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Abbott India to train medical device auditors

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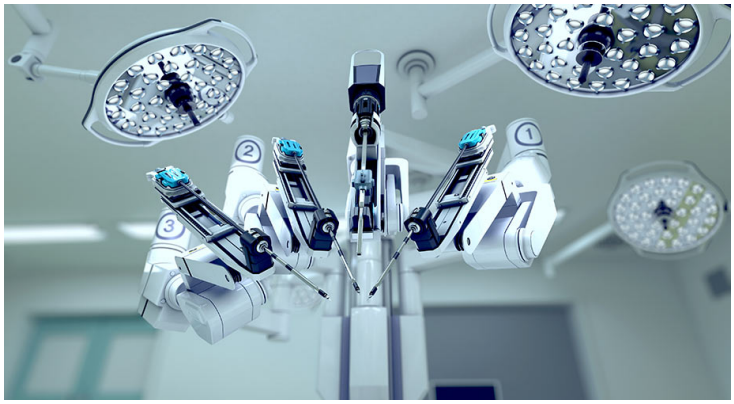

As part of the Gujarat Food and Drug Administration (FDCA)'s collaboration with Abbott India, hands-on training will be provided to around 62 newly recruited drug inspectors on auditing a medical device manufacturing facility.

Gujarat today boasts of having the highest number of 200 plus licensed medical device units under Central Licensing Approval Authority (CLAA) scheme as against a total 284 medical device units in the entire country.

The devices currently regulated under CLAA scheme include cardiac stents, drug eluting stents, catheters, intra ocular lenses, I.V. Cannula, bone cements, heart valves, scalp vein set, orthopaedic implants and internal prosthetic replacements.

CLAA scheme was formed to oversee the regulatory activities related to grant of manufacturing license for hi- tech medical devices in India. It aims at ensuring that the medical devices being manufactured in India follow the standard requirements set by the government to ensure safety, efficacy and quality of the devices.

Gujarat government had signed eight such strategic partnerships with overseas and Indian companies to upgrade the knowledge of the Gujarat FDCA officers on relevant areas of concern of the regulatory authorities globally and in India.

Gujarat FDCA had previously done a similar kind of exercise of training 50 drug inspectors to detect faulty medical devices and sub-standard drugs in line with the training imparted to US FDA inspectors through a collaboration with US-based Underwriters Laboratories (UL). This initiative was led by the compliance education and training services business division of UL, UL EduNeering.