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A Comprehensive Review On Regulatory Landscape Of Wearable Medical Devices Across India, USA, Japan, And China

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Abstract:

As therapeutic applications that are easily integrated and collaborated with wearable medical equipment, biosensors are essential in the diagnosis and monitoring of diseases. For this new medical device industry, several regulatory markets are putting development and management concepts into practice. We anticipate that wearable technology will become more integrated into people's daily lives and play a bigger role in the field of health care as science and technology advance and personalised health concepts gain popularity. To investigate more wearable device uses in the medical field, more research is necessary. We anticipate that this evaluation will serve as a helpful resource for the creation of wearable medical technology. In India, medical devices classified as medications under Section 3(b)(iv) of the medications and Cosmetics Act are sold, imported, and manufactured under the principal regulatory authority of the Central Drugs Standard Control Organization (CDSCO). The insecurity of wearable mobile devices is explained in this article. Examples are used to analyse their vulnerabilities. It is feasible to show wearable gadgets' weakness using concrete examples of hacking.Wearable technology and telemonitoring are revolutionising healthcare by facilitating ongoing patient monitoring and tailored therapies.

Keywords: Wearable, Biosensors, Regulatory Framework**,** Medical Devices**,** Regulatory Challenges

Introduction:

As therapeutic applications that are easily integrated and collaborated with wearable medical equipment, biosensors are essential in the diagnosis and monitoring of diseases. For this new medical device industry, several regulatory markets are putting development and management concepts into practice (1). The PMD Act has an impact on every aspect of Japanese medical product registration, including licensing, certification procedures, in-country representation, and quality control systems. On November 25, 2014, the PMD Act went into effect, repealing the Pharmaceutical Affairs Law. (PAL) (2). Information on patent status, market approvals in other regions as a legal requirement, safety and efficacy data, engineering aspects, etc., are just a few examples of the legal and technical issues that frequently complicate the vast and quickly developing field of medical device regulations. Regulations have occasionally been developed by a number of Regional Regulatory Authorities (RRAs). Through the Medical Device Amendment to the Food, Drugs, and Cosmetic Act of 1938, the USFDA established restrictions in 1976 (3). While a variety of intelligent wearables and apps will probably help consumers in their quest for health, entertainment, and higher living standards, these devices will monitor users continuously to gather information that could draw in advertisers, academic institutions, and even hackers (4). Businesses must do a Data Analysis Privacy Impact Assessment (DPIA) about corporate acceptability

to ascertain the necessity and suitability of the innovation they are currently utilising. Conversely, the European Medicines Agency (EMA) recognises the value of using sensors or telemedicine in drug development (5).

wearable transdermal delivery for regulated medication administration. According to the force applied by the touch on a worn patch, the TATD offers quantitative penetration control of the drug delivery (6). The capabilities of biomedical equipment have been greatly expanded by smart, wireless, and multifunctional sensors, which enable more precise diagnoses, real-time monitoring, and therapeutic treatments. With an emphasis on biocompatibility, durability, and long-term operation, these technical advancements and the incorporation of Internet of Things (IoT) platforms are changing the performance requirements for implantable devices (7). One of the main worldwide challenges is Japan's medical device gap. It describes the differing regulatory procedures and other issues between Japan and the EU/USA that cause delays in the approval and adoption of innovative medical devices (8). The USA is the center of the co-authorship network in the research area, as evidenced by the fact that the centrality measure of the network was higher in the USA than in China in terms of the number of articles. Furthermore, despite the disparity in the quantity of articles produced in recent years, the citation impact of the two nations was equal (9). The emergence of smartwatches in the market is an intriguing factor to consider when it comes to wearables. Smartwatches are not frequently employed in this field of study since their features are too extensive. Instead, wristbands, motes, and chest bands are frequently utilised (10). Because they can save lives, medical devices are regarded as a blessing for the healthcare system. Nevertheless, these devices have a number of negative effects in addition to their therapeutic benefits. To control such negative impacts, an efficient cohort vigilance system was required. As a result, materiovigilance was introduced (11). Businesses must comprehend the challenges they encounter when creating and promoting their products, both domestically and abroad in nations with diverse social and cultural backgrounds, if they are to succeed in the global market. Given the widespread use of healthcare wearables, it is important to evaluate how well the WATH model (Section 2.2.5) predicts consumers' intentions to use wearables in various nations (12). wearable technology that is gaining traction or entering the consumer market, as well as the user data and personal health information these gadgets gather. The impact of wearable technology on the industry is examined, as well as its applications in healthcare and wellbeing (13). "Any information about health status, provision of health care, or payment for health care that is created or collected by a covered entity (primarily health care providers and health plans) that can be linked to a specific individual" is the legal definition of PHI (14). The delivery of healthcare is made possible by wearable technology in several ways. However, wearables can provide serious privacy risks. Additionally, the patient's ability to give informed consent is hampered by information overload (15). Wearable medical devices (WMD) have become increasingly popular in recent years, affecting individuals of all ages, including workers. According to EU Directive 2013/35/EU, workers who handle WMDs are subject to a special risk from electromagnetic fields and must undergo an individual risk assessment (16). The phrase "ethical issue" refers to a wide range of terms, including "moral dilemmas" and "ethical challenges," which are frequently used by writers from various backgrounds to indicate facts or circumstances that call for ethical reflection (i.e., an argument-based reflection that adopts the tools of ethical analysis and follows a reasoned and logical argumentation, as stated in Howes and Gasman's, 2021) (17). However, the use of in-body wearables in the workplace is currently unregulated by either national or EU law, raising concerns about the preservation of employees' fundamental rights to data protection and privacy (18). Sensors that measure movement and position, such as accelerometers, gyroscopes, magnetometers, and global positioning systems, or those that evaluate electrophysiological and chemo-physiological function or other physiological characteristics, like body temperature, are frequently found in wearable technology. Body temperature monitors, respiration monitors, heart rate monitors, devices that measure electrocardiograms or electroencephalograms, pulse oximeters, blood pressure monitors, pH monitors, continuous glucose monitors (which, despite having subcutaneous components, are minimally invasive and fall under this category), and galvanic skin response detectors are a few examples of wearable sensors and devices used in medicine and healthcare (19). AI systems do more than just process data and help policymakers make important judgements. Numerous systems have direct and physical control over items in the human

