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Technology Transfer and CMO Site Transfer of Pharmaceutical Products: Strengthening Saudi Arabia's Local Manufacturing Capacity

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Abstract- ***Saudi Arabia is advancing pharmaceutical localization as part of a wider strategy encompassing health security, industrial diversification, and biotechnology development. However, localization achieves strategic significance only when the receiving manufacturer attains reproducible process knowledge, analytical control, quality-system ownership, and the capacity to sustain commercial supply. This review thoroughly examines pharmaceutical technology transfer and contract manufacturing/development organization (CMO/CDMO) site transfer as mechanisms to enhance local pharmaceutical manufacturing capacity in Saudi Arabia. A structured integrative review of literature and credible regulatory or policy sources published between 2020 and 2025 was conducted, focusing on manufacturing science, analytical transfer, quality risk management, lifecycle regulation, outsourced manufacturing, and Saudi localization policy. The evidence demonstrates that successful transfer involves a controlled transformation of explicit and tacit product knowledge into site-specific operational capability, rather than a mere exchange of documents. Key determinants include early CMO fit assessment, comprehensive technology packages, equipment and facility comparability, analytical method transfer, risk-based scale bridging, process performance qualification, stability commitments, data validity, and ongoing post-launch process verification. Effective CMO governance is also essential, as fragmented responsibilities, inadequate quality agreements, or delayed knowledge exchange can escalate technical differences into validation failures and supply disruptions. For Saudi Arabia, a staged localization model is proposed that corresponds transfer maturity with workforce development, supplier localization, digital quality systems, regulatory preparedness, and progressively higher-value manufacturing. The review concludes that technology transfer can serve as an instrument for industrial capability-building when success is evaluated by local process ownership, right-first-time performance, resilient supply, and the receiver's capacity to independently manage future lifecycle changes, as opposed to solely by the release of the first commercial batch.***

Keywords: ***technology transfer, CMO, CDMO, pharmaceutical manufacturing, localization, saudi arabia, vision 2030, GMP, process validation, supply resilience.***

I. INTRODUCTION

Pharmaceutical localization has moved from a narrow industrial policy issue to a core health-security concern. The COVID-19 period exposed how transport interruption, demand shocks, limited local manufacturing options, and concentration of upstream suppliers may impair access even when procurement budgets are available (Tirivangani et al., 2021; Bø et al., 2023; Aivazi et al., 2024). Saudi Arabia enters this discussion with a large medicines market, an established national regulator, central procurement capabilities, and explicit ambitions to expand pharmaceutical and biotechnology production. The Saudi medicines-policy discussion paper used as the contextual anchor for this review linked procurement, regulation, local research, manufacturing, technology transfer, and industrial workforce development to Vision 2030 objectives (Alghaith et al., 2020). More recent Saudi policy signals have reinforced biotechnology, bio-manufacturing, and localization as strategic priorities (Saudi Press Agency, 2024a).

The central operational question is not whether to increase local production, but rather how to transfer external product and process knowledge into Saudi manufacturing sites without undermining quality, elevating supply risk, or promoting ongoing dependence on the originating organization. Technology transfer delivers a structured solution to this challenge. In pharmaceutical manufacturing, technology transfer entails the systematic movement and verification of knowledge required to reproduce a product, process, analytical control strategy, packaging configuration, and quality performance at the receiving site. When the recipient is a contract manufacturing organization or contract development and manufacturing organization, the transfer also constitutes an inter-organizational governance process that spans technical, legal, regulatory, commercial,

and intellectual property domains (Ujam, 2020; Pasdar et al., 2024).

A site transfer is more demanding than copying a master batch record. Identical set points may produce different outcomes when equipment geometry, shear history, heat and mass transfer, automation architecture, cleanroom configuration, utilities, raw-material sources, laboratory platforms, or operator practices differ. Commercial scale bridging depends on understanding which process relationships must be preserved rather than mechanically reproducing parameters from the sending site (Vicente Martin et al., 2022; Tchessalov et al., 2022; Tchessalov et al., 2023; Singh et al., 2025). Likewise, real-time monitoring models and analytical procedures may require adaptation when instruments, sensors, software, sampling systems, or local laboratory conditions change (Christler et al., 2021; Kumar et al., 2024).

II. AIM AND OBJECTIVES

This review aims to critically evaluate pharmaceutical technology transfer and CMO/CDMO site transfer as mechanisms for developing sustainable local manufacturing capability in Saudi Arabia. Additionally, it seeks to establish a practical stage-gated framework that connects transfer execution with quality, regulatory, workforce, and industrial localization outcomes. Unlike general national medicines-policy analyses, this review specifically focuses on the manufacturing knowledge pathway between the originating organization and the Saudi receiving site.

