Journalof Pharmaceutical Sciences and Emerging Drugs

Research A SCITECHNOL JOURNAL

Standards for Medical Device across Regulatory Bodies

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Received date: 17 June, 2022, Manuscript No. JPSED-22-28029;

Editor assigned date: 20 June, 2022, PreQC No. JPSED-22-28029 (PQ);

Reviewed date: 04 July, 2022, QC No. JPSED-22-28029;

Revised date: 11 July, 2022, Manuscript No. JPSED-22-28029 (R);

Published date: 18 July, 2022, DOI: 10.4172/2380-9477.1000119

Abstract

Different approaches used by the various national regulatory bodies led to lack of harmonization in the medical device industries. This article explains the method, beginning with standards adopted and acknowledged in various regulatory systems by the International Organization for Standardization (ISO). Manufacturers will familiarize themselves with the updated standard list and provide correct certificates of adherence as part of their registration process to ensure compliance with those requirements. Regulatory bodies in different countries make changes, from time to time, to their set of approved criteria used in the medical device regulatory process. Although the software and emerging technology are increasingly becoming common elements in medical devices, vendors now have to ensure compliance with more existing specifications. Such principles are international norms, which ensure they extend to the globe. Consequently, they could be embraced by any given region or country, perhaps with modifications or limitations. Generally, international standards are denoted with three sections. First, the issuing organization; second, a number; and third, the problem year.

Keywords: Medical device; Regulation standards; ISO; Voluntary; Mandatory standard.

Introduction

Undertanding of standards systems, the process of developing standards and their use in conformity assessement has become essential for the establishment of regulations on medical devices. A general introduction to norm will be provided and accompanied by a review of current trends in the use of informal criteria in legislation pertaining to medical devices and GHTF relevand guidelines.

Standards are written documents tat include technical specification or other particular requirements that must be regularly used as regulations, instructions, or characteristic descriptions to ensure that materials, goods, procedures and facilities as appropriate for their function [1].

Disscussion

Types of specifications in standards

1. Prescriptive standards include component features, such as devic e measurements, biomaterials, processing or configuration metho ds, as well as words and terminology descriptions.
2. Product design requirements describe a product's basic design or technological aspect, e.g. operating room equipment or medical g as systems.
3. Quality standards guarantee that a device passes a specified standard, such as strength criteria, calculating performance, battery capacity, or optimum defibrillator resistance.
4. The management specifications for the processes and procedures that companies put in place, e.g. quality control systems or environmental management systems.[2]

A norm may include a mix of requirements. Specifications of prescriptive, product design and performance are popular in specifications. Recent years have seen the introduction and implementation of what is known as generic management system principles," where "simple" ensures that any company can implement the specifications of the standards; The "management system" relates to what the company does to handle its operations, irrespective of the commodity it produces or the service it provides. The ISO 9000 series for controlling production processes and the ISO 14000 series for environmental management systems are two of the most widely known sets of standardized management system codes. The specific ISO certification standard codes ISO13485 and ISO13488 are quality management systems standards for the manufacturing of the medical device.[3]

Standards can serve different purposes

1. Provide comparison standards that must be followed by a compa ny, method or service.
2. Provide Knowledge that improves the product, operation, and service health, efficiency and results.
3. Assure users of the durability or any other functionality of the services or goods delivered to the market.
4. Giver user's a greater option by enabling goods from one business to be replaced or merged with items from another company.

Quality structures and other principles of management could provide specific comparisons to the type of process, operation, or activity required by management. Without international standardization, global communication would have been very complicated as most medical devices are being used internationally. Thus, the protection, accuracy and consistent quality of medical devices is an international public health priority. International harmonization of standards and regulations pertaining to medical devices is therefore vital.

Voluntary and mandatory standards

Most standards are voluntary and may be mandated by a company, healthcare professional, industry, government or trade agreement. When it become compulsory a norm may be considered rules and regulation. When a provision is imposed by a statute or international

trade arrangement, it usually is legally binding on the basis of legislation or self-established law, or treaties with international bodies. Countries considering making requirements compulsory will take into account the potential impacts on technological barriers to trade under international agreements.[4]

Four growing manufacturing approaches are used to determine adherence to a pattern.

1. The conformity of a commodity to requirements is generally measured by direct inspection.
2. The evaluation process can be appraised. Qualification agencies or regulatory authorities affirm that by allowing the appearance of their certification mark (qualification label), the goods or procedures adhere to a standard.
3. An organization's adherence to the organizational framework is defined as certification of management systems. Certified auditors are accompanied by officially defined audit protocols that are endorsed by the audited sector technical experts. Registrars awarding identification certificates to organizations that follow a quality norm, such as ISO9000; or to suppliers or manufacturers of medical device meetings the requirements.
4. An official body uses accreditation to officially recognize that an agency or an individual has the ability to undertake a specific tas k.

