

Global medical device regulations update engineering essay

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Abstract:

This Article reviews the latest updates of Medical Device regulations in different regulatory and non-regulatory bodies across the globe, which includes countries like Australia, Brazil, Canada, China, Europe, and USA which are regulated and non-regulated bodies like India. Over 85 countries today regulate Medical Devices across the globe. Different regulatory bodies of respected nation provides regulations for placing medical devices in market and different quality systems and standards are involved in regulation of medical devices and also future developments in Regulations on Medical Devices. Keywords: Medical Devices; Regulatory bodies; Quality Systems; Standards.

INTRODUCTION:

A Medical Device is any instrument/ implant/ appliance/ diagnostic aid used to treat, prevent and diagnose the disease. Devices range from small syringes to highly sophisticated instruments like diagnostic X-ray instruments and MRI scanners. Medical Devices have been used since antiquity. As the regulations of Medical Devices involves well defined and stringent regulations, which is often difficult for technical authorities

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involving different governing bodies of particular nation to govern the regulations. The Medical Device regulations are evolved as a result of "thalidomide tragedy" in late 1960's, moreover the regulations on Medical Devices has developed much more lately than that of medicines. High Quality and safe medical devices ensures trust and faith in public for the use of them. The knowledge and compliance of devices with regulatory requirements is the key for success in globalisation of Medical Devices. The regulations of following countries are as follows:

AUSTRALIAN MDR:

The Australian's Medical Devices are regulated by TGA (Therapeutic Goods Administration), which is also a part of conformity assessment body for Australian's Manufacturers.

Regulations:

The current regulations are of Australian Regulations on Medical Devices, 2011, TGA, which are supported by many legislative standards & laws including animal tissue, sterilization which is originally EU derivative, 93/42/EEC. There are 3 committees, which provide advice on regulations, are-Advisory Committee on Medical Devices (ACMD). Therapeutic Goods Committee (TGC). National Coordinating Committee on Therapeutic Goods (NCCTG). TGA act-1989, based on risk assessment approach, designed to ensure the devices are of acceptable quality, safety & efficacy in market.

How devices are regulated?

TGA is the division of Australian Government Department of Health & Ageing is responsible for regulating medicines and medical devices in Australia. The

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Office of Devices Authorization (ODD) is the region within the TGA responsible for pre-market regulations of devices, while the post market regulations was controlled by Office Product Review (OPR) Based on safety and performance of medical devices throughout the lifecycle. The regulatory systems ensure public health, public trust and confidence in Medical Devices.

Life Cycle approach to Medical Device Regulations:

The life cycle approach is detailed in the Table no. 1 TGA assess devices- Before devices supply to market. Ongoing assessment on devices in market. Before any new device enters the market, the requirement, regulations of the particular device should meet the standards, which vary from device to device & risks associated with the devices are assessed, which also varies from little one to highly potential ones. The comparison of regulatory requirements v/s risks shown in following figure 1. TGA improves Medical Device regulations globally by negotiating with other international regulations, ranging from acceptance to recognition of regulatory requirements and decisions on medical devices & sharing information about the process involved in regulations on medical devices.

Key Elements:

Product Requirements-Before placing in market. Ongoing requirements of devices in the market. Device Classification. Regulatory controls for manufacturing process of medical devices. Provision for imposing penalties whose regulatory requirements are breached. Corrective action when a problem raised with the particular medical device.

Device Classification:

The regulatory framework classifies Medical Devices into different classes which are detailed in legislation as: Therapeutic Goods Act-1989. Regulation 3.2 of the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations) Schedule II of the Regulations. The levels of classification are given in Table No. 2.

Registration & Licences:

The Medical Devices application in ARTG (Australian Regulations & Therapeutic Goods) submitted through eBS1, which has different levels of access of registered users & general public, some areas of eBS (eBS - Electronic Business Service, page of TGA, part of Commonwealth Department of Health & Agency, Australia) access restricted by password. If the device to be included in ARTG, the TGA should provide an evidence of acceptable standards of quality, safety & efficacy of medical devices.