The review is structured around five objectives. First, it differentiates product knowledge transfer, manufacturing process transfer, analytical method transfer, and regulatory site-transfer activities to prevent the conflation of responsibilities. Second, it identifies technical, quality, regulatory, digital, and organizational failure modes that commonly occur throughout the transfer lifecycle. Third, it aligns these requirements with Saudi localization priorities and the capabilities expected of local CMOs or manufacturers. Fourth, it synthesizes practical success factors for transfer governance, including risk assessment, documentation, training, validation, and ongoing process verification. Fifth, it introduces measurable maturity indicators that assess localization based on durable process ownership and supply resilience, instead of solely on physical installation or packaging activities.

III. METHODOLOGY

A structured integrative review methodology was employed due to the research question's breadth, encompassing peer-reviewed manufacturing science, regulatory guidance, and country-specific industrial policy. A conventional systematic review limited to a single bibliographic database would have omitted critical primary regulatory sources that directly influence technology transfer. The review period was set from January 2020 to December 2025 to ensure contemporary relevance and to capture post-pandemic developments in supply resilience, quality risk management, lifecycle regulation, digital manufacturing, and localization policy. The evidence base was categorized into four source types: peer-reviewed pharmaceutical manufacturing literature; studies on CMO/CDMO operations and transfer; international regulatory guidance from WHO, ICH-aligned agencies, FDA, EMA, and the European Commission; and official Saudi policy or regulatory documents from the SFDA and national government.

Search concepts were combined iteratively around the terms pharmaceutical technology transfer, manufacturing site transfer, CMO, CDMO, process validation, analytical method transfer, quality by design, process analytical technology, lifecycle management, pharmaceutical localization, Saudi Arabia, Vision 2030, drug security, and supply resilience. Eligible sources had to be published from 2020 to 2025, be available in English, and address at least one substantive dimension of commercial pharmaceutical transfer, outsourced manufacturing, manufacturing science, analytical control, post-approval change, or local manufacturing capacity. Clinical-only studies, pre-2020 publications, commentary without transferable manufacturing content, and unrelated logistics studies were excluded. Following eligibility assessment and relevance screening, 30 sources were included in the final qualitative synthesis based on their direct contribution to the predefined review domains

A thematic synthesis approach was selected due to the heterogeneity of the included evidence in both design and outcomes. Each source was coded across four domains: technical transfer, analytical and quality control, CMO governance and regulatory lifecycle management, and Each source was coded across four domains: technical transfer; analytical and quality control; CMO governance and regulatory lifecycle management; and Saudi localization and manufacturing capacity. Evidence was compared across transfer phases, from partner selection to post-launch verification. Primary regulatory guidance was

prioritized where it established expectations, while peer-reviewed case studies were utilized to illustrate mechanisms and implementation challenges. Meta-analysis was not conducted, as common effect measures were lacking. Consequently, the produced framework serves as a review-based implementation model for policy and manufacturing decision support, rather than a quantitative estimate of transfer success probability.

IV. TECHNOLOGY TRANSFER AND CMO SITE TRANSFER: CONCEPTUAL FOUNDATION

WHO guidance describes technology transfer as an organized process through which knowledge, experience, and associated documentation are transferred between development or manufacturing units so that the receiving unit can perform the operation as intended (World Health Organization, 2022). In practice, four overlapping layers should be separated. Product knowledge transfer explains formulation rationale, critical quality attributes, degradation pathways, container-closure interactions, microbiological or sterility risks, and known sensitivities. Process transfer defines unit operations, material attributes, parameter limits, hold times, yields, in-process controls, sampling logic, and the scientific basis for the control strategy. Analytical transfer confirms that the receiving laboratory can produce comparable and reliable results. Regulatory transfer converts the new manufacturing arrangement into a compliant lifecycle change supported by appropriate comparability, stability, validation, and submission documentation.

This separation matters because one layer can succeed while another fails. A batch may meet release specification even though the receiving laboratory lacks method robustness, the deviation system has not absorbed historical failure knowledge, or the regulatory submission does not adequately justify a site-specific equipment difference. Conversely, a solid analytical transfer does not compensate for poor mixing, drying, granulation, aseptic processing, or packaging control. Quality by Design reinforces the need to connect product understanding, risk assessment, and control strategy rather than relying on end-product testing alone (Nunavath et al., 2024). ICH Q9(R1) similarly emphasizes that the level of formalness and effort applied to quality risk management should be commensurate with ambiguity and importance (U.S. Food and Drug Administration, 2023a).

