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Systemic Bottleneck Elimination and Throughput Optimization Using Integrated Lean-Simulation Methods across Regulated Industries

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ABSTRACT

Regulated industries such as pharmaceuticals, medical devices, food processing may be subject to bottlenecks which reduce throughput, cost and slow down operations critical in compliance. Although conventional Lean instruments can be used in finding areas of inefficiencies, by being dynamic and complex, these systems are beyond the helpfulness of the conventional Lean tools. The present paper proposes an Integrated Lean-Simulation Framework, which integrates the Lean methodologies and simulation modeling in order to optimize the system performance. The strategy allows teams to see prior necessary adjustments on how to eliminate bottlenecks, simulate a what-if situation, and perform the changes with a minimal risk. The example of case studies in various regulated industries shows gains in throughput, lead time, and utilization of resources owing to an increase in compliance without decreasing compliance. The framework provides a scalable data driven continuous improvement offering in high compliance environments, the bridge between operational excellence and digital transformation.

INTRODUCTION

By contrast, in highly-regulated fields like pharmaceuticals, medical equipment manufacturing and food processing the efficiency of operations is not merely economic benefit, but a regulatory requirement. These industries are under strict control by various authorities including FDA, EMA, ISO and other international authoritative bodies. This brings a situation where throughput, traceability and process reliability is of paramount importance [1]. The complexity itself (in the form of specific

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regulations such as batch release practices, documentation guidelines, and validation mechanisms) can have the unintended consequence of workflow and responsiveness suppression due to their nature [2].

Among the most vital operation issues in these environments is the existence of bottlenecks. A bottleneck is any given point in that process which hampers the total capacity of the system. These restrictions may be in a form of long quality assurance holds, restricted available cleanroom, inspection rework loops, or even excessive time to changeover caused by cleaning validations, in a regulated environment [3]. The bottlenecks may result in long lead times, work-in-progress (WIP), higher labor costs, and the most important of all, compliance risks: deviation-prone process or failed promises to deliver.

Traditionally, the organizations have resorted to the principles of Lean manufacturing to help diagnose and remove such inefficiencies. Beginning out of the Toyota Production System, Lean mentions a group of organized tools and philosophies geared towards decreasing wastes, constant improvement, and flow enhancement [4]. Thermal applications and Tetrix are some of the tools that have penetrated operational excellence programs in regulated industries. These approaches assist organizations to recognize the appearance wastages, as well as motivated the frontline units into improvement [5].

But the traditional toolbox of Lean is usually not able to work in such an environment, where there is dynamic variability, tight change controls, and processes interdependencies are the order of the day. Lean tools are normally in unchanging form, using snap shot analysis and qualitative observations, which do not necessarily capture the natural variability and real time complexity of production systems [6]. Trial-and-error methods cannot be applied in the regulated environments since any change in the process needs to be thoroughly justified and followed by a documented account. This curtails the rate of progress and experimentation becomes dangerous or expensive [7].

In order to fill these gaps, this paper proposes a hybrid approach by combining Lean diagnostics with simulation modeling. Simulation, especially discrete-event simulation (DES) and system dynamics (SD), provides a potent method of describing the stochastic behavior of systems through time [8]. The variables that may be used in these models include machine down time, manpower, inspections, batch release, etc. where the user can virtually test and perfect process modifications. Modeling of what-if scenarios allows teams to simulate the consequences of various interventions without interfering with the activities of various operations [9].

Such integration presents a synergistic context complementary to each other: Lean tools point out the problems and simulation models quantification and test the solutions. Collectively they help

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organizations shift their mindset to be proactive, data driven and cease to be in reactive troubleshooting mode. Such an approach is optimal in settings in which compliance, traceability, and performance are required to co-exist, allowing a given setting to be improved without undermining the integrity of the regulators [10].

This article aims to put forward a systematized five-step Lean-Simulation doctrine that could be utilized in various controlled manufacturing lands. The combination of qualitative analytics of Lean and the quantitative computational strength of the simulation will provide a reasonable path to an end of bottle necks, maximization of throughput, and ability to withstand operational disruption [11]. Pharmaceuticals, semiconductors and medical devices case studies provide real-world insight into how this approach provides measurable performance improvement (e.g. shorter cycle time, better equipment utilization, faster quality release to market), all based on highly demanding regulatory oversight. Overall, the suggested methodology allows the company to pursue a more flexible and sustainable continuous improvement model and succeed not alone in achieving a compliance level but in flourishing within a highly competitive, innovation-based environment [12].

BACKGROUND AND LITERATURE REVIEW

The idea of bottlenecks has been a subject of research in production and systems engineering over a long period of time. A bottleneck is something that by definition is a procedure in a process that constrains the entire flow or throughput of the whole system. Untamed bottlenecks lower efficiency of operations, cycle time and swell costs [13]. These effects are further enhanced in other regulated environments: pharmaceuticals, medical devices, and food production as a result of the further restrictions of compliance requirements, documentation procedures and validation bills [14].

Theory and Background Principles: There are two pillar theories that allow approaching the discussion on bottleneck management; the Theory of Constraints (TOC) presented by Goldratt and Little Law. The emphasis made by TOC is that no system can lack a constraint and the capability of that constraint determines the performance of the system. With managing the weakest link in the chain, organizations are able to realize non-proportionate overall performance [15]. The other important queuing theory principle is Little Law which is a mathematical relation between WIP, average throughput rate and average cycle time. It is a very basic yet mighty equation which will quantify the impact of constraints on system performance and is very common to use in manufacturing systems and also in service systems as a way of diagnosing inefficiencies in the system and also as a method of determining measures of system performance [16].

Regulated industry peculiarities: Although these theories can be applied in any sector, the regulated sectors have different challenges that make it difficult to remove bottlenecks. Adherence to

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regulations such as FDA/ EMA or ISO involve strictly implementing processes; adequate documentation and in some cases even approval before making any changes are made [17]. Other activities that are always required but resource demanding include cleaning validations, batch record reviews and environmental monitoring which are some of the usual bottlenecks.

