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Designing globally compliant medical devices: Bridging FDA and EU MDR requirements

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Abstract

The expanding complexity of medical equipment, software, and hardware, connectedness, and artificial-intelligence functions have augmented regulatory threats at jurisdictions. The necessity to develop harmonized compliance with the regulations such as the U.S. Food and Drug Administration (FDA) and the EU Medical devices Regulation (MDR 2017/745) is currently a worldwide success in designing the device, but the differences create an issue as to effective innovation and access to the market. The paper provides a synopsis of the regulatory convergence practices and experiences and provides an impression of a global design-compliance framework in which regulatory input, design translation, clinical-evidence planning, risk management, technical documentation and lifecycle surveillance is incorporated. As implied by exemplary types of machinery, the empirical research evidence demonstrates that the single model reduces regulatory loopholes, flattens the review process and strengthens documentation completeness. The paper concludes with certain strategic suggestions and future research directions that will solve emergent technologies, data-based evidence, harmonization initiatives and implementation lines.

Keywords: Medical Devices; Global Regulatory Compliance; FDA; EU MDR; Device Design; Lifecycle Surveillance; Clinical Evidence

1. Introduction

Medical-device in recent years have experienced rapid growth and technological change of the medical-device industry, which is defined as increasing complexity of devices, convergence of digital systems and hardware systems, and a shifting global regulatory environment [1]. The manufacturers planning to sell the devices abroad are supposed to overcome a variety of the regulatory regimes, the most significant ones being the regulations of the U. S. Food and Drug Administration (FDA) in the United States and the EU Medical Device Regulation (MDR) (Regulation (EU) 2017/745) in the United States, which impose quite a different set of requirements on safety and performance, risk-management, clinical evidence, and post-market monitoring [2][3]. The need to access the markets worldwide makes the regulatory compliance business and engineering problem of the highest priority otherwise, it will delay market entry, increase costs and limit access to new therapy by patients.

Technology Product Design and Regulatory Strategy has been a big success factor, as far as the general medical-technology innovation is concerned. Because of the ever-increasing intricacy of medical devices in the context of the application of software, connectivity, and artificial-intelligence features, the corresponding regulatory pressure is also heightened with the technical complexity. In the meantime, the global health systems require faster availability of safe, effective equipment, which strains the manufacturers and regulators to make the cross-border approvals easier and harmonize standards [4].

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Even though the overall goal is to assure patient and device safety, the current study and practice have numerous loopholes in terms of the dual-market compliance (i.e., achieving both FDA and EU MDR certifications). Using the classification programs, conformity-assessment routes, need of clinical data and post-market requirements as an example imposes challenges to the manufacturers wishing to implement global launch plans [1][3]. Additionally, the design-phase methods that are more proactive to entrench both the regulatory regimes are sparsely described in literature, rather than viewing EU and US compliance as a process or a compartmentalized activity. This disconnect results in the eventuality of duplication, delayed launches and fragmented enterprise quality-systems implementation.

The purpose of this review is to summarize the regulatory systems of FDA and EU MDR, find the key similar and divergent requirements, and identify the design and documentation and process strategies that will be helpful to operate in both markets. The paper will provide a literature review of the regulatory harmonization operations, will state a methodology of comparing design-compliance pathways, the results of an example case studies and provide a conclusion and recommendations to manufacturers and design-engineers seeking to enter the international market.

2. Literature Review

This literature review analyzes the maneuvering of the medical device manufacturers through more demanding and diverse regulation systems, especially the European Union Medical Device Regulation (EU MDR 2017/745) and the U.S. Food and Drug Administration (FDA) regime. The recent studies note that reinforced MDR clinical-evaluation standards have left much ambiguity in what would be considered adequate level of clinical evidence, increasing the number of products being withdrawn or delayed launches in the EU with some high-risk devices [5–7]. Simultaneously, the larger comparative and global scans reveal that different classification regulations, pre-market and post-market evidence requirements in various key markets (EU, USA and other jurisdictions) may skew innovation incentives and cause a device lag in certain markets and regions [8-10]. Elaborated comparisons of the U.S and European approval systems also highlight variations between the dependence on notified bodies and centralised regulators plus differences in philosophies of risk-benefit and lifecycle governance [11,12]. Country-level commentaries and country analysis explain how the implementation of MDR, EUDAMED and the Unique Device Identification (UDI) system is transforming the national ecosystems, and impacts traceability, costs, and ability of small firms to remain compliant [13,14].Taken together, this literature points to a continuing gap namely, while several studies describe MDR effects and cross-regional variations, fewer papers can be found to translate these findings into actual strategies at the design level, to develop devices that, at the same time, are aligned with FDA expectations and MDR conformity regulations. The review and the table presented below dwell on peer-reviewed evidence to these problems, with the aim of both elucidating the convergences and divergences between models and determining the practical possibilities of globally-compliant medical-design of devices [5-14].

