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PERSONALIZED MEDICAL DEVICES FROM CONCEPT TO CLINIC: A REVIEW OF REGULATORY PATHWAYS IN THE US, EU, AND INDIA.

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ABSTRACT

Personalized medical devices (PMDs) signify a revolutionary change in the field of health care that corresponds with the worldwide trend of the patient-oriented approach. Contrary to conventionally manufactured, mass-use devices, PMDs are tuned to correspond with the anatomical, physiological, and even genetic characteristics of individual patients. With the aid of new technologies, such as 3D printing, artificial intelligence, wearable technology, and biomedical engineering, the innovations should be used to improve therapeutic accuracy, clinical results, and patient comfort. As discussed in the paper, the classification of PMDs, namely custom-made, patient-matched, and adaptable devices, the pathway of their development, the technologies they employ, and the regulatory issues involved, are outlined. It also provides a comparative study of the regulatory systems worldwide, such as the US FDA, the EU MDR, and the CDSCO of India. Although PMDs have huge potential, the mainstream inclusion of this technology into healthcare is complicated by regulatory inequities, standardization problems, post-market surveillance, and ethical issues. In the conclusion of the article, the author suggests the use of universal rules, fair access, and technology-based forms of control that would facilitate the safe, effective, and universal implementation of PMDs in clinical areas.

INTRODUCTION

Medical devices are of great importance in the diagnosis, prevention, monitoring, and treatment of different health conditions, starting with simple instruments such as thermometers and syringes and advancing to advanced systems such as pacemakers and surgical robots(Dwivedi & Pandey, 2023). Conventionally, such devices have been manufactured and designed to accommodate a huge number of patients and are standardized in their form. Nevertheless, as the healthcare industry increasingly focuses on personalized care, the disadvantages of standard, mass-manufactured devices are becoming more apparent. The medical devices are transforming today due to the increased pace in 3D printing, biosensing, biomaterials, neuroengineering, and data analytics(Gualdrón et al., 2019). Personalized medical devices (PMDs) have followed this transformation. This is a new generation of innovation with one-of-a-kind capabilities to address the anatomical and physiologic patient-specific needs to support personalized medical care.

Based on such a premise, the IMDRF establishes a personalized medical device as a device made to fit a specific individual and differentiates these devices into three main categories:

1.1 **Customized medical devices:** Devices designed to the needs of one specific person, either through a prescription issued by a medical practitioner or based on his or her needs that the currently available products in the market cannot support.

1.2 **Patient-matched medical devices:** Devices created in a validated design envelope based on patient-specific anatomical information (e.g., CT scan or MRI scan) and commonly produced using digital modeling and 3D printing.

1.3 **Adaptable medical products:** Mass-produced products adapted at the point of care to fit the anatomical or physiological characteristics of a specific person, using the manufacturer-validated modification technique.

Though these advances expand the world of patient-specific medicine, they have also put the present regulatory frameworks under pressure as they cannot keep pace with the technologies that need to be used on a patient-by-patient basis. The regulators are also urgently trying to solve problems in the domains of design validation, clinical data generation, software compliance (SaMD), production repeatability, and post-market oversight through the US FDA, European Commission (MDR 2017/745), Therapeutic Goods Administration (TGA, Australia), and Health Canada.