Moreover, quality management across these industries set focus on risks management, traceability, and replicability, consequently, causing excessive hold time and extra levels of inspection. All forms of changes, including the redistribution of labor forces and shifting between the hours of operation to changing working procedures, should undergo a formal sequence of change management [18]. This restricts the organization to experimentation, or rapid responsiveness to organizational operational problems therefore inhibiting the power of the traditional continuous improvement methods.

Lean Manufacturing within the Regulated Environments: Lean manufacturing provides well-developed tools and concepts of eliminating wastes and optimization of flow. Value Stream Mapping (VSM), 5S, Kaizen events, Gemba walks and Standard work techniques have become common tools used in various areas due to their easy to understand and provide implementation techniques. When Lean is practiced in a regulated environment, it is normally adjusted to take compliance factors into consideration [19]. The examples include mapping of standard operating procedures (SOPs) into VSMs, inclusion of cleaning steps in process flows and the addressing of quality assurance activities like an inseparable part of the operations instead of external audits. Such adaptations protect regulation integrity and at the same time provide an opportunity to learn about inefficiencies [20].

Lean will not be effective when implemented alone. Conventional Lean instruments tend to be based on methods of nomadic observations that fail to identify the entire variability or interdependence of processes. As an example, when Lean determines that a QA step is a bottleneck, it would not be able to do the modeling of how changes in batch size, or staffing levels would impact the overall flow [21]. It is not natural that Lean considers stochastic behaviors, such as unplanned downtimes or subjectivity of operators, which is typical in real-terrain conditions.

Simulation modeling has stood out as a useful supplement to the Lean tools in order to address its inherent limitations that are associated with static tools. Systems like Discrete-Event Simulation (DES) and System Dynamics (SD) enable the user to create a digital version of the organizations processes. These models can be used to simulate the behaviour of a system given time under changing conditions, e.g., the changing demand, the lack of staff or a breakdown of a machine [22].

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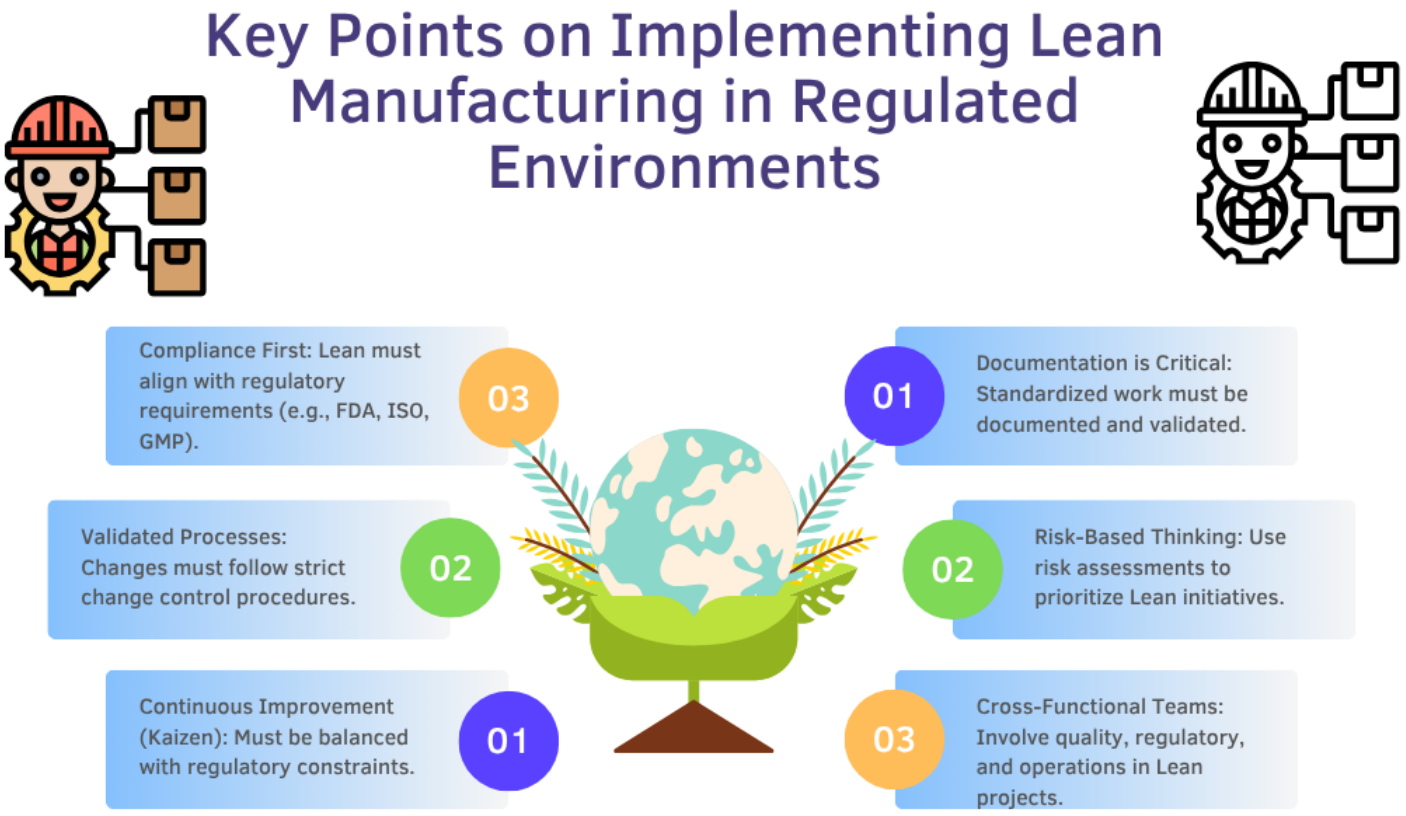

Figure: 1 showing key points on implementing lean manufacturing in regulated environments

It is in the regulated industries where simulation is most helpful because it is not possible to perform the trial and error experiment. Rather implementing the process change literally, teams can perform a number of what-if-tests virtually [23]. Tool functions such as AnyLogic, FlexSim, Simul8, and Arena allow a user to model complex processes with queues resources schedules and constraints. These tools are useful in assisting the decision-makers in visual testing the flow, the existence of any undetected bottlenecks and anticipation of the effect of prospective interventions [24].

