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Features of adapting Lean manufacturing methodology to the requirements of the ISO 13485 standard

Victor Armel Eyanga

Advanced Manufacturing Engineer, Umano Medical Inc., Levis, QC, Canada

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***Abstract*— *The article explores how Lean manufacturing methodology can be effectively adapted to meet the regulatory requirements of ISO 13485 in medical device production. The article used a structured narrative literature review of recent peer-reviewed studies published between 2021 and 2025, examining evidence from case studies, expert interviews, systematic reviews, and technology-focused investigations relevant to Lean, risk management, validation, documentation, and digitalisation in regulated environments. The review brings together a set of recurring features that appear to be essential when Lean is applied within an ISO 13485 quality system. One consistent theme is the need to build documentation and traceability requirements directly into Lean routines rather than managing them separately. Another is the limitation of relying solely on FMEA; the broader risk framework set out in ISO 14971 has to be reflected in improvement work. This point, along with the others identified in the review, should be of practical use to teams involved in Lean work within medical-device manufacturing, particularly where operations and quality or regulatory staff have to plan improvements together. The material may also give researchers a more concrete basis for examining the ways Lean methods intersect with ISO 13485 and where the existing models still fall short.*

Keywords*— *Lean manufacturing, ISO 13485, medical device industry, ISO 14971, process validation, documentation and traceability, Lean Six Sigma, Industry 4.0, continuous improvement, regulatory compliance.

I. INTRODUCTION

Lean manufacturing has become a familiar improvement strategy across a wide range of industries, largely because of its focus on cutting waste and keeping processes moving smoothly. The core tools—value-stream mapping, standardized work, 5S practices, and the various routines that support continuous improvement—were developed with fast-paced, highly flexible production settings in mind, where teams can adjust workflows quickly and respond to problems as they appear. Medical device manufacturing, however, operates under markedly different conditions. ISO 13485 establishes stringent requirements for documentation, traceability, risk management, design control, and process validation, creating a regulatory landscape in which change is tightly governed and process evidence must be meticulously maintained. These obligations shape every stage of production and can significantly affect how improvement methodologies are deployed. As a result, while Lean offers clear operational benefits, its direct transfer into a regulated setting is neither straightforward nor guaranteed to succeed.

Recent publications on Lean, Lean Six Sigma, Industry 4.0, and medical-device manufacturing touch on many of the issues that shape work in regulated settings, but they tend to do so in a piecemeal way. Some authors concentrate on how production systems can be reorganised to reflect design-control requirements [3]; others describe the use of machine-vision setups for in-process checks, or the shift to digital data capture to reduce the burden of manual compliance tasks [7]. There is also work on risk-management routines and on maintenance

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improvements informed by Lean ideas[1]. Collectively, these works demonstrate that Lean can support quality and reliability even in highly regulated environments, but they also reveal constraints stemming from extended validation requirements, documentation burdens, and gaps between common Lean tools (e.g., FMEA) and the expectations of ISO 13485 and ISO 14971 [8]. However, existing research tends to focus on narrow functional areas—such as equipment maintenance, individual production lines, or isolated technologies—rather than offering a comprehensive perspective on how Lean methodology itself must be adapted to meet ISO 13485 requirements.

Even though the field already has plenty of individual case reports, scattered reviews, and commentary from practitioners, none of these efforts pull the material together into a single, coherent account of what actually has to change when Lean is applied inside an ISO 13485 framework. As a result, people working in regulated manufacturing are left without a clear map: it is not obvious which parts of Lean fit neatly into the quality-system requirements, which parts need to be adjusted, or how newer digital tools might help connect day-to-day improvement work with the formal demands of compliance. This article addresses that gap by bringing together insights from recent peer-reviewed studies to identify the features, constraints, and enabling factors that shape Lean implementation in medical device manufacturing under ISO 13485.

