processes

MDPI

Review

A Review of Lean Methodology Application and Its Integration in Medical Device New Product Introduction Processes

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Abstract: The purpose of this study is to review the Lean tool application and its utilisation in medical device design and the new product introduction process to establish the benefits and best practices for its integration with existing new product introduction processes. A review of the literature on the current state of medical device New Product Introduction (NPI) processes is completed along with a comprehensive review of the literature on the history and development of Lean NPI. The review indicates that Lean can be combined with the predominant NPI execution tools, Stage-Gate and Concurrent Engineering within the medical device industry to achieve a best-in-class continuous improvement methodology within the NPI process. This integration eliminates waste, focusses on customer value, and ultimately reduces cost and lead time to market. This review highlights for the first time the main challenges and issues with Lean in the medical device sector NPI processes, identifying possible future strands of research. Limitations of the current review are that despite the heavy emphasis placed on Lean manufacturing processes, comparatively little emphasis is placed on the use of Lean in the medical device NPI process. Future longitudinal case studies on case study application of Lean in medical device NPI processes would be useful. This study has implications for identifying best practices for Lean in NPI in the device industry, improving what is considered state-of-the-art for the introduction of devices into the public domain.

Keywords: medical device; lean; new product introduction; stage-gate; concurrent engineering

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1. Introduction

Medical devices are a major contributor to the world economy with the two biggest medical device markets in the world being the United States (US) at 43% and the European Union (EU) at 27%, making up 70% of the medical world market [1]. Medical devices are highly substitutable with similar products of superior efficacy. Because of this, market success is dependent on the development and commercialisation of new products and technologies [2]. In order to be compliant with their regulatory obligations and ensure patient and customer safety, the medical device industry and indeed the regulators are generally perceived as risk-averse to change [3,4]. As a result, the development and launch of new medical devices can be difficult [5–9]. While the terms New Product Introduction (NPI) and New Product Development (NPD) are often used interchangeably [10], generally, NPI focuses on all activities commencing after initial product conception up until the point of mass manufacture [11].

Common activities in the NPI portion of the NPD cycle include Process Development (PD), Design for Manufacturability (DFM) assessments, Process Validation (PV) and administrative Design Transfer (DT) activities required as supporting evidence to regulatory submissions. Unlike the "fuzzy" front end of the NPD process, which focuses on initial design conception and development, the outputs of the NPI portion of the cycle are relatively understood engineering processes commonly used across the industry due to the universal conformance to the same applicable regulations and standards [6,8]. As a result,

this portion of the NPD cycle stands to gain greater benefits from the deployment of process excellence tools [10]. Reducing the NPI lead time will benefit manufacturers in the race to launch new products and new technologies to the market, providing financial benefits to them and the wider economy as well as benefits to potential patients as they will access new products and treatments sooner. Novel medical devices can be particularly difficult to launch, invoking additional regulatory requirements to demonstrate safety and efficacy prior to launch. This is perceived to be a barrier that stifles innovation in the industry and leads to most new products leveraging the regulatory approval of a predicate product of equivalent design and function, greatly limiting the scope for design changes and innovation [6,11–14]. A 2008 survey of UK- and Ireland-based medical device manufacturing companies found that 4.4% of new product development projects in large companies are new-to-world products, rising to 9.3% in Small and Medium Enterprises (SMEs) [15]. A focus on regulatory compliance and quality management is often cited as an impediment to the use of Lean and other continuous improvement tools in the highly regulated medical device industry [16,17] The resulting lead time to market arising from this stringent regulatory environment offers a large potential for improvement using Lean tools and techniques. There is greater scope to make changes to non-manufacturing processes in a medical device organisation, such as changes to the NPI process.

Lean has the greatest impact on reducing the lead time of all major organisation improvement programs, making it the most closely aligned approach to the goal of reducing lead time to market as it is a Key Performance Indicator (KPI) [18,19]. The use of Lean in the medical device industry has increased over time, being used commonly by a third of medical device manufacturers in the UK and Ireland regions and used by half of the companies to some extent [20]. The success of Lean in the medical device industry in Ireland is well documented, with many Irish-based companies receiving prestigious accolades in this area and transforming Ireland into a globally recognised hub of excellence [21]. The uptake of organisational excellence and process improvement methodologies was accelerated by the greater scrutiny from governments and insurance companies to demonstrate the cost/benefits of medical device products [16,22].

Lean NPD and NPI were researched and studied in manufacturing and pharmaceutical industries [9,23] with some limited research on Lean in NPI processes in medical device industries [24,25]. The study on the use of Lean tools and methodologies in the medical device sector has enormous potential for the improvement of both cost and lead times [26,27]. More recently Glazkova et al. have discussed the combination of Lean and Agile in developing wearable device products [28]. However, the use of Lean in the NPI process in medical device organisations creates a gap in the literature.

This review aims to investigate the following research questions (RQs):

1. Assess and review Lean tools and NPI methodologies in medical device NPI processes;
2. Benchmark and review the development of Lean NPI processes and methodologies in other industries;
3. Put forward the best practices, challenges and synergies between Lean NPI methodologies in the medical device sector and other industries as a model for integration.

The results will be disseminated into the formulation of a set of generic best practices which can be successful in medical device NPI. This will mostly focus on universal tools which will provide Lean solutions to improve the key performance indicators (KPIs) of any medical device NPI process. Section 2 outlines the literature review while Section 3 discusses the methodology taken to review the literature, Section 4 outlines the results from reviewing the literature while Section 5 is a discussion and conclusion of the results.

2. Literature Review

An extensive literature review was carried out on the literature related to regulations around design and NPI processes in the medical device industry and in other highly regulated industries and the application of Lean within the NPI processes of medical

devices and other industries. Despite the specificities of the medical device industry, drawing parallels from the NPD processes in other industries is not without precedent [2,5].

2.1. The Regulatory Landscape and Its Effect on NPI

The design, development and manufacture of medical devices are subject to strict regulations in all global jurisdictions. High-quality, well-designed medical devices are necessary to provide safe and effective clinical care for patients as well as to ensure the health and safety of professional and lay device users. Capturing the user requirements of users and incorporating these into the design is an essential component of this [29]. The standard for demonstrating regulatory safety and effectiveness is determined in part by the risk associated with the device in question. Devices in the United States, for example, are classified according to their perceived risk using a three-tiered system (class I, II, or III) with I representing low-risk devices and III being high-risk devices [30]. Other countries use similar or slightly different risk-type classifications, for example, Europe has four classes—I, IIa, IIb and III [31]. The higher the risk of the device, the more stringent the regulatory controls including the design controls.