Documentation:

The Australian legislation requires TGA to do an evaluation of conformity documentation which complies with essential principles for Australian Manufacturers. Specific high risk devices including materials of microbial or recombinant origin, derivatives of human blood/plasma There are 4 mechanisms for accessing unapproved Medical Devices-Clinical trial investigation in Australian market. Authorised prescribers. Special access schemes. Personal importation.

Quality Systems involved:

The standard for QMS is ISO 13408: 2008, QMS audit for all classes except Class I (Non-sterile / without measuring function). QMS audit carried out by notified body as CE mark certification.

BRAZILIAN MDR:

ANVISA (Agência Nacional de Vigilância Sanitária), established in 1999 under Brazilian Ministry of Health is responsible for regulation of Medical Device and maintenance of registered product database in Brazil. Regulations of Medical Devices is through a series of resolutions / RDC's, Resolution RDC No. 185 of October 22, 2011 is the primary regulation of medical devices in Brazil for their registration, covered by Resolution RDC No. 185, which elaborates registered protocol of devices applicable and lists documents required to legally register a medical device in Brazilian market. The present information / requirements regarding MDR are found in RDC 27/IN-3 & Resolution 350 published by Brazilian Regulatory authorities in June 2011.

Classification:

Under Annex II of RDC No. 185, Medical Devices classified into distinct risk Classes (I, II, III, IV) according to 18 rules, classification structure of medical devices corresponds to that used in EU under Council Directive 93/42/EEC of medical devices. Brazil is a member of Southern Market, also known as MERCOSUR, includes countries like Argentina, Uruguay & Paraguay. Registration of devices is partially harmonised by these countries, thus easing the registration process of devices, easily available in market. Unlike EU notified body, the 510 (k) system of USFDA / Canadian Medical Device

Conformity Assessment system (CMDCA's), ANVISA perform all registration and inspection functions of devices.

Classification of MDs:

Medical Devices are classified in to Class I, II, III based on the risk posed by each device (low, Moderate & High risk). Most of classification would fall under EU Classification of MDs.

Registration:

The registration of most Class I & Class II devices involves a relatively simple application process referred to as " Cadastro" meaning " Abbreviated registration" based on low to moderate risks associated with devices in these classes. Greater the risk in medical devices, more rigorous process for registration.

Documentation:

The documentation process is very complex, requires consulting various laws and decree (Law 6360: 1976, RDC No. 185: 2001 & RDC No, 59: 2000). The party applying for ANVISA registration require providing following documents with registration application. Free sale certificate (can be replaced by INMETRO)Brazilian GMP certificate. Instruction manual. Packaging & Labelling requirements. Letter from device manufacturer, authorized by Brazilian company, holding the product registration and distribution. Clinical trial report. Other device accessories. For Implant medical devices, cardiovascular products, IVD's requires Economic information report. INMETRO certificate, where applicable.

GMP Inspection & Certification:

Certification based on inspection done by ANVISA (RDC No. 25, May 21, 2009), GMP certificate along with registration application for class of medical devices noted on exemption list (Instruction IN-2, June 6, 2011) should be provided during certification process. GMP certificate is valid for 2 years. GMP documentation include-Device information (detailed description & indication of risk class)Payment receipt of GMP fee. GMP inspection check for compliance with RDC No. 59

Quality Systems:

It includes INMETRO (i. e., the National Institute of Metrology, Standardisation and Industrial Quality) certification process. INMETRO / National Institute of Metrology, Standardization & Industrial Quality is the body responsible for accrediting certification of organizations, that certify products for compliance with applicable requirements and authorizes the use of approved certification (CE) marks. The certification scheme is known as SBAC (Scheme of Brazilian Accreditation System). For qualification of INMETRO certification, Medical devices are tested by SBAC recognized standards by an INMETRO accredited testing laboratory & ABNT (Associação Brasileira de Normas Técnicas) / Brazilian Associate for Technical Standards is responsible for the approval of SBAC standards. According to requirements of RDC No. 27 & IN-3 published in June 2011, all medical devices sold in Brazil fall under following standards and they must be standards of INMETRO certified. NBR IEC 60601 Series. NBR ISO 6875: 1998: Dental chair. NBR ISO 7785-1: 1999: Dental hand pieces - Part 1: High speed air turbine hand pieces. NBR ISO 7785-2: 2004: Dental hand pieces - Part 2: Straight & geared

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angle hand pieces. NBR ISO 9680: 2001: Dentistry – Operating lights. NBR ISO 9919: 1997: Medical electrical equipment. NBR ISO 1195: 2000: Gas mixers for medical use. NBR ISO 8835-2: 2010: Inhalational anaesthetic systems. NBR IEC 61689: 1998: Ultrasonic-physiotherapy systems. Important is, under RDC No. 27 & Instruction IN-3, third edition of IEC 60601-1 is now acceptable in Brazil for INMETRO certification (a significant change which was previously omitted).

Certification Process:

The certification process for Brazilian MDR like pre-inspection and other issues are shown in Figure No. 2

CANADIAN MDR:

Canadian Medical Devices are regulated by Health Canada, Federal Department, and Canadian Medical Device Conformity Assessment System (CMDCAS). This regulatory bodies regulates all devices which are to be manufactured or sold in Canada.

Regulatory framework:

Health Canada is the Canadian agency that regulates Medical Devices in consistent to Food & Drugs (R. S., 1985c. F-27) and through Medical Device Regulations (SOR/98-282), manufacturer can apply for devices manufacture, sale, advertising of sale & importation of devices including invitro diagnostic devices, ensures that their medical devices meet the safety & effectiveness requires as defined in the Medical Device Regulations (SOR/98-282, Section 9). Canadian Medical Device Regulations (MDR) were first introduced in the year 2003, From this year the MDR did not undergo any significant changes

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and are now well established. Medium and High risk devices requires third party certification. Health Canada, in coaction with Standard Council Canada (SCC), help CMDCAS to support MDR to provide a framework to accredit CMDCAS Registrars. These registrars perform MDR certification audits and provide CMDCAS certificate against ISO 13485: 2003.

Scope & Classification of Devices:

Canadian MDR includes general medical devices, implantable devices, and IVD's. There are different rules for classification of medical devices & IVD's, one set for medical device and one set for IVD's. All medical devices are classified in four classes, which are class I, II, III & IV, based on their risk to human body. Class I represents lowest risk to the human body and Class IV represents highest risk to the body. The rules for medical devices are similar but not identical to rules in Annex IX of EC Directive 93/42/EEC. Canadian MDR (SOR/98-282, Schedule 1, and Part 1) provide detailed classification for medical devices. Canadian Medical Devices classification, determined by Canadian Risk Based Classification (RBCS) under auspices of Therapeutic Product Division (TPD) of Health Canada.

Distribution, Distribution Records & Technical Documentation:

Distributor selected for a nation should be provincial and with well-defined strategies and resources in an increasing competitive and changing Canadian market. The presence of technical support organizations and their services intrinsic to business of selling medical devices in the market, requires reliable, knowledgeable, loyal and well established dealers to offer their service to ensure effective market penetration. Under MDR, all <https://assignbuster.com/global-medical-device-regulations-update-engineering-essay/>

manufacturers, importers, distributors of devices should maintain the distribution records for each device to be sold in Canada (SOR/98-202. Sections 52-56). These records should provide complete and detailed information of each device and information for rapid withdrawal of device from the market, if found to be lethal. These records requirements are not applicable to retailers and health care units, which distribute device within a facility. The records are maintained from the shipment up to 2 years or up to the life period, as required. All medical devices should need a technical documentation for their efficacy and safety issues. Although there are some differences in requirements for safety and other issues, a standard of ISO are advisable to manufacturers for documentation of medical devices.

