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


## Abstract:

Saudi Arabia is pursuing pharmaceutical localization as part of a wider transformation of healthcare, industrial capability, supply-chain resilience, and the non-oil economy under Vision 2030. Yet localization is not achieved simply by constructing plants or transferring product licenses. It depends on the ability of domestic manufacturers to translate demand into executable production plans, allocate constrained resources, absorb new products, maintain regulatory compliance, and expand capacity at the right time. This review examines how production planning and capacity optimization can strengthen pharmaceutical manufacturing localization in Saudi Arabia. A structured integrative review was conducted using recent peer-reviewed literature on Saudi pharmaceutical manufacturing, production and capacity planning, pharmaceutical supply-chain resilience, operational excellence, and Pharma 4.0, together with official Saudi, WHO, ICH, and regulatory policy documents. The synthesis identifies five mutually reinforcing localization capabilities: demand-linked master production scheduling, integrated material and capacity planning, bottleneck and asset-performance management, technology-transfer readiness, and digital decision support. The paper proposes a Saudi pharmaceutical localization planning framework that connects national localization priorities with plant-level sales and operations planning, finite capacity decisions, quality systems, workforce development, and investment triggers. The analysis argues that localization performance should be measured not only by local content or the number of domestically produced products, but also by service level, schedule adherence, utilization, changeover performance, right-first-time quality, lead time, and resilience to supply disruptions. A phased implementation roadmap is proposed for 2026-2030. The review concludes that production planning and capacity optimization can function as strategic localization infrastructure, allowing Saudi manufacturers to convert installed assets, technology transfer, and policy incentives into reliable, scalable, and competitive domestic medicine supply.



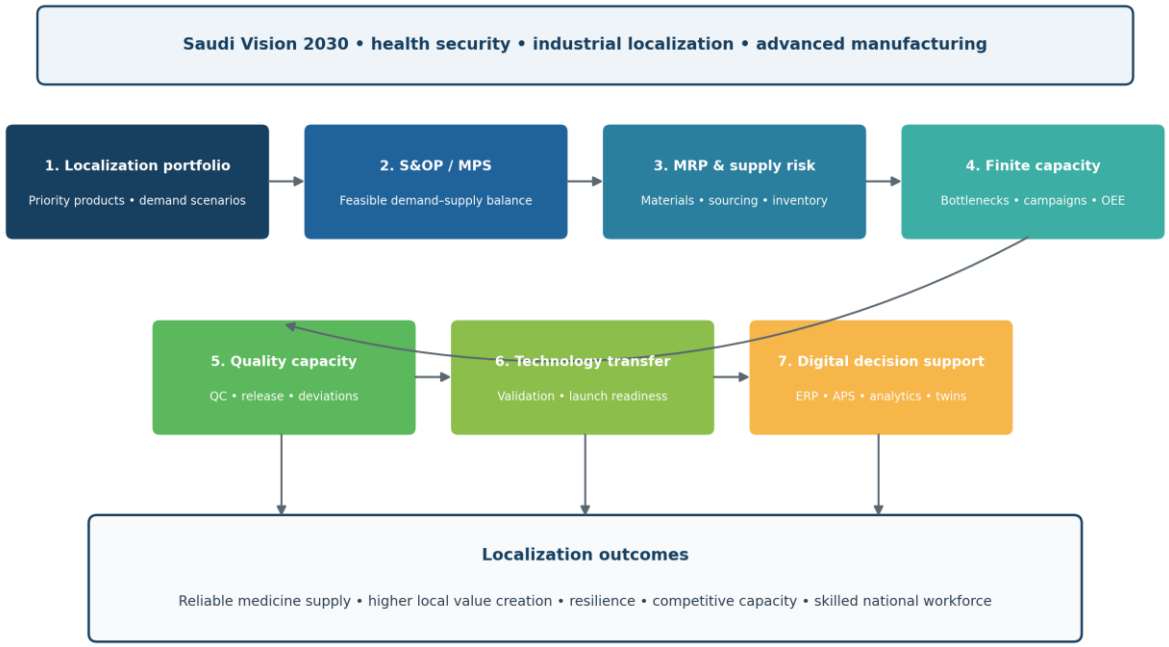
**Keywords:** Saudi Vision 2030; pharmaceutical localization; production planning; capacity optimization; pharmaceutical manufacturing; supply-chain resilience; technology transfer; Pharma 4.0; operational excellence; Saudi Arabia




# Highlights

- Positions production planning and capacity optimization as strategic infrastructure for Saudi pharmaceutical localization.

- Proposes a seven-layer framework linking localization priorities to S&OP, MPS, MRP, finite capacity, quality, technology transfer and digital support.
- Distinguishes nominal capacity from demonstrated and effective capacity in GMP-regulated multiproduct plants.
- Introduces a capability-based KPI suite covering service, planning, assets, quality, materials, technology transfer and workforce development.
- Provides a phased 2026–2030 implementation roadmap aligned with Vision 2030 industrial and health-system objectives.




***Graphical abstract / Figure 1. Integrated production-planning framework for pharmaceutical localization in Saudi Arabia (author synthesis).***

# 1. INTRODUCTION

Pharmaceutical localization has become a strategic component of Saudi Arabia's economic and health transformation. Vision 2030 seeks to diversify the national economy, develop promising manufacturing industries, strengthen supply chains, expand private-sector participation, and improve the quality and resilience of healthcare. Within this agenda, pharmaceuticals occupy a distinctive position because medicines are simultaneously industrial products, regulated health technologies, strategic goods, and essential inputs to public health. The National Industrial Development and Logistics Program (NIDLP), the Health Sector Transformation Program, the National Industrial Strategy, and newer biotechnology initiatives all reinforce the importance of building domestic manufacturing capability rather than depending excessively on imported finished products (Saudi Vision 2030, n.d.-a, n.d.-b, n.d.-c, n.d.-d; SFDA, n.d.-a). Local-content procurement instruments and investment promotion further reinforce the localization ecosystem (LCGPA, n.d.; MISA, n.d.).

