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Integrated Risk-Based Design and Global Regulatory Harmonization for Class IIb Medical Devices

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Abstract

Medical devices that are considered moderate-high risk and hence demanding strict regulatory controls include Class IIb medical devices that have the potential to affect patient safety. With the growing interconnectivity and technological dependence of the healthcare system, the task of the manufacturers in managing conflicting regulatory frameworks in international jurisdiction has become extremely challenging. In spite of the fact that the majority of regulatory systems implement risk-based classification principles, the dissimilarity in clinical evidence requirements, documentation structures, and post-market surveillance requirements, generates complexity and redundancy in access to the global market. This review analyzes how the risk-based design principles have been integrated into the lifecycle of Class IIb medical devices and reviews current initiatives regarding global regulatory harmonization. It puts a stress on the role of structured risk management, design controls, human factor engineering, clinical evaluation, and post-market data integration in the delivery of device safety and performance. The paper also examines harmonization efforts by other bodies like the International Medical device regulators forum and discusses the mechanisms of reliance, common standards and models of lifecycle regulation as avenues to regulatory convergence. A risk-based harmonization structure is suggested, which integrates technical documentation alignment on a global level, alignment of the post-market intelligence systems, and reliance-based assessment strategies. New issues, such as artificial intelligence, cybersecurity, and vulnerabilities in the supply chain are covered as a priority that should be considered in the future during the evolution of regulations. Enhancing the connection between engineering risk management and global regulatory collaboration can provide a viable long-term approach to improving patient safety and helping to innovate Class IIb medical technologies.

Keywords: *Risk-based design; Class IIb medical devices; Regulatory harmonization; Lifecycle risk management; Global medical device regulation.*

1. Introduction

Class IIb medical devices are a high-risk category of moderate risk that is vital to contemporary healthcare provision. According to the European Union Medical Device Regulation (EU MDR 2017/745), Class IIb devices comprise such products as long-term surgically invasive devices, infusion pumps, ventilators, orthopedic implants, and some active therapeutic devices that introduce or exchange energy to the human body [1]. Such devices are more risky than Class IIa and thus the conformity assessment procedures, such as the notified body evaluation and clinical device assessment are more stringent. Regulations around the world medical devices are categorised on the basis of risk based principle whereby increasing the degree of harm to the patient, the greater the degree of control of the regulator [2]. This proportional regulation philosophy is a risk-based approach that provides an easy time in innovation. Nevertheless, despite the use of risk-based classification models in major jurisdictions, like the European Union and the United States, there are variations between classification regulations, terms, clinical evidence considerations, and post-market surveillance. In practice, a product classified as Class IIb in Europe can be classified as Class II or even Class III in the United States based on the uses and technology features of the product [3]. This creates regulatory complexity to manufacturers who aim to access the global markets. Risk-based design has become an underpinning approach to curb the

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issue of safety and compliance. The international standards including ISO 14971 focus on the systematic identification, evaluation, control and monitoring risks in the total product lifecycle [4]. Instead of considering regulatory approval as a finite transition, modern regulatory science fosters lifecycle risk management that incorporates design controls, clinical assessment, production monitoring, and post-market monitoring. This combination is more crucial in case of Class IIb devices because they have stronger possibilities of serious adverse events in case of their ineffective design or monitoring. Simultaneously, regulatory harmonization processes are underway throughout the world, especially through the International Medical Device Regulators Forum (IMDRF), which seeks to minimize interjurisdictional unwarranted divergence through the establishment of shared fundamental principles of safety and performance. Although full harmonization is far away because of the differences in the law, political, and economic aspects, convergence on risk-based regulatory science provides a good direction. This review will discuss the concepts of integrated risk-based design of Class IIb medical devices and will analyze how regulatory harmonization work at the global level can contribute to more efficient, coherent and patient-focused regulatory systems.

2. Risk-Based Design Hypothesis in Class IIb Medical Devices

Risk-based design is a structured engineering method where the hazard identification and risk evaluation and risk control are incorporated in the product development life cycle. In the case of Class IIb medical equipment, where a failure could lead to severe injury or even long-term health effects, risk management is not only a regulatory mandate, but it is a primary design philosophy.

