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Operational Excellence in Saudi Pharmaceutical Manufacturing: Capacity Utilization, Bottleneck Reduction, and Production Performance

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Abstract- ***Saudi Arabia is expanding local pharmaceutical manufacturing as part of Vision 2030, the National Industrial Strategy, health-sector transformation, and biotechnology development. As installed capacity grows, the strategic question shifts from whether factories exist to whether regulated manufacturing assets can convert demand into reliable, high-quality output at competitive cost. This review examines operational excellence in Saudi pharmaceutical manufacturing through three connected lenses: capacity utilization, bottleneck reduction, and production performance. An integrative review of recent pharmaceutical operations, Lean Six Sigma, overall equipment effectiveness (OEE), total productive maintenance, production planning, capacity-management, supply-chain, and Pharma 4.0 literature is combined with Saudi policy and regulatory sources. The synthesis shows that pharmaceutical productivity cannot be represented by equipment utilization alone because validated process limits, cleaning and changeovers, material availability, quality-control release, maintenance, workforce capability, deviations, and technology-transfer activities all consume effective capacity. The paper proposes a six-stage operational excellence framework that begins with value-stream and capacity baselining, identifies the system constraint, removes dominant losses through focused improvement, synchronizes planning with finite capacity, integrates quality and reliability into performance control, and then uses digital technologies to sustain gains. A balanced KPI architecture is developed around OEE, schedule adherence, right-first-time performance, batch-release lead time, changeover efficiency, capacity utilization, on-time-in-full delivery, and deviation closure. The framework is translated into a phased 2026–2030 roadmap for Saudi manufacturers. The paper argues that operational excellence should be treated as industrial capability infrastructure: it raises usable capacity without unnecessary capital, strengthens medicine availability, improves the economics of localization, develops local technical skills, and creates a more resilient platform for future biologics and advanced manufacturing.***

Keywords: ***Saudi Vision 2030; pharmaceutical manufacturing; operational excellence; capacity utilization; bottleneck management; overall equipment effectiveness; Lean Six Sigma; production performance; Pharma 4.0; Saudi Arabia***

Highlights

- Reframes pharmaceutical operational excellence around usable capacity and end-to-end flow rather than equipment utilization alone.
- Integrates OEE, bottleneck management, Lean Six Sigma, finite-capacity planning, quality release, maintenance, and digital performance control.
- Proposes a balanced KPI architecture suitable for regulated multiproduct pharmaceutical plants.
- Provides a 2026–2030 implementation roadmap aligned with Saudi industrial localization and health-security objectives.
- Uses a model-based sensitivity illustration to show how bottleneck availability translates into effective capacity when performance and quality are held constant.

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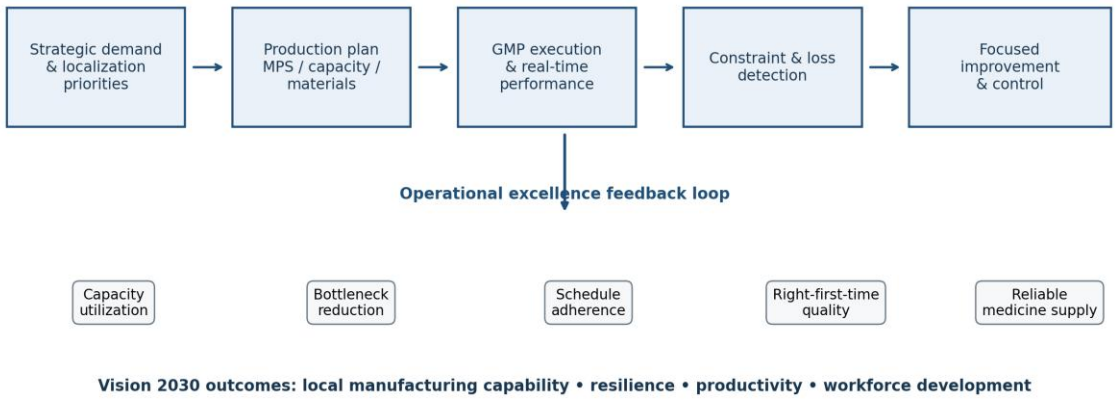
Figure 1. Graphical abstract: integrated operational excellence feedback loop for Saudi pharmaceutical manufacturing (author synthesis).



I. INTRODUCTION

Saudi Arabia's pharmaceutical manufacturing agenda is moving from market development toward deeper industrial capability. Vision 2030, the National Industrial Strategy, the National Industrial Development and Logistics Program (NIDLP), and the Health Sector Transformation Program all reinforce the importance of local production, supply-chain resilience, private-sector growth, and higher-value industrial activity. The National Biotechnology Strategy further extends this direction toward vaccines, biologics, biosimilars, genomics, and advanced biomanufacturing. Within this policy environment, the performance of local factories is not a narrow plant-management concern. It is part of the country's ability to convert investment, technology transfer, and regulatory approvals into dependable medicine supply and sustainable industrial value creation (Saudi Vision 2030, 2025a, 2025b; SFDA, 2023).

Saudi pharmaceutical localization research has mainly emphasized market structure, investment, local manufacturing share, drug security, and technology capability. Tawfik et al. (2022) argue that localization can strengthen medicine security, while Alshehri et al. (2023) identify continuing opportunities to expand domestic production and technological depth. Halwani et al. (2023) similarly highlight the need to move toward higher-value pharmaceutical technologies. These perspectives explain why local manufacturing matters, but they leave a practical operations question: how can a Saudi plant create more reliable output from existing and future assets while maintaining Good Manufacturing Practice (GMP), validated process control, and regulatory compliance?