2. CONVERGENCE OF MULTIDISCIPLINARY INNOVATIONS IN PERSONALIZED MEDICAL DEVICES :

This figure illustrates the convergence of multiple innovations in PMD

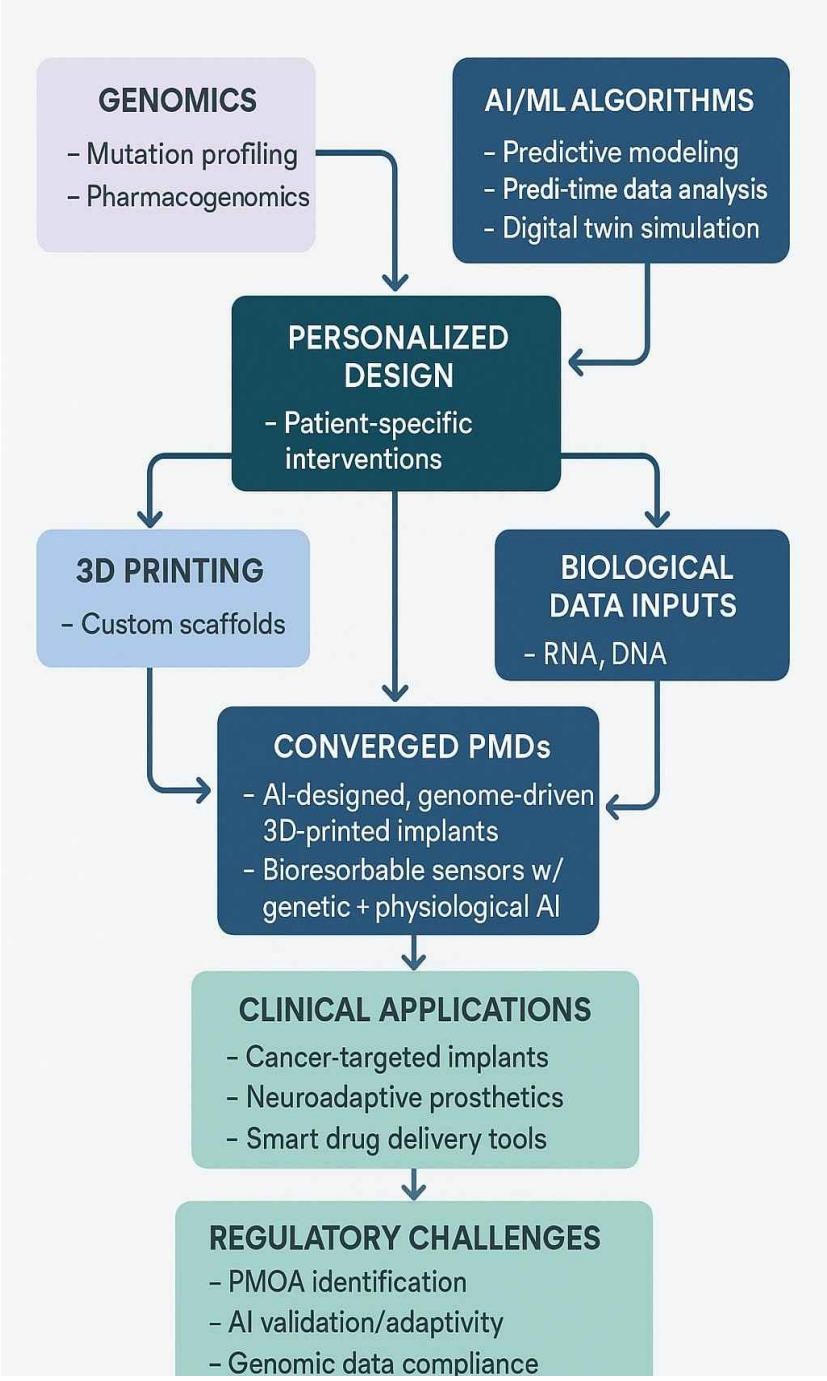

Fig.No.1 Integrated Framework for the Development of Converged Personalized Medical Devices

3. NEED FOR PERSONALIZED MEDICAL DEVICES:

3.1 Necessity, clinical and functional :

Individually manufactured devices come in handy in case of limitations in standard and mass-produced medical devices. It has been found that 30-50 percent of patients have suboptimal results with off-the-shelf implants or devices because of anatomical differences or poor fit. Global morbidity due to non-communicable diseases (NCDs), which is associated with 74% of all mortalities globally (WHO, 2022), also points to the necessity to have personalized instruments that will assist in improved diagnosis, surveillance, and intervention. Individualized equipment can enhance conformance to patient anatomy and pathology and result in reduced complications of surgery, reduced recovery time, and enhanced therapy accuracy(Jamróz et al., 2018).

3.2 Regulatory Incorporation and Demand Increase :

The personalized medical device market is growing at a great pace. The worldwide market of 3D-printed medical equipment is estimated at USD 6.9 billion in 2030 alone, with a compound annual growth rate (CAGR) of more than 16%. With the identification of this development, regulators like the FDA, European Commission, and TGA (Australia) have revised classification and oversight models to formally define and include custom-made, patient-matched, and adaptable devices. The changes allow safer and more scalable integration of PMDs into clinical practice.

3.3 Technological Enablement :

The development of imaging, CAD/CAM, and additive manufacturing technologies has made it a lot cheaper and faster to manufacture tailor-made medical equipment. As an example, using 3D-printing technologies has allowed more anatomical accuracy to be achieved in implants, up to the level of 95%, and it has also reduced the time of production by60-70 percent when

compared to conventional manufacturing. Another example of personalization is wearable sensor devices. They are becoming more and more information-driven: the number of connected wearable devices currently exceeds 1.1 billion worldwide, and a significant number of them are used in health monitoring applications(Walter et al., 2024).

3.4 Health and equity experts :

Despite their promises, the availability of personalized devices remains unequal. Research findings indicate that more than 80 percent of users of wearable health technology are in the high-income-earning brackets, with the underserved community being unable to access the technology, both in terms of cost and the digital literacy divide. This creates a risk of worsening health inequality unless steps are taken to make the technology more affordable and accessible through cost-effective innovation and public-private partnerships(Adepoju et al., 2024).

4. TYPES OF PERSONALIZED MEDICAL DEVICES :

Personalized medical devices (PMDs) can be divided into three main categories, generally defined by the type and extent of the customization, which are made when designing and utilizing them: custom-made medical devices, patient-matched medical devices, and adaptable medical devices. Each such category refers to the different approaches to the individualization of the healthcare process, and it is different regarding manufacturing control, clinical input, and scalability.

4.1 Tailor-Made Healthcare Machineries

Custom-made devices are tailored to a particular patient and may be developed completely de novo (i.e., based on a written prescription by a qualified healthcare professional). The devices are usually necessary in situations where there is no good off-the-shelf or flexible candidate. They are not made based on repeatable or validated production templates of any kind and are not supposed to be widely distributed or mass-produced. Special devices tend to be designed to meet unusual or complicated clinical requests, and their development needs a close interaction between the clinician and the developer(Kermavnar et al., 2021).

