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

Abstract

Purpose — Pharma 4.0 is commonly argued as a technology catalogue rather than a measured operating model, and the Saudi localization case is commonly argued from a single market projection. This paper reconstructs both arguments on traceable evidence and asks what automation can be shown to deliver in drug-delivery manufacturing while a validated state of control is preserved.

Design/methodology/approach — A structured secondary-data synthesis was conducted. Peer-reviewed manufacturing studies reporting observed plant data, Saudi regulatory and industrial-strategy sources, and normative GMP guidance were assembled under a four-tier source hierarchy. Every quantitative indicator was traced to its primary publication and recomputed from the published series; derived indicators are labelled as arithmetic scenarios rather than forecasts.

Findings — Three results follow. First, the Saudi localization baseline is metric-dependent and cannot be reduced to a single share: domestic manufacture accounts for 22.55 per cent of registered products, while independent estimates of the share of consumption range between 20 and 30 per cent. The incremental value implied by the 40 per cent market-value target therefore spans approximately SAR 4.4–7.7 billion at a 2030 market of SAR 44.1 billion. Second, the import profile is a drug-delivery profile: solutions and injections together account for 27.59 per cent of imported products while domestic packaging is dominated by blisters at 49.32 per cent, making localization a dosage-form capability problem rather than a volume problem. Third, published pharmaceutical OEE evidence locates loss in performance and availability rather than quality: across twenty-two reported months at one plant, mean quality was 96.39 per cent while mean performance was 28.0 per cent and mean OEE 16.5 per cent; a second plant reported 23 per cent OEE in a dry-suspension section.

Originality/value — The paper specifies an evidence-gated maturity model binding each technology to a quantified baseline loss, a target KPI, a GMP control and a local-capability test, and shows why benchmark figures repeated without traceability distort capital appraisal.

Keywords — pharmaceutical manufacturing; drug delivery; overall equipment effectiveness; process analytical technology; operational excellence; localization; Saudi Vision 2030; GMP.

1. Introduction

The case for automating pharmaceutical manufacturing is rarely made in a form that a capital committee could falsify. Claims of higher efficiency, better quality and greater resilience are asserted at a level of generality that survives any outcome. Drug-delivery manufacturing deserves a stricter standard, because the decisions at issue govern critical quality attributes, batch disposition, equipment reliability and continuity of supply to patients. The question is not whether process analytical technology (PAT), manufacturing execution systems (MES), machine learning, robotics or digital twins are technically advanced. It is whether a specified intervention measurably reduces a specified manufacturing loss without weakening the validated state of control.

The Saudi context sharpens the question rather than softening it. The Kingdom's industrial strategy projects the domestic pharmaceutical market to rise from approximately SAR 28 billion in 2020 to SAR 44.1 billion by 2030, and the National Industrial Development and Logistics Program (NIDLP) sets an objective of localizing 40 per cent of pharmaceutical market value. Those two figures are frequently combined into a single headline estimate of incremental local value. That arithmetic is only as sound as the baseline it subtracts, and the baseline is where the published record diverges most sharply from the figures in common circulation.

A parallel problem affects the manufacturing side of the argument. Benchmark values such as "85 per cent world-class OEE" and individual case-study results are repeated across the Pharma 4.0 literature with progressive loss of provenance, and occasionally with alteration. During preparation of this paper, several widely cited OEE values were traced to their primary publications and found not to correspond to any figure in the published data series. Because such numbers propagate into business cases, their verification is not a bibliographic courtesy; it is part of the analysis.

This paper therefore proceeds from primary sources only, and addresses three questions. Which manufacturing losses can automation be shown to address in pharmaceutical plants (RQ1)? Which operational-excellence practices convert digital capability into sustained KPI improvement (RQ2)? How can plant-level performance be connected to localization, technical ownership and supply resilience in the Saudi setting (RQ3)?

