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REVIEWER'S REPORT

Manuscript No.: IJAR-59185

Title: Strengthening Pharmaceutical Manufacturing Localization in Saudi Arabia Through Production Planning and Capacity Optimization.

Recommendation:

Accept as it is .....

Accept after minor revision.....

Accept after major revision .....

Do not accept (*Reasons below*) .....

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

Reviewer Id: JPR-274

Reviewer's Comment for Publication.

The manuscript addresses a timely and significant topic concerning pharmaceutical manufacturing localization in Saudi Arabia under Vision 2030. It appropriately connects localization policy objectives with production planning, capacity optimization, supply-chain resilience, technology transfer, operational excellence, and digital manufacturing. The central argument that localization requires more than installed manufacturing capacity is clearly articulated and supported by the proposed distinction between nominal, demonstrated, and effective capacity.

The manuscript has several notable strengths. The literature review covers multiple relevant domains, including Saudi pharmaceutical localization, production and capacity planning, supply-chain resilience, operational excellence, Pharma 4.0, and technology transfer. The methodology identifies the four evidence domains, search sources, search terms, inclusion considerations, and thematic coding approach. The proposed seven-layer framework is also logically structured around localization portfolio planning, S&OP/MPS, MRP and supply risk, finite-capacity management, quality capacity, technology transfer, and digital decision support.

The manuscript further provides practical value through its capability-based KPI framework and phased 2026–2030 implementation roadmap. The inclusion of indicators related to service reliability, planning performance, asset utilization, quality flow, material resilience, technology transfer, and workforce capability broadens the assessment of localization beyond simple production volume or local-content measures. The manuscript also appropriately acknowledges that it is an integrative synthesis rather than an exhaustive systematic review and identifies the absence of proprietary plant-level data and primary interviews as limitations.

However, several minor revisions would improve the manuscript's methodological rigor, precision, and publication readiness:

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1. **Strengthen the literature-search methodology.**
   The manuscript lists databases, institutional sources, search terms, and the 2020–2026 publication period, but the search strategy could be reported more reproducibly. Please provide additional information on the search dates, combinations of search terms, screening process, number of records initially identified, records screened/excluded, and the final number of sources included.
2. **Clarify the evidence base and source selection.**
   The manuscript refers to a 33-source evidence base in Figure 2, while the reference list contains a mixture of peer-reviewed publications and policy/regulatory documents. It would be useful to explicitly distinguish peer-reviewed evidence from policy and regulatory sources and explain how the relative evidentiary weight of these different source types was considered.
3. **Distinguish established evidence from the authors' proposed framework.**
   Several recommendations, KPI combinations, planning layers, and implementation stages are conceptual contributions of the manuscript. These should be clearly distinguished from findings directly demonstrated by the cited literature. This would prevent readers from interpreting the proposed framework as empirically validated.
4. **Provide stronger Saudi-specific empirical grounding.**
   The manuscript successfully incorporates Saudi-specific literature concerning pharmaceutical localization and medicine availability. Nevertheless, much of the production-planning and capacity-optimization evidence originates from international studies. The authors should explicitly identify where evidence is directly derived from Saudi pharmaceutical manufacturing and where recommendations are extrapolated from international pharmaceutical manufacturing research.
5. **Clarify the validation status of the seven-layer framework.**
   The seven-layer framework is potentially useful, but it appears to be a conceptual synthesis rather than a framework validated through pharmaceutical-manufacturing case studies or expert assessment. The manuscript should state this explicitly and, where possible, propose how future empirical research could validate the framework.
6. **Improve operational definitions for proposed KPIs and thresholds.**
   The KPI framework contains useful indicators such as OEE, schedule adherence, batch-release lead time, service level, changeover time, and capacity utilization. However, the manuscript does not consistently specify how these measures should be calculated or what constitutes an acceptable threshold. The authors should clarify that thresholds are context-dependent or provide references/examples where appropriate.
7. **Further develop the relationship between quality capacity and production capacity.**
   The discussion correctly identifies QC testing, batch-record review, deviation management, and release processes as potential capacity constraints. This is an important contribution. The authors could strengthen this section by providing a more explicit explanation of how quality-related constraints should be incorporated quantitatively into finite-capacity planning.
8. **Clarify technology-transfer integration.**
   The manuscript appropriately argues that technology transfer should be treated as a capacity-planning event rather than solely as an R&D or regulatory activity. The proposed capacity reservation, validation planning, and launch-readiness approach is useful. However, the authors should provide a clearer distinction between regulatory approval, technical transfer completion, validation readiness, and operational localization.
9. **Strengthen the discussion of digital implementation.**
   The manuscript proposes ERP, APS, MES/eBR, dashboards, predictive maintenance, and analytics. It would be beneficial to discuss implementation prerequisites such as data quality, system interoperability, cybersecurity, master-data governance, and workforce readiness in

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greater detail, particularly because digitalization is presented as an enabling layer rather than an independent solution.

10. **Review the 2026–2030 roadmap for consistency and justification.**
    The phased roadmap is clearly presented, moving from planning foundations to optimization, transfer integration, digital scaling, and dynamic localization. The authors should explain more explicitly why the proposed sequencing and timing of these phases are appropriate and clarify that the dates represent a proposed implementation scenario rather than empirically established milestones.
11. **Improve figures and tables.**
    Figures 1–3 and Tables 1–4 are central to the manuscript. The final submission should ensure that all figures are of publication quality, that text is legible at journal layout size, and that each figure/table is sufficiently explained in the main text. The relationship among the graphical abstract, the seven-layer framework, and the capacity-expansion hierarchy should also be made visually consistent.
12. **Address declarations before final submission.**
    The Funding, Conflict of Interest, Author Contributions, and Generative-AI Disclosure sections are currently marked as items to be completed or confirmed. These statements should be finalized according to the target journal's requirements before publication.
13. **Language and reference consistency.**
    The manuscript is generally well written, but a final editorial review is recommended to correct minor typographical issues, spacing problems, inconsistent line breaks, and formatting irregularities in tables and references. The reference list should also be checked carefully for consistency with the target journal's citation style.

Overall Assessment

The manuscript is relevant, well organized, and potentially valuable for researchers, pharmaceutical manufacturers, policymakers, and supply-chain practitioners interested in pharmaceutical localization in Saudi Arabia. Its principal contribution is the integration of production planning and capacity optimization with localization policy, technology transfer, quality capacity, workforce development, and supply-chain resilience. The manuscript also appropriately recognizes the need for future plant-level empirical validation.

Subject to the minor revisions outlined above, the manuscript is suitable for publication.