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Case Study

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From Reviewer to Consultant: Transforming Regulatory Affairs in the MDR Transition

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Abstract

The transition from the Medical Device Directive (MDD) to the Medical Device Regulation (MDR) introduced stringent requirements for clinical evidence, device reclassifications, and more robust post-market surveillance measures, creating significant challenges for the medical technology industry. The compliance of a portfolio exceeding 2,500 products within Dräger's Hospital Consumables and Accessories (HCA) Business Unit was managed, with MDR certification achieved prior to the regulatory deadline of May 26, 2024.

The study examines a methodological shift in Regulatory Affairs (RA) from a post-development review function to a proactive consultancy role. By optimizing processes, driving cultural change, and embedding RA expertise early in the R&D V-Model alongside Product Management (PM), this methodology streamlined development timelines, reduced costs, and prioritized resources for critical markets. The result was enhanced operational efficiency and adaptability on a global scale.

Keywords: MDR; Regulatory Affairs; Change Management; Medical Devices; Compliance; TRIZ; QSR; QMSR

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1. Introduction

The European Union's Medical Device Regulation (MDR, EU 2017/745), enacted on May 5, 2017, (1) replaced the Medical Device Directive (MDD, 93/42/EEC), (2) marking a significant shift in medical evice oversight. Designed to enhance patient safety and product quality, the MDR introduced stricter clinical evidence requirements, redefined device classifications based on risk profiles, and mandated comprehensive post-market surveillance. (3) These changes challenged manufacturers industry-wide, with audits indicating that approximately 60% of small and medium enterprises faced difficulties due to insufficient clinical datasets. At Drägerwerk AG & Co. KGaA ,(4) the transition of a portfolio exceeding 2,500 products within the Hospital Consumables and Accessories (HCA) Business Unit was coordinated, supported by regulatory oversight - including neonatal respiratory masks, ventilator accessories, and anesthesia consumables - achieving MDR compliance well ahead of the extended deadline of May 26, 2024. Although the MDR was often viewed as an operational challenge, the process adjustment facilitated the development of regulatory workflows and enhanced cross-departmental collaboration. Drawing on 17 years of experience, including a tenure as a Lead Auditor at TÜV Süd and contributions to the patented technology US-9566427-B2 - a patented electrostimulation device enhancing retinal treatment - this paper details how RA was transformed into a strategic enabler, offering a replicable model for the MedTech sector. (5)

2. Case description

Addressing the MDR's challenges at Dräger required a comprehensive reevaluation of regulatory workflows, combining structured optimization with insights gained from global auditing experience. The author's tenure as a Lead Auditor at TÜV Süd involved assessing compliance with MDD, MDR, Medical Device Single Audit Program (MDSAP), ISO 13485 and ISO 9001 standards across regions such as the United States, (6-7) China, and Europe. Experience from the auditing roles supported the identification of gaps - such as incomplete clinical datasets or delayed quality system updates - and implementing targeted solutions. At Dräger's Business Unit HCA, operational systems were aligned with ISO 13485:2016, enhanced by the application of the Theory of Inventive Problem Solving (TRIZ). (8) TRIZ provides a structured approach to address MDR-related challenges, such as balancing enhanced clinical evidence demands with accelerated project timelines. Preliminary estimates suggest transition times were reduced by approximately 30 %,

based on internal project reviews, though detailed validation is pending.

A key element of the process adjustment was a shift in the Regulatory Affairs (RA) role, supported by a change management initiative. Under the MDD, RA staff operated as reactive reviewers, evaluating compliance only after R&D completed product designs - a process prone to late-stage revisions. The MDR necessitated a proactive consultancy model, integrating RA into the R&D V-Model, a development framework emphasizing verification and validation from the concept phase.

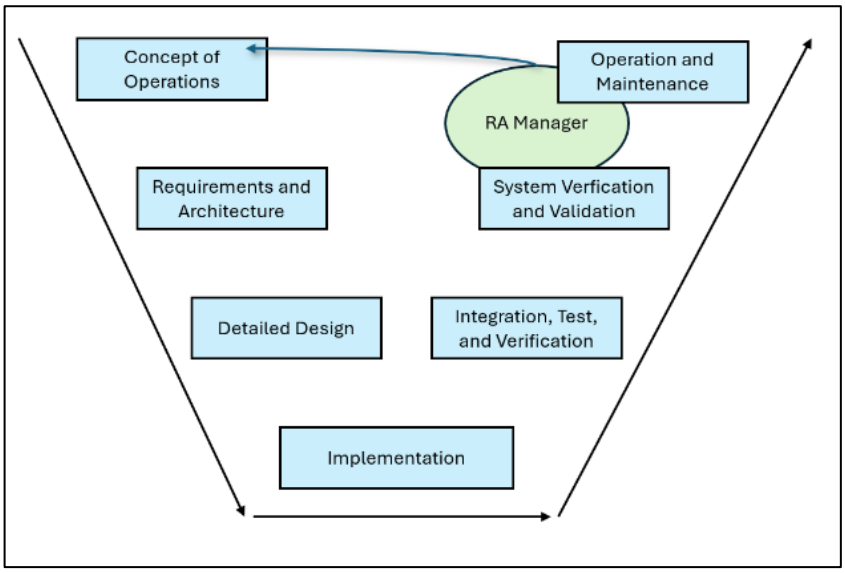

Figure 1. Shift from classical RA Management to new Involvement

This required a cultural shift among RA personnel, who were retrained through a series of two-day cross-functional workshops. These sessions conducted quarterly over 18 months, covered MDR-specific topics such as clinical evaluation methodologies, risk management per ISO 14971, (9) and post-market surveillance planning. Regulatory Affairs (RA) personnel were trained to collaborate with R&D engineers on design inputs - e.g., specifying clinical trial parameters for neonatal respiratory masks - and with PM teams to assess market-specific regulatory needs.