2.1. Lifecycle Risk Management Integration

New regulatory measures demand that manufacturers should incorporate risk management into the life cycle of the entire product and not on a retrospective basis. The FDA design control regulation (21 CFR 820.30) focuses on the structured development processes such the design inputs, design outputs, design verification, design validation, and design review processes with the aim of making sure that the safety requirements are converted into quantifiable engineering specifications [5]. Equally, the quality management systems that are consistent with ISO 13485 have documented procedures that associate the risk management outputs with the product realization and post-market processes [6]. The lifecycle approach provides the continuous evaluation of the risk measures that were taken in the development phase by monitoring the production process and after-marketing surveillance. Research has pointed out that risk management can minimize design failures and delays in the regulations later in the development stage, especially those of higher risk devices when they are put in place early during the design [7].

2.2. Hazards Identification and Risk Analysis

In Class IIb devices, the identification of hazards should take into account the biological, mechanical, electrical, software and usability-related hazards. The commonly used approaches in device development include Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA) and Hazard Analysis and Critical Control Points (HACCP) [8]. These systematic tools enable manufacturers to measure the risk depending on its severity and probability, and prioritise mitigation strategies. Class IIb devices that are software-intensive demand extra consideration to software lifecycle risk. The IEC 62304 standard creates the risk-based software classification and validation requirements, which makes sure that the software architecture and the software verification activities correlate with the possible harm to patients [9]. Cybersecurity risk has become a significant issue as digital health integration is growing. Design validation of devices connected to a network in terms of cybersecurity risk is a growing requirement of the regulatory guidance [10].

2.3. Usability and Human Engineering

The rate of side effects involved with Class IIb machines is largely related to human error, but not machine failure. Human factors engineering (HFE) incorporates usability testing in the process of developing devices to reduce the use-related risks. According to the human factors guidance provided by the FDA, a focus is laid on simulated-use validation testing to provide a safe operation of the device in real-world settings [11]. It is supported by evidence that integration of usability engineering into the development process at an early stage will minimize avoidable negative evenings and improve the overall performance of safety [12]. In devices where human-centered design reduces risk exposure, including infusion pumps and ventilators which frequently work in stressful clinical conditions, human-centered design has a major role to play. Risk-based design thus goes further than technical performance into cognitive load, labeling clarity and the effectiveness of an alarm system.

2.4.Clinical Evaluation and Benefit-Risk Determination

It will be conducted to identify the actual accomplishments and the advantages gained following the implementation of the suggested enhancement. Class IIb devices are usually subject to clinical approval to show the compliance with safety and performance standards. MedDev guidelines by European Commission provide a systematic method of clinical data appraisal, literature review and planning post-market clinical follow-ups [13]. The benefit-risk analysis has to show that residual risks are acceptable when compared to the clinical benefits. More and more regulators are promoting the application of real-world evidence (RWE) to supplement benefit-risk analyses across the device lifecycle. The framework of RWE by FDA emphasizes how it is involved in supporting regulatory decision-making, especially in device modification and expanded indications [14]. In the case of Class IIb devices, regulatory submissions and post-market compliance are enhanced by the incorporation of clinical evidence generation into the continuing risk management process.

3. Regulatory Environment of Class IIb Medical Devices around the World

Despite this method of risk-based classification being a regulatory similarity in many parts of the world, regulatory controls on moderate and high-risk devices like Class IIb differ considerably across jurisdictions. Such differences affect the process of approval, documentation, expectations of clinical evidence, and post-market requirements (Figure 1).

3.1.European Union -EU MDR Framework

The regulation (EU) 2017/745 implies that Class IIb devices are subject to a high-risk conformity assessment in which the review of the technical documentation, quality management system, and the clinical evaluation reports undergoes a review of a Notified Body. In contrast to Class IIa products, Class IIb products need a more in-depth examination of risk management files, benefit-risk justifications, and post-market clinical follow-up (PMCF) plans. The EU MDR enhanced the expectancies of clinical evidence and post-market monitoring with a focus on constant assessment of safety and performance throughout the lifecycle of the product. Manufacturers should write periodic safety update reports (PSURs) and have proactive PMS systems in accordance with the risk of the device [15]. The regulation also increased transparency by means of EUDAMED database which created traceability and vigilance reporting. These heightened regulatory expectations have added to the compliance burden of manufacturers but have additionally resulted in better alignments between premarket risk assessment and post-monitoring.

