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Medical device – Compliance challenges against legislation & regulation

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

Biography

Syed Abid Hassan is founder of Bismil Welfare Society. He has completed his D Pharma from RLSY College, MSc in Chemistry from VM University, MBA (in International Business) from EILM-India. He is pursuing his PhD in Chemistry. He is Certified Lead Auditor for QMS (Quality Management System), by BSI (British Standard Institute) UK, and for ISO13485 (Medical Device) by IRCA (International Register of Certificated Auditor) UK. He has 17 years plus experi¬ence of QA/Regulatory and R&D. He is the member of RAPS (Regulatory Affairs Professional Society) – US, and CQI (Continuous Quality Improvement) UK. He has authored several publications in various journals of US and Germany. He has participated as Chairperson, Moderator, Panelist, Trainer or Speaker in several International Conferences in KSA, Egypt, UAE, Germany and USA. Presently he is working as Head of Regulatory Compliance and Team Leader of Variation Management Committee, in Jamjoom Pharmaceuticals Company - KSA

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