A complete transfer package therefore functions as a knowledge architecture. It should include the quality target product profile where available, critical quality attributes, formulation and material specifications, bills of material, process descriptions, equipment requirements, master records, development reports, risk assessments, validation history, change and deviation history, analytical methods, reference standards, stability data, cleaning strategy, packaging and serialization requirements, storage and distribution conditions, and the reasoning behind critical limits. The highest-value content is often tacit: what experienced scientists watch during a batch, which trends precede failure, which raw-material properties matter despite meeting specification, and how deviations were previously resolved. Capturing this knowledge requires structured workshops, floor-level observation, and joint execution rather than document exchange alone.

V. END-TO-END TRANSFER LIFECYCLE

A strong transfer begins before the CMO is selected. Technical due diligence should determine whether the proposed receiving site can reproduce the product within its licensed facility, equipment train, containment capability, cleanroom classification, utilities, laboratory infrastructure, digital systems, and available capacity. The assessment should examine not only whether equipment exists but whether its operating principles, geometry, scale, control resolution, and product-contact materials are sufficiently comparable. For sterile products, the contamination control strategy, environmental monitoring program, aseptic process simulation capability, sterilization systems, barrier technology, and operator qualification are central considerations under modern GMP expectations (European Commission, 2022). For highly potent, biological, sensitizing, or temperature-sensitive products, cross-contamination control and cold-chain constraints may become decisive.

After selection, the sending and receiving teams should create a joint gap assessment and transfer risk register. Differences can be classified as facility, equipment, material, method, automation, procedural, regulatory, or competency gaps. Failure mode and effects analysis is useful when it is connected to specific evidence and mitigation rather than treated as a scoring exercise. Each key gap should have an owner, due date, verification method, and decision threshold for escalation. The transfer protocol should then define scope, roles, batches, sampling, tests, acceptance criteria, deviation handling, change-control rules, document hierarchy, and the conditions

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required to proceed from engineering to qualification and commercial manufacture.

Scale bridging is the phase in which process understanding is tested against real receiving-site conditions. The goal is not necessarily to reproduce every sending-site parameter but to preserve the relationships that determine product quality. In twin-screw granulation, for example, commercial transfer has been supported by scale-relevant energy relationships and deliberate challenge of process parameters rather than simple parameter copying (Vicente Martin et al., 2022). Lyophilization offers an even clearer example: matching shelf temperature and chamber pressure across dryers can be insufficient because vial heat transfer, refrigeration capacity, sublimation limits, and dryer geometry differ (Tchessalov et al., 2023a, 2023b). These cases demonstrate why mechanistic understanding and documented rationale are valuable assets during localization.

Engineering batches should be designed to close uncertainty, not simply rehearse a validation batch. They can verify blending times, endpoint detection, filter behavior, hold-time practicality, in-process sampling, line speed, packaging performance, and operator execution. Data from these batches should feed an updated risk assessment and determine whether ranges remain scientifically justified. Where advanced process analytics are available, real-time measurements can expose site differences that routine release testing would detect only after processing is complete. Wasalathanthri et al. (2020) describe the role of process analytical technology in immediate monitoring of critical process parameters and quality attributes, while Neugebauer et al. (2024) show its continuing expansion in downstream drug-substance processing.

Figure 1. Stage-gated Saudi CMO site-transfer lifecycle. Author-developed synthesis based on the reviewed literature.

Table 1. Critical deliverables and acceptance evidence across the pharmaceutical site-transfer lifecycle.

Transfer phase	Critical deliverables	Principal failure modes	Acceptance evidence	Localization value
Strategic fit / CMO selection	Product-class fit; GMP history; capacity; facility and equipment screening	Choosing on price/capacity only; containment or scale mismatch	Technical due-diligence report; approved business and quality risk case	Directs investment to transfers the local site can sustainably own