Example:

A cranial plate is made to fit in a skull defect using CT scan information regarding one particular patient, which is made to be used only once in the surgical operation.

4.2 Patient-matched Medical Devices

The patient-matched device manufacturing uses personal patient information, like scanning or anatomic measurements, but within a preset design constraint. This implies that every single piece is tailored to be worn by a particular patient, but it is created by a standardized production process, which complies with regulations and is validated. These tools balance the customization benefits of a custom production process with the consistency of production workflows.

Example:

An orthopedic implant produced to fit the geometry of a knee of a specific patient, based on the information gathered using MRI, but printed according to proven design and manufacturing procedures.

4.3 Flexible Medical Devices

The medical equipment is adjustable. Many of the most frequently used medical tools are mass-produced in universally standard forms but are constructed to be customized, assembled, or tailored at the point of care by the healthcare worker. Adaptable devices are not personalized during fabrication as compared to custom-made or patient-matched devices. Instead, the manufacturer sets well-defined parameters of use at the clinical application level for personalization. This provides the freedom to manage patients and keeps control over their safety and performance.

Example:

Spinal fixation system consisting of modular rods and screws that are cut and fitted during surgery to suit the particular spinal curve of a patient.

DEVELOPMENT STAGES OF PERSONALIZED MEDICAL DEVICES FROM CONCEPT TO CLINICAL USE :

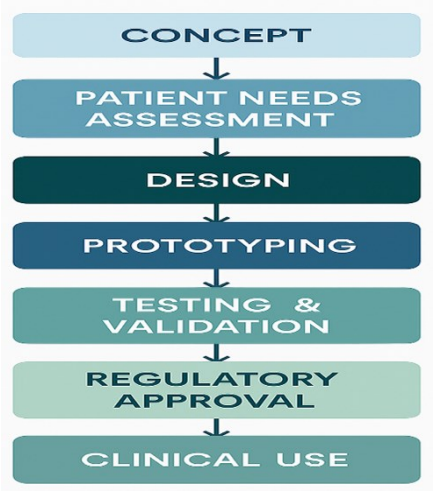

Fig.No.2. Developmental Roadmap of Personalized Medical Devices (PMDs): Concept to Clinical Application

5. APPLIED TECHNOLOGIES IN PERSONALIZED MEDICAL DEVICES:

The personalized medical devices are transforming with the advancement of 3D printing and artificial intelligence, imaging, and wearable sensors. Such technologies allow the development of patient-specific solutions, which are better fitting, working, and treating. They have a common aim to improve patient outcomes using a more precise, personal, and fast response in the sphere of healthcare. Five transformative categories of PMDs are as follows, and can be considered an excellent illustration of how innovative technologies are facilitating precision, flexibility, and patient-specific treatment. Each of these categories shows not only innovation but also presents special concerns in both manufacturing and regulation, as well as integration into clinical practice.

5.1 3D-printed medical devices

The term 3D-printed devices was also coined to focus on the fact that patient-specific images are constructed by 3D printing using additive manufacturing methodology, therefore achieving a good anatomical fit. They find extensive application in orthopedic surgeries and maxillofacial and reconstructive surgery(Kermavnar et al., 2021). The devices enhance surgery results via a good fit and minimize adjustments during the operation. They, however, question the conventional regulatory systems as they are highly individualistic. It is hard to ensure the safety, reproducibility, and quality of one-off or small-batch devices within the standards that were initially designed to be applied to mass-produced objects(Morrison et al., 2015). Regulators worldwide are also concerned about the obstacles they face when checking material continuity, authorizing post-processing processes, and overseeing the practices at manufacturing points of care(Beitler et al., 2022).

5.2 BCI devices BRAIN-COMPUTER INTERFACE (BCI) DEVICES

BCI devices help patients with neurological disorders because they enable direct communication of the brain with external systems, restoring mobility or communication. The systems are

programmed using the brain signals of each person to make them respond better(Maiseli et al., 2023). The devices present significant problems to regulatory agencies, more so in cases of adaptive machine learning. Long-term implantation, unpredictable signals, and privacy of information are safety issues(Xia et al., 2024). In addition, AI algorithms are dynamic, and this makes it more difficult to validate them, and neuroethical considerations related to cognitive autonomy and consent also necessitate the consideration of regulation (Gordon & Seth, 2024; Lavazza et al., 2025).

Examples include

Brain Gate system, Neurable EEG headsets, and Neuralink neural interface.

5.3 BIODEGRADABLE IMPLANTS:

The biodegradable devices are constructed to serve a specific temporary use and then biodegrade safely within the body so as to negate the need to undergo the removal surgery(Li et al., 2020). Examples of uses are in the delivery of drugs, orthopedic fixation, and cardiovascular scaffolds(Ali et al., 2023). The patient's healing speed, anatomy, and treatment requirements influence their personalization. However, predicting how these devices behave in vivo is difficult, complicating their regulation. The timeline of degradation depends on the patient and the biocompatibility of the device, and its by-products have to be proven. Regulatory approval in different countries across the world is complicated by the lack of a standard model of degradation and long-term data, particularly when a new material is used.