environment, such as the software that operates an aeroplane on autopilot or a completely autonomous vehicle. Other systems, such as medical and radiological equipment, offer delicate services that call for certification and training when carried out by doctors (20). We anticipate that wearable technology will become more integrated into people's daily lives and play a bigger role in the field of health care as science and technology advance and personalised health concepts gain popularity. To investigate more wearable device uses in the medical field, more research is necessary. We anticipate that this evaluation will serve as a helpful resource for the creation of wearable medical technology (21). This alerts medical professionals whether the patient has to be admitted to the hospital. This minimises interaction between infected patients and healthcare personnel while enabling critically ill patients to receive prompt medical attention (22).

Challenges for Deploying IoT Wearable Medical Devices Among the Ageing Population:

We suggest a strategy that emphasises distributed risk, patient-entered outcomes, and iterative change based on legal analysis, case studies, and ethical considerations. The potential of wearable health technology could be jeopardised by escalating disparities, abuse, and diminished public confidence in the absence of a more diverse and dynamic framework (24). Security, privacy, interoperability, and data integrity are among the issues raised by the network's sharing of health data and the influx of patient-generated health data (PGHD). In order to enhance the security, privacy, interoperability, and data integrity of FDA-approved medical wearables, we outline these difficulties in this article and offer a conceptual architecture that makes use of blockchain technology (25). The Food and Drug Administration (FDA) published its Final Guidance—nonbinding guidelines for mobile medical application (MMA) manufacturers—in September 2013 following two years of consideration. Questions that beset the health information technology (IT) sector were addressed by this updated guidance (27).

Device type	Data collected	Examples
Wrist worn	Actigraphy, HR (Heart Rate), BP (Blood Pressure), EDA (Electrodermal activity)	Actiwatch Spectrum by Phillips, Actigraph Link by Actigraph, E4 by Empatica, ViSi Mobile by Sotera Wireless
Skin patch	ECG (Electrocardiography), actigraphy, skin temperature	Biostamp RC by MC10, Health Patch by Vital Connect, Body Guardian by Preventive
Cuffs	BP, HR	IntelliSense Digital BP Monitor by Omron Healthcare
Finger worn	HR, SpO2	iSpO2 Pulse Oximeter by Massimo
Clothing embedded sensors	HR, HRV (Heart Rate Variability), ECG, Breathing Rate, actigraphy	Smart shirts by Hexoskin
Headbands	EEG (Electroencephalogram), EMG (Electromyography)	EMOTIV EPOC by Emotiv, 4D FORCE by 4D FORCE

(28)

Medical Device Regulatory Framework

India:

In India, medical devices classified as medications under Section 3(b)(iv) of the medications and Cosmetics Act are sold, imported, and manufactured under the principal regulatory authority of the Central Drugs Standard Control Organization (CDSCO). The CDSCO grants permits to producers and importers and establishes standards for pharmaceuticals, cosmetics, medical equipment, and diagnostics (51). Even though the Medical Devices Rules (MDR)-2017 have made significant progress, there are still a number of issues that need to be resolved in order to enable a multiple-fold increase in the medical device market share. These issues include specific compliance requirements for software as medical devices (SaMD), futuristic healthcare technology regulations, and limited designated labs for performance evaluation of In-vitro diagnostics (IVD) medical devices (52). Since the quality of COVID-19 products is crucial in the current situation, the medical device industry is finding it more challenging to meet demand with high-quality products as sales of some of the most important medical devices have increased. Even though it can be challenging to supply enough medical supplies during a pandemic, they are working to adjust to the situation (53). The previous ten years have seen significant changes in the medical and healthcare sector, which has led to a significant gap in India's current medical and related equipment supply and demand systems (54). In order to empower people with disabilities and increase their everyday autonomy, biomechanics and rehabilitation engineering combine biomechanical concepts with assistive technologies. Through wearable and implantable technologies, biomedical sensors, gadgets, and nanotechnology are advancing personalised healthcare solutions and improving illness management (55). According to the Justice Putt Swamy case 4, the right to privacy is recognised as a basic right in India under Article 21 of the Constitution. The importance of health data and how different national and international organisations handle it will be discussed in this essay (56). Orthopaedics and prosthetic equipment, imaging, dental implants, orthodontics, electromedical equipment, surgical instruments, and cancer diagnostics are all in high demand. India's inadequate regulatory environment, which results from restricted regulation on certain categories of medical equipment, poses serious hurdles for foreign manufacturers working with regulated medical devices (57). Wearables, sensors, mobile phones, and computers are examples of newer technology that provide opportunity to monitor critical physiological indicators and address healthcare issues, enhancing access and care quality (58).

