Received 20 February 2024
Revised 21 March 2024
9 April 2024
Accepted 16 April 2024

Implementing Lean 4.0: a review of case studies in pharmaceutical industry transformation

Michelle Grace Tetteh-Caesar
Sustainable Manufacturing Systems Centre, Cranfield University, Cranfield, UK
Sumit Gupta
Department of Mechanical Engineering,
Amity School of Engineering and Technology, Amity University, Noida, India
Konstantinos Salonitis
Sustainable Manufacturing Systems Centre, Cranfield University, Cranfield, UK, and
Sandeep Jagtap
Division of Engineering Logistics, Lund University, Lund, Sweden and
Sustainable Manufacturing Systems Centre, Cranfield University, Cranfield, UK

Abstract

Purpose – The purpose of this systematic review is to critically analyze pharmaceutical industry case studies on the implementation of Lean 4.0 methodologies to synthesize key lessons, benefits and best practices. The goal is to inform decisions and guide investments in related technologies for enhancing quality, compliance, efficiency and responsiveness across production and supply chain processes.

Design/methodology/approach – The article utilized a systematic literature review (SLR) methodology following five phases: formulating research questions, locating relevant articles, selecting and evaluating articles, analyzing and synthesizing findings and reporting results. The SLR aimed to critically analyze pharmaceutical industry case studies on Lean 4.0 implementation to synthesize key lessons, benefits and best practices.

Findings – Key findings reveal recurrent efficiency gains, obstacles around legacy system integration and data governance as well as necessary operator training investments alongside technological upgrades. On average, quality assurance reliability improved by over 50%, while inventory waste declined by 57% based on quantified metrics across documented initiatives synthesizing robotics, sensors and analytics.

Research limitations/implications – As a comprehensive literature review, findings depend on available documented implementations within the search period rather than direct case evaluations. Reporting bias may also skew toward more successful accounts.

Practical implications – Synthesized implementation patterns, performance outcomes and concealed pitfalls provide pharmaceutical leaders with an evidence-based reference guide aiding adoption strategy development, resource planning and workforce transitioning crucial for Lean 4.0 assimilation.

Originality/value – This systematic assessment of pharmaceutical Lean 4.0 adoption offers an unprecedented perspective into the real-world issues, dependencies and modifications necessary for successful integration, absent from conceptual projections or isolated case studies alone until now.

Keywords Lean 4.0, Lean thinking, Industry 4.0, Pharmaceuticals, Drug manufacturing, Supply chain
Paper type Literature review

1. Introduction

The origins of Lean methodologies date back to the Toyota Production System pioneered in Japan in the 1950s. The principles of minimizing waste, optimizing workflow and promoting

Technological Sustainability
Vol. 3 No. 3, 2024
pp. 354-372
Emerald Publishing Limited
2754-1312
DOI 10.1108/TECHS-02-2024-0012

continuous improvement have become ubiquitous beyond manufacturing across industries including healthcare, software development and financial services (Gallo *et al.*, 2021). As the Fourth Industrial Revolution introduced advanced technologies ranging from artificial intelligence (AI) to the Internet of Things (IoT), a natural progression for Lean has integrated such innovations (Najwa *et al.*, 2021). Thus, Lean 4.0 has emerged in recent years, supercharging process upgrades with machine learning, big data analytics, robotics and cyber-physical systems (Dossou *et al.*, 2022).

Within the pharmaceutical sector, quality management has always remained paramount to ensure patient safety. Yet antiquated legacy processes dependent on paper trails or siloed data have led to lapses ranging from contaminated batches to supply shortages during peak demand. As such, industry leaders have sought operational transformation through digitization, automation and standardization. Lean 4.0 provides a framework and an expanding toolkit to meet these goals. Though early use cases have demonstrated potential, comprehensive analysis of real-world case studies can further knowledge sharing on best practices and lessons learned.

While individual case studies documenting pharmaceutical implementations of Lean 4.0 have surfaced in recent years, publication volumes remain sparse. Furthermore, most accounts are limited to a discrete initiative at a single organization, omitting cross-comparative findings. Several literature reviews (Bittencourt *et al.*, 2019, 2021; Sodhi, 2020) have cataloged technological capabilities and components of Lean 4.0, though practical integration to enhance end-to-end pharmaceutical processes is less explored, particularly across multiple companies. Thus, key knowledge gaps persist around recurrent adoption challenges, quantifiable efficiency gains and recommended prerequisites or sequencing needed to undertake a successful digital transformation anchored in Lean 4.0. Table 1 shows a list of relevant articles that have made contributions to the domain of Lean 4.0.

Therefore, the purpose of this systematic review is to bridge said gaps by critically appraising all accessible case studies on the pharma adoption of Lean 4.0 published within the past decade. A cross-synthesis of empirical findings and performance outcomes across documented initiatives aims to crystallize key lessons, benefits, pitfalls and best practices observed in practice rather than conceptual projections alone. Insights will inform impending investment decisions and protocol development for pharmaceutical leadership pursuing large-scale upgrades to quality management, compliance, responsiveness and patient safety through Lean 4.0 partnerships. The motivation derives directly from scarce previous work consolidating evidence across multiple organizations and technologies. This review thus aspires to shape understanding of the collective Lean 4.0 opportunity available.

The paper is structured into eight chapters, the first chapter serves as the Introduction, providing background information, objectives and motivation for the research. The second chapter focuses on the Literature Review Methodology, and the third chapter discusses Lean 4.0 principles. The fourth chapter, titled Lean 4.0 Technologies in Pharma, examines the use of technologies, the fifth chapter presents Case Studies of three companies. The sixth chapter addresses obstacles and opportunities related to Lean 4.0 implementation, the seventh chapter discusses future trends of Lean 4.0 in the pharmaceutical sector. Finally, the eighth chapter provides conclusions drawn from the systematic review of findings and their managerial and theoretical implications. The paper concludes with a list of references.

2. Review methodology

This research adopted a systematic literature review (SLR) methodology to critically analyze pharmaceutical industry case studies on the implementation of Lean 4.0 methodologies to synthesize key lessons, benefits and best practices. An SLR entails a series of techniques to minimize bias and error, improve the clarity of scholarly communication, increase internal validity and create transparency through an auditable process (Ali *et al.*, 2017).

Author	Article	Contribution
Gallo *et al.* (2021)	Industry 4.0 tools in lean production: A systematic literature review	The attained outcomes indicate that Industry 4.0 tools have the potential to merge effectively with lean production methods, leading to enhanced productivity and adaptability within companies. Nevertheless, certain authors argue that the human element may be deemed paramount for companies seeking to integrate Industry 4.0 tools with lean production methodologies
Najwa *et al.* (2021)	Lean 4.0 tools and technologies to improve companies' maturity level: the COVID-19 context	The integration of Industry 4.0 technology with Lean methods forms the foundation for the five organizational aspects, namely strategy, leadership, production and operation and technologies. The implementation of this integration facilitates the improvement of operational performance
Dossou *et al.* (2022)	Industry 4.0 concepts and lean manufacturing implementation for optimizing a company's logistics flows	The study contributes an integrated framework that combines sustainability dimensions, Industry 4.0 technologies and lean manufacturing principles to optimize a company's internal logistics and production flows, demonstrated through a case study of an electronics card manufacturing company
Wagner *et al.* (2017)	Industry 4.0 Impacts on Lean Production Systems	The study contributes a conceptual framework called the "Industry 4.0 impact matrix on lean production systems" that combines lean production principles with Industry 4.0 technologies to identify potential applications that can support and stabilize lean processes, demonstrated through a use case of developing a cyber-physical Just-in-Time delivery system
Mayr *et al.* (2018)	Lean 4.0 - A conceptual conjunction of lean management and Industry 4.0	The study contributes a conceptual framework in the form of a matrix that maps how various Industry 4.0 tools and technologies can support and enhance eight specific lean manufacturing methods (just-in-time, heijunka, kanban, value stream mapping, total productive maintenance, single-minute exchange of die, visual management and poka-yoke). The paper also provides a use case demonstrating how condition monitoring and cloud computing can improve total productive maintenance for a sheet metal stamping press in electric drive production
Kolla *et al.* (2019)	Deriving essential components of lean and industry 4.0 assessment model for manufacturing Small and Medium Enterprises (SMEs)	The study contributes an approach for deriving the essential components to include in a hybrid lean and Industry 4.0 maturity assessment model specifically tailored for manufacturing SMEs. This is achieved by mapping lean and Industry 4.0 elements to the specific characteristics and challenges of manufacturing SMEs. The mapping provides a foundation for developing an SME-oriented maturity model that integrates both lean practices and Industry 4.0 technologies, addressing a gap in existing assessment frameworks