Operational excellence provides a useful lens for answering that question. In manufacturing, operational excellence is often associated with Lean, Six Sigma, total productive maintenance (TPM), overall equipment effectiveness (OEE), standard work, visual management, and continuous improvement. In pharmaceuticals, however, the concept must be interpreted through a regulated operating model. A tablet press cannot be maximized without considering upstream granulation, downstream coating and packaging, cleaning validation, campaign rules, laboratory release, deviations, maintenance, data integrity, and material status. A filling line may appear underutilized while the actual system constraint sits in sterilization, microbiology, inspection, warehouse staging, or quality review. Therefore, a pharmaceutical plant can have unused nominal hours and still be capacity constrained in practice.

Recent pharmaceutical studies support this logic. OEE analyses show that availability, performance, and quality losses can materially reduce productive output even when equipment exists (Chikwendu et al., 2020; Zubair et al., 2021). Lean Six Sigma case research demonstrates that structured problem solving can reduce waste and process variability in regulated environments (Byrne et al., 2021; Silva et al., 2023). TPM-based work in an active pharmaceutical ingredient plant links reliability improvement to sustained operational performance (Shannon et al., 2023). At the same time, integrated capacity and production-planning models show that production decisions and investment decisions should be connected under uncertainty (Lindahl et al., 2023, 2024).

The purpose of this paper is to synthesize these streams for the Saudi pharmaceutical context. It addresses the research question: how can Saudi pharmaceutical manufacturers improve usable capacity and production performance by systematically identifying and reducing operational bottlenecks? Four objectives guide the review. First, it clarifies the meaning of capacity utilization and OEE in regulated multiproduct manufacturing. Second, it develops an end-to-end taxonomy of bottlenecks beyond equipment. Third, it integrates Lean Six Sigma, reliability, planning, quality, and digital tools into one operational excellence framework. Fourth, it translates the framework into a KPI system and phased roadmap aligned with Vision 2030. The paper is an integrative review and conceptual synthesis; it does not claim plant-level empirical results.

II. SAUDI PHARMACEUTICAL MANUFACTURING AND THE PERFORMANCE IMPERATIVE

Saudi industrial policy increasingly links localization with resilience and competitiveness rather than simple domestic assembly. The National Industrial Strategy emphasizes expansion of local production, stronger supply chains, technology adoption, and higher-value exports. NIDLP positions industry and logistics as engines of economic diversification, while SFDA initiatives explicitly support local pharmaceutical manufacturing, product availability, regulatory clarity, biological products, genetics, and advanced therapy medicinal products (Saudi Vision 2030, 2025b; SFDA, n.d.-a). This means that plant performance affects more than corporate profitability: persistent downtime, long release cycles, unstable schedules, or low right-first-time rates can weaken the national value expected from localization investments.

A localized product has to be routinely manufactured, tested, released, and replenished. Registration alone does not guarantee this operating capability. WHO's technology-transfer guidance emphasizes process knowledge, defined responsibilities, documentation, risk management, analytical transfer, equipment suitability, training, and lifecycle control (WHO, 2022). In practical terms, each transfer introduces temporary load on development, production, engineering, quality control, quality assurance, warehousing, and planning. Saudi manufacturers that are simultaneously scaling existing portfolios and absorbing new technology therefore need a performance system capable of protecting commercial supply while increasing technical complexity.

The local operating environment also encourages a broader definition of resilience. Drug shortages can originate from imported materials, supplier failure, transport disruption, quality defects, equipment failure, or slow recovery from unexpected demand. Tucker and Daskin (2022) show that pharmaceutical supply reliability depends on network structure and manufacturing robustness, while Badejo and Ierapetritou (2024) demonstrate the value of disruption-aware planning. Alzhrani et al. (2025), studying sterile injectable shortages in Saudi Arabia, reinforce the practical importance of availability risk. Operational excellence cannot eliminate external disruptions, but it can reduce internal amplification by shortening recovery time, improving schedule stability, and releasing latent capacity.

For this reason, Saudi pharmaceutical plants should distinguish three capacity concepts. Nominal capacity is the theoretical output implied by equipment ratings and available calendar time. Demonstrated capacity is

the sustained output shown under validated operating conditions with the real product mix. Effective capacity is what remains after planned maintenance, cleaning, campaign changeovers, calibration, material constraints, staffing, quality losses, and release processes are considered. Strategic investment should be based on effective and demonstrated capacity, not nameplate capacity. Without this distinction, local manufacturing programs can overestimate readiness or underestimate the improvement potential already embedded in existing assets.

The performance imperative is therefore dual. Plants must increase throughput and responsiveness, but they must do so without weakening GMP, data integrity, process validation, contamination control, or patient protection. This is why operational excellence in pharmaceuticals differs from a simple high-speed manufacturing strategy. The desired state is not maximum machine utilization; it is stable, predictable, compliant flow that converts demand into released product with minimal avoidable loss.

III. REVIEW APPROACH AND ANALYTICAL FRAME

This study uses an integrative review design suitable for combining operations-management research, pharmaceutical manufacturing studies, and Saudi policy sources. The literature base emphasizes work published from 2020 to 2025 on OEE, Lean Six Sigma, TPM and reliability, bottleneck analysis, production and capacity planning, Pharma 4.0, digital twins, supply-chain resilience, and Saudi pharmaceutical localization. Peer-reviewed studies were complemented by official Saudi Vision 2030, SFDA, WHO, ICH, and FDA sources because the topic spans operational methods and regulated-policy context. The review is not presented as a PRISMA systematic review and does not claim exhaustive database coverage.

