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A REVIEW ON MEDICAL DEVICE PACKAGING & ITS REGULATION

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- ***Abstract:*** This paper aims to review the packaging of medical devices and its regulation. According to the World Health Organization (WHO), Healthcare Associated Infections (HAIs) are the most common adverse event in the delivery of Health care services worldwide, disquieting hundreds of millions of patients each year. Ensuring the sterility of medical devices is an important tactic in the overall attempt to decrease the rate of infections in hospitals and other health care settings. Effective packaging and packaging materials are crucial to help preserve the sterility of medical devices. However, the integrity of packaging material can degrade/destroy overtime due to environmental exposure, or be compromised through normal handling encountered during storage and transportation. As a result, rigorous testing of packaging systems used with medical devices is obligatory in most major jurisdictions around the globe.

Index Terms **- Medical devices, packaging, sterilization, USFDA, GHTF, Regulation.**

I. INTRODUCTION

D & C act: Instrument proposed for external or internal use in the diagnosis, treatment, mitigation or avoidance of disease/disorder in human beings or animals, as can be specified from time to time by the central government by notification in the official Gazette, after meeting with the board.

as per USFDA :"An machine/implant/instrument/ devices in vitro reagent, or similar/related article ,containing/comprising an element ,attachment which is familiar in the Official National Formulary (NF) /the United State Pharmacopoeias(USP) ,or any supplement to them, designed for use in the identification of disease or other condition/the cure ,mitigation ,treatment or prevention of disease or other animals or proposed/intended to affect the structure/any function of the body of man or other animals ,and which does not recognize any of its primary intended purpose through chemical action within or on the body of man/ other animals and which is not dependent upon being metabolized for the attainment of any of its primary intended purposes.

Table 1: Classification of Medical Devices as per USFDA

CLASS I	LOW RISK	Elastic bandages, examination glove
CLASS II	MEDIUM RISK	Catheter, dialyzer, piston syringe, needle.
CLASS III	HIGH RISK	Pacemaker, dental lasers, valves.

Harmonized definition of the term "medical device" `Medical device 'means any instrument, apparatus, implement, machine, appliance, implant, in-vitro reagent or calibrator, software, material/any other similar or correlated article:

a) Intended /planned by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes(s) of:

- Diagnosis, prevention, monitoring, treatment oral levitation of disease,
- Identification, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of an anatomy or of a physiological process
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,

- Providing information for medical or diagnostic purposes by means of in-vitro examination of specimens derived from the human body; and

b) Which doesn't achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means **(GHTF).**On July27, 2006 Study Group1 (SG1) published its recommendations for device classification entitled 'Principles of Medical Devices Classification'[1] .

Table 2: Classification of Medical Devices as per (GHTF)

Class	Risk Level	Device Examples
A	Low	Surgical retractors Tongue depressors
B	Low to moderate	Hypodermic needles Suction equipment
C	Moderate to high	Lung ventilators Bone fixation plates
D	High	Heart valves Implantable defibrillators

Packaging and product integration

Sterility, purity and safety of patient, this is not only desirable in the development of medical device and packaging but it is mandated by laws and regulation. Medical device packaging is integrated with the process, manufacturing and packaging process and the sterilization method.

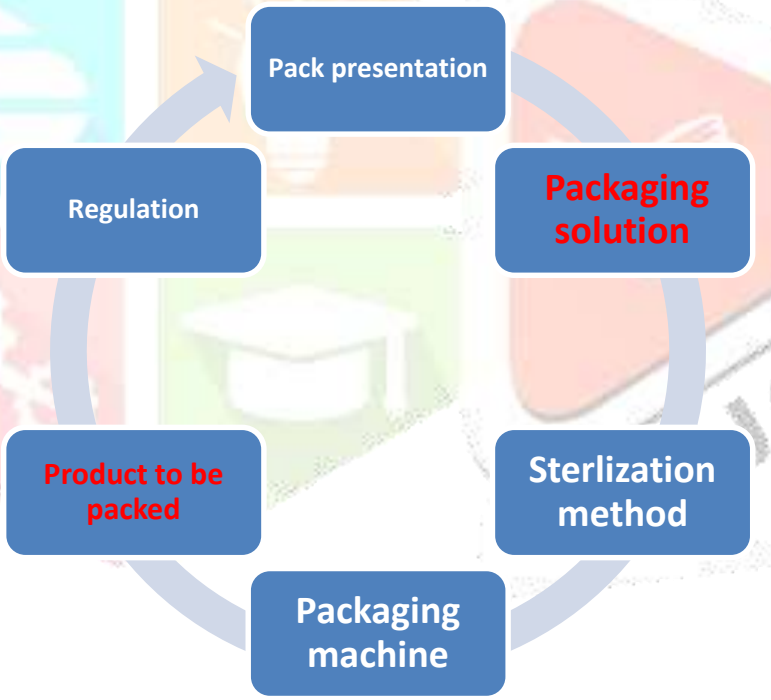


Figure 1: Decision model for medical device packaging

BASIC CONSIDERATIONS FOR THE DEVELOPMENT OF MEDICAL DEVICE PACKAGING:

Sterilization compatibility

- For each sterilization process used, appropriate selection of material is imperative. Material properties should be able to withstand the worst-case process conditions and not be adversely affected (Edmund A. Leonard, 1996) (Sherman, 1998) (Nicolette, 1996).