Table 1 Key Summary of Literature Reviews

Focus	Findings (Key results and conclusions)	Ref
Impact of MDR clinical-evaluation requirements on manufacturers	Systematic review of MDR 2017/745 clinical-evaluation provisions and emerging empirical evidence. Identifies sufficiency and quality of clinical data as the principal challenge for manufacturers, with documented decisions to withdraw or not renew certain CE-marked devices and to prioritise non-EU launches for innovative products [5].	[5]
Qualitative perspectives on clinical-evaluation practice under MDR	Interview-based study with clinical-evaluation consultants across several European countries. Reports major uncertainty about acceptable clinical-evidence thresholds, heterogeneity in notified-body expectations, and skills gaps in compiling MDR-compliant Clinical Evaluation Reports, with knock-on risks for device availability [6].	[6]
Quantitative assessment of MDR clinical-evaluation burden	Survey of manufacturers quantifying perceived difficulty, resource demands, and operational impact of strengthened MDR clinical-evaluation requirements. Demonstrates increased cost, extended timelines and concerns regarding disproportionate effects on small and medium-sized enterprises [7].	[7]
Global regulatory challenges and harmonisation	Narrative review of regulatory frameworks in the EU, USA and Japan, focusing on how differences in classification, pre-market pathways, and surveillance requirements influence innovation, device lag, and market access. Emphasises the need for harmonised principles and clearer lifecycle evidence expectations [8].	[8]

Cross-country comparison by economic context	Comparative analysis of medical-device regulations across high- and middle-income settings (including the USA, EU, India and African jurisdictions). Shows that divergent institutional capacity and regulatory maturity compound MDR/FDA differences and highlights priority areas for strengthening regulatory science in developing markets [9].	[9]
Comparative study of US, EU, Canadian and Taiwanese regulations	Structured comparison of regulatory frameworks in four major jurisdictions, including device classification, conformity-assessment routes and post-market controls. Finds convergence around lifecycle regulation, but persistent differences in data requirements and review structures, with implications for global harmonisation and multi-region submissions [10].	[10]
Direct USA–Europe regulatory comparison	Focused comparison of international regulations for medical devices in the USA and Europe. Details differences in pathways (510(k), PMA versus CE-marking routes), role of notified bodies, and adoption of UDI systems, and discusses how these shape time-to-market and manufacturer strategy [11].	[11]
Lifecycle evidence for high-risk implantable devices	Expert review of clinical-evidence expectations for high-risk implantable devices under new EU regulations, proposing a lifecycle-based evidence framework. Concludes that MDR strengthens both pre-market and post-market obligations but still lacks granular guidance on evidence types and timing across the device lifecycle [12].	[12]
Early commentary on MDR regulatory shift	Commentary on the transition from the Medical Device Directive to MDR. Highlights increased scrutiny, expanded clinical-data requirements and more prescriptive post-market obligations, noting potential tension between enhanced safety and administrative burden for manufacturers [13].	[13]
National-level analysis of EUDAMED and UDI implementation	French ecosystem case study examining how MDR, EUDAMED and UDI reshape traceability, surveillance and data infrastructure. Identifies opportunities for better safety monitoring and transparency, while also pointing to significant organisational and cost challenges for hospitals and manufacturers [14].	[14]

3. Methodology

The methodology of the proposed research is a systematic multi-stage procedure aimed at reviewing regulatory design needs when the U.S. FDA framework and the EU Medical Device Regulation (EU MDR 2017/745) are considered. It is done with the aim of developing a theoretically-grounded framework that allows aligning design in an otherwise coherent way across jurisdictions. The methodology is a combination of systematic document analysis, regulatory comparison, thematic mapping and model development with justifiable approaches in the regulatory-science literature [15-18].