II. METHODS AND MATERIALS

This article employs a structured narrative literature-review methodology to synthesise recent research on Lean manufacturing within ISO 13485–regulated medical device environments. Boylan, McDermott, and Kinahan examined the development of manufacturing control systems for an in-vitro diagnostic instrument, focusing on design outputs and testing procedures essential for safe performance [1]. Foley, McDermott, Rosa, and Kharub reported a case study of a multinational medical device company implementing a "Lean 4.0" project (combining Lean and digital technologies) to reduce non-value-added waste while enhancing regulatory compliance [2]. Guha, Moore, and Huyghe developed and validated a real-time machine vision inspection system for high-volume catheter manufacturing, demonstrating how automated in-process inspection can replace destructive quality checks in a strict regulatory environment [3]. Ibrahim and Kumar proposed an integrated Lean Six Sigma–Industry 4.0 framework for sustainable manufacturing, identifying and prioritizing critical success factors (e.g. clear goals, progress monitoring, skilled workforce) via literature review and TOPSIS multi-criteria analysis [4].

Lepasepp and Hurst approached the topic by stepping back from individual case studies and carrying out a full systematic review of Industry 4.0 applications in medical-device production. Their survey was unusually broad: they identified more than three hundred distinct advantages that smart technologies can offer, along with over a hundred regulatory hurdles that tend to accompany their use in a tightly controlled environment [5]. A different angle was taken by McDermott and colleagues, who relied on interviews with senior figures in the MedTech sector. Their respondents described how the move toward digital systems often lightens the compliance load rather than adds to it, mainly because digitalisation improves traceability and reduces the amount of manual documentation needed during the product lifecycle [6]. McGrane et al. compared Lean Six Sigma project implementation in a regulated (medical device) setting versus an unregulated industry through two case studies, showing that regulatory requirements lengthen project timelines and complicate continuous improvement [7].

Nolan and McDermott interviewed medical device risk-management experts to study the use of Failure Modes and Effects Analysis (FMEA), finding that FMEA is the most common risk tool but has limitations under ISO 14971/13485 (e.g. it misses hazards during normal device use) [8]. Shamim and Ruddro performed a systematic review of 42 studies on Lean and Six Sigma in medical imaging equipment maintenance, showing that Lean methods (5S, VSM, TPM) combined with Six Sigma tools improve uptime and operator documentation, aligning with ISO 13485 requirements for traceability and risk-based maintenance [9]. Slattery et al. reviewed Lean applications in medical device new product introduction (NPI) processes, showing that Lean tools can integrate with Stage-Gate and concurrent

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engineering to eliminate waste and shorten time-to-market, while noting that strict compliance and risk aversion in medtech can limit Lean gains [10].

These studies used diverse methods: case studies and experiments (Boylan, Foley, Guha, McGrane), literature reviews (Lepasepp, Shamim, Slattery), expert interviews (McDermott et al., Nolan) and decision-analysis (Ibrahim). Most were qualitative or single-case in nature, limiting generalizability. Many focus on specific technologies (industry 4.0, machine vision, Six Sigma) or functions (maintenance, NPI) rather than the broad question of Lean under ISO 13485. Crucially, none specifically address how Lean must be adapted to satisfy ISO 13485 standards. This review aims to bridge that gap by synthesizing the findings of these studies. Existing research is limited by narrow scopes (e.g. single-plant case studies) and often omits explicit discussion of regulatory integration. Thus a comprehensive synthesis can highlight common themes and limitations – such as the need for documentation or risk-analysis tools – that are not fully resolved in the literature.

III. RESULTS AND DISCUSSION

The literature indicates several key features and challenges in adapting Lean to ISO 13485 requirements. A primary theme is rigorous documentation and traceability. ISO 13485 mandates that all critical processes, including design changes and maintenance, have documented evidence (e.g. calibration and validation records). Lean systems must therefore incorporate documentation as a core part of "value-added" processes. For instance, Boylan et al. describe how design control outputs and test protocols in a diagnostic instrument must be managed through a formal manufacturing control system to ensure device safety [1]. While lean principles would seek to streamline testing, the study emphasizes using lean thinking to optimally locate and time these required tests without sacrificing oversight. Likewise, Shamim and Ruddro report that implementing Lean Six Sigma in equipment maintenance led to improved maintenance logs and preventive planning – practices that directly satisfy ISO 13485 traceability requirements [9]. In other words, lean initiatives can be aligned with compliance by treating documentation and quality records not as waste, but as necessary "value" for regulated production. Figure 1 illustrates how Lean documentation practices intersect with the mandatory documentation and traceability requirements of ISO 13485 by arranging both sides as parallel panels connected through a shared value zone.

