IMDRF International Medical Device Regulators Forum

Final Document

International Medical Device Regulators Forum

Title: Statement regarding Use of ISO 10993-1:2009 "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process"

Authoring Group: IMDRF Management Committee

Date: 2 October 2015

Toshiyoshi Tominaga, IMDRF Chair

Use of ISO 10993:2009 "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process" in each jurisdiction

Australia Therapeutic Goods Administration (TGA)	All medical devices are required to meet Australian Essential Principles (EPs)**.** The TGA's non-mandatory *Medical Devices Standards Order (Standards for biological safety of medical devices)*, 2008 (MDSO) specifies ISO 10993-1:2009 and the relevant parts and compliance with this standard is used as evidence of compliance with EP 7.
Brazil National Health Surveillance Agency (ANVISA)	It is mandatory for manufacturers and importers of medical materials to prove that they meet the requirements set by standard ISO 10993. Several ANVISA regulations mention ISO 10993 and it is applicable to pre- and post-market stages.
Canada Health Canada (HC)	In Canada, conformance to specific standards is not mandatory. However, evidence of conformity to recognised standards can be submitted to demonstrate that specific requirements of the Medical Devices Regulations have been met. HC publishes a list of recognised standards, and the level of evidence expected is "equivalent or better" to these recognised standards. ISO 10993-1:2009 is currently a recognised standard. This standard is relied on as the primary source of guidance for the selection of appropriate biocompatibility tests. Justification of pass/fail limits applied are expected in submissions and are reviewed in detail for Class III and IV medical device license applications**.**
China China Food and Drug Administration (CFDA)	The ISO 10993-1：2009 had been translated into China national standard: GB/T 16886.1-2011 equally and implement from 2011.12.1, it isn't mandatory standard, but , It is very important standard for industry to evaluate the biological of their medical device, and the evaluation center also investigate the biological of the medical device according to the series standard.
Europe European Commission (EC)	The corresponding European standard EN ISO 10993-1:2009 is a harmonized standard which provides presumption of conformity with certain legal requirements regarding chemical, physical and biological properties of devices. The use of this standard (to the extent specified in its Annex ZZ) provides one solution for compliance with the relevant legal requirements. Compliance with the legal requirements can however be ensured also by other means.
Japan Ministry of Health, Labour and Welfare	All medical devices are required to satisfy the EPs that align with those defined in GHTF/SG1/N68:2012 *Essential Principles of Safety and Performance of Medical Devices*. ISO 10993-1:2009 can be used for its purpose, which is clearly referred to in checklist of

(MHLW) Pharmaceuticals and Medical Devices Agency (PMDA)	EPs or certification/approval standards for each medical device.
Russia Russian Ministry of Health Roszdravnadzor	In current regulation using of standards is voluntary in premarket MD evaluation. And Regulator does not recognize any standard which could provide presumption of conformity. But when on the market, some types of MD have to be certified for particular mandatory standards (list of mandatory standards and types of MD is available on Regulator's web site). It should be noted, that this regulation is to be canceled on 01/01/2016.
The United States of America US Food and Drug Administration (US FDA)	ISO 10993:2009 is recognized by the US FDA medical device program as a consensus standard for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirements to which a standard is applicable. US FDA by recognizing ISO 10993:2009 and ISO 10993-1:2013 believes these standards can successfully serve to address many of the issues associated with the biocompatibility evaluation of medical device. The standard is used by CDRH to identify the types of issues relevant to a biocompatibility risk assessment, and to determine if the currently available information (e.g., formulation, manufacturing, previously collected data, literature information) is sufficient, or if additional testing might be needed (per other parts of the 10993 standard).