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REVIEWER'S REPORT

Manuscript No.: IJAR-59222
Title: ,Automation and Operational Excellence in Pharmaceutical Drug-Delivery Manufacturing: An Evidence-Gated Framework for Saudi Vision 2030

Recommendation:
Accept as it is .....
Accept after minor revision.....
Accept after major revision ...YES.....
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality	✓			
Techn. Quality		✓		
Clarity	✓			
Significance		✓		

Reviewer's ID: JPR-094

Detailed Reviewer's Report

Reviewer Report

Manuscript

"Automation and Operational Excellence in Pharmaceutical Drug-Delivery Manufacturing: An Evidence-Gated Framework for Saudi Vision 2030"

Overall assessment

This manuscript addresses an important and timely intersection of pharmaceutical manufacturing automation, operational excellence, GMP, OEE, and Saudi pharmaceutical localization. Its central proposition—that automation should be justified by a quantified manufacturing loss, measurable KPI, GMP-control requirement, and local technical-ownership criterion—is potentially useful and more disciplined than technology-led "Pharma 4.0" discussions.

The manuscript also demonstrates commendable caution about extrapolating non-Saudi OEE data to Saudi manufacturing. The use of primary quantitative studies and explicit separation between observed data and arithmetic scenarios is a significant strength.

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However, in its present form, I would recommend major revision. The main issue is not the basic idea, but the strength of inference relative to the evidence base. The manuscript sometimes moves from a small number of heterogeneous plant studies and a Saudi product-registration dataset to broad conclusions about pharmaceutical manufacturing and Saudi drug-delivery localization. Some claims are stronger than the underlying evidence permits.

1. Strengths of the manuscript

1.1 Strong and relevant research problem

The manuscript identifies a genuine problem: automation discussions frequently list technologies—PAT, MES, AI, robotics, digital twins, predictive maintenance—without establishing which measurable operational loss the technology is intended to address.

The proposed question is therefore practically relevant:

What manufacturing loss is being addressed, what KPI should change, and can the improvement occur without compromising the validated state of control?

This is particularly appropriate for pharmaceutical manufacturing, where productivity cannot simply be optimized independently of quality, validation, traceability and GMP.

1.2 Strong evidence-discipline philosophy

One of the strongest aspects is the explicit distinction between:

- observed empirical evidence;
- regulatory/normative requirements;
- technical feasibility;
- author-derived calculations;
- strategic projections.

The four-tier source hierarchy is a useful methodological contribution.

The manuscript is also correct to distinguish registered-product share, consumption share and market-value share rather than treating them as interchangeable. The underlying Alshehri study

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indeed reports Saudi-manufactured products as 22.55% of registered pharmaceutical products. PubMed+1

This is one of the paper's more convincing analytical contributions.

1.3 Excellent attention to provenance of quantitative evidence

The manuscript's emphasis on tracing OEE values back to primary publications is valuable.

The Chikwendu et al. paper does report very high quality relative to availability and performance, with reported means of approximately 96.39% quality, 60.49% availability and 27.62% performance. ScienceDirect+1

Likewise, the Zubair et al. study reports an OEE of 23% for the dry-suspension section. ResearchGate+1

The manuscript's effort to recompute reported data rather than simply repeat secondary citations is therefore a substantive strength.

1.4 The technology-to-loss matrix is potentially publishable as a framework contribution

Table 2 is arguably the manuscript's most practically useful element.

The logic:

technology → baseline loss → KPI → GMP evidence

is clear and operationally meaningful.

For example:

- predictive maintenance → unplanned downtime → MTBF/downtime/OEE availability;
- MES → transcription/reconciliation delay → record errors/review cycle;
- machine vision → inspection inconsistency → false acceptance/rejection;
- PAT → process-drift detection latency → detection latency/Cpk/Ppk.

This makes the paper more actionable than a conventional narrative review.

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1.5 The evidence-gated maturity model is a useful conceptual contribution

Table 3 also has potential originality.

The progression from:

1. digital foundation;
2. connected control;
3. predictive operations;
4. adaptive excellence

is not merely based on the amount of technology installed. Instead, advancement requires demonstrable evidence.

That is a strong conceptual distinction from maturity models that effectively measure technology adoption rather than operational capability.

1.6 Local technical ownership is an interesting addition

The concept of measuring localization through technical ownership rather than only manufacturing value is potentially important.