Initially, R&D and Product Management (PM) teams showed reluctance toward early involvement, which was associated with delays in ideation. Through iterative workshops and the establishment of shared KPIs (e.g. reduced revision cycles), these teams adapted. RA consultants began conducting joint feasibility reviews with PM, identifying high-priority markets (e.g., U.S., EU) and deprioritizing less critical regions (e.g., low-volume markets with high regulatory overhead). This streamlined submission packages, cutting redundant documentation by an estimated 20 % and aligning development with strategic goals from the outset.

The MDR transition exposed systemic industry challenges: clinical data deficiencies affecting 60% of SMEs, Notified Body review delays averaging 18 months, (10) and heightened quality expectations. Dräger's adjusted processes addressed these challenges. Early RA consultancy within the V-Model enabled proactive evidence generation - for neonatal masks (tested for leakage rates below 5%) and ventilator accessories (validated for flow rates within ±2% of specs) - reducing reliance on prolonged Notified Body assessments. As a result, over 2,500 HCA products met MDR compliance by May 2024, with certification completed for items under the extension period.

This approach delivered enterprise-wide benefits. R&D and PM, initially skeptical, now endorse RA's early role, which aligns projects with regulatory and market priorities, cutting development costs and focusing efforts on high-impact regions like the U.S. and EU. An analysis indicated that 20% of over 200 registered countries accounted for 80% of HCA revenue (Pareto principle), supporting resource allocation adjustments. Between 2022 and 2024, U.S. 510(k) submissions under regulatory oversight increased by 300%, achieving a 100% FDA acceptance rate, as the focus was readjusted to just necessary standards. Globally, the "Empowered Local RA" initiative standardized procedures, slashing ASEAN approval times for over 700 products from 255 to 56 days. RA evolved into strategic partners, collaborating with R&D on design validation (e.g., neonatal mask ergonomics) and with PM on market entry strategies, enhancing Dräger's operational agility and competitiveness.

3. Discussion

The MDR transition highlighted inefficiencies in traditional compliance models - data silos and reactive workflows - that contributed to operational challenges. At Dräger, TRIZ-based process redesign and RA's shift to consultancy mitigated these by embedding regulatory foresight into development. This required R&D and PM to adapt, a transition facilitated by change management that fostered a collaborative mindsetThe early integration of RA into the V-Model has supported Dräger's operational adjustments,

influencing development timelines and market strategies. Limitations include the need for precise time metrics - e.g., exact revision cycle reductions - though qualitative feedback from R&D and PM confirms the approach's impact.

4. Application to the U.S. QSR-QMSR Adaptation in February 2026

The transformative RA model developed during Dräger's MDR transition offers a blueprint for U.S. medical device manufacturers preparing for the FDA's Quality system regulation (QSR) to the new Quality Management System Regulation (QMSR) transition, (11-12) effective February 2, 2026, which integrates ISO 13485:2016 standards into the existing Quality System Regulation (QSR). This shift demands a proactive RA consultancy approach to harmonize design controls, risk management, and post-market surveillance across global markets, much like the MDR required. By embedding RA early in the R&D V-Model and decentralizing compliance through initiatives like Empowered Local RA, U.S. firms can prioritize high-impact products (e.g., ventilators and consumables), reduce redundant documentation by 20–30%, and accelerate 510(k) submissions—potentially cutting timelines by 8x, as demonstrated at Dräger. For many U.S. companies facing QMSR's unified ISO 13485 requirements, this methodology enables seamless alignment with EU MDR, minimizing costs (estimated 20% savings via MDSAP) and ensuring timely market entry, fostering innovation in the $200B MedTech sector while maintaining patient safety.

5. Conclusion

The MDR transition within Dräger's HCA Business Unit adjusted regulatory compliance processes, supported by methodological innovations and the shift of RA to consultancy roles. By embedding RA early in the V-Model with PM and R&D collaboration new products could be released earlier and more cost effective. In Lifecycle management over 2,500 products met the standards ahead of schedule, bolstering safety, efficiency, and market competitiveness. This approach, supported by coordinated oversight, provides the MedTech industry with a model for replication for streamlined processes, proactive regulatory engagement, and cross-departmental alignment that can enhance global standards and operational performance. This model is particularly applicable to the upcoming U.S. FDA transition from QSR to QMSR in February 2026, where early RA integration can facilitate ISO 13485 alignment and minimize disruptions in global compliance.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article. The views and statements expressed in this article are solely those of the author and do not represent the official position or opinions of Drägerwerk AG & Co. KGaA.

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