MEDICAL DEVICE STANDARDS

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Abstract

The medical device industry relies heavily on standards, whether it is the transfer of medical information through distances, or designing and developing an artificial heart. Therefore, this research paper will discuss the role of the private sector in the development of medical device standards and the relationship between the private sector and the government in the development of such standards. The paper will also illustrate that one can market a medical device in United States by conforming to the Food and Drug Administration (FDA) recognized medical devices standards. Furthermore, the paper will give a hypothetical example of how to use medical device standards in order to gain market approval for a medical glove from the FDA.

Introduction

Medical devices cover a variety of products designed to diagnose and treat patients. These devices range from a simple medical glove to a complicated Magnetic Resonance Imaging machine (MRI). However different their composition may be, medical devices are all designed with the purpose of improving patient care.

According to the International Trade Administration (ITA), an agency of United States Department of Commerce, The U.S. is the largest consumer of medical devices and also leads the world in the production of medical devices. In 2008 the medical device market in the U.S. was valued at more than $100 billion, that's roughly 42 percent of the world's total. Moreover, Global demand for medical devices is being driven by advancement in medical care, increasing expenditures and greater attention to health care by developing markets, construction of hospitals and clinics, and increasing public

accessibility to health insurance.[1] This demand drives the medical device industry to continually produce and innovate new products.

In correlation with the demand for medical devices, there is a demand for the development of international standards that insure the safety and performance of the devices.

What are medical device standards?

The International Organization for Standardization (ISO), the world's largest developer and publisher of International Standards, defines standards that should be adopted in the medical device domain as:

> *Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process and services are fit for their purpose.*[2]

According to page 18 of the publication entitled *Medical Device Regulations: Global Overview and Guiding Principles* authored by Dr. Michael Cheng; standards can establish prescriptive specifications, design specifications, performance specifications, and management specifications for products, processes and services. Also, according to Dr. Michael Cheng; Prescriptive specifications require product characteristics, such as:

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[1] Ferman, Jamie. *MEDICAL DEVICES INDUSTRY ASSESSMENT.* Rep. Office of Health and Consumer Goods -Health Team International Trade Administration, 24 Mar. 2010. Web. 12 July 2010. <http://www.trade.gov/td/health/Medical%20Device%20Industry%20Assessment%20FINAL%20II%203-24-10.pdf>.

[2] Cheng, Michael. *Medical Device Regulations : Global Overview and Guiding Principles.* Rep. World Health Organization, 2003. Web. 13 July 2010. <http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf>.

dimensions of the device, test or calibration procedures, in addition to definitions of terms and terminologies. Design specifications are for the specific design or technical characteristics of a product. Performance specifications ensure that a product meets approved tests, such as: strength requirements, measurement and accuracy. Management specifications incorporate requirements for the processes and procedures companies put in place, e.g. quality systems for manufacturing or environmental management systems. (Cheng, 2003) [3]

Why do we need medical device standards?

Medical devices are used by a large number of people; the safety, performance and consistent quality of medical devices are a public health concern. Thus, it is critical to have national and international medical device standards and regulations. According to page 19 of the publication entitled *Medical Device Regulations: Global Overview and Guiding Principles* authored by Dr. Michael Cheng; these medical device standards can provide reference criteria that a product, process or service must meet. Also, according to Dr. Michael Cheng; they can provide information that enhances safety, reliability and performance of products, processes and services. Medical devices standards assure consumers about reliability or other characteristics of goods or services provided in the marketplace. (Cheng, 2003) [4]

[3] Cheng, Michael. *Medical Device Regulations : Global Overview and Guiding Principles.* Rep. World Health Organization, 2003. Page 18. Web. 13 July 2010. <http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf>.

[4] Cheng, Michael. *Medical Device Regulations : Global Overview and Guiding Principles.* Rep. World Health Organization, 2003. Page 19 Web. 13 July 2010. <http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf>.

