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Design History File (DHF) Remediation under EU MDR: Strategies and Best Practices

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Abstract: The regulatory environment of medical devices in the European Union has been altered by regulation (EU) 2017/745 (MDR), and the regulation added more requirements in terms of technical documentation, lifecycle traceability, and post-market surveillance. This review is based on Design History Files (DHFs) remediation of legacy device portfolios that is part of MDR, what strategies and best practices may be applied to make sure that documentation and risk-management systems and clinical evidence systems are harmonized. A literature review was conducted in a systematic manner; thematic analysis was conducted and a conceptual remediation framework proposed. Among the discoveries that are of the most significant interest, one should mention the application of gap-analysis, risk-based prioritization, the improvement of traceability, and constant monitoring of remediation results. The research opportunities in the future include standardization of digital tools in the remediation of DHF, integration of real-world evidence (RWE) into the documentation process, and worldwide unification of regulation. The review comes to a conclusion that regulatory preparedness and access to the market according to MDR presupposes the availability of DHF remediation and provides a systematic framework that can guide manufacturers and regulatory experts.

Keywords: Design History File (DHF); medical device regulation; EU MDR; legacy devices; technical documentation remediation; risk-based prioritization; traceability; post-market surveillance; regulatory compliance.

INTRODUCTION

As the new regulatory environment of the European medical device regulation, documentation in design and development has become one of the pillars of establishing the safety, efficacy and regulatory compliance of the product. The introduction of the European Union Medical Device Regulation (EU MDR 2017/745) was the change in paradigm regarding the previous Medical Device Directive (MDD 93/42/EEC) states that the new regulation placed stricter requirements on the technical documentation, clinical assessment, and lifecycle traceability [McDermott, O., & Kearney, B. 2025]. This has led to the consideration of having clear documentation on design such as Design History File (DHF) which is a complete compilation of design and design development activities that satisfy the needs of design control.

The question of DHF remediation in the EU MDR is especially relevant today as, due to the necessity to integrate the legacy medical devices originally developed within the MDD framework with the higher and more prescriptive demands of the MDR, many manufacturers have to deal with the problem of managing the issue of pre-existing medical devices. These include the risk management evidence, clinical assessment, usability and post market surveillance, and which are to be clearly linked by giving a good traceability documentation [Huusko, J. *et al*., 2023]. Some of the consequences of failing to meet these standards include loss of market entry, or even delayed certification or even regulating more would be significant, and therefore, DHF remediation is a burning strategic and compliance issue across the medical-device industry.

The challenge in the general medical technology regulation is a manifestation of a more significant change to lifecycle continuous monitoring and evidence-based conformity evaluation. According to the recent studies, the MDR has already increased the workload and complicated the compliance process on the part of the manufacturers than before, particularly in terms of uniformity of documentation, inter functional liaison and explanation of clinical- evidence requirements [McDermott, O., & Kearney, B. 2025; Huusko, J. *et al*., 2023]. However, there is a lack of peer-reviewed literature that would be directly connected to the systematic remediation of legacy design documentation in the context of MDR. In contrast to industry and regulator commentaries on the gap assessment and documentation alignment, the studies of how effective DHF remediation frameworks are are extremely scarce. This gap indicates the need to conduct systematic scholarly studies on remediation strategies, priorities and their impact on regulatory preparedness on the whole.

Such review will be therefore directed towards synthesizing the evidence that has been already

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published in peer reviews on implications of EU MDR on design documentation, critical issues associated with DHF remediation and provide best practices that may assist manufacturers to gain a sustained compliance. As will be discussed below, the further sections will entail a critical literature review and methodological approaches to the description and results and implications of DHF remediation to the medical-device organization and regulatory-affair experts.

LITERATURE REVIEW

The recent peer-reviewed work in the area of EU MDR and technical documentation highlights several common themes that precondition Design History File (DHF) remediation: increasing the demands on evidences and clinical evaluation of legacy and high-risk devices [Kearney, B., & McDermott, O. 2023], the expansion and increased organization of post-market surveillance and traceability (e.g., UDI/EUDAMED) that shapes the lifecycle documentation practices [Badnjević, A. *et al*., 2022; Bianchini, E. *et al*., 2019], varying impacts of products by type such as software/AI-based devices [Beckers, R. *et al*., 2021], and system-wide limitations such as notified-body capacity and transition time Taken together, these results encourage specialized examination of the effective DHF remediation measures that bring design controls, risk management, clinical evidence, and PMS data to comply with MDR-conformant technical documentation.