Quality Systems:

The Quality Systems for Medical Devices is of Registered Quality Management System (QMS), which meets Canadian National Standard CAN/CSA ISO 13485: 2003, modelled after ISO, Medical Devices: Quality Management Systems: Regulatory Purposes. QMS regulations does not apply to Class I devices.

Licence & Registration:

The Medical Devices distribution in Canada does not requires local authorised representatives. If used need to hold medical device establishment licence (MDEL) from Health Canada and those who are importing devices in Canada requires regulatory appointment and use for licence and other regulatory issues. The market devices are shown in a Medical Device Active Licence Listing (MDALL).

Current and Future Developments:

The probability of changing MDR is very less in near future, however Guidance Document GD 211 enforce specific requirements on audit reports produced by CMDCA recognised registrars. The certified manufacturers notify a change in MDR and report in a format, formally this process is harmonisation between US FDA and Health Canada.

CHINA MDR:

State Food Drug Administration (SFDA) is responsible for medical device regulations in china. Under supervision of SFDA, the main role of medical device regulation department is: To organise and set the standards for medical devices and their supervision. To draw the classification of Medical Devices. To regulate registration process. To draw up good clinical trial practice and their implementation. To maintain distribution records for each device. To monitor and report adverse events occurred and their re-evaluation and elimination.

Scope and Device Classification:

All medical devices are classified in four classes i. e., Class I, II, III, IV and it covers general medical devices, active implantable devices and In-vitro diagnostic (IVD's) agents. There are different set of rules for medical devices and IVD's classification and rules for medical devices are similar but not identical to rules in Annex IX of EU Directive 93/42/EEC.

Technical Documentation:

The medical devices must meet the Chinese state standards or industrial product standards. Class II & III devices should include recent Type Test

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Report produced by medical device Quality testing agency recognised by SFDA. Some medical devices requires clinical trial report in accordance to SFDA order no. 16 as specified in appendix 12 of the Provision of Medical Device Registration.

Quality System:

Application for Manufacturers Enterprise Licence for medical devices requires assessment of Quality Management Systems (QMS) involved from SFDA in accordance with Provision of Medical Device Quality System Assessment. The devices should meet the requirements of regulations and quality standards. Each device requires SFDA certification, if not, for class II devices or parts, manufacturers needs to hold a valid YY/T0287-2003 (identical to ISO 13485: 2003) certificate recognised by SFDA certified body. GMP requirements for sterile medical devices and implantable devices registration must be audited by SFDA or provincial FDA as per GMP interim requirements (SFDA Order [2009] 833 issued in Dec 2009). Foreign manufacturers require accredited ISO 13485: 2003 certificate for distribution of devices in market.

Distribution, Licences and Registration:

All Class II/III devices requires Medical Device Distribution Enterprise Licence. Devices to be sold in china must need a registration certificate and for foreign manufacturers requires SFDA approval via foreign manufacturer's legal representative in china. The distributor or importer holding Medical Device Distributing Enterprise Licence must be approved by provincial FDA.

EUROPEAN MDR:

The medical device directives, are the set of EU legislative texts which governs laws on safety and efficacy of medical devices to be sold in the European market. There are three directives which govern the medical device regulations in EU are: Directive 90/385/EEC for Active Implantable Devices. Directive 93/42/EEC for Medical Devices. Directive 98/79/EC for Invitro Diagnostic Devices. EC directives are the main requirements for placing any medical in the market EU, EFTA, Switzerland and many other countries who wish to join EU. For majority of devices, a certification done by EU notified body is necessary. To understand EU regulations medical devices, there is a need to understand each directive and regulations involved in it. Medical Devices approval process by each directive is as follows.

Directive 90/385/EEC for Active Implantable Devices:

It is the first directive introduced in 1993, used to implant permanently in human body, has been significantly amended by Directive 2007/47/EC. It requires certification by EU notified body for their distribution in the market.

