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A COMPREHENSIVE SURVEY ON MEDICAL DEVICE REGULATIONS IN DIFFERENT SECTORS OF PHARMACY

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ABSTRACT

Medical device is a significant component of patient treatment. So, it requires effective regulation for manufacturing, sell and distribution. The design, development, and marketing of advanced medical technology are greatly affected by the medical device regulations. So, the foundation of successful medical device innovation is a thorough understanding of the numerous regulatory requirements and their practical application. Throughout the past twenty years, there has been a significant increase in the quantity, variety, and complexity of medical equipment. The need for a stable regulatory perspective has led to advancements in the regulation of these devices as well. In this research paper, we conduct survey in different sectors of pharmacy such as students and industries. This is completely questionnaire based online survey on regulation of medical device in India and USA, circulated via google form to different professions (students and industry) through email and several social media platforms, including WhatsApp, Telegram, etc. We analysed the received responses and the received responses defines knowledge of regulation of medical device. The study finds that professionals in the industry are better knowledgeable about medical device regulation than students, which necessitates the inclusion of more sources for students in order to give them more readily understood knowledge in the future.

Keywords: Medical device, Survey, CDSCO, USFDA, Regulation

INTRODUCTION: [1-3]

A Medical device is any apparatus, instrument, , implant, appliance, material or other object, whether used alone or in combination, including a software or an accessory, which is used only or in combination, which includes software or an accessory, meant by its manufacturer to be used specifically for humans or animals but which may support its intended function by such means for one or more of the specified conditions— (i) Any disease or disorder's diagnosis, prevention, surveillance, treatment, or alleviation; (ii) any injury or disability's diagnosis, evaluation, treatment, or assistance; (iii) study, substitution, or alteration or support of the the body's anatomy or of a physiological procedures; (iv) supporting or preserving life; (v) sterilization of medical devices; (vi) management of conception.

India classified medical devices in 4 classes based on their risk:

Table 1: Medical device classification as per CDSCO

CLASS	EXAMPLE	LEVEL OF RISK	REGULATION TYPE
A	Tongue depressors, Thermometers	Low	No requirement of licence, but voluntarily applied for State Licensing Authorities (SLA) licensing.
B	Hypodermic needle	Low to moderate	SLAs approval required.
C	Lung ventilators	Moderate to high	Central Licensing Authority (CLA) approval required.
D	Pacemakers, Heart valves	High	Central Licensing Authority (CLA) approval required.

One of the top marketplaces for pharmaceutical goods is now India. In India, the development of the private healthcare facilities, the growth of rural markets, and the adoption of newer technologies have made healthcare a stand-alone industry. The commercialization of healthcare has led to a growth in the medical device sector. In order to regulate various activities involving pharmaceuticals & cosmetics, India developed the Drugs and Cosmetics Act 1940.

In India, class D medical device undergo performance testing through NIB for approval. Whereas class B and C medical device undergo performance testing at Indian lab which is accredited by CDSCO.

USA classified medical devices in 3 classes depend on the specific type of control required to ensure safety and effectiveness of medical device and on the basis of marketing requirements.

Table 2: Medical device classification as per USFDA

CLASS	EXAMPLE	TYPE OF CONTROL	APPROVAL PATHWAY
Class I	Examination gloves	General controls	Exempt from premarket submission, Notification only
Class II	Ultrasound imaging systems, Infusion pumps	General control and special controls	510(k)
Class III	silicone gel-filled breast implants, Heart valves	General controls and premarket approval	Pre-Market Approval

510(k) is a premarket filing given to the USFDA, to demonstrate the safety and efficacy of medical device that will be commercialized. Pre-market entry notification is required for most class II devices. Basically, this is a simpler regulatory assessment process than the PMA process. Only preclinical testing is used as the basis for the 510(k) process. When there are concerns about safety and efficacy, the FDA may occasionally request clinical evidence for 510(k) clearance.