Figure 1 Integrated Risk-Based Design Framework for Class IIb Medical Devices

3.2.United States FDA Regulatory Structure

In the United States, similar devices to those of the EU Class IIb can come under FDA Class II (510(k) clearance needed) or in some instances Class III (PMA needed), based on risk and novelty of technology. Although the systems in both the EU and the U.S. are risk-based, the FDA considers the concept of substantial equivalence on most moderate-risk devices. The FDA regulation system

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incorporates the premarket review, Quality System Regulation (QSR), and Medical Device Reporting (MDR). Other post-market requirements are adverse event reporting and in certain instances post-approval studies. The U.S. system can have fewer requirements of clinical data on devices proving to be equivalent compared to the EU MDR, whereas tougher enforcement provisions are implemented in the procedure of inspection and compliance audits. The Total Product Lifecycle (TPLC) model of the FDA highlights the fact that regulatory control extends well after clearance or approval, and post-market indicators and actual on-the-job experience are included in the regulatory decision process [16]. This lifecycle model is very similar to integrated risk-based design principles mentioned above.

3.3.United Kingdom, Australia and Canada

After Brexit, the United Kingdom replaced CE marking with the UKCA marking system which is overseen by Medicines and Healthcare products Regulatory Agency (MHRA). Although the UK regulatory framework is now in compliance with the EU requirements, it shows a gradual shift towards the more independent model in the future, with the possibility of divergence. Therapeutic goods administration (TGA) of Australia classifies devices on a system that is highly aligned with the EU risk-based approach. The Class IIb devices need conformity assessment evidence and to be listed in the Australian Register of Therapeutic Goods (ARTG). Mutual recognition mechanisms eliminate duplication of manufacturers who already have EU certification. Health Canada has divided devices into Class I to Class IV. Equipments similar to EU Class IIb often end up in Class IIIed that needs a Medical Device License (MDL) backed by clinical evidence and quality system certification. The key characteristics of the Canadian system are post-market vigilance and obligatory reporting of the problems.

3.4.Regulatory Divergence and its effects

In spite of common risk-based grounds of origin, there is still divergence in:

- Clinical evidence levels.
- Documentation structure
- Timelines of post-market reporting.
- Software and cybersecurity requirements.

The differences cause redundant submission procedures and augment the expense of regulations to the world manufacturers. The harmonization efforts focus on attaining a reduction of these inefficiencies without interfering with national sovereignty.

Table 1 Regulatory Comparison of Class IIb Equivalent Devices

Region	Risk Class Equivalent	Premarket Pathway	Clinical Evidence Level	Post-Market Obligations
European Union	Class IIb	Notified Body Conformity Assessment	Extensive clinical evaluation + PMCF	PSUR + PMS + EUDAMED reporting
United States	Class II (sometimes III)	510(k) or PMA	Substantial equivalence or clinical trials	MDR reporting + inspections
United Kingdom	Class IIb	UKCA Conformity Assessment	Similar to EU MDR	Vigilance reporting
Australia	Class IIb	TGA Conformity Assessment	EU-aligned evidence requirements	PMS + ARTG compliance
Canada	Class III	Medical Device License (MDL)	Clinical data required	Mandatory problem reporting

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4. Effort to Harmonize Regulations

Regulatory harmonization has come out to be a strategic priority as medical device markets grow more global to decrease duplication and improve patient safety and innovation. Although complete regulatory convergence is probably not possible, a movement toward mutual scientific standards, especially risk-based regulation, has become quite popular. This organization, known as the International Medical Device Regulators Forum (IMDRF) is a non-profit entity headquartered in Switzerland.

4.1. International Medical Device Regulators Forum (IMDRF)

The International Medical Device Regulators Forum (IMDRF), is a non-profit organization based in Switzerland. The International Medical device regulators forum (IMDRF) is at the center stage of ensuring a convergence of major jurisdictions regulatory frameworks such as the United States, European Union, Japan, Canada, and Australia. IMDRF prepares globally accepted guidance documents which member regulators can incorporate into their systems. The development of Essential Principles of Safety and Performance is one of the most powerful IMDRF contributions as it sets the requirements of the medical devices globally as the standard baselines [17]. The principles facilitate the process of uniform assessment of the safety, performance, labeling, and clinical evidence of such devices across regulatory frameworks. The other emerging fields that IMDRF has enhanced harmonization include Software as a Medical Device (SaMD) which presents a risk categorization system, founded on the nature of the information offered by software in addition to the condition of the healthcare situation [18]. This model balances regulatory oversight and patient impact, and supports the philosophy of risk-based regulatory across jurisdictions.