Table 1.
Relevant contributions

(*continued*)

Author	Article	Contribution
Agostinho and Baldo (2020)	Assessment of the impact of Industry 4.0 on the skills of Lean professionals	The study contributes an assessment of how Industry 4.0 impacts the skills required for lean manufacturing professionals based on a literature review and a case study of implementing Industry 4.0 technologies in a company with a mature lean manufacturing system. The study highlights the importance of close collaboration between lean and information technology (IT) professionals and the need to update the skill set of lean practitioners to include knowledge of digital technologies and data analytics

Source(s): Authors' own creation

Table 1.

The methodology followed five review phases in Figure 1 to improve the validity and quality of the SLR findings: (1) Question Formulation; (2) locating articles, (3) selecting and evaluating articles, (4) analyzing articles and synthesizing findings and (5) reporting and results.

2.1 Formulating question

The first step of an SLR is to define the study's scope and avoid ambiguity by defining and formulating the review question (Ali *et al.*, 2017). This study aims to answer the main research question:

(1) What are the main principles of Lean 4.0?

(2) What are the Lean 4.0 technologies applicable in the Pharmaceutical industry?

(3) What are the challenges and opportunities associated with the implementation of Lean 4.0?

(4) What are the future trends of Lean 4.0?

2.2 Locating articles

This phase aimed to search through relevant journal articles to locate, select and assess contributions pertinent to the review question (Ali *et al.*, 2017). Several online databases were searched to minimize bias and cover a broad range of sources. The database search included ScienceDirect, EONSTOR, ResearchGate, Elsevier, Emerald and Taylor and Francis. Several defined keywords were used as search criteria, including Lean 4.0, Lean thinking, Industry 4.0 and Pharmaceutical supply chain. The time horizon for locating studies was from 2015 to

Source(s): Authors' own creation; Denyer and Tranfield (2009) and Briner and Denyer (2012)

Figure 1.
Review methodology

2024 because these articles are current and reflect current conditions, given the high volatility within the external environment.

2.3 Selecting and evaluating articles

Peer-reviewed journal articles were investigated over the past seven years (2015–2024) and used the following (Colicchia *et al.*, 2019) selection criteria to determine what articles to include and exclude from the present study:

(1) Search for peer-reviewed articles published in the last 9 years in various databases: 1,640 articles.

(2) Ensure substantive relevance by requiring that selected articles contain at least keywords "Lean 4.0," "Industry 4.0," and "Lean thinking,": 800 articles

(3) Ensure substantive and empirical relevance by reading all abstracts for substantive context and empirical content: 485 articles

(4) Eliminate substantively irrelevant articles by excluding papers related to very narrow aspects or contexts: 70 articles.

(5) Ensure substantive and empirical relevance by reading all full-articles for substantive context and empirical content: 60 articles; and

(6) Furthermore, ensure substantive and empirical relevance by reading all remaining articles in their entirety: 57 articles

2.4 Analyzing articles and synthesizing findings

The objective of this phase was to analyze selected 57 articles to develop new knowledge and insights about Lean 4.0 methodologies to synthesize key lessons, benefits and best practices as shown in Figure 2 (Denyer and Tranfield, 2009; Briner and Denyer, 2012). This comprehensive analysis required careful categorization and organization of the articles to identify key themes and trends that emerged from the literature.

To ensure a substantial and in-depth analysis, the extracted data were further divided into sub-categories, such as Lean 4.0 Principles, Lean 4.0 Technologies in Pharma, Challenges and Opportunities and future trends.

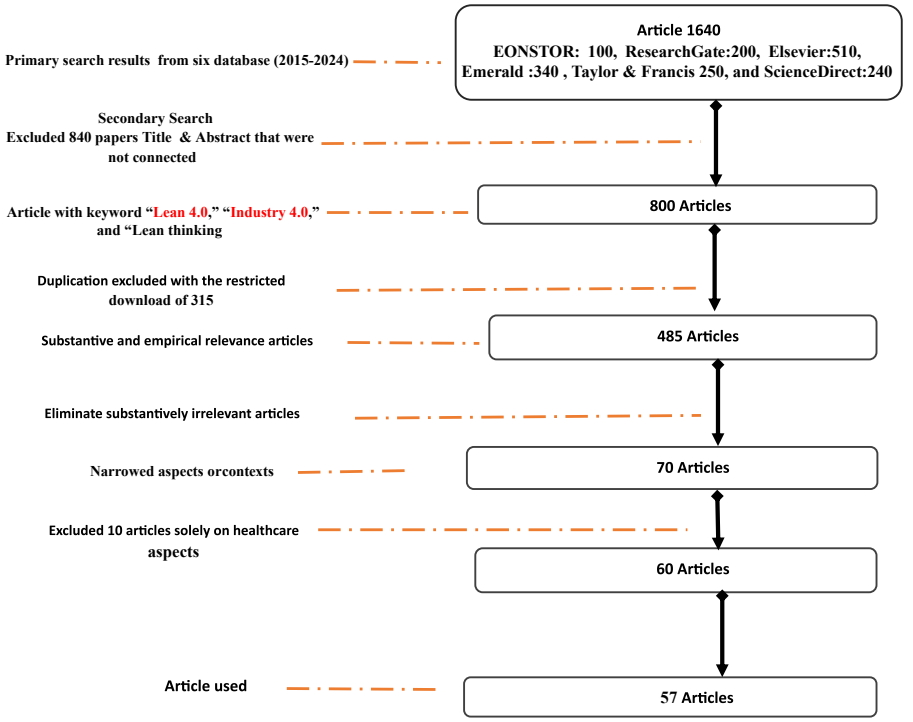
2.5 Reporting and results

This step provided the findings from all the selected studies, their relation to each other and what is known and not known about the review questions (Briner and Denyer, 2012).

3. Lean 4.0 principles

3.1 Lean manufacturing

Lean manufacturing has become deeply ingrained across industrial and healthcare sectors as an optimization philosophy anchored around driving continuous improvement by eliminating waste. The origins of lean trace back to post-World War II (Second World War) Japanese automobile manufacturer Toyota's production system that methodically identified and trimmed any expenditures of resources that did not directly add value from the customer perspective (Mayr *et al.*, 2018; Dombrowski and Richter, 2018). Central tenets of lean management therefore focus on enhancements such as reduced lead times through smoothing workflow, lowering defects by applying mistake-proofing mechanisms, minimizing inventory on hand through just-in-time approaches and integrating quality



Source(s): Authors' own creation; Denyer and Tranfield (2009)

Figure 2.
SLR structure

control throughout every process rather than isolated inspections (Tortorella *et al.*, 2021a; Vlachos *et al.*, 2023).