The policy rationale is supported by the structure of the Saudi pharmaceutical market. Studies of the Kingdom's manufacturing base have repeatedly observed that domestic production remains

concentrated in a narrower range of products than the total national demand portfolio and that imports continue to play a large role in medicine supply. Tawfik et al. (2022) identified localization as central to national drug security and highlighted challenges involving research and development, supply-chain dependence, coordination, investment, and the limited breadth of local product portfolios. Alshehri et al. (2023) similarly found a relatively modest contribution of local manufacturers to dispensed medicines and emphasized the need to increase domestic manufacturing to support Vision 2030. Halwani et al. (2023) extended the argument to higher-value technologies such as nanomedicines and called for stronger local research, development, and manufacturing ecosystems.

The localization challenge is frequently framed in terms of investment, technology transfer, regulatory incentives, or local-content procurement. These are necessary, but they are insufficient if manufacturing operations cannot reliably convert demand into finished products. A plant can possess equipment, licenses, trained employees, and approved formulations yet still suffer low schedule adherence, excessive changeovers, long release lead times, bottlenecks, material shortages, unbalanced capacities, or poor visibility of future demand. In pharmaceutical manufacturing, such operational weaknesses are particularly consequential because production is constrained by good manufacturing practice (GMP), validated processes, campaign rules, cleaning requirements, environmental classifications, batch release procedures, shelf-life limitations, and regulatory commitments.

Production planning therefore deserves greater attention as a localization mechanism. At the strategic level, capacity planning determines what products can be localized, which technologies should be installed, how much redundancy is required, and when investments should be triggered. At the tactical level, sales and operations planning (S&OP), master production scheduling (MPS), material requirements planning (MRP), and finite capacity planning translate market demand into feasible monthly and weekly plans. At the operational level, sequencing, campaign design, changeover control, maintenance coordination, and short-interval scheduling determine whether the plan is actually executed. These layers are interdependent. Lindahl et al. (2023) show that integrating capacity and production planning can improve decisions across pharmaceutical manufacturing networks, while Lindahl et al. (2024) demonstrate the value of explicitly planning capacity expansion under uncertainty. The implication for Saudi localization is important: investment and production decisions should be designed as one system rather than as separate activities.

Capacity optimization also directly supports health security. Drug shortages are often linked to supply disruptions, manufacturing constraints, quality failures, and limited alternative sources. Tucker and Daskin (2022) show that pharmaceutical supply reliability depends on network configuration, disruption risk, and recovery capability. In Saudi Arabia, recent evidence on sterile injectable shortages indicates that poor demand forecasting and limited sourcing capabilities can contribute to availability problems and that stakeholders support stronger forecasting, inventory management, advanced technology, and local manufacturing (Alzhrani et al., 2025). Alyousef et al. (2025) similarly report the need for better coordination, transparency, and inventory monitoring across the Saudi pharmaceutical supply chain. These findings suggest that localization should be assessed not simply as an industrial policy target but as a capacity-and-reliability problem.

This paper examines the question: how can production planning and capacity optimization accelerate and strengthen pharmaceutical manufacturing localization in Saudi Arabia under Vision 2030? The paper has four objectives. First, it synthesizes recent evidence on Saudi pharmaceutical localization and the operational barriers that affect domestic supply. Second, it identifies production-planning and capacity-management practices that are especially relevant to regulated pharmaceutical operations. Third, it develops an integrated framework connecting policy-level localization goals with plant-level planning, technology transfer, quality, digitalization, and asset utilization. Fourth, it proposes practical performance indicators and a phased implementation roadmap for 2026-2030.

# 2. SAUDI PHARMACEUTICAL LOCALIZATION AND THE OPERATIONAL CHALLENGE

## 2.1 Localization as industrial and health-security policy

Saudi pharmaceutical localization is embedded within a broader national strategy to expand local production and increase the value captured domestically from strategic sectors. Vision 2030's industrial programs emphasize localization of promising manufacturing industries and the development of resilient supply chains. NIDLP positions industry and logistics as engines of diversification, while the National Industrial Strategy emphasizes local production, global supply-chain security, advanced technology, and export capability (Saudi Vision 2030, n.d.-a, n.d.-c). In parallel, the Health Sector Transformation Program seeks a more effective and integrated health system, meaning that medicine availability and supply resilience have direct consequences for health-sector performance (Saudi Vision 2030, n.d.-b).

The Saudi Food and Drug Authority (SFDA) contributes to localization through regulatory support, product availability initiatives, manufacturer guidance, the Saudi Pharmacopoeia, and NIDLP-related activities (SFDA, 2025; SFDA, n.d.-a, n.d.-b). Its localization agenda includes support for biologics, genetic products, and advanced therapy medicinal products, indicating that the future of domestic manufacturing extends beyond conventional generic tablets toward technologically demanding products (SFDA, n.d.-a). The National Biotechnology Strategy similarly places biomanufacturing and localization within the long-term national innovation agenda (Saudi Vision 2030, n.d.-d). These directions increase the importance of operational capability because biologics, sterile products, and other advanced therapies typically involve tighter process control, specialized facilities, complex cold chains, and more difficult scale-up and technology-transfer requirements.

## 2.2 Why installed capacity does not equal usable capacity

A key distinction for localization is the difference between nominal, demonstrated, and effective capacity. Nominal capacity represents theoretical output under ideal assumptions. Demonstrated capacity reflects what a line can sustain under validated operating conditions. Effective capacity is lower because it incorporates product mix, campaign length, cleaning, changeovers, preventive maintenance, quality holds, labor patterns, yields, line clearances, testing, and release processes. In multiproduct pharmaceutical plants, the gap between nominal and effective capacity can be substantial.