2. Method

2.1 Design and source hierarchy

The study is a structured secondary-data synthesis, not a primary plant experiment; no site-level Saudi production dataset was available. Evidence was ranked in four tiers. Tier 1 comprised official Saudi industrial-strategy, regulatory and procurement sources. Tier 2 comprised peer-reviewed studies reporting observed quantitative results from operating pharmaceutical plants. Tier 3 comprised process-modelling, digital-twin and machine-learning studies establishing technical feasibility. Tier 4 comprised review literature used only to interpret mechanisms. The FDA PAT framework, ICH Q9(R1), Q10 and Q13, and EU GMP Annex 1 were treated as normative governance sources, never as performance evidence.

2.2 Verification and derivation rules

Three rules were applied. First, every quantitative claim was traced to its primary publication; figures available only through secondary citation were excluded. Where a primary paper published a data series, descriptive statistics were recomputed from that series rather than quoted from intermediaries, and the recomputation was checked against any statistic the paper itself reported. Second, national indicators were reported with their measurement basis attached, because market-value share, registered-product share and consumption share are not interchangeable. Third, derived indicators were labelled as arithmetic scenarios. Market growth is (44.1/28.0 − 1) = 57.5 per cent, with an implied 2020–2030 compound annual growth rate of 4.65 per cent; on the frequently quoted unrounded base of SAR 27.9 billion these become 58.1 per cent and 4.68 per cent. The difference is immaterial to the argument but is stated because precision claimed beyond the source is a defect in itself.

3. The Saudi baseline: what the evidence establishes and what it does not

3.1 The localization baseline is metric-dependent

No single figure for domestic production share is supportable. Alshehri and colleagues (2023), working from the full SFDA formulary of registered products, found that 22.55 per cent of registered pharmaceutical products are manufactured in Saudi Arabia, against 43.86 per cent from Europe, 20.47 per cent from China and India, 10.24 per cent from the Americas and 2.61 per cent from other origins (Figure 1a). Tawfik and colleagues (2022) report that approximately 30 per cent of drugs in the Saudi market are manufactured locally, and note

that more than forty registered manufacturers cover only 20–25 per cent of the Kingdom's consumption of dispensed medicines.

These are not contradictory findings; they are different denominators. A count of registered products weights a rarely dispensed specialty item equally with a high-volume generic. A consumption share weights by units dispensed. A market-value share — the basis of the NIDLP target — weights by price, and therefore moves against local producers concentrated in low-priced generics. Any localization arithmetic that subtracts one basis from another is invalid.

Table 1 states the consequence. At a 2030 market of SAR 44.1 billion, a 40 per cent market-value share corresponds to SAR 17.64 billion of domestic value. The increment relative to plausible baselines ranges from SAR 4.41 billion (against a 30 per cent baseline) to SAR 7.70 billion (against 22.55 per cent). Reporting a point estimate within that range as an established requirement overstates what the evidence supports by a factor approaching two.

Table 1. Localization value scenarios at a 2030 market of SAR 44.1 billion

Baseline share	Basis of the baseline	Value at baseline	Value at 40% target	Increment
22.55%	Registered products (Alshehri et al., 2023)	SAR 9.94 bn	SAR 17.64 bn	SAR 7.70 bn
25%	Upper bound of consumption estimate (Alshehri et al., 2023)	SAR 11.03 bn	SAR 17.64 bn	SAR 6.62 bn
30%	Locally manufactured market share (Tawfik et al., 2022)	SAR 13.23 bn	SAR 17.64 bn	SAR 4.41 bn

Arithmetic scenarios computed on official market-value projections. The 2030 figure is a strategy projection, not an observed outcome, and the three baselines are measured on non-equivalent bases.