Examples include

Bioabsorbable Vascular scaffolds, custom biodegradable bone screws, and focal Drug-releasing implants.

5.4 AI-BASED WEARABLE DEVICES

Wearable devices assist in monitoring, analysing, and reacting to physiological data in real time with the help of AI. Such devices are currently commonly used in monitoring chronic diseases, rehabilitation, and early detection and are custom-programmed according to personal trends, including heart rhythm, glucose levels, or stress levels. These devices prove to be in a grey area; regulatory agencies find it difficult to categorize them because, in many cases, they exist on the border of wellness and medicine. Continuous changes in AI algorithms pose the problem of verifying their performance consistency, transparency, and the safety of health data because of the possibility of using personal data for commercial purposes. Global harmonization efforts are scarce, and real-time algorithmic changes typically surpass current approval processes.

Examples include

Intelligent electrocardiogram monitors, intelligent, selective stress-sensing straps, and foretelling glucose-measuring patches.

5.5 Therapeutic Devices—Based on the genome, Therapeutic devices

The application of such gadgets relies on genetic information to regulate treatment, diagnosis, or the workings of the device itself. Precision oncology, pharmacogenomics, and rare disease management can also utilize these devices. They provide an extremely specific intervention by being integrated with such tools or pieces of software as diagnostic tools. Regulators have been struggling globally when it comes to assessing the accuracy of data interpretation, software-device integration, and the privacy of genes. Genetic software platforms mixed with therapeutic hardware are a burden to traditional approaches to approval. Moreover, genetic imbalances in reference databases warn of clinical untruthfulness in various populations.

Examples include

Implants that allow biological drug delivery with genetically directed properties, implants that may treat cancer in a mutation-specific way, and implants placed according to the statistical risk of rejection based on the genes involved.

6. FUTURE PERSPECTIVE OF PERSONALIZED MEDICAL DEVICES:

It is believed that the presence of advanced technologies, the evolution of clinical demands, and dynamic regulation will define the future of personalized medical devices.

6.1 Matter of Artificial Intelligence and Predictive Technologies Integration

Among the most dramatic changes comes the integration of artificial intelligence (AI) and predictive modeling into the design of devices and the care of patients. Data is very complex to analyze, including imaging, genetics, and clinical records, using these technologies to support the production of fully individualized devices, anticipating and adapting to patient-specific conditions(Iqbal et al., 2024).

6.2 Improvements in 3D and 4D Printing

The other evident opportunity lies in the fast-paced development of 3D printing and emerging 4D printing technology. Although 3D printing has already transformed the fabrication of anatomical models and surgical guides, future revisions will give rise to more complex, multi-material, and bioresorbable implants, as well as the feature of dynamic implants and functional responsiveness due to 4D printing(Leong et al., 2024).

6.3 Point-of-Care Manufacturing and Decentralized Manufacturing

The decentralization of device manufacturing, as well, is expected to change the clinical workflows. Due to the development of the Medical Device Production Systems (MDPS), customized devices can also be manufactured closer to the point of care. The model will potentially cut production schedules and improve response to emergency patient demands, but it will also necessitate the instatement of quality control systems and checks to regulate the system.

6.4 The combination of Regenerative and Therapeutic Solutions

The concept of combining regenerative treatments with custom-made implants is also presumed to augment the value of PMDs as a treatment method. Such hybrid solutions would complicate any existing regulatory classification and would necessitate a cross-disciplinary approach to assessment that does not dismiss either the safety of a device or the therapeutic efficacy of the biological application.

6.5 Regulatory Harmonization of the Globe

There is increased pressure to harmonize across the world to express the global scope of PMD development and distribution. The IMDRF frameworks can be used as a model on which participants can align because there can be mutual recognition of conformity assessment, as well as promotion of cross-border innovation(Leong et al., 2024).

7. Outlook of the Personalized Medical Devices Market

The international personalized medical devices (PMD) market is worth advancing continuously, with an amount of USD 1,050.9 million in 2021 reaching billions in the approximation of USD 1,350 in 2024. Such development is influenced by increased demand for individual patients' medication, the development of 3D printing, and the development of digital health. The trend reveals that its expansion would only increase after 2024 because of regulatory structures and rapid innovation.

Considering the development of artificial intelligence, 3D printing, and precision medicine, the rate of use of custom medical equipment is going to increase incredibly within the next few years. Both the patient and the clinician are learning to embrace more devices specific to individual anatomical, physiological, or genetic profiles as treatment becomes more individualized. The diagnostics, monitoring, and therapy based on a range of innovations identifying AI-enabled wearables, patient-matched implants, and genomics-guided therapeutic tools make a breakthrough in the realm.

Regulatory agencies, including the FDA and the EU MDR, have been modifying the models to meet the events of personalized technology by dealing with concerns of patient safety, data integrity, and device traceability. These developing rules are meant to balance between ensuring that individualized devices are of the highest standards and promoting innovation and integration in clinics.