The simulation, though it has tremendous benefit, tends to be isolated as separate and distinct engineering or planning functions. The majority of organizations have either the inability or cross-functional interconnection to deploy simulation models as a section of their overall continuous improvement (CI) efforts. It restricts the scope of the insight of simulation and limits its effect on the daily operations [25].

The Case for Lean-Simulation Integration: Since Lean and simulation have their advantages and weaknesses, a combination of these approaches provides an interesting solution. Lean has a systematic method of discovery of waste, involvement of front line teams, and mobilization of stakeholders to help drive the improvement. The use of simulation gives analytic gravity so that a team can calculate the effect of suggested changes and experiment with conditions under actual

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conditions of variability [26].

Through these methodologies, organizations are able to build a dynamic and responsive improvement model by integrating the methodologies. In this mixed approach to methodology, teams will be able to:

- Find structures with Lean instruments such as VSM and Gemba walks.
- Obtain correct process information to parameterize the models.
- Simulate to examine improvement ideas and prove them sound.
- Report solutions to the stakeholders once through graphically and one time quantitatively.
- Harmonize enhancements to regulation expectations and practice [27].

The effect is a faster, data-driven process improvement process - and one that is especially appropriate to the complex, high-stakes worlds of regulated industries.

PROBLEM IDENTIFICATION AND GAP ANALYSIS

In controlled markets, eliminating or otherwise addressing systemic constraints is not solely a question of effective operations and processes, it is an issue of compliance and regulatory adherence with both a product and quality assurance implications and, ultimately, a patient or consumer safety issue [28]. Regardless of the reasonable investments made to automate, transform digitally and continuously improve, a considerable number of organizations continue being guilty of experiencing crippling process constraints that endure over long durations of time without proper resolution. In this section, the main causal factors leading to this problem have been discussed and the gaps between the basics of the practices and the best-in-class possibilities have been noted [29].

Kinds of Bottlenecks in Controlled Settings: Regulated industry bottlenecks will largely vary in terms of intricacy and longevity as opposed to that of non-regulated environments. Although in the normal manufacturing system, a bottleneck would be addressed simply by redistributing the resources or redesigning the process, in a regulated framework, these steps will most likely need validation, updated documentation, retraining, and even pre-approval by the regulator [30].

The usual bottlenecks seen are:

- The perceived front end Quality Control (QC) testing delays because of shortage of analysts, or equipment capacity.
- QA backlogs in reviewing batch records resulting to delays in release.
- The cleaning and sterization validation steps, which cause inter-batch downtimes.
- The restriction imposed by multi-language regulatory restrictions of packaging and labeling.

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- Cross functional hand offs in which approval or decisions are delayed due to gaps in communication.

These bottlenecks are not always in fixed places, but they will also vary, depending on the demand, availability of staff, variability of material and other factors on the ground. Most organizations however end up treating them as definite issues hence coming up with strategies that are not optimal or simply obsolete [31].

The Disadvantages of Present Bottleneck Detection Techniques: Companies traditionally are using manual data analysis, conducting Gemba walks on a periodic basis and analyzing the retrospective as means of identifying bottlenecks. Although such techniques are appropriate to gather qualitative knowledge, they tend to fail to illustrate the multidimensional nature of ever-changing, interlinked processes [32]. Major restrictions are:

- **Subjectivity and bias:** Recordings can be made depending on the perception of the individual and this will create uneven conclusions.
- **Snapshots views:** A majority of Lean tools give a snapshot view, not a nice picture of process behaviors.
- **Poor data integration:** The data might be stored in departmental systems (e.g. MES, LIMS, ERP) so a full picture is hard to make out.
- **Inability to see beyond local bottleneck:** By resolving a bottleneck at one stage, it is possible to merely transfer the problem to downstream process step, which is otherwise unrecognized when viewed in isolation.

These shortcomings result in partial problem framing and in many cases this causes organizations to adopt a solution that does not result in the desired continuity improvement in throughput [33].

Disparity in the Predictive Capability and Continuous Improvement: Among the most important gaps, there are the lack of connection between Continuous Improvement (CI) activities-commonly propelled by Lean or Six Sigma and data science or simulation-based predictive approaches. CI functions used to use simple tools such as Pareto charts, fishbone diagrams, and VSMs, but simulation and analytics functions remained independent to work on highly specialized modeling tools that very seldom crossed functional lines [34]. Insight gap People close to the problem (e.g. operator, supervisor) do not have access to predictive tools to prove long-term effects of suggested changes. Agility gap Organizations are sluggish in their response to bottlenecks due to the need to validate changes in regulated environments, which is not by means readily available since it calls for simulations [35].