USFDA:

These devices must adhere to the Quality System rules (QSR) outlined in 21 CFR Part 820 and be branded in accordance with 21 CFR Part 821. Since their failure offers minimal risk to life, they are subject to general control and require the fewest rules. Despite this, the majority are free from the 510(k) pathway, and several are even exempt from QSR. For instance, when a tongue depressor is used, it is free from 510(k). Annex IX of MDD 93/42/EEC lays forth the requirements for class determination.

China:

The Framework of the 2030 Healthy China Action Plan, "Developing and promoting digital intelligent devices for health care," was released by the State Council in June 2016. supporting AI research and development in the health sector, 3D biological printing technologies, medical robots, major medical equipment, health and rehabilitation auxiliary devices, smart wearables, and pertinent microsensor devices. In February 2022, the State Council published the 14th five-year plan for development of the anti-ageing national program and pension security stressing demand for “rehabilitation treatment of neurological disorders, post-traumatic cognitive brain disorders, support for people in paralysis, revolutionary brain-computer interface and other technologies, assistive robots for rehabilitative support for various injuries, and implementation of the action plan for development of intelligent service robots, R&D of wearable dynamic devices for physiological parameter testing and ECG monitoring, portable health monitoring devices, self-service and other health monitoring tools, and the creation of new microchips for signal recording and intelligent digital health terminals. In terms of administrative law, China's personal data security legislative framework is dispersed over a number of rules, guidelines, etc. For instance, medical and physiological data, as well as biometric personal data, are considered personal

confidential information under the Data Security Technology Specifications for Personal Data Protection (GB/T 35273-2020). Standards are essential for the protection of bio-data (4).

Japan:

In cooperation with the MHLW, the independent Pharmaceutical and Medical Device Organization (PMDA) evaluates drug and medical device applications. A federal legislation known as the drugs and Medical Devices Act (PMD Act) governs the production, marketing, and distribution of drugs and medical devices. The current PMDA legislation in Japan are outlined in the Pharmaceuticals and Medical Devices Act (PMD Act), often referred to as the Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics. The PMD Act affects every aspect of Japanese medical product registration, including licensing, quality assurance systems, certification procedures, and in-country representation On November 25, 2014, the PMD Act went into effect, repealing the Pharmaceutical Affairs Law. (PAL) (2).

Classification of Wearable Medical Device:

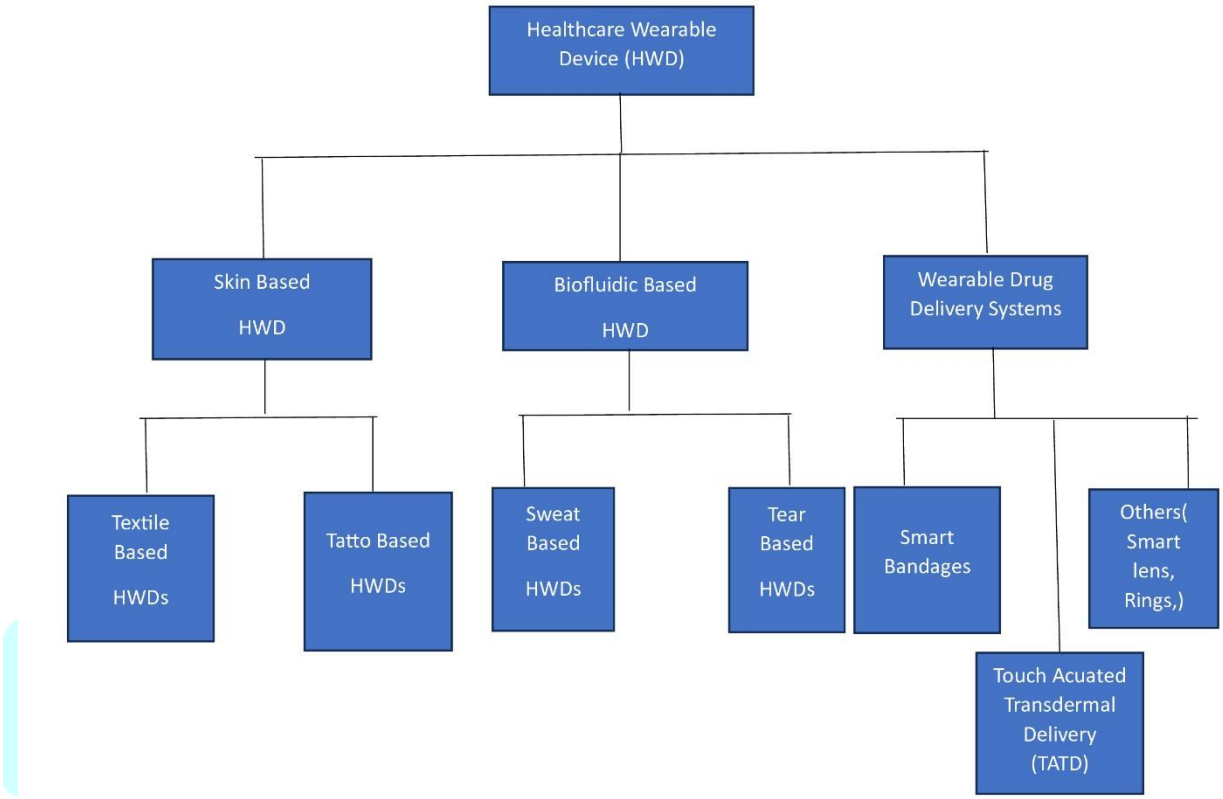

Fig1 Classification of wearable medical device

Wearable Medical Devices Strategies:

It offers a targeted examination of the security vulnerabilities that make it possible for health data to be shared or exploited without users' awareness. Examined are potential remedies such as strengthening rules, increasing transparency, empowering user control, and boosting protections. Effective transformation, it is said, must take into account human decision-making behaviours and strike a balance between privacy concerns and health advantages (29). Healthcare has advanced significantly as a result of the increasing use of wearable medical devices, which enable real-time monitoring and personalised care. However, because of security and privacy issues, safety continues to be a major worry. This chapter delves deeply into these topics and offers insightful analysis and suggestions for researchers, politicians, and healthcare professionals (30). Medical device regulations, such as ISO 10993, FDA, and CE, are currently somewhat extensive. But as was already said, there are still gaps that could result in unanticipated accidents even when pertinent regulations are followed. Furthermore, these rules are too stringent and have not kept up with technology developments, which causes delays in the interchange of medical data and impedes medical communication. Composite materials are currently being used in an increasing variety of flexible wearable gadgets (31). In the context of medicine and healthcare, this paper provides an overview of the most recent advancements in flexible electronic technology, with a focus on the safety and efficacy assessment of such breakthroughs for medical devices from a regulatory science standpoint (32). The insecurity of wearable mobile devices is explained in this article. Examples are used to analyse their vulnerabilities. It is feasible to show wearable gadgets' weakness using concrete examples of hacking. Additionally, algorithms for resolving issues that arose during their creation will be given. Additionally, it gives a summary of the laws governing wearable cybersecurity (33). The increasing number of regulatory frameworks and recommendations produced by Competent Authorities and international initiatives that embrace real-world data (RWD) sources reflects the use of real-world evidence (RWE) to support international regulatory decision-making. Numerous sources, such as electronic health and medical records, pharmacy and insurance claims, patient-reported outcomes, product and disease registries, biobanks, and observational studies, can provide RWD (34). Examined are potential remedies such as strengthening rules, increasing transparency, empowering user control, and boosting protections. Effective transformation, it is said, must take into account human decision-making behaviours and strike a balance between privacy concerns and health advantages. In order to facilitate informed decisions on wearable health data, the paper's conclusion suggests a variety of strategies (35). Additionally, the suitability of using GAMP to validate a clinical data management system with wearable and/or smart devices was examined (36).

The US has embraced wearable medical technology to monitor several health metrics, including body temperature and heart rate. Given the growing popularity of smart devices, the global market for mobile healthcare is expected to reach $90.4 billion or more (37). Numerous industries, including entertainment, industry education, and healthcare, have been impacted by the Internet of Things' (IoT) rapid expansion and development. Wearable IoT (WIoT) devices have improved the delivery of healthcare services and given patients access to a new level of comprehensive treatment (38). The flexible electronic components of e-skin, such as conductive links (such as graphene, gold nanorods, liquid metal alloys for printing ultrathin circuits, or different polymers with a rubber backing), enable each patient to be managed as a distinct database of medical information that is pertinent to the medical personnel providing care (39). Higher levels of digital technology usage to support home care and telehealth/telemedicine have been sparked by COVID-19. The US healthcare system is changing into a data-driven environment, which is necessary to lower costs and enhance the quality of care, while it works to establish an interoperable environment through CMS regulations (40).