Classification of Devices:

This directive applies only to implantable devices, made a classification in to general, custom and non-custom devices. This classified devices strictly requires a clinical evaluation. It includes heart pacemakers, and other radioactive devices.

Technical Documentation:

The technical documentation prepared by manufacturers should be in European language, supporting EU directive compliance. Manufacturers wish to get CE mark should follow this process for documentation as in EU directive. Risk Management and Clinical evaluation is necessary for this documentation. This documentation assessed by EU notified body as EC Design Examination (Annex 2) or EC Text type Examination (Annex 3).

Quality Systems involved:

EN ISO 13485: 2012 is standard for Quality system compliance under EU Directive 90/385/EEC. Different devices has different Quality standards, showing in different Annexes shown as follows: For General Active Implantable Medical Devices (AIMD's) - Annex 2/ Combination of Annex 3/ Coupled with Annex 4/ EC conformity to type (Annex 5). For Custom Medical Devices - Annex 5 is required to follow by manufacturer.

Distributors, Licence and Registration:

AIMD's registration must be with the competent state authority of member state in which they are legally registered for business. Foreign manufacturers requires an Authorised Representative (AR) within EU member state to register. EU data bank allows to share the information with other competent authorities.

Current & Future Developments:

The regulatory guidelines required for combining AIMD with MDD (Medical Device Directive) was published in 2012. There is no extra requirements for

recent ISO 13485: 2012 standard, only change is table linking of this standard to AIMD.

Directive 93/42/EEC for Medical Devices:

This directive covers all medical devices, which are not included in other two directives. The full version of this directive was implemented in June 1998. The requirements were amended significantly by Directive 2007/47/EC.

Classification of Devices:

It includes Class I, Class IIa, IIb, Class III devices. Directive 93/42/EEC contains 19 rules in Annex IX for correct classification. Classification is necessary for notified body to allow certification. Generally devices included in this directive require CE certification except custom medical devices, devices for clinical evaluation and systems/ procedure packs. Quality Systems involved involves EN ISO 13485: 2012 harmonized standard under this directive.

Registration and Licence:

Class I devices are to be registered under this directive and licence is not required for the devices under this directive.

Directive 98/79/EC for In Vitro Diagnostic Devices:

Since December 2003, this directive has become mandatory in EU. The Common Technical Specifications (CTS) provides conformity assessment requirements for list A (Annex IV/ Annex V + Annex VII) devices. Notified body certification is required for List A, List B and Self-test devices.

Classification of In-vitro Diagnostic (IVDD's) Devices:

The classification of IVDD's are given in the Table No. 3 List A - High Risk Devices (HIV kits), List B - Medium Risk Devices (Blood Glucose Meters), Self-test Devices (Pregnancy Test Kits).

Technical Documentation:

It should be in European language to support the compliance of their devices with the essential requirements of IVD directive. Risk Management and Clinical Evaluation is mandatory for this documentation, where notified body involved, the technical documentation is assessed, for list A devices specific in-depth ' Design Dossier' examination is performed on device design (Annex IV).

Quality Systems involved:

EN ISO 13485: 2012 is standard for Quality system compliance under EU Directive 90/385/EEC. Different devices has different Quality standards, showing in different Annexes shown in Table No. 3. List A devices - Annex IV or Annex V or Annex VII. List B devices - Annex IV or Annex V or Annex VII and Annex VI (Production Verification). Self-test Devices - Design Examination under Annex III.

Current & Future Developments:

There is no extra requirements for recent ISO 13485: 2012 standard, only change is table linking of this standard to AIMD. An amendment to CTS was included to specifically include vCJD (Variant Creutzfeldt - Jakob disease) in List A device classification.

USA MDR:

The regulations on Medical Devices is controlled by US Food Drug Administration (US FDA). It was introduced in May 28, 1976 by Federal Food Drug and Cosmetic Act. It was implemented by Title 21 CFR (Code for Federal Regulations) parts 800-1299, covers general medical devices and IVD's.