All class III devices must undergo the PMA evaluation procedure to determine their safety and effectiveness. This is very strictest regulatory assessment procedure.

MATERIALS AND METHODS: [4-6]

Materials:

Statement of survey: survey on regulation of medical device in pharma sector carried out for determine understanding of students and industrial area.

Purpose:

1. To investigate the information about medical device regulation to different levels in pharmacy.
2. To determine individuals' attentiveness in this topic.

Research methodology:

The study design is cohort. We use this type of survey to test medical device regulation knowledge and perception to different sectors in pharmaceutical field. Online surveys are used to gather the necessary data for analysis.

Sample:

A cohort study with 30 randomly chosen people from different pharmaceutical fields was conducted. The samples were chosen from the industrial sector and pharmacy students. For the purpose of conducting this survey, participants were given access to a google form that had 10 medical device regulation related quiz questions.

Data collection tool:

A question from an online quiz was used to gather data. The survey was created in Google Form and distributed via email and several social media platforms, including WhatsApp, Telegram, etc. The distribution of this form to more than 40 participants resulted in a tentative decision of 30 participants. In order to prevent participants from becoming confused by the questions and ensure that the right data is obtained,

the questionnaire was built using multiple choice questions.

Ethical issues:

Parul Institute of Pharmacy & Research, Parul University, Vadodara, Gujarat, gave its approval to the study protocol. Participants received guarantees on the privacy of their personal information, their choice to participate, and the lack of any conflicts of interest.

Sources of information:

Primary data served as the major information source for this research. Online surveys and quizzes that are properly constructed and primarily intended to fulfil the study's objectives were used to gather primary data. It is discovered that more sources should be included for students by considering the significance of medical device regulation. In this research, we conducted survey with titled “A SURVEY ON MEDICAL DEVICE REGULATION IN DIFFERENT SECTORS OF PHARMACY".

Statistical analysis:

Received data are tabulated in suitable ways for interpretation.

Table 3: Questionnaire

QUESTION NO.	QUESTION	OPTIONS	CORRECT ANSWER
1.	Regulatory submission of medical device is known as...	A. Common Technical Document B. Investigational Product Dossier C. Summary Technical Document D. Device Submission Documentation	C. Summary Technical Document
2.	In India class C medical device is regulated by which authority?	A. State Licensing Authority B. Central Licensing Authority C. National Institute of Biologics D. Medical Device Agency	B. Central Licensing Authority
3.	Which of the following is class B medical device according to CDSCO?	A. Thermometer B. Lung ventilator C. Bandage D. Hypodermic needle	D. Hypodermic needle
4.	Latest amendment of medical device rule,2017 is…	A. 2018 B. 2020 C. 2021 D. 2022	C. 2022
5.	CDRH is work under which of the following regulatory authority?	A. CDSCO B. USFDA C. CFDA D. ANVISA	B. USFDA
6.	Which of the following is class II medical device according to USFDA?	A. Tongue depressors B. Cardiac monitors C. Pacemakers D. Crutches	B. Cardiac monitors
7.	Another name for 510(k) is…	A. Premarket notification B. Premarket approval C. Humanitarian use devices D. Post-market surveillance	A. Premarket notification
8.	Is ISO13485 necessary for medical device regulation?	A. Yes B. No	A. Yes
9.	A company wants to modify its device such that there is a major change to the fundamental scientific	A. Special 510(k) B. Abbreviated 510(k) C. Traditional 510(k) D. PMA	C. Traditional 510(k)

	technology of the device. FDA has published guidance on this technology, and special control have been established. This change would be best filed as….		
10.	A legally marketed device to which equivalence is drawn in premarketing submission is known as the:	A. Market comparator device B. Placebo device C. Predicated device D. Substantially equivalent device	C. Predicated device

RESULT:

Particulars response count:

More than 40 participants were selected for survey randomly. We obtained responses from 30 interested participants after a one-month survey. The remaining participants were determined to be uninterested. So, we collected all data from 30 participants from various fields of pharmacy. The received data was divided into 2 categories: the number of correct and incorrect replies for each question. This data is sufficient for verification of Participants' wise knowledge. This demonstrated that more than 60% participants are well knowledgeable with regulation regarding medical device **(as shown in Table no. 4)**. Participants' incorrect responses showed that they had no or little knowledge for that specific question.