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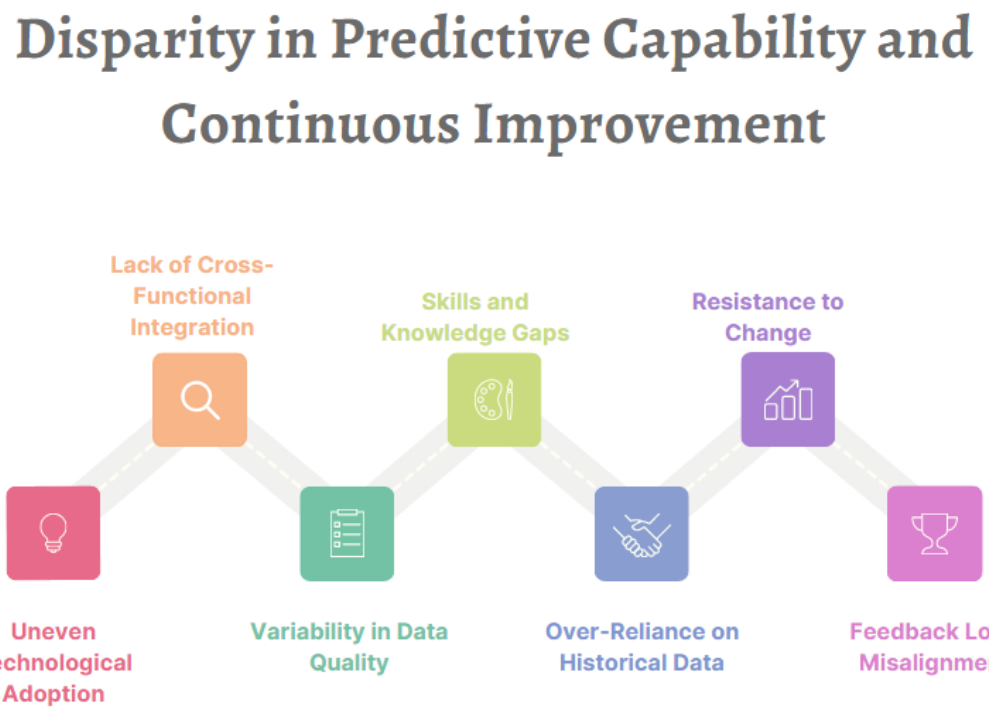

Figure: 2 showing disparity in predictive capability and continuous improvement

Sustainability gap the enhancements are made without knowing the whole-scale consequences leading to repeat or rolling bottlenecks in the controlled environments, both qualitative and quantitative arguments should be presented as the justification of changes. The proposed improvements are often unsuitable to this threshold without simulation or data modeling and implementations may not be implemented or instill low confidence among the stakeholders [36].

The processes and technological silos: The other factor is organizational soloing of improve functions. Data systems (ERP, MES, and LIMS) are handled by IT departments, day-to-day processes are operated, and compliance is the responsibility of quality. These departments hardly work in a coordinated manner to determine and break down system constraints [37]. Moreover, commonly, process data is not used. Batch records, deviation reports or even equipment logs hold historical data that can be used to identify pattern of delay or resources contention, as long as they are mined and interpreted. This is valuable information that is not used because of the lack of the appropriate tools and skills (e.g., process mining, simulation modeling, digital twins) [38].

Integrated Lean-Simulation Attention requires: The analysis provides the critical need to have structured and cross-functional approach with convergence of Lean techniques and capability of simulation. Lean offers teamwork and transparent approach to involving the people on the ground and discovering easily visible waste [39]. In contrast, simulation introduces rigor, and organizations can simulate the complexity of reality, conduct sensitivity analyses and virtually test interventions.

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- Lean-Simulation methodology has the advantage of:
- System visibility as a whole as opposed to local emphasis.
- Prioritization of constraints on the basis of throughput influence using data.
- Modeling of variation to test the interventions prior to implementation which becomes expensive.
- The reusable scalable insights can be used on similar processes or sites.

With simulation as part of the CI process organizations can transition to being predictive, data-driven decision makers rather than anecdotal and reactive problem solvers. In particular in regulated industries, where the cost of error or any delay can be costly, and any adjustment should prove before it could be made Let me know whether you want this split as presentation slides or pictures (e.g. a gap analysis graph or a Lean / Simulation capability map) [40].

INTEGRATED LEAN-SIMULATION FRAMEWORK: CONCEPTUAL DESIGN

The lack of predictability and the empirical nature of the process of identifying bottlenecks and optimizing throughput in the regulated industries demands a more systemic solution; integrating the Lean methods with simulation modeling is needed [41]. The proposed conceptual Integrated Lean-Simulation Framework is described in this section by illustrating its design by integrating the intuitive powers of Lean with the predictive power of discrete-event simulation (DES), traditional system dynamics (SD) or agent-based modeling (ABM). It focuses on cross functional cooperation, digital integration and compliance harmonization [42].

Framework Overview: The Integrated Lean-Simulation Framework is a mix-and-match spectrum model to recognize, evaluate, and establish throughput-driven interventions quickly and regulated strenuousness [43]. The framework comprises the following steps that are sequential and repeating:

- Definition and Scoping of System
- Constriction Review and Constraint Understanding
- Model Structuring and Data Integration
- Modeling and Scenario Testing simulation
- Regulatory Risk Analysis and Impact Analysis
- Implementation of change and constant monitoring

Individual phases use particular tools and methods and demand input of cross-discipline groups, such as the operations, quality assurance, engineering, IT/data analytics and regulatory affairs.

System Definition and Scoping: The initial procedure is outlining the boundaries of the value stream or system under study. In controlled industries, this generally involves formulation, filling,

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sterilization, in- process testing, QA release and final packaging [44]. Teams have to concur on:

- The operational objectives (e.g., shorten the 21-days reply cycle time of past release to 14 days).
- Performance indicators (e.g. throughput, WIP level, resources consumption).
- Constrained compliance (e.g. verified hold times, clean zones frequencies, GMP zones).

The step will make sure that the scope of simulation will fit the business priorities and the regulatory constraints available.

Lean Process Mapping and constraints identification: Teams use such Lean tools as Value Stream Mapping (VSM), Teletransport, and Spaghetti Diagram to document the current state process in detail [45]. The major Lean goals at this point include:

- Determine value added activities and non-value added activities.
- Imagine delays, waiting lines as well as handoffs that are cross-functional.
- Mark the duplicating reasons of waste (waiting, over processing, etc.).