Scope & Classification:

According to US FDA, 21 CFR 862-892 the medical devices were classified in to different classes based on their level of control required to assure the safety and effectiveness of the device. Medical Classification shown in above Table No. 4

Routes for Regulatory Approval:

The FDA issues all the regulatory approvals required for medical devices and it depends on the class of device. It also specify the requirements like labelling and adverse event reporting. Class I exempt devices does not need any premarket notification or FDA clearance for sale in the USA. Class I non-exempt, most of the Class II devices and some of the Class III devices require Premarket Notification 510(k) (21 CFR Part 807). An application for marketing clearance is submitted to the FDA within 90 days before marketing. The manufacturer has to demonstrate Substantial Equivalence (SE) for a medical device marketed legally in the USA. Class III devices along with other medical devices that cannot demonstrate SE, and ' New' devices having no basis for SE require a PMA (21 CFR Part 814) from FDA preceding to sale in the US.

Technical Documentation:

Premarket Notification 510(k):

PMA is not required for Class I, II, and III devices proposed for human use in US and submitting a 510(k) is mandatory to the FDA by the manufacturers in order to place the device in the market, if the device is exempted from the 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not surpass the boundaries of exceptions. 21 CFR 807 Subpart E defines the requirements for a 510(k) and submission must be in English. Prior to marketing any device, each manufacturer must get an order letter from the FDA which tracks the device to be SE and assures that the devices can be placed in the market. The SE determination is usually made within 90 days and is made based on the information submitted.

Premarket Approval (PMA):

It is the FDA's technical and regulatory review process to assess the safety and efficacy of Class III medical devices. Class III devices, which support or sustain human life, are of considerable importance in avoiding impairment of human health, or which pose a probable, unreasonable risk of disease or grievance. Premarket Approval, the furthestmost stringent type of medical device marketing application required by the FDA. The manufacturer should receive FDA approval and its PMA application before placing the device in market. FDA determines PMA approval that the PMA contains adequate effective technical evidence to assure that the devices are of good quality and safety for the use by humans. PMA submission should be in English. FDA provides 180 days to review the PMA application submitted by manufacturer and suggest necessary corrections to be done by manufacturer. Prior to

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approve or reject a PMA, the appropriate FDA recommended committee may review the PMA in a public conference and provide FDA with the committee's suggestion on whether FDA should approve the submission by manufacturer. Later FDA informs the manufacturer that the PMA has been approved or rejected notice is published on the Internet, based on which decisions are made by FDA and provides opportunity for interested persons to petition the FDA within 30 days for reassessment of the decision.

Quality Systems involved:

21 CFR Part 820 describes QMS and described as GMP, as it is not completely parallel with the requirements of ISO 13485: 2003. An ISO 13485: 2003 QMS states much of the GMP requirements and certification is considered beneficial and be able to be used as a part of the " Voluntary Audit Report Submission Pilot Program" 21 CFR Part 820 outlines the requirements for QMS and administration, device design, constructions, equipment, manufacture and development controls, packing and cataloguing control, purchase and handling of components, device assessment, supply, installation, complaint handling, repairing, and records. Manufacturers must note that there are numerous important requirements that surpass the requirements of ISO 13485: 2003 and that numerous supplementary regulations must be combined into the QMS. Contrasting other regulatory systems, before sale of medical device in the US market there is no need to have a requirement for QMS audit. Premarket approval is necessary for devices requires an FDA audit (site inspection) before placing in the market. Accredited Persons Program can start an audit on behalf of the FDA, but principal audit programme can be done by the FDA themselves.