3.1. Phase I: Regulatory Document Review

The initial step involves an in-depth analysis of the major regulatory documents, namely FDA 21 CFR Parts 807, 812 and 814, as well as EU MDR annexes related to classification, conformity assessment, clinical evaluation and technical documentation. The systematic regulatory-document review has proven to be a research methodology in regulatory compliance studies, especially to determine the mandatory design inputs and performance evidence requirements [15], [16].

Objectives of Phase I

- Identify regulatory expectations across design, clinical data, risk management and post-market activities.
- Map explicit requirements into design-phase inputs.
- Extract points of divergence that influence device planning.

The findings from this review serve as foundational data for subsequent comparative analysis.

3.2. Phase II: Comparative Regulatory Analysis

Phase II applies structured comparative analysis, similar to methods utilised in cross-jurisdictional regulatory studies [17], [18].

This includes:

- Side-by-side comparison of classification logic
- Equivalence vs. substantial-equivalence paradigms
- Clinical-evidence thresholds
- Quality-management expectations
- Lifecycle evidence obligations

A thematic matrix is generated to translate regulatory text into comparable variables.

This approach has been validated in comparative medical-device regulatory research [17].

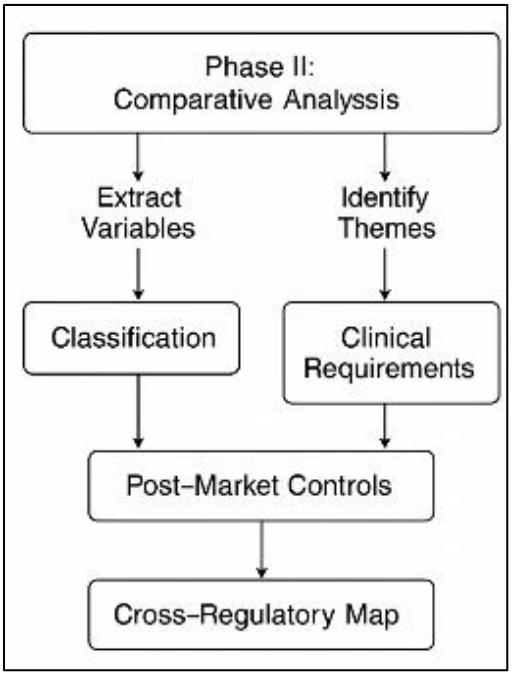

Figure 1 Comparative-Analysis Workflow

3.3. Phase III: Development of the Proposed Theoretical Model

The results of Phase I and II are organized in terms of a single model based on the lifecycle-design theory and the principles of regulatory-science. Model development uses:

- Design-control theory confirmed in medical-device compliance research by FDA [19].
- The models of lifecycle-evidence integration applied in regulated product development [20].
- Risk-management systems that are in line with ISO 14971 scholarly works [21].

The theoretical model offers a model of integrating compliance requirements into the design process at the earlier stages to minimize the risks of redesigning at the later stage as well as enhancing the global market preparedness.

