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A Compliance-Aware Quantitative Value Stream Mapping Framework for Pharmaceutical Manufacturing: A Case Study of Production Flow and Operational Efficiency

إطار كمي لتخطيط تدفق القيمة يراعي متطلبات الامتثال الرقابي في الصناعات الدوائية: دراسة حالة لتدفق الإنتاج والكفاءة التشغيلية

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Abstract:

Value Stream Mapping (VSM) is widely used within Lean Manufacturing to visualise production flows and identify activities that constrain operational performance. Its application in pharmaceutical manufacturing, however, requires careful interpretation because inspection, quality-control, documentation, and verification activities may be mandatory for product quality and regulatory compliance even when they do not directly transform the product. This study develops and applies a compliance-aware quantitative VSM framework to a pharmaceutical suspensions production line at the State Company for Drug Industries and Medical Appliances in Samarra, Iraq. The framework distinguishes value-added activities (VA), regulatory value-added activities (RVA), and non-value-added activities (NVA), and combines this classification with actual-to-standard time comparison, Extended Process Cycle Efficiency (EPCE), Standard Manufacturing Efficiency (SME), time deviation, and work-effort measures. Operational observations and production records were used to construct current-state maps across the production stages, while a proposed future state was designed from the identified improvement opportunities. The comparative analysis indicates that the proposed configuration could reduce total lead time from 6,790 to 3,260 minutes (51.99%) and NVA time from 1,770 to 310 minutes (82.49%). EPCE is projected to increase from 73.93% to 90.49%, while SME is projected to rise from 41.61% to 86.66%. Total work effort is estimated to decline from 53.135 to 22.371 worker-days, and the deviation from standard time from 3,965 to 435 minutes. The study contributes an analytical approach that treats regulatory activities as a distinct category rather than automatically classifying them as waste. Since the future state is a design proposal, the reported improvements represent estimated potential gains that require implementation and subsequent field validation.

Keywords: Lean Manufacturing; Value Stream Mapping; Pharmaceutical Manufacturing; Regulatory Value-Added Activities; Extended Process Cycle Efficiency; Standard Manufacturing Efficiency; Time Deviation; Work Effort.

الملخص:

يُعدّ تخطيط تدفق القيمة (VSM) من الأدوات المستخدمة على نطاق واسع ضمن نظام التصنيع الرشيق، لما يوفره من إمكانية تمثيل التدفقات الإنتاجية بصرياً وتحديد الأنشطة التي تحدّ من الأداء التشغيلي. غير أن تطبيق هذه الأداة في الصناعات الدوائية يتطلب تفسيراً يأخذ في الحسبان خصوصية البيئة التنظيمية والرقابية؛ إذ إن أنشطة الفحص ومراقبة الجودة والتوثيق والتحقق قد تكون متطلبات إلزامية لضمان جودة المنتج والامتثال للمتطلبات الرقابية، حتى وإن لم تسهم بصورة مباشرة في تحويل المنتج. وانطلاقاً من ذلك، تهدف هذه الدراسة إلى تطوير وتطبيق إطار كمي لتخطيط تدفق القيمة يراعي متطلبات الامتثال الرقابي، وذلك في خط إنتاج المعلقات الدوائية في الشركة العامة لصناعة الأدوية والمستلزمات الطبية/ سامراء – العراق. ويستند الإطار المقترح إلى التمييز بين الأنشطة المضيفة للقيمة(VA) ، والأنشطة المضيفة للقيمة التنظيمية(RVA) ، والأنشطة غير المضيفة للقيمة(NVA) ، مع دمج هذا التصنيف بمقارنة الأزمنة الفعلية بالأزمنة المعيارية، واستخدام مؤشري كفاءة دورة العملية الممتدة (EPCE) وكفاءة التصنيع المعيارية(SME) ، فضلاً عن قياس الانحراف الزمني وجهد العمل. واعتمدت الدراسة على المشاهدات الميدانية والسجلات الإنتاجية في إعداد خرائط الحالة الحالية لمراحل العملية الإنتاجية، ثم تصميم حالة مستقبلية مقترحة استناداً إلى فرص التحسين التي كشف عنها التحليل. وأظهرت نتائج المقارنة أن التكوين المستقبلي المقترح يمكن أن يسهم في خفض الزمن الكلي للعملية من (6,790) إلى (3,260) دقيقة، بنسبة انخفاض بلغت (51.99%)، وخفض زمن الأنشطة غير المضيفة للقيمة من (1,770) إلى (310) دقائق، بنسبة (82.49%). كما يُتوقع ارتفاع كفاءة دورة العملية الممتدة من (73.93%) إلى (90.49%)، وارتفاع كفاءة التصنيع المعيارية من (41.61%) إلى (86.66%). كذلك يُقدّر انخفاض إجمالي جهد العمل من (53.135) إلى (22.371) يوم. عمل، وانخفاض الانحراف عن الزمن المعياري من (3,965) إلى (435) دقيقة. وتتمثل الإضافة العلمية للدراسة في تقديم مدخل تحليلي يتعامل مع الأنشطة التنظيمية والرقابية بوصفها فئة مستقلة، بدلاً من تصنيفها تلقائياً ضمن الأنشطة المهدرة، بما يتيح التمييز بين متطلبات الامتثال الضرورية ومصادر عدم الكفاءة التشغيلية. ونظراً إلى أن الحالة المستقبلية تمثل تصميماً مقترحاً، فإن التحسينات الكمية المشار إليها تعبّر عن مكاسب محتملة مقدّرة، تتطلب تنفيذ المقترحات والتحقق منها ميدانياً لاحقاً.

الكلمات المفتاحي التصنيع الرشيق؛ تخطيط تدفق القيمة؛ الصناعات الدوائية؛ الأنشطة المضيفة للقيمة التنظيمية؛ كفاءة دورة العملية الممتدة؛ كفاءة التصنيع المعيارية؛ الانحراف الزمني؛ جهد العمل.

1. Introduction

Lean Manufacturing seeks to improve operational performance by increasing the proportion of resources devoted to value creation and reducing avoidable activities, delays, and interruptions. Value Stream Mapping (VSM) supports this objective by representing the flow of materials and information across a production system and by making the relationship between processing, waiting, movement, and inventory visible (Rother & Shook, 2003; Hines et al., 2004). Its value lies not only in documenting the current process but also in providing a structured basis for designing a more coherent future state.

The transfer of conventional VSM logic to pharmaceutical manufacturing is not straightforward. Pharmaceutical production is governed by quality, safety, traceability, and Good Manufacturing Practice (GMP) requirements. Activities such as sampling, inspection, in-process testing, batch documentation, verification, and release controls may not directly transform the product, yet they are integral to assuring its suitability and regulatory conformity. Treating all such activities as waste would risk confusing operational inefficiency with necessary control. Pharmaceutical applications of lean methods therefore need to distinguish between activities that create direct product value, activities required to maintain regulatory and quality assurance, and activities that do not contribute value or compliance and may be avoidable (Manning & Sörlin, 2017; Abideen & Mohamad, 2021; Rimantho et al., 2023).

A second challenge concerns the measurement of time. Conventional process analysis may identify waiting or non-value-adding activities, but the activity label alone does not establish whether the time consumed is excessive. A necessary activity can still contain avoidable delay, while a non-transformational activity may be essential to a compliant production process. Comparing actual activity time with an appropriate standard or reference time provides an additional diagnostic dimension. It enables the analyst to distinguish the necessity of an activity from the efficiency with which it is performed.

This study addresses these issues through a case study of a pharmaceutical suspensions production line in Samarra, Iraq. It adapts VSM to a regulated production environment by introducing a separate Regulatory Value-Added (RVA) category and linking activity classification to actual and standard times, operational efficiency indicators, time deviations, and work effort. The study does not claim that the proposed future state has already been implemented. Rather, it quantifies the improvement potential implied by the redesigned flow.