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Distributors, Licence & Registration:

Before commercialising devices, all manufacturers must register for establishing and listing them, including contract manufacturers & sterilisers. FDA registration annually must be done by the manufacturers or workers of places of business, involved in the manufacture and delivery of medical devices intended for use in the US market. This is an establishment registration procedure. Prior to sale in US for a device needing premarket approval or notification, the FDA premarket submission number (510(k)) must be submitted by manufacturer to FDA. In order to market the devices of foreigners, an Authorized representative or agent is required to register and distribute the devices on their be-half.

Current & Future Developments:

Working with other GHTF regulatory authorities (Canada, Australia, Japan, and Europe) FDA, recently reduced the duplicate site audits. Combining CMDCAS and FDA inspections allowing certain certification bodies by a pMAP program, Launched in 2012, the Voluntary Audit Report Submission Pilot Program allows to submit ISO 13485 reports to the FDA, with definite conditions by manufacturers.

INDIAN MDR:

The Government of India (GOI) is in the course of mounting a regulatory system planned to make sure the quality, safety and performance of MDs. The Central Drug Standard Control Organization (CDSCO) in the Ministry of Health is principally accountable for regulation of drugs, medical devices, diagnostic devices and cosmetics. Legislature is under deliberation in the

Parliament and officers in the Ministry of Health and Family Welfare (MoHFW) and Drugs Controller General of India (DCG (I)) now appear involved, still ample remains to be done prior to an effective regulatory system is established in India. Medicines and medical devices defined as drugs and are regulated under the D & C Act 1940 and the D & C Rules 1945 and device registration is must prior to sale in India.

Registration:

The registration can be done according to Rule 24A of the D & C Act and Form 40 must be filed. The applicant may be the manufacturer, the trader or AR/agent in India. All MDs vended in this country (except for conventionally made devices, intended for a specific patient usage) must bear the ICAC mark to specify their conformism with the requirements of this program. Considering the use of remote third-party conformism evaluation bodies (denoted as " Notified Bodies" and alike to Notified Bodies under the EU MDDs) to carry out conformity assessments. They would be evaluate MD manufacturing locations on the basis of the ISO 13485 QMS standard and submit their outcomes to the regulatory authority (CDSCO or CDA) to take a decision on granting a manufacturing permit.

Classification of MDs:

Constant with GHTF control and the EU MDD, devices are classified as:-Class A (devices involving lowest risk levels), Class B (low to moderate risks), Class C (moderate to high risks) and Class D (highest risks) for efficient monitoring and regulation. The conformity evaluation necessities will be comparable to device classification, which is illustrated in following Table no. 5

Technical Documentation:

The newest document is the GD on Common Submission Format for Import Licence in Form 10 of Medical Devices in India. It presents the submission leaflets for a medical device import license. Medicinal product import certificates are effective for three years after issued by govt. in India. The documents include:-Cover LetterApproval LetterForm 27 (a common application form for medical device manufacturing license application in India). Form 8 (a common application for medical product import license)Form 9 (a " form of undertaking" that comprised with any import license applications)ChallanConstituents Details (documents related to the constitution of the firm, article of association, etc.)Accepted Industrial Locations (Plan/Layout, a constituent of the Site Master File)Complete Details of Capable and Consistent Technical Workforce about staffs, such as educational qualifications, selection letters, and extra). Site Master FileParticular Requirements (needs info on moulding/association/protective material areas and testing amenities)Device Master File (requires info on medical device proposed use, suggestion for use, classification, new features, sterilization, like devices in India, local price of the device in country of origin, advertising history of the device, regulatory authorisations/marketing permissions, labelling, risk analysis and control, biocompatibility, biological protection, clinical sign, post marketing surveillance data, etc..,.)Product Responsibility by Company (an essential signed form)ISO 13485: 2003 Certificate. Complete Quality Assurance Certificate. CE Design Examination Certificate. Declaration of Conformism. Any other approvals.

Post Marketing Surveillance:

The DCG (I) has stated that adverse event and complaint reporting for medical devices is considered essential, and GHTF Study Group 2 guidance document " N 54" on Post Market Surveillance and Vigilance is under consideration for adoption.