Development of standard for medical device

Europian Union, Notified bodies shall be informed or authorized to carry out compliance tests of medical devices by the appropriate State authority concerned. Throughout Canada, Health Canada needs accreditation from a Quality System Registrar before that Registrar begins reviewing suppliers of medical devices for conformity with quality system requirements Accreditation is used by the International Laboratory Accreditation Cooperation (ILAC) to formally recognize qualified laboratories around the globe [7].

International and national standards system

A country may have various bodies of voluntary standards. Normally, however, there is one official national body, which oversees and accredits the country's standards implementation bodies. The official national body, in compliance with statutory guidelines, would have the power to approve a text as a national standard, and it also represents the country in the various international standards organizations.

1. In the United States, an official national agency is the American National Standards Institute (ANSI), a nonprofit organization, a private.
2. Standards Council of Canada (SCC), a body of the crown (governing) in Canada.
3. In Europe, there is a body consisting of CEN (Comité Européen de Normalisation), CENELEC (European Body for Electrotechnical Standardization) and ETSI (European Telecommunications Standards Institute), which supervises the numerous previously established European national standards bodies.

The International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and the International Telecommunication Union (ITU) are the three major international standardization bodies. ITU generally covers communications, IEC covers electrical and electronic infrastructure and ISO covers the rest. Joint ISO/IEC professional committees implement standardization for information technology, risk management, safety processes, and many other fields.

Many organizations also create voluntary standardization materials. Their publications are usually accepted as international standards by ISO / IEC / ITU if they have been established according to principles of international consensus. Each community of 5 member countries may also submit a standard to be recognized as an international standard by ISO for acceptance.

Standards Identification

No	Standard	Description
1	ISO 13485 : 2003	Quality Management System : Requirements For Regulatory Purposes
2	EN540	Clinical Investigation of Medical Devices
3	EN285	Sterilization - Steam Sterilizer - Large Sterilizers
4	ISO 14971 : 2000	Application of risk management to medical devices
5	EN550	Validation and routine control of ethylene oxide sterilization appliances for household and similar purposes, electric tools and similar electric apparatus
6	EN552	Validation and routine control of sterilization by irradiation
7	EN554	Sterilization by Moist Heat
8	EN556	Requirement for terminally-sterilized devices to be labeled Sterile polyurethane thermal insulation and outer casing of polyethylene.
9	EN556-1 : 2001	Part1 : Requirements for terminally sterilized medical devices

10	EN793	Particular Requirements for Safety of Medical Supply Units
11	EN867-2	Non-Biological System for use in Sterilizers Part 2 : Process Indicator
12	EN867-3	Non-Biological System for use in Sterilizers Part 2: Process Indicator for Class B for use in the Bowie and Dick Test
13	EN868-1	Packaging Materials and Systems for Medical Devices which are to be sterilized – Part 1: General Requirements and Test Method
14	EN980A1	Graphical Symbols for use in the labeling
15	EN1401	Information supplied by the manufacturer
16	EN1174-1	Estimation of the population of Micro-Organisms on Product – Part 1: Color Coding
17	EN1174-2	Estimation of the population of Micro-Organisms on Product – Part 2: Guidance
18	EN1174-3	Estimation of the population of Micro-Organisms on Product – Part 3: Guide to the methods for validation of microbiological techniques
19	EN1422	Sterilizers for Medical Purposes – Ethylene Oxide Sterilizers – Requirements and methods
20	EN1639	Dentistry –Instruments
21	EN1641	Dentistry –Material
22	EN1642	Dentistry –Dental Implants
23	EN1782	Tracheal Tubes and Connectors
24	EN1789:1999/A1: 2003	Medical Vehicles and their equipment – Road Ambulances
25	EN1865	Specifications for stretchers and other patient handling equipment used in road ambulances
26	EN ISO 8395	Oxygen Connectors for Medical Use – Safety Requirement
27	EN ISO 10079-1	Medical Suction Equipment – Part 1: Electrically Powered Suction Equipment Safety Requirement
28	EN ISO 10079-2	Medical Suction Equipment – Part 2: Manually powered suction equipment (ISO 10079-2:1999)
29	EN ISO 10079-3	Medical Suction Equipment – Part 3: Suction Equipment powered from a vacuum or pressure source (ISO 10079-3:1999)
30	EN ISO 10993-1	Biological evaluation– Part 1: Evaluation and Testing (ISO 10993-1:1997)
31	EN ISO 10993-4: 2002	Biological evaluation– Part 4: Selection of tests for interactions with blood (ISO 10993- 4:2002)
32	EN ISO 10993-5	Biological evaluation– Part 5: Test for in vitro cytotoxicity (ISO 10993-7:1995)
33	EN ISO 10993-7	Biological evaluation– Part 7: Sterilization residuals (ISO 10993-7:1995)
34	EN ISO 10993-8	Biological evaluation– Part 8: Selection and qualification of reference for materials for biological tests (ISO 10993-8:2000)