Knowledge package and gap assessment	CQAs/CPPs; material attributes; development and deviation history; risk register	Document handover without rationale; tacit knowledge loss	Approved transfer plan; critical gaps assigned and closed or mitigated	Builds local scientific understanding instead of procedural dependence
Analytical transfer	Methods; standards; system suitability; comparative protocol; analyst training	Instrument/software differences; sample-preparation variability	Predefined transfer acceptance met; deviations resolved scientifically	Creates independent release and troubleshooting capability
Engineering and scale bridging	Site-specific operating ranges; sampling; hold times; automation and equipment evidence	Copying set points despite geometry or scale differences	Engineering data support control strategy and updated risk assessment	Converts imported know-how into receiver-specific process knowledge
Validation / PPQ and cleaning	PPQ, cleaning, computerized-system and shipping evidence; sterile simulations if relevant	Schedule-driven validation; unresolved critical gaps	Successful qualification with acceptable variability and controlled deviations	Demonstrates reproducible GMP execution at the Saudi site
Stability and regulatory implementation	Stability commitments; CMC variation package; inspection readiness	Late filing strategy; insufficient comparability data	Regulatory acceptance / implementation permission; stability on track	Makes local manufacture legally usable and export-ready
Launch and CPV	Enhanced monitoring; deviation trending; local investigation leadership	Hidden drift; continued dependency on sending experts	Stable CPV trends; right-first-time batches; declining external support	Shows durable ownership, resilience, and ability to manage lifecycle change

VI. ANALYTICAL, QUALITY, AND REGULATORY CONTROL

Analytical transfer is frequently underestimated because the written method appears precise. In reality, performance can be affected by instrument configuration, column history, software settings, sample preparation technique, environmental conditions, reference standards, analyst behavior, and local laboratory practices. A receiving laboratory should first assess method purpose and maturity, then define whether transfer will use comparative testing, co-validation, partial revalidation, verification, or another justified approach. Modern expectations under ICH Q2(R2) and Q14 place greater emphasis on method understanding, performance characteristics, development knowledge, and lifecycle management (U.S. Food and Drug Administration, 2024a; U.S. Food and Drug Administration, 2024b). A documented transfer protocol should specify samples, replicates, laboratories, statistical and predefined acceptance criteria, deviation rules, and training requirements.

Published transfer experience confirms that comparability cannot be presumed. Christler et al. (2021) transferred a real-time chromatographic monitoring system between sites and found that sensor differences prevented direct model transfer until adaptation was performed. Kumar et al. (2024) demonstrated that a validated chromatographic method could be transferred between laboratories when equipment differences were explicitly addressed and predefined performance was verified. The general lesson is that transfer success depends on demonstrating fitness at the receiving site, not asserting sameness. For a Saudi CMO, building local analytical troubleshooting capability is notably important because reliance on the sending laboratory for every atypical result weakens operational independence.

Quality agreements should translate the transfer design into routine governance. They should clearly assign responsibilities for batch disposition, deviations, complaints, recalls, change control, supplier qualification, stability, reference standards, retention samples, data review, audits, regulatory inspections, and communication of changes that could affect the product. CMO protocols can impose operational demands that compete with existing facility routines, especially where multiple sponsors use the same GMP infrastructure (Sutherland et al., 2022). Capacity planning must therefore include quality-system workload, laboratory throughput, validation resources, and review timelines, not only manufacturing hours.

Regulatory planning should run in parallel with technical execution. A new manufacturing site may require post-approval submissions, supporting stability, comparability evidence, updated specifications, validation data, or inspection readiness before commercial implementation. ICH Q12 provides a lifecycle framework for managing post-approval CMC changes and encourages greater predictability through established conditions and planned change-management approaches (European Medicines Agency, 2020; U.S. Food and Drug Administration, 2021). Technology transfer teams should map each proposed change to its regulatory reporting category early, because a technically successful transfer can still miss launch targets if filing strategy, data expectations, or approval timelines are addressed late.

Saudi receiving sites must also comply with SFDA GMP and product-specific stability expectations. The SFDA's GMP framework places manufacturing quality within a controlled pharmaceutical quality system, while its stability guidance supports evidence that product quality is maintained throughout the proposed shelf life (Saudi Food and Drug Authority, 2022; Saudi Food and Drug Authority, 2023). Transfer planning should therefore protect the traceability of development and manufacturing knowledge, guarantee data integrity, and maintain a clear link among risk assessments, validation decisions, stability commitments, and regulatory submissions. This agreement is essential for local supply and for any later ambition to export from Saudi facilities.