Development of Medical device standards

Role of the private sector

Non-government standards development organizations use many stages in the development process of standards, whether it's a medical device standard or not. For example ISO's International standards are developed using a six-stage process:

- Stage 1: Proposal stage
- Stage 2: Preparatory stage
- Stage 3: Committee stage
- Stage 4: Enquiry stage
- Stage 5: Approval stage
- Stage 6: Publication stage

Stage 1: Proposal stage

The first step in the development of an International Standard by the ISO is to confirm that there is a need for such standard. To establish that there is a need for a standard, the members of the relevant technical committees or subcommittees submit a new work item proposal for a vote. The proposal will only be accepted if the majority of the votes are in its favor and if at least five participating members commit to participate actively in the project. Once the proposal has been accepted a project leader responsible for the work item is appointed.[5] (See www.ISO.com for more information)

[5] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

Stage 2: Preparatory stage

At this stage, the appointed project leader chairs a group of experts, which is set up by the technical committees and subcommittees, for the preparation of a working draft. Afterwards, the draft is forwarded to the working group's parent committee for the consensus-building phase.[6] (See www.ISO.com for more information)

Stage 3: Committee stage

Once a committee draft is available, it is registered by the ISO Central Secretariat. It is then, distributed for comment and voting (if required), by the participating members of the technical committees and subcommittees. Once agreement has been reached, the text is finalized for submission as an International Standard Draft (DIS).[7] (See www.ISO.com for more information)

Stage 4: Enquiry stage

At this stage, the ISO Central Secretariat circulates the International Standard Draft (DIS) for a period of five months to all ISO member bodies for voting and comment. It is approved for submission as a final draft International Standard (FDIS). If a two-thirds majority of the participating members of the technical committees and subcommittees are in favor and not more than one-quarter of the total number of votes cast are negative it will be approved.[8] (See www.ISO.com for more information)

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[6] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

[7] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

[8] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

Stage 5: Approval stage

At this stage the final International Standard Draft (FDIS) is circulated to all ISO member bodies by the ISO Central Secretariat for a final Yes or No vote within a period of two months (ISO). If a two-thirds majority of the participating members of the technical committees and subcommittees are in favor and not more than one-quarter of the total number of votes cast are negative it will be approved. However, if the approval criteria are not met, the text is again returned to the originating technical committees and subcommittees for reconsideration.[9] (See www.ISO.com for more information)

Stage 6: Publication stage

After a final International Standard Draft has been approved, the final text is sent to the ISO Central Secretariat, which publishes the International Standard. All International Standards are reviewed at the least three years after publication and every five years after the first review by all the ISO member bodies. A majority vote of the participating members of the technical committees and subcommittees decides whether an International Standard should be confirmed, revised or withdrawn.[10] (See www.ISO.com for more information)

[9] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

[10] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

Role of the Government in the development of standards

The Center for Devices and Radiological Health (CDRH), an operating unit of the FDA, is responsible for protecting the public by assuring the safety, effectiveness, and quality of medical devices in the United States. According to an FDA guidance document entitled *Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards* issued on September 17, 2007; CDRH believes that conformance with recognized standards can support a reasonable assurance of safety and effectiveness for many applicable aspects of medical devices.[11] Therefore, its not surprising for CDRH to be invested in the development of medical device standards by participates significantly in the development process. The Standards Management Staff (SMS) at CDRH is responsible for facilitating the recognition of national and international medical device standards. The standards program, works closely with the standards developing organizations, by facilitating a center recommendation to serve on a particular standards activity. SMS also continually updates currently recognized standards and coordinates the recognition of new voluntary standards for medical devices. According to the SMS page on the FDA's website; The Standards Program was created as a result of the Food and Drug Administration Modernization Act (FDAMA) of 1997. It should be noted that CDRH has been involved in the development of medical device standards for decades, before FDAMA formalized the process. (FDA)[12] (See www.FDA.gov for more information)

[11] "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards." *U S Food and Drug Administration Home Page*. 06 Nov. 2009. Web. 15 July 2010. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm#f1>.

[12] "Standards Management Staff." *U S Food and Drug Administration Home Page*. 07 Aug. 2009. Web. 15 July 2010. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123780.htm>.