Within the regulatory landscape, the term design or development is used more commonly than new product development and new product introduction. There was much cooperation between the EU and the FDA at the time of the Code of Federal Regulations (CFR) updates in the 1990s to incorporate design controls (or product development guidelines). The FDA Design Control Guidance for Medical Device Manufacturers, published in 1997 [32], describes the relationship and linkages between the FDA's design control guidance and the ISO 13485 standard for a quality management system in medical devices as being "cross-referenced" to each other [33]. This publication addressed the entire area of design controls in a "waterfall" iterative format from design and development planning, design input, design output, design reviews and design transfer and then design changes, verification, and validation, and finally the design history file [32,34]. The critical issue for the device development processes is that most items in the guidance require a formal review and approval step [35]. This is the reason why most companies that develop medical devices have chosen to use a quality system process that follows a sequential waterfall model in which development is seen as flowing steadily downwards through the phases of requirements, design, implementation, testing (validation), and maintenance for their development [36]. The design process is intended to assist manufacturers with their quality management system (QMS) requirements in relation to design controls and new product development. There are interrelated sets of practices and procedures that are embedded into the design and development process within the device regulations [33]. These provide managers with better visibility of the design process itself, thereby enabling them to identify opportunities earlier in the process, thus avoiding costly errors later in the cycle. As the medical devices industry encompasses a great range of devices from simple tongue depressors to complex implanted devices [30], this is the reason that regulatory agencies do not prescribe how to bring a product through the development cycle. The product's complexity as well as the organisation's structure has a greater impact on how design controls are applied. The FDA and all global jurisdictions demand that there is a QMS in place commensurate with both the product complexity and the risk to the patient [14]. Global regulatory bodies do not prescribe "how" manufacturers achieve their quality system requirements as they deem the organisation itself as best placed to document a means that works for their product types on how best to achieve and maintain compliance with the quality regulations [33].

Design regulations are important because of the volumes of information that are created as a result of product development. Typically, every piece of work output, i.e., deliverable item, created as part of the design effort is design output, and the design output from one stage is often the design input for the next. There should be documentation, procedures, records, specifications, and prototypes all kept up to date and as part of a QMS application [6]. This creates time and delays for manufacturers in getting a product to

market [37,38]. Thus, manufacturers are starting to look at ways of reducing waste within their NPI development processes and using continuous improvement methods to optimise the process. This all has to be carried out without compromising adherence and compliance with regulations. To do this, manufacturers are increasingly utilising Lean methods and other NPI approaches.

2.2. Current Medical Device NPI Approaches

In order to meet NPI/NPI and design process outputs, many approaches are utilised for product development. The FDA's design control model has resulted in the almost universal deployment of that model within the medical device industry. This design control model is not the only model available for complex product development, and studies from other industries have demonstrated that it is not the most efficient approach for product development either [33]. Alternative approaches have many advantages over the traditional approach, achieving better designs, fewer development risks and better turn-around time [39]. Thus, in the following sections, various approaches for NPI and NPD are reviewed. Santos et al. [2,22] examined the state of product development in the medical device industry. The papers put forward a description of the current NPI approach and the fragmented approach to excellence and concluded that the medical device development process would profit from a dedicated product development methodology [2,22]. Figure 1 illustrates how a concurrent engineering approach is aligned with the stage-gate process, and with the application of design for X methods, including methods such as Design for Assembly (DfA), Design for Manufacturing (DfM), Design for Reliability (DfR), Design for Quality (DfQ), Design for Validation (DfV) and Design for Usability (DfU) [2].

Figure 1. Current Medical device NPI Approach [2].

While the predominant medical device NPI approach using CE and Stage-Gate® systems remains valid from a project execution viewpoint, these systems continue to lack the ability to systematically change the nature in which projects are executed and transform processes. For example, CE eliminates waste associated with sequential task scheduling but does not offer a means to identify and eradicate other wastes within the system [9]. Lean may offer a bridge between the execution of best practices and process transformation,

questioning "why" and "how" processes are performed, instead of prescribing "what" to do [9].

2.2.1. Stage-Gate

The previous research on MedTech development methodologies is limited to a single phase of development [8]. Generic phase-gate approaches, more commonly known as "Stage-Gate®" [40], are a de facto element of medical device development due to alignment with FDA guidelines for Design Control [10,33].

A stage-gate system is both a conceptual and an operational model for moving a new product from idea to launch. It is a blueprint for managing the new product process to improve effectiveness and efficiency [40]. Stage-gate systems recognise that product innovation is a process, and, like other processes, innovation can be managed. Stage-gate systems simply apply process-management methodologies to this innovation process. Most companies use Stage-Gate to ensure stakeholder consensus prior to progressing to the next stage of a project, but no universal NPI methodology is employed across the industry despite adherence to the same regulatory requirements. A standard model describing the different stages of the medical device NPD process was established [10]. Other models can be seen in Figure 2 and are broadly similar. For example, in Figure 2, several models of medical device development from the literature were put forward which have incorporated a regulatory influence based on FDA regulatory design guidelines. The blue tick symbolises where the different models have incorporated regulatory principles.

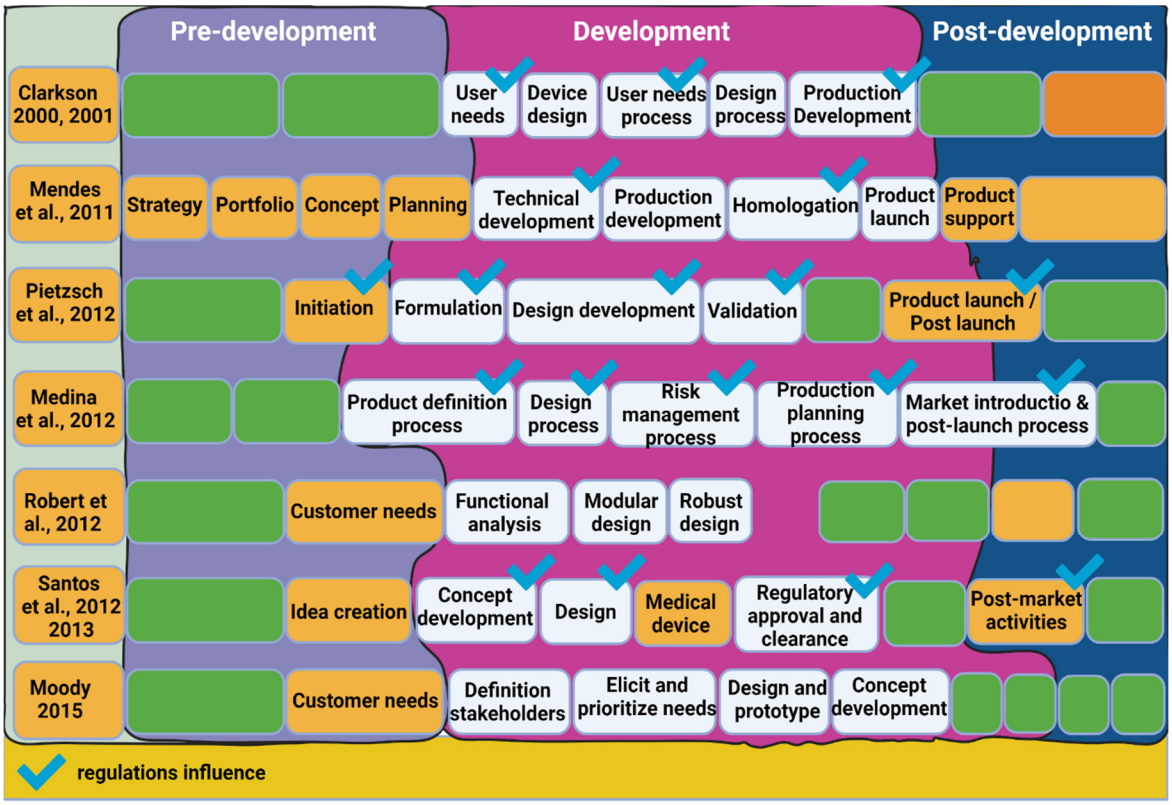

Figure 2. Overview of Medical device Development models from the Literature [7].