3.2 The gap is a dosage-form gap

The more consequential finding for drug-delivery manufacturing is compositional rather than proportional. Among imported products, tablets account for 35.00 per cent, solutions 18.24 per cent, injections 9.35 per cent, capsules 7.65 per cent and powders or granules 6.34 per cent (Figure 1b). Domestic packaging output is dominated by blisters at 49.32 per cent,

followed by bottles at 22.13 per cent, with ampoules at 3.66 per cent, vials at 3.47 per cent and dropper containers at 2.11 per cent.

Read together, these distributions describe a domestic base configured for conventional solid oral dosage forms and thinly configured for sterile liquid, parenteral and device-based delivery. Solutions and injections alone constitute 27.59 per cent of imported products, while the aseptic container formats that would displace them represent under 8 per cent of domestic packaging output. Closing a market-value gap therefore requires capability in precisely the technologies where domestic capacity is weakest — aseptic processing, blow-fill-seal and prefilled or auto-injector device assembly — not additional tablet capacity.

The agreement concluded between Sanofi, Sudair Pharma Company and the National Unified Procurement Company illustrates both the opportunity and its difficulty. The facility is to manufacture, assemble and package SoloStar insulin pens domestically, with a reported capacity of approximately fifteen million pens annually serving around 500,000 patients in a population with diabetes prevalence of 18.7 per cent. Device assembly and packaging of this kind is governed by line reliability, changeover discipline and assembly defect rates — that is, by exactly the loss structure examined in Section 4.

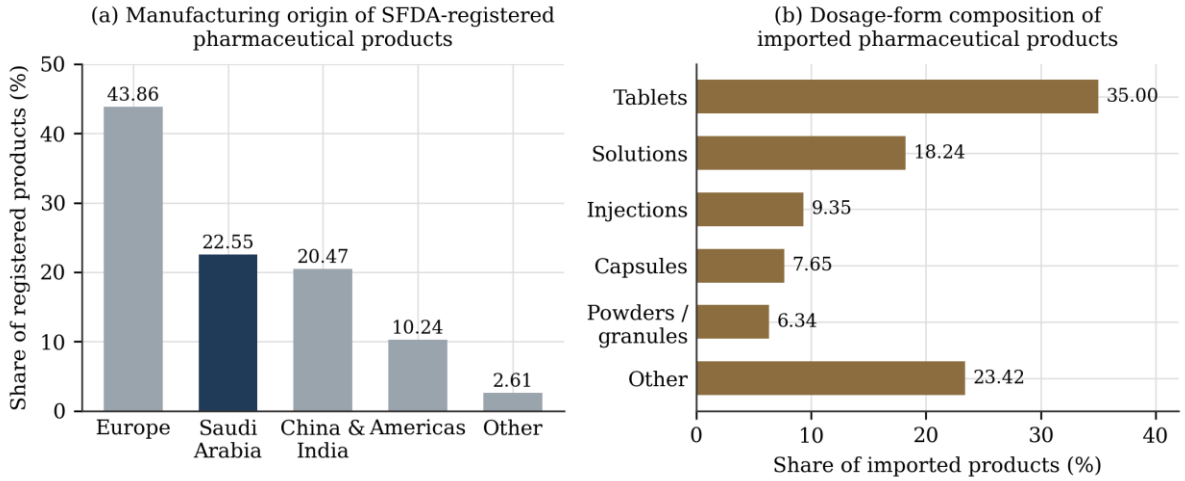

Figure 1. (a) Manufacturing origin of pharmaceutical products registered with the Saudi Food and Drug Authority; (b) dosage-form composition of imported pharmaceutical products. Both panels plot published values from Alshehri et al. (2023), Saudi Pharmaceutical Journal, 31(4), pp. 605–616.

4. Where the losses actually occur

4.1 Published pharmaceutical OEE evidence

Overall equipment effectiveness decomposes productive capability into availability, performance and quality. Nakajima's world-class threshold of approximately 85 per cent is the product of component targets of 90 per cent availability, 95 per cent performance and 99 per cent quality; it is a derived target from discrete automotive manufacturing in the 1970s, not an empirical survey result, and it transfers into GMP environments only with qualification (Section 4.2).