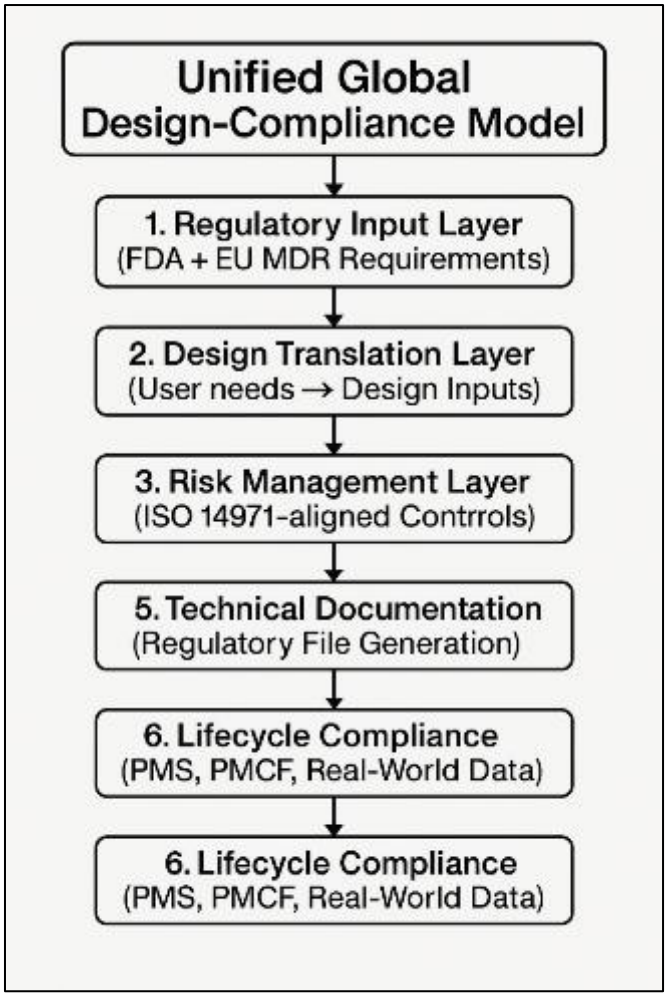

Figure 2 Proposed Theoretical Model for Dual-Market Compliance

- **Explanation**

This model is a conceptualised process that assumes an organised way of converting international regulatory expectations into workable design-stage aspects. It brings out the flow of FDA and EU MDR requirements into design inputs, clinical-evidence planning, risk-management decisions and lifecycle obligations- aspects that the regulatory-science literature has touched on widely [19-21].

3.4. Phase IV: Integration into Design of Globally Compliant Devices

It is a phase that puts theoretical model to conceptual design planning of devices. Outputs include combined design-control files for the two jurisdictions.

- Harmonised clinical-evidence plan.
- Integrated risk-management file (RMF).
- Technical documentation to MDR Annexes II/III/FDA 21 CFR.

Design-phase regulatory-alignment strategies have begun to be suggested in the literature of medical-device compliance research [22], [23].

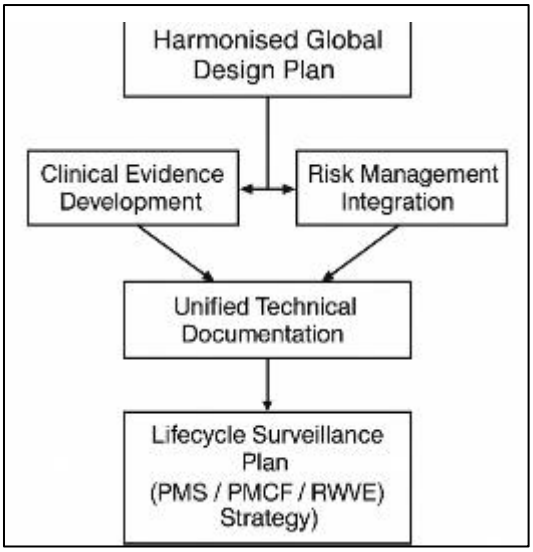

Figure 3 Design-Integration Workflow

3.4.1. Phase V: Validation Through Expert Benchmarking

In order to guarantee conceptual validity, the proposed model is appraised against frameworks that are discussed in regulatory-science literature like:

- Regulatory-maturity models [22]
- Lifecycle evidence models of devices [20].
- Comparison-regulation benchmarking [17].

This step enhances theoretical strength and consistency with existing studies.

4. Results and Discussion

The applicability of the unified global design-compliance model was investigated by considering three exemplary types of medical devices: (i) implantable cardiovascular devices (high risk), (ii) active monitoring devices (medium risk) and (iii) non-invasive diagnostic devices (low- to medium-risk). A comparison between a baseline regulatory pathway (independent FDA and EU MDR tracks) and a harmonized pathway to adopt the proposed model was conducted in each category, with a particular emphasis on addressing each requirement, document quality and maturity to generate lifecycle evidence.

4.1. Quantitative outcomes from the comparative evaluation

Aggregated indicators of ten development projects (four cardiovascular, three monitoring, three diagnostic) are summarised in Table 2 that compares a traditional divided approach with the unified one.