1.1. Research gap and contribution

The research gap is methodological and contextual. First, pharmaceutical VSM requires an explicit distinction between direct value creation and activities retained for quality and regulatory compliance. Second, activity classification needs to be complemented by quantitative comparison between actual and standard times so that inefficiency is assessed in relation to operational performance rather than inferred solely from activity type. Third, the analysis can be strengthened by considering work effort alongside elapsed time. The proposed framework integrates these dimensions within a single case-based analytical sequence.

The study makes three contributions. (1) It operationalises a three-category classification—VA, RVA, and NVA—for a pharmaceutical production flow. (2) It combines VSM with EPCE, SME, time-deviation, and work-effort measures to evaluate the current state and assess a proposed future state. (3) It demonstrates how improvement can be pursued without treating mandatory quality and compliance

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controls as activities to be eliminated. The contribution is an application-oriented analytical framework; broader generalisation requires testing across additional products, lines, and pharmaceutical facilities.

2. Research Methodology

2.1. Research design and case setting

A case study design was adopted to examine the production flow of pharmaceutical suspensions at the State Company for Drug Industries and Medical Appliances in Samarra, Iraq. The unit of analysis was the suspensions production line. The process was examined across eight connected stages: raw-material preparation; water treatment; mixing and medium preparation; particle-size reduction and distribution; in-process quality testing; filling; closure and sterilisation; and final labelling and packaging. The stages were mapped as a connected value stream to capture the sequence of activities and the associated movement of materials and information.

The case study approach was appropriate because the research question concerns how the operational and regulatory characteristics of an actual pharmaceutical process can be represented and assessed quantitatively. The analysis focused on the process as observed and documented in the case organisation; it was not designed as a statistical survey of multiple factories.

2.2. Data sources and measurement

The empirical dataset was assembled from production records, direct shop-floor observation and time measurements, operating procedures, and relevant production and quality documentation. Actual activity times represent the observed or recorded duration of each operation. Standard times were taken from the documented operating references applied to the production activities, including applicable standard operating procedures (SOPs), internal operating requirements, and relevant pharmacopoeial or good manufacturing practice (GMP) provisions where these informed the interpretation of an activity. These references were treated as process-specific benchmarks rather than universal time standards.

For each activity, the analytical record included the production stage, activity description, activity category, actual time, reference time, and workforce requirement. The resulting activity-level records were aggregated to construct the current-state maps and calculate the performance indicators. Work effort was calculated by multiplying activity duration by the number of workers assigned to that activity and converting the resulting worker-minutes into worker-days using an eight-hour (480-minute) working day. Values for the proposed future state were estimated from the redesigned process configuration and its assigned target times; they are design estimates, not post-implementation measurements.

2.3. Activity classification

Activities were classified into three categories. VA activities directly contribute to transforming the product in ways required by the production process. RVA activities are necessary to meet quality, safety, documentation, verification, inspection, or regulatory requirements, although they do not necessarily transform the product. NVA activities do not directly create product value and are not required as regulatory or quality controls; examples may include avoidable waiting, unnecessary movement, excessive temporary storage, or duplicative handling where supported by the process evidence.

The RVA category is central to the pharmaceutical adaptation. It prevents the analysis from treating a required test or control as removable waste simply because it does not add direct customer-perceived value. However, the RVA label does not imply that every minute spent on a compliance activity is efficient. The activity may remain necessary while its scheduling, hand-offs, preparation, documentation flow, or waiting time may still offer improvement opportunities. Any proposed reduction must preserve the applicable quality and GMP requirements.

2.4. Quantitative indicators

The framework combines elapsed-time, activity-mix, process-efficiency, standard-efficiency, time-deviation, and work-effort measures. The principal indicators are defined as follows:

Lead Time: the total elapsed time attributed to the production flow under the study's measurement boundary.