There is an absence of data correlating stage-gate approaches with NPI success [20], with motivation for using such approaches stemming from regulatory compliance rather than process excellence [8]. Stage-Gate® methodologies have permeated virtually all engineering industries, with examples in the oil and gas [41], toy [42], pharmaceutical drug [43], food [44], automotive [45], and aerospace [46] industries. Cooper and Edgett's Stage-Gate® resembles Toyota's NPD approach while also allowing for greater scalability

and flexibility compared with traditional Stage-Gate® methods. The stage-gate system breaks the innovation process down into a predetermined set of stages, each stage consisting of a set of prescribed, cross-functional, and parallel activities [47]. The entrance to each stage is a gate: these gates control the process and serve as the quality control and Go/Kill checkpoints.

Numerous publications have highlighted that the linear nature of generic Stage-Gate® approaches is not compatible with the iterative nature of the development of complex products such as medical devices [7,48,49]. For example, within the stage-gate model, although each development phase is presented in a discrete manner, the iterative process of device development does not always follow the linear idealised model, but rather involves fuzzy boundaries between decision gates [10]. Because of iterations in the device development process, some parts of a development project may already be in a more advanced phase, while certain activities of a previous phase need to be repeated at the same time.

2.2.2. Concurrent Engineering

Over 75% of aerospace companies use a Concurrent Engineering (CE) approach to NPI [9]. The most widely accepted definition of CE asserts that a CE approach systematically integrates product design activities with their related manufacturing and support processes, resulting in a heightened awareness of all elements in the product life cycle [5,9]. Core tenets of CE include collaboration, strong stakeholder and customer engagement and supplier integration [5]. This approach, like Integrated Product Development, relies heavily on project management (PM) best practices, and reduces the critical path of a product launch by sequencing activities in a manner that results in them being executed concurrently where possible [50]. It is now widely considered to be a core element of Lean NPI [51]. Reviews are used to ensure agreement across the cross-functional team throughout the project, resembling the stage-gate model described previously. In the context of the MedTech sector, there are three groups of design attributes to consider: customer attributes, functional attributes, and regulatory attributes. A key difference in the use of CE in MedTech is design convergence and selection being required earlier than in other engineering industries due to regulatory submission requirements [5].

Design for Manufacturability (DFM), Quality Function Deployment (QFD), Design of Experiments (DoE) and Stage-Gate® approaches were commonly used in many medical device companies as surveyed by Brown et al. [15] and while the Lean NPI toolbox considers these to be extensions of Lean product development [52], Lean specifically was found to be commonly used in just a third of companies, and it is unclear if this use of Lean proliferated beyond manufacturing processes [20]. Considering that numerous publications describe the MedTech NPI process as a Stage-Gate® process [10], it is inferred that there is a degree of overlap and coexistence between CE and Stage-Gate® in the industry. There are inconclusive results on CE improving NPI performance in the medical device industry [20] due to an absence of case studies. The previous research has been primarily focused on possible philosophies and adaptations needed in the regulatory context of MedTech instead of measuring the success of implementation [33]. Alternative the MedTech NPI strategies proposed to address deficiencies of the Stage-Gate® methods align with the values of CE through the acceptance of iterative processing [49]. Within broader engineering applications, CE has shown to be effective in reducing time to market. Lead time reductions of approximately 25–30% were noted in early studies [5]. A comparative lack of success stories relative to the number of past research studies has highlighted a need for more case study-orientated research with more clarity on the core tenets of CE and a well-organised methodology for the implementation of potential solutions.

2.2.3. Agile

Agile project management is a means that has been used by companies such as Toyota and Honda for years. It is an alternative approach towards project management whereby

there is an increased emphasis on cross-functional project teams working on highly complex products, coping with both mechanical- and software-related issues and is utilised in the device industry [33]. Agile methodology has been heavily applied to IT project management (PM) in the past decade [53]. Research into the use of Agile in projects in other fields has been emerging in recent years, with some notable studies on its application in improving the overall product development cycle [54]. There are still challenges bridging Agile from software applications to physical product applications [55].

There is a large degree of confounding issues between Agile and Lean methodologies given the origins of Agile, to the extent where they were combined as a single hybrid approach known as "Leagile" in some industries [56]. Given its primary application in software applications, most of the literature concerning agile product development in the medical device field relates to medical device software, with no major work concerning physical medical devices. Uptake in medical device software development is slow, with other waterfall-style development methodologies used to adhere to regulatory requirements [57]. This may be overcome through adaptations of Agile [58]. Of relevance to this review is the publication of a case study on the application of Agile methodology to medical device product development [59], which may be indicative of a creep into medical device NPI settings.

A hybrid model was successfully used by the toy company LEGO®, featuring a combination of Agile and the predominant medical device NPI approach, Stage-Gate®. The relative success of this method in a physical setting and the familiarity of these methods with medical device organisations is promising [48]. In recent years, Agile was adopted into the latest revision of the Project Management Body of Knowledge (PMBOK®) [60], the most widely used PM guide [61], and the basis for the ISO standard on PM guidance [62]. This is indicative of its emergence as a mainstream PM methodology.

2.2.4. Design Approaches and Methodologies

Individual process excellence tools were used to some extent to improve the NPI process. QFD is a useful approach for converting customer requirements into quantifiable product characteristics and may complement CE [9,63]. Excellence in the way of Design for X (DfX) tools was documented in the industry; however, these tools are generally limited to individual facets of the overall NPI life cycle [22]. Most notable is DfM, an embodiment of the CE mindset through advocacy of consideration of downstream consequences [64]. This is commonly applied in medical device process development with some success in reducing costs and lead time [65]. Validation, an element common to all medical device NPI projects, can be improved using DoE [66] and Design for Validation (DfV) approaches [67].

2.3. Emergence of Lean NPD and NPI

Lean NPD was first officially introduced in a frame of Toyota's development system [68–72]. Fundamental differences in the Toyota product development process from those in MedTech mean it is not possible to directly apply their techniques because Toyota's methodology is based on the development of a range of alternative designs [73]. NPI in the MedTech sector emphasises that the selection of a product design is recommended to occur at an early stage to proceed with regulatory submissions and further to ensure a quick lead time to market [5]. Regulatory authorisation is generally based on substantial equivalence with a predicate product design, therefore design changes during CE activities in the MedTech sector are generally limited in scope to individual product features, with regulatory design attributes firmly set. The resulting product development system still features feedback, but it aligns more closely with that of traditional point-based CE [74]. Toyota's NPD approach is not considered to be as effective as current Lean NPI best practices [9]. The conflation of Toyota's product development system with Lean NPD has led to ambiguity around what constitutes Lean NPD, a feature of earlier research in the field and requires further research.