The analysis was organized around five questions. What losses reduce usable capacity? Where can bottlenecks arise in a pharmaceutical value stream? Which continuous-improvement methods are supported by recent evidence? How should performance be measured to avoid local optimization? And how can digital technologies support, rather than substitute for, process discipline? Evidence was coded conceptually into six operational domains: equipment effectiveness, flow and bottlenecks, planning and scheduling, quality and release, maintenance and reliability, and digital decision support.

A key analytical assumption is that the unit of improvement should be the value stream rather than an isolated machine. OEE remains important, but OEE is interpreted as a diagnostic measure within a larger system. High OEE on a non-bottleneck asset can create excess work in process without increasing finished-goods output. Conversely, modest utilization on a shared resource can be appropriate if it protects flexibility or quality. The review therefore combines OEE with schedule adherence, throughput, right-first-time quality, release lead time, changeover efficiency, service level, and deviation performance.

The conceptual framework was then developed by linking recurring themes across the evidence: establish a trustworthy baseline; identify the constraint; remove the dominant source of loss; synchronize planning to real capacity; stabilize quality and reliability; and digitalize control after the process is understood. This sequence reflects a central principle found across Lean, Six Sigma, TPM, bottleneck management, and Pharma 4.0 literature: sustainable improvement depends on disciplined problem definition and process control before advanced technology is layered onto the system (Byrne et al., 2021; Shannon et al., 2023; McDermott et al., 2024).

Table 1. Selected evidence informing the operational excellence framework

Study	Focus	Key evidence	Operational implication
Chikwendu et al. (2020)	Pharmaceutical OEE	OEE factor optimization identifies availability, performance, and quality losses.	Use OEE on constrained assets as a diagnostic, not as a stand-alone site objective.

Zubair et al. (2021)	Pharmaceutical productivity	OEE can quantify manufacturing productivity and expose equipment loss patterns.	Translate lost bottleneck hours into capacity and service impact.
Byrne et al. (2021)	Lean Six Sigma case	DMAIC and Lean tools can improve regulated manufacturing processes.	Use cross-functional, data-based root-cause elimination.
McDermott et al. (2022)	Continuous improvement	Leadership, culture, skills, and resources influence CI adoption in pharma.	Build governance and workforce capability alongside technical tools.
Shannon et al. (2023)	TPM / reliability	Reliability-centered improvement supports sustainable performance in an API plant.	Protect bottleneck uptime through planned maintenance and recurrence elimination.
Lindahl et al. (2023, 2024)	Capacity planning	Production and capacity decisions should be integrated under uncertainty.	Separate recoverable loss from true structural capacity gaps.
McDermott et al. (2024)	Pharma 4.0	Digitalization can support operational excellence and compliance when readiness exists.	Stabilize and standardize before scaling advanced digital tools.

IV. EVIDENCE SYNTHESIS: CAPACITY, BOTTLENECKS, AND PRODUCTION PERFORMANCE

OEE is one of the most widely used manufacturing performance indicators because it separates equipment losses into availability, performance, and quality components. Corrales et al. (2020) show that OEE has evolved into a broad improvement metric across manufacturing, while pharmaceutical studies demonstrate its practical value in identifying loss patterns. Chikwendu et al. (2020) examined OEE factors in a pharmaceutical company and showed that equipment effectiveness can be improved by targeting the dominant components of loss. Zubair et al. (2021) similarly applied OEE to pharmaceutical productivity analysis. These studies support OEE as a structured starting point, particularly for highly utilized or strategically constrained equipment.

Yet OEE can be misleading when interpreted as the single objective. Availability may be reduced by planned sanitation or changeover activities that are necessary for GMP. Performance may be influenced by validated speed ranges, product-specific dwell times, environmental controls, or inspection requirements. Quality losses may involve both scrap and time consumed by investigation, rework, or repeat testing. Furthermore, OEE does not directly capture material shortages, laboratory queues, batch-record review, or schedule volatility. Therefore, OEE should answer the question 'how effectively did this resource perform when it was intended to run?' rather than 'is the entire factory operating optimally?'.

Bottleneck reduction requires a system view. A bottleneck is the resource or decision point that limits flow over a defined planning horizon. In multiproduct pharmaceutical manufacturing, the bottleneck can migrate. During one period, compression may constrain output; after a campaign change, coating may become limiting; during another week, packaging components or quality-control testing may determine release. Tang et al. (2024), reviewing manufacturing bottleneck research, emphasize the need to identify dynamic constraints rather than assume a fixed bottleneck. This principle is particularly relevant in plants with multiple dosage forms, shared utilities, and frequent product changes.
Changeovers are a major source of hidden capacity consumption. Pharmaceutical changeovers can include line clearance, dismantling, cleaning, verification, sampling, reassembly, start-up checks, and documentation. Unlike some discrete-manufacturing setups, these steps cannot be indiscriminately compressed because validated cleaning and contamination-control requirements must be preserved. The improvement opportunity is therefore to distinguish mandatory control from avoidable waiting, motion, searching, sequencing,

and coordination delay. Lean tools such as single-minute exchange of dies (SMED) logic, standardized work, visual management, and parallel preparation can reduce non-value-adding time while keeping validated steps intact.

Lean Six Sigma provides a structured way to tackle this distinction. Byrne et al. (2021) demonstrate application of Lean Six Sigma methodology within a pharmaceutical manufacturing facility, using data-driven problem solving to identify root causes and improve process performance. Silva et al. (2023) report that pharmaceutical Lean Six Sigma programs commonly use standardized work, OEE, 5S, SMED, Pareto analysis, Ishikawa diagrams, five-whys analysis, and related tools. McDermott et al. (2022) show that continuous-improvement programs in pharmaceutical settings face both enabling factors and barriers, including leadership, culture, skills, resources, and regulatory perceptions. Together, the studies suggest that technical tools work best when embedded in governance and workforce capability.