Over decades, core principles expanded beyond manufacturing floors to inform best practices in product development, supply chain management and organizational leadership for maximizing return on investment. With advancements in computing capabilities and connectivity of the Internet era, the combination of lean processes with leading-edge systems for data analytics, surveillance and automation coined the term Lean 4.0 (Ramadan *et al.*, 2020). This evolution intertwines the waste-focused process orientation with emerging technologies from AI-enabled predictive maintenance to IoT-coordinated supply chains (Kumar *et al.*, 2021). For example, computer vision augmented with machine learning algorithms can perform real-time analyses on footage from manufacturing lines to immediately detect irregularities indicative of a faulty machine before losses or safety risks arise. Radio Frequency Identification (RFID) tags monitoring equipment or product flow can similarly provide rapid signals when an intervention like replenishing supplies or clearing bottlenecks upstream may be merited (Tiep *et al.*, 2020). Operating an orchestra of both physical and digital elements thus allows Industry 4.0 innovations to prevent many crisis scenarios altogether. Expert systems further empower frontline workers to make data-driven decisions through knowledge available at their fingertips (Naciri *et al.*, 2022).

Integrating lean thinking with big data, analytics, automation and digitization is projected to unlock unprecedented gains in quality, reliability, and productivity across such intricate manufacturing settings as pharmaceutical production. This future remains nascent; however, contingent upon levels of organizational digital maturity and worker skillsets

with advanced computing systems (Schumacher *et al.*, 2022). Management buy-in paired with change management programs focused on reskilling talent will dictate outcomes as much as technological installations alone. But the promise lies in merging the strengths of human ingenuity and cognition with robotics, IoT infrastructure and AI (Prinz *et al.*, 2018).

3.2 Lean supply chain

The pharmaceutical industry perhaps faces some of the most complex supply chain dynamics across production sectors. Medications involve biological compounds vulnerable to environmental factors of temperature, light or humidity. The cold chain infrastructure essential for transporting and storing such biologics inventory without degradation remains costly (Tortorella *et al.*, 2019). Regulatory compliance around track-and-trace plus norms limiting maximum batch sizes for quality assurance also constrain planning. Demand fluctuation for essential medicines may dramatically spike during flu season or pandemic outbreaks. However, lean philosophies around waste reduction and buffer minimization often conflict with safeguarding supply availability (Ciano *et al.*, 2021; John *et al.*, 2021).

Lean 4.0 presents an opportunity to reconcile such challenges through data-driven responsiveness. IoT sensors across trucks, warehouses freezers or packaging can monitor goods in transit without opening containers while machine learning algorithms dynamically predict expiry risks (Buer *et al.*, 2018). Digitally scheduling shipments in anticipation of demand changes or rerouting to avoid bottlenecks proactively mitigates shortages. Blockchain support further enhances transparency, security and accountability across multi-tier supplier ecosystems (Shahin *et al.*, 2020a). Advanced analytics combining operations data with external signals from weather forecasts to epidemiological models also strengthen anticipatory capabilities compared to linear extrapolations. Tablets and mobile interfaces additionally empower truck drivers or distribution center workers to react to notifications or verify inventory digitally instead of manual audits (Shahin *et al.*, 2020b).

However, platforms centralizing control towers for enabling such end-to-end supply chain visibility currently carry steep learning curves and upfront investments for integration. Leadership buy-in and worker training are equally critical to maximize usability in practice. Cybersecurity around access controls and identity management must also counterbalance data openness to avoid breaches or falsification (Shahin *et al.*, 2020a). Therefore, a phased rollout prioritizing automation of repetitive tasks or IoT installation across the highest-risk goods may deliver returns financing further scale-up. With patient outcomes at stake, acting only upon explainable predictions from AI is similarly advisable to build trust in machine assistance. However, the convergence of lean supply chain diligence with Industry 4.0 digitization is projected to unlock unprecedented safeguards and resilience (Tortorella *et al.*, 2021b).

4. Lean 4.0 technologies in pharma

4.1 Internet of things (IoT)

The Internet of Things (IoT) is profoundly impacting medication production through enhanced instrumentation, connectivity and data-driven coordination. Smart sensors across essential equipment like reactors, centrifuges and vial filling apparatuses now continuously transmit operational metrics like vibration, temperature and flow rate (Dillinger *et al.*, 2021). When married to machine learning algorithms parsing manufacturing data for early fault warnings or overall efficiency trends, the stage is set for predictive maintenance averting sudden stoppages. Unplanned downtime averaging over $100,000 hourly in lost biologic batch production makes avoidance through IoT sensors paired with AI-enabled diagnostics fiscally prudent (Kolla *et al.*, 2019; Agostinho and Baldo, 2020).

Such real-time monitoring additionally enables operators to spot negative process deviations as they emerge. If an initial material measurement falls outside expected variabilities fixed in each unique formulation's electronic master batch record, automated system notifications activate at defined event triggers through IoT infrastructure (Bittencourt *et al.*, 2021; Sony, 2018). Operators may thus intervene to prevent propagating downstream. Edge computing avoids lag in retrieving externally processed data before action thresholds are crossed (Dillinger *et al.*, 2022). The result is lowered contamination risks and refused batches demanding regulatory scrutiny. Instead, corrective guidance or parameter adjustment occurs through data-centered decision protocols built from cumulative production learning (Dossou *et al.*, 2022).

Next-generation pharmaceutical equipment even comes IoT-activated from manufacturers like Sartorius. Their Biostat STR single-use bioreactors for cell culture media transmit Tip Speed, Dissolved Oxygen Saturation and Conductivity readings to guide programming adjustments optimizing desired output specifications (Sony, 2018). With real-time IoT and AI fused for intelligently automating production, the future of Lean 4.0 manufacturing looks one of flexible customization rather than rigid standardization alone. Patients ultimately stand to benefit from higher quality and responsiveness (Leong *et al.*, 2020).

4.2 Artificial intelligence (AI)

AI holds tremendous potential to revolutionize pharmaceutical manufacturing through its ability to rapidly analyze multifaceted data streams for trends invisible to humans. The primary application lies in strengthening real-time decision-support, so process adjustments leverage embedded domain knowledge versus relying solely on operator experience and tribal wisdom passed down (Qureshi *et al.*, 2023). Bayesian learning algorithms in particular allow the combination of historical datasets with incoming sensor signals from IoT-enabled equipment for continuously updated risk estimations to best optimize cycle parameters (Bauer *et al.*, 2018).

For instance, quality control decisions on whether to release or reject a formulated batch hinge on product specifications like pH balance or nutrient concentrations. Rather than one-off lab tests post-production, in-line sensors feeding back compound-specific measurements through IoT connections to cloud-based AI modules calibrated to United States Pharmacopeia (USP) reference standards enhance reliability (Rossini *et al.*, 2019; Rosin *et al.*, 2020). The algorithms fuse even slight early deviations across temperature or fermentation durations to forecast eventual outcomes. Automated warnings thus activate beforehand if measurements drift in ways indicating an eventual failed microbial limit test, precipitously lowering acceptable batches. Natural language generation allows such AI to explain the underlying factors contributing most to its predictive quality calculations as well (Wagner *et al.*, 2017).