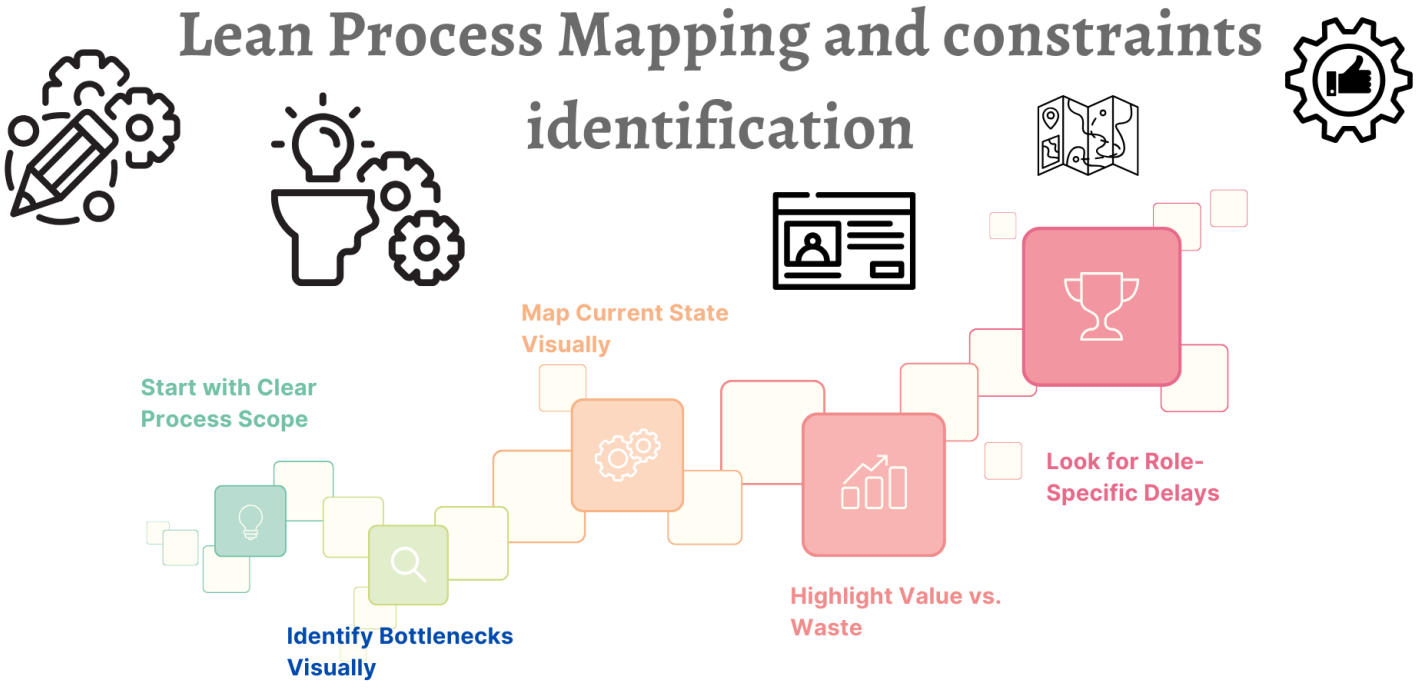

Figure: 3 showing lean process mapping and constraints identification

The analysis of constraints is then conducted by means of Throughput Accounting, Little Law and Gemba observations. This reveals the probable bottlenecks and creates the foundation of simulation modeling. Notably, Lean is the universal language amongst grass-root workers and analysts [46].

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Integration of Data and Structuring of Models: At this stage, the experts in the field of simulation start to build the digital process model. Inputs are usually the following:

- Changeover times, cycles, batch size.
- The availability of equipment and its capacities.
- The availability of the resources (e.g. the availability of the operators, QC analysts).
- The interdependencies and the failure rates of processes.

Past deviation or lag data: Such information is extracted as ERP, MES, LIMS, maintenance records, and batch records. To make the data usable in a simulation, the data itself might require ETL (Extract, Transform, Load) pipelines or APIs in order to both standardize and clean it [47]. Different models are developed according to the most suitable method of simulation:

- DES: fine grain resource, event-oriented processes (such as pharma batch processing).
- SD of high-level systems, continuous feedback (e.g. supply-chain of drugs).
- ABM when modeling self-determining decision-makers (e.g. operator behavior or scheduling).

Simulation and Scenario testing: Simulation runs may now be performed with a validated model. Some of the what-if scenarios tested by teams include:

- Additions/ removals by equipment or staff.
- Planning to change policy (e.g: push to pull scheduling).
- Campaign strategies or optimization of the batch size.
- The QC or QA of product families sharing resources.

Regulatory Risk Discussion Impact Analysis: Even positive change of agent processes must be screened on compliance, risk in a regulated environment [48]. During this step, simulation outputs are linked with:

- Validation requirements (e.g. revalidation of processes, cleaning validation).
- Change control records (e.g. impact analyses, procedures).
- GMP and data integrity requirement (e.g. audit-trails, ALCOA+ principle).
- Such Risk Management Tools as FMEA or HACCP.

The aim is to make sure that the suggested interventions are not only successful but also workable under regulatory system of the organization. Also, there are visual reports and dashboards of simulation results that are presented to the operations, quality and compliance stakeholders. These assist in reaching agreement and executive support [49].

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Monitoring and Implementation of Change: After approvals of interventions, the Lean project management methods (e.g., PDCA, A3) can be applied to bring changes. The simulation model is maintained as a Digital Twin and allows to continuously feed the model back and enables continuous monitoring of:

- Throughput trends.
- Reemergence of the old bottlenecks.
- New post-change process limitations.

Also, this structure is a dynamic system that changes with the organization since simulation models can be applied in subsequent Kaizen events or scale-up work [50].