2.4. Lean NPI Best Practices

2.4.1. Lean NPI Deployment Framework

The turn of the 20th century saw the publishing of several seminal resources on the use of Lean in engineering and NPI applications as research in this area gained attention, with a heavy focus on aerospace engineering. One such standout publication was the manuscript authored by Hugh L. McManus and published in 2005 [75]. This manual was the result of a collaboration between the Massachusetts Institute of Technology (MIT) and other industry and academic partners. This publication was heavily cited in the field and has become a 'playbook' for the practical implementation of Lean in NPI. Tyagi et al. [76] stated that their literature review demonstrated a shortfall in research in this area to the extent that, despite a decade passing between publications, little emphasis had been placed on Lean thinking implementation frameworks in NPI outside of McManus' 2005 publication [75]. This shortfall in research was continuously highlighted in the literature [9,54]. In particular, the practical guidelines for adopting Value Stream Mapping (VSM) as a structured Lean implementation approach for NPI are of relevance [75]. VSM offers an opportunity to take tools that medical device organisations are familiar with and deploy them in a more structured and targeted manner to address improvement opportunities unearthed as part of the mapping process, as shown in Figure 3.

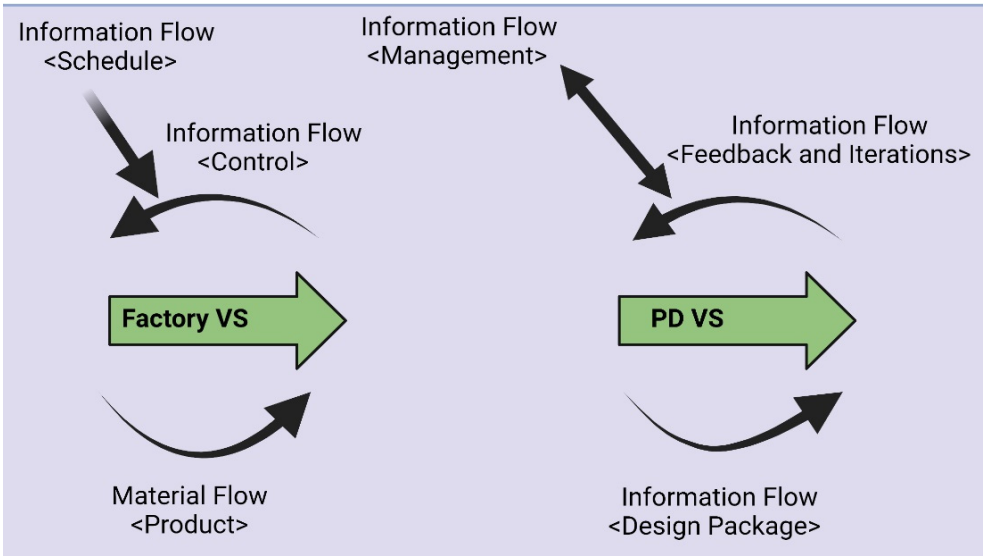

Figure 3. Adapting VSM for NPD/NPI processes [75].

VSM quickly gained traction in the broader manufacturing industry following the publication of *Learning to See* by Rother and Shook [74]. Their VSM method did show "information flow" of scheduling and control information from management and external sources back up the value stream, but this was tertiary to the "product" or material flow [77]. Instead of "information" being considered as a tertiary element, McManus offers a transactional VSM approach where information replaces material as the main element of value flowing through the value stream [75]. McManus's work acknowledged the greater complexity associated with the nature of NPI processes relative to manufacturing processes through the acceptance of two-way information flow and iterative processes—elements that are often overlooked in simplified bodies of work associated with Lean product development [78]. This is a fundamental change to Lean and somewhat of an acknowledgment that CE methods must be adopted into the Lean NPI toolkit to facilitate the transition from the manufacturing floor to an NPI setting. CE's presence in the highest-impact Lean NPI frameworks presented in the past decade affirms this theory [76,79].

Case studies have demonstrated the success of VSM in NPI spaces. Freire and Alarcón [80], one of the first publications on the use of VSM in NDP, claimed an error

reduction rate of 44%, a waiting time reduction of 53%, and an NVA reduction of 31% Cooper and Edgett's study [81] on the proprietary NexGen Stage-Gate® system claimed benefits using a VSM approach to reduce waste at each step of the process.

A 2015 study applied the work of McManus [75] with a reduction in product development lead time of 50% [76]. This is at the lower scale of McManus's estimate of a 50–75% reduction in cycle times but is sizeable [75]. Broader applications in other "transactional" settings return lead time reductions of up to 80% [26,27].

2.4.2. Lean Principles

Following "The Machine that Changed the World", [69] developed a comprehensive Lean philosophy based on five Lean principles. Their intention was that these principles would extend Lean thinking beyond the manufacturing floor, providing a philosophy and framework used for complete organisational excellence. Subsequent publications have built upon the original Lean principles, adapting them for specific areas of deployment but remaining true to their original intent. Failure in applying Lean to NPI settings is primarily attributed to the companies attempting to "*manufacturise*" Lean, transferring Lean manufacturing techniques to NPI settings without any adaption [82]. Haque and James-Moore [72] discussed the application of Lean in NPI and were one of the first to fully define the Lean principles in an NPI context. The paper focused on the aerospace industry's NPI process, but this can be considered analogous to the medical device NPI process given the similar flow and outputs. The output was the identification of "value" in the context of NPI, the application of VSM to Lean NPI and the incorporation of the seven wastes [9]. Robust guidelines on rethinking the Lean toolbox in the context of NPI were issued. Fundamentally, the five Lean principles, as described by Womack and Jones, remain applicable and act as sequential steps to implementation, as shown in Table 1 [70].

Table 1. Lean Principles in Manufacturing vs. NPI [70].

	Manufacturing	**Engineering**
Value	Visible at each step, defined goal	Harder to see, emergent goals
Value Stream	Parts and material	Information and knowledge
Flow	Iterations are waste	Planned iterations must be efficient
Pull	Driven by takt time	Driven by needs of enterprise
Perfection	Process repeatable without errors	Process enables enterprise improvement

However, value and flow are framed in the context of information and knowledge outputs in an NPI process. Waste is considered in a more abstract manner than a traditional manufacturing process [9,72]. The use of modular designs is also discussed, concepts that are anecdotally widespread in the medical device sector to develop families of products of similar design but different sizes for differing anatomical requirements (e.g., differing sizes of stents and implants). The adapted Lean principles serve as a foundation from which all other Lean tools and techniques can be adapted, as shown in Figure 4.