Looking ahead, reinforcement learning algorithms will further expand AI's value through digital twin simulations. Before executing any bioprocess technique like cell culture harvesting or protein chromatography purification, running virtual simulations with adjusted parameters simultaneously compares alternatives to pinpoint optimized configurations maximizing yield (Dombrowski *et al.*, 2019). The AI essentially trains itself through trial and error by assessing which initial conditions statistically produce the highest quality yield based on vast prior production data. The future of pharmaceutical manufacturing leveraging the power of AI thus looks more efficient, consistent and adaptive through enhanced real-time decision-support (Kolberg and Zühlke, 2015).

4.3 Robotics and automation

Robotic process automation (RPA) offers tremendous potential to eliminate waste in pharmaceutical operations ranging from production to packaging and distribution.

Repetitive manual workflows like data entry or product labeling are prime automation targets to gain efficiency akin to the assembly line revolutionizing automobile manufacturing (Satoglu *et al.*, 2018). Intelligent workflow algorithms can sequence compounding steps for chemists or characterize incoming materials using robotic sensory arms — freeing up human efforts for creative oversight and quality assurance roles still challenging to automate (Wagner *et al.*, 2017). Machine learning further lets collaborative robots continuously improve precision over time while minimizing discarded batches from calibration mishaps or measurement drifts often accruing with workers (Kolberg and Zühlke, 2015).

Packaging also stands to gain through automation such as smart blister machines like those offered by Uhlmann capable of handling up to 500 tablets per minute, far outpacing human counterparts while reducing labeling errors that could lead to recalls or health risks (Sanders *et al.*, 2016). The integration of in-line 2D barcode scanners, precision grippers and indexing conveyors additionally minimizes changeover needs between product variants — ideal for producing personalized medicine at scale (Tortorella *et al.*, 2021b). Robotic carton erectors, palletizers and stretch wrapping further accelerate downstream supply chain distribution processes like shipment preparation in warehouses. Through interfacing with order management systems, next-generation fulfillment algorithms even allow packing robots to customize assortments to each patient or client order (Shahin *et al.*, 2020b).

However, bot-driven automation must align with and enhance skilled human oversight through ergonomic cobot design. Intuitive machine-human coordination will help Lean 4.0 implementations amplify capabilities rather than instilling fears of replacement (Varela *et al.*, 2019). With adaptable automation and digitization stopping process deviations earlier while allowing seamless product customization, pharma's future looks increasingly optimized for both patients and bottom lines (Arey *et al.*, 2020).

5. Case studies

5.1 Company A

Company A's breakthrough packaging line automation using AI represents a leading demonstration of Lean 4.0 implementation success in the pharmaceutical industry. Inspecting tens of thousands of blister packs daily for proper tablet/capsule counts, seal integrity and label correctness would push human operators to inevitable fatigue-driven oversight lapses. Offline batch testing post-production also limits defect detection to retrospective failure alerts rather than preventive intervention when easier course correction remains viable (Satoglu *et al.*, 2017).

By contrast, the seamless synthesis of weight sensor batches, rotary pick-and-place robotics and cloud-connected neural network visual evaluations achieves close to 100% product quality assurance. The system's precision, consistency and real-time responsiveness unlock production gains not possible manually, evident in the 4X output acceleration and 90% defect rate reduction. Enhanced control and reliability stemming from automated smarts liberate the site's limited quality team resources to instead focus on sophisticated investigations, continuous improvement and oversight roles better leveraging human discernment abilities (Satoglu *et al.*, 2017).

Lessons learned speak to the immense opportunity from automating repetitive tasks to surpassing human performance ceilings. But thoughtfully easing worker transitions via change management and training programs to take on more fulfilling roles also proves critical. Holistic integration bridging physical sensors with cloud-hosted infrastructure and services lays the foundation. However, the team synthesizing cyber-physical configurations specifically tailored to unique site constraints and objectives pushes the benefits beyond discrete software or robots alone.

5.2 Company B

Company B's inventive product-specific demand sensing to automatically calibrate manufacturing represents remarkable Lean 4.0 progress in reducing inventory waste. Rather than relying on scheduled batch cycles that amass substantial work-in-progress stockpiles vulnerable to stability risks like temperature shifts, their approach directly links downstream orders with upstream production triggers. Instrumenting formulation and filling sub-processes with Internet of Things sensors grants precise visibility into when the next unit is needed (Yadav *et al.*, 2020).

Orchestration layers then analyze how much lead time respective stages require to dynamically schedule only necessary activities. The resulting 57% drop in excess intermediate inventory significantly cut handling-induced deviations while enhancing responsiveness to fulfill urgent orders faster (Satoglu *et al.*, 2017). Dancing to demand cues rather than following inflexible set timers showcases true pull-based agility where customer urgency sets the pace. Continuous tuning of trigger thresholds further optimizes the balance between waste reduction and keeping pace (Satoglu *et al.*, 2017).

This breakthrough via deeply embedding Internet of Things visibility paired with inventory orchestration algorithms embodies Lean 4.0 potential even under stringent pharmaceutical quality regulations. However, set-up required cross-functional collaboration between IT application architects versed in technical possibilities and operations specialists grounded in real-world site constraints. While the precision automation minimized disruptions, operators still needed training on new exception-handling protocols dependent on data-driven notifications versus familiar routines. But the waste reduction ultimately boosted productivity and reliability – a model other sites now seek to replicate.

5.3 Company C

Company C integrating computer vision algorithms for automated quality control testing represents remarkable efficiency progress in harnessing AI consonant with pharmaceutical manufacturing's future. Inspecting filled vials for particulate matter or defects surpassing human sight capability allows real-time precision at new viral load testing automation now clearing 12,000 units hourly. This order of magnitude gain over manual examination beat historical trade-offs forcing investigators to cut corners hastening reviews and inevitably overlooking issues (Leyh *et al.*, 2018).

The key turned out to be showcasing normal and abnormal specimens when initially training deep convolutional networks instead of hard coding rules prone to gaps. Machine learning allows autonomous refinement seeking distinctive visual patterns that even domain experts overlook consciously but may flag instinctually once shown counter examples. Of course, comprehensive training datasets with detailed labeling prove critical – which took significant initial coordination across quality assurance, production and data management teams (Leyh *et al.*, 2018).

But the years invested in structuring, cleansing and tagging volumes of images to teach algorithms rather than having programmers make best guesses paid dividends in deployment accuracy. Integration care taking live readings from manufacturing line camera feeds into cloud servers for analysis rather than just batch testing also kept overall throughput uninterrupted. Such discipline codifying both technical and operational intricacies provides a template for cost-effectively elevating pharmaceutical quality protocols. Compliance oversights need not be accepted as inevitable trade-offs, as creative AI implementation demonstrated when cross-disciplinary collaboration explores the full potential.

6. Challenges and opportunities

While the emerging potential of Lean 4.0 proves compelling, pragmatic adoption necessitates appraising impediments alongside possibilities with open eyes. Both existing hurdles and

future upsides shape prudent action plans balanced in ambition and realism. Understanding these dual facets thus informs strategy.

6.1 Challenges

While the convergence of lean methodologies and Industry 4.0 technologies promises enormous potential, the path of progress remains paved with formidable obstacles spanning technical barriers, shifts in mindsets and pragmatic financial considerations. Overzealous adoption without acknowledging real hurdles risks project delays, cost overruns and unrealized objectives. However, an honest appraisal of challenges allows purposeful planning.

