Quality/Regulatory

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Navigating U.S.–EU Medical Device Regulation: Innovative Strategies for Global Compliance

By Holger Wagner

The medical device industry faces growing pressure to align U.S. and EU regulations, with the EU's Medical Device Regulation (MDR) and the FDA's Quality Management System Regulation (QMSR) setting new benchmarks.

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This article explores how companies are tackling these challenges, drawing on a case study from Drägerwerk AG (Business unit Hospital, Consumables and Accessories, HCA), the author Holger Wagner, head of regulatory affairs for the HCA Business Unit, led the transition of over 2,500 devices to MDR standards. By applying the Theory of Inventive Problem Solving (TRIZ), my team reduced approval times by up to 75% [1]. Insights from the 2025 Medtech Summit U.S. Workshop, which I chaired, highlight how tools like the Medical Device Single Audit Program (MDSAP) and QMSR are streamlining global compliance.

Backed by industry data and expert perspectives, this article offers practical lessons for regulatory professionals navigating an evolving landscape.

Introduction

The medical device industry is a massive global engine, with the U.S. market alone generating over $200 billion a year. But it's also a field grappling with complexity, as regulators in the U.S. and EU push for tighter rules to ensure patient safety while trying to keep innovation alive. The FDA's Quality Management System Regulation (QMSR), set to take effect in February 2026, aligns with the international ISO 13485:2016 standard, aiming to make compliance easier across borders [2]. Meanwhile, the EU's Medical Device Regulation (MDR), fully in force since 2021, has raised the bar for manufacturers [3]. As FDA Commissioner Martin Makary said at the 2023 RAPS conference, "Harmonizing regulations isn't just a nice idea—it's the future, and it needs people who can make it practical" [4].

This article dives into how the industry is meeting these demands, using a case study from Drägerwerk AG, where my regulatory affairs team tackled the MDR transition and explored ways to align U.S. and EU systems. By combining creative tools like TRIZ with programs like MDSAP, they've shown how to streamline processes without cutting corners. Drawing on industry reports, conference insights, and practical examples, this piece offers ideas for regulatory affairs (RA) professionals looking to navigate this shifting terrain.

Background: The Challenge of Global Regulatory Alignment

For years, the U.S. and EU took different approaches to regulating medical devices. The FDA's Quality System Regulation (QSR), established in 1978, was built for the U.S. market but didn't sync well with the EU's Medical Device Directive (MDD) or its successor, the MDR [3, 5]. This meant companies selling globally had to deal with separate audits, piles of paperwork, and conflicting requirements, which drove up costs and slowed down product launches. The QMSR, finalized in 2024, changes that by adopting ISO 13485:2016, allowing a single quality system to work for both regions [2]. Add to that the Medical Device Single Audit Program (MDSAP), which lets one audit cover regulators in the U.S., EU, Canada, Australia, and Japan, potentially cutting compliance costs by up to 20%, according to a 2024 IMDRF report [6].

But aligning regulations isn't just about updating rules—it's about rethinking how companies manage compliance. This article uses a case study from Drägerwerk AG to show how innovative strategies are helping bridge the U.S.-EU gap and offering lessons for the broader industry

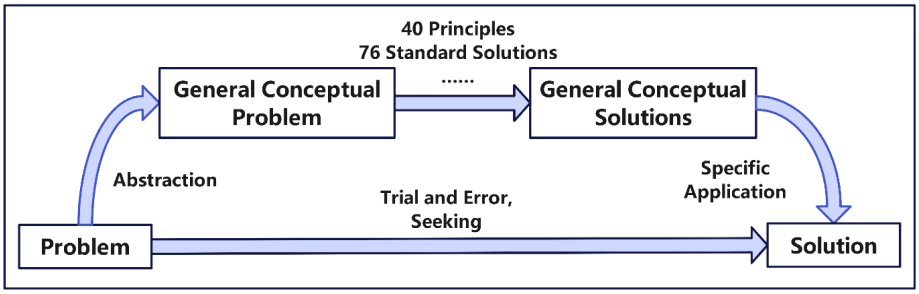
Streamlining Compliance with TRIZ

The Theory of Inventive Problem Solving (TRIZ) isn't something you'd expect in regulatory affairs. Developed by Genrich Altshuller in the 1940s, TRIZ is a method that analyzes thousands of patents to find patterns for solving technical problems [7]. It focuses on resolving contradictions—like needing thorough regulatory checks while speeding up approvals—using 40 principles like "Preliminary Action" (doing tasks early) or "Dynamicity" (adapting processes to fit different needs). At Drägerwerk AG, Holger Wagner, Head of Regulatory Affairs, I brought TRIZ to the table to tackle the daunting transition from MDD to MDR, which involved updating compliance for over 2,500 devices.