Maintenance is another direct contributor to capacity utilization. Shannon et al. (2023) developed a TPM and reliability framework for an active pharmaceutical ingredient plant using design for Lean Six Sigma. The study highlights the relationship among equipment reliability, maintenance strategy, root-cause analysis, and performance stability. For Saudi plants pursuing higher utilization, reliability is critical because raising planned load on unstable assets can increase breakdowns, overtime, deviations, and schedule failure. Operational excellence should therefore increase load only as preventive maintenance, spare-parts readiness, calibration, utilities, and technical support become capable of sustaining it.

Production planning determines whether local improvement translates into business performance. Lindahl et al. (2023) integrate production and capacity planning in pharmaceutical supply chains, connecting short- and medium-term production decisions with longer-term capacity choices. Their later work addresses capacity expansion under uncertainty (Lindahl et al., 2024). These models reinforce an important operational principle: a plant should first understand whether service failure is caused by insufficient structural capacity or by poor use of existing capacity. Finite-capacity planning can expose overloaded resources, unrealistic due dates, unstable campaign patterns, and hidden queues that infinite-capacity planning may mask.

Schedule adherence is therefore an essential companion to OEE. A line can show strong OEE while producing the wrong product, starting late, or disrupting downstream packaging. Master production scheduling should create a feasible sequence that accounts for product families, allergens or sensitizing compounds where relevant, cleaning matrices, labor, tooling, quality resources, and material availability. Once the schedule is frozen within an agreed window, changes should be governed because excessive rescheduling creates nervousness throughout procurement, warehousing, quality, and operations. Chen et al. (2025) demonstrate the continuing development of pharmaceutical production-planning models under uncertainty, supporting greater use of analytical decision methods where data maturity permits.

Quality capacity is frequently underestimated. Batch-release lead time can become a bottleneck even when manufacturing equipment has available hours. Samples may queue for chemical or microbiological testing; deviations may delay disposition; batch records may require correction; stability chambers may be constrained; and quality reviewers may face peaks caused by poorly leveled production. Right-first-time performance is thus a capacity measure as well as a quality measure. Every avoidable deviation consumes investigation time, management attention, laboratory time, and sometimes replacement manufacturing. In a localization strategy, improving right-first-time release can expand effective supply without adding a new production line.

Digital technologies can improve visibility and decision quality when foundational processes are stable. Arden et al. (2021) describe Industry 4.0 technologies that can enable smart pharmaceutical factories, including interconnected systems, analytics, automation, and advanced control. Chen et al. (2020) review digital twins in pharmaceutical and

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biopharmaceutical manufacturing, illustrating the potential to connect physical processes with virtual representations. Debnath et al. (2023) identify critical success factors for Industry 4.0 adoption in pharmaceutical supply chains, while McDermott et al. (2024) show in a pharma manufacturing case that digitalization can support operational excellence and regulatory compliance. Importantly, the latter study emphasizes that organizations should establish Lean discipline before attempting to digitalize waste.

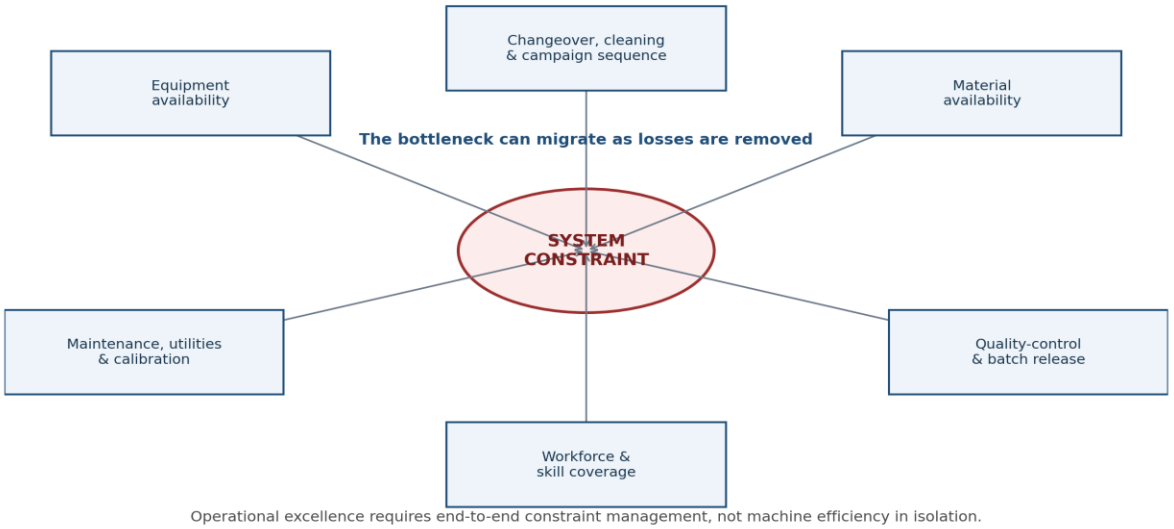

Figure 2. End-to-end pharmaceutical bottleneck architecture: the system constraint can migrate among equipment, changeovers, materials, quality release, maintenance/utilities, and workforce (author synthesis).