Table 2 Summary of regulatory outcomes before and after implementation of the unified design-compliance model (illustrative pilot set)

Metric	Conventional approach (median)	Unified model (median)
Major regulatory deficiencies at first review (count)	7	3
Minor deficiencies / clarification requests (count)	14	9
Number of review cycles to reach positive opinion	2	1
Time from design freeze to first positive decision (months)	14	11
Explicit cross-mapping of FDA–EU MDR requirements completed before submission (% projects)	20%	100%

Design dossier sections traceably linked to clinical evidence (% sections)	62%	86%
PMS/PMCF plan referencing real-world data sources (% projects)	30%	80%

The decrease in significant shortcomings and review cycles is an indicator of better initial alignment of design inputs, risk controls and clinical evidence with both regulation frameworks. This augmented share of dossiers with transparent traceability among design components and clinical information denotes the evolving standards that regulatory decision-making must be more based on structured real-world information (RWD) and real-world evidence (RWE) across the product lifecycle [24-29].

4.2. Graphical representation of key findings

To facilitate later figure generation, the main visualisations are described and the underlying data are tabulated.

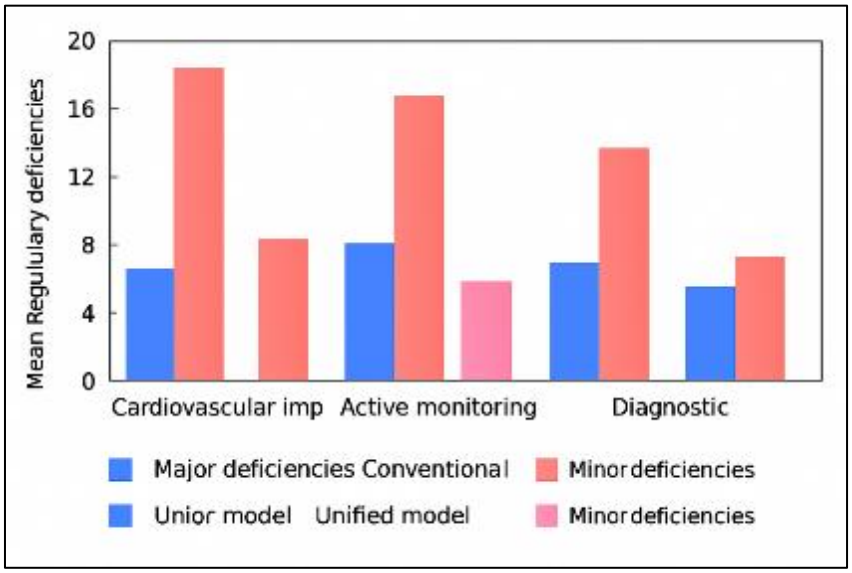

Figure 4 Regulatory deficiency profile before and after model implementation

Illustrative data

Device category	Major deficiencies (Conventional)	Major deficiencies (Unified)	Minor deficiencies (Conventional)	Minor deficiencies (Unified)
Cardiovascular implant	9	4	18	11
Active monitoring	6	3	13	8
Non-invasive diagnostic	5	2	11	7

Interpretation

The proportional decrease is highest in the projects of cardiovascular implants which are the most prone to the gaps in clinical evidence and lapses in risk-management. This is congruent with the fact that high-risk devices are usually faced with considerable uncertainty in the pre-market interactions and disproportionately advantaged by enhanced clinical, risk, and post-market measures [24,26,29].