Particular response count (n= 30).

Analysis of understanding:

This method is used in pharmacy to detect question wise correct responses by various areas of expertise. All correct answers were divided into two categories: pharmacy student, and industrial individual. This data assemble for student response and found that 64.37% student were soundly aware about regulation of medical device. The data collected from 14 industrial people is significant, with 74.55% of them being informed about regulation regarding medical device. According to the findings of this survey, industrial expertise is far more reliable and knowledgeable than student expertise.

Question wise analysis: (Table 5)

Table 4: Response count particulars

Question No.	Correct responses	Incorrect responses	% of correct responses for knowledge analysis	% of incorrect responses for knowledge analysis
1	19	11	63.33%	36.66%
2	18	12	60%	40%
3	22	08	73.33%	26.66%

4	**11**	**19**	**36.66%**	**63.33%**
5	**23**	**07**	**76.66%**	**23.33%**
6	**17**	**13**	**56.66%**	**43.33%**
7	**26**	**04**	**86.66%**	**13.33%**
8	**27**	**03**	**90%**	**10%**
9	**16**	**14**	**53.33%**	**46.66%**
10	**21**	**09**	**70%**	**30%**

Table 5: Knowledge analysis as per expertise area

Question No.	Student (n= 16) (Correct response)	Industrial (n= 14) (Correct response)
	% Count	% Count
1	**50**	**78.57**
2	**37.5**	**85.71**
3	**68.75**	**78.57**
4	**50**	**14.28**
5	**62.5**	**92.85**
6	**37.5**	**78.57**
7	**81.25**	**81.25**
8	**87.5**	**92.85**
9	**43.75**	**64.28**
10	**62.5**	**78.57**
% Count Average	**64.37**	**74.55**

DISCUSSION:

According to GHTF guidance, The term "medical device" refers to any apparatus, instrument, machine, implement, implant, machine, appliance, reagent for in vitro use, software, thereby material, or other associated or related item that is intended to be used by a manufacturer for any or all of the following particular medical purposes: diagnosis, prevention, surveillance, treatment of a disease or injury; investigation, replacement, alteration, or support of the body's anatomy or of physiological processes; supporting or preserving life, regulation of conception; sterilisation of medical devices, and providing information through in vitro study of specimens obtained from the human body; and doesn't accomplish its primary intention by in or on the human body, but which might be aided in its intended function by pharmacological, metabolic or immunological processes **[7]**.

The number of research being conducted in the field of medical devices has grown significantly with the advancement of technology and scientific development. The

increased production of medical devices demands new and improved manufacturing regulations in order to keep quality and prevent the introduction of defective goods into the market. Each nation has its own regulatory body in place to carry out this function. Regulatory organisations have established rules for various types of activities regarding these devices.

Regulation of Medical device in INDIA: [8]

Central Drug Standards Control Organization, a division of the Ministry of Health and Family Welfare, manages medical device regulation in India. The Medical Devices Regulation Bill was presented in 2006 with the goal of strengthening medical device laws and establishing the Medical Device Regulatory Authority of India. A national system of controls for quality and safety of the medical devices in the country was to be established and maintained with the help of this bill. Currently, medical device activities are governed by the Medical device rules,2017.

Regulation of Medical device in USA:

The Federal Food, Drug, and Cosmetic Act governs medical devices in the United States. Before marketing a medical device in United States, a marketing application must be submitted with Food and Drug Administration and approval obtained. The Centre for Devices and Radiological Health of the FDA is mainly responsible for pre- and post-market surveillance of medical devices in the United States.