Two peer-reviewed studies report observed values from operating pharmaceutical plants. Zubair and colleagues (2021) found OEE of 23 per cent in the dry-suspension section of a pharmaceutical plant, attributing the shortfall to breakdown-driven maintenance and waste generation. Chikwendu and colleagues (2020) published a twenty-two-month series of monthly availability, performance, quality and OEE values from a syrup and tablet manufacturer. Recomputation from that published series gives mean availability of 61.0 per cent (range 42.7–72.9), mean performance of 28.0 per cent (range 21.3–41.4), mean quality of 96.39 per cent (range 93.8–98.9) and mean OEE of 16.5 per cent (range 13.2–29.5). The recomputed quality mean reproduces the value reported in that paper's own abstract, confirming the series is complete as extracted.

Figure 2a plots these distributions against the Nakajima component thresholds. The diagnostic pattern is unambiguous and is the central manufacturing finding of this review. Quality sits close to its world-class threshold in every month observed. Performance sits roughly seventy percentage points below its threshold. Availability sits roughly thirty points below. A site monitoring conformance alone would have recorded a healthy plant throughout a period in which more than eighty per cent of planned productive capacity was being lost to speed and downtime. In pharmaceutical manufacturing this failure mode is structural rather than accidental, because quality is the metric the quality system is built to surveil.

The practical consequence is a sequencing rule. Where performance loss dominates, an additional inspection or analytics system will improve neither throughput nor cost per good unit, however sophisticated it is. The first automation investment must address the dominant loss category identified in a line-level loss tree.

4.2 Why the 85 per cent benchmark travels poorly into GMP manufacturing

Applying the Nakajima threshold to a regulated plant without adjustment is an analytical error with real consequences for capital appraisal. Cleaning validation cycles, sterility assurance holds, environmental monitoring, line clearance between campaigns and mandated

changeover sequences are compliance obligations, not remediable downtime. A sterile line operating with full regulatory discipline may record availability that a discrete manufacturer would treat as failure while representing correct practice. Benchmarking such a plant against 85 per cent conflates compliance with inefficiency and invites exactly the wrong intervention.

The defensible use of OEE in a GMP environment is longitudinal and internal: the same line, the same definitions of planned time and ideal cycle rate, tracked against itself, with the compliance-mandated component of downtime separated and reported explicitly. Cross-site and cross-industry comparison requires disclosure of those definitions, without which OEE values are not comparable — a limitation established in the metrology literature (Muchiri and Pintelon, 2008) and routinely ignored in practice.

4.3 Capacity sensitivity

Holding planned production time, ideal cycle rate and product mix constant, effective good-output capacity is approximately proportional to OEE. From the published 23 per cent baseline, attaining 30 per cent corresponds to 1.30 times the effective output, 40 per cent to 1.74 times, 50 per cent to 2.17 times and 60 per cent to 2.61 times (Figure 2b). These are mathematical sensitivities, not forecasts: realized output also depends on demand, batch sizing, changeover frequency, quality holds and bottleneck migration.

The localization relevance is direct. Fixed capital, qualification infrastructure and skilled labour are amortized over good units produced. A line recovering from 23 to 40 per cent OEE delivers most of the output of a second line without a second qualification, a second validation exercise or a second regulatory inspection history. Where domestic capacity must expand into aseptic and device-assembly formats with long qualification lead times, effective-capacity recovery on installed assets is the faster of the two available levers.