8. Regulatory Approach for Personalized Medical Devices (PMDs) :

The International Medical Device Regulators Forum (IMDRF) suggests a harmonised regulatory approach to the increasing complexity of personalized medical devices (PMDs), which are devices that are specific to the individual patient's anatomy or pathology. IMDRF categorizes the PMDs into three categories, and

each category must have a different regulatory approach, depending on the level of customization and design responsibility.

8.1 Custom-Made Devices

They are uniquely tailored to a person on the basis of a written request by a healthcare professional (1). They are normally exempt from requiring premarket approval, although they are expected to be safe and adhere to safety and performance principles. Documentaries, lengthy records (15/5 years), and post-market surveillance are mandatory.

8.2 Patient-Matched Devices

Manufactured by the manufacturer in an approved range of designs involving patient-specific information (e.g., imaging). Such devices are subject to the entire regulatory system, such as classification, pre-market approval, conformity assessment, labeling, and after-market requirements.

8.3 Adaptable Devices

Commercially manufactured devices that are set up at the point of care, usually following the instructions that the manufacturers provide. These must be regulatory ready, i.e., they must be validated both in terms of methods used to adapt and user instructions, so that patient safety is ensured.

To advocate these categories, IMDRF further identifies such tools as a regulatory decision tree and the idea of a Medical Device Production System (MDPS) of point-of-care manufacturing. It has also identified three forms of oversight of the production based on healthcare: special exemptions, MDPS-based use, or regulatory compliance to the full extent.

9. CHALLENGES TO REGULATION OF PERSONALIZED MEDICAL DEVICES (PMDS)

With the rise of personalized medical devices (PMDs), precision treatment and improved patient outcomes are becoming more common. However, their custom nature—such as AI-driven wearables and bespoke implants—poses significant regulatory challenges. Traditional frameworks designed for mass-produced devices struggle to accommodate the adaptability and complexity of PMDs. As technologies like AI, bio fabrication, and genomics evolve, regulatory bodies face a lack of precedents, often requiring a complete overhaul of existing systems. This regulatory uncertainty hampers both innovation and safety assurance.

9.1 non-standardization

The traditional regulatory systems rely on homogeneous product specifications and mass production. Nevertheless, PMDs, especially 3D-printed ones or specifically customized PMDs, are frequently produced one at a time. It becomes hard to exercise uniform pre-clinical testing, quality control, or performance testing. Lacking standardized models, the quality assessment of devices is not effective.

9.2 Adaptive Technologies Verification

Artificial intelligence algorithms, or machine learning, are being included in many PMDs to learn about the patient data over time. This active behavior negates the use of conventional approval processes, which are suited to a stationary device. There is a challenge of evaluating safety, performance, and predictability caused by the regulators, particularly when the software changes after deployment.

9.3 Genomic-Physiological Data Integration

Implants and wearables that employ genetic or physiologic profiling, e.g., genomics-directed implants or physiologic profiling, need validation in diverse populations. It is not easy to make such information precise and clinically relevant. In addition, regulatory agencies should ensure data confidentiality, safe storage, and informed consent of the patient in cases where such machines handle sensitive personal data.

9.4 Post-market oversight and traceability

The post-market surveillance of PMDs is often hampered by their often being made to order or in a hospital environment. They do not bear batch traceability, unlike mass production devices, without which it becomes easier to prescribe a product for future usage or recall a defective batch. The regulators should come up with new methods of following up on the results and quality throughout the life of a device.

9.5 Disparity in Regulations across the World

PMDs have no general regulatory system. The sunway is quite varied in different regions, and so are discrepancies in the classification of devices, the approval process, and technical documentation. Despite efforts of harmony by bodies such as the IMDRF, implementing harmonized guidance on a global basis is limited, and this retards international market accessibility.

10. COMPARATIVE OVERVIEW OF REGULATORY FRAMEWORKS:

This table gives a comparative outline of the regulations in various countries

Table No.1. Comparison of PMD Regulations: FDA, EU MDR, and CDSCO

Aspect	US FDA	EU MDR (2017/745)	India (CDSCO)
Definition of PMD	Covered under *Custom Device Exemption (CDE)*	Defined as *custom-made devices* under **Annex XIII**	Not explicitly defined; often grouped under Class C/D devices
Premarket Pathway	Notification required for ≤5 custom devices/year under CDE	Requires CE-mark and declaration of conformity via notified bodies	Form MD-14 submission with unclear differentiation for PMDs
Clinical Evaluation	Exempted under CDE; limited oversight	Mandatory clinical evaluation under **Annex XIV**	May be required; lacks a structured pathway for PMDs
Labelling & UDI	UDI required; may have patient-specific details	UDI and patient-labelling are required	The UDI framework was proposed (2019), but not fully enforced
Post-market Requirements	Post-market surveillance varies; real-world data encouraged	Robust vigilance and PMS are required	Pharmacovigilance required; PMS plans unclear for patient-specific