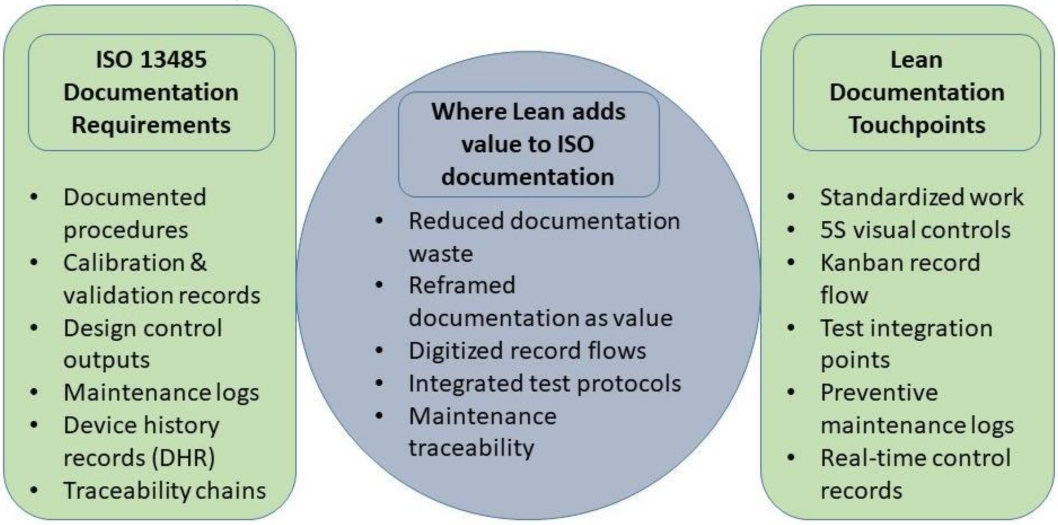

Fig.1. The author's illustration of the alignment between Lean documentation practices and ISO 13485 traceability requirements

On the left, Figure 1 lists core ISO 13485 obligations—such as documented procedures, calibration and validation records, design control outputs, maintenance logs, device history records,

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and full traceability chains—highlighting the regulatory burden placed on medical device manufacturers. On the right, the diagram highlights the specific documentation points that Lean projects commonly interact with: standardized work sheets, the visual cues used in 5S, simple Kanban card or record flows, in-line test checks, maintenance notes, and the real-time control records mentioned across several studies. These are shown as the concrete places where everyday work produces formal evidence. In the middle, the shared zone shifts the perspective. Instead of treating these requirements as paperwork that sits outside the process, Lean reframes them as part of the value stream: trimming documentation that does not help the operator, digitising the pieces that move frequently, building test steps directly into the workflow, and tightening how maintenance information is captured and used. The overlap is meant to show that many regulatory documents become lighter and more useful once they are pulled into Lean routines rather than kept separate. Combined, the graphic communicates that Lean and ISO 13485 are not opposing systems but can be aligned to reinforce both efficiency and compliance.

Table 1. Comparison of FMEA coverage versus ISO 14971 Risk-Management Requirements and the proposed integrated Lean risk toolkit

Risk-Management Requirement	FMEA (Current Lean Practice)	ISO 14971 (Regulatory Requirement)	Proposed Integrated Lean Risk Toolkit (FMEA + PHA + FTA + URRA)
Hazard identification	—	Comprehensive hazard identification across lifecycle	FMEA + PHA + URRA provide full hazard coverage
Failure modes in normal use	Covers operational failures	Requires explicit analysis of hazards in normal & reasonably foreseeable use	URRA strengthens normal-use analysis
Common-cause failures	—	Explicit expectation to evaluate shared/common-cause failures	FTA systematically identifies common-cause failures
Residual risk evaluation	—	Mandatory residual-risk evaluation and acceptability criteria	Integrated toolkit supports structured residual-risk evaluation (FMEA + FTA)
Benefit–risk analysis	—	Required when risks cannot be reduced further	Supported through ISO-aligned decision steps added to Lean events
Traceability of controls	—	Full traceability from hazard → control → verification	Toolkit enables mapped traceability across methods (PHA + FMEA + URRA)
Post-market surveillance inputs	—	Required as part of continuous risk management	URRA + updated FMEA cycles incorporate field data
Link to design controls	—	Strong integration with design verification and validation	Toolkit embeds risk analysis into design stages (PHA early; FTA for architecture; URRA for usability)