Protection

- More than simply containing the products for purposes of unit identity or shipping, protection in medical device industry has two meanings: providing an adequate sterile barrier if the devices are needed in a sterile application; and minimizing physical damage to the product throughout its entire life (Sherman, 1998).
- More specifically, the packages are required to provide protection from shock and vibrating, crushing, puncturing, tearing, bursting, cracking, splitting, humidity, heat, so that integrity could be maintained (Ramona Conner, 2006) (Laura Bix, 2009).

Identification

- Critical information including: product type, size, product code, instructions for use, expiration date and precautions must be clearly marked, or affixed to the package (Sherman, 1998). In addition, the quality of printing must be legible, accurate and clear (Sherman, 1998) (Laura Bix, 2009).

Environmental friendly

- Thorough design considers the entire-life circle of the package. The solid waste the package generates has raised concern among healthcare professionals since the packaging materials constitute a large volume of hospital waste (Sherman, 1998).

End of Use

- Although quite dependent on the setting of use, for many medical device packages, quick and easy opening and sterile removal of contents from primary packaging is crucial (Laura Bix, 2009). The need for asepsis, coupled with the sometimes chaotic conditions of use, mandate human factors considerations (Sherman, 1998). Packaging materials should be strong enough to be opened without tearing, yet facilitate manual opening without imposing excessive stress on the device or user (Sherman, 1998) (Laura Bix, 2009).

Table 3: BASIC CONSIDERATIONS FOR THE DEVELOPMENT OF MEDICAL DEVICE PACKAGING

- **Pack presentation**

Medical device packaging is divided into two groups 2D and 3D {dimensional} packaging.

- **Material driven selection**

Whether it is disposable device or a reusable instrument that is to be packaged, as well as the sterilization method used, is important to make decision about packaging material selection.

- **2D PACKAGING**

It can take the outward appearance of pouches, bags or 4 side sealed packs. These packs should provide sufficient space for the product and should be able to be sealed without the package crumpling or bursting. Typical material combinations include paper and film or paper and paper if the product does not need to be viewed from outside the

pack .Pouched sand bags are selected for lower volume production and for steam sterilization of reusable devices.4-side seal packs are selected for high volume products such as advanced wound care and surgeon's gloves.

Figure 2: 2D PACKAGING

- **3D PACKAGING**

For products with a considerable depth, 3D packaging is the best suited. A 3D pack typically consists of a thermo-formable plastic bottom web sealed to an on-forming lidding material such as a medical paper. Low volume and high value products may use a pre-formed semi-rigid tray, e.g. PETG. High volume production would use a flexible film base web, thermoformed, filled and sealed on an automatic packing line.

- **STERILIZATION**

A manufactured product may appear clean to the naked eye, but it is almost always contaminated with thousands of bacteria. To prevent these bacteria from reaching a patient, the product needs to be sterilized before use.

- **POROSITY**–

For gas and steam sterilization, the package should be porous to allow the sterilizing medium to pass into and, just as importantly, out of the pack. With its good and even porosity, a medical paper is cost effective and an excellent choice. It is import and that the sterilization process is reliable and kills the bacteria effectively, and it is equally important that the product is kept sterilized during transport and storage.

PACKAGING PROPERTIES WHEN STERILIZING:

- The materials must be durable,
- Be of high and even quality and be certified for the sterilization process in question. In the case of medical packaging paper, very high demands are made on surface finishing order to facilitate secure sealing and even opening. The paper must be strong in order to reduce the risk of breakage at the same time as it should have even porosity with finer pores that allow the sterilization medium to pass through. The paper's barriers prevent bacteria from penetrating the sterilized surface and contaminating the device. Approval as a materials supplier is conditional on the manufacturing process being certified.
- Plastic and paper adapted and permitted for the purpose
- Smooth surface of the paper for strong seals and clean peel
- Right porosity with small, even pores in the paper
- Bacteria barriers to prevent contamination
- High strength to withstand the medium
- Certified manufacturing process for product safety

MEDICAL DEVICE PACKAGING TYPES:

Medical device packaging varies in sizes, materials, opening features, and shapes according to its intended use and the sterilization methods that are utilized. Medical device packaging is commonly separated into two categories: flexible pouches and lidded thermoformed trays (Sherman, 1998).