Table 2. Operational loss and bottleneck taxonomy for regulated pharmaceutical manufacturing

Domain	Typical loss / constraint	Diagnostic measures	Improvement levers
Equipment	Breakdown, micro-stops, speed loss, repeated faults	OEE loss tree; downtime Pareto; MTBF	TPM, RCA, spare-parts readiness, condition monitoring
Changeover / cleaning	Long campaign transitions, waiting, searching, rework	Changeover duration; internal/external task map	Validated SMED logic, standard work, pre-staging, sequencing
Materials	API/excipient/packaging unavailability, status delays	Material shortage hours; supplier OTIF; risk segmentation	MRP parameter review, dual sourcing, local sourcing, safety stock
Planning	Unfeasible schedules, frequent resequencing, overload	Schedule adherence; frozen-window changes; load/capacity	Finite-capacity planning, time fences, campaign leveling
Quality / release	Testing queues, deviations, record correction, retest	RFT; release lead time; deviation aging	Right-first-time review, lab capacity planning, RCA, visual queue control
Workforce	Skill gaps, poor shift coverage, training delays	Constraint skill matrix; overtime; training completion	Cross-training, standard work, tiered problem solving

Utilities / facilities	HVAC, compressed air, water, environmental or room constraints	Utility downtime; room utilization; alarm trends	Reliability planning, redundancy based on criticality, preventive maintenance

V. AN INTEGRATED OPERATIONAL EXCELLENCE FRAMEWORK FOR SAUDI PHARMACEUTICAL PLANTS

Stage 1 is to establish a trustworthy operational baseline. Plants should map the end-to-end flow from demand signal to released batch and distinguish value-adding processing time from queue, waiting, movement, changeover, testing, review, and downtime. Capacity calculations should use actual routings, validated batch sizes, demonstrated rates, planned sanitation, maintenance, shift calendars, and historical loss distributions. Product families should be segmented because the capacity consumed by one million tablets can vary significantly by formulation, coating requirement, compression speed, packaging configuration, yield, or cleaning class. A baseline that ignores product mix will misstate both utilization and bottlenecks.

Stage 2 is to identify the system constraint. Constraint identification should be repeated by horizon because the limiting resource can shift between daily execution, monthly planning, and strategic expansion. Useful evidence includes persistent queues, high load-to-capacity ratios, overtime, late starts, backlog, repeated schedule displacement, long testing queues, and sensitivity of finished-goods output to small changes in a resource's availability. A practical rule is that improvement on the constraint should change total output or service performance; improvement on a non-constraint should mainly create local spare capacity.

Stage 3 is focused loss elimination. Once the constraint is known, the plant should analyze its Pareto of lost time and performance. If unplanned breakdowns dominate, TPM and reliability engineering take priority. If cleaning and changeovers dominate, standardized preparation, sequencing, visual management, and validated SMED-style improvements are appropriate. If speed losses dominate, process capability, equipment condition, operating windows, and operator methods should be studied. If material shortages dominate, the solution belongs in procurement, inventory policy, supplier qualification, or MRP parameters rather than on the shop floor. If deviations dominate, quality risk management and root-cause elimination are required.
Stage 4 is to synchronize planning with finite capacity. The master production schedule should be built from demonstrated capacity and explicit constraints, not unconstrained demand. Critical resources should have time-phased load profiles, including reservations for preventive maintenance, calibration, technology-transfer batches, validation, training, and planned shutdowns. Campaign sequencing should minimize avoidable changeovers while preserving service priorities and expiry considerations. Planners should use agreed time fences: near-term schedules become increasingly stable, while changes outside the frozen zone remain flexible.

The planning system should also connect materials to the bottleneck. A high-value constrained line should not lose hours because an imported excipient, printed packaging component, tooling set, or test reagent is unavailable. Materials should therefore be segmented by supply risk and impact on the constraint. Critical items may justify earlier call-off, supplier redundancy, local sourcing, or strategic safety stock, while low-risk items can remain leaner. This approach connects operational excellence with localization because local supplier development can be prioritized where imported dependency threatens effective capacity.

Stage 5 integrates quality and reliability into performance control. Quality should not be treated as a downstream gate after manufacturing; it is part of flow design. Batch documentation should be reviewed for recurring corrections, laboratories should be capacity planned, deviation aging should be monitored, and first-pass release performance should be made visible. Similarly, maintenance plans

should be synchronized with production campaigns and constraint criticality. A short planned intervention on the bottleneck can be economically superior to a longer unplanned failure during peak demand.

Stage 6 is digital performance control and learning. Once definitions, routings, and workflows are stable, ERP, manufacturing execution systems, laboratory information systems, computerized maintenance systems, historians, and analytics platforms can create near-real-time visibility. Dashboards should show schedule adherence, OEE of constrained assets, reasons for lost time, quality status, release queues, and material risk in one operational picture. Advanced analytics can then support predictive maintenance, dynamic scheduling, anomaly detection, and digital twins. The purpose of technology is to shorten the feedback cycle from deviation to learning, not to replace process ownership.

VI. KPI ARCHITECTURE FOR PRODUCTION PERFORMANCE

A credible operational excellence system needs a balanced KPI architecture because no single measure captures pharmaceutical performance. The architecture should answer four questions: Are we producing the required mix on time? Are constrained resources used effectively? Are batches manufactured and released right first time? And are improvements sustainable without excessive inventory, overtime, or compliance risk? The proposed KPI suite therefore combines service, planning, equipment, flow, quality, maintenance, and people measures.