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Another major consideration is risk management. ISO 13485 (via ISO 14971) requires a systematic risk-based approach to production. Nolan and McDermott found that the most common Lean risk tool, FMEA, is widely used in medtech but does not capture all required risk elements [8]. FMEA typically assesses failures during operation, but experts note it often misses hazards in normal use or common-cause failures. Thus, adapting Lean to ISO 13485 calls for integrating additional risk techniques. Lean problem-solving events (kaizen workshops, process mapping) must include risk analysis steps beyond simple FMEA – for example, incorporating hazard analysis or fault-tree methods – to meet ISO standards [4]. As Nolan and McDermott suggest, benchmarking FMEA against ISO 14971 shows gaps; Lean teams should combine FMEA with other tools to satisfy regulatory risk requirements. Moreover, the standard's risk focus has cultural implications: McGrane et al. observed that firms so emphasize compliance that little time remains for waste-reduction initiatives [7]. Adapting Lean thus involves educating teams that improving efficiency and reducing risk are complementary goals, and embedding risk thinking into Lean projects. For example, Slattery et al. note that Stage-Gate processes (required by regulators) can incorporate Lean value-stream mapping and design-for-manufacturability checks, thereby marrying risk control with waste elimination [10]. Table 1 contrasts the capability of traditional FMEA with the broader risk-management requirements of ISO 14971 and shows how an integrated Lean risk toolkit closes the gaps.

In Table 1, the pale-orange cells mark the weak spots of FMEA. These include its tendency to miss hazards linked to user behaviour, its poor treatment of common-cause failures, the absence of any residual-risk or benefit–risk reasoning, and the limited traceability it provides back to design controls or post-market findings. The cyan cells show the few areas where FMEA offers only a partial fit, mostly because it can still help teams identify operational failure modes even if it does not address the wider regulatory expectations around risk. The light green cells in the integrated toolkit column show how combining FMEA with PHA, FTA, and URRA provides full lifecycle hazard identification, stronger analysis of foreseeable use, systematic evaluation of common-cause failures, structured residual-risk assessment, benefit–risk reasoning, traceability across controls, incorporation of field data, and alignment with design controls. Together, the color coding makes it clear that while FMEA alone is insufficient for ISO 14971 compliance, a multi-method approach enables Lean teams to satisfy regulatory demands while maintaining the efficiency of their improvement framework

Process validation and change management also emerged as critical. In regulated industries, proposed improvements must often be validated and approved before implementation. McGrane's case studies show that Lean projects in medical device manufacturing are delayed by necessary regulatory reviews, slowing progress [7]. Similarly, Boylan et al. highlight that engineering change processes must be scaled and controlled so that any Lean-driven process alteration still maintains product safety [1]. The implication is that Lean adaptation requires planning for validation steps: process changes and new tools should be piloted under controlled conditions, with documentation fed into the QMS. Lean teams should collaborate closely with quality/regulatory experts to map how proposed waste reductions fit existing design controls and submission requirements. In practice, this might mean running Lean Kaizen events in parallel with Quality Management System documentation updates, rather than treating documentation as an afterthought. Figure 2 compares the simple, fast-moving standard Lean improvement cycle with the expanded version required in ISO 13485–regulated environments, illustrating how regulatory steps lengthen and complicate change implementation.

On the left of Figure 2, the traditional Lean cycle proceeds through five straightforward phases—identifying waste, mapping the current state, implementing changes, measuring results, and standardizing improvements. On the right, the ISO 13485 version retains these core Lean steps but inserts several mandatory activities: risk assessment under ISO 14971, design-control review and change requests, creation of validation plans, execution of process validation (IQ/OQ/PQ), quality-assurance approval, and updates to regulatory documentation

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before changes can be fully implemented and monitored. The timeline bar beneath the diagram highlights this contrast by showing the short duration of Lean-only projects compared with the substantially longer Lean-plus-validation pathway. Together, the figure conveys how regulatory compliance expands the Lean cycle, slows execution, and necessitates more structured planning when operating under ISO 13485.