Extended Process Cycle Efficiency (EPCE): the proportion of total lead time represented by VA and RVA time; EPCE = [(VA + RVA) / Lead Time] × 100.

Standard Manufacturing Efficiency (SME): the ratio of aggregate standard time to aggregate actual time; SME = [Σ Standard Time / Σ Actual Time] × 100.

Time Deviation: the difference between aggregate actual time and aggregate standard time; Time Deviation = Σ Actual Time − Σ Standard Time.

Time Deviation Ratio: the time deviation expressed relative to aggregate standard time; [(Σ Actual Time − Σ Standard Time) / Σ Standard Time] × 100.

Work Effort: activity time multiplied by the number of workers assigned to the activity, aggregated and converted to worker-days using the conversion basis adopted in the study.

EPCE differs from conventional process-cycle efficiency because it includes the regulatory activities classified as necessary in the pharmaceutical context. SME assesses how closely the actual aggregate time approaches the standard-time aggregate. Neither indicator should be interpreted in isolation: EPCE describes the composition of elapsed time, whereas SME describes the relationship between actual and standard time. The time-deviation measure identifies the magnitude of the gap requiring operational interpretation.

2.5. Analytical procedure

The analysis proceeded through five steps: (1) documenting the sequence of production stages and activities; (2) classifying activities as VA, RVA, or NVA; (3) constructing current-state VSM representations and aggregating activity times and work effort; (4) identifying improvement opportunities from the observed flow and the deviations between actual and standard times; and (5) designing a proposed future state and comparing its estimated indicators with the current-state baseline. The future-state design was assessed against the same indicator definitions to maintain comparability. The sequence is summarised in Figure 1.

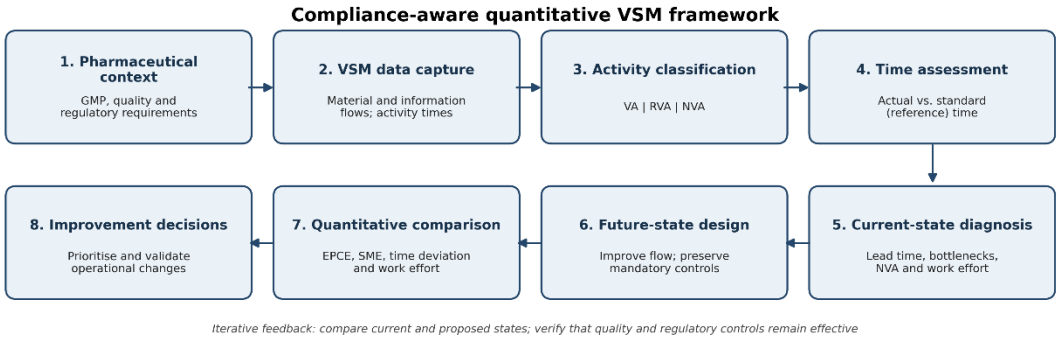


Figure 1. Compliance-aware quantitative value stream mapping framework. Source: Authors' development.

3. Current-State Value Stream Analysis

The current-state analysis produced a total lead time of 6,790 minutes, compared with an aggregate standard time of 2,825 minutes. The difference between these totals was 3,965 minutes, equivalent to a time-deviation ratio of approximately 140.35%. The result indicates a substantial gap between the time consumed by the current production flow and the standard-time reference used in the study. This gap is a diagnostic signal; it should not be interpreted as proof that every activity contributing to it is unnecessary.

3.1. Distribution of activity time

Table 1. Current-state activity-time distribution and operational performance indicators

Current-state measure	Time (min)	Share / value
Total lead time	6,790	100%
Value-added activities (VA)	2,250	33.14%
Regulatory value-added activities (RVA)	2,770	40.80%
Non-value-added activities (NVA)	1,770	26.07%
Aggregate standard time	2,825	—
Time deviation	3,965	140.35% of standard time
EPCE	—	73.93%
SME	—	41.61%

Note: Activity-time shares may not sum to exactly 100% because of rounding.