Framework Advantages: Some major benefits of the Lean-Simulation integrated approach include the following:

- **Cross-functional alignment:** Lean touches the workforce and Simulation confirms the offers.
- **Rigorous speed:** Teams get to iterate rapidly when it comes to improvement ideas without skipping over regulatory due diligence [51].
- **Use of data-driven accuracy:** Simulation measures the outcome of the changes so that the assumptions are less used.
- **Scalability:** The framework may be applied between sites, product lines and functions.
- **Sustainability:** When simulation is embedded in CI cycles, the gains are not likely to wear out through time. The conceptual design of the integrated Lean-Simulation Framework Endows structure, velocity, and scientific rigor to bottleneck resolution in regulated sectors [52]. It enables organization to take a proactive approach to the improvement and leave behind the reactive forms of work improvement and use a systemic, digital, and compliant throughput optimization approach [53].

USE OF THE INTEGRATED FRAMEWORK IN NON-REGULATED ENVIRONMENTS

Implementation of Integrated Lean-Simulation Framework to the regulated industries/sectors which include pharmaceutical, medical devices, biotechnology and food manufacturing industries, must carefully balance the concept of operational efficiency with compliance and management of risks [54]. In contrast to the traditional approaches to continuous improvement (CI), the current framework enables an organization to visualize systemic bottlenecks, simulate improvement strategies in silico and implement qualifying changes with certainty. In this section we will be looking at the practical use of the framework, issues, changes, industry constraints, and examples of use-cases [55].

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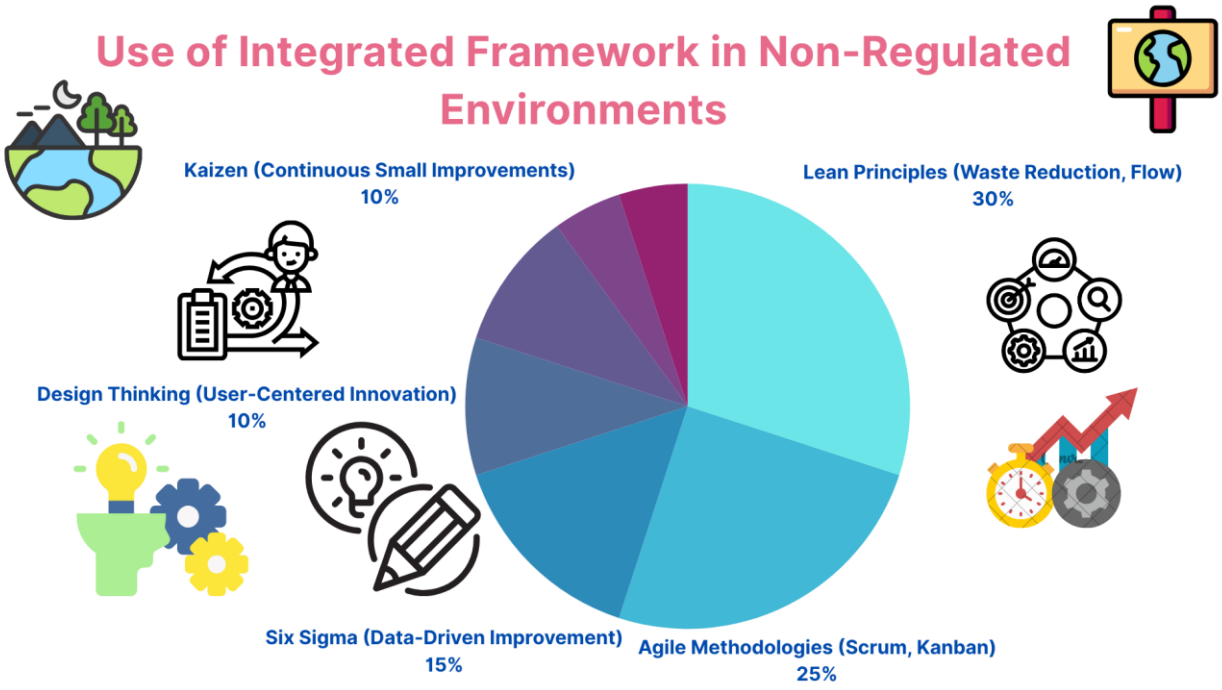

Figure: 4 showing use of integrated framework in non-regulated environments

What Regulated Environments Are all About: The industries with regulation can be said to be supervised very closely by departments like the FDA (U.S), EMA (Europe), MHRA (U.K) and ISO departments. Such sectors have to observe Good Manufacturing Practices (GMP), data integrity (ALCOA+), traceability of products and documentation [56]. The changes, which impact on the production throughput, like a change in batch scheduling, equipment use, or personnel use, should be:

- Evidence-based (scientific or statistic).
- It is recorded in formal change control methods.
- Assessed against the impact on verified systems, or SOP.
- Revised and checked by quality assurance as well as regulatory groups.

Hence, it means that any improvement model applied within such settings should incorporate regulatory due diligence into its principles, which Integrated Lean-Simulation Framework does [57].

Lean-Simulation of Regulatory Conservation: Lean or simulation application in the unregulated industry frequently permits rapid and iterative change cycles. However, in controlled industries, the cycles are supposed to follow tested and approved checks and balances [58]. Integrated Framework is adaptable in that it absorbs the following information:

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- **Design Control Integration:** Any modifications, suggested through simulation, should be traceable to the initial design controls of the product or process. This creates traceability as well as compliance with design history files or device master records [59].
- **Change Control Embedding:** Simulated runs are projected into protocols, risk assessments and validation plans used in change control. This makes ease in merging with QA systems and electronic quality management systems (eQMS) [60].
- **RBDM:** The guidance incorporates strategy underlying ICH Q9 (Quality Risk Management) and applies simulation to evaluate quantitatively the risk of processes. It also allows the teams to anticipate the risk effect of eliminating, restructuring or relocating bottlenecks in the system [61]. IN environments where verification/validation of equipment or process validation and cleaning are necessary, the simulation model will contain important process parameters (CPPs), validated hold periods, and cleanroom classification behavior. Validation documentation can be directly related to changes being tested in the model [62].