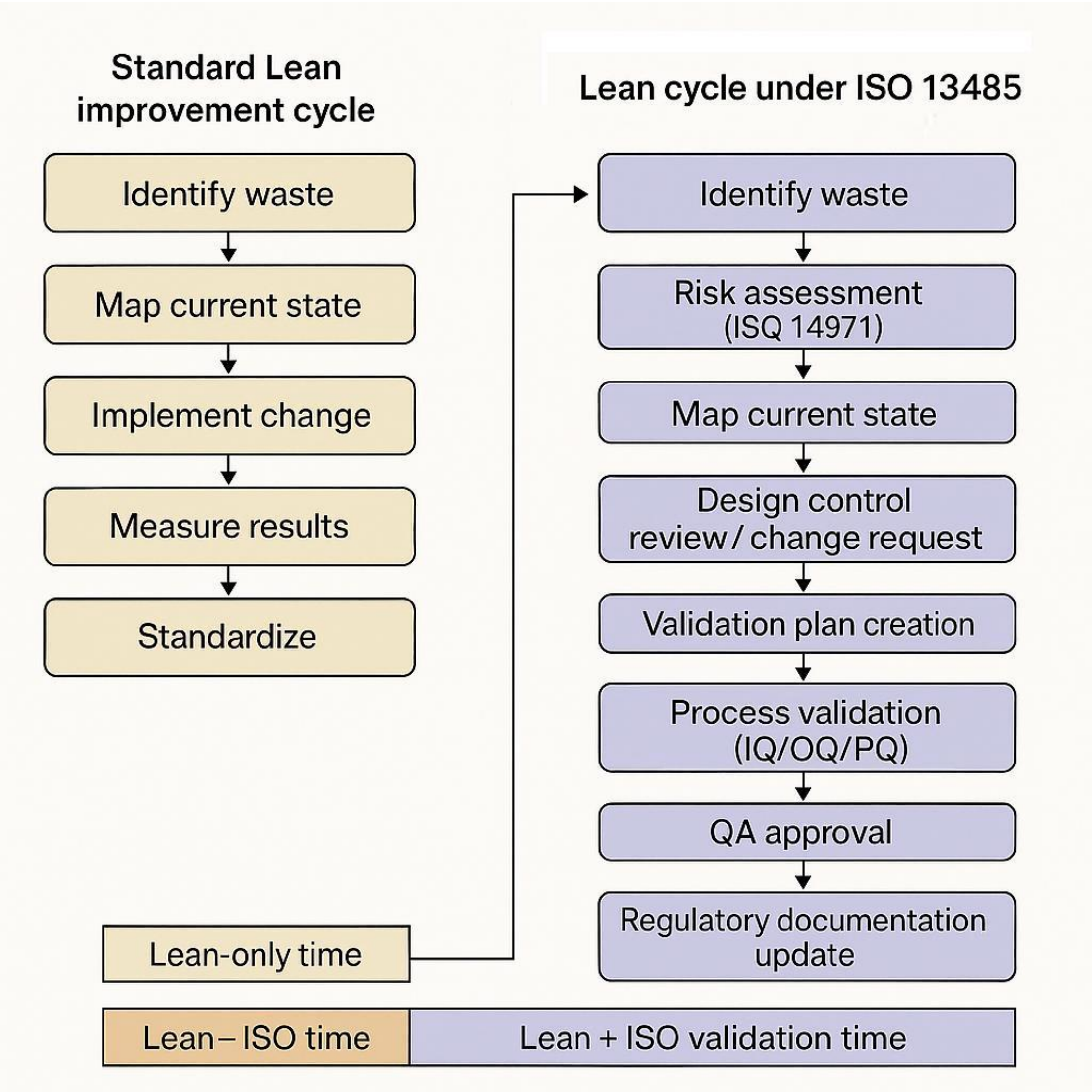

Fig.2. Expanded Lean Improvement Cycle Incorporating ISO 13485 Validation and Change-Management Requirements (the author's illustration)

A recurring insight is that digitalization (Industry 4.0) can facilitate compliance within lean operations. Several studies report that smart technologies both improve efficiency and make it easier to meet ISO 13485 requirements. Foley et al. demonstrate this synergy: by applying sensors and data analytics, the company not only reduced non-value waste but also achieved better product lifecycle traceability [2]. McDermott et al.'s interviews likewise found that Industry 4.0 generally "eases" regulatory compliance – for instance by automating data collection and audit trails. Lepasepp and Hurst catalogued hundreds of "smart" features (like IoT-enabled monitoring, AI-driven QC) that could optimize medtech manufacturing, though they also list regulatory obstacles to new tech. The practical lesson is that adapting Lean often involves using digital tools to satisfy ISO 13485 demands. One example that keeps appearing in the recent literature is the shift from batch checks to continuous verification. In the study by Guha and colleagues, a machine-vision setup took over most of the visual