Regulatory Challenges:

The review would be helpful to policymakers in APAC nations that lack health technology assessment and device manufacturing capabilities. The results demonstrated the existence of a gap in device manufacture, innovation, and marketing both within the APAC area and between APAC and western nations. There is an urgent need to harmonise regulatory standards because many APAC countries currently lack strict regulations and quality indicators (41). From both product (adaptability,

variability, variety, novelty, accessibility) and industry-structural (new entrants, shifting roles of actors, new delivery models) perspectives, digital health technologies pose new problems to regulators. Although they usually fall within the medical device regulation category, authorities in the US and Europe do not currently carry out their legal obligation to restrict market access to only safe and effective products (42). The environment in which economic processes, among others, occur is largely determined by the intricate process of regulation. In certain situations, the environment is shaped by regulation beforehand; in other situations, the environment's flaws are addressed by regulation as a result of the innovative behaviours of the participants. In order to achieve the ideal state of equilibrium that does not unduly burden the impacted organisations, including their efforts to innovate, regulation is frequently a continual process that oscillates between the extremes of excessive and insufficient regulation (43).

Table 1: Challenges faced by CIMD stakeholders – Summary of responses to Activities 1-3 at "The Future of Medical Device Regulation and Standards: Dealing with Software Challenges" Roundtable"

Artificial Intelligence	Cybersecurity	Data Governance
Lack of regulatory guidance on how to make updates to AI models in a timely fashion (similar to FDA's ACP concept	Foreseeing,-future cybersecurity threats.	Laack of data access, both for development and for evidence generation in line with standards (e.g. demographic data)
Unsure as to how existing soft-ware-related standards, which concentrate on gaining pre-market approval, can be used for dynamic medical device algorithms that may adapt once deployed	Fraud detection (e.g. when end users try to "fool" an algorithm with imitation target input)	Cloud suppliers' standards
Difficulty in updating ML models as data or context requires	Cybersecurity for dynamic algorithms within connected medical device.	Uncertainty as to patient data sharing
Ensuring that the data the ML model is initially trained on is representative of the operational environment	Management of identified vulnerabilities and cybersecurity issues	Lack of mechanisms to obtain ground truth data during post market surveillance
Regulatory frameworks not up to date with changes in AI	Clear communication and aware-ness of software update period	Determining how data quality should be assessed and assured
Verification of design outputs for black box AIaMD	Lack of clarity for when regulatory documents need updating if up-grading software	Limited clarity over amount of data required to show efficacy and safety
Lack of guidance on best practices for integrating AI development into an ISO 13485 compliance quality management system (QMS)	Cybersecurity training for device users, such as clinicians	Limited post market surveillance data

(44)

Future Innovations:

Software issue, One important risk to be considered is software malfunction, which includes bugs, data loss, and/or poor performance. The wearable sensor's inability to give information can have a range of negative effects, from minor annoyance to the real loss of a life-saving device's functionality. Software needs to be carefully built and thoroughly validated in all wearable devices, but especially in those that are part of closed loop controllers. Data hoarding: Clinical data are valuable, intangible resources. From a cybersecurity perspective, medical device protection is subject to special rules. The Food and Drug Administration (FDA) contains comprehensive standards for both the premarket (U.S. Food Drug Administration, 2018) and post-market (U.S. Food & Drug Administration, 2016) phases (45). Wearable technology and telemonitoring are revolutionising healthcare by facilitating ongoing patient monitoring and tailored therapies. However, because of obstacles related to technology, ethics, and regulations, their integration is still scattered. In accordance with PRISMA 2020 criteria, this systematic review summarises findings from 165 investigations (2020–2024) in order to evaluate significant developments and enduring difficulties (46).

By increasing patient engagement and boosting adherence to expert guidance, the technologies have the potential to improve outcomes. The chapter also explores disparities in access to wearable technology and solutions, as well as important issues including data privacy, legal frameworks, and the need for strong validation of wearable health measures (47). By creating more precise frameworks (such as TPPs for infection diagnostics and recommendations for digital and molecular diagnostics), regulatory authorities have made some progress in resolving these problems. To promote innovation without sacrificing safety, stakeholders still need to coordinate more effectively and harmonise globally (48). Medical devices continue to account for more than 35% of the wearable IT industry, but their share is expected to decline in the years to come (Transparency industry Research, 2015). Rather than a stagnation or decline in the demand for or innovation in medical devices, this is primarily because of the explosive growth in other areas, like smart watches, active baby monitors, and fitness trackers (49). Numerous studies using longitudinal monitoring have shown the biological potential of wearables for early detection, diagnosis, and management of acute and chronic clinical problems. Additionally, wearables have demonstrated potential in lowering hospital readmission rates, minimising ER visits, preventing major and expensive medical events, and improving post-treatment and rehabilitation results (50).

Conclusion:

A combination of smart wearable devices and applications is likely to satisfy users in their strife for entertainment and health as well as better living standards. Smart wearable devices and the relevant micro-sensor devices regulatory challenges. Wearable medical devices were regulated or were notified to be regulated in the near future in India prior to the modification. Wearable sensors, international standards, can foster innovation while respecting regulatory requirements.