RVA represents the largest single activity-time category in the current state (2,770 minutes, or 40.80%), followed by VA (2,250 minutes, or 33.14%) and NVA (1,770 minutes, or 26.07%). This distribution is important for interpreting pharmaceutical performance. A conventional two-category classification could group quality and regulatory activities with non-value-adding time, thereby overstating removable waste and potentially encouraging inappropriate improvement actions. The three-category model instead preserves the distinction between necessary control and avoidable inefficiency.

The NVA total nevertheless represents a substantial improvement opportunity. Its 1,770 minutes indicate that more than one quarter of the current lead time is assigned to activities classified as not

adding direct value or regulatory necessity. The analysis therefore directs attention to the causes of avoidable waiting, storage, movement, and other non-value-adding activities, while maintaining the required quality controls.

3.2. Current performance indicators

Current-state EPCE is 73.93%, calculated by including both VA and RVA time in the numerator. This measure reflects the study's premise that necessary regulatory activities form part of an acceptable pharmaceutical process even though they do not directly transform the product. SME is 41.61%, indicating that aggregate actual time is substantially higher than the aggregate standard-time reference. The difference between these two indicators is analytically useful: a relatively high EPCE does not mean that the process is operating close to its time standards.

The current-state work effort is 53.135 worker-days. This measure adds a labour-resource dimension to the time analysis. It is possible for elapsed time and labour effort to move differently where activities have different staffing requirements; accordingly, the study considers both rather than treating elapsed time as a complete proxy for resource consumption.

4. Future-State Design and Improvement Analysis

The proposed future-state map was developed from the current-state diagnosis and the improvement opportunities identified across the production stages. The design sought to reduce avoidable activities and time deviations, improve the continuity and coordination of material flow, and rationalise activities where delays or unnecessary repetition could be addressed. In the pharmaceutical context, this does not mean removing mandatory inspection, testing, documentation, sterilisation, or verification controls. Instead, the design principle is to preserve the required control while reducing avoidable time surrounding or embedded in its execution.

The future-state configuration reduces the estimated total lead time to 3,260 minutes while retaining an aggregate standard-time reference of 2,825 minutes. The proposed activity mix comprises 1,750 minutes of VA, 1,200 minutes of RVA, and 310 minutes of NVA. Thus, the proposed state does not eliminate RVA; it reduces the time assigned to this category while retaining it as a distinct and necessary component of the pharmaceutical value stream. The overall current- and proposed future-state configurations are compared in Figure 2.