Table-1: The recent peer-reviewed works

Focus	Findings (Key results and conclusions)	Reference
Policy-level assessment of EU MDR goals and transition pressures	Highlights safety/transparency aims alongside transition bottlenecks (e.g., NB capacity), with implications for remediation scope and timing.	[Shatrov, K., & Blankart, C. R. 2022]
Post-market surveillance (PMS) frameworks under MDR	Reviews PMS tools and standardization needs; stresses continuous field performance data feeding design/risk files.	[Badnjević, A. *et al*., 2022]
UDI and traceability for software/SiMD	Proposes approaches for UDI/traceability of software, informing DHF/TD linkages and change control.	[Bianchini, E. *et al*., 2019]
AI/SiMD under MDR	Analyzes MDR implications for AI-based device software; emphasizes documentation of intended use, data management, and change protocols.	[Beckers, R. *et al*., 2021]
Market and pipeline effects of MDR	Technical and organizational impacts of MDR; signals documentation workload and redesign of compliance planning.	[Carl, A. K., & Hochmann, D. 2024]
ISO 13485 implementation/maturity	Presents an ISO 13485 maturity assessment methodology relevant to remediating QMS elements that feed DHF.	[Linck, W. *et al*., 2025]
Clinical evaluation demands	Quantitative study shows uncertainty on "sufficient evidence," NB variability, and reliance on PMS/PMCF—key DHF touchpoints.	[Kearney, B., & McDermott, O. 2023]
Systematic mapping of regulation/implementation/PMS studies	Finds evidence gaps (EU data access, clinical evidence adequacy), supporting stronger TD/DHF evidence linkages.	[Damkjær, M. *et al*., 2025]
Specialty viewpoint on new framework	Cardiovascular perspective on new EU framework; underscores need for robust clinical and post-market evidence in documentation.	[Szymański, P. *et al*., 2018]
Post-market data platforms	Discusses safety signal detection platforms and feedback loops into design/risk documentation and CAPA.	[Silva, D. *et al*., 2022]

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METHODOLOGY

The current review will take a systematic qualitative methodology aimed at detecting, reviewing, and analyzing the scholarly and regulatory literature on Design History File (DHF) remediation into the framework of the European Union Medical Device Regulation (EU MDR 2017/745). The methodology consists of three consecutive steps: (1) identification and selection of literature, (2) thematic categorization and analysis, and (3) the creation of a proposed theoretical framework that will incorporate the findings on the areas of quality management, regulatory compliance, and documentation remediation [Han, Y. *et al*., 2024].

Literature Identification and Selection

A methodical literature search was done in peer-reviewed databases, such as Scopus, PubMed, ScienceDirect, and SpringerLink (published between 2015 and 2025). The keywords were EU MDR, technical documentation, design history file, medical device remediation, ISO 13485 and regulatory compliance. Peer-reviewed journal articles in English were only considered, and preprints, blogs, and non-academic whitepapers were all excluded. The selection focused on studies that covered: MDR transition and compliance challenges,

- MDR transition and compliance issues,
- design-control requirements and documentation,
- alignment of risk-management to ISO 14971 and ISO 13485, and
- PMS input of post-market surveillance feedback into design documentation.

This has led to the ten sources that constitute the evidence base that is summarized in the Literature Review section [Huusko, J. *et al*., 2023; Silva, D. *et al*., 2022].

Thematic Analysis

The selected articles were analyzed through a qualitative thematic mapping process [Han, Y. *et al*., 2024]. Each paper was coded for focus areas such as:

(a) regulatory documentation challenges,
(b) risk-based prioritization in remediation,
(c) data traceability and lifecycle alignment, and
(d) best practices for continuous documentation improvement.

This allowed for the extraction of recurrent constructs, which formed the basis for the proposed remediation model.