4.2. Convergence using International Standards

In addition to policy instructions, international technical standards are used as working harmonization tools. Regulators in most parts of the world accept the standards that are set by ISO and IEC and this gives vendors the opportunity to show that they met the necessary requirements in various regions. In its formative years as Global Harmonization Task Force (GHTF), the antecedent of IMDRF led to the development of the principles of organized convergence in regulation by suggesting standardized rules of classification and patterns of quality systems and vigilance models. Its classification guidelines stressed that the level of regulatory controls must be at the same level as the level of device risk, which impacts the contemporary classification systems worldwide [19]. By building upon internationally accepted standards and common guidance material, regulators may continue to have national responsibility at a cost of minimizing unnecessary technical divergence.

4.3. Unremaining Barriers to Harmonization.

Nonetheless, there are still some serious issues:

- Variances in legal authority and statutory requirements.
- Healthcare policy priorities in the nation.
- Differences in the culture of enforcement.
- Hegemonical and economic factors.

To illustrate this, IMDRF guidance facilitates shared values although enforcement is not compulsory. Depending on domestic legislations, regulators can understand or interpret guidance in different ways. Besides, the differences in resources between regulatory agencies may impact the inspections capacity and the strictness of post-market enforcement. However, harmonization has had a positive impact on fragmentation, which is less than it used to be decades ago. The move towards a convergence of regulations can be seen as a gradual process due to the growing use of similar risk-based approaches, the exchange of post-market data, and the acknowledgment of global standards (Figure 2).

5. Combined Risk-Based Harmonization Model of Class IIb Devices

Although convergence in the regulatory process has been achieved under the IMDRF guidelines and international standards, submission organization, documentation intensity, and after sales expectation, fragmentation has been a challenge to Class IIb medical device manufacturers. To seal these loopholes, a comprehensive risk-based harmonization framework is suggested, which will be

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developed on lifecycle risk governance, standardized technical documentation, and synchronized post-market intelligence sharing. The main idea of this model is the globally structured technical documentation. The Medical Device Single Audit Program (MDSAP) shows how audits of harmonized quality systems can lead to less redundant inspection in the jurisdictions where the program is implemented (United States, Canada, Australia, Brazil, and Japan) [20]. MDSAP offers a viable example of harmonizing operations through the alignment of audit criteria on common quality management principles. The extension of similar reliance mechanisms to Class IIb devices to technical documentation review could go a long way in minimizing duplication and still retain regulatory independence.

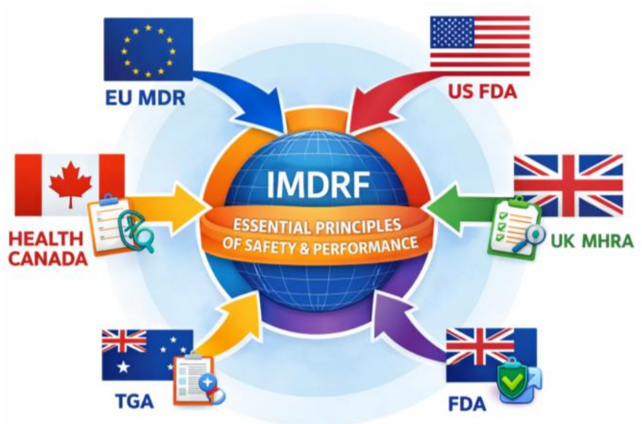

Figure 2 **Global Regulatory Convergence Model for Class IIb Medical Devices. The Figure Illustrates the International Medical Device Regulators Forum (IMDRF) Essential Principles of Safety and Performance Positioned at the Center of Global Regulatory Alignment**