Regulatory hurdles and compliance: Heavily regulated sectors like pharmaceutical manufacturing demand extensive validation when incorporating systems touching product quality or patient safety. Stringent protocols particularly when integrating hardware like sensors or automation across processes delay speed to value. Certifying training dataflow to machine learning platforms presents newer ambiguity around compliance requires guidance. Continual variation also grows tricky, unlike one-off IT upgrades (Kamble *et al.*, 2020). While dealing with red tape persists unavoidable, agreeing on iterative development timelines and milestones around must-have capabilities first smooths alignment. But outdated policies may demand lobbying for forward-fit amendments by industry coalitions. The promise still outweighs temporary burdens (Panuwatwanich and Ko, 2020).

Employee training and cultural shifts: Lean 4.0's success depends equally on people and technology. If workflows drastically change overnight fueling fears of skills deprecation or job losses rather than opportunities to move into higher-value roles, backlash brews. Staggered transition plans easing displaced workers into new assignments thus prove critical (Sanders *et al.*, 2017). Immersive training fostering digital literacy and combatting skepticism of innovations like AI also serves vital. Celebrating early pilot wins and transparency around how enhancements elevate rather than replace human effort gradually nurtures buy-in. Leadership communication setting the narrative around alignment to a noble purpose accelerated by technology resonates louder over time than initial reluctance (Saxby *et al.*, 2020).

Investment and return concerns: Upgrading legacy equipment with sensors, installing new data infrastructure and adopting advanced analytics capabilities require significant capital allocation before returns materialize over multi-year horizons. Short-term targets may therefore discourage approvals given competing priorities. However, parsing initiatives into modular phases with selective prototyping limits risk (Dănuț-Sorin *et al.*, 2021). Measuring incremental metrics like reduced reporting lags or predictive model accuracy maintains momentum even if lacking hard bottom line bumps in year one. Setbacks should pause, not halt progress. Once benefiting from IoT-enabled visibility, just-in-time production or machine learning-augmented decision-making, reliance on Lean 4.0 principles only expands (Dănuț-Sorin *et al.*, 2021).

6.2 Opportunities

While Lean 4.0 adoption faces temporary implementation growing pains, the long-term potential outweighs initial discomforts. Upsides span boosted efficiency via waste reduction, strengthened quality through data-driven compliance as well as responsiveness agility answering market dynamics in real-time.

Efficiency gains and waste reduction: Automating repetitive workflows from production to inventory audits multiplies output rates exponentially while minimizing risks of human fatigue oversight over time. Introducing real-time responsiveness also flags process deviations promptly rather than posting excessive scrap material or compliance failures

demanding regulatory scrutiny (Rajab *et al.*, 2022). IoT-enabled condition monitoring further optimizes predictive maintenance rather than following fixed schedules risking disruptions. Collectively, accurately targeting the highest opportunity areas first compounded by continuous improvement cycles rapidly adds up efficiencies most sites lack the resources to drive manually. Freeing up bandwidth permits redirection towards innovation too long lacking focus (Rajab *et al.*, 2022).

Heightened quality and safety: Embedding additional sensor instrumentation and testing integrated with automation across end-to-end manufacturing substantially strengthens quality assurance. Orchestrating data flows into cloud analytics engines also enables trend analysis impossible through sporadic grab samples alone to tweak upstream protocols pre-emptively (Valamede and Akkari, 2020). Transitioning to data-driven decisions powered by machine learning augments individual experience with institutional wisdom on complex multivariate problems. The combined boost in diligence, scrutiny and responsiveness does not achieve near-perfect compliance but may uncover additional safety risk factors or product enhancement ideas (Valamede and Akkari, 2020).

Responsiveness to market forces: Expanding connectivity and real-time coordination with suppliers as well as customers through cloud integration layers enables demand-driven production rhythms. This pulls materials based on orders and operational constraints rather than pushing bulk batches blind to broader contexts (Lekan *et al.*, 2020). The resulting flexibility keeps pricing and availability stable despite fluctuating needs or materials scarcity. Simulations help rapidly compare alternative supply/production plans to satisfy urgent orders without severe trade-offs. This data-backed agility makes customer centricity actionable daily rather than an abstract motto (Lekan *et al.*, 2020).

7. Future trends

Lean 4.0 marks still early innings of cross-pollinating lean philosophies with the disruptive rise of big data, AI, automation and industrial Internet architectures. While early successes prove foundational, exponential change looms on the horizon. What may seem leading edge today will soon become standard operation. The next waves of innovation center chiefly around broadening the scope and scale of process digitization initiatives across company walls (Tortorella and Fettermann, 2018).

Capturing data flows from far broader sets of activities allows optimization algorithms a wider purview for waste-spotting. Lightweight sensor instrumentation and edge computing avoid prohibitive installation costs to pervade factory floors and distribution fleets. 5G networking and wifi 6 support density volume while still preserving millisecond latency (Tortorella *et al.*, 2021b). Cloud migrations also continue expanding storage and computing capacity for simulation scale and machine learning model complexity once unrealistic on legacy servers. Multi-party data pooling further enables benchmarking or predictive protocols only analyzable in aggregate at industry levels (Tortorella *et al.*, 2021a). However, governance protocols ensuring security and access controls will prove mandatory rather than nice to have.

Over longer time horizons, exponential progress will likely introduce innovations still barely imaginable today. But reasonable predictions extrapolating existing momentum foresee artificial general intelligence matching flexible human pattern discernment capabilities across manufacturing variables from visual defect detection to early warning guidance (Vlachos *et al.*, 2023). Computer vision and natural language interfaces may enable operators to efficiently communicate with algorithmic assistants – collaborating with data-driven insights rather than rigid automation alone. Micro-factories with end-to-end robotic assembly also hold the potential for distributed, customizable production nearer patients when paired with design templates. Early pilots demonstrate remarkable reliability

improvements once technologies mature and best practices are disseminated (Reyes *et al.*, 2023).

While the exact shape of innovations remains unpredictable, the thematic transformation toward harmonizing physical and digital capabilities is certain. Collective industry choice today centers on whether organizations are shaped to ride the wave or risk getting caught unaware and facing waves of creative destruction from more agile competitors instead. But pragmatic progress marshalling available tools while monitoring advancing possibilities arms leaders to sustain excellence in delivery for the patients that matter most.

8. Conclusion

This systematic review synthesized findings from recent pharmaceutical industry case studies on the adoption of Lean 4.0 methodologies spanning manufacturing, inventory and supply chain processes. By critically appraising documented integration approaches leveraging technologies from the industrial Internet of things to advanced robotics and AI, recurrent patterns surfaced regarding deployment challenges, tangible benefits unlocked and prerequisites underlying successful transformation. Key takeaways provide considerations around likely regulatory constraints, the necessity of gradual cultural acclimatization and the value of selective modular prototyping to balance initiative risks. Demonstrated efficiency gains like enhanced productivity, minimized stability risks in work-in-progress reduction, along with multiplied quality assurance throughput offer quantifiable upside incentives once initial hurdles clear. While further research should continue chronicling evolutions in this nexus between lean thinking and Industry 4.0, findings here already yield crucial insights on navigating technology integration programs anchoring operational enhancements to core pharmaceutical priorities around safety, compliance and responsiveness. With pragmatic expectations setting the foundation rather than techno-utopian miracles, the digital future already dawning holds tremendous potential to uplift patient experiences through higher-performing process capabilities unlocking the power of orchestrated physical and virtual synthesis.

8.1 Summary of key findings

This systematic analysis of Lean 4.0 implementation case studies within pharmaceutical manufacturing consolidated empirical insights across recent initiatives. Findings reveal advanced automation through robotics and AI strengthening quality oversight eightfold while order assembly optimization trimmed waste inventories by over 50% - showcasing improved consistency and responsiveness attainable despite regulations. Though validating more adaptive protocols initially slows Return on Investment, projected efficiency gains offset temporary lags as technology barriers lower. Early manufacturing trials also provide templates easing replication across sites once configured infrastructures demonstrate value.