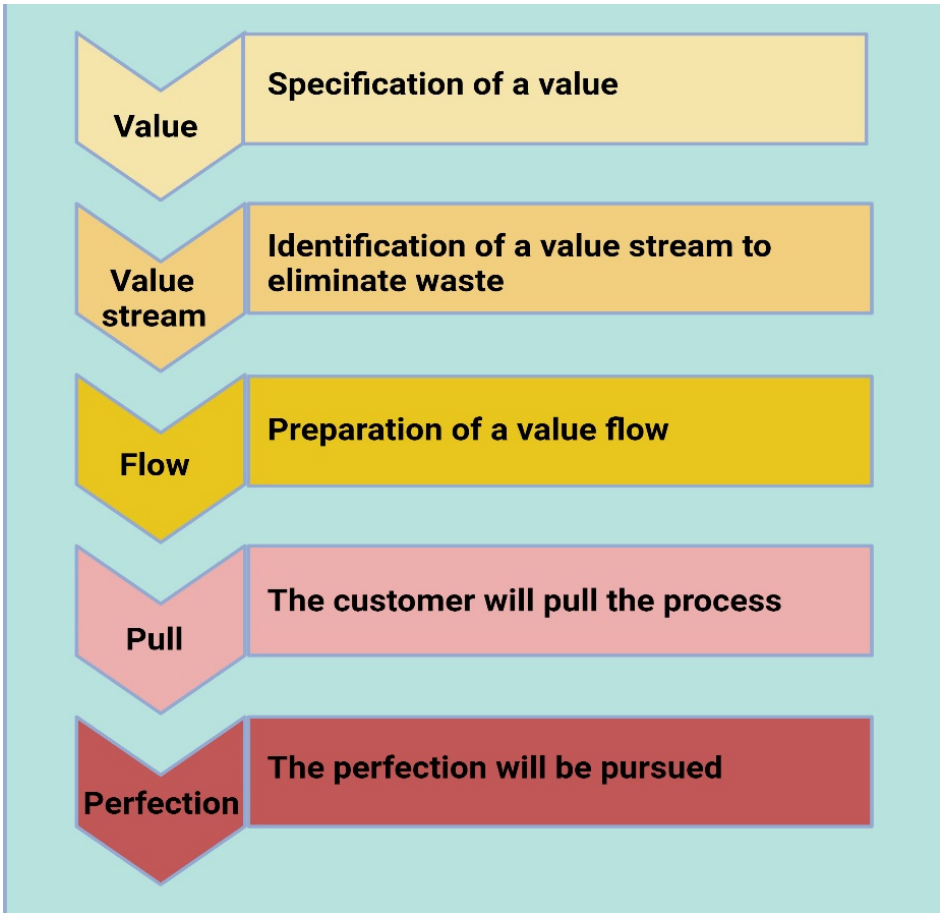

Figure 4. Lean Principles in Transactional Engineering Contexts (adapted from Womack and Jones [70] and Haques and James-Moore [9,72].

Publications on the application of Lean to medical device NPI are sparse; however, there are some case study examples relating directly to this topic but these are limited to the deployment of individual tools from the Lean toolbox [71].

2.4.3. Metrics

Lean manufacturing benefited from an established performance measuring culture which preceded it [9]. As is the case with Lean manufacturing, metrics are also essential to the success of Lean in NPI, serving as the basics for process characterisation and benchmarking efforts [83–85]. A review of 15 years of VSM literature analysed 57 papers and concluded that problems measuring processes were the most common impediment to the success of VSM, highlighting the importance of metrics [86].

From a business perspective, productivity in an overall NPD context may be measured as a factor of revenue/profit from a new product relative to the cost of developing and launching it [87]. This metric resembles the NPI Effectiveness Index (2004). Metrics may be measures of the NPI process itself, measures of the output of the NPI program, but more commonly, a combination of both [84,85]. Further metrics were proposed to establish the degree to which Lean is embedded within the organisation's NPI process [77].

Within NPI, the customer may be the organisation, the sustaining engineering team, or a downstream process. Along with cost, lead time is the most heavily emphasised NPI metric, but is relatively easy to measure. Value is a particularly difficult metric to define in NPI [88]. The value must be defined as part of the first Lean principle [89]. It is a foundational metric in VSM used to calculate the 'Value Stream Index', a ratio of VA activities compared to total NPI lead time [90]. It is also needed to separate Value-Added (VA) and Non-Value-Added (NVA) activities. Darwish et al. [91] generated standard definitions

which can be used to overcome the lack of well-established standardised productivity metrics in this space.

Costa et al. [85] characterised the relationship between Lean principles and NPI metrics through a series of focus groups with industry experts, further defining the understanding between individual Lean principles and specific program metrics. The Lean implementation metrics were distinguished from program performance metrics. The most comprehensive practical guidance on measuring VA and NVA in an NPI setting was proposed in other works which distinguished between wasteful and non-wasteful iterations [86].

A common theme in the research into metrics in Lean NPI is the identification of prohibitively large numbers of metrics in use [9,78,79]. Metrics should be practical and appropriate to the scale of examination—performance and value add (VA)/non-value add (NVA) should be emphasised over business program metrics such as the NPI Effectiveness Index when examining at a process level, while macro-level program analysis should be pitched more at customer and business value views. Tools such as QFD and CE may be leveraged to help integrate the needs of all stakeholders and translate customer requirements into specific product metrics [63].

Independently, others have built upon the understanding of waste in a Lean NPI context [9,80,92–94]. Because of the information-based workflows in NPI settings, waste is not as visible or tangible compared with the visible waste from a physical product in a manufacturing setting. A survey of waste in product development in the aerospace industry revealed waiting and over-processing account for approximately half of the waste identified [95]. Inventory (information waiting to be used) and overproduction of information are closely aligned waste categories and are featured prominently. Similarly, locating and waiting for information was found to be responsible for almost half of the waste in a design-based NPD process [92]. Detailed guidance on the seven wastes in an NPI setting can be found in Table 2.

The tool 5S is a fundamental tool often deployed as a company embarks on a Lean transformation. It is easy to understand at an abstract level but is underutilised and often overlooked [96,97]. It can be used to holistically embed concepts such as visual management, neatness, organisation, and standardisation into the workplace [98]. Information management is important in a transactional setting. Limited literature exists on the use of 5S in an NPI setting directly. It was briefly discussed in [9,78] but there is a greater wealth of information from the service industry with comprehensive guidelines which can be leveraged [99,100].

Conformance to the same regulatory requirements and quality systems standards resulted in a range of outputs that are common across medical device organisations [6]. Opportunities for standardisation and the use of re-usable knowledge continue to grow as regulations converge. This is particularly true of documentation-based processes, with best practices abundantly available within the literature. Khan et al. [74] found that approximately 80% of NPI tasks are routine tasks, while lessons learned captured are not used effectively, demonstrating the clear opportunities for standardisation and creation of re-usable knowledge.

Table 2. Seven wastes and their application to NPI [9,75].

Seven Wastes	Applied to NPI
Transportation	• Complex structure for decision making and approval • Information incompatibility. File transfer • Information handled by multiple people before arrival • Poor data interface and management
Unnecessary motion	• Retrieving printed materials • Poor physical layout and 5S • Information forwarded to wrong people • Data acquired then not used
Unnecessary inventory	• Unnecessary detail or "just-in-case" information • Poor configuration/revision management • Obsolete and outdated documents/information
Waiting	• Information waiting—information is delivered too early—maybe absolute by the time it is used • People waiting—information is delivered too late—process cannot continue without this information
Inappropriate/overprocessing	• Too many meetings yielding no results or consensus • Failure to identify and manage design risk requirements • Avoiding use of technological advances/aides • Excessive approvals • Excessive formatting and customization of documents • Unnecessary serial processing • Too many iterations or re-work, out of sequence working • Excessive verification and testing • Underutilization of knowledge • Overspecification/overdesign
Overproduction or early production	• Too many products, designs, or projects • Over design, over-specification, over tolerancing • Reductant development—i.e., Reuse not practiced

3. Methodology

A literature review was utilised in this study. A systematic approach was taken. Burgess, Singh and Koroglu [101] defined a systematic literature review (SLR) searching different databases and sources and then selecting relevant articles related to a search theme.

