster towards improving standards and making testing capacity cheaper for the MSMEs sector in India.

Dr Subramanian said that defects or disturbances in the functions of medical devices may expose patients to serious risks which is particularly true for devices that transfer energy or pharmaceuticals to patients; hence the safety standards must be high for all medical devices and the devices shall be safe, reliable and well suited for their intended purposes.

Dr Gupta said that the emphasis should be on quality and ease of getting regulatory approvals. He mentioned that MedTech has shown very tremendous growth in the last few years and urged that all safety standards must be very high for all medical devices as it deals with patient life.

Sumit Kumar, Scientist-C- Medical Equipment & Hospital Planning Department, Bureau of Indian Standards mentioned that BIS is in close association with other standards developing organisations to make one nation one standard.

Manish Airan, AVP- Quality & Regulatory, Transasia Bio-medicals Limited said that better co-ordination and co-operation is expected among all the three bodies, CDSCO, BIS and QCI. This will help to reduce redundancy, ease the adherence and the effective implementation of regulations to all the medical device manufacturers. He further mentioned that public procurement agencies including GEM, need to be educated on the Indian standards so that the need of CE and US FDA to be eliminated."

Dr Rajiv Chhibber, Vice President, External Affairs, Sahajanand Medical Technologies Pvt Ltd, said, "The need is to be looking at harmonising Indian standards and international standards for ease of doing business, focus on developing domestic prowess in key areas like laboratory infrastructure, innovation, R&D and manufacturing. Dr Popli in her closing remarks mentioned that the state government should also set up a funding scheme to support the industry.