Market a medical device by conforming to FDA recognized medical devices standards

In order to market a medical device in the United States, the FDA must approve a premarket application such as: Premarket Notification (510(k)), Investigational Device Exemptions application (IDE) and, a Premarket Approval application (PMA). According to the FDA guidance document entitled *Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards* issued on September 17, 2007; these applications provide information as required by the statute and regulations to allow CDRH to make an appropriate decision regarding the clearance or approval of the submission. To simplify and accelerate the premarket review process, applicants may utilize FDA recognized standards in premarket submissions. Also, according to the guidance document, recognized standards serve as complete performance criteria for medical devices. Therefore, information submitted on conformance with such standards should have a direct bearing on safety and effectiveness determinations made during the review of IDEs, PMAs, and 510(k)s. Furthermore, conformance with such standards may be used to show that the new device is as safe and effective as the predicate in the areas covered by the standards. Conformance and declarations of conformance to any recognized standard that clearly spells out acceptance criteria can effectively expedite the premarket approval process. Used this way, standards will reduce the amount of documentation that you need to submit resulting faster approval from the FDA. [13] (See www.FDA.gov for more information)

[13] "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards." *U S Food and Drug Administration Home Page*. 06 Nov. 2009. Web. 15 July 2010. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm#f1>.

Example: Using medical device standards to gain approval from the FDA for a medical glove.

This example will show how one can use FDA recognized medical device standards to demonstrate the safety and effectiveness of a medical glove. Conformity to the following FDA recognized standards may help establish that the medical glove is safe and effective in the areas covered by the standards. This information may reduce the amount of documentation as well as reduce the device review time, improving the chance of getting the product to the market faster. Please note that this example and the glove used in this example are hypothetical, the purpose is just to illustrate the different FDA recognized medical device standards that can be used to gain market approval from the FDA. Let's call the hypothetical glove: "HI FIVE glove".

HI FIVE Glove intended use:

The HI FIVE Glove purpose is to decrease the likelihood of glove puncture and tear in disposable exam gloves to decrease the transmission of blood borne pathogens. The gloves' intended use is to have the glove worn on the examiner's hand to prevent contamination between the patient and examiner.

Safety and effectiveness verified by conformity to the following recognized standards and test.

A combination of bench, non-clinical, and clinical tests were hypothetical conducted on the HI FIVE. As indicated later in this paper, the HI FIVE hypothetical met or exceeded all standards. Thus, pending FDA clearance, the HI FIVE hypothetical will be ready to go into production and serves to significantly reduce the hundreds of thousands of needle stick injuries that occur each year.

SHELF LIFE TESTING

ASTM D7160

Standard Practice for Determination of Expiration Dating for Medical Glove

This test is done to determine the expiration date of our glove. The glove will be tested for stability and shelf life in the test's method requirements. The expiration date is determined from accelerated stability tests and real time aging test.
Source: http://www.astm.org/Standards/D7160.htm

ASTM D7161

Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions

This practice provides a study design for determining shelf life of medical gloves by testing a glove in its final packaging configuration that has been stored under typical warehouse conditions.
Source: http://www.astm.org/Standards/D7161.htm

ASTM F1980

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

This guide provides information for developing accelerated aging protocols to determine the effects, if any, due to the passage of time on the sterile integrity of the sterile barrier system.
Source: http://www.astm.org/Standards/F1980.htm

Table I: Summary of Shelf Life Testing

TEST	RESULT
ASTM D7160	365 days
ASTM D7161	372 days
ASTM F1980	No evidence of adverse effect

BIOCOMPATIBILITY TESTING

ASTM F748

Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices.
This practice provides guidance in selecting different biological testing to determine a realistic level of confidence concerning the biological response to our glove.
Source:http://www.astm.org/Standards/F748.htm

ISO 10993-3

Test for Genotoxicity
This test uses cell cultures to determine changes in chromosome structures and number, and other gene toxicities caused by the material of out glove.
Source:http://www.nelsonlabs.com/medical-device/toxicology-biocompatibility.jsp

ISO 10993-5, USP 87

Test for Cytotoxicity
This quick inexpensive test determines if the materials in our medical glove contain harmful extractables. The test also determines the effect of the extractables on cellular components. This is done when Agar overlay media is placed on top of a monolayer of L-929 cells, and a sample is placed on top of the agar media then incubated. For both methods the cells are scored for cytopathic effect.