The researchers systematically searched for articles relating to the subject matter published between 2011 and up to and including 2021, using the search engines of the academic databases of the Web of Science, Scopus, and MEDLINE. The search strings that were applied to search all the databases were related to the research questions and topics; "Lean" and "NPI" and "Lean" and "NPD", "Lean" and "NPI" and Devices", amongst other search strings.

Figure 5 summarises the methodology for carrying out the literature review with a summary of the inclusion/exclusion criteria. Finally, grey literature (magazine-related articles, workshops, editorials, prefaces) were excluded. A flowchart was utilised to draw out and map the steps within the SLR process (Figure 5). The flowchart allows future researchers to follow, replicate and draw implications from the research findings [102]. Reviews and independent assessments of the articles were carried out by the authors to assess the inclusion eligibility of the retrieved studies based on the search criteria [103]. Inclusion was decided and agreed upon by discussions and gaining consensus among the author reviewers. At this stage of the review, 220 studies for final inclusion were yielded. An independent review of each paper was carried out by the authors and coding was carried out utilising a meta-framework. After extraction of the final articles and recording these in Excel coding was utilised to minimise errors. Based on the sub-themes under investigation in relation to the research questions further analysis was conducted. This

analysis themes such as methods for integrating Lean in NPI, regulatory considerations of Lean and NPI in devices, Lean and NPI in other industries, as outlined in Section 2. Utilising the literature review methodology, 135 articles or relevant research papers were filtered out for more exploratory analysis of the sub-themes of Lean in NPI in medical devices and in other industries.

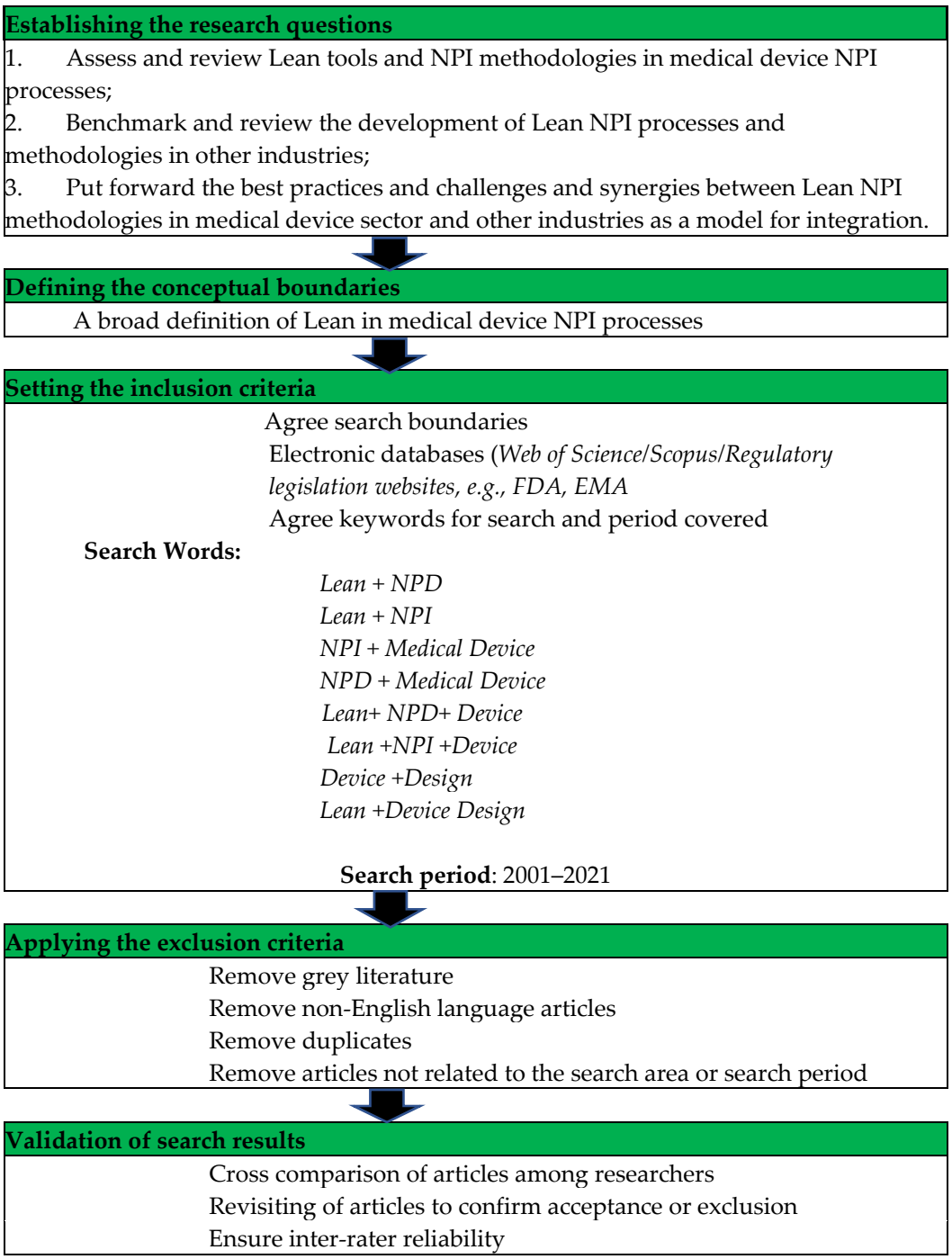

Figure 5. The Literature Review Process Flow char.

4. Results from the Literature Research

These results discuss the integration of a Lean NPI approach in the medical device industry as well as the regulatory considerations which affect NPI in the device industry.

4.1. Integrating a Lean NPI Approach in the Medical Device Industry

CE may appear to be at odds with Lean as the iterative approach could be construed as wasteful when looked at through a traditional Lean manufacturing lens, as shown in Haque and James-Moore's [9] examination in Table 3. However, CE is a key element of adapting Lean for iterative design activities in NPI spaces [9,78,104].

Table 3. CE and Traditional Lean Philosophies Compared [9].

Concurrent Engineering Philosophy	Lean Philosophy
• Lacks an enterprise-wide common strategic direction or statement for implementation. It is naturally directed towards improving NPD process and thus promotes specialized tools such as DfX tools, etc. • It lacks a life-cycle approach, and the focus is not on 'how to', but on 'what to do' • Liable to different interpretations and definitions • It does not classify and contextualize waste and waste elimination occurs as a by-product of CE activities • It promotes customer focus and improves the information flow without a clearly defined systematic approach • It provides overlapping activities and the flow of partial information based on downstream process needs. It greatly improves the information flow and is seen as the engineering version of a manufacturing-type pull system.	• Lean is by definition an enterprise initiative with a common format for various business processes with the single strategic goal of eliminating waste and improving the flow of value. Its basic/original definition does not, however, address adequately the needs of NPI processes • Life cycle approach is used to drive continuous waste elimination to provide an implementation route map for Lean • 'Value' and 'Waste' are considered the main factors • Waste is initially identified, and then classified and contextualized within given value streams to be eliminated in the last step • It promotes (a) creation of value stream maps based on customer demands and (b) flow is only possible after waste is eliminated, and (c) the value-creating process can be eliminated at a customer-defined rate • The concepts of takt time, single piece flow and the pacemaker process are promoted

The underpinnings of Lean NPI described by Womack et al. [68] include "Simultaneous development", a concept resembling CE. Simultaneous development was featured alongside the following additional elements: an effective authoritative project leader, teamwork, and early and controlled communication. Early studies indicated that CE cannot be achieved in the absence of these other additional elements presented by Womack [68]. Therefore, from a cultural perspective, the prevalence of CE in the current medical device NPI environment is promising for the goal of Lean NPI integration and uptake.