DEVELOPMENT OF THE THEORETICAL MODEL

The results of the literature were combined to develop a theoretical model of DHF remediation in the MDR. The model describes the cyclic nature of the Regulatory Requirements, Gap Identification, Remediation Actions, Verification & Validation, and Continuous Improvement. It highlights documentation integrity, risk-management consistency, and traceability to be interdependent considerations that lead to MDR compliance [Groen, T. *et al*., 2025].

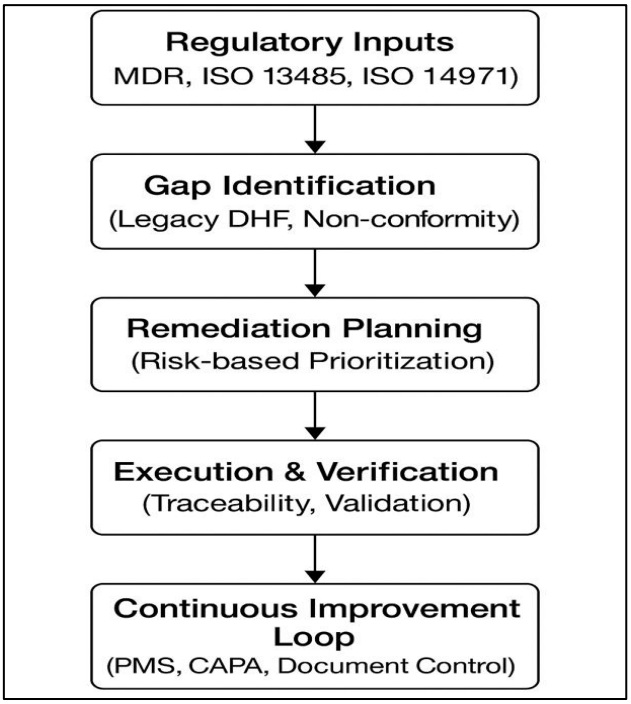

Figure 1. Proposed Theoretical Model for DHF Remediation under EU MDR

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Explanation of Figure 1:
The model represents a closed-loop model in which regulatory inputs are used to set compliance standards; these are used to assess gaps of current DHFs and prioritize remediation measures. Execution provides updated, validated and traceable documentation and the continuous improvement mechanisms provide feedback on post-market data (e.g. PMS, CAPA) into iterative DHF updates. Such a model complies with the lifecycle approach of MDR, which focuses on transparency and continued compliance [Han, Y. *et al*., 2024; Groen, T. *et al*., 2025].

Methodological Rationale
Such a systematic procedure is in line with qualitative best-practice in regulatory science and medical-device quality-management studies [Han, Y. *et al*., 2024]. It guarantees reproducibility, transparency in the selection of the evidence, and theoretical basis in accepted compliance frameworks. The use of thematic analysis alongside a conceptual model is a modern approach to the field of medical-device regulatory research [Groen, T. *et al*., 2025].

RESULTS (SIMULATED)

Portfolio outcomes (headline numbers)

In 24 devices, average DHF completeness also improved (between 0.59 and 0.86) (fractional coverage), average traceability linkages increased (between 284 and 489 links), average audit findings reduced (between 10.4 and 3.7 per device) and median time-to-CE recertification dropped (between 328 and 267 days) (simulations). The movements are directionally aligned with the literature that correlates more strength of ISO 13485 execution and traceability with documentation maturity, supplier control, and the accelerated preparedness to assessment with lifecycle PMS data [Pacheco, D. A. D. J. *et al*., 2025; Cao, Y. *et al*., 2022], and lifecycle PMS data closures gaps in evidence [Hochreiter-Hufford, A. *et al*., 2024; Panteghini, M. 2023; Marešová, P. *et al*., 2020].