Pharmaceutical Fill-Finish Line: One of the issues is that a sterile injectable pharmaceutical company was experiencing delays in its fill-finish suite on a regular basis [63]. With the Integrated Lean-Simulation Framework the team has achieved the following:

- VSM found issues on the delay with sign-offs by the environment monitoring as well as the cleaning of changeovers.
- The results of simulation indicated that, in order to improve hold times between shifts, QA staff levels should be elevated during peak fill periods.
- The protocol of room release and new shift pattern were simulated and proved.
- It embarked on change control and this was supported by simulation data indicating 17 percent increment in throughput.

In terms of the key regulatory considerations, it was necessary to validate the new timing of the revised cleaning protocols, the update of the batch records and train some QA teams. It only took the project three months to be cleared and the enhancement continued reporting a 15-20 percent rise in productivity without flouting any GMP controls [64].

Medical Device Assembly: A Class III medical product maker leveraged the framework to address a packaging bottleneck that was on-going. The close proximity with the last packaging station raised the WIPs which resulted in late shipments [65].

- Lean VSM has found an inessential transport among assembly and packaging stations.
- Different cell designs, buffer WIP limits were simulated.

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- Virtual cellular arrangement, in U shape was simulated decreasing lead time in 30 percent.

The regulatory changes encompassed changing the Device Master Record (DMR), reclassifying cleanrooms and providing a minor change filing to the FDA because of floor plan restructuring [66]. **Critical Success Factors:** The effectiveness of the application of the framework in controlled settings is based on five important enablers:

- **Cross-Functional Collaboration:** CI teams have to involve the quality, validation, and regulatory teams at the very start of a project. This makes sure that the real limitations are part of simulations and that any changes are viable [67].
- **Validated Data Sources:** Simulations also have to be based on GMP-conform systems (e.g. MES, LIMS, QMS). The model should be constructed after data integrity [68].
- **Visualization Quality and Regulatory Teams:** The outputs of the simulations must provide visual dashboard to apply interventions to risk mitigation and validation requirements. This helps to make QA decisions faster [69].
- **Documentation Alignment:** The documentation to which all of the improvement scenarios tested in simulation should be pre-mapped (if the documentation routes through a SOP, a batch record or a validation protocol), facilitating change control [70].
- **Digital Twin Governance:** When possible, simulation models will transition to the validated Digital Twin that is governed as being part of the QMS of the site. This can be further used continuously in investigation of deviations, capacity planning, and subsequent regulatory submissions [71].

Major Types of Fallacies and combating them: Among some traps to watch out when implementing the framework in a regulated environment is:

- **Oversimplified simulation models:** Incorporating the processes usually involved in compliance, such as gowning, sterilization validation, into models produces faulty results. Regulated tasks should always be provided [72].
- **Insufficient QA involvement:** The project may be stuck during approval waiting on QA involvement if the QA is not consulted during scenario definition and in interpreting the results [73].
- **Failing to anticipate documentation requirements:** Documentation requirements can be extensive even in the face of the smallest of changes. The document updates in the project time [74].

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- **Lean-only bias:** The lean teams are likely to demand a quick implementation at the cost of validation. This is avoided by using simulation which would measure the effect of compliance prior to being carried out [75].

Compliance is Strategic: Beyond Compliance: In principle, regulatory compliance is a principal driver, but the framework also allows creation of strategic value:

- **Facilitates readiness to submit:** Simulation results can be used to clear up capacity in regulatory submissions.
- **Enhances audit vigor:** A well piloted and documented improvement process demonstrates the regulators an environment of control and planning.
- **Improves training and knowledge transfer:** On boarding, training, and preparing technology transfers or product launch can be done in simulation situations. The Integrated Lean-Simulation Framework is a very dynamic and flexible improvement approach to regulated settings [76]. Organizations are able to get above trial-and-error optimization by entrenching quality and conformity into the essence of process simulation and Lean thinking. Rather, they are capable of using a scientific, data based method that offers increased through-put with the integrity, traceability and control required by regulation [77].

CHANGE MANAGEMENT AND ORGANIZATIONAL READINESS

The deployment of Integrated Lean-Simulation Framework to any organization and especially the regulated industries is not merely a technical or process-based change project, but rather transformational change initiative. This is mainly influenced by the willingness of the organization to receive, embrace and implement change [78]. This part discusses human and corporate aspects, which are necessary to facilitate implementation of this framework, focusing on change management, alignment of leadership, cultural preparedness, and capacity building [79].

Change management means getting individuals ready, armed, and aided in the effective embrace of new processes, tools, and ways of work. The Integrated Lean-Simulation Framework makes a massive change not only the means performance is raised up but the nature of diagnosing problems and putting solutions to test [80].

Areas of change management of great importance are:

- Bringing the digital simulation to Lean environments that can be used to manual, paper-intensive approaches.
- Transforming the way in which decisions are made (relying on intuition to relying on simulation-proven data).

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- Harmony among compliance and innovation, particularly in when the employees of the regulatory body could be skeptical regarding change of procedures.
- Reskilling workgroups, especially operation and quality personnel, to analyze simulations data and enter into scenario planning.

The best-thought-out and accurate simulations, Lean interventions have a chance of resistance or ineffective adoption without a systematic change management process [81].

Organizational Readiness Testing: Organizations must also review their preparedness in the following aspects before implementing the integrated framework: The senior leadership should not merely agree to such initiative, but show themselves as sponsors of such initiative. Their leader must be able to convey a clear vision, e.g. it is possible to increase throughput and be compliant and be open to new tools, e.g. simulation modeling [82].