- **Flexible pouches**

Flexible pouches have been widely adopted by the medical device industry to fit the needs of adverse range of products. Flexible pouches are commonly chosen for low-cost, high- volume and light weight devices including: gloves, catheters, tubing, dressing and others (Sherman, 1998). They also can offer the advantage of transparency. The usual construction of pouches includes adhesive coated paper to paper; coated or uncoated paper to film; coated or uncoated Tyvek® to film; coated Tyvek® to Tyvek®; and coated or uncoated film to film. It should be noted that not all types of pouches are suitable for all sterilization methods. Pouches fabricated from porous materials, like paper and Tyvek®, can be used with sterilization methods which need gas to pass through the package, such as ethylene oxide (EtO). Tyvek®, however, is limited to low temperature methods only (L. Jones,1995) (Brunch,1993). Pouches composed entirely of non-porous materials (e.g. film to film) are usually limited to radiation sterilization or (under controlled-conditions) steam autoclaving (Sherman,1998) (Nicolette,1996).

Flexible packaging types follows, including: flat pouches, gusset pouches, paper bags, vented bags, header bags and chevron header pouches (Sherman,1998). Chevron pouches, corner peel pouches, tear pouches represent the three typical opening features in medical device packaging. Chevron, corner peel pouches, are peel-to-open while tear pouches are tear-to-open.

a. Chevron pouch

The most popular form of peel pouch is known as the "chevron" pouch (Sherman, 1998). The peak- shaped chevron seal at one end of package is designed to distribute peel forces along the relatively narrow seals that generally parallel the length of the package. This concentrates the opening force at the tip of the peak so the health care personnel have a better control when presenting contents (Sherman, 1998). This is particularly vital for packs of medical or surgical items.

Figure 3: Chevron pouch

b. Corner peel pouch

A corner peel pouch is formed with the incorporation of a seal across one or two corners of the pouch. This approach leaves a peel tabs at the corner (Sherman, 1998). The use of a stud embossed in one of the two web scans beaded in an attempt to separate the webs, in the interest of aiding the user. For a given size pouch, corner peel opening features can provide greater inner spaces in cether remaining seals are at the outer most edges of the package (Sherman,1998).

Figure 4: Corner peel pouch

c. Tear pouches

Tear pouches are generally squared at the corners and incorporate a notch which catalyzes the tearing of the pouch as the mechanism for opening. Tower® Tear is one solution to the tear-open medical device packaging. Tear pouches were first used in 1962, then a U.S. federal trademark registration was filed for Tower Tear by AMCOR FLEXIBLE INC., in 2008. They feature a linear-tear capability as an integral part of the packaging which is usually incorporated into pouches and bags. This patented feature, built into the film during its formation, enables the user to tear the packaging open cleanly along a straight, sharp line, without the irregular tearing that is typical of plastics. This eliminates the need for scissors or other instruments to open the package, and is used as an alternative to peel-able pouches.

Figure 5: Tear pouch

d. Header bags

Header bags are designed with a porous material such as a peel-able paper or Tyvek® strip running completely across the top (Sherman, 1998). Compared with the normal chevron pouch, which uses the Tyvek® web as an entire face, header bags offer cost savings by reducing the amount of Tyvek® material present in the pouch. Aseptic presentation is possible for header bags when careful technique is employed (Sherman, 1998).

Figure 6: Header bag

e. Chevron header pouches

Being inspired by the concepts of header bags and chevron pouches, Duet introduced a new hybrid design which is called chevron header pouch to the market in 2007. By borrowing the "header" concept from the header bag, the amount of Tyvek® typically found in a chevron pouch is reduced, thereby removing the cost. The chevron header pouch is composed of two portions with different materials. The top web is constructed by sealing a Tyvek strip to a polyester/extrusion-coated sealant. The bottom web is composed of polyester/poly. Different from the typical chevron pouches, dual chevron opening features are created at the bottom of the pouch with the polyester/extrusion-coated layer extending beyond the polyester/poly film side to create access tabs at both corners. This, in theory, provides an easier opening method and facilitates aseptic presentation.

Figure7: Chevron header pouch

ii. Lidded thermoformed trays

Trays have become a standard form of packaging for surgical procedure kits and, unlike pouches, are ideally suited for high-profile, irregularly shaped products. Trays are also known as three-dimensional packaging (Sherman, 1998). Two styles of trays are commonly used in the industry: rigid and flexible.

a. Lidded rigid trays

Due to their rigidity, rigid trays are less prone to puncture and can provide enhanced product protection, which make them particularly suitable for high-profile, heavier or products consisting of multiple components which are likely to require support or physical protection, such as procedural kits. The materials and forms of rigid trays can be manipulated to accommodate a wide range of instrument sets and intended uses. Common materials are high density polyethylene (HDPE), polyvinyl chloride (PVC), polystyrene (PS), polycarbonate (PC), polyacrylonitrile (PAN), polypropylene (PP) and polyester copolymer (Sherman, 1998) (Laura Bix, 2009). Lids can be fabricated from varied stocks, including: paper, Tyvek®, or a film (Sherman, 1998). Lids are commonly coated with a heat-sealable, peel-able adhesive. The trays can be obtained from a manufacturer specializing in thermoforming or may be formed right on the filling line using a form-fill-seal (FFS) process.