35	EN ISO 10993-9	Biological evaluation– Part 9: Framework for identification and qualification of potential degradation products (ISO 10993-9:1999)
36	EN ISO 10993-10: 2002	Biological evaluation– Part 10: Tests for irritation and sensitization (ISO 10993-10:2002)
37	EN ISO 10993-12	Biological evaluation– Part 12: Sample preparation and reference materials (ISO 10993- 1:1996)
38	EN ISO 10993-13	Biological evaluation– Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-12:1998)
39	EN ISO 10993-14	Biological evaluation– Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)
40	EN ISO 10993-15	Biological evaluation– Part 15: Identification and quantification of degradation products from metal and alloys (ISO 10993-15:2000)
41	EN ISO 10993-16	Biological evaluation– Part 16: Toxicokinetic study design for degradation products and leachable (ISO 10993-16:1997)
42	EN ISO 10993-17: 2002	Biological evaluation– Part 17: Establishment of allowable limits for leachable substances (ISO 10993-117:2002)
43	EN 12010	Non active surgical implants – Joint replacement implants – Particular requirements
44	ISO 12572; Pt 10	Guide for evaluation of medical devices for biological hazards: Part 10: Methods of biological testing and evaluation of dental materials
45	ISO 7405	Dentistry – Preclinical evaluation of biocompatibility of medical devices used in dentistry –test method for dental materials
46	ISO 9626	Stainless steel needle tubing for the manufacture of medical devices
47	ISO 12572; Pt 11	Guide for evaluation of medical devices for biological hazards; Part 11: Methods of test for eye irritation
48	ISO 10993-2	Biological evaluation: part 2 : Animal welfare requirements
49	ISO 10993-3	Biological evaluation: part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity
50	ISO 10993-5	Biological evaluation: Part 5: Tests for in vitro cytotoxicity
51	ASTM 13.01	Annual book of ASTM standards: Section 13: Medical Devices and Services: Volume 13.01: Emergency medical services
52	ISO 10993 Pt 11	Biological evaluation: Part 11: Test for systematic toxicity
53	BS EN 46001	Specification for application of EN ISO 9001 to the manufacturer of medical devices
54	BS EN 46002	Specification for application of EN ISO 9002 to the manufacturer of medical devices
55	ISO 11135	Validation and routine control of ethylene oxide sterilization

56	ISO 11137	Sterilization of health care products – Radiation
57	ISO 10555	Intravascular catheters - Sterile and single-use catheters
58	DS EN 46001	Quality System- Particular requirements for the application of EN 29001
59	DS EN 46002	Quality system- Particular requirements for the application of EN 29002
60	AAMI/OPEO	Guideline for industrial ethylene oxide sterilization: Process design validation routine sterilization
61	ISO 10993-6	Biological evaluation: Part 6: Test for local effect after implantation
62	ISO 10993-3	Biological evaluation: Part 3: test for genotoxicity, carcinogenicity and reproductive toxicity.
63	BS EN 724	Guidance on the application of EN 29001 and EN 46001 and EN 29002 and EN 46002 for non-active medical devices
64	BS EN 30993-6: ISO 10993-6	Biological evaluation: Part 6: Test for local effects after implantation
65	BS EN 475	Medical devices- Electrically-generated alarm signals
66	ISO 11737-1	Microbiological methods: part 1: Estimation of population of microorganisms on products
67	ANSI/AAMI OPEO- 12	Guideline for industrial ethylene oxide sterilization of medical devices: process design, validation, routine sterilization
68	DIN EN 30993-6	Biological evaluation- Test for local effects after implantation (ISO 10993-6: 1994)
69	ISO 14708	Implants for surgery - Active implantable medical devices
70	BS 5736:Part 1	Evaluation of medical devices for biological hazards: part 1; Guide for the selection of biological methods
71	BS 5736:Part 2	Evaluation of medical devices for biological hazards: part 2; Method of testing by tissue implantation
72	BS 5736: Part 4	Evaluation of medical device for biological hazards: part 4: Method of test for intracutaneous reactivity of extract from medical devices.
73	BS 5736: Part 5	Evaluation of medical device for biological hazards: part 5: Method of test for systematic toxicity; assessment of pyrogenicity in rabbits of extracts from medical devices
74	BS 5736: Part 6	Evaluation of medical device for biological hazards: part 6: Method of test for sensitization: assessment of the potential of medical devices to produce delayed contact dermatitis
75	BS 5736: Part 7	Evaluation of medical device for biological hazards: part 7: Method of test for skin irritation of extracts from medical devices
76	BS 5736: Part 8	Evaluation of medical device for biological hazards: part 8: Method of test for skin irritation of solid medical devices