4.2. Regulatory Considerations

Regulatory constraints were shown to limit the uptake of operation excellence tools in general in medical device companies [16]. One proposed approach for managing regulatory requirements during medical device NPI is the Design for Food and Drug Administration (DfFDA) method first, as shown in Figure 6 [6].

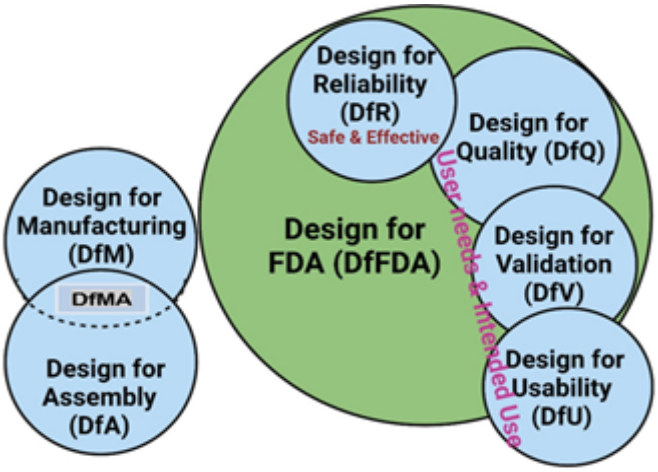

Figure 6. DfX for the MedTech sector [6].

DfFDA is an overlap between Design for X (DfX) methods and medical device regulations [6] and offers the potential in reducing regulatory lead times through consideration of regulatory attributes in design. The COVID-19 vaccination development demonstrated how the traditional NPI cycle for a pharmaceutical product can be collapsed. From a medical device perspective, high volumes of basic PPE and test swabs made it to market quickly but are considered 510(k) exempt Class I devices. Class II medical devices such as N95 respirators and powered air-purifying respirators (PAPRs) made it to market at a relatively quick pace due to temporary. The Voluntary Manufacturing and Product Quality Pilot Program was launched by the FDA in 2018. As part of their wider Case for Quality Program, the FDA aimed to shift the focus in the medical device industry beyond regulatory compliance while also demonstrating a positive impact on patients by streamlining regulatory processes and reducing waste. The pilot was successful and is earmarked for wider implementation [16,17]. Additionally, the increasing popularity of product combinations can further add to regulatory complexity [8].

The lack of direct research concerning the application of enterprise excellence tools to Medical device NPI is apparent. The automotive industry is the leading application of Lean NPI followed closely by the aerospace industry, from which much of the 21st-century research is derived [52]. It was suggested that the lag in the uptake of Lean NPI methods may be 10–15 years in other engineering settings, a possible explanation for the lack of publications [86]. The confidential nature of medical device organisations may be another reason for the lack of publications [37].

Stage-Gate® approaches were identified as a core element of all medical device NPI projects, mirroring process guidance set down by regulatory bodies. Stage-Gate® is effective to ensure that standards are followed but it can also continuously highlight a deficient when compared to NPI tools in use in other industries. CE is commonplace in medical device NPI based on the literature reviewed and CE compliments Stage-Gate's deficiencies [5]. Many medical device companies, more commonly smaller companies, have a large focus on regulatory compliance and not enough consideration for customer and stakeholder value [20,49]. CE is a potential remedy to this due to the fully integrated product life cycle approach. CE can also overcome the linear development cycles commonly associated with the Stage-Gate® PM techniques employed in the industry. Iterations must be assessed and planned carefully. Used appropriately, they can reduce the cost and lead time of activities such as product design, but it is obvious that iterations of high-cost activities such as clinical trials should be avoided. CE ensures concept feasibility is established before commitment, eliminating late rework of product and process designs. It is considered a key enabler of Lean NPI [100]. This use of iterative processing within the Stage-Gate® approach resembles that of the medical device development system proposed by Ocampo and Kaminski [7] and later adaptions of Stage-Gate® by its founder to iterative or "spiral development".

While this may serve as a barrier to true innovation, it does reduce waste seen in new product development activities from other fields where previous designs are not effectively leveraged.

It should be noted that there is a need for further literature publication on the latest NPI methodologies in use in the industry, as the literature is sparse and not very up-to-date [20]. Beyond the medical device sector, this review sought to trace the development and underpinnings of Lean NPI theory through its initial origins, and the subsequent publications further defining facets of NPI in recent years. Executing a review of Lean NPI literature was hampered to a degree by the loose definition of what constitutes "Lean" in engineering settings [52,74]. The literature supports the hypothesis that Lean thinking can be successfully deployed in NPI settings. There is a degree of consensus amongst authors surrounding some best practices and key factors for success. Firstly, the five Lean principles described by Womack and Jones [68] must be tailored to this application. This fundamental change in thinking is needed to consider the value and flow in the more abstract context of information and not material goods, as illustrated in Figure 5. The five principles can be used as sequential steps for implementation. The transformation of the Lean principles from traditional settings to a transactional space is further described by Haque and James-Moore [9,72].

The deployment of Lean using VSM complements the sequence of the five Lean principles. In-depth characterisation of an NPI project using Value Stream Mapping (VSM) techniques will allow for a more accurate portrayal of the current state of the NPI Value Stream. Through this characterisation, issues within the NPI process will become apparent. Individual standalone tools and techniques within the Lean toolkit which are already used within the medical device industry can now be selected and deployed in a more targeted manner. Lean and VSM may address the lack of strategic direction and implementation strategy associated with CE [9].

Metrics are essential in the use of VSM. Initial efforts to calculate the Value Stream Index may begin by measuring lead time and "elapsed time" in lieu of traditional "cycle time"—the time it takes the engineer and tool from beginning to delivering the output. VSM may begin with individual NPI processes, e.g., a process validation, individual phases within the NPI process, e.g., design and development, or the overall NPI cycle. This allows for scalability within an organisation and proof-of-concept verification. Greater complexities in deploying VSM will be apparent due to the iterative nature of NPI processes relative to manufacturing processes. Adaptions to VSM proposed by McManus [75] will require training and practice. Specific mapping symbols and mapping templates can be seen in previous research [75,88]. When deployed in analogous settings, VSM results in lead time reductions of 50–80%. VSM is most effective at improving the core engineering processes in the NPI cycle [75]. Thus, it has the greatest impact on the formulation, design and development and final validation phases of the five-stage model (as represented in Table 1 and Figure 4). The adaptation of the seven wastes to Lean NPI and the provision of examples of opportunities to reduce waste may be identified using VSM tools.

Opportunities for standardisation and re-usable knowledge creation are abundant in an NPI setting, including but not limited to the use of electronic document management systems, harmonised software systems and file types, electronic document templates and streamlined approval processes. Within companies, there are further opportunities to standardise using modularity in terms of interrelated platforms and components. Lessons learned from databases regularly used in PM forums can be actioned into re-usable knowledge, while Corrective and Preventative Action (CAPA) and Non-Conformance (NC) data can be continuously reviewed to ensure Right-First-Time (RFT) in future efforts. As outlined in the initial research objectives, this review has put generic best practices and theories associated with Lean thinking in medical device NPI. The interaction of proposed tools in medical device NPI phases is summarised in Figure 7.