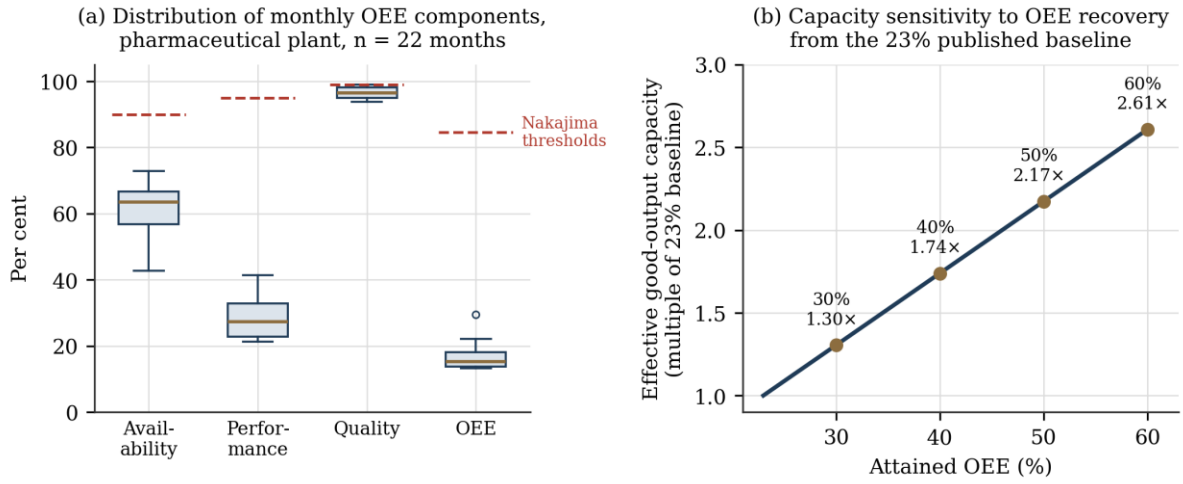

Figure 2. (a) Distribution of monthly OEE components across twenty-two reported months at a pharmaceutical plant, plotted against Nakajima's world-class component thresholds; recomputed from the published series in Chikwendu et al. (2020), Heliyon, 6(4), e03796. (b) Effective good-output capacity as a multiple of the 23 per cent baseline reported by Zubair et al. (2021), Cogent Engineering, 8(1), 1953681.

4.4 Predictive maintenance: feasibility is established, plant-level benefit is not

Kavasidis and colleagues (2023) evaluated transformer-based predictive maintenance using real sensor data from two pharmaceutical manufacturing lines, predicting both malfunction timing and severity. The study establishes technical feasibility on production data rather than simulation, which distinguishes it from much of the surrounding literature. It does not, however, yield a transferable plant-level reduction in downtime, and it should not be cited as though it did. The realized benefit must be demonstrated site by site against unplanned-downtime hours, mean time between failures, maintenance response time and avoided production loss. The same discipline applies to digital twins: Coito and colleagues (2022) quantified the impact of automation in pharmaceutical quality-control laboratories by comparing as-is and to-be workflows, and Moreno-Benito and colleagues (2022) validated a hybrid flowsheet digital twin of a continuous direct compression line. Both demonstrate decision-quality improvement within defined boundaries; neither supports a general claim about factory-wide economics.

5. Binding technology to loss, KPI and GMP evidence

Table 2 states the binding rule proposed by this paper: no digital capability enters a capital plan without a quantified baseline loss, a primary KPI and the GMP evidence its validated use requires.

Table 2. Technology-to-loss binding matrix

Capability	**Baseline loss to quantify**	**Primary KPI**	**GMP evidence required**
PAT / smart sensing	Latency between process drift and reliable signal	Detection latency; Cpk/Ppk; right-first-time	Calibration, sampling rationale, model lifecycle, change control
MES / electronic batch records	Manual entry, reconciliation and review waiting	Record errors; review cycle; schedule adherence	Audit trails, access control, master data, interface validation
Predictive maintenance	Unplanned downtime and reactive maintenance	Downtime hours; MTBF; OEE availability	Sensor integrity, alert rules, work-order integration, verification
Machine vision	Inconsistent or late defect detection	False accept/reject; defect ppm; recurrence	Validated challenge sets, lighting and configuration control, drift checks
Digital twin	Slow or high-risk scenario testing	Cycle time; forecast error; utilization	Defined intended use, model bounds, calibration, version