77	BS 5736: Part 9	Evaluation of medical device for biological hazards: part 9: Method of test for eye irritation
78	BS 5736: Part 10	Evaluation of medical device for biological hazards: part 10: Method of test for toxicity to cells in culture of extract from medical devices.
79	BS 5736: Part 11	Evaluation of medical device for biological hazards: part 11: Method of test for hemolysis
80	ISO 14155	Clinical investigation
81	AS/NZS 3551	Technical management programs for medical devices
82	BS 7547	Stainless steel needle tubing for the manufacture of medical devices
83	BS EN 928	Guidance on the application of EN 29001 and EN 46001 and of EN 29002 and EN 46002 for in vitro diagnostic medical devices
84	DS/EN 475	Medical devices- electrically-generated alarm signals
85	DIN EN 46002	Quality systems Medical devices particular requirements for the application of EN ISO 9002
86	DIN EN 46001	Quality systems Medical devices particular requirements for the application of EN ISO 9001
87	DIN EN 1640	Medical Devices for dentistry equipment
88	ANSI/AAMI ST35	Safe handling and biological decontamination of medical devices in healthcare facilities and in non-clinical settings
89	AS/NZS 2696	Polymer Urethral catheters for general medical use
90	DIN EN 475	Electrically generated alarm signals to a part of the body
91	BS ISO/IEC 14709-1	Information technology- Configuration of Customer Premises Cabling (CPC) for application Part 1: ISDN basic access
92	DIN EN 46001	Quality system- Particular requirements for the application of EN 29001
93	BS EN ISO 7405	Dentistry- Preclinical evaluation of biocompatibility of medical devices used in dentistry- Test Methods for dental materials
94	BS EN 1441	Risk Analysis
95	BS EN 45502-1	AIMD Part 1: General requirements for safety marking and information to be provided by the manufacturer.
96	BS EN 868-1	Packaging materials and systems for medical devices which are to be sterilized- Part 1: General requirements and test methods
97	ISO 11607	Packaging for terminally sterilized medical devices
98	DIN EN 868-1	Packaging materials and systems for medicals devices which are to be sterilized-Part 1: General requirements and test methods.
99	ISO 14160: 2011	Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives

		-- Requirements for characterization, development, validation and routine control of a sterilization
100	ISO 15225:2000	Nomenclature-Specification for a nomenclature system for medical devices for purposes of regulatory data exchange
101	IEC 60601-1-1-1:2000	Part 1 General Requirement For safety- Collateral standard: Safety requirements for medical electrical systems
102	IEC 80601-2-58:2016- Ed.2.1	Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery
103	IEC 62304:2015	Software life cycle processes
104	ISO 22442	Medical devices utilizing animal tissues and their derivatives

Current trends in the use of standards in the medical device

The use of voluntary guidelines emerged from the recognition that while regulations typically cover the basic values of health, safety, and efficiency, suppliers and consumers still need to learn precise requirements for particular products. Providing these standards and comprehensive criteria for the multitude of products provides regulatory authorities with an enormous task. Luckily, the abundance of already established or being created voluntary criteria provides these detailed requirements. The use of traditional volunteer/consensus has many benefits including:

1. Experts with exposure to the vast resources available in the technical and manufacturing sectors usually establish them.

2. Through utilizing these existing resources, the government may resolve its own limited resources to provide specific technical specifications and functionality for the drug.

3. An approved third party (such as a notified entity in Europe) can also determine adherence to regulations, which is a well-established industry norm around the world.

4. The implementation of international standards promotes harmonized administrative frameworks and world trade while enhancing regional access to new technologies.

5. When technology advances, upgrading specifications is much easier than changing the legislation.

Timely implementation and regular evaluation by committees of specialists make medical product guidelines efficient and effective tools to support health care.

6. Manufacturers have the freedom to choose appropriate criteria or other ways of demonstrating conformity with regulatory requirements.

Conclusion

Regulatory authorities can accept a requirement, in whole or in part, if their purpose is clearly defined and made public. Additionally, many criteria can be known as a category to meet the requirements for a specific unit. The introduction of government-recognized requirements in some countries ensures conformity with the goods.

International standards would extend to medical devices designed for worldwide applications. For starters, the ISO Technical Report (ISO 16142:2000) lists a number of important international requirements that may be sufficient to show conformity with certain aspects of the basic safety principles and performance of diagnostic apparatuses. Many organizations also create universal standardization materials. Their publications are generally accepted as international standards by ISO / IEC / ITU if they have been established according to principles of international consensus. Any grouping of five member countries may also propose a standard to be regarded as an international standard by ISO for adoption.

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