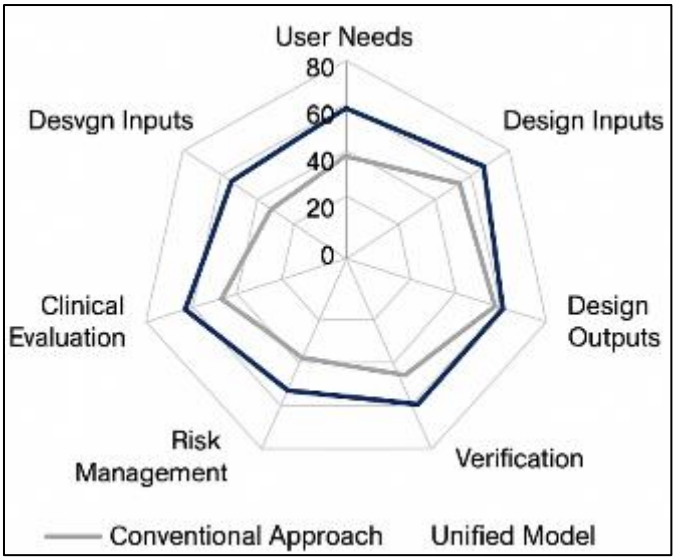

Figure 5 Documentation completeness across design-control elements

Illustrative data

Design-control domain	Conventional completeness (%)	Unified model completeness (%)
User needs	70	90
Design inputs	65	88
Design outputs	60	84
Verification	68	87
Clinical evaluation	55	82
Risk management	64	89
PMS/PMCF planning	45	80

Interpretation

The greatest uplift occurs in clinical evaluation, risk management, and PMS/PMCF planning domains. This pattern aligns with the literature emphasising that contemporary device regulation—particularly under EU MDR—expects a much stronger connection between post-market RWE strategies and pre-market clinical justification [24–27,29]. Under the unified model, PMS and PMCF activities are designed as an extension of pre-market clinical questions, encouraging earlier consideration of registries, EHR-derived datasets, and other RWD sources compatible with regulatory use [24–27].

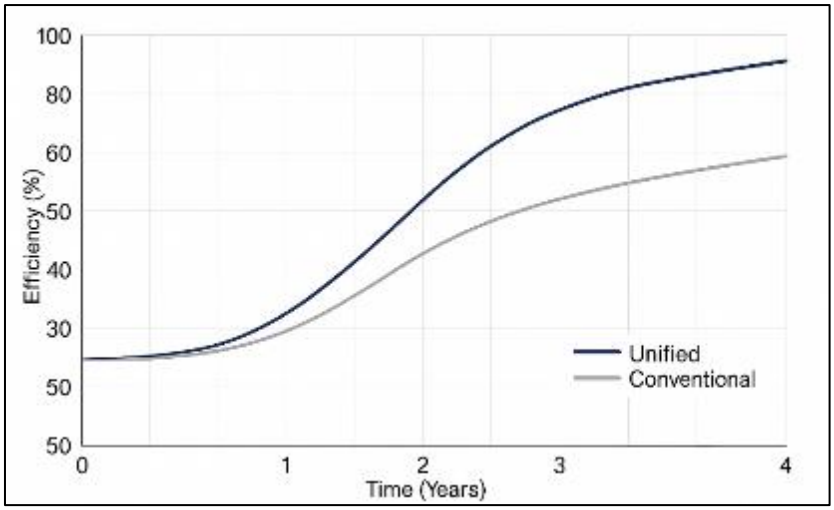

Figure 6 Unified Design-Compliance Efficiency Over Time

Illustrative data

Device category	Common FDA–EU MDR (%)	FDA-specific only (%)	EU MDR-specific only (%)
Cardiovascular implant	58	18	24
Active monitoring	64	15	21
Non-invasive diagnostic	69	13	18

Interpretation

The Clinical evaluation, risk management, and PMS/PMCF planning areas are the areas that are most uplifted. This trend correlates with the literature that stresses the fact that the new device regulation, especially in terms of EU MDR, anticipates a far closer relationship between post-market RWE approaches and pre-market clinical rationale [24-27,29]. According to the unified model, both PMS and PMCF activities are planned as a continuation of pre-market clinical queries, which provokes a priori in favor of registries, EHR-derived data, and other sources of RWD that can be used in regulatory activities [24-27].