Capacity utilization should be calculated against demonstrated available capacity rather than theoretical nameplate hours. For a constrained resource, utilization can be expressed as actual productive load divided by demonstrated available time after planned exclusions. OEE should retain its conventional availability × performance × quality logic but should be reported with the loss tree behind the number. A single OEE percentage without the loss categories can hide whether the main problem is breakdown, minor stops, speed, yield, or quality rejection. The KPI should also be limited to resources where it supports decisions rather than being indiscriminately imposed on every asset.

Schedule adherence measures execution discipline. It can be defined at batch start, batch completion, or quantity level, but the definition must be stable. A useful companion is schedule change rate inside the frozen window, which reveals planning nervousness. On-time-in-full (OTIF) or service level then connects plant execution to customer and patient-facing supply. Together, schedule adherence and service level distinguish a factory that is busy from a factory that is meeting the right demand.

Right-first-time (RFT) performance should include both manufacturing and documentation. A batch that physically meets specification but requires repeated record correction or extended investigation still consumes hidden capacity. Deviation rate, deviation recurrence, and deviation-closure lead time should therefore be linked to RFT. Batch-release lead time should be tracked separately because long queues in QA or QC can delay market availability even when production is complete. For critical products, the distribution of release time is often more informative than an average because extreme delays create service risk.

Changeover efficiency should measure both duration and schedule impact. The plant can compare actual changeover time with a validated standard and analyze internal versus external tasks. Maintenance performance should include planned maintenance compliance, mean time between failures where appropriate, repeat failure rate, and emergency work. Workforce metrics can include cross-skill coverage on the constraint, problem-solving participation, completion of critical training, and improvement sustainability after 90 or 180 days. These measures turn human-capital development into an operational capability rather than a training-count exercise.

The KPI system should be tiered. Shift teams need actionable measures such as constraint status, downtime reason, quality status, and plan-versus-actual. Department leaders need weekly trends in OEE loss categories, schedule adherence, deviations,

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maintenance compliance, and release queues. Site leadership needs monthly capacity risk, service performance, improvement benefits, labor productivity, capital-avoidance opportunities, and localization priorities. A tiered system prevents the common failure of presenting senior executives with dozens of shop-floor metrics while operators receive only lagging financial targets.

Table 3. Balanced KPI architecture for pharmaceutical operational excellence

Dimension	KPI	Definition / calculation	Review cadence
Service	OTIF / service level	Orders or demand fulfilled in full and on time	Weekly / monthly
Planning	Schedule adherence	Batches or quantities completed against frozen plan	Daily / weekly
Capacity	Constraint utilization	Productive load ÷ demonstrated available constraint time	Daily / weekly
Equipment	OEE	Availability × performance × quality	Shift / daily
Flow	Manufacturing lead time	Elapsed time from batch start to manufacturing completion	Batch / weekly
Quality	Right-first-time	Batches passing execution/documentation without avoidable rework	Batch / monthly
Release	Batch-release lead time	Time from manufacturing completion to disposition/release	Batch / weekly
Changeover	Changeover efficiency	Actual validated changeover time vs standard / target	Event / weekly
Maintenance	Planned maintenance compliance	Completed planned work ÷ scheduled planned work	Weekly / monthly
Improvement	Recovered constraint hours	Verified bottleneck hours released by sustained improvement	Monthly / quarterly

VII. MODEL-BASED VIEW OF CAPACITY UTILIZATION AND BOTTLENECK IMPROVEMENT

The relationship between bottleneck availability and effective capacity can be illustrated using a simple OEE-based sensitivity model. If performance and quality remain stable, a change in bottleneck availability translates directly into additional effective run time. Figure 3 holds performance at 90% and quality at 98% and varies availability from 70% to 95%. The result is not empirical plant data; it is a normalized illustration of the arithmetic that links lost bottleneck hours to effective capacity. Under these assumptions, moving availability from 70% to 85% raises the capacity index by roughly 21% relative to the 70% condition, without adding a second line.

The managerial value of this illustration lies in capital discipline. A proposed capacity expansion should be compared with an improvement scenario that recovers avoidable constraint losses. If breakdowns, waiting, or changeovers consume a substantial share of scheduled bottleneck time, reliability and process improvement may defer capital while improving service. However, the same model also shows the limit of continuous improvement. Once availability, performance, and quality are stable at high levels and demand remains above demonstrated capacity, additional equipment, shifts, parallelization, or technology change becomes justified. Operational excellence is therefore not anti-investment; it improves the evidence base for investment timing and sizing.

In pharmaceuticals, the model should be expanded beyond OEE before decisions are made. Quality-control throughput, material readiness, labor,

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cleanroom occupancy, utilities, batch-release resources, and validated campaign rules can all create effective-capacity constraints. Scenario models should therefore calculate end-to-end throughput rather than only machine time. Lindahl et al. (2023, 2024) provide a stronger mathematical foundation for integrated capacity and production decisions, while digital-twin and advanced-scheduling approaches can further improve scenario fidelity as plant data maturity grows (Chen et al., 2020).

The most useful improvement business case is consequently a constraint-based capacity bridge. It starts with nominal capacity, subtracts mandatory planned losses, separates avoidable losses by cause, estimates the recoverable portion, and then compares the remaining gap with forecast demand. This bridge helps leadership see whether the problem is structural capacity, reliability, planning, quality, or materials. It also makes improvement benefits auditable: recovered hours on a true constraint can be converted into incremental batches, reduced backlog, lower overtime, or capital avoidance.