This distinction matters because localization projects are often assessed using equipment nameplate capacity or annual unit estimates. Such measures can overstate what the local system can actually supply. A filling line, compression suite, or packaging line may be technically capable of high throughput but still become a constraint when numerous products compete for the same resource, frequent changeovers are required, or upstream and downstream operations are unbalanced. Capacity can also be lost through long batch-release cycles, maintenance instability, deviation investigations, or material non-availability. Shannon et al. (2023), in a pharmaceutical API setting, demonstrate how maintenance and reliability practices can influence overall equipment effectiveness and therefore the usable capacity of existing assets.

A localization program should therefore begin with a resource-based capacity model rather than a simple annual-volume target. The model should identify critical shared equipment, cleanroom classes, utilities, warehouse constraints, quality-control testing capacity, labor skills, and release resources. It should also differentiate between product families because a plant that is unconstrained for one dosage form can be severely constrained for another. This is especially relevant in Saudi facilities that manufacture solid, liquid, and semi-solid products or that plan to add sterile, biologic, or high-containment technologies.

## 2.3 Demand uncertainty and product-mix complexity

Localization planning must deal with uncertain demand. Pharmaceutical demand is influenced by population growth, disease prevalence, prescribing practices, tenders, formulary decisions, reimbursement, competitive entry, seasonality, epidemiological events, and inventory policies. Public procurement can create large, discrete demand changes, while product launches and tender awards can rapidly alter the required product mix. Forecast error therefore has a direct impact on both service level and manufacturing efficiency.

Traditional approaches may respond to uncertainty by carrying more finished-goods inventory. However, inventory is not a universal solution because medicines have shelf-life constraints and may require temperature-controlled storage. Excess inventory creates expiry risk and working-capital costs, while insufficient inventory can cause shortages. The production-planning objective is therefore to create a balanced policy across forecast accuracy, safety stocks, campaign frequency, responsiveness, and capacity flexibility. Hamzehlou (2024) demonstrates through system dynamics that agility in pharmaceutical supply chains depends on coordinated responses across supply, production, and inventory variables. Badejo and Ierapetritou (2024) similarly show the value of planning for disruptions and resilience rather than optimizing only for normal conditions.

## 2.4 Technology transfer as a capacity-planning event

Technology transfer is often treated as an R&D, quality, or regulatory project. Operationally, however, it is also a capacity-planning event. Engineering batches, process validation, stability batches, cleaning validation, analytical method transfer, and launch inventories all compete with commercial production for equipment, quality-control capacity, materials, and technical staff. Poor integration of technology-transfer activities into the master schedule can disrupt existing supply and delay commercialization of the localized product.

WHO (2022) emphasizes that successful technology transfer requires defined responsibilities, knowledge transfer, documented process understanding, risk management, and lifecycle control; its Local Production and Assistance program similarly frames sustainable local production as a route to more timely access to quality-assured health products (WHO, n.d.). From a planning perspective, these principles should be translated into protected capacity windows, launch-readiness milestones, material availability dates, validation resource plans, and escalation rules. A localization portfolio that simultaneously transfers many products without considering shared bottlenecks can create congestion and reduce overall throughput. By contrast, an integrated portfolio plan can sequence transfers based on national priority, demand value, technical similarity, equipment fit, and available capacity.

# 3. LITERATURE REVIEW: PRODUCTION PLANNING, CAPACITY OPTIMIZATION, AND PHARMA 4.0

## 3.1 Integrated production and capacity planning

The most direct evidence for the paper's thesis comes from research that explicitly integrates production and capacity decisions in pharmaceutical manufacturing. Lindahl et al. (2023) developed a framework for integrated capacity and production planning that combines manufacturing-network decisions with detailed production requirements. Their work demonstrates that a capacity level should not be treated as fixed when production planning is performed. Instead, production volumes, resource allocation, and expansion options can be considered together. For localization policy, this means that decisions about which products to localize and when to add capacity should be evaluated simultaneously.

Lindahl et al. (2024) extend this logic to uncertainty. Their framework identifies bottlenecks, evaluates the best use of existing resources, and selects capacity expansion projects under uncertain demand. This is particularly relevant in Saudi Arabia because localization investments may involve long lead times and significant capital expenditure, while demand can shift through tenders, new treatment patterns, and policy incentives. A robust localization program should therefore use scenario-based capacity planning with demand ranges rather than a single deterministic forecast.

At the tactical and operational levels, recent studies reinforce the value of more advanced planning methods. Chen et al. (2025) propose an evolutionary fuzzy approach to pharmaceutical supply-chain production planning and control, illustrating how decision models can support planning under multiple criteria and uncertainty. Tucker and Daskin (2022) show that redundancy and recovery capability can reduce shortage risk, implying that the most cost-efficient capacity configuration is not always the most resilient. The localization implication is that capacity buffers, backup resources, alternative packaging routes, qualified secondary suppliers, and flexible product-routing rules may be economically justified when national medicine security is considered.

## 3.2 Operational excellence and asset utilization

Capacity optimization is not limited to capital expansion. In many cases, the first source of additional capacity is better utilization of existing assets. Continuous improvement, total productive

maintenance (TPM), changeover reduction, right-first-time quality, and bottleneck management can release hidden capacity without constructing new facilities. McDermott et al. (2022) identify leadership, culture, employee engagement, resources, and regulatory considerations as important enablers or barriers to continuous improvement in the pharmaceutical industry. Shannon et al. (2023) demonstrate that an integrated maintenance and reliability framework can improve pharmaceutical asset performance and overall equipment effectiveness.