Figure 8: Thermoformed lidded rigid tray

b. Lidded flexible trays

Flat style flexible trays are available in a variety of structures and are usually the combination of two or more plastics (Sherman, 1998). The lidded flexible tray is also referred to the "three-dimensional flexible trays" (Sherman, 1998). Flexible bottom webs are made from a less diversified group of plastics than the rigid. For several years, laminations of nylon to polyethylene or formable polyester to polyethylene have been the standards of formable "soft" bottom webs. Since the flexible tray is not self-supporting, the only way to use the flexible material in three-dimensional packaging, other than bags, is via the form-fill-seal process. For devices that do not require barriers to gas or moisture, the top webs most commonly used with flexible trays are papers and Tyvek®; this is the case regardless of whether they are sterilized with ETO or radiation. When barrier to gasses or moisture are required, typical top webs include paper/foil/heat seal (H-S), film/foil/H-S, paper/film/H-S, or metallize film lamination (Sherman, 1998).

Figure 9: IV start kit as Lidded flexible tray

Characteristics according to regulations

Medical packaging paper differs from many other packaging qualities. The paper's properties are tested and measured in accordance with a number of parameters to ensure product safety and packaging function at every stage.

1. Grammage
2. Porosity
   - Air resistance Gurley
   - Air resistance Bendtsen
   - Air permeance
3. Pore size
4. Surface roughness
5. Tear strength
6. Wet & Dry strength
   - Tensile strength
   - Burst strength
7. Water absorption Cobb/60
8. Water repellency
9. pH

1. Grammages (a measurement of paper weight):

It is necessary for safe packaging. For packaging of sharp and heavy products, a high grammmage is recommended to ensure that the paper does not break during storage, transportation and handling.

2. Porosity:

It should be equal so that it allows sterilization medium to pass through it and thus protects the product from growth of bacteria.

- Three methods can be used to determine the porosity of paper being used as packaging material.

2.1. Air resistance–GURLEY

It is the time at which the100ml of air passes through a paper of specific surface area. (Unit: s)

2.1. Air resistance–BENDSTEN

It is the time (60sec) required for specific milliliters of air to pass through paper of specific surface area. (Unit: ml/min)

2.3. Air permeance-

The air which is passing through the paper is divided by the area and difference between air pressures of two sides of the paper. (Unit: um/Pas)

3.Pore size-

It is the important aspect, as it deals with sterility and barrier properties of paper. It is measured by wetting the paper with liquid of known surface tension the pressure required to break air bubbles through the interstices is measured. From these pressure and surface tension of the liquid, pore size is determined. (Unit: um)

4.Surface roughness:

It might affect appearance and printing ability of the paper. It is measured by volume of air per unit time that passes between the edge of a measuring head and the surface under examination at operating pressure. (Unit: ml/min)

5.Tear strength

It is needed to determine the force required to break the paper. (Unit: mN)

6. Wet and dry strength-burst strength

It is used to determine the pressure required to burst /rupture the packaging. Packaging should withstand the pressure. Force while handling, storage or transportation. (Unit: kPa)

7.Wet and dry strength-tensile strength

Tensile strength is necessary for keeping intactness of the product in both, wet and dry condition. It is maximum strength that applied to paper while being pulled or stretched prior to breaking. (Unit: kN/m)

8.Water absorption & repellency:

water absorption by the paper may affect its barrier property. It must have the capacity to resist water. Other way to determine water absorption or repellence capacity of the paper is by placing the paper sample on top of a specified amount of water and measurement of the time it takes for it to become saturated.

9. pH: The paper's pH value should be 7.

THE ESSENTIALS OF MEDICAL DEVICE PACKAGING:

When preparing a sterile barrier system for medical devices, there are various aspects that need to be considered in selecting packaging and qualifying sterile barrier system (SBS).

MATERIAL CONSIDERATIONS:

The material and type of SBS might be considered at the start of any new development project. Consider the approximate size and weight of the device or system, the sterilization method(s), and the planned quantity of sterile barriers (single barrier or double barrier) when preparing/designing the SBS. Determining all the requirements early will help diminish lead times typically connected with packaging design and will allow for early possibility studies.

EQUIPMENT QUALIFICATIONS

IQ (Installation Qualification)

This testing provides documented proof/evidence that the utilities, safety features and ancillary systems used in the role of the equipment meet the user's specified necessities.

OQ (Operation Qualification)

This testing provides documented proof/evidence that the upper and lower limit/range sealing operating parameters of a piece of equipment provide seals that meet predetermined acceptance criteria for a specific material combination. Engineering studies should be completed prior to the OQ to determine these limit/range and acceptance criterion.