Capability	Baseline loss to quantify	Primary KPI	GMP evidence required
			control
Robotics / aseptic isolation	Manual intervention and handling variability	Interventions per batch; cycle time	Contamination control strategy, recovery validation
Continuous manufacturing	Batch waiting, work in progress, lead time	Lead time; yield; inventory	Residence-time distribution, diversion, traceability, state of control

KPI definitions must be fixed before baseline measurement and held constant through post-implementation verification.

6. Operational excellence as the causal link

Technology does not improve OEE, right-first-time or release cycle time on its own; management routines convert signals into controlled action. Quality by design establishes which material attributes and process parameters matter. Lean exposes waiting, handoffs and non-value-adding flow. Six Sigma establishes measurement-system adequacy before capability is claimed. Total productive maintenance structures asset reliability. The pharmaceutical quality system governs change, deviation, CAPA and knowledge management under ICH Q10.

The published OEE evidence demonstrates why this sequence matters. 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. It has a measurement-scope problem: the management system was surveilling the one dimension already under control. Conversely, an aggressive utilization target pursued without quality-system discipline can raise deviation rates and weaken contamination control. The optimization objective for pharmaceutical manufacturing is quality-adjusted throughput under a stable state of control — never maximum machine speed.

A balanced scorecard should accordingly span five dimensions: quality (right-first-time, deviation recurrence, Cpk/Ppk); reliability (availability, MTBF, unplanned downtime); flow (release cycle, schedule adherence, work in progress); digital control (data errors, model drift,

alarm performance); and resilience (local troubleshooting capability, critical-spares coverage, supplier dependency).

7. An evidence-gated maturity model

Table 3 sets out a four-stage model in which progression depends on demonstrated evidence rather than installed software. Each gate requires stable evidence from the preceding stage, preventing digital maturity from degenerating into a procurement inventory.

Table 3. Evidence-gated maturity model for Saudi drug-delivery manufacturing

Stage	Evidence required before progression	KPI set	Local-capability test
1. Digital foundation Stable process, trustworthy records	Line-level loss tree; criticality map; deviation-recurrence trend; named data owners	OEE components; right-first-time; record errors	Can local teams reconstruct batch and asset history and recover equipment without vendor dependence?
2. Connected control Integrated execution, PAT, e-	Validated interfaces; common master data; time synchronization;	Review cycle; transcription errors; detection latency	Is system configuration and first-line support owned in country?

Stage	Evidence required before progression	KPI set	Local-capability test
records	controlled access		
3. Predictive operations Validated prediction and simulation	Defined intended use; train/test provenance; performance limits; drift monitoring; fallback procedures	Unplanned downtime; MTBF; prediction lead time; avoided-loss value	Can local engineers challenge, retrain or safely retire the model?
4. Adaptive excellence Bounded closed-loop control	Approved control strategy; automated decision rights; exception escalation; continued process verification	Quality-adjusted throughput; release time; energy per good unit	Can the site sustain advanced control through supplier or workforce disruption?

A site advances only where the preceding stage has produced stable, auditable evidence.

8. Technical ownership as a measurable outcome

Localization policy is expressed in market value, but market value can be captured by a plant that remains externally dependent for every consequential engineering decision. A highly automated facility whose troubleshooting, model updates, configuration access, critical spares and validation expertise are controlled abroad contributes to the localization statistic while adding little to supply resilience — the outcome the policy exists to secure.

This paper therefore proposes local technical ownership as a measurable strategic indicator: the proportion of critical automation, validation, reliability and model-governance tasks executable by qualified in-country personnel within an agreed recovery time. Candidate measures include the share of critical faults resolved without overseas escalation; the share of validated system changes executed locally; in-country availability of critical spares; median vendor-response dependency time; and the share of deployed models with locally documented retraining, rollback and retirement procedures.