### 3.3 Digitalization and Pharma 4.0

Digital technologies can improve localization by increasing visibility, forecast responsiveness, traceability, and control. Arden et al. (2021) describe Industry 4.0 applications in pharmaceutical manufacturing, including interconnected systems, advanced analytics, smart manufacturing, and more adaptive operations. Chen et al. (2020) discuss digital twins as a mechanism for representing pharmaceutical and biopharmaceutical processes and supporting monitoring, optimization, and decision-making. Ma et al. (2023) provide empirical evidence that digital transformation can improve pharmaceutical sustainable supply-chain performance, with traceability playing a mediating role.

However, technology alone does not guarantee improvement. Debnath et al. (2023) identify critical success factors for Industry 4.0 implementation in pharmaceutical supply chains, emphasizing organizational, technological, and managerial conditions. McDermott et al. (2024) show that Pharma 4.0 readiness in a real manufacturing site is shaped by regulatory compliance, data systems, implementation maturity, and operational context. These findings suggest that Saudi manufacturers should prioritize digital use cases tied to specific planning and capacity problems rather than implement technology for its own sake.

### 3.4 Supply-chain resilience and local manufacturing

Localization can reduce certain external dependencies, but it also creates new domestic dependencies. A locally manufactured tablet is not fully localized if the active pharmaceutical ingredient, critical excipients, packaging materials, spare parts, or analytical standards are unavailable when required. The relevant concept is therefore supply-chain localization depth rather than simply finished-product localization.

Zighan et al. (2024) find that knowledge management supports pharmaceutical supply-chain resilience by improving agility, adaptability, problem solving, and innovation. Badejo and Ierapetritou (2024) show that disruption-aware planning can strengthen resilience, while Tucker and Daskin (2022) demonstrate the value of backup options and recovery capability. In the Saudi context, Alzhrani et al. (2025) identify forecasting and sourcing weaknesses as contributors to sterile injectable shortages. Alyousef et al. (2025) call for coordinated monitoring and improved information flows across manufacturers, distributors, and healthcare providers.

## 4. METHODOLOGY

This study adopts an integrative review and policy-analysis design. The purpose is to synthesize evidence across several connected fields rather than estimate a single pooled effect. The review was structured around four evidence domains: (1) Saudi pharmaceutical localization and Vision 2030

policy; (2) pharmaceutical production planning and capacity management; (3) pharmaceutical supply-chain resilience and medicine availability; and (4) operational excellence, digital manufacturing, and technology transfer.

Peer-reviewed literature and authoritative policy or regulatory documents published primarily between 2020 and 2026 were prioritized. Sources were retrieved from PubMed/PMC, ScienceDirect, PLOS, Springer, Emerald, institutional research repositories, and official Saudi Vision 2030, SFDA, WHO, ICH, FDA, MISA, and local-content websites. Search combinations included terms such as "Saudi pharmaceutical manufacturing", "pharmaceutical localization Saudi Arabia", "production planning pharmaceutical manufacturing", "capacity planning pharmaceutical", "drug shortages Saudi Arabia", "pharmaceutical supply chain resilience", "Pharma 4.0", "technology transfer pharmaceutical manufacturing", "overall equipment effectiveness pharmaceutical", and "continuous manufacturing".

Sources were included when they contributed directly to at least one of the four evidence domains and when their methods, policy status, or institutional authority were clear. The synthesis emphasized operational relevance to Saudi localization. Evidence was coded according to the mechanism through which it could influence localization: demand and planning, capacity and assets, materials and resilience, technology transfer, quality and regulatory integration, digital enablement, or policy and ecosystem support. The final conceptual framework was developed by connecting these mechanisms across strategic, tactical, and operational planning levels.

***Table 1. Selected evidence underpinning the review and its operational relevance to localization***

| Source | Context | Evidence type | Key finding used in this review | Localization implication |
|---|---|---|---|---|
| Saudi Vision 2030 / SFDA | Saudi Arabia | Policy and regulatory strategy | Localization, health transformation, industrial diversification and advanced manufacturing require domestic capability, not only market access. | Frames localization objectives and ecosystem support. |
| Tawfik et al. (2022) | Saudi Arabia | Review / strategic analysis | Localization is linked to drug security; R&D, supply dependence and portfolio breadth remain important constraints. | Prioritize products by health criticality, dependency and feasible manufacturing capability. |
| Alshehri et al. (2023) | Saudi Arabia | Manufacturing landscape analysis | Local production covers only part of national pharmaceutical demand and product diversity. | Capacity decisions should target gaps in dosage forms and strategic product categories. |
| Halwani et al. (2023) | Saudi Arabia | Industry review | Advanced products such as nanomedicines require stronger local R&D and manufacturing ecosystems. | Build capability pathways for higher-complexity technologies. |
| Alzhrani et al. (2025) | Saudi Arabia | Cross-sectional survey | Forecasting and sourcing weaknesses were associated with sterile injectable shortage risk. | Use demand scenarios, sourcing risk and constrained-capacity planning. |
| Alyousef et al. (2025) | Saudi Arabia | Mixed-method survey | Stakeholders identified coordination, monitoring and regulatory-availability gaps across the supply chain. | Create shared planning visibility and escalation mechanisms. |
| Lindahl et al. (2023; 2024) | Pharmaceutical manufacturing | Optimization / case studies | Production and capacity decisions are stronger when integrated and evaluated under uncertainty. | Link localization portfolio choices to resource constraints and expansion triggers. |