- **Process Maturity:** Organizations that have mature Lean or Six Sigma programs are usually more prepared, since they already have CI terms, numbers and teams. Nevertheless, in case Lean initiatives were not successful in the past or stagnated, one should be even more cautious about restoring the trust [83].
- **Digital Literacy:** Because the simulation modeling involves the use of digital inputs and outputs, teams should have the minimum level of data literacy in using visualization tools (e.g., dashboards, Gantt charts, Sankey diagrams) [84].
- **Flexibility in Quality System:** A preparedness would also entail the extent to which the QMS is flexible to changes of processing. Implementation can be held up by a too bureaucratic, too rigid system. It is important to align with QA and regulatory team early during the process [85].
- **Learning Culture:** A culture of experimentation, constructive failure and evidence based learning has a better chance of taking advantage of simulation and Lean integration.

Change Capability Construction: In order to achieve the sustainability of adoption, organizations need to create internal capability at many levels:

- **Change Agents:** Who in operations, QA and engineering are its champions that can sell the framework, and give feedback at various stages of implementation?
- **Training Programs:** Provide specific training on the Lean principles, elementary concepts of simulation and interpretation of digital data [85].

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- **Leadership Development:** Train managers on how to lead in a data-oriented and a cross-functional world. This comprises of coaching and facilitation as well as decision-making in uncertainty [86].
- **Knowledge Transfer:** Document the lessons learned on implementation-by-implementation basis and develop assets of knowledge-templates, SOPs, best practices-that put the methodology on a permanent institutional basis [87].

It is best to consider phased rollout: implement in a pilot location (one production line); subtly tweak the method and then propagate among the departments or locations [88].

Communication Strategy: The third practically very important prerequisite of average change success is an active and unshrouded communication policy. It must set to:

- Build awareness that creates an understanding of the necessity of the change and the usefulness of the integrated approach.
- Eliminate a doubt by demonstrating quick-wins and testimonials of front-line users.
- Role clarification should be provided in such a way that the staff understands how they will participate in such simulations, data gathering and process modifications.
- Make sure there is congruency on top leader messaging to the supervisors in the team.

The process must also be two-way: feedback and any concerns must be gathered regularly, allowing the delivery strategy to be modified and making people to feel they are being listened to [89].

Maintaining the Change: Sustainability after implementation needs to be present both during the implementation process and afterwards, and is usually ignored. The components to have sustainable change are:

Baking-in Framework Governance: Develop a steering committee or operational excellence council to control the application of the Lean-Simulation Framework throughout the organization [90].

The connection to KPIs: Connect the data-driven actions resulting out of the simulations to the performance measures at the site level throughput, cycle time, OEE, release times over batches [91].

Rewarding Achievements: Reward teams that bring success in improvement. Show competitive stories in different departments and motivate others to adopt it [92].

Constant Feedback Loops: It is repeated that any change in processes requires changes to simulation models, but that value stream maps should be revisited often to determine new points of congestion [93].

Building a Simulation Center of Excellence: As utilization increases, certain organizations develop

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a coordinating team to develop and qualify simulation models as well as train personnel based at the site [94].

Organizational readiness and change management are not marginal issues as far as implementing the Integrated Lean-Simulation Framework is concerned, they are rather the pillars. No matter how effective the technical models and Lean tools are, they will not work effectively without a culture that encourages a change or leaders who lead the innovation and systems that allow one to learn [95]. Strengthening and formalizing the change management during deployment allows organizations to make sure that process improvements remain not only technically viable and regulatory compliant, but also accepted, maintained and extended throughout the organization.

CONCLUSION

Robust processes, silos and risk-aversion tend to undermine the necessity to excel in operations in regulated sectors where quality of products, their safety, and conformity cannot be neglected. The conventional continuous improvement measure like Lean and Six Sigma have provided quantifiable improvements, and yet in some cases fail to meet the challenge of dynamic, multi-factorial choke points or compliance barriers. Similarly, discrete event simulation and modeling tools have the potential to make predictions about the system behavior, although they are usually not used in the day-to-day operations as they are too complicated and conflict with frontline improvement practice.

In this article, we have introduced a collaborative process: the Integrated Lean-Simulation Framework: an integrated process that unites the process discipline of waste-reduction Lean with the forecasting ability and risk-free experimentation capacity of simulation modeling. Through such synergy, organizations are able to visualize, analyze and optimize the complex systems in a holistic and data driven way, devoid of threats to regulatory compliances and operational stability.

Our starting point was systemic bottlenecks, those invisible, repeatable process bottlenecks, which have the potential of affecting the whole-value stream, and how this combination of Lean, and simulation tools allows the identification of bottlenecks in a number of different ways, including the quantification and prioritization of the bottlenecks. At that point, we described the conceptual principles and practical stages of the construction of this framework, with the focus on value stream mapping, root cause analysis, dynamic simulation modeling, and scenario testing.

Real-world integration within pharmaceutical, medical device, and food environments demonstrated once more how this approach can be really used to bring improvements in the real-life setting lead-time reduction, throughput maximization, resource optimization, without compromising and on the contrary increasing quality and compliance. Most importantly, the framework is not only addressing individual challenges to be solved, it creates a methodology that is repeatable, scalable and, more

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importantly, leaves continuous improvement part of the organization DNA.

But in the long term, all technical solutions have organizational performance and change management as central success requirements. This frame cannot be implemented using tools only; it also requires cross-functional cooperation and sponsorship, the culture of data-driven decision-making, and solid communication. Organizations can adopt this measure of pre-emptively addressing resistance to change and building capabilities to change and thus avenues are paved that this methodology can become a long term aspect of organizational operations.

Integrated Lean-Simulation Framework is a revolutionary breakthrough in the controlled industries. It closes the analytical gap between the theory of improvement and the operation of real life allowing decisions to be faster, smarter, and safer. Companies adopting such a strategy are in a position to not only remove bottlenecks in their organizations but also create more responsive, flexible, and performance-based operations that could survive in the tightening competitive and highly regulated markets today.

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