None of these is a regulatory requirement. Each converts a technology-transfer commitment into auditable evidence, and each is directly relevant to device-assembly localization of the kind described in Section 3.2, where line reliability and rapid fault recovery determine whether nameplate capacity becomes delivered supply.

9. Implementation sequence

A manufacturer should begin with a measurement cycle rather than a procurement list. Build the line-level loss tree first, quantifying planned time, downtime, speed loss, rejects, changeover and review waiting, and separating compliance-mandated downtime from remediable downtime. Establish a data-integrity baseline next — record errors, missing timestamps, master-data mismatches, audit-trail exceptions — because analytics built on unreliable source data will produce confident and wrong conclusions. Only then select three to five use cases, each carrying a baseline KPI, an expected mechanism, a GMP risk assessment, a named owner and an economic hypothesis.

Pilot with pre- and post-measurement over a period long enough to separate normal variation from genuine change, using identical KPI definitions on both sides. Where sample sizes permit, control charts, confidence intervals or interrupted time-series methods should replace comparison of single before-and-after averages. Validate operational integration before scaling: if alerts do not change controlled decisions, the system has not been implemented, only installed. Scale only where the gain persists and the governance burden remains manageable.

10. Evidence quality and the propagation of unverified figures

A methodological finding emerged during preparation that bears directly on how automation business cases should be appraised. Several OEE values in wide circulation in the Pharma 4.0 literature were traced to their cited primary publications and could not be located in the published data. In the most consequential instance, a set of component values attributed to a named pharmaceutical case study — availability of 78.1 per cent, performance of 40.0 per cent, quality of 99.4 per cent and OEE of 31.7 per cent — does not correspond to any month in that study's published twenty-two-month series, whose observed ranges are 42.7–72.9, 21.3–41.4, 93.8–98.9 and 13.2–29.5 per cent respectively. No month reaches the quoted availability, quality or OEE figures.

This matters beyond bibliographic accuracy for two reasons. First, the substituted figures invert the diagnostic conclusion. Values of 78.1 per cent availability and 31.7 per cent OEE describe a plant with moderate reliability and a recoverable gap; the published values of 61.0 per cent mean availability and 16.5 per cent mean OEE describe a plant losing the majority of its capacity, where the intervention priority is entirely different. A capital plan built on the former would target the wrong loss. Second, derived quantities inherit the defect silently.

Improvement percentages, capacity multipliers and payback estimates computed from unverified inputs carry an appearance of rigour that their provenance does not support, and they are rarely re-examined once they enter a strategy document.

The practical safeguard is procedural rather than technical. Any figure entering an investment appraisal should be traceable to a primary publication, reported with its measurement basis, and — where the source publishes a data series — recomputed from that series rather than quoted from an intermediary. Where a paper reports its own summary statistics, recomputation should reproduce them; failure to do so indicates either an incomplete extraction or an altered figure. This check is inexpensive and, on the evidence of this review, not reliably performed.

11. Limitations

This is a secondary-data study. The Saudi market and localization figures are strategy projections and policy targets, not observed outcomes. The OEE evidence derives from pharmaceutical plants outside Saudi Arabia and outside sterile drug-delivery manufacturing; it is appropriate for mechanism analysis and loss-structure diagnosis, and inappropriate as an estimate of Saudi plant performance. The published OEE series analysed here reports monthly aggregates without disclosed definitions of planned production time or ideal cycle rate, which limits cross-site comparability. Scenario calculations hold market value and operating conditions constant for illustration. Finally, much of the digital-manufacturing literature reports feasibility rather than standardized plant-level economic outcomes, which precludes quantitative meta-analysis and is itself a finding.

The priority empirical study is a multi-site Saudi design collecting monthly line-level data before and after defined interventions, with product-mix and planned-maintenance controls and, where comparator lines exist, a difference-in-differences specification.