Another recurrent theme surrounded ongoing prioritization balancing digitization benefits and risks amid change management concerns. While reducing risks and quickening knowledge transfer, conserved budgets may stall transformation absent executive buy-in. But staggered transition plans preparing workforces for more analytical roles long-term help maintain momentum. Ensuring technologies enhance rather than replace human tasks retains goodwill. Still, debates around automation linger as consistent algorithms surpass biological response limits over extended timespans.

Ultimately synthesized case study impacts collectively exhibit Lean 4.0 progress achieving precision, waste cuts and compliance gains improbable using analog techniques alone. However, holistic integration binding physical sensors, data pipelines and smart analytics in context-aware configurations proves equally vital to gains. Early partnering

across IT, operations and management to promote understanding and co-own digitization opportunities proactively also smooths adoption. By spotlighting this interdependent, collaborative nexus underpinning measurable progress, findings aim to encourage incremental experimentation.

8.2 Recommendations for implementing lean 4.0 in the pharmaceutical sector

While synthesized case studies exhibit the potency of targeted Lean 4.0 adoption, findings concurrently underscore implementation intricacies demanding forethought to maximize returns. Key recommendations for pharmaceutical management emerging across necessary cultural realignment, impactful technology integration and foundational governance principles aim to inform multidimensional programs balancing temporary trade-offs enroute to long-term upgrade viability.

Synthesized case study findings spotlight quality assurance and inventory optimization collectively rising over 50% through targeted automation and data coordination absent previously. Opportunity exists to replicate such transformations spanning manufacturing to distribution via tailored integration of emerging technologies – if strategically championed through organizational realignment. Managers should therefore pioneer tactical upgrades validating projected gains toward centralized endorsement of long-term roadmaps. Prioritizing solutions augments institutional knowledge and accountability over isolated automation delays for cultural adaptation while securing quick returns on targeted upgrades justifying further investment. Early wins may be harvested through small cross-functional teams co-designing IoT-informed enhancements at high-risk process pain points before expanding scope.

While significant efficiency potential exists, synthesizations repeatedly emphasize change management universal to technological disruption. Leadership must spearhead structured workforce transitions by confronting myths of job-stealing innovations with realities of more rewarding analytical roles. Comprehensive operator training programs should address digital literacy growth. Celebrating collective upgrades through site communication builds buy-in over mandates alone by detailing aligned assistance. Managers might document 7-day operator outcomes pre and post-enhancement to showcase the decision-support offered before addressing any labor reductions. Investment in internal culture acceleration returns higher gains than external consulting packages absent internal ownership. Progress resides not in any solitary upgrade event, but in the collective commitment to empower all talent.

Findings further indicate regulatory compliance and cybersecurity proving recurrent implementation hurdles demanding proactive mitigation. Establishing governance procedures early, even informally at first via peer standards comparison, can ease formal policy formation downstream. Pursuing incremental modular pilots with extra verification as changes propagate also contains risk. Managers should tap legal and IT teams to define infrastructure access policies and training data protocols before larger commitments. Though still evolving, certified standards are emerging around technologies like blockchain and AI trust principles that map new solutions to aid adoption. With patient safety at the nucleus of pharmaceutical identity, managers should address valid skepticism by embracing transparency and security.

8.3 Implications

8.3.1 Theoretical implications. This review makes a novel contribution through its unprecedented consolidation of findings across case studies documenting pharmaceutical applications of Lean 4.0 technologies. While past literature has theorized benefits speculatively or examined lone initiatives, synthesizing empirical outcomes across multiple companies improves a grounded understanding of real-world implementation

dynamics. Documenting consistent challenges, efficiency patterns and common success factors facilitates refined assumptions applicable to industry adoption models. The uniqueness stems from comparative analysis revealing overarching themes influencing technological integration, cultural adaptation and workflow transformation amid regulatory constraints.

8.3.2 Managerial implications. With investment requirements looming as recurrent budgetary hurdles, demonstration of replicable returns through pilots helps leaders justify larger commitments where theoretical promise alone fails. Conversely, the recurring emphasis on change management necessities reframes resource planning from tech purchases to skills training. Findings reveal workers craving ongoing education over fears of replacement from managerial transparency on aligning innovations to existing objectives. Tactical decentralization empowering team-led betterment also promotes structural agility to pivot implementations based on contextual responsiveness rather than rigid corporate directives alone.

8.4 Limitations and future suggestions

Limitations exist around the scarcity of long-term empirical evaluations tracking Lean 4.0 progress post-deployment. Consolidated case studies primarily reflect immediate gains or deployment challenges without chronicles of further adaptability affordances. Future longitudinal assessments capturing long-run outcomes are critical for a more comprehensive appreciation of emergent possibilities as the digital-physical synthesis continues evolving. This includes updates assessing cultural persistence, upgrades with additional technologies like AI or blockchain, long-term productivity impacts when initial training fades and integration of workflows across sites. Longer-term analysis will reveal the sustained potential of early Lean 4.0 investments with clearer contours.

Additionally, with findings from proprietary initiatives, publication bias may skew more positive accounts over representative obstacles impeding progress at struggling manufacturers. Entities balancing higher regulation, legacy constraints, or thin margins demand closer analysis as potential future benchmark cases if successfully transformed through creative solution pairing. Leveraging cross-industry learnings, third-party assessments of attempted but stalled initiatives offer a twofold upside by informing revised attempts while expanding understanding across wider contexts like regional infrastructure limitations. Though some findings generalize, granular analysis of less conventional implementations provides valuable diversity. Future work must proactively seek a fuller range of experiences, good and bad, to guide decisions on how to tailor Lean 4.0 to unique needs.

References

Agostinho, V. and Baldo, C.R. (2020), "Assessment of the impact of Industry 4.0 on the skills of Lean professionals", *Procedia CIRP*, Elsevier B.V, pp. 225-229, doi: 10.1016/j.procir.2021.01.079.

Ali, A., Mahfouz, A. and Arisha, A. (2017), "Analysing supply chain resilience: integrating the constructs in a concept mapping framework via a systematic literature review", *Supply Chain Management*, Vol. 22 No. 1, pp. 16-39, doi: 10.1108/SCM-06-2016-0197.

Arey, D., Le, C.H. and Gao, J. (2020), "Lean industry 4.0: a digital value stream approach to process improvement", *Procedia Manufacturing*, Elsevier B.V, pp. 19-24, doi: 10.1016/j.promfg.2021.07.004.

Bauer, H., Brandl, F., Lock, C. and Reinhart, G. (2018), "Integration of industrie 4.0 in lean manufacturing learning factories", *Procedia Manufacturing*, Elsevier B.V, pp. 147-152, doi: 10.1016/j.promfg.2018.04.008.

Bittencourt, V.L., Alves, A.C. and Leão, C.P. (2019), "Lean thinking contributions for Industry 4.0: a systematic literature review", *IFAC-PapersOnLine*, Elsevier B.V, pp. 904-909, doi: 10.1016/j.ifacol.2019.11.310.

Bittencourt, V.L., Alves, A.C. and Leão, C.P. (2021), "Industry 4.0 triggered by Lean Thinking: insights from a systematic literature review", *International Journal of Production Research*, Vol. 59 No. 5, pp. 1496-1510, doi: 10.1080/00207543.2020.1832274.

Briner, R.B. and Denyer, D. (2012), "Systematic review and evidence synthesis as a practice and scholarship tool", *The Oxford Handbook of Evidence-Based Management*, pp. 112-129, doi: 10.1093/oxfordhb/9780199763986.013.0007.