The proposed indicators—such as:

- critical faults resolved without overseas escalation;
- validated changes executed locally;
- critical-spares availability;
- vendor-response dependency;
- locally documented model retraining/rollback—

could provide a useful bridge between industrial localization policy and operational resilience.

This may be one of the more original elements of the manuscript.

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2. Key weaknesses

2.1 The evidence base is too small to support some of the manuscript's broad conclusions

This is the principal weakness.

The core OEE conclusion rests essentially on **two pharmaceutical plant studies**:

- one 22-month study;
- one dry-suspension case study.

The manuscript itself acknowledges that these are outside Saudi Arabia and do not represent sterile drug-delivery manufacturing.

That limitation is important enough that several statements need to be softened.

For example, the manuscript states:

"The published evidence is consistent and pointed."

Two studies are not sufficient to establish a generally consistent pharmaceutical-manufacturing evidence base.

A more defensible formulation would be:

"The limited plant-level evidence reviewed here suggests…"

That distinction is important for peer review.

2.2 The manuscript sometimes confuses "pharmaceutical manufacturing" with "drug-delivery manufacturing"

This is a conceptual issue.

The title specifically emphasizes **drug-delivery manufacturing**, but the principal OEE evidence comes from:

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- syrup/tablet production;
- dry-suspension manufacturing.

Those are pharmaceutical manufacturing examples, but they do not necessarily establish evidence for:

- aseptic filling;
- biologics;
- prefilled syringes;
- autoinjectors;
- blow-fill-seal;
- sterile injectables;
- device combination products.

The manuscript makes a persuasive argument that these areas matter for Saudi localization, but it does not have corresponding empirical operational data.

Therefore, the paper should distinguish explicitly between:

Evidence directly demonstrated in pharmaceutical plants

and

framework implications proposed for drug-delivery manufacturing.

That distinction would significantly improve scientific rigor.

3. Important methodological issue: the localization arithmetic

This section is intellectually interesting but requires tightening.

The manuscript correctly says that registered-product share, consumption share and market-value share are different denominators.

However, it then constructs a scenario using:

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- 22.55%;
- 25%;
- 30%;

against a 40% market-value target.

The 22.55% figure is explicitly a **share of registered pharmaceutical products**, not necessarily a share of pharmaceutical market value. The underlying 2023 study used an SFDA formulary containing registered products and found 22.55% manufactured in Saudi Arabia. PubMed+1

Consequently, calculating:

40% − 22.55% = 17.45%

and multiplying that difference by SAR 44.1 billion can be presented as an **illustrative arithmetic scenario**, but it should not be interpreted as an actual localization-value gap.

The manuscript does partly acknowledge this, which is good. Nevertheless, I recommend making the warning substantially more prominent.

Recommended change

Rename Table 1:

"Illustrative arithmetic scenarios using non-equivalent localization indicators"

rather than:

"Localization value scenarios."

This would prevent readers from interpreting the SAR 4.4–7.7 billion range as an empirically established investment requirement.

4. The 25% row is insufficiently justified

This is a specific problem.

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The table contains:

25% — Upper bound of consumption estimate (Alshehri et al., 2023)

But elsewhere the manuscript says:

"more than forty registered manufacturers cover only 20–25 per cent…"

and attributes this to Tawfik et al. / related evidence.

The provenance of the **25% figure should be checked carefully** and the citation should correspond exactly to the statement.

I would ask the authors to provide:

- exact source;
- page/table/figure;
- exact wording in the source;
- whether 25% represents products, units, consumption, or another denominator.

This is especially important because the paper's principal methodological argument is itself about denominator discipline.

5. The OEE recomputation needs to be made reproducible

The paper says:

"Recomputation from that published series gives mean availability of 61.0 per cent…"

but the source paper reports approximately 60.49% availability and 27.6188% performance. ScienceDirect

This does not necessarily mean the manuscript is wrong—the authors may have recomputed from the underlying monthly observations—but the manuscript should show the calculation explicitly.

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I recommend adding a supplementary table containing:

Month	Availability	Performance	Quality	OEE
1	...	...	...	...
2	...	...	...	...
...	...	...	...	...
22	...	...	...	...

Then report:

- arithmetic mean;
- median;
- standard deviation;
- minimum;
- maximum.

This would make the claimed verification genuinely reproducible.

6. One statement is too strong: "more than eighty per cent of productive capacity was being lost"

This follows mathematically from the reported OEE, but the wording needs refinement.