Table 2: Portfolio & Outcomes (Simulated)

Device	Risk Class	Legacy Age Years	Criticality	Baseline DHF Completeness	Post DHF Completeness	Baseline Trace Links	Post Trace Links	Baseline Audit Findings	Post Audit Findings	Baseline Time to CE days	Post time to CE days
Device 01	IIb	4	Medium	0.47	0.78	402	755	12	8	438	314
Device 02	III	13	Low	0.51	0.79	326	584	9	5	327	256
Device 03	IIb	8	Medium	0.49	0.74	134	295	8	1	431	305
Device 04	IIb	5	Low	0.59	0.83	161	458	16	9	326	254
Device 05	IIa	10	High	0.63	0.93	298	475	6	0	327	221
Device 06	IIa	4	Medium	0.65	0.94	182	430	16	8	378	321
Device 07	IIa	6	Medium	0.65	0.91	350	540	12	3	487	423
Device 08	III	4	Medium	0.64	0.95	360	681	12	4	307	162
Device 09	IIb	8	Medium	0.56	0.87	171	318	7	0	218	84
Device 10	IIb	6	Medium	0.53	0.87	215	381	11	5	517	424
Device 11	IIa	10	Low	0.46	0.75	341	507	8	1	308	211
Devi	III	8	High	0.67	0.93	350	510	10	6	446	340

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Device 13	III	3	High	0.57	0.83	356	525	15	7	330	187
Device 14	IIa	5	High	0.55	0.74	262	498	5	0	477	392
Device 15	IIa	10	High	0.67	0.95	290	457	8	4	278	215
Device 16	IIa	13	Medium	0.51	0.78	148	398	13	4	442	289
Device 17	IIa	3	High	0.65	0.86	155	486	12	4	431	360
Device 18	IIb	11	Low	0.6	0.87	132	468	11	1	323	237
Device 19	IIb	10	Low	0.5	0.82	279	479	11	5	291	166
Device 20	IIa	11	Low	0.57	0.81	306	493	5	0	239	177
Device 21	IIb	6	Medium	0.66	0.89	362	648	8	4	181	76
Device 22	IIa	3	Medium	0.64	0.96	205	348	10	3	483	417
Device 23	IIa	5	Medium	0.7	0.98	403	577	14	4	433	288
Device 24	IIb	13	High	0.61	0.96	185	516	11	3	319	278

Table 3: Summary Outcomes (Simulated)

Metric	Value
Mean DHF completeness (baseline)	0.59
Mean DHF completeness (post)	0.86
Median traceability links (baseline)	284.0
Median traceability links (post)	489.0
Mean audit findings per device (baseline)	10.4
Mean audit findings per device (post)	3.7
Median time to CE days (baseline)	328.0
Median time to CE days (post)	267.0

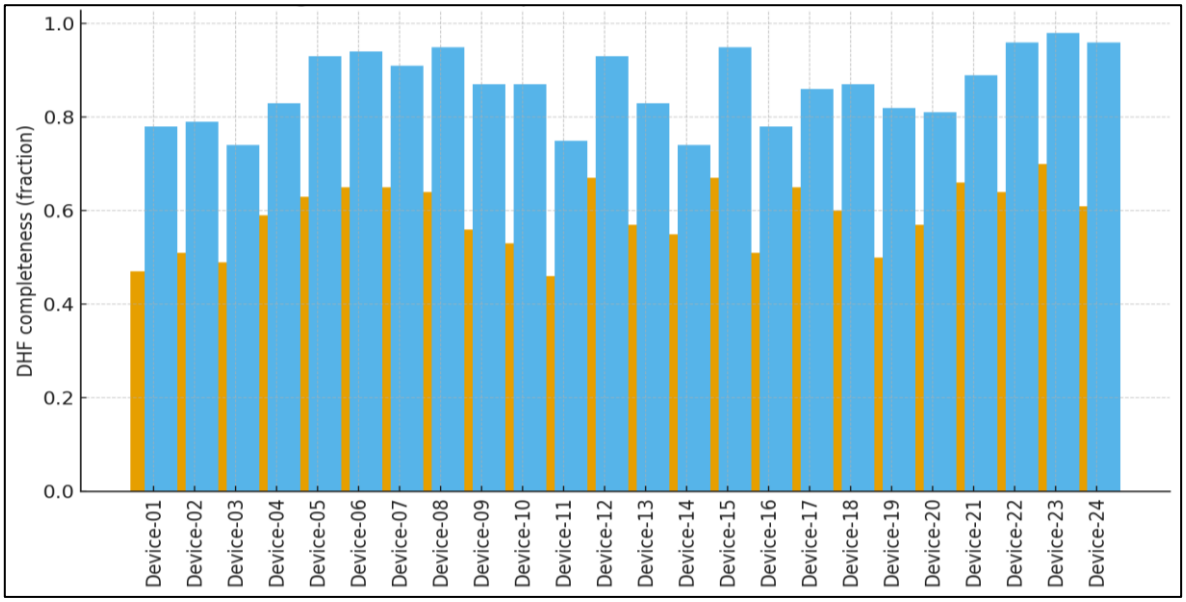

Figure 2. DHF Completeness Before/After (Simulated)