| Source | Context | Evidence type | Key finding used in this review | Localization implication |
|---|---|---|---|---|
| Tucker & Daskin (2022) | Pharmaceutical supply chain | Reliability modeling | Redundancy, disruption rate and recovery speed materially affect shortage risk. | Design resilience buffers for critical localized medicines. |
| Badejo & Ierapetritou (2024) | Pharmaceutical supply chain | Multi-objective optimization | Disruption-aware planning improves resilience compared with normal-state optimization alone. | Evaluate service and resilience together with cost. |
| Arden et al. (2021); Chen et al. (2020) | Pharmaceutical manufacturing | Review | Industry 4.0 and digital twins enable connected, adaptive and model-supported operations. | Use digital tools after master-data and process foundations are stable. |
| McDermott et al. (2022; 2024) | Pharmaceutical manufacturing | Survey / case study | Culture, regulatory context, data maturity and leadership affect continuous improvement and Pharma 4.0 readiness. | Treat workforce and governance as forms of localization capacity. |
| WHO (2022); ICH (2022) | Global regulatory guidance | Technical guidance | Technology transfer and continuous manufacturing require structured lifecycle control and regulatory integration. | Reserve capacity and resources for transfer, validation and lifecycle execution. |

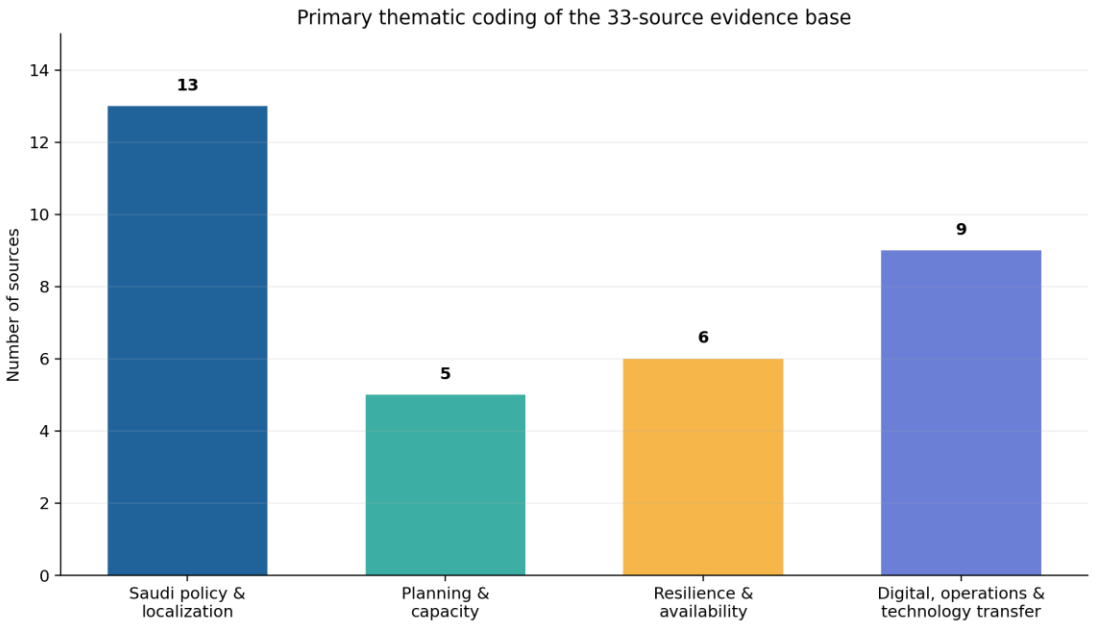



***Figure 2. Primary thematic coding of the 33-source evidence base. Each source was assigned one primary theme for visualization (author synthesis).***

# 5. AN INTEGRATED FRAMEWORK FOR LOCALIZATION THROUGH PRODUCTION PLANNING AND CAPACITY OPTIMIZATION

## 5.1 Layer 1: national localization portfolio and demand prioritization

The first layer is a national or enterprise localization portfolio that answers which products should be localized first. Selection should combine public-health importance, current import dependence, demand volume and stability, supply vulnerability, local technical feasibility, economic value, and strategic technology capability. A purely revenue-driven list may neglect critical medicines, while a

purely public-health list may ignore manufacturing feasibility. A weighted portfolio approach can balance both.

***Table 2. Seven-layer pharmaceutical localization planning framework***

| Layer | Core question | Planning mechanisms | Primary outputs / KPIs |
|---|---|---|---|
| 1. Localization portfolio | Which products should be localized first? | Health criticality, import dependence, demand range, technical fit, economic value | Prioritized pipeline with base/upside/downside scenarios |
| 2. S&OP / MPS | Can demand be converted into a stable feasible plan? | Cross-functional S&OP, frozen/slushy/flexible horizons, campaign planning | Schedule adherence, service level, plan stability |
| 3. MRP & supply risk | Will materials be available at the right time and risk level? | MRP, supplier segmentation, safety time/stock, dual sourcing where feasible | Material availability, supplier OTIF, inventory days, expiry |
| 4. Finite capacity | Where are future constraints? | Resource calendars, changeovers, maintenance, yields, labor, QC constraints | Utilization by bottleneck, OEE, backlog, overtime |
| 5. Quality capacity | Can batches be tested, reviewed and released without delay? | QC workload planning, release queues, deviation reduction, right-first-time | Release lead time, repeat tests, deviation rate, RFT |
| 6. Technology transfer | Can new products be absorbed without destabilizing supply? | Protected transfer windows, validation plan, launch-readiness gates | Transfer cycle time, validation success, launch service |
| 7. Digital support | Are decisions based on reliable, timely information? | ERP master data, APS, MES/eBR, dashboards, predictive analytics | Data accuracy, exception closure, planning latency |

For each candidate product, demand should be translated into a multi-year volume range rather than a single-point forecast. Base, upside, downside, and disruption scenarios can then be used to test whether existing local resources can absorb the product. This step links policy ambition to realistic capacity. Products that appear attractive but require unique high-cost technology may be placed in a longer-term investment portfolio, while products compatible with existing equipment can be accelerated through technology transfer.