Comparison of salient features:

Table 6: Comparison of salient features

SALIENT FEATURE	INDIA	USA
Regulatory authority	Central Drug Standards Control Organization (CDSCO)	Food and Drug Administration (FDA)
Regulation of medical device	Medical device rules,2017	FFDCA
Risk classification	Four class scheme (Class A, Class B, Class C, Class D)	Three-tiered system (Class I-lowest risk; Class II-intermediate risk; Class III- highest risk)
Approval system	Class A and B: SLA, Class C and D: CLA	Class I: general controls; Class II: premarket notification 510(k) process; class III: premarket approval
Pre and post marketing supervision	Within CDSCO, Medical device division is responsible	Centre for Devices and Radiological Health

In this research paper, we framed 10 questions which are based on medical device regulation in India and USA. Each question has four options from which respondents must select the right option for each question. We received responses for this survey from all respondents via survey. So, after analysis it seems we need

inclusion of more sources for students in order to give them more readily understood knowledge in the future.

In this survey, students finds less aware compare to the industrial individual. There are 2 probabilities either they have limited understanding or no sources to understand about medical device regulation. In group of Industry, it founds they are more aware. Again, if we investigate for this same industrial group, it finds more possibilities of their expertise which means they are aware of filing and reporting of medical device through their practical work in this field.

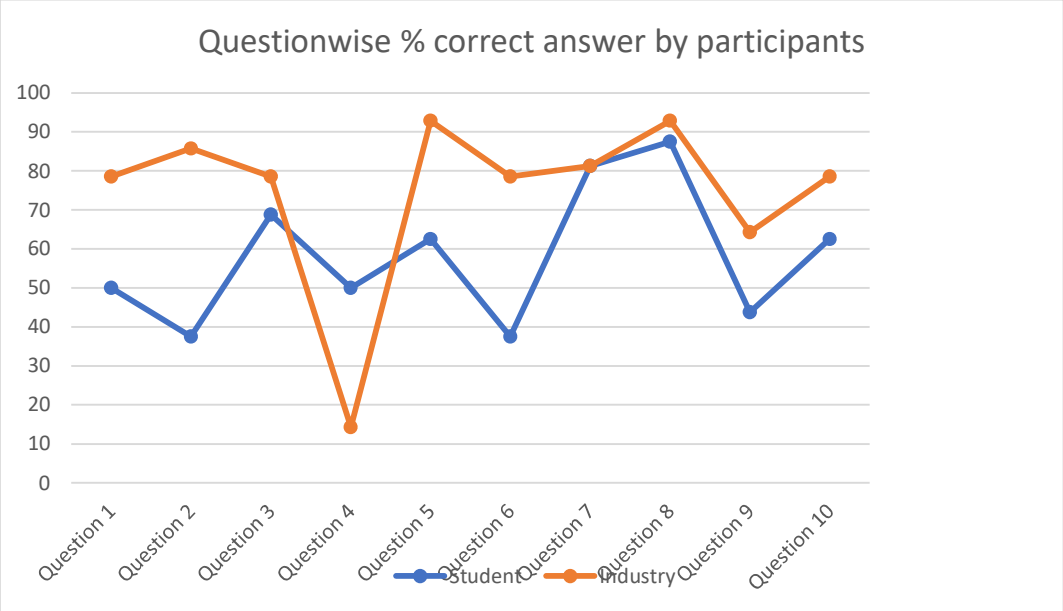

Figure 1: Question wise % correct answers by participants

CONCLUSION:

This survey is performed to assess medical device regulation in various pharmacy fields. The survey findings are quite satisfactory, indicating that more sources should be developed. This can be accomplished by inclusion of more sources for students in order to give them more readily understood knowledge in the future, which attracts and motivates youth as a career choice than traditional options.

CONFLICT OF INTEREST:

The authors have no conflict of interest regarding this investigation.

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