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Original Research Article

Localization of Advanced Drug-Delivery Manufacturing in Saudi Arabia Through Technology Transfer and Pharmaceutical Process Scale-Up

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Abstract: Saudi Arabia is enlarging its pharmaceutical and biotechnology base as part of a wider retreat from import dependence. For advanced drug-delivery products, however, adding capacity is not the same as adding capability. Performance in these products is governed by particle size, polymer microstructure, mixing history, sterile handling, device geometry, release kinetics and analytical control, and these variables prove stubbornly difficult to reproduce once a manufacturing site changes. This review examines how technology transfer and process scale-up must be combined if advanced drug-delivery manufacture is to take root in the Kingdom, covering modified-release oral products, hot-melt-extruded systems, lipid and polymeric nanoparticles, long-acting injectables, microneedle platforms and digitally manufactured dosage forms. A structured narrative method was used to assemble peer-reviewed evidence published between 2020 and 2025 together with the quality frameworks issued in that period. The Kingdom's starting position is quantified rather than asserted: analysis of the Saudi Food and Drug Authority formulary shows that 22.55% of registered items are manufactured domestically against 43.86% originating in Europe, that four producers account for 63% of domestic output, and that approximately 86% of surveyed national manufacturers cannot at present enable nanotechnology-based medicines even though more than 93% regard such products as important. Against this baseline the review argues that localization should be treated as a capability-transfer programme rather than an equipment-purchase exercise, requiring a product-specific knowledge package covering critical material attributes, critical process parameters, critical quality attributes, analytical procedures, process models and change-control logic. A phased pathway is proposed in which secondary operations and sterile fill-and-finish establish a learning base, followed by formulation ownership, platform manufacturing, advanced process control and regional export.

Keywords: Saudi Arabia, Pharmaceutical Localization, Technology Transfer, Process Scale-Up, Advanced Drug Delivery, Continuous Manufacturing, Nanomedicine, Long-Acting Injectables, Process Analytical Technology.

1. INTRODUCTION

Pharmaceutical localization is now understood as a matter of health security as much as industrial policy. Saudi Arabia operates the largest medicines market in the Middle East and North Africa, yet a long-standing reliance on imported

finished products and imported inputs leaves the health system exposed to external disruption. Successive evaluations of the Saudi market identify the same constraints: limited research capability, a narrow range of manufactured dosage forms, human-resource shortages, supply-chain dependence, and a weak link between academic innovation and industrial production [1–3].

The policy environment has changed considerably. The National Biotechnology Strategy, launched on 25 January 2024, sets out four strategic plays — vaccines, biomanufacturing and localization, genomics, and plant optimization — with the ambition of making the Kingdom the regional biotechnology leader by 2030 and a global hub by 2040, contributing roughly 3% of non-oil gross domestic product, or about SAR 130 billion, by that date [4]. Regulatory credibility has advanced in parallel: on 30 October 2023 the World Health Organization confirmed that the Saudi Food and Drug Authority had reached Maturity Level 4 under the Global Benchmarking Tool, the first authority in the Eastern Mediterranean Region and the third worldwide to do so [5]. Demand-side instruments have followed. In September 2020 the Local Content and Government Procurement Authority launched an Additional Price Preference initiative covering 208 national products across the pharmaceutical, medical-supply and wider industrial sectors, under which the statutory ten per cent preference in government tendering may rise to a sector-dependent maximum of thirty per cent, with a further increment available where the active pharmaceutical ingredient is made domestically [6].

This is a favourable environment for investment. It does not, by itself, deliver advanced manufacturing. Localizing a technologically sophisticated medicine is not achieved by constructing a facility, licensing a product or transferring a batch record.