12. Conclusion

A credible automation strategy for Saudi drug-delivery manufacturing begins by establishing which numbers are load-bearing and whether they survive inspection. On the national side, the market projection is sound but the localization baseline is not a single figure: measured on registered products it is 22.55 per cent, and estimates of consumption share range from 20 to 30 per cent, placing the incremental value implied by the 40 per cent target between roughly SAR 4.4 and 7.7 billion. More importantly, the import profile shows the gap to be

compositional. Solutions and injections account for 27.59 per cent of imported products while aseptic container formats represent under 8 per cent of domestic packaging output, so localization demands capability in sterile liquid, parenteral and device-based delivery rather than additional solid-oral capacity.

On the plant side, the published evidence is consistent and pointed. Mean quality of 96.39 per cent coexisting with mean OEE of 16.5 per cent, and an independent report of 23 per cent OEE in a dry-suspension section, show that conformance metrics can remain excellent while the majority of productive capacity is lost to speed and downtime. The correct response is not automation as such but automation bound to the dominant loss: predictive maintenance against downtime, PAT against detection latency, MES against review delay, vision against inspection consistency, digital twins against bounded decisions, and continuous processing where portfolio economics justify it.

The framework proposed here is therefore evidence-gated rather than technology-led. Every stage requires a quantified baseline, a target KPI, a GMP control and a local-capability test, which makes the value proposition falsifiable: a technology succeeds only when the relevant manufacturing KPI improves durably without weakening the validated state of control. On that standard, effective-capacity recovery on qualified assets is the most immediately available contribution that Saudi manufacturers can make to the Kingdom's localization objective.

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The market projection (SAR 28 billion in 2020 rising to SAR 44.1 billion by 2030) and the 40-per-cent market-value localization target are consistently attributed across independent reports to the National Industrial Strategy and the National Industrial Development and Logistics Program. The primary NIDLP publication was not obtained during this review, and the author should cite it directly, with document title, issuing body, year and page, before submission. The Sanofi – Sudair Pharma Company – NUPCO insulin-pen localization agreement is reported through corporate and press announcements made at the Global Health Exhibition, Riyadh, October 2024, and should be cited as a company announcement rather than as peer-reviewed evidence.

Appendix A. Data provenance and interpretation rules

Data point	Source type	How used	Caution
SAR 28 bn (2020) and SAR 44.1 bn (2030)	National industrial strategy	Market scale and growth arithmetic	2030 is a strategy projection, not an observed outcome

Data point	Source type	How used	Caution
40% localization target	NIDLP policy objective	Scenario calculation	Expressed in market value, not physical volume
22.55% locally manufactured	Peer-reviewed census of SFDA-registered products	Lower baseline of the localization range	Counts registered items, not units dispensed or value
≈30% locally manufactured; 20–25% of consumption	Peer-reviewed Saudi review	Upper baselines of the localization range	Different denominators; not interchangeable with the above
Dosage-form and packaging distributions	Peer-reviewed census of SFDA-registered products	Diagnosis of the drug-delivery capability gap	Composition by item count, not by volume or value
OEE 23% (dry-suspension section)	Peer-reviewed plant case study	Operational baseline for capacity sensitivity	Not a Saudi plant; single section of one facility
Monthly OEE series (22 months)	Peer-reviewed plant case study	Loss decomposition; recomputed descriptive statistics	Not a Saudi plant; planned-time and ideal-rate definitions undisclosed
85% world-class OEE	Nakajima (1988)	External reference threshold	Derived target from discrete manufacturing; requires GMP qualification
Capacity multipliers (1.30–2.61×)	Author calculation	Sensitivity analysis	Assumes planned time, ideal rate and product mix held constant

All values in this paper are traceable to the numbered references. No figure has been estimated, interpolated or carried forward from secondary citation.