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inspection work and made it possible to check every single unit as it moved down the line, rather than pulling samples and destroying them in the process [3]. The system also recorded the results automatically, so the quality documentation was created as a by-product of the process instead of a separate task. This kind of "Lean 4.0" arrangement removes waste on the shop floor—no scrapped samples, no manual logging—while still giving QA the electronic records it needs. Looking ahead, companies working under ISO 13485 will probably have to treat data-driven tools (sensors, digital logs, PLM environments, and similar systems) not as optional add-ons but as routine elements that help them meet both efficiency and compliance goals.

Cross-functional integration and culture is another feature of successful adaptation. Multiple studies note that Lean succeeds when production, quality, and regulatory teams collaborate. Shamim and Ruddro identify cross-functional teamwork and operator involvement as key enablers of sustaining Lean improvements in medical equipment manufacturing [9]. Similarly, Slattery et al. emphasize that Lean adoption in product introduction requires engagement across departments (e.g. engineering, manufacturing, regulatory) [10]. Because ISO 13485 involves design control, document control, and risk functions, Lean projects must bridge these silos. For example, a value-stream mapping in a medical device line should involve regulatory representatives to ensure all required steps (e.g. design verification) are included as "value-adding" or necessary steps. Embedding Lean coaches with knowledge of ISO 13485 can help reframe compliance steps (like process validation) as integral parts of the Lean workflow rather than non-productive add-ons.

In summary, the reviewed literature suggests that Lean in a regulated medical context must feature: robust process documentation (to meet audit requirements), explicit risk management (using multiple techniques to cover ISO 14971 scopes), validated change protocols, and digital supports for traceability. At the same time, Lean's core benefits – waste reduction, continuous improvement, shorter lead times – remain valuable. Case studies show that medical companies can achieve significant gains (shorter cycle times, reduced defects) even under ISO 13485, if Lean initiatives are properly adjusted. However, regulatory constraints do impose limitations: expectations for improvement may need to be tempered, and projects must account for extended timelines for approval. These insights point toward a balanced approach: Lean principles should not be abandoned, but applied with an eye to compliance requirements. For instance, tools like 5S or standardized work (used by Lean) help with consistent documentation; equipment and processes can be organized (Lean 5S) in ways that also simplify inspection and validation.

IV. CONCLUSION

Adapting Lean manufacturing to the stringent requirements of ISO 13485 demands a hybrid approach that preserves efficiency while ensuring compliance. Key features include incorporating rigorous documentation and traceability into Lean processes, embedding comprehensive risk-analysis alongside waste reduction, and planning for validation of any process changes.Recent work suggests that the relationship between digitalisation and Lean practice is more complementary than competitive. When firms adopt Industry 4.0 tools, the data they generate often takes over routine documentation and monitoring work that normally slows down regulated operations. This makes it easier for teams to push continuous-improvement projects through without getting stuck in paperwork. At the same time, the same regulatory expectations that protect product safety—risk reviews, formal approvals, and staged assessments—tend to stretch timelines and narrow what can be changed at each step.

For companies in the medical-device sector, the practical takeaway is straightforward: Lean efforts cannot run in isolation. Teams need at least a working grasp of both Lean methods and the fundamentals of quality management, and improvement projects have to be coordinated with design-control activities and gate reviews. Cross-functional work is essential here, because most delays come not from the Lean tools themselves but from gaps between engineering, QA, and operations.

Future research should empirically explore Lean adaptation in ISO 13485 contexts. Longitudinal case studies of Lean implementation in medical device

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production would help quantify impacts on lead time, cost, and quality under compliance constraints. Studies could also test customized Lean–Six Sigma frameworks that integrate digital tools and compliance documentation, as recommended by Shamim and Ruddro. Finally, developing practical guidelines or decision tools (for example, risk checklists to accompany Lean projects) would support practitioners. Such work would extend the current literature by providing actionable models for Lean 4.0 transformation in regulated industries, thereby strengthening the alignment of continuous improvement with ISO 13485 standards.

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