VII. SAUDI ARABIA: LOCALIZATION OPPORTUNITY AND CAPACITY REQUIREMENTS

Saudi pharmaceutical localization is underpinned by a strong policy rationale; however, the quality of localization is as critical as its scale. The 2020 national medicines-policy discussion stressed the potential for procurement, pricing, and regulation to foster local research and manufacturing, while cautioning that industrial incentives should not compromise quality or limit access (Alghaith et al., 2020). Tawfik et al. (2022) further identified local manufacturing as vital for drug security and highlighted constraints related to research capability, regulation, governance, and human resources. This evidence indicate that technology transfer should function as an institutional learning mechanism, rather than merely serving as a means to replace imported finished products.

The National Biotechnology Strategy strengthens this interpretation by positioning vaccines and bio-manufacturing/localization among Saudi Arabia's priority biotechnology directions (Saudi Press Agency, 2024a). Local-content policy also increasingly uses procurement instruments to create demand for national products; in 2024, additional medicines and preparations were added to the mandatory list for government procurement (Saudi Press Agency, 2024b). Such demand signals can improve the business case for transfer, but procurement preference alone cannot create technical capability. It must be paired with transfer requirements that make knowledge depth, quality maturity, workforce development, and supply resilience visible and measurable.

Human capital serves as the critical link between transferred documentation and sustained local ownership. The Saudi medicines-policy analysis specifically identified industrial chemistry, regulatory science, procurement, logistics, and data management as essential capabilities, in addition to clinical skills (Alghaith et al., 2020). Consequently, technology transfer programs should incorporate structured competency matrices, supervised execution, troubleshooting scenarios, analytical mentorship, and the qualification of Saudi technical staff. Training should progress beyond only attendance records to demonstrated competence, including the ability to articulate process rationale, detect deviations, lead investigations, justify changes, and defend control strategies during inspections.

Supplier localization is another dimension. A Saudi site can manufacture finished product locally while remaining highly exposed to imported active ingredients, excipients, filters, single-use components, primary packaging, reference standards, or specialized spare parts. Resilience requires charting these dependencies and deciding which should be dual-sourced, regionally sourced, locally developed, or strategically stockpiled. Pandemic-era supply studies show that detailed contingency planning and strong upstream and downstream relationships boost resilience when ordinary transport and demand assumptions fail (Bø et al., 2023; Tirivangani et al., 2021). Localization strategy should therefore distinguish domestic conversion from genuine reduction of critical external dependencies.

VIII. MAJOR RISKS AND MITIGATION PRIORITIES

A primary recurring risk is the incomplete transfer of tacit knowledge. While documents specify procedural expectations, experienced personnel possess knowledge of underlying reasons, sources of

variability, and critical weak signals. This risk can be reduced through joint workshops, shadowing, sending-site observation, receiving-site coaching, structured lessons-learned sessions, and retention of subject-matter experts during early commercial campaigns. A knowledge map should identify decisions reliant on individual experience and translate them into structured training, rationale documentation, or troubleshooting guides.

An additional significant risk is localization absent genuine capability. A project may achieve a local-production designation while remaining dependent on imported intermediates, foreign troubleshooting, external laboratories, or decisions from the sending site. While such arrangements may be acceptable during transitional phases, they should not be equated with mature localization. Transfer contracts should incorporate staged capability milestones, such as local batch-record ownership, qualified Saudi technical leads, analytical independence, local deviation leadership, approved alternative suppliers, reduced release lead times, and ultimately, the capacity to implement justified lifecycle improvements.

IX. PROPOSED SAUDI CMO LOCALIZATION FRAMEWORK

This review proposes a six-stage Saudi CMO localization framework. Stage one, strategic fit, selects products whose health-security importance, demand volume, technology profile, and economic case justify transfer. CMO assessment covers quality history, regulatory standing, capacity, product-class experience, facility fit, digital maturity, workforce depth, business continuity, and willingness to share risk. A decision to localize should specify the intended depth of capability, because the transfer design for packaging differs essentially from a transfer intended to establish full process ownership.

Stage two, knowledge mapping and gap filling, converts the sending-site knowledge base into a receiver-specific transfer plan. The teams identify critical quality attributes, critical process parameters, material attributes, known failure modes, analytical sensitivities, and regulatory commitments. Facility, equipment, laboratory, supplier, and personnel gaps are ranked through formal quality risk management. Each key gap is linked to a mitigation and evidence requirement. The key output is not a document inventory but a common scientific model of what must remain controlled at the Saudi site.

Stage three, analytical and engineering bridging, proves that the receiving laboratory and process train can generate interpretable, comparable evidence. Methods are transferred or verified first where appropriate. Engineering batches challenge scale-dependent assumptions and confirm practical operating ranges, sampling plans, hold times, and automation logic. Real-time or at-line technologies can strengthen process understanding, including continuous manufacturing applications (U.S. Food and Drug Administration, 2023b). PAT and integrated data systems enable Saudi sites to build capability rather than recreate legacy manufacturing architectures (Wasalathanthri et al., 2020; Chen et al., 2023; Neugebauer et al., 2024).

