

AIMED, QCI & NABCB form steering committee to roll out voluntary quality certification for devices

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To fill the regulatory vacuum in quality certification space for medical devices in the country, Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and National Accreditation Board for Certification Bodies (NABCB) recently constituted a steering committee to roll out voluntary quality certification scheme.

More than twenty government and non-government organizations have already come on board as part of the steering committee to support and enroll for the scheme and met for the first time Delhi. Dr M K Bhan, former secretary, department of biotechnology is the chairman and Rajiv Nath, forum coordinator of AIMED is the vice chairman of steering committee.

Under the scheme, QCI with the help of AIMED will identify globally accepted quality norms for various categories of medical devices and its suitability for India. Once these quality standards are identified, NABCB will step in by providing accreditation services to conformity assessment and certifying firms which undertake quality audit of manufacturers.

The soon-to-be launched scheme is intended to enhance patient safety, provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers. It also aims to bring down the substantial time and cost-run to obtain globally accepted quality accreditation for Indian companies and eliminate the malpractices of sub-standard or fraudulent certification or quality audits.

Nath who is also the joint managing director of Hindustan Medical Syringes and Device (HMD), informed that this move is also intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market.

Nath informed that QCI and AIMED will vouch for only those quality certificates which have been accredited by NABCB. Speaking on fraudulent and sub-standard practices going on in the name of certification, Nath said that vision and strategic plan for new certification regime is to eliminate such practices and put in place a non-corrupt professional merit based transparent system.

He further added that new scheme will substantially enhance compliance to essential principles of patient safety (GHTF) and compliance to labeling requirements for consumer protection. The move for voluntary quality certification norm was kick started with the signing of an MoU between AIMED, QCI and NABCB in October 2014 to provide trust in Indian medical devices in terms of credibility and reliability as per best international practices and standards for medical devices.