## 5.2 Layer 2: sales and operations planning and master production scheduling

Once products are localized, S&OP should become the central mechanism for balancing demand, supply, inventory, and capacity. The process should include commercial teams, production, supply chain, procurement, warehouse, quality assurance, quality control, regulatory affairs, engineering, and finance. In a localized pharmaceutical environment, S&OP must also track transfer and validation batches because they consume the same resources as commercial products.

The master production schedule should be constrained by demonstrated capacity, not aspirational demand. It should explicitly account for campaign rules, batch sizes, product families, cleaning matrices, packaging configurations, validation windows, maintenance, and quality-control constraints. MPS stability is important because excessive rescheduling creates material disruption, overtime, changeover losses, and execution confusion. A practical rule is to establish frozen, slushy, and flexible planning horizons: near-term production is protected from avoidable changes, medium-term plans can be adjusted through controlled governance, and longer-term demand remains scenario based.

## 5.3 Layer 3: material requirements and localization depth

MRP converts the master schedule into time-phased requirements for active ingredients, excipients, printed packaging, components, and consumables. For localization, standard MRP should be enhanced with supply-risk segmentation. Critical imported items should have longer planning horizons, explicit safety-time or safety-stock policies, dual-sourcing plans where feasible, and clear escalation triggers. Local supplier-development opportunities should be identified not only by spend but also by risk reduction and strategic importance.

## 5.4 Layer 4: finite capacity and bottleneck management

Finite-capacity planning is the operational core of the framework. Each critical resource should have a time-based capacity model that subtracts planned downtime, maintenance, calibration, sanitation, changeovers, training, and expected yield or performance losses. Demand loads can then be compared with available hours by resource and period. This reveals future bottlenecks before they become shortages.

Bottlenecks should be managed through a hierarchy of responses. The first response is planning: rebalance campaigns, sequence products more efficiently, move work between qualified resources, or adjust inventory positioning. The second is operational improvement: reduce setup time, improve reliability, increase right-first-time performance, remove minor stops, or align labor. The third is technical debottlenecking: modify equipment, utilities, automation, or process steps. The fourth is capital expansion: add new lines, shifts, suites, warehouses, or testing capacity. This hierarchy prevents premature capital expenditure while ensuring that expansion is not delayed when structural constraints are real.

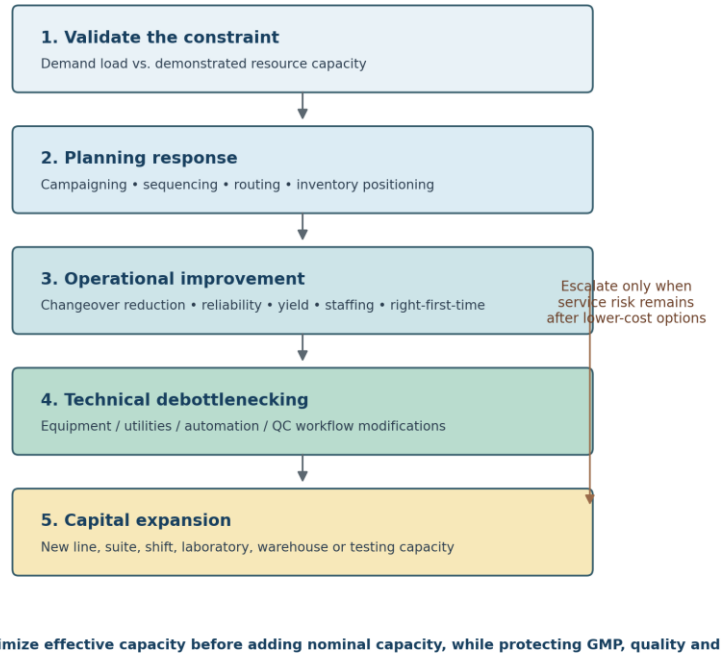



***Figure 3. Capacity optimization and expansion hierarchy for regulated pharmaceutical manufacturing (author synthesis).***

Capacity expansion should be triggered by evidence. Appropriate triggers may include sustained utilization above a defined threshold, chronic backlog, unacceptable service risk, increasing overtime, inability to schedule validation work, or demand scenarios that exceed demonstrated capacity over a defined horizon. Lindahl et al. (2024) support this approach by showing how expansion decisions can be integrated with production planning under uncertainty.

## 5.5 Layer 5: quality, release, and regulatory capacity

Pharmaceutical capacity is often constrained outside the production line. Quality-control laboratories, sampling, microbiology, stability chambers, batch-record review, deviation closure, and qualified-person or authorized-release processes can become hidden bottlenecks. A localization strategy must therefore include quality capacity in the same planning model.

Right-first-time quality is especially important. Deviations and repeat testing consume capacity twice: once through the original activity and again through investigation, rework, or replacement production. Quality performance should therefore be treated as a capacity variable. Metrics such as deviation rate, review cycle time, batch-release lead time, laboratory turnaround time, and repeat-test frequency should sit alongside OEE and schedule adherence in the localization performance dashboard.

## 5.6 Layer 6: technology transfer and launch readiness

Every technology-transfer project should have a capacity reservation plan. The receiving site should define when engineering, exhibit, validation, cleaning, stability, and launch batches will occur and how these activities interact with routine commercial production. The plan should include technical-transfer milestones, equipment readiness, analytical method readiness, materials, training, documentation, and regulatory dependencies.

A transfer should not be considered "localized" at dossier approval alone. Operational localization is achieved when the receiving site can repeatedly manufacture, test, release, and replenish the product at required quality and service levels. This distinction aligns with WHO's emphasis on sustainable knowledge absorption and lifecycle control (WHO, 2022).