Reference:

1) Pawnikar, V. and Patel, M., 2025, February. Biosensors in wearable medical devices: Regulatory framework and compliance across US, EU, and Indian markets. In *Annales Pharmaceutiques Françaises*. Elsevier Masson.

2) Ravizza, A., De Maria, C., Di Pietro, L., Sternini, F., Audenino, A.L. and Bignardi, C., 2019. Comprehensive review on current and future regulatory requirements on wearable sensors in preclinical and clinical testing. *Frontiers in bioengineering and biotechnology*, *7*, p.313.

3) Chandan B. V. a, M. P. Venkatesh a*, Arjun M. a, Pasupuleti Dheeraj Krishna a and Indraprasad S, Comparison of Medical Device Regulations in India, Japan and South Korea

4) Legal Regulation of Smart Wearable Devices in China Institute for Foreign-Related Rule of Law, East China University of Political Science and Law, 555 Longyuan Str ., Area Songjiang, Shanghai, 201620, China, yaozaihenmang@mail .ru, ORCID 0000-0002-9933-7513

5) Raju, K. & Sree, M & Bonthagarala, Brahmaiah & Nori, Lakshmi. (2024). Wearable medical deVices: standards, approVal pro- cess and reGUlatory issUes. Pharma Times. 56. 24-31.

6) Sheikh M. A. Iqbal1,2, Imadeldin Mahgoub1,EDu3, Mary Ann Leavitt4 and Waseem Asghar, Advances in healthcare wearable devices.
7) Mahalakshmi, K., Palanivelu, V.R. and Kirubakaran, D., 2025. Global Market Trends in Biomedical Sensors: Materials, Device Engineering, and Healthcare Applications. *Biomedical Materials & Devices*, pp.1-19.
8) Amaral, C., Paiva, M., Rodrigues, A.R., Veiga, F. and Bell, V., 2024. Global regulatory challenges for medical devices: impact on innovation and market access. *Applied Sciences*, *14*(20), p.9304.
9) Kageyama, I., Kurata, K., Miyashita, S., Lim, Y., Sengoku, S. and Kodama, K., 2022. A bibliometric analysis of wearable device research trends 2001–2022—a study on the reversal of number of publications and research trends in China and the USA. *International Journal of Environmental Research and Public Health*, *19*(24), p.16427.
10) Escobar-Linero, E., Muñoz-Saavedra, L., Luna-Perejón, F., Sevillano, J.L. and Domínguez-Morales, M., 2023. Wearable health devices for diagnosis support: evolution and future tendencies. *Sensors*, *23*(3), p.1678.
11) Joshi, D., Sharma, I., Gupta, S., Singh, T.G., Dhiman, S., Prashar, A., Gulati, M., Kumar, B., Vishwas, S., Chellappan, D.K. and Gupta, G., 2021. A global comparison of implementation and effectiveness of materiovigilance program: overview of regulations. *Environmental Science and Pollution Research*, *28*(42), pp.59608-59629.
12) Meier, D.Y., 2019. Influence of cultural factors on wearable technology acceptance in healthcare: an empirical study with Chinese and Swiss consumers.
13) Erdmier, C., Hatcher, J. and Lee, M., 2016. Wearable device implications in the healthcare industry. *Journal of medical engineering & technology*, *40*(4), pp.141-148.
14) Sifaoui, A. and Eastin, M.S., 2024. "Whispers from the wrist": wearable health monitoring devices and privacy regulations in the US: the loopholes, the challenges, and the opportunities. *Cryptography*, *8*(2), p.26.
15) Banerjee, S., Hemphill, T. and Longstreet, P., 2018. Wearable devices and healthcare: Data sharing and privacy. *The Information Society*, *34*(1), pp.49-57.
16) Vivarelli, C., Censi, F., Calcagnini, G., Falsaperla, R. and Mattei, E., 2024. Risk Assessment for Workers with Wearable Medical Devices Exposed to Electromagnetic Fields. *Health Physics*, *127*(2), pp.269-275.
17) Capulli, E., Druda, Y., Palmese, F., Butt, A.H., Domenicali, M., Macchiarelli, A.G., Silvani, A., Bedogni, G. and Ingravallo, F., 2025. Ethical and legal implications of health monitoring wearable devices: A scoping review. *Social Science & Medicine*, p.117685.
18) Marassi, S. and Földes, M.É., 2025. From healthcare to employment: Tackling the regulatory challenges of in-body wearable devices at work in the European Union. *European Labour Law Journal*, *16*(2), pp.195-211.
19) Byrom, B., Watson, C., Doll, H., Coons, S.J., Eremenco, S., Ballinger, R., Mc Carthy, M., Crescioni, M., O'Donohoe, P., Howry, C. and ePRO Consortium, 2018. Selection of and evidentiary considerations for wearable devices and their measurements for use in regulatory decision making: recommendations from the ePRO consortium. *Value in Health*, *21*(6), pp.631-639.
20) Pesapane, F., Volonté, C., Codari, M. and Sardanelli, F., 2018. Artificial intelligence as a medical device in radiology: ethical and regulatory issues in Europe and the United States. *Insights into imaging*, *9*(5), pp.745-753.
21) Lu, L., Zhang, J., Xie, Y., Gao, F., Xu, S., Wu, X. and Ye, Z., 2020. Wearable health devices in health care: narrative systematic review. *JMIR mHealth and uHealth*, *8*(11), p.e18907.
22) Brophy, K., Davies, S., Olenik, S., Çotur, Y., Ming, D., Van Zalk, N., O'Hare, D., Guder, F. and Yetisen, A.K., 2021. The future of wearable technologies. *Imperial College London: London, UK*.
23) Xing, F., Peng, G., Liang, T. and Jiang, J., 2018, May. Challenges for deploying iot wearable medical devices among the ageing population. In *International Conference on Distributed, Ambient, and Pervasive Interactions* (pp. 286-295). Cham: Springer International Publishing.
24) Kelshiker, A., Cheng, S., Achar, J., Celi, L.A., Jain, D., Nguyen, T., Patel, H., Prakash, N., Wong, A. and Evans, B., 2025. Bridging the Regulatory Divide: Ensuring Safety and Equity in Wearable Health Technologies. *arXiv preprint arXiv:2508.20031*.