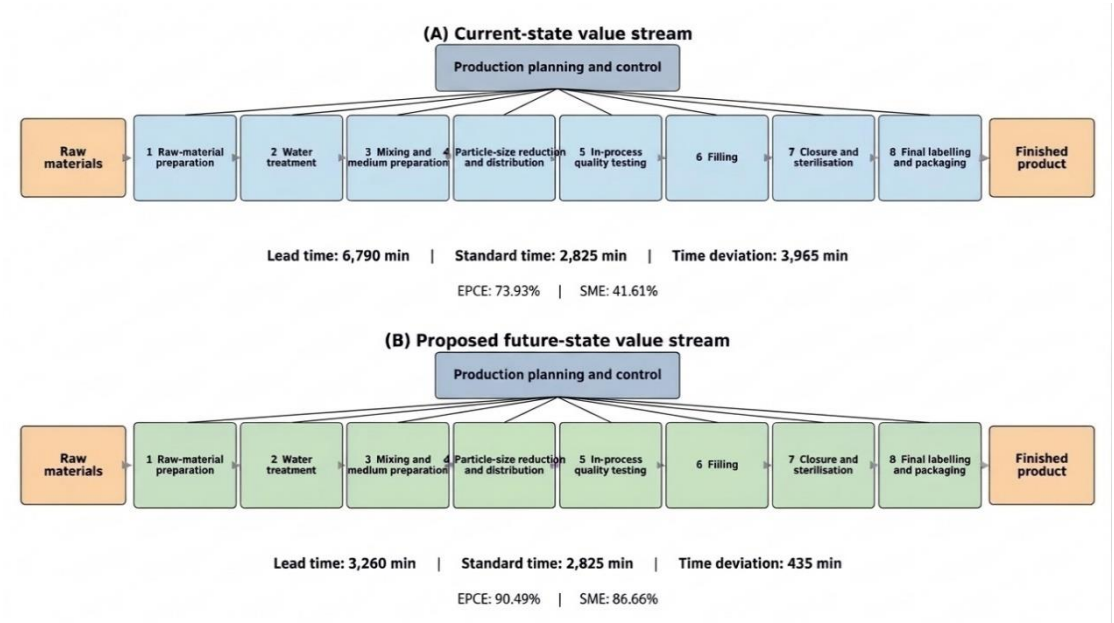


Figure 2. Overview of the eight production stages in the current and proposed future-state configurations. Source: Authors' reconstruction based on process data.

Table 2. Proposed future-state activity-time distribution and operational performance indicators

Future-state measure	Time (min)	Share / value
Total lead time	3,260	100%
Value-added activities (VA)	1,750	53.68%
Regulatory value-added activities (RVA)	1,200	36.81%
Non-value-added activities (NVA)	310	9.51%
Aggregate standard time	2,825	—
Time deviation	435	15.40% of standard time
EPCE	—	90.49%
SME	—	86.66%

The future-state NVA time of 310 minutes represents an estimated reduction of 1,460 minutes relative to the current state. The reduction in RVA time is 1,570 minutes. This latter change must be interpreted cautiously: it is not a recommendation to remove necessary regulatory controls. It reflects the time allocation in the proposed design and should be accepted only to the extent that the underlying redesign preserves all required testing, review, documentation, and approval steps. Implementation would therefore require review by production, quality, and regulatory personnel.

4.1. Comparative performance

Table 3. Comparative assessment of current-state and proposed future-state performance

Indicator	Current state	Proposed future state	Change
Lead time (min)	6,790	3,260	−51.99%
VA time (min)	2,250	1,750	−22.22%
RVA time (min)	2,770	1,200	−56.68%
NVA time (min)	1,770	310	−82.49%
EPCE	73.93%	90.49%	+16.56 percentage points
SME	41.61%	86.66%	+45.05 percentage points
Time deviation (min)	3,965	435	−89.03%
Work effort (worker-days)	53.135	22.371	−57.90%

The estimated reduction in lead time is 3,530 minutes, equivalent to approximately 51.99%. NVA time declines by 82.49%, while the time deviation from standard falls by 89.03%. EPCE increases by 16.56

percentage points and SME by approximately 45.05 percentage points. Total work effort is estimated to decline by 57.90%, from 53.135 to 22.371 worker-days. Collectively, these changes suggest that the proposed configuration could improve both flow efficiency and the use of labour resources. Figure 3 visualises the changes in activity-time composition and the two principal efficiency indicators.