## 5.7 Layer 7: digital decision support

Digitalization connects the framework. ERP master data should provide a single source for bills of material, routings, batch sizes, lead times, inventory, and purchase parameters. Advanced planning tools can then use this data to model constraints, sequence campaigns, and run scenarios. Manufacturing execution systems and electronic batch records can improve real-time visibility, while equipment data can support predictive maintenance and OEE analysis.

# 6. DISCUSSION: HOW THE FRAMEWORK ADVANCES VISION 2030

## 6.1 From localization quantity to localization capability

A central argument of this paper is that Saudi pharmaceutical localization should be measured as capability, not only quantity. Counting local products or estimating local market share is useful, but it does not reveal whether domestic supply is reliable, flexible, economically sustainable, and technologically progressive. A manufacturer may increase local volume while simultaneously accumulating high inventory, poor utilization, and imported single-source dependencies. Conversely, a strategically designed facility may initially produce fewer products but create high-value capabilities in sterile manufacturing, biologics, or complex delivery systems.

Capability-based localization requires a balanced scorecard. At least five dimensions are needed: localization depth, service reliability, operational efficiency, quality and compliance, and resilience. Localization depth captures domestic value creation. Service reliability measures whether medicines are available when needed. Operational efficiency reflects capacity utilization and cost competitiveness. Quality measures the robustness of validated manufacturing. Resilience measures the ability to absorb disruptions and recover.

***Table 3. Proposed capability-based KPI suite for pharmaceutical localization***

| Dimension | Illustrative measures | Why it matters for localization |
|---|---|---|
| Localization depth | Share of production steps, testing, materials and technical value executed domestically | Move beyond simple local finishing or packaging counts |
| Service reliability | Customer service level / fill rate; shortage events; backlog | Connect industrial localization to medicine availability |
| Planning performance | Forecast accuracy; MPS adherence; reschedule frequency | Measure whether demand is translated into executable plans |
| Asset performance | OEE; bottleneck utilization; unplanned downtime; changeover time | Release hidden capacity before premature expansion |
| Quality flow | Right-first-time; deviation rate; QC turnaround; batch-release lead time | Recognize quality and release as capacity constraints |
| Material resilience | Supplier OTIF; critical single-source items; safety coverage; expiry | Make import and material dependency visible |
| Technology transfer | Transfer cycle time; validation success; launch readiness | Measure the speed and stability of capability absorption |
| Workforce capability | Certified planners, validation specialists, data/automation skills, Saudi technical participation | Link localization to sustainable national capability building |

## 6.2 Production planning as a workforce-development platform

Vision 2030 places strong emphasis on national human-capital development. Production planning is well suited to this objective because it is inherently cross-functional and analytical. Planners must understand demand, materials, manufacturing processes, quality constraints, ERP systems, inventory,

and finance. Developing Saudi capability in planning, scheduling, industrial engineering, reliability, validation coordination, and supply analytics can therefore create high-value technical and managerial roles.

## 6.3 Connecting local procurement with feasible operations

Local-content policy and government procurement can create demand signals that encourage domestic investment. However, these signals should be synchronized with manufacturing readiness. If procurement commitments rise faster than validated capacity, companies may face service failures or costly emergency imports. Conversely, if capacity is built without stable demand visibility, utilization may remain low and the economics of local production may weaken.

A collaborative planning mechanism among major purchasers, manufacturers, regulators, and localization authorities could reduce this mismatch. Aggregated, privacy-protected demand signals for priority products could help manufacturers plan capacity and technology transfer earlier. In return, manufacturers could provide readiness milestones and risk indicators. Alyousef et al. (2025) show that Saudi supply-chain stakeholders already identify transparency, harmonization, and centralized monitoring as areas for improvement.

## 6.4 Advanced manufacturing and future readiness

Saudi Arabia's future pharmaceutical agenda increasingly includes biologics, advanced therapies, and biotechnology. These products require more sophisticated capacity planning than conventional oral solids. Facilities may depend on specialized single-use systems, cold storage, cell-culture suites, aseptic filling, highly trained operators, and limited testing capacity. Small demand volumes can coexist with very high product value and severe shortage consequences.

Advanced manufacturing technologies can improve flexibility. ICH Q13 provides a regulatory framework for continuous manufacturing (ICH, 2022), while FDA and other regulators are actively exploring advanced manufacturing and AI-enabled production (FDA, 2023). Continuous manufacturing can reduce certain scale constraints and enable more responsive production where the business case and regulatory strategy are appropriate. Industry 4.0 and digital twins can also support process understanding and scenario analysis (Arden et al., 2021; Chen et al., 2020). For Saudi Arabia, these technologies should be linked to specific localization problems such as flexible multiproduct capacity, faster scale-up, improved traceability, or reduced dependence on large imported inventories.

## 6.5 Resilience without inefficient overcapacity

A common concern is that localization for security may produce inefficient overcapacity. The framework proposed here avoids treating resilience as unlimited redundancy. Instead, it recommends targeted buffers based on criticality and risk. Some essential medicines may justify backup local capacity, qualified alternative routes, or strategic inventories. Other products may be efficiently supplied through regional or global networks. The correct decision depends on shortage impact, demand predictability, lead time, supplier concentration, and substitution possibilities.

# 7. STRATEGIC ROADMAP FOR 2026-2030

A phased roadmap can translate the framework into implementation. The first phase should establish data and planning discipline. Manufacturers should validate ERP master data, standardize capacity calculations, define production families, map bottlenecks, measure schedule adherence, and create cross-functional S&OP governance. At the ecosystem level, priority medicine categories and localization pipelines should be clearly communicated.

The second phase should focus on optimization and technology-transfer integration. Plants should implement finite-capacity planning for constrained resources, formalize transfer-capacity reservations, strengthen supplier-risk segmentation, and deploy OEE and loss-tree management. Quality-control and batch-release capacity should be included in planning. Localization projects should be gated by operational readiness criteria, not only regulatory milestones.