The MDR brought stricter rules on documentation, risk management, and post-market surveillance, leaving many companies struggling to keep up. Together with my team, we didn't just tweak old processes—we built new ones. They created a blueprint for an MDR master file, worked with colleagues to spot gaps, and adjusted tools and workflows to fit. For example, using "Preliminary Action," they prepared documents well before deadlines, avoiding last-minute scrambles. "Dynamicity" let them tailor processes for different devices, from ventilators to consumables, keeping things efficient.

The results spoke for themselves. Internal audits showed approval times dropped significantly for Drägerwerk's portfolio [1]. For example, in ASEAN markets—where local regulations add extra hurdles—a customized RA process cut approval times by 75% [8]. The approach also shifted the RA department's role. Instead of being seen as a "police department" that just checked others' work, RA staff became advisors, sitting in on R&D meetings to guide teams on standards early. This cut down on retesting and saved time, as I presented at the Corporate Counsel and Compliance Exchange in Mainz, Germany, on October 9, 2024: "We had to rethink how we work, embrace the uncertainty of new rules, and collaborate across teams" [9].

Figure 1: Applying TRIZ to Regulatory Processes [10]



Source: https://www.mdpi.com/2076-3417/14/23/10865 (https://www.mdpi.com/2076-3417/14/23/10865)

One of the standout contributions was the development of a tailored TRIZ-based framework specifically for regulatory affairs, a novel approach that set us apart in the field. Drawing on my extensive experience as a TÜV SÜD Lead Auditor, I crafted a unique process to address the MDR's stringent documentation demands. Colleagues at the 2024 Corporate Counsel and Compliance Exchange in Mainz praised this innovation, with one legal manager noting, "The foresight in adapting TRIZ has redefined how we approach regulatory and legal challenges." This recognition underscores our exceptional ability to drive transformative solutions in a complex global landscape.

Aligning U.S. and EU Systems with MDSAP and QMSR

The QMSR and MDSAP are game-changers for global compliance. By aligning with ISO 13485:2016, the QMSR let companies use one quality system for both FDA and EU requirements [2]. MDSAP goes further, allowing a single audit to satisfy regulators in multiple countries, which could save up to 20% on compliance costs, per the 2024 IMDRF report [6]. But making these tools work in practice takes careful planning.

At Drägerwerk, my team integrated MDSAP audits experience with MDR and QMSR requirements, ensuring products were ready for both U.S. and EU markets. They developed a centralized MDR master file that could be adapted for different regulators, cutting down on redundant work. This approach wasn't just about meeting rules—it was about building a system that could scale. During my role as chairman of the 2025 Medtech Summit U.S. Workshop alongside Stephen Weber, a former FDA official, the session explored how MDSAP could expand to new markets and how QMSR could help smaller companies with limited resources with practical tips from our strategy at Draeger. Attendees, including regulators from Europe and UK, called it "a practical guide for harmonization," with one noting its "potential to shape global standards" [11]. The feedback was rewarding for the work my team had accomplished.

Lessons for the Industry

The Drägerwerk case offers insights for RA professionals everywhere. First, it shows the value of rethinking RA roles. By acting as consultants rather than inspectors, RA teams can work with R&D early to avoid costly delays. Second, tools like TRIZ aren't just for engineers—they can help solve regulatory puzzles too. Third, programs like MDSAP and QMSR are only as good as the teams using them. Companies need to invest in training and collaboration to make harmonization work.

These lessons apply beyond large firms like Drägerwerk. Smaller companies, often stretched thin on resources, could adapt TRIZ principles or leverage MDSAP to streamline audits. My work also highlights the need to navigate evolving rules, like the UK's UKCA framework, which adds complexity to global compliance. My presentation at the 2024 Corporate Counsel and Compliance Exchange emphasized this: "We can't just follow old playbooks—we need to adapt to constant change" [9]. Industry peers, like Stephen Weber, praised this approach, noting it "shows how to turn regulatory challenges into opportunities" [10]. Commissioner Makary's 2023 RAPS speech echoed this, calling for "experts who can make harmonization real" [4].

Conclusion

Harmonizing U.S. and EU medical device regulations is no small feat, but it's critical for getting safe, innovative products to patients faster. The Drägerwerk case shows how creative tools like TRIZ and programs like MDSAP and QMSR can make compliance more efficient. These strategies aren't just for big companies—they offer a roadmap for the industry as a whole. Looking ahead, as new technologies like AI start to play a role in regulatory processes, the lessons from this case could help RA professionals stay ahead of the curve.

Disclaimer This article is solely attributed to Holger Wagner and is not associated with his respective employment with Drägerwerk or TÜV SÜD. The views expressed in the article are his own and does not represent those of his respective employers. No conflicts of interest are declared.

Abbreviations

1. FDA: Food and Drug Administration
2. MDR: Medical Device Regulation

3. QMSR: Quality Management System Regulation
4. ISO: International Organization for Standardization
5. RA: Regulatory Affairs
6. IMDRF: International Medical Device Regulators Forum
7. MDSAP: Medical Device Single Audit Program
8. TRIZ: Theory of Inventive Problem Solving

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