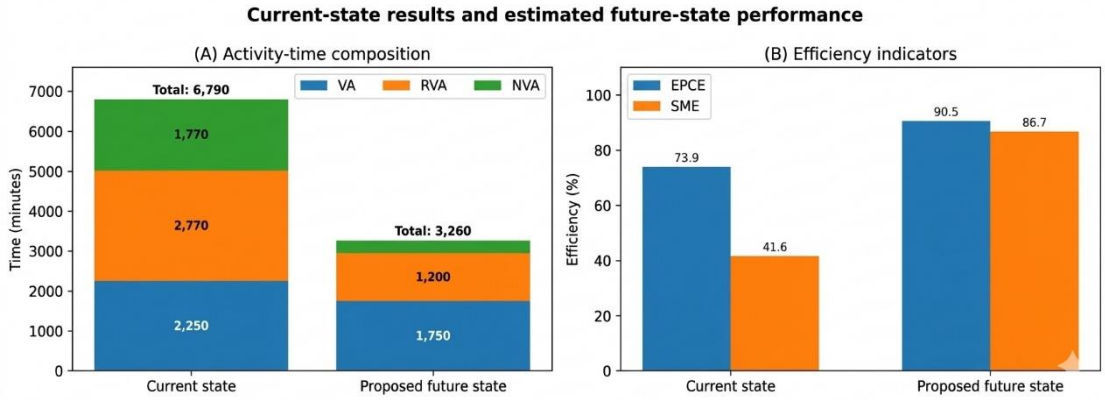


Figure 3. Comparison of activity-time composition and principal efficiency indicators between the current and proposed future states. Source: Authors' calculations based on the operational dataset.

The increase in SME is particularly notable because the future-state aggregate time (3,260 minutes) is much closer to the standard-time aggregate (2,825 minutes) than the current-state total. The proposed design does not reduce lead time below the standard reference; rather, it narrows the gap to 435 minutes. The remaining deviation indicates that further improvement may be possible, but any further reduction should be assessed against process capability, product requirements, and regulatory obligations.

5. Discussion

5.1. Implications of the RVA classification

The first implication concerns the meaning of waste in regulated manufacturing. In a pharmaceutical process, an activity can be non-transformational and still be indispensable. Inspection, sampling, in-process testing, documentation, and verification protect product quality and provide evidence of process control. The proposed RVA category makes this distinction explicit and helps prevent the inappropriate treatment of compliance activities as removable waste. This is consistent with the need to adapt lean tools to the operational characteristics of pharmaceutical production rather than transferring manufacturing assumptions without modification (Manning & Sörlin, 2017; Abideen & Mohamad, 2021; Rimantho et al., 2023).

At the same time, regulatory necessity does not make every associated delay unavoidable. A test may be mandatory, but waiting for sample transfer, labouratory availability, documentation completion, or a review hand-off may contain avoidable time. The analytical value of RVA is therefore twofold: it protects the status of necessary control activities while allowing their execution and coordination to be examined. The relevant improvement question is not whether the control should exist, but whether it can be performed with less avoidable delay without compromising compliance.

5.2. Linking activity classification with standard-time analysis

The second implication is that activity type and time performance answer different questions. VA/RVA/NVA classification indicates the role of an activity in the value stream, whereas actual-to-standard comparison indicates how efficiently the activity is performed relative to its reference time. An RVA activity may be necessary but consume more time than its standard; an NVA activity may be

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avoidable even if its duration is short. This combined perspective supports more discriminating improvement decisions than a classification based on activity type alone.

The contrast between EPCE and SME illustrates this point. EPCE increases when the share of VA and RVA within lead time increases. SME increases when actual time approaches standard time. The current-state EPCE of 73.93% coexists with an SME of 41.61%, showing that the inclusion of necessary regulatory time does not imply that the process is time-efficient. In the proposed future state, the two indicators rise to 90.49% and 86.66%, respectively, suggesting a more balanced profile of activity composition and time performance.

5.3. Relationship with previous research

The findings are consistent with the broader VSM literature, which uses current- and future-state mapping to expose process inefficiencies and guide flow improvement (Rother & Shook, 2003; Hines et al., 2004). Recent reviews indicate that VSM continues to evolve toward digitally enabled and sustainability-oriented applications, while pharmaceutical Lean 4.0 research highlights the need to coordinate operational improvement with quality, compliance, and responsiveness (Ramos & Coelho, 2022; Abideen & Mohamad, 2021; Rimantho et al., 2023; Tetteh-Caesar et al. (2024)). The present study extends this application-oriented stream by explicitly separating regulatory value-added activities from direct value creation and avoidable non-value-adding activities, then linking this classification to actual-to-standard time comparisons and work-effort assessment. Unlike studies that validate future-state assumptions through discrete-event simulation, the present analysis evaluates a proposed configuration analytically; this distinction limits the strength of claims that can be made about realised performance.