PQ (Performance Qualification)

This testing provides documented evidence/proof that the equipment used to apply a final seal will constantly produce seals that meet predetermined specifications underspecified operating conditions. This usually consists of three production runs produced at nominal equipment settings using multiple material batch/lots. Three runs allow for the ability to estimate variability due to material lots, machine equilibrium, personnel changes, and day-to-day environment changes.

PACKAGE TESTING

Packaging Distribution

Prior to receiving regulatory approvals, the SBS must prove that it is capable of withstanding the predictable transit lifecycle. Package distribution test samples must contain product /representative product(dunnage/simulant) that has been sealed at equipment poorer case conditions and sterilized .Predictable/Expected transit life includes processing ,handling ,sterilization ,transit and warehousing .Typical distribution simulation for medical devices is defined in ASTMD4169 Standard Practice for Performance Testing of transport Containers and Systems, DC-13. Testing intensity is determined based on the specific device and device system. Final testing after simulation proves/confirms strength and integrity of the SBS.

Aging

Aging studies must be done prior to receiving regulatory approvals to prove the SBS is still intact at the end of the labeled shelf life. Testing must authenticate package strength and integrity after the desired time point. Accelerated aging can be concluded for regulatory submission, but real time aging samples must run in parallel.

Types of Package Testing

Package Integrity Testing is essential in determining the sterility and the shelf life of a medical device or product. This is done by documenting that the SBS system has no measurable path through, channels or punctures that allow the introduction of microbes into the system. Examples of package integrity testing consist of ASTMF1929 Standard Test Method for Detect Seal Leaks in Porous Medical Packaging by Dye Penetration /ASTMF 2096 Standard Test Method of detecting Leaks in Packaging by Internal Pressurization (Bubble Test).Visual inspection should also be used to prove package integrity .Standard for visual inspection /testing is ASTMF 1886/ F1886M Standard Test Method for determining Integrity of Seals for Flexible Packaging by inspecting it visually.

Package Strength Testing shows the strength required to separate the two components of the sterile barrier system. Packaging strength is important to confirm that the package protecting the product is strong enough to have the product system after distribution or aging. Seal strength also allows the medical device manufacturer to confirm the reproducibility of their sealing process and adherence to design specifications. Examples of package strength testing include ASTMF88/F88M Standard Test Method for Seal Strength of Flexible Barrier Materials or ASTMF1140/F1140M Standard Test method for Internal Pressurization Failure Resistance of Unrestrained Packages.

When these tests are performed together, integrity and strength testing provide documented evidence both qualitatively and quantitatively that the SBS is robust and appropriate to maintain product integrity.

RFID in medical devices:

- **RFID** stands for **Radiofrequency identification** is a technology which utilizes radio waves for data collection and transfer. RFID demonstrations greater promise in aiding healthcare, improve patient safety and attains operational efficiency, but it also presents implementation challenges such as interference with medical devices, privacy concerns, prohibitive costs, and lack of global standards.

  The main constituents of an RFID system include the hardware (tags, readers and antennas) and the software systems.

- **The Needs of RFID in Healthcare**

Hospitals are presently facing challenges of improving patient safety and reducing operational costs, which are often compromised by human and systemic errors.

Sr.No.	Need of RFID in medical devices	Comment
1.	**Product Traceability:**	By embedding a durable, passive RFID tag directly into their products, it can automate work-in-process tracking. With a unique RFID identifier built into the device at the start of the manufacturing process, it can then automatically collect data about the drawing/revision level to which it was built, numbers and configuration data for constituent parts.
2.	**Supply Chain Management**	Products having integrated RFID technology can be easily and accurately tracked throughout the supply chain at the serial number level. This means the self-identity of the distributor and end customer for any individual product can be accessed immediately.
3.	**UID Compliance Backup:**	Onboard RFID abolishes problems posed by missing or illegible UID tags. This simplifies both life cycle management (items can easily be identified for preventative maintenance or upgrades) &possible recalls. These factors are critical for patient safety and compliance with new FDA rules.
4.	**Real-Time Location Tracking:**	In the hospital or practice setting, an accurately set up combination of onboard RFID and readers significantly decreases the risk of devices being lost or misplaced. This decreases excessive device replacement, cuts discretionary budget waste and all but eliminates staff hoarding.
5.	**Life Cycle Management:**	A best practices asset tracking resolution based on embedded RFID technology creates an additional layer of patient safety by ensuring that sunset devices or instruments are never accidentally put into use, and improving infection control and sterilization compliance.
6.	**Customer Inventory Management:**	Similarly, better inventory control on consumables ultimately provides device manufacturers and their customers with improved usage data, helping them manage their inventory.
7.	**IP & Brand Protection:**	With a properly implemented system, embedded RFID can protect it against counterfeit and other market devices, and help to confirm that only properly certified consumables are employed in their devices.