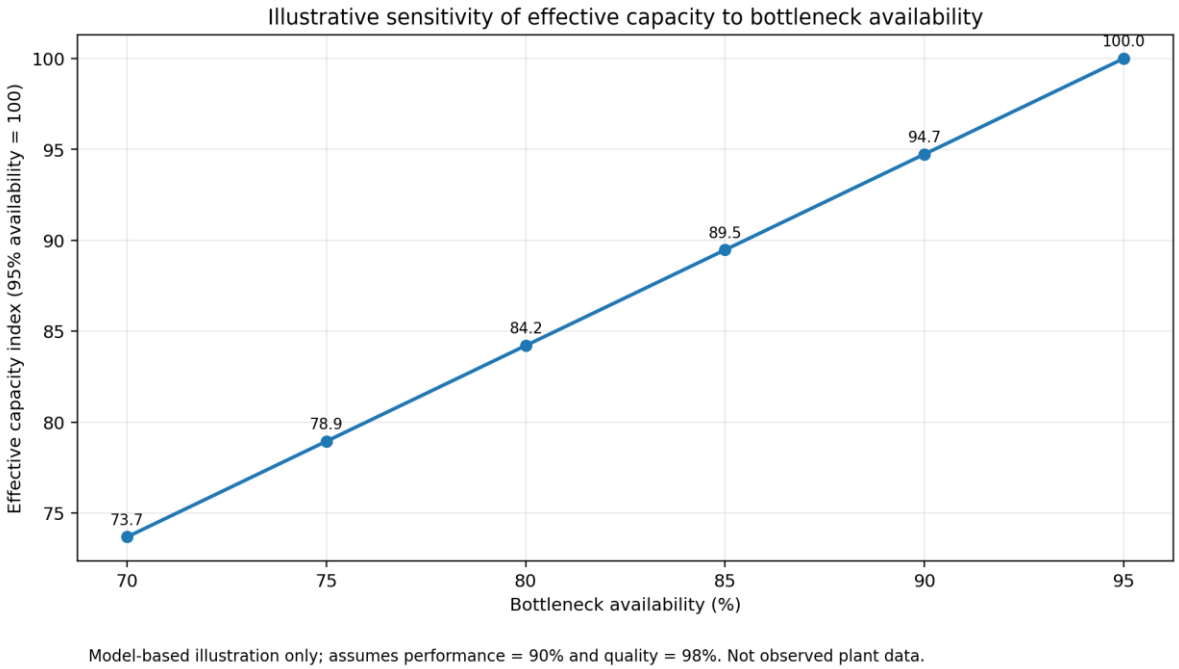

Figure 3. Illustrative sensitivity of effective capacity to bottleneck availability at fixed performance (90%) and quality (98%). The figure is model-based and does not represent observed plant data.

VIII. VISION 2030 IMPLEMENTATION ROADMAP, 2026–2030

A phased roadmap can align plant-level operational excellence with Saudi industrial objectives. Phase 1, during 2026, should focus on measurement and governance. Manufacturers should standardize OEE definitions, establish demonstrated-capacity models, validate ERP master data, map value streams, define bottleneck-identification rules, and create cross-functional tier meetings. Pilot lines should be selected based on strategic product importance, service risk, and improvement potential. The objective is a reliable performance baseline rather than immediate digital complexity.

Phase 2, during 2027, should focus on constraint removal and planning stability. Plants can deploy Lean Six Sigma on dominant losses, implement TPM on critical assets, reduce validated changeover waste, strengthen frozen-schedule governance, and introduce finite-capacity load reviews. QA and QC queues should be included in the same operational review as production because release capacity

determines market availability. Benefits should be translated into recovered hours, added batches, improved service, and reduced overtime to demonstrate economic value.

Phase 3, during 2028, should integrate technology transfer and supplier resilience. New-product transfers should carry explicit resource reservations and readiness gates. Critical imported materials should be mapped against constrained resources, and localization or dual-sourcing projects should be prioritized where supply risk can idle strategic capacity. Workforce programs should develop Saudi capability in production planning, continuous improvement, industrial engineering, reliability, automation, validation, and data analytics. This directly supports Vision 2030's human-capital and industrial-development goals.

Phase 4, during 2029, should scale digital decision support. Plants with stable data can connect ERP, manufacturing execution, maintenance, laboratory, and quality systems into integrated operational dashboards. Predictive-maintenance models should be piloted on high-criticality assets, and advanced planning and scheduling can be introduced for complex multiproduct environments. Digital twins should be used where their model fidelity can support validated process understanding, capacity scenarios, or operator learning. Digitalization should remain risk based and consistent with data-integrity and computerized-system requirements.

Phase 5, during 2030, should institutionalize network-level operational excellence. Leading manufacturers should compare sites and product families using standardized capacity and service metrics, share proven improvement methods, and connect portfolio localization decisions to demonstrated operational capability. The national ecosystem can benefit if regulators, purchasers, manufacturers, academic institutions, and suppliers use aggregated evidence to anticipate capacity gaps in strategically important medicines. The end state is a more responsive pharmaceutical manufacturing network that can absorb new products, recover from disruptions, and progress toward biologics and advanced technologies without losing execution discipline.

Table 4. Proposed 2026–2030 implementation roadmap

Year	Priority	Core actions	Expected capability outcome
2026	Baseline & governance	Standard definitions, value-stream maps, capacity model, bottleneck rules, tier meetings	Trusted data and first pilot value stream
2027	Constraint removal	Lean Six Sigma, TPM, changeover reduction, finite-capacity reviews, QA/QC queue management	Recovered hours, better schedule adherence and service
2028	Transfer & resilience integration	Capacity reservations for technology transfer; supplier-risk mapping; workforce capability	Faster NPI with less disruption; stronger local capability
2029	Digital scale-up	Integrated dashboards, APS pilots, predictive maintenance, digital-twin use cases	Shorter feedback loops and better scenario decisions
2030	Network maturity	Cross-site benchmarking, portfolio capacity governance, strategic localization prioritization	Resilient, scalable national manufacturing capability

IX. DISCUSSION

The central argument of this review is that operational excellence should be treated as infrastructure for pharmaceutical localization. Saudi Arabia can attract investment, license factories, and transfer products, but the economic and health-security value of these activities depends on repeatable operational performance. A plant that improves the utilization of its real constraint, reduces avoidable changeover and waiting, improves schedule adherence, and shortens batch release can increase medicine availability with little or no additional fixed asset. These gains strengthen the

business case for local manufacturing because fixed costs are spread over more saleable output and service becomes more dependable.