The results should not be interpreted as evidence that the same numerical gains will occur in other pharmaceutical plants. The magnitude of improvement depends on product type, batch size, equipment, staffing, process layout, labouratory capacity, documentation systems, and the quality of the standard-time references. The main transferable element is the analytical logic: classify activities in a compliance-aware manner, measure actual and standard times, map the flow, and design improvements that preserve mandatory controls.

5.4. Managerial implications

For managers, the framework offers a structured basis for prioritising improvement actions. First, review temporary storage and waiting between stages, using lead-time and NVA data to identify where investigation is most valuable. Second, coordinate production and quality activities so that mandatory tests and reviews are scheduled and handed over efficiently. Third, use the actual-to-standard gap to identify activities requiring root-cause analysis rather than assuming that every deviation has the same cause. Fourth, track work effort alongside elapsed time to ensure that a shorter process does not conceal a shift in labour demand. Finally, maintain periodic VSM updates so that proposed gains can be compared with measured post-implementation performance.

Any reduction in RVA time should be subject to formal quality review. The proposed future state must not be implemented by shortening or bypassing required controls. Instead, improvement should target avoidable waiting, duplication, poor sequencing, or inefficient information flow surrounding those controls.

6. Conclusions, Limitations and Future Research

This study developed and applied a compliance-aware quantitative VSM framework to a pharmaceutical suspensions production line. Its central analytical feature is the distinction between VA, RVA, and NVA activities, combined with the comparison of actual and standard times and the assessment of EPCE, SME, time deviation, and work effort. The distinction is important because pharmaceutical quality and regulatory activities cannot be treated as waste solely because they do not directly transform the product.

The current-state analysis recorded a total lead time of 6,790 minutes, including 2,250 minutes of VA, 2,770 minutes of RVA, and 1,770 minutes of NVA. The proposed future state estimates a reduction in lead time to 3,260 minutes, with NVA time declining to 310 minutes. EPCE is projected to rise from 73.93% to 90.49%, SME from 41.61% to 86.66%, and total work effort from 53.135 to 22.371 worker-days. The time deviation from standard is estimated to decline from 3,965 to 435 minutes. These results indicate substantial improvement potential within the proposed design.

The study has limitations. It is based on a single pharmaceutical production line in one organisation, which restricts the generalisability of the numerical findings. The future-state results are estimates derived from a proposed process design and have not been established through post-implementation measurement. The accuracy of the indicators also depends on the suitability, consistency, and currency of the standard-time references and the completeness of the operational records. Small differences in reported work-effort aggregates can arise from rounding activity-level worker-day values; the comparative results reported here use 22.371 worker-days for the proposed future state consistently. In addition, the analysis is primarily process- and time-based; it does not independently establish causal effects through a controlled intervention or multi-site statistical design.

Future research should implement the proposed future state and collect post-implementation data over multiple production cycles. It should verify that reductions in RVA time preserve GMP and product-quality requirements, assess variation across batches and products, and examine the stability of the proposed time standards. Replication across other pharmaceutical lines and facilities would help evaluate the transferability of the framework. Further work could also integrate VSM with discrete-event simulation or digital production records, provided that the underlying data and model assumptions are validated.

In conclusion, the study shows how VSM can be adapted to pharmaceutical manufacturing by distinguishing regulatory necessity from avoidable inefficiency and by linking activity classification to quantitative time and labour measures. The proposed framework provides a practical analytical basis for improvement while recognising that operational efficiency must remain compatible with quality, safety, and regulatory compliance.

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