An OEE of 16.5% does not necessarily mean that 83.5% of economically useful plant capacity was lost.

OEE is a particular metric constructed from availability, performance and quality under specific definitions of:

- planned production time;
- ideal cycle time;
- good units;
- downtime.

The manuscript itself acknowledges that these definitions were not fully disclosed.

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Therefore, the safer statement is:

"The measured OEE indicates that approximately 83.5% of the defined OEE opportunity was not realized under the study's measurement definitions."

That is much more defensible.

7. The "quality problem / data problem / technology problem" statement should be revised

The manuscript states:

"A plant sustaining 96.39 per cent mean quality while losing more than eighty per cent of productive capacity does not have a quality problem, a data problem or a technology problem."

This is rhetorically strong but scientifically too categorical.

A high quality component of OEE does not establish that the plant has no quality problems.

There could be:

- deviations;
- complaints;
- stability failures;
- batch-release delays;
- CAPA recurrence;
- process capability issues;
- regulatory observations;

that are not captured by the OEE quality component.

I recommend changing it to:

"The OEE decomposition suggests that the dominant measured loss in this case lies in performance and availability rather than the OEE quality component."

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That preserves the insight without overinterpreting the metric.

8. "Structural rather than accidental" is not demonstrated

The statement:

"this failure mode is structural rather than accidental"

goes beyond the evidence.

A 22-month dataset from one pharmaceutical manufacturer can demonstrate persistence at that site, but not necessarily that the phenomenon is structural across pharmaceutical manufacturing.

A better formulation:

"The persistence of low performance and availability across the observed series suggests that the losses were not confined to a single isolated month."

That conclusion is directly supported by the data.

9. The 85% OEE benchmark discussion is valuable but needs better sourcing

The manuscript correctly emphasizes that the commonly cited 85% OEE value is derived from component targets rather than necessarily being a universal empirical pharmaceutical benchmark.

This is a strong point.

However, the paper should provide a more explicit distinction between:

- Nakajima's TPM-derived benchmark;
- later "world-class OEE" literature;
- pharmaceutical-industry benchmarks;

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- GMP-specific OEE practices.

Otherwise readers may perceive the argument as attacking a benchmark without fully reviewing the literature surrounding it.

10. The causal claim concerning automation is not established

The paper's title and research questions suggest automation and operational excellence.

But the empirical evidence does not actually demonstrate that:

automation → improved OEE → increased localization.

Instead, the paper demonstrates:

existing manufacturing losses → candidate technologies that theoretically address those losses.

That is a valuable framework, but it is different from demonstrating automation effectiveness.

The manuscript should therefore call itself a:

framework / evidence synthesis / conceptual framework

rather than implying that it provides empirical evidence of automation's causal impact.

This distinction is essential.

11. The manuscript needs a stronger literature-search methodology

The paper calls itself a "structured secondary-data synthesis," but there is insufficient information about the search process.

A reviewer would reasonably ask:

- Which databases were searched?

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- What dates were covered?
- What search strings were used?
- How many records were identified?
- How many were screened?
- What inclusion/exclusion criteria were used?
- Were duplicates removed?
- Were studies assessed for methodological quality?
- Why were particular studies selected?
- Was PRISMA used or deliberately not used?

Without this information, "structured synthesis" remains somewhat asserted rather than demonstrated.

Recommendation

Add a short methodology subsection:

2.3 Literature identification and selection

with:

- databases;
- search terms;
- publication period;
- inclusion criteria;
- exclusion criteria;
- screening process;
- final number of included studies.

A PRISMA-style flow diagram would strengthen the paper considerably if the authors intend to position it as a systematic or structured review.

12. Technology coverage is broader than the actual evidence

Table 2 includes:

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- PAT;
- MES;
- predictive maintenance;
- machine vision;
- digital twins;
- robotics;
- aseptic isolation;
- continuous manufacturing.

But only a subset is supported by quantitative pharmaceutical plant evidence.

This creates a risk that readers interpret the table as an evidence-based effectiveness matrix when it is actually a proposed decision framework.

The table should therefore include another column:

"Evidence status"

with categories such as:

- demonstrated plant-level evidence;
- demonstrated technical feasibility;
- conceptual application;
- regulatory/normative requirement.

That would make the framework much stronger.