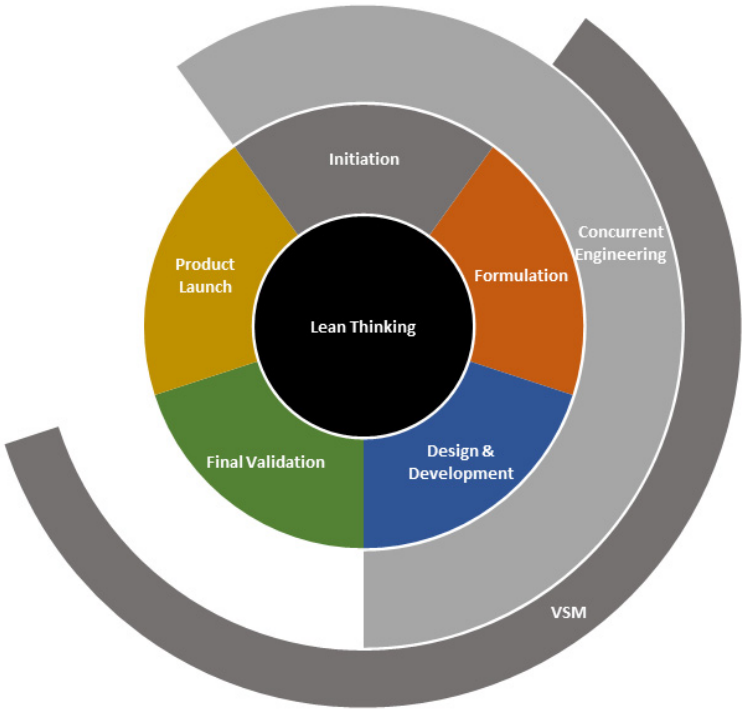

Figure 7. Interaction of proposed tools in Medical device NPI Phases (author constructed).

The combination of various tools and best practices associated with Lean thinking in medical device NPI can support the overcome of cultural, philosophical, and educational bridges and support the successful integration of Lean methodologies. There are prescriptive existing resources such as the Lean Enablers outlined by Costa et al. [85] providing an example of a detailed implementation roadmap. The Lean NPI system proposed has not been tailored to factors such as product design complexity and novelty, which have a major impact on time to market and time to regulatory approval, nor the experience of the NPI team, another major factor in time to market [6,11]. Regardless of complexity, novelty, and experience, all NPI projects stand to reduce cycle time using the proposed methodology. Successful implementation of Lean in transactional engineering spaces is dependent on the same success factors as traditional Lean implementation in manufacturing, with buy-in from executive leadership and the entire value stream critical to success [98].

4.3. Implications, Limitations and Outlook

Criticism was leveled at Lean, such as the perceived lack of systems analysis and statistical analysis [18] and a narrow focus on waste [20]. There were instances of Lean NPI failing, with Leon and Farris [105] publishing a review on the topic. The primary reason cited for the lack of Lean NPI implementation and success was the greater complexity associated with information/engineering processes when compared with the manufacturing processes with which Lean thinking was first developed. The complexity was combined with a potential increase in the number of activity interdependencies and the associated implication of relying on information from upstream tasks, making the exchange of information among activities more difficult to manage. This is attributed to the use of CE, which features overlapping activities with the intention of accelerating the process by combining sets of iterative and parallel processing activities for delivering value. It was also asserted that CE lacks an enterprise-wide common strategic direction or statement for implementation [9].

It was argued that Lean product development methods are little more than an amalgamation of tools and techniques that already exist in the space, falling short in novelty in their approach to improving NPI [52]. As Lean generally co-exists with other organisational excellence tools [20], it could be argued that Lean's success is somewhat conflated with

that of other tools and methods. Salgado and Dekkers [52] also argue that Lean product development publications fail to account for the true complexity of engineering processes, implying that authors transpose over-simplified strategies from Lean manufacturing from the shop floor to engineering settings. This position overlooks McManus's [75] publication which offers a comprehensive insight into the complexity of information flow and task interdependency in the context of Lean product development, albeit at the risk of blurring the line between CE and Lean NPI [105].

There is a paradigm shift occurring known as fourth-generation manufacturing, or Industry 4.0. This shift comes with both new challenges and new opportunities for Lean NPI. The increasing pace of technological advances puts companies under increasing pressure to reduce lead time to market for new products and technologies. There is also a demand for greater product customisation, which is spreading to healthcare products [106]. The increasing competitiveness in the industry is further highlighted by a survey revealing only 12% of new medical device companies provide significant returns on investment [49]. Lean NPI may be a potential enabler of Industry 4.0 as it may reduce the need for costly redesigns, a form of waste of heightened importance in the context of complex product designs being produced using automated manufacturing systems [107].

Reciprocally, virtual manufacturing and simulation software reduce the lead time of the design iteration process, facilitating Lean NPI [108]. Existing end-of-line sampled inspection methods must be substituted with Industry 4.0 systems capable of ensuring quality at point-of-process [109].

5. Conclusions

This review has assessed and reviewed Lean tools and methodologies in medical device NPI processes (RQ1), benchmarked and reviewed the development of Lean NPI in other industries (RQ2) and put forward the best practices and challenges and synergies between Lean NPI methodologies in the medical device sector and other industries as a model for integration (RQ3). There is a need for a specific medical device NPI methodology to accelerate product launch at lower costs in an increasingly competitive marketplace. The industry has traditionally lagged behind automotive and aerospace in the uptake of enterprise excellence tools, sheltered historically to some extent by higher profit margins which are now eroding. The regulatory environment poses a notable challenge to the implementation of alternative NPI strategies, with the well-established Stage-Gate® system mirroring the structure of pathways set down by regulatory bodies. This review has shown that CE remains the standard approach to managing planned product and process design iterations, whereas Stage-Gate® Project Management is retained to manage project phase transition and regulatory design control requirements. Lean tools and techniques complement these project execution tools to affect change in what work is carried out and how it is completed. These methods are implemented using Value Stream Mapping for structured implementation and targeted removal of waste from the NPI process. Implementation is scalable from the sub-process to the overall NPI cycle. There are cultural, philosophical, and educational bridges needed to embed the proposed methodologies into the medical device industry. An absence of literature relating directly to the application of Lean systems to medical device NPI makes it difficult to estimate the potential improvements to KPIs such as cost and lead time to market despite the significant cost savings cited in other industries.

Regulatory constraints mean that expectations for improvements in the medical device industry should be scaled back. Future research is suggested by this review to focus on a longitudinal case study of Lean NPI application in the medical device NPI process as well as qualitative and quantitative studies exploring Lean use in NPI/NPD processes within the device sector. This study is of value to academics as there is a dearth of studies on Lean application in medical device NPI processes as well as aiding the device industry in understanding the advantages and benefits of Lean to NPI processes. This research can be utilized to advocate Lean NPI as a potential enabler of Industry 4.0 as it may reduce

the need for costly redesigns. The study also highlights how Lean NPI can ensure society and the public gain access to the latest state-of-the-art devices in a timely manner through well-thought-out Lean NPD/NPI processes.

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