Co-ordinated post-market surveillance systems should also be a part of an integrated harmonization structure. In the United States, the National Evaluation System of health Technology (NEST) depicts the way in which the real-life data infrastructures can be used to provide regulatory decisions across the entire lifecycle of the product [21]. The connection of international vigilance databases and the promotion of the real-life evidence sharing in the format of structured information would contribute to the improved timely identification of threat indicators with moderate-to-high-risk equipment. In case of Class IIb technologies in which the technology may also continue to stay in the market longer, continuous data integration helps benefit-risk analysis to go beyond its initial approval. Moreover, dependency and credit models among regulators provide another way towards convergence. The mechanisms of regulatory reliance as promoted by the World Health Organization are that a regulatory body can use assessment conducted by another credible body but maintain the sovereign authority of making independent decisions [22]. These methods of reliance are specifically useful to resource-constrained jurisdictions and can hasten the delivery of necessary Class IIb equipment without compromising the level of safety. The suggested composite model works on three interdependent levels, then, harmonized quality oversight, shared post-market intelligence, and structured reliance pathways. Instead of aiming at full legal convergence, this framework does encourage the scientific alignment concerning the risk classification, lifecycle monitoring and the proportional regulation. In the case of Class IIb devices, where the risks are high but can be addressed via a structured mitigation strategy, such a balancing act is able to help save lives of more patients without the extra administrative cost. Regulators can proceed to functional harmonization by incorporating risk-based design documentation into globally accepted quality infrastructures, aligning clinical and post-market data systems, and facilitating dependence mechanisms. This convergence increases predictability amongst the manufacturers, transparency among the regulators and eventually providing enhanced protection to patients worldwide.

6. Issues and Prospects of Risk-Based Global Harmonization

Even as major steps have been made in the area of risk-based regulatory science and converged internationally, a number of new issues are still in the process of defining the future regulation of Class IIb medical devices. The traditional scope of device risk management is growing with the technological change, specifically the integration of artificial

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intelligence and the development of software-based systems, and connected medical platforms. The devices that use artificial intelligence and machine learning pose dynamic risk profiles since they may change in performance over time through adaptive algorithms. There is an increased realization among regulatory authorities that continuous system learning might not be adequately covered by statical premarket evaluation. The FDA policy debates on artificial intelligence in recent years suggest a predetermined change control strategy to address altering the algorithms in a risk-based lifecycle paradigm [23]. This is indicative of a greater transition of single time approval to continuous control in line with actual performance monitoring. In the case of Class IIb devices with adaptive software, the safety process must be upheld with an organized update control, cybersecurity, and post-market performance analytics. Cybersecurity is another unceasing regulatory problem. Considering the increasing network-connectivity of Class IIb devices, there is a direct potential of patient safety and data integrity vulnerabilities. It has become more important that cybersecurity risk management is incorporated into premarket submissions and quality systems. To avoid regulatory fragmentation in the digital health control, harmonization will necessitate synchronized world expectations regarding vulnerability disclosure, patch control, and after-market security surveillance. Besides this, the complexity in the global supply chain presents new risk variables. Disruption in manufacturing, shortages in components and political unrest may influence the availability and quality of devices. The COVID-19 pandemic has shown that regulatory responsiveness and cooperation between nations are important in maintaining supply continuity of essential medical technologies. These systemic risks may be reduced in the future by strengthening systems of global reliance and common results of inspections. Combination of real-life evidence and post-market data is likely to become a growing aspect in the future regulatory schemes. European Medicines Agency has highlighted the increasing significance of the real-world data infrastructures in regulatory decision-making processes in all healthcare technologies, including medical devices [24]. Enhancement of the international cooperation in post-market data share may be able to improve the early signal recognition and the reassessment of benefits and risks over time. The lifecycle data transparency will be crucial to the preservation of the public confidence in the case of Class IIb devices which are usually implanted or in long-run use.

Finally, the future of the integrated risk-based harmonization will rely on striking the right balance between innovation and matching controls. Although complete legal integration of international regulation systems is unlikely, convergence in the form of the same science, digital watchdog platforms, and paths of dependence are a viable and sustainable way to go.

Conclusion

Class IIb medical devices play a significant role in the healthcare systems of the world as they have moderate-to-high risk profiles and are heavily used in clinical practice. The governance of these technologies cannot be achieved by just adhering to specific regulatory standards on a case-by-case basis; it is about lifecycle risk management that is part of the harmonized international frameworks. As has been seen during this review, the principles of risk based design, the structured quality systems, coordinated post-market surveillance and reliance mechanisms on regulation are all building blocks of functional global convergence. Despite the current regulatory divergence among jurisdictions, the trend of greater convergence due to IMDRF guidance, international standards and the use of reliance programs is a positive sign of progressive step toward scientific harmonization. The emergence of new issues like artificial intelligence, cybersecurity, and global supply chain vulnerabilities also support the argument of adaptive lifecycle-based oversight models. Through an improved balance of risk-based engineering and international regulatory collaboration, stakeholders will be able to improve patient safety and promote sustainable innovation in the Class IIb medical devices.

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