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Medical Device

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Medical device is an instrument, appliance, apparatus, implement, machine, software, calibrator, contrivance, implant, In-vitro reagent, or other similar or related article, along or in combination, including a component part, or accessory or other article which is intended for the following.

Diagnosis, prevention, monitoring, treatment, mitigation, cure or alleviation of disease, Investigation, replacement, or modification of the anatomy or of a physiological process.

Supporting or sustaining life

Providing information for medical or diagnostic purposes by means of *In-vitro* examination of specimens derived from the human body. To affect the structure or any function of the body of man or other animals, and/but does NOT achieve any of its primary intended purposes through its chemical action (within or on the body). A medical device should not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means. Medical device classification determinations should be based on a device's potential to harm a patient, its intended use and also the technology it uses:

Manufacturers should document their justifications for assigning their devices to Class A, B, C or D

RAs should establish a device classification system consisting of four classes where Class A represents the lowest hazard, and Class D the highest hazard.

Principle of medical device classification by GHTF through doc number GHTF/SG1/N77:2012 was developed and intended for use by RAs (Regulatory Authorities), CABs (Conformity & Assessment Bodies) and Industry. Regulatory Authority (RA): A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements. Conformity Assessment Body (CAB): A body, other than a regulatory authority, engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled. The actual classification of each device depends on the claims made by the manufacturer for its intended use and the technologies. As an aid to interpreting the purpose of each rule, illustrative examples of medical devices that should conform to the rule have been provided in the table of previous slide. However, it must be emphasized that a manufacturer of the medical device should NOT rely on its appearing as an example, but should instead make an independent decision on classification taking account of its particular design and intended use: Manufacturers of Class A devices should implement and maintain the basic elements of a QMS, but have the option of excluding design and development controls from it. The QMS is normally not subject to premarket on-site audit by the RA or CAB, except where assurance of sterility or of a measuring function is required. Manufacturers of Class B devices should implement and maintain an effective QMS, but may have the option of excluding design and development controls from it. Manufacturers of Class C and D devices should implement and maintain an effective QMS that includes design and development controls, and complies with GHTF SG3 guidance documents. For Class B, C, and D devices, the RA or CAB needs to have confidence that the manufacturer has an appropriate and effective QMS in place.

Note: An accessory is NOT considered as medical device. However, where it is intended specifically by its manufacturer to be used together with the 'parent' medical device (to enable the medical device to achieve its intended purpose), it should be subject to the same procedures of GHTF guidance

Biography

Mr. Abid is Certified Lead Auditor for ISO13485 (Medical Device) from BSI & IRCA, UK. He has 16 years plus experience of QA/Regulatory and R&D pharma Industries. At present he is working as following in Jamjoom Pharmaceuticals Company in KSA as Head Regulatory Compliance & Team Leader Variation Management Committee. Mr. Abid is the member of RAPS (Regulatory Affairs Professional Society) – US. He is fee launcher consultant. He is an International Speaker, Moderator, Panelist and Trainer as well.

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