Stage four, validation and regulatory readiness, integrates PPQ, cleaning, computerized systems, shipping, stability, and, where relevant, aseptic process simulation into one readiness decision. The regulatory dossier strategy is finalized in parallel. The transfer team demonstrates that deviations are understood, acceptance criteria are fulfilled without uncontrolled intervention, and data packages are inspection-ready. SFDA GMP expectations should be embedded in site routines before the first commercial campaign rather than treated as an audit-preparation exercise (Saudi Food and Drug Authority, 2023).

Stage five, launch and continued verification, uses augmented monitoring to confirm ongoing performance. Recommended indicators include right-first-time batch execution, deviation recurrence, yield, cycle time, laboratory invalid rate, out-of-trend frequency, environmental or sterility-assurance signals where relevant, batch-release lead time, complaint trends, and stability performance. The receiver should progressively lead investigations and change assessments. A transfer is operationally mature when routine decisions no longer depend on continuous sending-site intervention.

Stage six, capability multiplication, converts one successful transfer into a platform for future products. The CMO standardizes reusable equipment knowledge, validation approaches, data structures, training modules, and supplier qualification practices. It can then shorten subsequent transfers, broaden therapeutic or dosage-form capability, and support export-oriented manufacturing. This stage connects localization with national industrial learning: the value of the first transfer is multiplied when its systems, competencies, and lessons reduce the cost and risk of the next one.

A maturity ladder can make progress visible. Level one is transactional localization, dominated by packaging or narrowly supervised execution. Level

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two is controlled product transfer with local GMP execution but continued external troubleshooting. Level three is process ownership, characterized by independent analytical release, investigation leadership, and local lifecycle management. Level four is platform capability, where the CMO can transfer multiple related products efficiently and sustain high digital and quality maturity. Level five is innovation-linked manufacturing, where local teams contribute process improvement, advanced analytics, development, or biomanufacturing know-how and can support international registrations. The ladder avoids a binary local-versus-imported classification and instead measures the depth of manufacturing competence.