Source:http://www.nelsonlabs.com/medical-device/toxicology-biocompatibility.jsp

ISO 10993-11

Test for Systemic Toxicity
This test evaluates potential adverse effects of the glove on the body's organs and tissues that are distant form the site of contact. There are four categories: acute (24 hours), subacute (14 to 28 days) subchronic (90 days), and chronic (anything longer).
Source:http://www.nelsonlabs.com/medical-device/toxicology-biocompatibility.jsp

Table II: Summary of Biocompatibility Testing

Test	Result
Skin irritation testing	No evidence of skin iteration
Test for Genotoxicity	No changes in chromosome structures and number
Test for Cytotoxicity	Material does not contain harmful extractables
Test for Systemic Toxicity	No potential adverse effects from the glove

BENCH TESTING

STRETCH / FLEX

ASTM D638

Standard Test Method for Tensile Properties of Plastics. Determines and validates a material's elastic modulus (E), which is useful for engineering different types of plastic. Testing must be conducted utilizing different environmental conditions in order to validate all possible scenarios in which the product may be used. Materials up to 14 mm in thickness may be measured. This test is equivalent to ISO 527-1.
Souce: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>

ASTM D732

Standard Test Method for Shear Strength of Plastics by Punch Tool. Useful for comparing the different materials that will be combined to form the core glove material. Test cannot account for stress concentration or rate of shear. Can be used on plastics 1.27 mm to 12.7 mm in thickness.
Souce: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>

ASTM D790

Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials. Utilizes 3-point bend method to acquire flexural data for quality control assurances. Protocol recommends that materials that do not fail by a significant margin should be re-tested using a 4-point bend (D6272). To test the glove, Procedure B would be utilized, as the glove materials undergo large deflection during testing.
Souce: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>

Table III: Summary of Stretch / Flex Testing

Test	Result
ASTM D638	Device conforms to the standards.
ASTM D732	Device conforms to the standards.
ASTM D790	Device conforms to the standards.

Puncture, Leakage, Tear Resistance

ASTM D1709

Standard Test Methods for Impact Resistance of Plastic Film by the Free-Falling Dart Method.

A dart is dropped from a set distance onto an awaiting sheet of the material being tested. The ability of the dart to puncture the material is determined. Equivalent to ISO 776. These tests are the industry standards to determine a material's resistance to puncture. Determines the puncture force required for 50% of specimens to fail.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>

ASTM D5151

Standard Test Method for Detection of Holes in Medical Gloves.

Each glove is filled with 1000 ml of water to check for pinholes. Historically, the FDA mandated that the maximum AQL is 4.0 (i.e. if more than four gloves per batch of 100 contain holes, the batch must be discarded). In December 2008, this was amended to an AQL of 2.5.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010. <http://www.astm.org>

ASTM D1004

Standard Test Method for Tear Resistance (Graves Tear) of Plastic Film and Sheeting.

Best utilized on non-brittle materials (such as those to be utilized in the construction of the HI FIVE glove). Tear resistance has no direct correlation with material thickness. Tear force expressed in newtons. Load rate of tearing instrument is 51 mm per minute.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010. <http://www.astm.org>.

Table IV: Summary of Puncture, Leakage, and Tear Resistance Testing

TEST	RESULT
ASTM D1709	Device conforms to the standards.
ASTM D5151	Device conforms to the standards.
ASTM D1004	Device conforms to the standards.

Temperature and Density

ASTM D696

Standard Test Method for Coefficient of Linear Thermal Expansion of Plastics Between -30°C and 30°C With a Vitreous Silica Dilatometer. Tests thermal expansion while operating under standard temperature range (-22°F to 86°F). This test only offers an approximation of thermal expansion due to limiting factors such as changes in moisture content and stresses, which cannot be completely eliminated.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010. <http://www.astm.org.>

ASTM D1043

Standard Test Method for Stiffness Properties of Plastics as a Function of Temperature by Means of a Torsion Test. Test measures modulus of rigidity (G), as opposed to elastic modulus (E). Tests plastic stiffness over a wide temperature range. Torque is applied at different temperature intervals to gauge the changes in stiffness in differing environments.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010. <http://www.astm.org>

ASTM D792

Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement. Utilize Test Method A, which tests solid plastics by displacing water. By determining a material's density, further tests may then be conducted to determine strength-weight ratio and other additional properties.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>.