25) Sneha, S., Panjwani, A., Lade, B., Randolph, J. and Vickery, M., 2021. Alleviating challenges related to FDA-approved medical wearables using blockchain technology. *IT professional*, *23*(4), pp.21-27.
26) Khachatryan, K., 2015. Medical device regulation in the information age: a mobile health perspective. *Jurimetrics*, pp.477-507.
27) Keutzer, L. and Simonsson, U.S., 2020. Medical device apps: an introduction to regulatory affairs for developers. *JMIR mHealth and uHealth*, *8*(6), p.e17567.
28) Izmailova, E.S., Wagner, J.A. and Perakslis, E.D., 2018. Wearable devices in clinical trials: hype and hypothesis. *Clinical Pharmacology & Therapeutics*, *104*(1), pp.42-52.
29) Sivakumar, C.L.V., Mone, V. and Abdumukhtor, R., 2024. Addressing privacy concerns with wearable health monitoring technology. *Wiley Interdisciplinary Reviews: Data Mining and Knowledge Discovery*, *14*(3), p.e1535.
30) Sharma, A., 2024. Securing the future of healthcare: Ensuring privacy and security in wearable and implantable medical devices. In *Security, Privacy, and Trust in WBANs and E-Healthcare* (pp. 105-125). CRC Press.
31) Zhou, J., Zhang, Q., Zhang, M., Aikebaier, S., Zhu, X. and Zhou, X., 2025. Flexible wearable medical devices: from material innovations and data processing to intelligent healthcare applications. *Journal of Advanced Research*.
32) Chen, K., Ren, J., Chen, C., Xu, W. and Zhang, S., 2020. Safety and effectiveness evaluation of flexible electronic materials for next generation wearable and implantable medical devices. *Nano Today*, *35*, p.100939.
33) Minbaleev, A.V., Nikolskaia, K.Y. and Zhernova, V.M., 2020, December. Legal enforcement of cybersecurity of wearable mobile devices in healthcare. In *2nd International Scientific and Practical Conference on Digital Economy (ISCDE 2020)* (pp. 674-678). Atlantis Press.
34) Valla, V., Tzelepi, K., Charitou, P., Lewis, A., Polatidis, B., Koukoura, A., Karapatsia, A., Antonopoulou, K., Prodromidou, K., Papadaki, E. and Vassiliadis, E., 2023. Use of real-world evidence for international regulatory decision making in medical devices. *International Journal of Digital Health*, *3*(1), p.1.
35) Sivakumar, C.L.V., Mone, V. and Abdumukhtor, R., 2024. Addressing privacy concerns with wearable health monitoring technology. *Wiley Interdisciplinary Reviews: Data Mining and Knowledge Discovery*, *14*(3), p.e1535.
36) Wakabayashi, Y., Matsui, H., Ikai, K., Hayashi, M., Wakabayashi, H. and Yamamoto, K., 2017. Developing a practical method for validation of computerized systems integrated with smart and/or wearable devices for regulatory compliance of clinical trials. *Therapeutic Innovation & Regulatory Science*, *51*(1), pp.118-124.
37) KIM, J.H. and KANG, E., 2022. The Role of Wearable Devices for the Success of the Healthcare Business: Verification from PRISMA Approach. *융합경영연구*, *10*(4), pp.13-24.
38) Alharbi, R. and Almagwashi, H., 2019, August. The Privacy requirments for wearable IoT devices in healthcare domain. In *2019 7th International Conference on Future Internet of Things and Cloud Workshops (FiCloudW)* (pp. 18-25). IEEE.
39) Prieto-Avalos, G., Cruz-Ramos, N.A., Alor-Hernandez, G., Sánchez-Cervantes, J.L., Rodriguez-Mazahua, L. and Guarneros-Nolasco, L.R., 2022. Wearable devices for physical monitoring of heart: a review. *Biosensors*, *12*(5), p.292.
40) Davis, M.W., 2022. Regulatory and emerging standards. In *Closing the Care Gap with Wearable Devices* (pp. 87-90). Productivity Press.
41) Sapkota, B., Palaian, S., Shrestha, S., Ozaki, A., Mohamed Ibrahim, M.I. and Jakovljevic, M., 2022. Gap analysis in manufacturing, innovation and marketing of medical devices in the Asia-Pacific region. *Expert Review of Pharmacoeconomics & Outcomes Research*, *22*(7), pp.1043-1050.
42) Iqbal, J.D. and Biller-Andorno, N., 2022. The regulatory gap in digital health and alternative pathways to bridge it. *Health Policy and Technology*, *11*(3), p.100663.
43) Maci, J. and Marešová, P., 2022. Critical factors and economic methods for regulatory impact assessment in the medical device industry. *Risk management and healthcare policy*, pp.71-91.