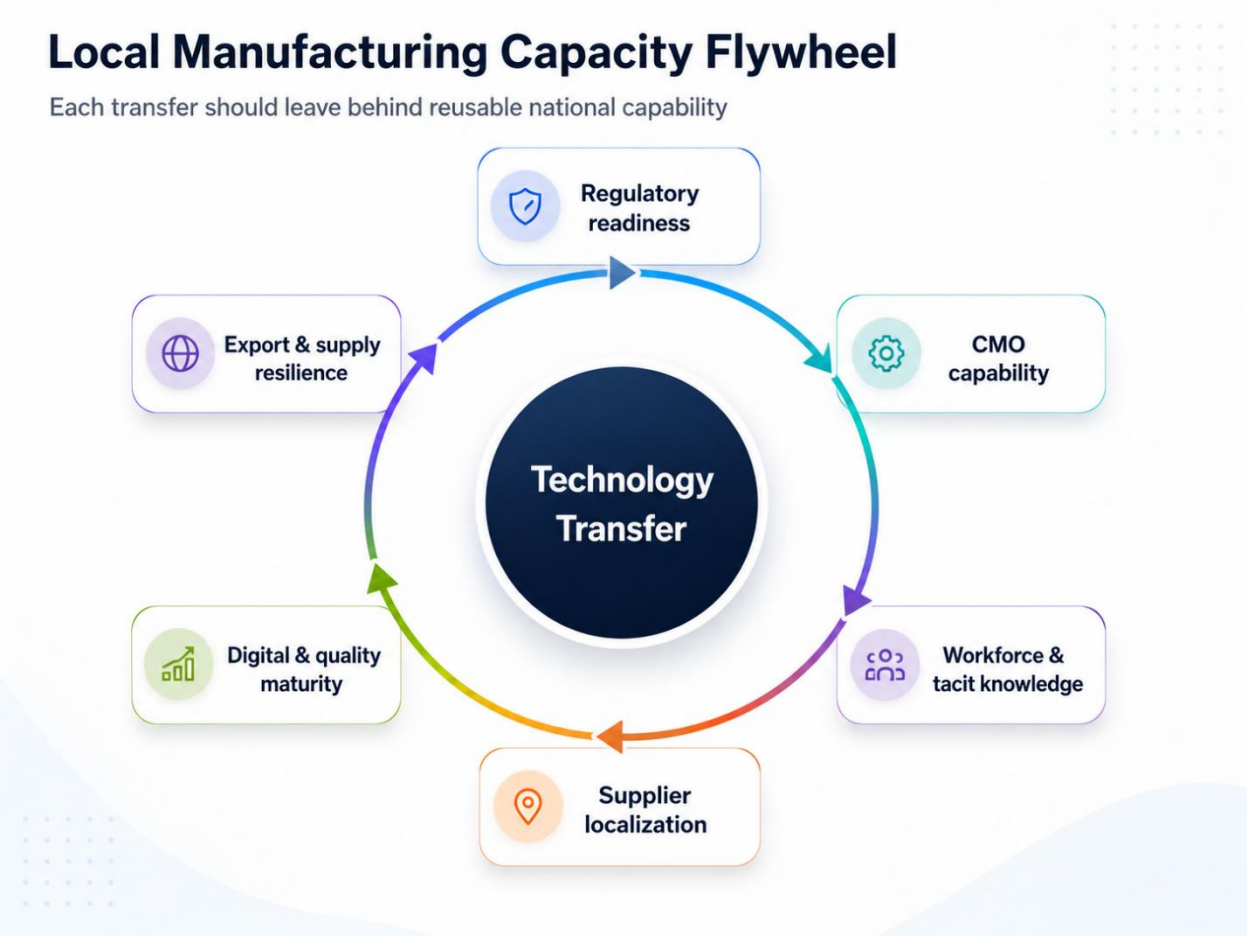

Figure 2. Local manufacturing capacity flywheel: technology transfer creates value when quality, workforce, suppliers, digital systems, and regulatory capability reinforce one another.

Table 2. Saudi localization barriers, transfer symptoms, interventions, and indicative KPIs.

Capacity barrier	Observable transfer symptom	Recommended intervention	Indicative KPI	Lead actors
Tacit knowledge gap	Repeated escalation to sending site; weak deviation hypotheses	Knowledge mapping; floor coaching; scenario-based competency assessment	Share of investigations led locally; critical-role competency rate	Product owner, CMO MS&T, Quality
Facility/equipment mismatch	Engineering variability; repeated parameter adjustment	Risk-based equipment comparability; modeling/PAT where justified	Critical gaps closed before PPQ; right-first-time PPQ	CMO engineering, MS&T, Quality

Analytical variability	Invalid runs, OOS ambiguity, inconsistent inter-lab results	Structured analytical transfer; instrument bridging; control-chart baselines	First-pass method-transfer rate; laboratory invalid rate	QC laboratories, analytical development
Regulatory lag	Validated site unable to supply market on planned date	Early CMC change map; integrated stability and filing plan	Validation-to-market-release lead time	Regulatory affairs, SFDA interface, Quality
Critical import dependence	Local fill/finish but single-source API/components	Dependency mapping; dual sourcing; strategic stocks; supplier development	Share of critical materials dual/local sourced; continuity-test result	Supply chain, procurement, suppliers
Workforce depth	Foreign SME dependence; slow troubleshooting	Role-based qualification; mentoring; industrial placements	Qualified Saudi technical FTEs; time to independent shift leadership	CMO, universities, workforce bodies
CMO governance / IP	Slow decisions; unclear change ownership; information withholding	Integrated governance; detailed quality agreement; protected knowledge channels	Issue-resolution cycle time; overdue change controls	Sponsor, CMO leadership, legal, Quality
Digital/data fragmentation	Manual reconciliation; weak CPV trend visibility	Validated integrated process/lab/quality data model	Batch review time; CPV data completeness; recurrence detection time	IT/OT, Quality, manufacturing science

X. DISCUSSION

The literature consistently supports the central proposition that pharmaceutical technology transfer is successful when knowledge becomes operational at the receiving site. WHO guidance establishes the organizational foundation, while recent case studies show that factors such as scale, equipment, sensors, laboratories, and facility conditions are able to significantly influence performance, even when the nominal process remains unchanged (World Health Organization, 2022; Christler et al., 2021; Vicente Martin et al., 2022). Regulatory lifecycle guidance further stresses that technology transfer should be managed as a controlled change, substantiated by scientific evidence, rather than as an isolated manufacturing project (European Medicines Agency, 2020; U.S. Food and Drug Administration, 2021).