The third phase should scale digital and advanced planning capability. Companies with stable data can adopt advanced planning and scheduling, predictive maintenance, integrated dashboards, scenario analytics, and selected AI applications. Digital systems should connect demand, material risk, production constraints, and release status. Workforce programs should develop planners, industrial engineers, supply analysts, validation coordinators, and digital-manufacturing specialists.

The fourth phase should establish a mature localization network capable of dynamic portfolio management. By 2030, leading Saudi manufacturers should be able to evaluate new localization opportunities using integrated economic, health-security, and capacity models; execute technology transfers without destabilizing existing supply; and make evidence-based decisions about debottlenecking versus capital expansion. The ecosystem should increasingly support higher-complexity products, including biologics and advanced therapies, while maintaining strong performance in essential conventional medicines.

Key performance indicators should be tracked at plant and portfolio levels. Plant-level indicators include forecast accuracy, schedule adherence, customer service level, batch-release lead time, OEE, planned versus unplanned downtime, changeover duration, right-first-time rate, inventory days, expiry/write-off rate, capacity utilization by bottleneck resource, and supplier on-time performance. Portfolio-level indicators can include number of priority products operationally localized, proportion of demand covered by qualified local capacity, localization depth, number of critical single-source dependencies eliminated, transfer cycle time, national workforce participation in technical roles, and resilience coverage for essential medicines.

***Table 4. Phased implementation roadmap for 2026–2030***

| Phase | Priority actions | Expected capability | Example KPIs |
|---|---|---|---|
| 2026 — Foundation | Clean ERP master data; establish S&OP; map bottlenecks; define capacity standards; baseline KPIs | Reliable planning inputs and transparent constraints | Master-data accuracy; forecast accuracy; schedule adherence |
| 2027 — Optimization | Finite-capacity planning; OEE/loss-tree routines; changeover reduction; supplier-risk segmentation; QC capacity planning | More usable capacity from current assets | OEE; changeover time; QC turnaround; material availability |

| Phase | Priority actions | Expected capability | Example KPIs |
|---|---|---|---|
| 2028 — Transfer integration | Reserve transfer/validation capacity; launch-readiness gates; portfolio sequencing; supplier development | Faster localization without destabilizing existing supply | Transfer cycle time; validation success; launch OTIF |
| 2029 — Digital scaling | APS/advanced analytics; predictive maintenance; integrated dashboards; scenario planning; selected AI use cases | Faster exception response and better scenario decisions | Planning latency; predictive alerts; downtime reduction |
| 2030 — Dynamic localization network | Integrated portfolio/capacity investment model; resilience coverage; higher-complexity products; evidence-based expansion | Scalable, resilient and internationally competitive localized supply | Demand covered by qualified local capacity; critical dependencies removed; export readiness |

# 8. RESEARCH IMPLICATIONS AND LIMITATIONS

The framework creates several opportunities for future empirical research. First, Saudi manufacturers could be studied using plant-level panel data to test how schedule adherence, OEE, changeover time, quality losses, and planning maturity affect service level and localization output. Second, researchers could develop optimization models for the Saudi product portfolio that combine health criticality, import dependence, technology-transfer cost, local capacity, and supply risk. Third, scenario models could evaluate how different localization strategies affect national shortage risk under disruptions.

This review has limitations. It is an integrative synthesis rather than an exhaustive systematic review, and it does not include proprietary plant data or primary interviews. The Saudi pharmaceutical ecosystem is also evolving rapidly, so policy instruments and market conditions may change. Finally, operational performance differs substantially by dosage form and technology; recommendations for oral solids cannot be transferred unchanged to sterile biologics or advanced therapies. These limitations reinforce the need for future sector-specific and plant-level validation.

# 9. CONCLUSION

Saudi Arabia's pharmaceutical localization ambition is strategically important for health security, industrial diversification, innovation, and workforce development. Achieving this ambition requires more than investment announcements, product registrations, or installed equipment. Localization becomes sustainable only when domestic manufacturers can convert demand into reliable, compliant, and economically efficient supply.

This review shows that production planning and capacity optimization provide the operational architecture for that conversion. Integrated demand planning, master scheduling, material-risk management, finite-capacity modeling, bottleneck improvement, quality-capacity planning, technology-transfer integration, and digital decision support can collectively increase the value created from existing and future Saudi pharmaceutical assets. The most important policy implication is that localization should be managed as a dynamic capability system rather than a static percentage target.

A mature localization ecosystem will know not only how much is produced locally, but also whether the local system can respond to demand changes, absorb new products, recover from disruptions, maintain GMP performance, use capital efficiently, and progress toward more complex technologies.

By embedding production planning and capacity optimization into Vision 2030 implementation, Saudi Arabia can strengthen the connection between industrial policy and medicine availability and build a pharmaceutical manufacturing base that is resilient, scalable, and internationally competitive.

# 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. The manuscript synthesizes published literature and public policy/regulatory sources.

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# Abbreviations

| Abbreviation | Meaning |
|---|---|
| APS | Advanced Planning and Scheduling |
| cGMP/GMP | current Good Manufacturing Practice / Good Manufacturing Practice |
| ICH | International Council for Harmonisation |
| LCGPA | Local Content and Government Procurement Authority |
| MPS | Master Production Scheduling |
| MRP | Material Requirements Planning |
| NIDLP | National Industrial Development and Logistics Program |
| OEE | Overall Equipment Effectiveness |
| QC | Quality Control |
| RFT | Right First Time |
| SFDA | Saudi Food and Drug Authority |
| S&OP | Sales and Operations Planning |
| WHO | World Health Organization |