44) Mkwashi, A. and Brass, I., 2022. The future of medical device regulation and standards: dealing with critical challenges for connected, intelligent medical devices. *PETRAS National Centre of Excellent in IoT Systems Cybersecurity: London (2022), DOI*, *10*.
45) Ravizza, A., De Maria, C., Di Pietro, L., Sternini, F., Audenino, A.L. and Bignardi, C., 2019. Comprehensive review on current and future regulatory requirements on wearable sensors in preclinical and clinical testing. *Frontiers in bioengineering and biotechnology*, *7*, p.313.
46) Stan, I.E., D'Auria, D. and Napoletano, P., 2025. A systematic literature review of innovations, challenges, and future directions in telemonitoring and wearable health technologies. *IEEE Journal of Biomedical and Health Informatics*.
47) Verma, V. and Saxena, C., 2025. The Future of Wearable Devices in Healthcare. In *Remote Monitoring and Wearable Devices in Healthcare* (pp. 209-236). Cham: Springer Nature Switzerland.
48) Rodriguez-Manzano, J., Subramaniam, S., Uchea, C., Szostak-Lipowicz, K.M., Freeman, J., Rauch, M., Tinto, H., Zar, H.J., D'Alessandro, U., Holmes, A.H. and Awandare, G.A., 2024. Innovative diagnostic technologies: navigating regulatory frameworks through advances, challenges, and future prospects. *The Lancet Digital Health*.
49) Casselman, J., Onopa, N. and Khansa, L., 2017. Wearable healthcare: Lessons from the past and a peek into the future. *Telematics and Informatics*, *34*(7), pp.1011-1023.
50) Babu, M., Lautman, Z., Lin, X., Sobota, M.H. and Snyder, M.P., 2024. Wearable devices: implications for precision medicine and the future of health care. *Annual review of medicine*, *75*(1), pp.401-415.
51) Class, I. and Class, I.I., Understanding Medical Device Regulations In India: A Guide to Regulatory Compliance.
52) Kumar, R., Verma, M.M., Batra, J., Singhal, G., Sahu, A., Gupta, D.K. and Markan, S., 2025. A Leap for Medical Devices Regulation in India and its Comparison with United States and European Union Regulations. *Modern Journal of Health and Applied Sciences*, *2*(1), pp.12-34.
53) Saini, G., Budhwar, V. and Choudhary, M., 2022. Review on people's trust on home use medical devices during COVID-19 pandemic in India. *Health and Technology*, *12*(2), pp.527-546.
54) Paul, P.K., 2022. Medical device and equipment sector in India: towards sophisticated digital healthcare systems—an overview. *Next-Generation Nanobiosensor Devices for Point-Of-Care Diagnostics*, pp.211-225.
55) PANDIAN, S., Murugan, R., Sudherson, M. and Sahil, S.M., 2024. THE INFLUENCE OF BIOMEDICAL ENGINEERING IN INDIA. *i-manager's Journal on Future Engineering & Technology*, *19*(3).
56) Mahamuni, R., 2024. HEALTH DATA CONFIDENTIALITY AND OWNERSHIP IN INDIAN WEARABLE TECHNOLOGY. *Available at SSRN 5180319*.
57) Aggarwal, M., Sahore, K., Kumar, V. and Sinha, J., 2023, November. Impact of Healthcare Digitalization on Medical Device Trade in India. In *International Conference on Advances in Health, Safety, Fire, Environment, Allied Sciences and Sustainability* (pp. 93-105). Singapore: Springer Nature Singapore.
58) Mony, P.K., Thankachan, P., Bhat, S., Rao, S., Washington, M., Antony, S., Thomas, A., Nagarajarao, S.C., Rao, H. and Amrutur, B., 2018. Remote biomonitoring of temperatures in mothers and newborns: design, development and testing of a wearable sensor device in a tertiary-care hospital in southern India. *BMJ innovations*, *4*(2).