Second, CMO development might be a strategic accelerator if governance is strong. A local CMO can spread facility, quality-system, analytical, and workforce investments across multiple sponsors. This may be more efficient than duplicating small dedicated sites, particularly for specialized technologies. Yet the CMO model also concentrates operational complexity. Selection criteria should therefore include quality maturity, transparent data practices, change-control discipline, project management, sponsor communication, and realistic capacity. The 5C perspective is useful because technical capability without communication, culture, and coordination multiple products over time.e multiple products over time a disciplined economic framework. Not all products warrant full localization, and excessive protectionism may increase costs or diminish supply diversity. Strategic determination should account for therapeutic importance, volume, technical feasibility, supplier concentration, emergency relevance, export potential, and total cost of ownership. The most effective policy is selective and capability-driven: prioritize localization where manufacturing knowledge delivers lasting health and industrial value, maintain diversified international sourcing to strengthen resilience, and leverage technology transfer to establish platforms capable of supporting multiple products over time.e multiple products over time.

XI. POLICY AND MANAGERIAL IMPLICATIONS

For policy makers, technology-transfer depth can be incorporated into localization incentives and procurement evaluation. Tender advantages may be linked to verified manufacturing steps, local technical employment, analytical capability, supplier-development milestones, validated continuity plans, and evidence of process ownership. Such criteria would discourage superficial localization while preserving flexibility for justified staged transfers.

Regulatory and industrial agencies can also coordinate early scientific advice for priority transfers so that manufacturing investment, filing strategy, and inspection readiness progress on compatible timelines. For product owners, the central managerial implication is to select Saudi CMOs based on lifecycle capability and strategic fit rather than quoted unit cost alone .Due diligence should test the partner's capacity to absorb knowledge, close gaps, protect data and intellectual property, maintain transparent quality communication, and retain competent staff. Contracts and quality agreements should define escalation routes, change-control rights, audit access, data ownership, deviation timelines, and the availability of sending-site experts during transition. Transfer governance should use one integrated plan rather than separate technical, quality, regulatory, and commercial schedules that discover conflicts late.

For Saudi CMOs, the priority is to turn individual transfers into reusable organizational capability. Investments in training academies, platform equipment knowledge, analytical centers of excellence, standardized risk tools, electronic knowledge repositories, and strong continued-verification systems can shorten future transfers. Performance dashboards should include both project and capability measures. Useful indicators include percentage of major gaps closed before engineering batches, analytical-transfer first-pass success, right-first-time PPQ, time from validation to market release, deviation recurrence, percentage of investigations led locally, Saudi technical full-time equivalents qualified for critical roles, local or dual-sourced critical materials, release lead time, and export registrations supported from the site.

XII. LIMITATIONS

This review has several limitations. It uses an integrative methodology rather than a registered systematic-review protocol, and the heterogeneous source base does not support meta-analysis. Public information on proprietary commercial transfers is limited because detailed failures, process ranges, and CMO performance are often confidential. Some evidence comes from specialized dosage forms or international settings and therefore requires contextual interpretation before application to a Saudi site. The review also focuses on sources published from 2020 through 2025, which strengthens contemporaneity but excludes older foundational technology-transfer literature. Finally, the proposed maturity framework is conceptual and should be supported through case studies, expert consensus, and longitudinal performance data from Saudi manufacturers and CMOs.

XIII. CONCLUSION

Technology transfer and CMO site transfer can greatly improve Saudi Arabia's local pharmaceutical manufacturing capacity when structured as knowledge-transfer and capability-building initiatives, rather than simple changes in production location. The evidence supports a stage-gated approach that begins withstrategic product and manufacturing-partner selection, followed by knowledge mapping, risk-based gap resolution, analytical and engineering bridging, integrated validation, regulatory readiness, and comprehensive post-launch verification. Throughout these stages, the critical requirement is the receiving site's ability to independently understand and control the product.

Saudi localization policy provides a favorable commercial and strategic context, while SFDA quality expectations create the regulatory foundation for credible manufacturing. The next step is to connect rewards with maturity indicators that reveal whether local sites possess durable analytical, process, quality, digital, supplier, and workforce capability. A successful transfer should therefore be judged by more than the release of a first Saudi-made batch. Its stronger indicators are reproducible performance, local investigation leadership, managed lifecycle change, resilient supply, progressive reduction of essential dependencies, and the ability to transfer the next product faster and with less external support. Used in this way, technology transfer remains both a pharmaceutical quality discipline and a practical engine of Vision 2030 industrial capability.

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