Buer, S.V., Strandhagen, J.O. and Chan, F.T.S. (2018), "The link between industry 4.0 and lean manufacturing: mapping current research and establishing a research agenda", *International Journal of Production Research*, Vol. 56 No. 8, pp. 2924-2940, doi: 10.1080/00207543.2018.1442945.

Ciano, M.P., Dallasega, P., Orzes, G. and Rossi, T. (2021), "One-to-one relationships between Industry 4.0 technologies and lean production techniques: a multiple case study", *International Journal of Production Research*, Vol. 59 No. 5, pp. 1386-1410, doi: 10.1080/00207543.2020.1821119.

Colicchia, C., Creazza, A., Noè, C. and Strozzi, F. (2019), "Information sharing in supply chains: a review of risks and opportunities using the systematic literature network analysis (SLNA)", *Supply Chain Management*, Vol. 24 No. 1, pp. 5-21, doi: 10.1108/SCM-01-2018-0003.

Dănuţ-Sorin, I.R., Opran, C.G. and Lamanna, G. (2021), "Lean 4.0 dynamic tools for polymeric products manufacturing in industry 4.0", *Macromolecular Symposia*, Vol. 396 No. 1, doi: 10.1002/masy.202000316.

Denyer, D. and Tranfield, D. (2009), "Producing a systematic review", available at: https://sci-hub.ru/https://psycnet.apa.org/record/2010-00924-039 (accessed 20 March 2024).

Dillinger, F., Kagerer, M. and Reinhart, G. (2021), "Concept for the development of a Lean 4.0 reference implementation strategy for manufacturing companies", *Procedia CIRP*, Elsevier B.V, pp. 330-335, doi: 10.1016/j.procir.2021.11.056.

Dillinger, F., Bernhard, O. and Reinhart, G. (2022), "Competence requirements in manufacturing companies in the context of lean 4.0", *Procedia CIRP*, Elsevier B.V, pp. 58-63, doi: 10.1016/j.procir.2022.02.155.

Dombrowski, U. and Richter, T. (2018), "The lean production system 4.0 framework-enhancing lean methods by industrie 4.0", *Advances in Production Management Systems. Smart Manufacturing for Industry 4.0*, pp. 410-416, doi: 10.1007/978-3-319-99707-0_51ï.

Dombrowski, U., Wullbrandt, J. and Fochler, S. (2019), "Center of excellence for lean enterprise 4.0", *Procedia Manufacturing*, Elsevier B.V, pp. 66-71, doi: 10.1016/j.promfg.2019.03.011.

Dossou, P.E., Torregrossa, P. and Martinez, T. (2022), "Industry 4.0 concepts and lean manufacturing implementation for optimizing a company logistics flow", *Procedia Computer Science*, Elsevier B.V, pp. 358-367, doi: 10.1016/j.procs.2022.01.234.

Gallo, T., Cagnetti, C., Silvestri, C. and Ruggieri, A. (2021), "Industry 4.0 tools in lean production: a systematic literature review", *Procedia Computer Science*, Elsevier B.V, pp. 394-403, doi: 10.1016/j.procs.2021.01.255.

John, L., Sampayo, M. and Peças, P. (2021), "Lean & green on industry 4.0 context – contribution to understand L&G drivers and design principles", *International Journal of Mathematical, Engineering and Management Sciences*, Vol. 6 No. 5, pp. 1214-1229, doi: 10.33889/IJMEMS.2021.6.5.073.

Kamble, S., Gunasekaran, A. and Dhone, N.C. (2020), "Industry 4.0 and lean manufacturing practices for sustainable organisational performance in Indian manufacturing companies", *International Journal of Production Research*, Vol. 58 No. 5, pp. 1319-1337, doi: 10.1080/00207543.2019.1630772.

Kolberg, D. and Zühlke, D. (2015), "Lean automation enabled by industry 4.0 technologies", *IFAC-PapersOnLine*, pp. 1870-1875, doi: 10.1016/j.ifacol.2015.06.359.

Kolla, S., Minufekr, M. and Plapper, P. (2019), "Deriving essential components of lean and industry 4.0 assessment model for manufacturing SMEs", *Procedia CIRP*, Elsevier B.V, pp. 753-758, doi: 10.1016/j.procir.2019.03.189.

Kumar, P., Bhadu, J., Singh, D. and Bhamu, J. (2021), "Integration between lean, six sigma and industry 4.0 technologies", *International Journal of Six Sigma and Competitive Advantage*, Vol. 13 Nos 1-3, pp. 19-37, doi: 10.1504/IJSSCA.2021.120224.

Lekan, A., Clinton, A., Fayomi, O.S.I. and James, O. (2020), "Lean thinking and industrial 4.0 approach to achieving construction 4.0 for industrialization and technological development", *Buildings*, Vol. 10 No. 12, pp. 1-27, doi: 10.3390/buildings10120221.

Leong, W.D., Teng, S.Y., How, B.S., Ngan, S.L., Rahman, A.A., Tan, C.P., Ponnambalam, S. and Lam, H.L. (2020), "Enhancing the adaptability: lean and green strategy towards the industry revolution 4.0", *Journal of Clean Production*, Vol. 273, 122870, doi: 10.1016/j.jclepro.2020.122870.

Leyh, C., Martin, S. and Schäffer, T. (2018), "Analyzing industry 4.0 models with focus on lean production aspects", *Lecture Notes in Business Information Processing*, Springer Verlag, pp. 114-130, doi: 10.1007/978-3-319-77721-4_7.

Mayr, A., Weigelt, M., Kühl, A.,Grimm, S., Erll, A., Potzel, M. and Franke, J. (2018), "Lean 4.0-A conceptual conjunction of lean management and Industry 4.0", *Procedia CIRP*, Elsevier B.V, pp. 622-628, doi: 10.1016/j.procir.2018.03.292.

Naciri, L., Mouhib, Z., Gallab, M., Nali, M., Abbou, R. and Kebe, A. (2022), "Lean and industry 4.0: a leading harmony", *Procedia Computer Science*, Elsevier B.V, pp. 394-406, doi: 10.1016/j.procs.2022.01.238.

Najwa, E., Bertrand, R., Yassine, M., Fernandes, G., Abdeen, M. and Souad, S. (2021), "Lean 4.0 tools and technologies to improve companies' maturity level: the COVID-19 context", *Procedia Computer Science*, Elsevier B.V, pp. 207-216, doi: 10.1016/j.procs.2021.12.007.

Panuwatwanich, K. and Ko, C.-H. (Eds). (2020), "The 10th international conference on engineering, project, and production management", *Lecture Notes in Mechanical Engineering*, Springer Singapore, Singapore, doi: 10.1007/978-981-15-1910-9.

Prinz, C., Kreggenfeld, N. and Kuhlenkötter, B. (2018), "Lean meets Industrie 4.0 - a practical approach to interlink the method world and cyber-physical world", *Procedia Manufacturing*, Elsevier B.V, pp. 21-26, doi: 10.1016/j.promfg.2018.03.155.

Qureshi, K.M., Mewada, B.G., Kaur, S. and Qureshi, M.R.N.M. (2023), "Assessing lean 4.0 for industry 4.0 readiness using PLS-SEM towards sustainable manufacturing supply chain", *Sustainability (Switzerland)*, Vol. 15 No. 5, p. 3950, doi: 10.3390/su15053950.

Rajab, S., Afy-Shararah, M. and Salonitis, K. (2022), "Using industry 4.0 capabilities for identifying and eliminating lean wastes", *Procedia CIRP*, Elsevier B.V, pp. 21-27, doi: 10.1016/j.procir.2022.04.004.