Advanced drug-delivery systems are demanding precisely because the process forms part of the product's clinical function. A modified-release tablet depends on controlled polymer distribution and a defined granule density; an amorphous solid dispersion on its thermal and shear history; a lipid nanoparticle on tight control of mixing time, flow-rate ratio, particle size and encapsulation; a poly(lactic-co-glycolic acid) microsphere on polymer molecular characteristics and solvent-removal conditions; a microneedle patch couples drug potency to geometry, mechanical strength, dissolution behaviour and device integrity. A transfer that copies nominal equipment settings without reproducing the underlying mechanisms can yield a product that passes routine release testing while deviating in clinically significant performance. The central problem is therefore the transfer of manufacturing knowledge and control capability, not the relocation of machinery.

This review approaches the question from the standpoint of implementation. Its objective is an integrated framework for localizing advanced drug-delivery manufacture in Saudi Arabia, linking technology-transfer maturity to process scale-up, control strategy and regulatory comparability. Four aims structure the analysis: to identify the platforms whose manufacturing features materially affect transferability; to define the knowledge package required to move a product between sites; to compare scale-up strategies across continuous, nano-enabled, sterile and device-associated processes; and to propose a phased roadmap with capability milestones matched to Saudi industrial conditions. The emphasis falls on principles that support repeated localization programmes across a portfolio.

2. REVIEW METHODOLOGY

A structured narrative design was selected because the research question spans formulation science, process engineering, technology transfer, regulatory quality systems and national industrial policy. The intent was integrative rather than meta-analytic, but the search was conducted transparently.

Searches concentrated on records published between 2020 and 2025 and combined the terms: pharmaceutical localization, technology transfer, process scale-up, continuous manufacturing, twin-screw granulation, hot-melt extrusion, process analytical technology, digital twin, lipid nanoparticle manufacturing, microfluidics, long-acting injectable, PLGA microsphere, microneedle manufacturing, Saudi pharmaceutical industry, and biopharmaceutical manufacturing. Every peer-reviewed record cited here was verified against PubMed or publisher metadata at the level of author list, journal, volume, pagination and digital object identifier. Quality and manufacturing frameworks were taken from official sources issued by the International Council for Harmonisation and the United States Food and Drug Administration [7–11]. Statements about Saudi industrial and regulatory developments were traced to primary announcements from the responsible institution rather than to secondary reporting.

Quantitative statements about the Saudi baseline were drawn only from primary studies reporting an identifiable dataset and sampling frame. Market-research estimates were excluded, because published values for domestic market share diverge substantially between vendors and cannot be reconciled from the public record.

Sources were included if they contributed to one or more of four evidence domains: Saudi localization readiness; manufacturing scale-up or transfer; control strategy and analytical monitoring; and industrialization of advanced delivery platforms. Preference was given to primary process studies and official regulatory documents. Sources were excluded if they fell outside the 2020–2025 window, lacked verifiable bibliographic detail, or addressed delivery efficacy without manufacturing relevance.

Because the evidence varies by platform, scale and outcome, numerical pooling was inappropriate. Findings were synthesized by mechanism-to-capability mapping: for each platform, the critical materials, unit operations, scale-sensitive variables, analytical requirements and receiving-site capabilities were examined in turn. This permits comparison of transfer risk across technically dissimilar dosage forms.

3. The Saudi Baseline: What the Data Show

Saudi Arabia starts from a stronger position than a simple import-substitution narrative implies. Local companies already conduct conventional formulation, packaging and a range of manufacturing operations, and policy is increasingly supportive of higher-value production. The published data nevertheless describe a steep capability gradient, and it is worth stating the numbers rather than the impression.

Alshehri and colleagues analysed the SFDA drug formulary covering 9,457 registered items and found that 43.86% were manufactured in Europe, 22.55% in Saudi Arabia, 20.47% in China and India, 10.24% in the Americas and 2.61% elsewhere; 90.62% were prescription products [3]. The same analysis reports that Saudi firms are well equipped to produce generics in conventional dosage forms such as tablets and capsules, but not inhalers, biologicals or plasma-derived products (Figure 1).