13. The Saudi-specific contribution is promising but insufficiently validated

The manuscript's Saudi component is mostly derived from:

- national strategy;
- SFDA registration data;
- published Saudi pharmaceutical studies;

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- policy targets.

There is no Saudi plant-level automation/OEE dataset.

The authors correctly admit this.

However, this means the phrase:

"for Saudi drug-delivery manufacturing"

should be interpreted as a contextual application, not empirical validation.

I would explicitly describe the framework as:

"a Saudi-contextualized evidence framework"

rather than implying it has been empirically validated in Saudi plants.

14. "Technical ownership" needs operational validation

This is an interesting idea but currently conceptual.

For example:

"proportion of critical automation, validation, reliability and model-governance tasks executable by qualified in-country personnel…"

is promising, but the paper needs to define:

- What constitutes a "critical" task?
- What qualification is required?
- What is the recovery-time threshold?
- How is task complexity assessed?
- Who verifies competence?
- What percentage constitutes adequate local ownership?

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The paper should explicitly say that these are proposed indicators requiring validation, rather than established measures.

15. The implementation section is useful but could be more scientific

Section 9 is practical and good.

The recommendation to use:

- pre/post measurement;
- identical KPI definitions;
- control charts;
- confidence intervals;
- interrupted time-series analysis;
- difference-in-differences;

is strong.

However, the manuscript could go further by specifying a proposed evaluation design.

For example:

Intervention line vs comparator line

with:

- baseline period;
- implementation period;
- post-intervention period;
- product mix;
- planned maintenance;
- batch size;
- changeover;
- demand;

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- operator changes;
- regulatory holds.

This would turn the framework into a clear future empirical research protocol.

16. Novelty/originality

What appears genuinely novel

The strongest potential contributions are:

1. Evidence-gated automation framework
    - technology cannot enter the capital plan without a quantified loss and KPI.
2. Technology–loss–KPI–GMP linkage
    - this is practically useful and conceptually coherent.
3. Localization treated as capability rather than simply market share
    - especially the technical-ownership concept.
4. Explicit denominator discipline in Saudi localization
    - registered products ≠ consumption ≠ market value.
5. Reproducibility/provenance treatment of OEE evidence
    - particularly the effort to distinguish published data from secondary numbers.

These should be highlighted much more strongly in the revised manuscript.

17. Significance

I would assess the potential significance as moderate to high, provided the authors substantially strengthen the methodological foundation.

Academic significance

The manuscript potentially contributes to the literature by connecting three areas that are often treated separately:

Pharma 4.0 + operational excellence + industrial localization.

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Most importantly, it shifts the question from:

"Which digital technologies should pharmaceutical manufacturers adopt?"

to:

"Which measured manufacturing loss justifies which technology, under which GMP controls?"

That is a meaningful conceptual contribution.

Industrial significance

The framework could help pharmaceutical manufacturers avoid technology investments that do not address the dominant loss.

The proposed sequence:

measure → identify loss → select intervention → validate → scale

is highly relevant to capital-intensive GMP manufacturing.

Saudi policy significance

The paper also provides a potentially useful perspective on Vision 2030 by arguing that localization should not be measured only by manufacturing value but also by:

- technical capability;
- troubleshooting capacity;
- validation expertise;
- engineering autonomy;
- supply resilience.

This is potentially significant, but it needs stronger empirical support before being presented as an established finding.

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18. Major points requiring revision

I would ask the authors to address the following before publication:

Major Revision 1 — Strengthen the review methodology

Provide:

- databases searched;
- search strings;
- date range;
- inclusion/exclusion criteria;
- screening process;
- number of studies identified/included;
- quality-assessment method.

Major Revision 2 — Separate evidence from framework proposals

Clearly distinguish:

empirically demonstrated

from:

technically feasible

from:

proposed by the authors.

This should be done throughout Tables 2 and 3.

Major Revision 3 — Correct the strength of generalizations

Replace broad statements derived from one or two plants with appropriately qualified language.

For example:

"The limited evidence reviewed suggests…"

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rather than:

"The published evidence is consistent and pointed."

Major Revision 4 — Clarify the localization arithmetic

Make absolutely clear that the SAR 4.4–7.7 billion values are illustrative arithmetic scenarios based on non-equivalent denominators, not estimates of an actual Saudi investment or localization gap.

Major Revision 5 — Make OEE calculations reproducible

Provide the underlying 22-month values or supplementary calculations.