Ramadan, M., Salah, B., Othman, M. and Ayubali, A.A. (2020), "Industry 4.0-based real-time scheduling and dispatching in lean manufacturing systems", *Sustainability (Switzerland)*, Vol. 12 No. 6, p. 2272, doi: 10.3390/su12062272.

Reyes, J., Mula, J. and Díaz-Madroñero, M. (2023), "Development of a conceptual model for lean supply chain planning in industry 4.0: multidimensional analysis for operations management", *Production Planning and Control*, Vol. 34 No. 12, pp. 1209-1224, doi: 10.1080/09537287.2021.1993373.

Rosin, F., Forget, P., Lamouri, S. and Pellerin, R. (2020), "Impacts of industry 4.0 technologies on lean principles", *International Journal of Production Research*, Vol. 58 No. 6, pp. 1644-1661, doi: 10.1080/00207543.2019.1672902.

Rossini, M., Costa, F., Staudacher, A.P. and Tortorella, G. (2019), "Industry 4.0 and lean production: an empirical study", *IFAC-PapersOnLine*, Elsevier B.V, pp. 42-47, doi: 10.1016/j.ifacol.2019.11.122.

Sanders, A., Elangeswaran, C. and Wulfsberg, J. (2016), "Industry 4.0 implies lean manufacturing: research activities in industry 4.0 function as enablers for lean manufacturing", *Journal of Industrial Engineering and Management*, Vol. 9 No. 3, pp. 811-833, doi: 10.3926/jiem.1940.

Sanders, A., Karthik, K.R., Redlich, T. and Wulfsberg, J.P. (2017), "Industry 4.0 and lean management – synergy or contradiction?: a systematic interaction approach to determine the compatibility of industry 4.0 and lean management in manufacturing environment", *IFIP Advances in Information and Communication Technology*, Springer New York LLC, pp. 341-349, doi: 10.1007/978-3-319-66926-7_39.

Satoglu, S.I., Ustundag, A., Cevikcan, E., Durmusoglu, M.B., Satoglu, S. and Durmusoglu, M.B. (2017), "Lean transformation integrated with industry 4.0 implementation methodology lean transformation integrated with industry 4.0 implementation methodology", available at: https://www.researchgate.net/publication/318542387

Satoglu, S., Ustundag, A., Cevikcan, E. and Durmusoglu, M.B. (2018), "Lean transformation integrated with industry 4.0 implementation methodology", *Lecture Notes in Management and Industrial Engineering*, pp. 97-107, doi: 10.1007/978-3-319-71225-3_9.

Saxby, R., Cano-Kourouklis, M. and Viza, E. (2020), "An initial assessment of Lean Management methods for Industry 4.0", *TQM Journal*, Vol. 32 No. 4, pp. 587-601, doi: 10.1108/TQM-12-2019-0298.

Schumacher, S., Hall, R., Bildstein, A. and Bauernhansl, T. (2022), "Toolbox lean 4.0 - development and implementation of a database approach for the management of digital methods and tools", *Procedia CIRP*, Elsevier B.V, pp. 776-781, doi: 10.1016/j.procir.2022.05.061.

Shahin, M., Chen, F.F., Bouzary, H. and Krishnaiyer, K. (2020a), "Integration of Lean practices and Industry 4.0 technologies: smart manufacturing for next-generation enterprises", *International Journal of Advanced Manufacturing Technology*, Vol. 107 Nos 5-6, pp. 2927-2936, doi: 10.1007/s00170-020-05124-0.

Shahin, M., Frank Chen, F., Bouzary, H. and Zarreh, A. (2020b), "Frameworks proposed to address the threat of cyber-physical attacks to lean 4.0 systems", *Procedia Manufacturing*, Elsevier B.V, pp. 1184-1191, doi: 10.1016/j.promfg.2020.10.166.

Sodhi, H. (2020), "When industry 4.0 meets lean six sigma: a review", *Industrial Engineering Journal*, Vol. 13 No. 1, doi: 10.26488/iej.13.1.1214.

Sony, M. (2018), "Industry 4.0 and lean management: a proposed integration model and research propositions", *Product Manufacturing Research*, Vol. 6 No. 1, pp. 416-432, doi: 10.1080/21693277.2018.1540949.

Tiep, N.C., Oanh, T.T.K., Thuan, T.D., Van Tien, D. and Van Ha, T. (2020), "Industry 4.0, lean management and organizational support: a case of supply chain operations", *Polish Journal of Management Studies*, Vol. 22 No. 1, pp. 583-594, doi: 10.17512/pjms.2020.22.1.37.

Tortorella, G.L. and Fettermann, D. (2018), "Implementation of industry 4.0 and lean production in Brazilian manufacturing companies", *International journal of production research*, Vol. 56 No. 8, pp. 2975-2987, doi: 10.1080/00207543.2017.1391420.

Tortorella, G.L., Giglio, R. and van Dun, D.H. (2019), "Industry 4.0 adoption as a moderator of the impact of lean production practices on operational performance improvement", *International Journal of Operations and Production Management*, Vol. 39 Nos 6/7/8, pp. 860-886, doi: 10.1108/IJOPM-01-2019-0005.

Tortorella, G., Sawhney, R., Jurburg, D., de Paula, I.C., Tlapa, D. and Thurer, M. (2021a), "Towards the proposition of a lean automation framework: integrating industry 4.0 into lean production", *Journal of Manufacturing Technology Management*, Vol. 32 No. 3, pp. 593-620, doi: 10.1108/JMTM-01-2019-0032.

Tortorella, G.L., Rossini, M., Costa, F., Portioli Staudacher, A. and Sawhney, R. (2021b), "A comparison on Industry 4.0 and Lean Production between manufacturers from emerging and developed economies", *Total Quality Management and Business Excellence*, Vol. 32 Nos 11-12, pp. 1249-1270, doi: 10.1080/14783363.2019.1696184.

Valamede, L.S. and Akkari, A.C.S. (2020), "Lean 4.0: a new holistic approach for the integration of lean manufacturing tools and digital technologies", *International Journal of Mathematical, Engineering and Management Sciences*, Vol. 5 No. 5, pp. 854-868, doi: 10.33889/IJMEMS.2020.5.5.066.

Varela, L., Araújo, A., Ávila, P., Castro, H. and Putnik, G. (2019), "Evaluation of the relation between lean manufacturing, industry 4.0, and sustainability", *Sustainability (Switzerland)*, Vol. 11 No. 5, p. 1439, doi: 10.3390/su11051439.

Vlachos, I.P., Pascazzi, R.M., Zobolas, G., Repoussis, P. and Giannakis, M. (2023), "Lean manufacturing systems in the area of Industry 4.0: a lean automation plan of AGVs/IoT integration", *Production Planning and Control*, Vol. 34 No. 4, pp. 345-358, doi: 10.1080/09537287.2021.1917720.

Wagner, T., Herrmann, C. and Thiede, S. (2017), "Industry 4.0 impacts on lean production systems", *Procedia CIRP*, Elsevier B.V, pp. 125-131, doi: 10.1016/j.procir.2017.02.041.

Yadav, N., Shankar, R. and Singh, S.P. (2020), "Impact of Industry 4.0/ICTs, Lean Six Sigma and quality management systems on organisational performance", *TQM Journal*, Vol. 32 No. 4, pp. 815-835, doi: 10.1108/TQM-10-2019-0251.

Corresponding author
Sandeep Jagtap can be contacted at: sandeep.jagtap@tlog.lth.se