Quality Systems involved:

Quality systems for MDs does not exist, although CE-marked or FDA approved products are preferred because of their quality and performance. Manufacturers of medical devices defined as drugs must apply Good Manufacturing Practices (GMP) and bearing appropriate tests to verify the product quality. India will change near to the use of global standard ISO 13485: 2003 QMS for MD, issued by the Bureau of Indian Standards (BIS) as Indian national standard IS 15579: 2005. Unlike EU or GHTF guidance, however, compliance with IS 15579 may be made mandatory. Furthermore a list of EU harmonized product and process standards and list of BIS standards were exchanged, and industry will provide remarks advising which out of these should be considered pertinent.

Current & Future Developments:

Presently MoHFW, DCG(I), Bureau of Indian Standards (BIS) and Nuclear Medicine Board of the Bhabha Atomic Regulatory Commission (BARC) regulate several aspects of the healthcare sector (including MDs). As part of GOI's efforts to advance a regulatory structure for MDs, DCG (I) formed a minor " core group" of CDSCO officers and industry agents. In April 2008 a core assembly conference was organized to discourse the scheduled MDR

rules in light of remarks submitted by sponsors, suggestions made, and additional GOI review. Legislatures from industry and GOI officers conferred a "road map" and approvals arranged by industry. This road map comprised of present status review as well as administrative principles and a regulatory procedure execution steps to sort it a comprehensive procedure. A paper set by industry - "Proposals for Implementation" - was also presented and stated to sustenance the road map offered. CONCLUSION: With the rapid growth in the global market for medical devices, there is a need to harmonize national standards in order to minimize regulatory barriers and to facilitate trade. Harmonization also reduces the cost of local industry, government regulations & increases communication between the countries to a better level.

APPENDIX:

ABNT - Associacao Brazilian de Normas Technicas. ACMD - Advisory Committee on Medical Devices. AIMD - Active Implantable Medical Devices. ANVISA - Agência Nacional de Vigilância Sanitária. ARTG - Australian Regulations & Therapeutic Goods. AR - Authorized Representative. BARC - Bhabha Atomic Regulatory Commission. BIS - Bureau of Indian Standards. CDSCO - Central Drugs Standard Control Organization. CE mark - Certification mark. CFR - Code for Federal Regulations. CMDCAS - Canadian Medical Device Conformity Assessment System. CTS - Common Technical Specifications. D & C Act - Drugs & Cosmetics Act. DCG (I) - Drugs Controller General of India. eBS - electronic Business Review. EEC - European Economic Countries. EFTA - European Free Trade Association. EN - European Nation. EU - European Union. ICAC - Indian Conformity Assessment Certificate. IDE - Investigational

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Device Exemption. IEC -Institutional Ethics Committee. INMETRO - National Institute of Metrology, Standardization and Industrial Quality. ISO - International Organization for Standardization. IS - Indian Standard IVDD - Invitro Diagnostic Devices. GD - Guidance Document. GHTF - Global Harmonization Task Force. MDA - Medical Device Agency. MDALL - Medical Device Active Licence Listing. MDEL - Medical Device Establishment Licence. MDs - Medical Devices. MDD - Medical Device Directive. MDR - Medical Device Regulations. MoHFW - Ministry of Health and Family Welfare. NBR - New Brazilian Regulations. NCCTG - National Coordinating Committee on Therapeutic Goods. ODD - Office of Device Authorization. OPR - Office Product Review. PMA - Pre-market Approval. RBCS - Risk Based Classification System. SBACS - Scheme of Brazilian Accreditation System. SCC - State Council Canada. SE - Substantial Equivalence. SFDA - State Food Drug Administration. SOR - State of Regulations. TGA - Therapeutic Goods Administration. TGC - Therapeutic Goods Committee. TPD - Therapeutic Product Division. USFDA - United States Food Drug Administration. vCJD - variant Crutzfeldt Jakob Disease. QMS - Quality Management System.