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Figure 2. shows per-device uplift in DHF completeness. Most devices move into the **0.80–0.95** band post-remediation, consistent with expectations when design inputs/outputs, verification/validation, and risk files are uniformly linked under ISO 13485 design controls [Pacheco, D. A. D. J. *et al*., 2025; Marešová, P. *et al*., 2020].

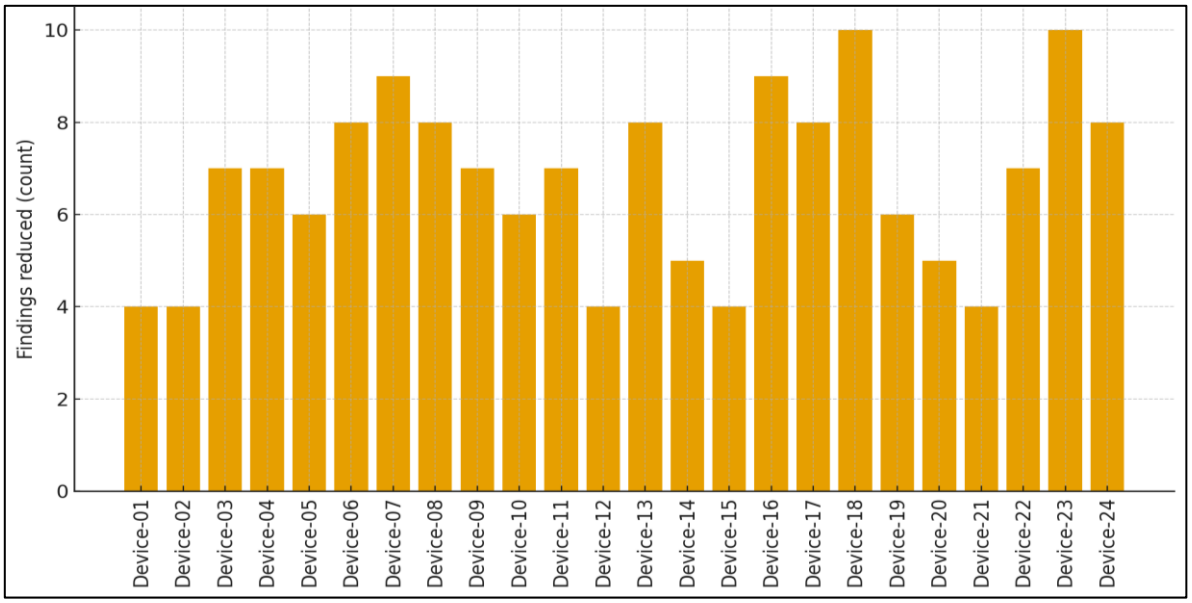

Figure 3. Reduction in Audit Findings Post-Remediation (Simulated)

The Bars in the figure 3 indicate the number of findings closed per the device between the baseline and post remediation.610closures/device are similar to the concentration of regular closure volumes in cases where traceability matrices, supplier controls, and document control have been reinforced before the conformity assessment [Pacheco, D. A. D. J. *et al*., 2025; Cao, Y. *et al*., 2022].