A third implication concerns workforce development. Operational excellence creates cross-functional technical roles that are valuable for localization: planners who understand finite capacity, engineers who analyze reliability, pharmacists and quality professionals who connect compliance with flow, operators who solve problems at source, and data specialists who translate manufacturing signals into decisions. This is consistent with the broader Vision 2030 emphasis on human-capital development and high-value employment. Improvement capability is therefore not simply a consulting program; it is a form of industrial knowledge localization.

The framework also provides a bridge toward Pharma 4.0. Digital technologies can create major advantages in traceability, predictive control, scheduling, and decision speed, but digital transformation is most effective when the underlying process is stable and performance definitions are trusted. A dashboard that automatically reports poor master data only accelerates confusion. Saudi manufacturers should therefore adopt a 'lean first, digital next, intelligent later' maturity logic: standardize and stabilize the process, digitize the workflow and data capture, then apply advanced analytics to high-value decisions. This sequence is consistent with evidence from pharmaceutical Industry 4.0 studies (Debnath et al., 2023; McDermott et al., 2024).

Finally, operational excellence strengthens resilience without requiring indiscriminate redundancy. Some strategically critical medicines may justify backup capacity or safety stock, but resilience also comes from short changeovers, multi-skilled teams, reliable equipment, alternative qualified suppliers, fast deviation resolution, and realistic planning. These capabilities make the system more adaptable during disruption. As Saudi Arabia moves toward more complex manufacturing such as biologics and advanced therapies, the importance of disciplined capacity and constraint management will increase because these technologies often depend on specialized facilities, cold chains, analytical capacity, and scarce technical skills.

X. RESEARCH IMPLICATIONS AND LIMITATIONS

The proposed framework creates several opportunities for empirical research in Saudi Arabia. Plant-level longitudinal studies could test how changes in OEE loss categories, schedule adherence, changeover time, maintenance reliability, right-first-time rate, and release lead time affect service level and effective capacity. Comparative research across oral-solid, liquid, semi-solid, sterile, and biologics facilities could examine whether bottleneck patterns differ by dosage form and regulatory complexity. Operations-research models could quantify the trade-off among campaign size, changeover burden, inventory, expiry risk, and service for Saudi demand profiles.

Future research could also evaluate the organizational side of operational excellence. Studies could examine leadership behavior, continuous-improvement culture, planner capability, operator participation, and cross-functional governance in Saudi pharmaceutical plants. Digital-maturity research could identify the point at which advanced planning, predictive maintenance, or digital twins deliver measurable incremental value beyond disciplined Lean and TPM systems. Supplier-resilience studies could connect local-content development with the probability of constraint starvation caused by imported materials or components.

This paper has limitations. It is an integrative review and conceptual synthesis rather than a systematic meta-analysis. It does not use proprietary Saudi plant data, and the model-based capacity sensitivity figure is illustrative rather than empirical. The Saudi pharmaceutical ecosystem is evolving rapidly, so policies, investment priorities, and technology adoption will continue to change. In addition, performance metrics can be defined differently across companies; therefore, cross-site benchmarking requires careful standardization before numerical comparisons are made. These limitations create a

clear next step: validate the framework with real plant data and multi-site case studies.

XI. CONCLUSION

Saudi Arabia's pharmaceutical manufacturing ambitions require operating systems that can convert industrial investment into reliable medicine supply. Capacity utilization, bottleneck reduction, and production performance are therefore strategic capabilities rather than only factory metrics. This review shows that usable pharmaceutical capacity is shaped by equipment effectiveness, changeovers, materials, maintenance, quality release, scheduling, workforce capability, and technology-transfer load. Improving one machine in isolation will not necessarily improve the system; the priority is to identify and elevate the constraint that governs compliant released-product flow.

The six-stage framework proposed in this paper provides a practical sequence: establish a trustworthy capacity baseline, identify the system constraint, eliminate dominant losses, synchronize planning to finite capacity, integrate quality and reliability into performance control, and then scale digital decision support. A balanced KPI architecture combining OEE, capacity utilization, schedule adherence, OTIF, right-first-time performance, release lead time, deviation performance, changeover efficiency, and maintenance reliability can prevent local optimization and keep improvement connected to service and patient availability.

For Vision 2030, the broader value is clear. Operational excellence can release latent capacity before new capital is committed, improve the economics of pharmaceutical localization, strengthen resilience, develop local technical skills, and create a stronger platform for biologics and advanced manufacturing. By 2030, the most competitive Saudi pharmaceutical plants will not be those that simply own the most equipment. They will be those that understand their constraints, learn from performance data, protect GMP while eliminating avoidable loss, and repeatedly convert demand into compliant product with speed, predictability, and resilience.

Declarations

Article type: Integrative review and conceptual framework; no new primary human or animal data were collected for this manuscript.

Ethics approval: Not applicable to the review design.
Data availability: No new empirical dataset was generated. Figure 3 is a transparent model-based illustration using stated assumptions.

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