11. COMPARATIVE REGULATORY PATHWAYS FOR PERSONALIZED MEDICAL DEVICES IN THE US, EU, AND INDIA:

11.1 Regulatory Pathway for Personalized Medical Devices in the **UNITED STATES**

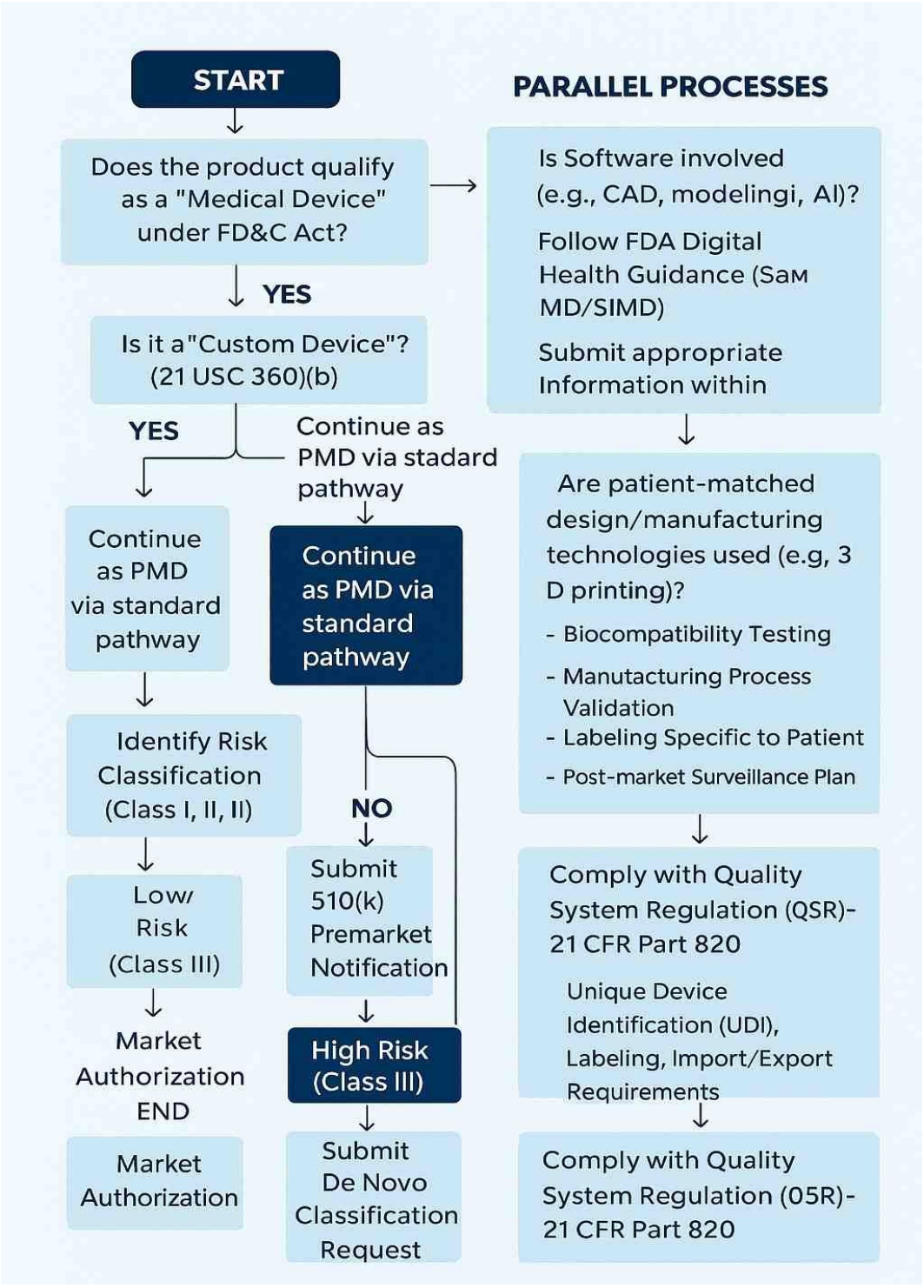

Fig.No.3 Regulatory Pathway for Personalized Medical Devices in the **UNITED STATES**