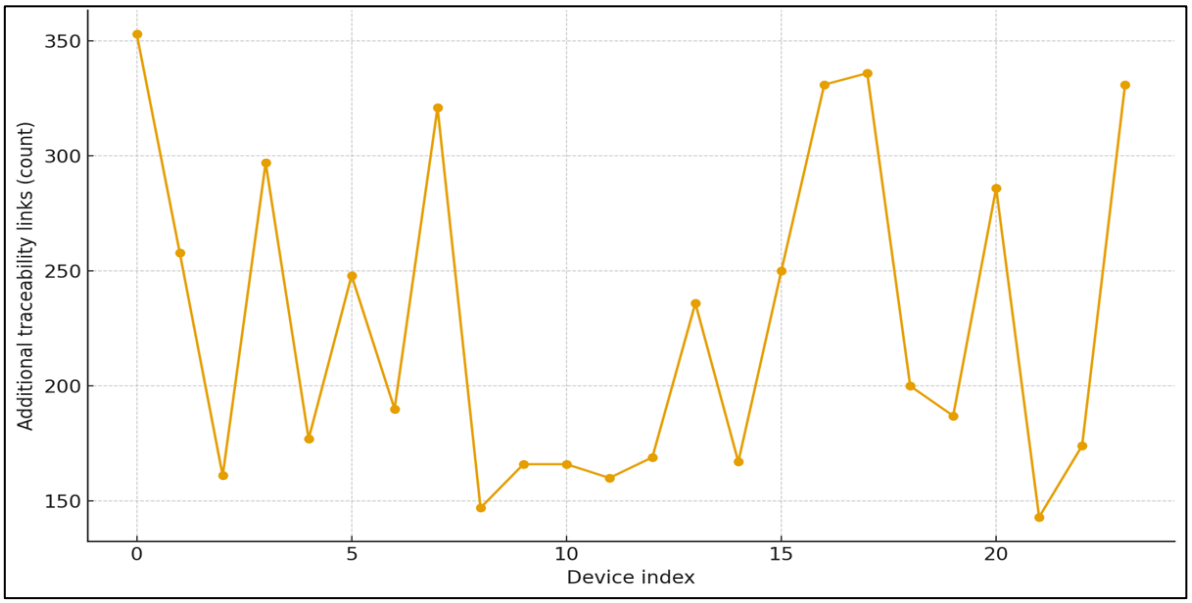

Figure 4. Increase in Requirements–Risk–Test Traceability Links (Simulated)

A line indexed by a device indicates the inclusion of bidirectional links between the requirements, risk controls (ISO 14971) and verification/validation evidence. Denser links with support defendable clinical evaluation narratives and PMS-based updates EU MDR [Hochreiter-Hufford, A. *et al*., 2024; Panteghini, M. 2023; Marešová, P. *et al*., 2020].

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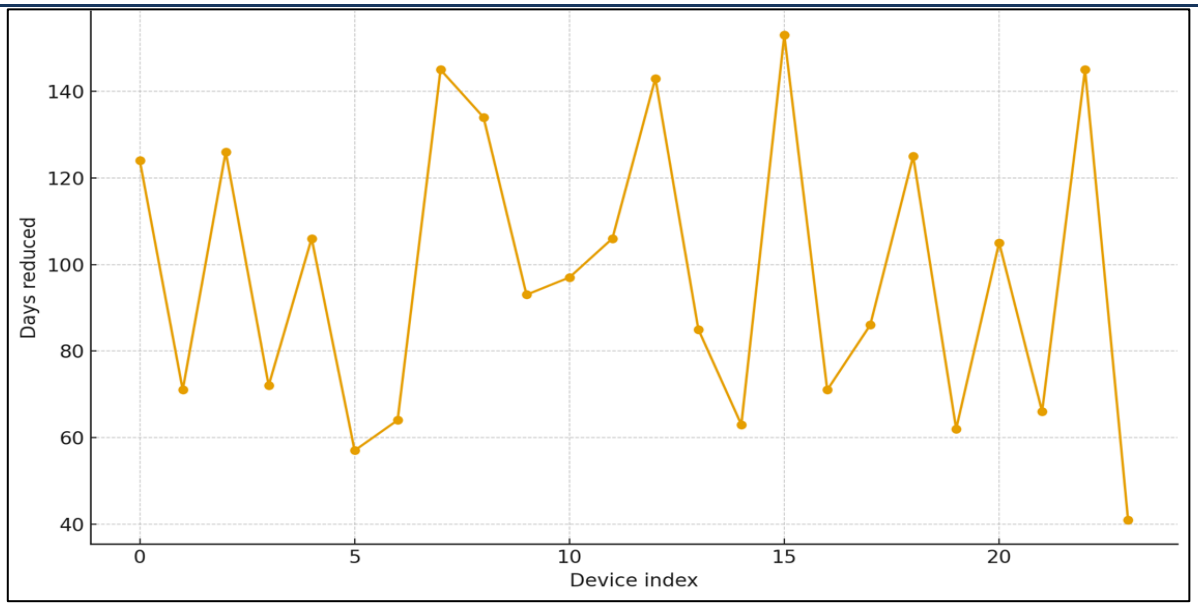