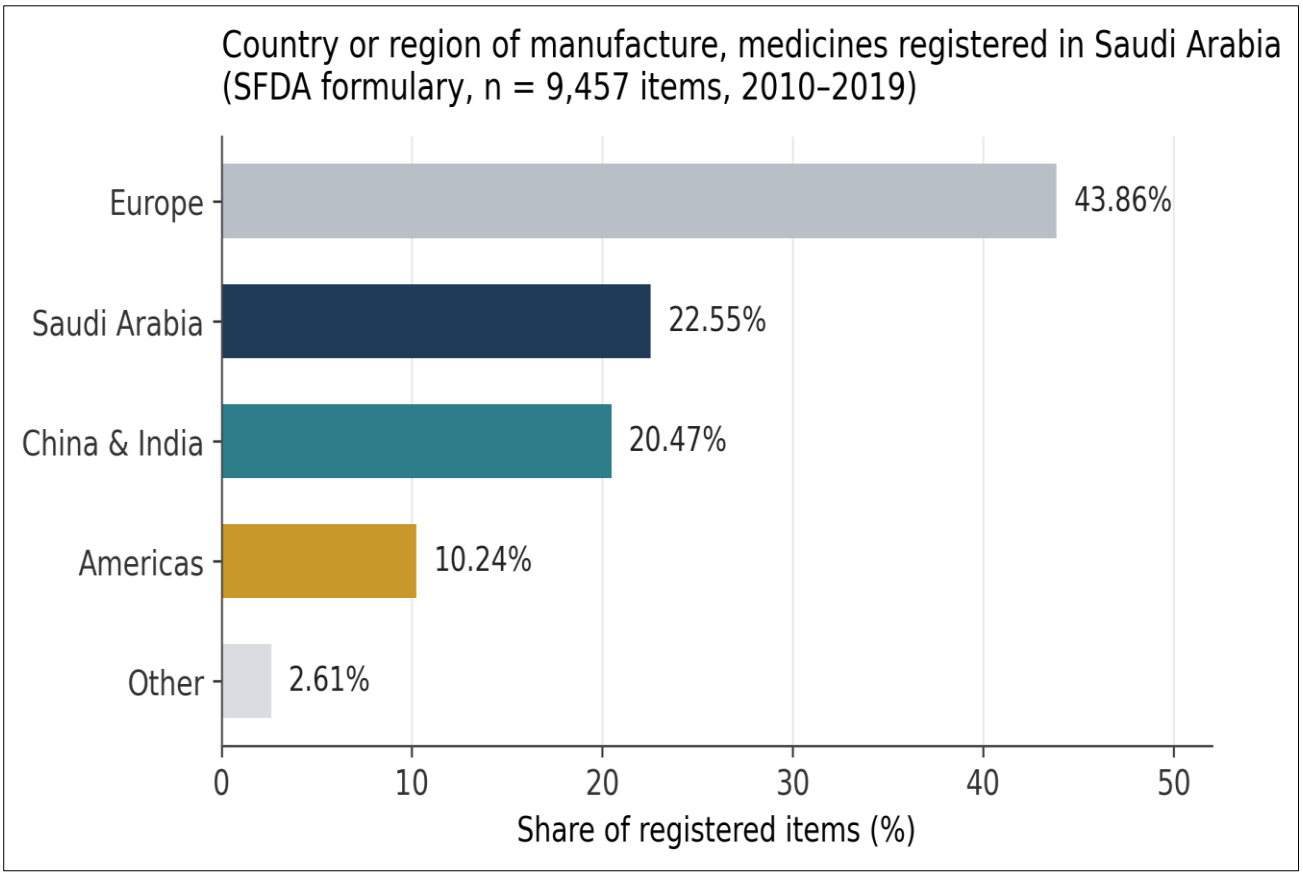

Figure 1: Country or region of manufacture for medicines registered in the Saudi market. Data from Alshehri *et al.*, (2023), SFDA formulary, n = 9,457 registered items covering 2010–2019 [3].