11.2 Regulatory Pathway for Personalized Medical Devices in the EUROPEAN UNION

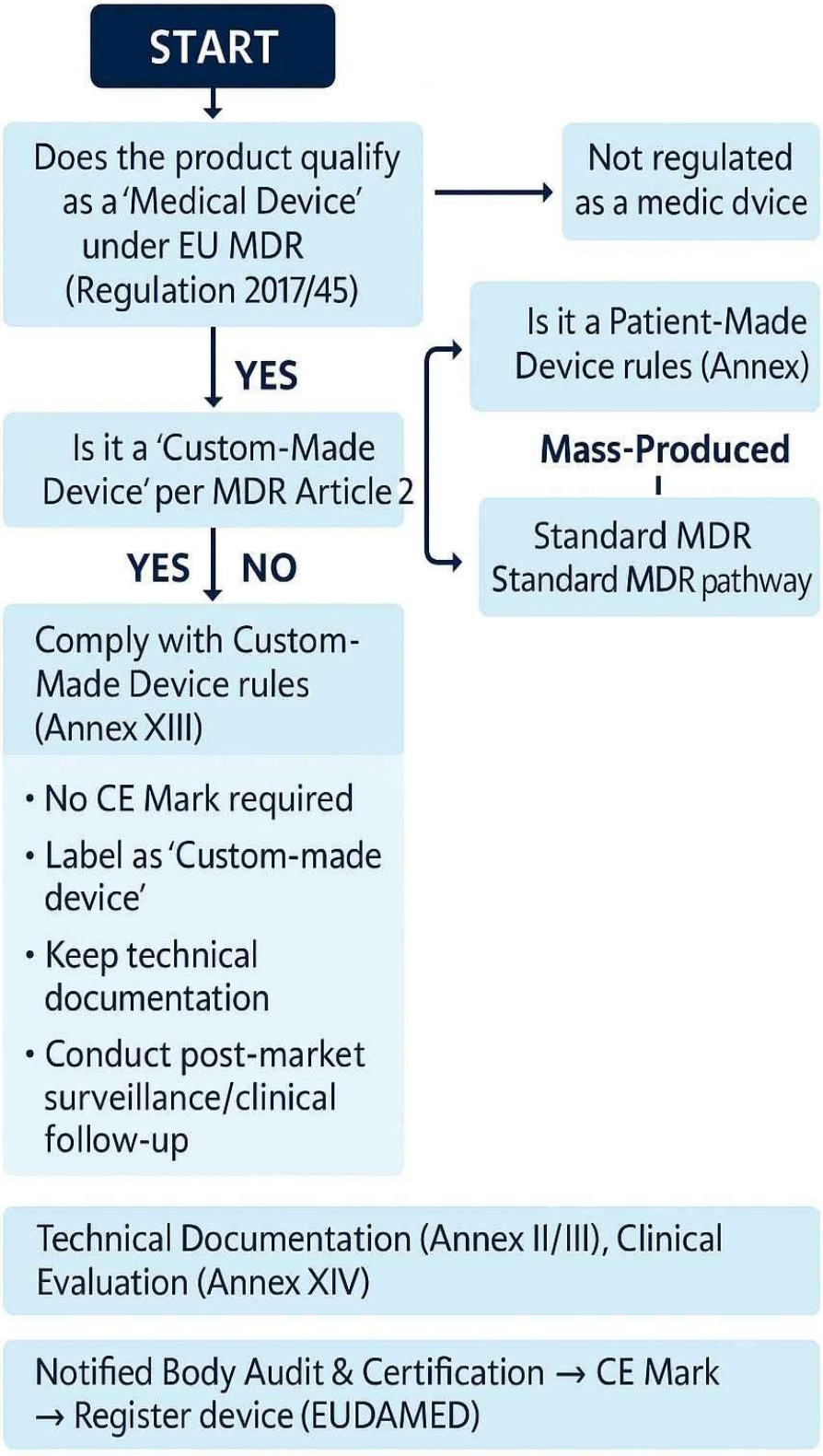

Fig.No.4. Regulatory Pathway for Personalized Medical Devices in the **EUROPEAN UNION**