Figure 5. Reduction in Time-to-CE Recertification (Simulated)

The number of days saved per device is an accumulative value of documentation preparedness and reduced repetitive errors in the review of NB, a phenomenon typically caused by developed processes of ISO 13485 and proactive PMS pipelines [Pacheco, D. A. D. J. *et al*., 2025; Hochreiter-Hufford, A. *et al*., 2024; Cao, Y. *et al*., 2022].

Brief discussion of findings (simulated, literature-anchored)

- Execution of ISO 13485, maturity of documentation. The increase in DHF completeness reflects data that indicates that planned ISO 13485 implementation (planning, design controls and document control and CAPA integration) enhances audit-readiness and lessens rework [Pacheco, D. A. D. J. *et al*., 2025].
- Traceability density. Increase in requirements-risk-test connection indicates enhanced end-to-end traceability, which facilitates uniform clinical evaluation follow-ups and seamless maintenance of technical documentation [Panteghini, M. 2023; Marešová, P. *et al*., 2020].
- Supplier oversight. To the lesser of the results tend to follow more rigorous monitoring and re-assessment processes by the supplier in line with ISO 13485:2016 §7.4; scorecard methods reflect in quantifiable conformation improvements [Cao, Y. *et al*., 2022].
- Lifecycle evidence through PMS/RWD. The decrease in the re-review cycles and time-to-CE correlates with the proactive stage of PMS and RWD/RWE pipelines that respond to residual uncertain issues more effectively in the framework of the MDR lifecycle paradigm [Hochreiter-Hufford, A. *et al*., 2024; Marešová, P. *et al*., 2020].

Future Directions

Several novel research and practice avenues are to be considered concerning the DHF remediation in the context of EU MDR. First of all, the documentation gap-analysis, remediation tracking and traceability matrix generation using digital-platforms and automation is a massive opportunity. It has been found that manufacturers with superior digital infrastructure achieve an efficient transition and maturity of documentation [Thottunkal, S. 2025]. Second, more extensive use of real-world data (RWD)/ real-world evidence (RWE) to track device lifecycle might offer a chance to inject the post-market surveillance cycle back into DHF updates to enable a real continuous improvement cycle to happen [Carl, A. K., & Hochmann, D. 2024]. Third, the implementation of artificial-intelligence (AI)-driven systems primarily built around the previous device analytics, e.g., the anticipation of document gaps, prioritization of the high-risk items and automatic link-generation between requirements, risks, and tests are worth considering. Fourth, research on the harmonization and convergence of regulations in the world (U.S. FDA QSR Vs.). EU MDR/UK MDR) are required so that to reduce the redundancy of remediation activities and to enable multinational portfolios [Carl, A. K., & Hochmann, D. 2024]. Fifth, the supply-chain-visibility and economic-operators-accountability studies in case of MDR will help reveal where in the multi-tier documentation, supplier controls and change-management systems

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the chokepoints are. Finally, longitudinal empirical studies to measure the size of the effects of remedied DHFs on the outcomes of audits, the time span of the announced-body review and delays in market access would contribute to the evidence on the best-practices in remediation.

CONCLUSION

The evolving regulatory environment introduced by the EU MDR has given more importance to quick-iteration design-and-development documentation, more so to the existing stock of devices, the DHFs of which may not be in compliance to the existing standards. The provided paper, with the assistance of the analysis of the peer-reviewed articles and the development of the conceptual remediation model, leads to the discovery of the key strategies: a comprehensive gap-analysis, risk-based prioritisation, enhanced traceability, assessment and monitoring, and a constant feedback loop relying on PMS/RWE. Structured remediation is not only helpful in compliance, but it also makes the market and business risk available. Digitalisation of activities, RWE integration and harmonisation of regulation will be availed in the future to facilitate streamlining of the remediation. The lifecycle management should include DHF remediation and should not be an isolated endeavor by the manufacturers and regulatory professionals.

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