Table V: Summary of Temperature and Density Testing

TEST	RESULT
ASTM D696	Device conforms to the standards.
ASTM D1043	Device conforms to the standards.
ASTM D792	Device conforms to the standards.

TENSION

ASTM D1708

Standard Test Method for Tensile Properties of Plastics by Use of Microtensile Specimens. Determines tensile and elongation properties using predetermined temperature and humidity conditions.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>

ASTM D2990

Standard Test Methods for Tensile, Compressive, and Flexural Creep and Creep-Rupture of Plastics. Establish material strength under long-term load via determination of tensile and compressive creep. Utilizes a 3-point load test. Tension is the preferred modality, as flexion and compression do not always rupture ductile plastics.
Source: ASTM International - Standards Worldwide. Web. 28 Feb. 2010.<http://www.astm.org>

ASTM D3039

Standard Test Method for Tensile Properties of Polymer Matrix Composite Materials. This test is able to determine a composite material's ultimate tensile strength and strain, modulus of elasticity (E), Poisson's ratio, and transition strain. The polymer matrix must be aligned symmetrically to the direction of the applied force.
Source: ASTM International – Standards Worldwide. Web. 28 Feb. 2010. <http://www.astm.org>

Table VI: Summary of Tension Testing

TEST	RESULT
ASTM D1708	Device conforms to the standards.
ASTM D2990	Device conforms to the standards.
ASTM D3039	Device conforms to the standards.

NON-CLINICAL TESTING

ANIMAL TESTING

ISO 10993-10

Test for Sensitization

Tests for adverse reactions in animals by exposing the animal skin to the glove. The test can be also done by taking extracts from the materials and injecting them into the animal. The Sensitization reactions are studied by observing redness and swelling as it interacts with the animal's skin or immune system.
Source:http://www.nelsonlabs.com/medical-device/toxicology-biocompatibility.jsp

ASTM F720

Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test.

This practice is done to ensure that the material will not stimulate the immune system to produce an allergic reaction. The reaction would be due to substances which could leak out of the glove's material. The idea behind using guinea pigs is based on the fact that the guinea pig has been shown to be the best animal model for human allergic contact dermatitis.
Source: http://www.astm.org/Standards/F720.htm

Table VII: Summary of Animal Testing

TEST	RESULT
Test for Sensitization	No evidence of skin sensitization.
Guinea Pig Maximization Test	No evidence of skin sensitization.

Conclusion

This research paper explained medical device standards and the need for them. The role of the private sector in the development of standards and the relationship between the private sector and the government in the development of standards was extensively discussed. Also, the paper demonstrated that one can market a medical device in United States by conforming to the Food and Drug Administration recognized medical devices standards.

Furthermore, the paper gave an example of how to use medical device standards in order to gain market approval for a medical glove from the FDA. Conformity to the FDA recognized standards in the paper may help establish that the medical glove is safe and effective in the areas covered by the standards. This information may reduce the amount of documentation as well as reduce FDA approval time for a device, improving the chance of getting the product to the market faster.

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[2,3, & 4] Cheng, Michael. *Medical Device Regulations : Global Overview and Guiding Principles.* Rep. World Health Organization, 2003. Pages 18-19.Web. 13 July 2010. <http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf>.

[5,6,7,8,9, &10] "ISO - Standards Development Processes - Stages of Development of International Standards." *ISO - International Organization for Standardization*. 2010. Web. 13 July 2010. <http://www.iso.org/iso/standards_development/processes_and_procedures/stages_description.htm>.

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[12] "Standards Management Staff." *U S Food and Drug Administration Home Page*. 07 Aug. 2009. Web. 15 July 2010. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123780.htm>.

Reference for the Standards:

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2. "ASTM D1043 -09 Standard Test Method for Stiffness Properties of Plastics as a Function Of..." *ASTM International - Standards Worldwide*. Web. <http://www.astm.org/Standards/D1043.htm>.
3. "ASTM D1708 -06a Standard Test Method for Tensile Properties of Plastics by Use Of..." *ASTM International - Standards Worldwide*. Web. <http://www.astm.org/Standards/D1708.htm>.
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