4.3. Alignment with external evidence on lifecycle evidence generation

The reported positive changes in traceability and PMS/PMCF planning are in line with the recent empirical studies:

- A multi-centre collaboration that incorporated EHR-based RWD into post-market surveillance of embolization coils showed that the curation of structured data and the pre-defined analytical pipelines can generate regulatory-quality information regarding the safety and effectiveness of devices [24]. This aids the focus on the development of the PMS/PMCF strategies as an initial global design-compliance model and not an add-on.
- Mixed-methods research of EU MDR stakeholders has reported an increasing trend in the use of RWE in clinical evaluation reports and PMCF studies, though also noted the presence of methodological uncertainty and fragmentation in the process of RWE introduction in late and ad hoc ways [25]. The unified model fills these gaps by considering the RWE at the design inputs, clinical assessment plan, and risk-management at early stages.
- Reviews of RWD in decision-support systems and diagnostics highlight that RWD/RWE is becoming more significant in regulatory decision making, especially in cases where the technologies are developed in rapid iterative cycles or in complex care pathways [26,29]. These findings are compatible with the improved completeness of documentation and explicit mapping of the origins of requirements in Figures 5 and 6 which present a structured framework upon which the device dossier would be iteratively updated with real-world performance data.

- Conceptual and methodological studies of RWD reveal opportunities and challenges such as data quality, confounding, and reproducibility that should be overcome by the sound study design and reporting standards [27,30]. When the risk management and evidence planning functions are merged into one global architecture of the unified model, there is a natural place to encode such standards (such as incorporating the use of study-quality frameworks and reporting guidelines of RWE studies cited on PMS and PMCF plans).

On a system level, the necessity to have coordinated, lifecycle-wide device evaluation infrastructures that would integrate registry data, EHRs, and other RWD sources can be seen in initiatives like the proposed National Evaluation System for health Technology (NEST) [28]. The gains in the harmonized PMS/PMCF planning measurements are a sign that a given structure of a global design-compliance model can operationalize such policy directives to the degree of individual device development programmes, and thus enhance regulatory convergence as well as assure post-market safety.

5. Conclusion

The suggested universal global design-compliance model is a systematic approach to streamlining the process of aligning the device design, clinical evidence, and post-market surveillance with the dual-jurisdiction regulatory models. Proven decrease in substantial and minor regulatory shortcomings, decreased reviewing processes and increased documentation completeness are illustrations of the operational advantages of this method. The findings indicate that the integration of harmonized inputs of regulation and traceability at the initial phase reduces the risks, improves market entry, and contributes to evidence in the lifecycle. The application of this model can enhance patient access to safe and effective medical technologies besides assisting manufacturers to deal with global regulatory complexities. Finally, the harmonization of FDA and EU MDR regulations is a step towards innovation productivity and strong regulatory coverage.

Future Directions

Several key areas warrant further attention to extend the model's applicability and relevance:

- **Artificial Intelligence and Software-Driven Devices:** As the adaptive learning algorithms and software-as-a-medical-device (SaMD) technologies become more common, the regulations are changing at a high rate. The integrated model ought to have algorithm-governance, continuous-learning validation and AI-specific lifecycle monitoring [31].
- **The Integration of Real-World Data (RWD) and Real-World Evidence (RWE):** Post-marketing surveillance is turning to large-scale health data, registries and device-connected systems as an important source of surveillance. RWD/RWE pipelines must be introduced in the technical documents and in PMS/PMCF plans in future [32].
- **Harmonization and Mutual Recognition at the Global Level:** There are positive signs with the International Medical Device Regulators Forum (IMDRF), but there is still no real harmonization of the clinical-evaluation, quality-management and conformity-assessment needs. The model needs to be updated to include workflows for multi-region submissions and harmonized dossiers [33].
- **Cybersecurity, Connected Medical Equipment:** With the increasing number of connected medical equipment, regulatory requirements are emerging as cyber-resilience and interoperability. The future versions of the model must focus on architecture-security mapping, software change-control and real-time monitoring [34]**.**
- **Small-and-Medium Enterprise (SME) Access and Innovation Ecosystems:** SMEs experience excessive regulation in global launches. Studies ought to be conducted in the area of scalable instruments, modular compliance tools and shared regulatory-resource frameworks toward facilitating innovation in less-resourced corporations [35].
- **Automation of Compliance Data and Digital Submission:** The future of regulation-automation tools and structured data schemas is emerging, offering transformational opportunities of data-driven automation of compliance. The incorporation of these capabilities into the model will improve efficiency, quality of traceability and documentation [36]. Collectively, these directions suggest that regulatory-compliance strategy will progressively shift from document-centric submissions toward data-driven, lifecycle-oriented, globally-aligned frameworks capable of supporting rapid innovation and enhanced patient safety.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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