Major Revision 6 — Reconsider the "83% capacity loss" terminology

Use "OEE opportunity not realized" or equivalent terminology rather than equating OEE directly with total plant capacity loss.

Major Revision 7 — Strengthen the novelty argument

The introduction should explicitly state what existing Pharma 4.0/OEE/localization frameworks fail to provide and exactly what this paper adds.

Major Revision 8 — Add an evidence-status column to Table 2

This would significantly strengthen the manuscript.

19. Minor comments

- The title is somewhat long. Consider shortening it.
- "Drug-delivery manufacturing" needs an explicit definition.
- Define Pharma 4.0 more formally.
- Define OEE components before using them extensively.
- Avoid "world-class" where it could imply universal validity.
- "The correct response" should generally be changed to "the framework suggests" or similar.

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- "Unambiguous" is too strong given the limited evidence.
- "Structural rather than accidental" should be softened.
- The phrase "the faster of the two available levers" is not demonstrated and should be revised.
- The manuscript should distinguish capacity, effective capacity, throughput, and OEE opportunity more carefully.
- Check all author names against publisher indexing. The manuscript itself notes alternate author-name forms for Chikwendu et al.; this should be standardized.
- The direct primary source for the NIDLP 40% target should be added, as the manuscript itself acknowledges.
- The 2024 Sanofi/Sudair/NUPCO example should remain clearly identified as an industry/company announcement rather than peer-reviewed evidence.
- Consider adding a dedicated "Research propositions" section.

20. Suggested reviewer decision

Recommendation: Major Revision

I would not recommend rejection because the manuscript contains a potentially useful conceptual contribution and addresses a relevant industrial problem.

However, I would also not recommend acceptance in its current form, primarily because the empirical evidence is too limited to support several of the manuscript's stronger generalizations, and the review methodology is not sufficiently reproducible.

The paper becomes considerably stronger if it is repositioned as:

a Saudi-contextualized evidence synthesis and decision framework

rather than as empirical evidence demonstrating the effectiveness of automation in Saudi pharmaceutical manufacturing.

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21. Reviewer-style final recommendation

Recommendation to the Editor: Major Revision

Overall evaluation: The manuscript addresses an important and under-integrated topic at the intersection of pharmaceutical manufacturing automation, operational excellence, GMP governance, OEE measurement and Saudi pharmaceutical localization. Its principal strengths are the emphasis on evidence provenance, the distinction between localization denominators, the technology-to-loss-KPI-GMP matrix, and the proposed evidence-gated maturity model. The concept of technical ownership as a dimension of localization is also potentially original and practically significant.

The principal concern is that the empirical foundation is relatively narrow. The central OEE conclusions rely on a small number of pharmaceutical plant case studies outside Saudi Arabia, while the proposed implications concern Saudi drug-delivery manufacturing, including sterile and device-based production. The manuscript generally acknowledges this limitation, but several statements nevertheless extend beyond what the evidence can establish. In addition, the methodology for identifying and selecting the secondary literature requires greater transparency, and the localization-value calculations need stronger safeguards against interpretation as actual market-value gaps.

The manuscript should therefore undergo major revision, with particular attention to methodological reproducibility, separation of empirical findings from conceptual proposals, qualification of generalizations, reproducibility of OEE calculations, and clarification of the non-equivalence of localization denominators.

If these issues are adequately addressed, the manuscript could make a useful conceptual and managerial contribution to the pharmaceutical manufacturing and Pharma 4.0 literature, particularly in the context of Saudi localization and GMP-constrained automation.

Bottom-line assessment

Criterion	Assessment
Relevance	**High**
Practical significance	**High**
Conceptual contribution	**Moderate–High**
Originality	**Moderate–High**

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Criterion	Assessment
Empirical evidence	**Moderate–Low**
Methodological transparency	**Moderate–Low**
Saudi-specific evidence	**Low–Moderate**
Framework quality	**High potential**
Current manuscript readiness	**Requires major revision**
Recommended decision	**Major Revision**

One particularly important point: the underlying cited evidence does support several of the manuscript's numerical foundations—the 2023 Saudi study reports 22.55% Saudi-manufactured registered products, while the 2020 OEE study reports the very high quality/low performance pattern used by your manuscript. . The problem is therefore not that the paper has no evidence; it is that the manuscript sometimes makes claims broader than what those sources can establish. That is a fixable problem and, in my view, the main issue to address before submission.