- BENEFITS OF RFID APPLICATIONS IN HEALTHCARE

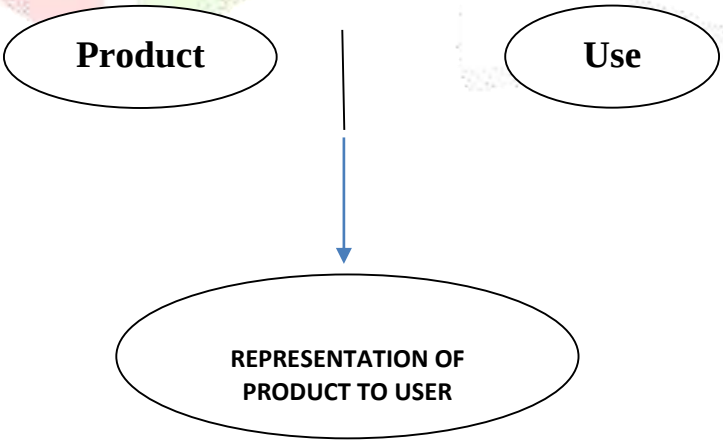
Sr.No	Benefits	Application
1	Improved safety or decrease medical errors	• Reduce misidentification of patients, medical articles • Increase patient drug compliance by monitoring dosage taking process affection control during disease fashion
2	Real-time data access	• Runs real-time data access for health professionals via hand-held wireless PDA, e.g., contact history of patients, online laboratory data and radiology report
3	Time saving	• Identify a time reduction of extra 50% in the daily activities of hospital staff
4	Cost saving	• Reduce theft loss and excessive waste
5	Improved medical process	• Streamline patient admission to ICU • Process can be improved so patients can have not as much of waiting time and enhanced care experience
6	Other benefits	• Improve drug supply • improve resource utilization • improve patient satisfaction

- **Governmental regulation of medical devices**

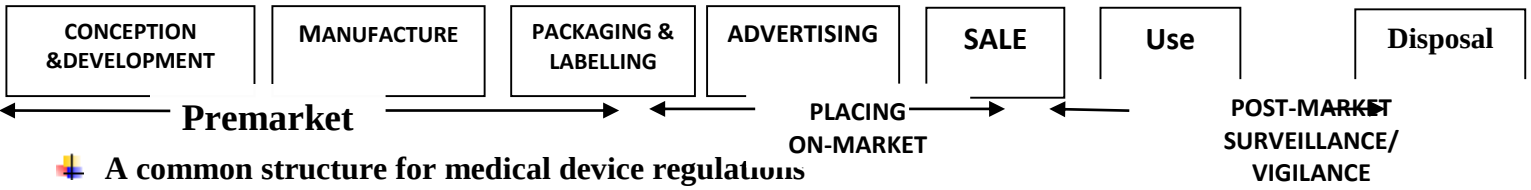
Critical elements for regulatory attention

The safety and performance of medical devices depend on 2critical elements

Pre-market review contributes to product control, and **post- market surveillance** ensures that medical devices in use continue to be safe and effective. There is an important 3rdelement, which is the representation of the product to the user. This is controlled through labeling (during the pre-market stage) and advertising of the product. Another portion of product representation, however, is verbal presentation by the vendor. User/public education is key in guarding against distortion.



We can identify the control of these 3 critical elements by relating them to the now familiar Life Span diagram shown below.



- **A common structure for medical device regulations**

The items/activities that are most normally subjected to regulation are show in Table

Table 4: Regulatory activities (Medical devices regulation: Global overview and guiding principles, WHO, GENEVA, Table 1, and Pg. No. 10)

STAGE	**PRE-MARKET**	**PLACINGON-MARKET**	**POST-MARKET**
CONTROL/MONITOR	**PRODUCT**	**SALE**	**AFTER-SALE/USE**
PERSON	**MANUFACTURER**	**VENDOR**	**VENDOR/USER**
Items or activities regulated	**Device attributes** •Safety and performance **Manufacturing** •Quality systems	**Establishment registration** •List products available or in use •Requires vendor to accomplish after-sale obligations	**Surveillance/vigilance** •After-sale obligations •Monitoring of device's clinical performance •Problem identification and alerts
	Labeling •Accurate description of •Prohibits misleading or product •Instructions for use	**Advertising** •Prohibits misleading or fraudulent advertisement	

- **Regulatory tools and general requirements** the requirements for the 3stages of regulatory control of the 5founding members of the GHTF are summarized below.

Table 5: Regulatory tools and general (Medical devices regulation: Global overview and guiding principles, WHO, GENEVA, Table 2, and Pg. No. 11)

COUNTRY /REGION	**PRE-MARKET**	**PLACING ON-MARKET**
	Tools for acknowledging product cleared for the market	**Medical device` establishment control**
Australia	ARTG number	Enterprise Identification (ENTID)
Canada	Device license	Establishment license
European Union	Compliance label (CE mark)	Responsible person registration
Japan	Shoun in (approval) or Todokede	Seizo-Gyo (Manufacturer License) Yunyu Hanbai-Gyo (Import License)
United States of America	Approval Letter (PMA) or Marketing Clearance(510k)	Establishment registration

Australia's new medical devices legislation was passed by the Australian Parliament in April 2002 (www.health.gov.au/tga/)

Japan's PAL (Pharmaceutical Administration Law) is scheduled for 2005.