11.3 Regulatory Pathway for Personalized Medical Devices in INDIA

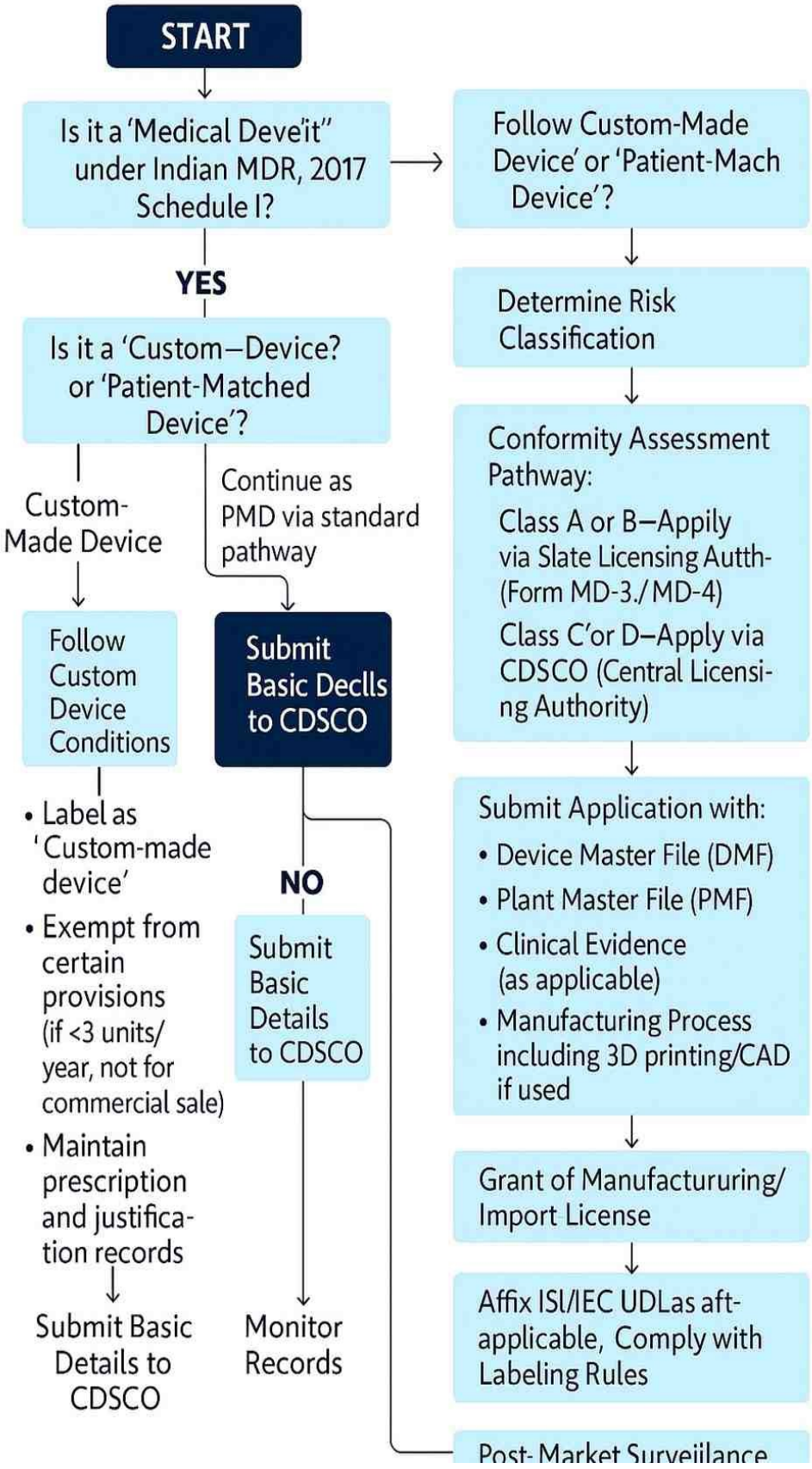

Fig.No.5. Regulatory Pathway for Personalized Medical Devices in **INDIA**

12. Regulatory gaps in personalized and customized medical devices and proposed improvements.

The existing framework of medical device regulations in the global arena was set up to regulate mass-produced devices, and it is important that this not be a challenge regarding dealing with personalized or customized medical devices (PMDs/CMDs). These solutions are implants/patient-specific, 3D-printed prosthetics, and AI-personalized therapy solutions, and these solutions require special oversight mechanisms. Regulation systems have not adjusted accordingly to such an extent; however, most of them have developed significant regulatory gaps.

12.1 Contrasting Definitions and Non-Consistent Classifications

The use of discrepant terms to describe PMDs and their classification is among the major regulatory issues. Global manufacturers find it difficult to comply with the customization and personalization of devices because different regions use dissimilar requirements to define and categorize custom-made and personalized devices.

12.2 The Issue of the Inadequate Premarket and Clinical Evaluation Frameworks

The majority of PMDs will not face intense premarket review because of their ad hoc nature, and there are few opportunities to test safety and performance in the traditional clinical trials. What is more, little information is available on how to evaluate the clinical performance of such devices through other methods, such as simulation models or real-world data(Amaral et al., 2024).

12.3 Incomplete Post-market surveillance and adverse event reporting

The existing post-market surveillance measures are not well prepared to monitor individualized results of PMDs. Reporting of adverse events of custom-made devices is usually voluntary and does not offer the granularity required in reporting patient-specific outcomes. Healthcare facilities manufacturing point-of-care devices are also not obliged to report adverse events in an organized manner in many healthcare facilities.

12.4 Ambiguity in Quality System Requirements and Risk Assessment

PMD manufacturers, most importantly the ones producing at the point of care (i.e., hospitals), are commonly not required to meet the same quality management standards as traditional ones. It is also deficient in customized risk measurement tools that take into account variance in creating the design, the anatomy of patients, and the protocols of the software algorithm in AI-powered PMDs(Connole & McDermott, 2025).

12.5 Emergent questions in the Algorithmic/AI-based Personalisation and Learning Algorithm

There are further problems of AI-personalized medical devices whose user data they learn. Over time, these devices have changed, and they are at variance with the fixed regulatory review frameworks. The rules that would govern the adaptive AI/ML systems, which alter themselves after they have been deployed, are still in their development stages, and thus, it is challenging to monitor them.

CONCLUSION

The development of tailor-made medical devices is a significant progress in the current healthcare industry because such devices provide individual solutions that enhance patient experiences by anatomical, physiologic, and genetic customization. As the technology behind PMDs, including AI-integrated wearables or 3D-printed implants, continues to advance at breakneck speed, regulatory systems across the world look to play catch-up. The fact that different definitions are used, there are not many premarket assessment tools, and the post-market surveillance methods are insufficient, highlights the redress that need for a solution. Regulatory harmonization, an inclusive approach composed of innovation and ethical governance of PMDs, is necessary to achieve their full potential on the global level. On the one hand, the availability of properly constructed frameworks enables personalized devices to reframe precision medicine and build a more technologically progressive yet fairer and patient-oriented healthcare ecosystem.

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