- **Quality system standards used by various authorities:**

COUNTRY/ REGION	STANDARDS/REGULATIONS	CONFORMITY ASSESSMENT
Australia	ISO13485orEN46001 ISO13488orEN46002	Government and Third party
Canada	ISO13485, ISO13488	Third party
European Union	EN46001orISO13485 EN46002orISO13488	Third party
Japan	GMP40 ordinance GMPI63 ordinance QS Standard for medical devices1128notice	Government
United States	QS (21CFRpart820)	Government

EN46001 and EN 46002 are being phased out by the end of March 2004.

Table 6: Quality system standards used by various authorities (Medical devices regulation: Global overview and guiding principles, WHO, GENEVA, Table 3, and Pg. No. 14).

- **MEDICAL DEVICE REGULATION IN EUROPE:**

MDD/Medical Device Directive (93/42/EEC)

To promote the free movement of goods and services in the European Union, all the producers in the union are subject to the same legislation. Manufacturers of plastic film and paper must certify their products in accordance with the European standard EN868 or the global standard ISO11607.

These standards guide manufacturers of articles so that they can chooses a seal and approved materials for their packaging. The manufacturer is liable to ensuring that the product is safe. In the case of the hospital packaging market, e.g. autoclaving pouches and wraps, it is the manufacturer of barriers who must guarantee safety.

The packaging must preserve the sterility of the product during transportation, handling and storage, until it is opened and used. The packaging material may not have a toxic effect or contaminate the product in any way during or after sterilization. Are commended requirement being that the package's barriers should protect the product for five years from the date of manufacture.

Table 7: European standard EN868 or the global standard ISO11607 (BILLERUDKORSNÄS, Your guide to product safety m Medical packaging, first aid for smarter packaging, in regulations, Pg.No. 32).

ISO11607-1	Packaging for terminally sterilized medical devices •ReplacesEN868-1:1997. •Is a mandated standard and must be followed to meet the requirements of the MDD93/42/EC
ISO11607-2	requirements for forming, sealing and assembly process •Processes for making seals and closure systems must be validated
ISO/PDTS16775	Guidance on the application of ISO11607 part1 and 2 •Under construction by ISO/TC198/WG7 •Guidance in the implementation of ISO11607 and what test methods are typically used to show compliance

STANDARDS FOR MEDICAL PACKAGING–EN868C EN STANDARDS:

EN 868 parts2-10 are referenced as informative documents in ISO11607 and are optional

- Can be used to express compliance with parts of ISO 11607-1
- Provide detailed provision for individual materials and packaging solutions

EN868-2	Applies to hospital wraps
EN868-3	Applies to base paper or hospital packaging
EN868-4	Applies to hospital packaging–bags
EN868-5	Applies to hospital packaging–pouches and wraps
EN868-6	Applies to base paper for medical device packaging
EN868-7	Applies to coated papers for medical device packaging
EN868-8	Applies to reusable sterilization containers
EN868-9	Applies to uncoated Tyvek
EN868-10	Applies to coated Tyvek

Table 8: EN868C EN Standards (BILLERUDKORSNÄS, Your guide to product safety, Medical packaging, first aid for smarter packaging, in regulations, Pg.No.33).

THE RELEVANT STANDARDS FOR MEDICAL PACKAGING:

ISO9001:2000	Management Systems (QMS)–Requirements •Demonstrate the ability to consistently provide products that meet customers' and regulatory requirements •Normally sufficient to satisfy the requirements of the customer
ISO13485:2003	Quality Management Systems–Medical Devices-Necessities for regulatory purposes •Modifications of ISO 9001 developed to fulfill the requirements in MDD •Some manufacturers of sterile barrier systems have also Chosen to be certified in accordance with ISO 13485
ISO14001	Environmental Management •Minimize the risk to the environment from their products and processes
OHSAS18001:1999	Controls the occupational health and safety risk
Hygiene Standards	•E.g. BRC/ IOP, focus on the risks to consumer safety and product integrity and the control of hygiene in the manufacture and supply of food packaging

Table 9: Relevant Standards for Medical Packaging
(BILLERUDKORSNÄS, Your guide to product safety, Medical packaging, first aid for smarter packaging, in regulations, Pg.No.34).

Regulatory Approval process for Manufacturing for Sale or Distribution

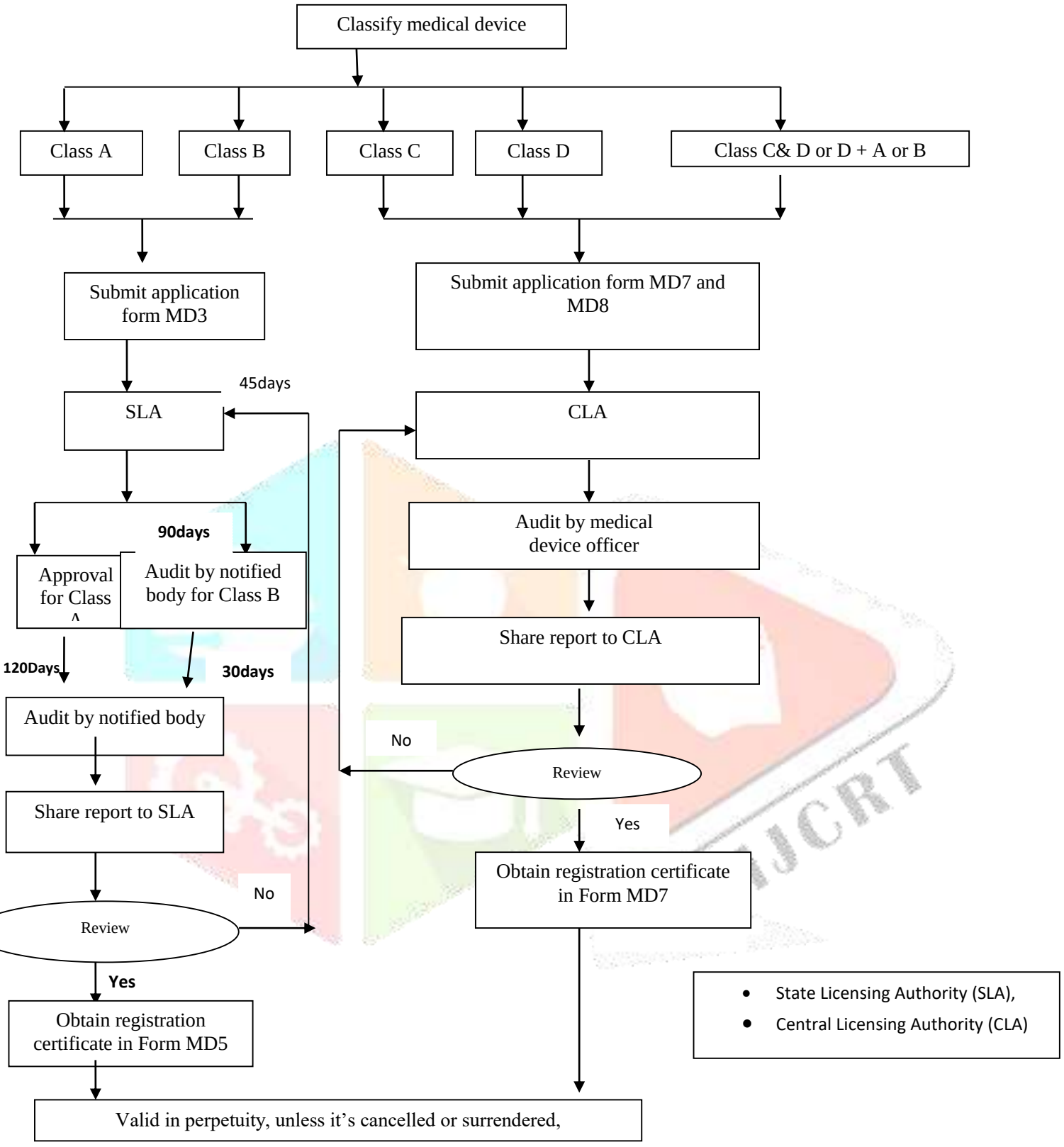


Figure 10: Regulatory Approval process for Manufacturing for Sale or Distribution (A New Regulatory paradigm for Medical Devices in India, by Vibhu Yadav, Dushyant Kumar and Nancy Mathewson regulatoryfocus.org, November, 2017, Pg. No. 11).

Acronyms and abbreviation

SLA	State Licensing Authority
CLA	Central Licensing Authority
OHSAS	Occupational health and safety assessment series
MDD	Medical device design
ISO	International standards organization
ISO/TS	International standards organization/Technical specification
EN	European norms (European standards)
CEN	European committee for standardization
BRC	British retail commission
IOP	Institute of packaging
QMS	Quality Management system
EEC	European Economic Community
GMP	Good manufacturing practices
ARTG	Australian register of therapeutic goods
ASTM	American society for testing and materials
GHTF	Global harmonization task force

CONCLUSION:

In the word of new research and development, technology may have curse and bless for the lives of people. Hence a proper strict rule and regulations need to be put forth in the practice. Different regulatory bodies exist which regulates various activities. Looking at the scope and requirement of medical device, thus proper rules and regulation are needed to encourage the efficient growth of industry. This article serves as guide to various material and types of packaging material used for medical device packaging.

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