Domestic output is also concentrated. Among the 2,133 locally manufactured registered items, Pharmaceutical Solution Industries accounted for 21%, Tabuk Pharmaceutical Manufacturing 18%, SPIMACO 15% and Jamjoom Pharma 9% — four firms producing 63% of domestic items [3]. (Figure 2). Concentration of this kind matters for localization policy, because it means the national learning curve for any new platform will in practice be climbed by a small number of organizations.

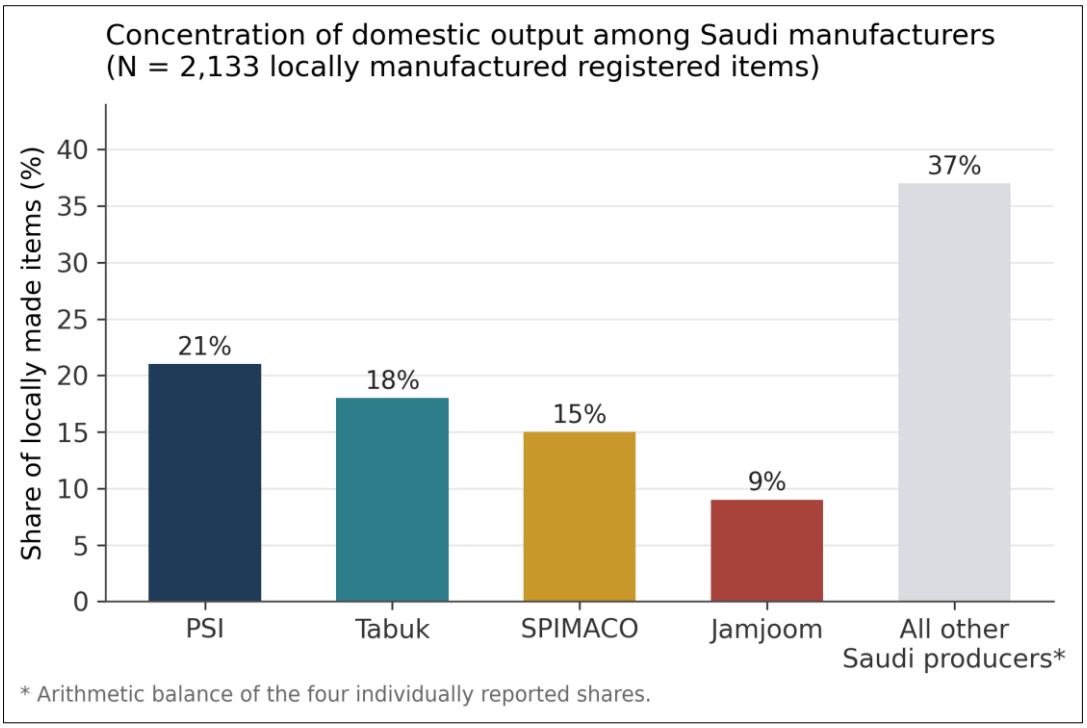

Figure 2: Concentration of domestic output among Saudi manufacturers, N = 2,133 locally manufactured registered items. Data from Alshehri *et al.*, (2023) [3], the residual category is the arithmetic balance of the four individually reported shares

The advanced-platform gap is sharper still, and its shape is instructive. Halwani and colleagues surveyed the national pharmaceutical industries and found that approximately 86% of leading Saudi companies could not enable nanotechnology-based medicines within their manufacturing operations, while more than 93% agreed that developing such products represents an important step for the sector [2]. (Figure 3). Respondents reported deficits in specialized expertise, facilities, scale-up resources and regulatory clarity. The gap is therefore one of capability rather than intent, and that distinction determines what a localization programme must supply: intent can be created by policy; capability cannot.

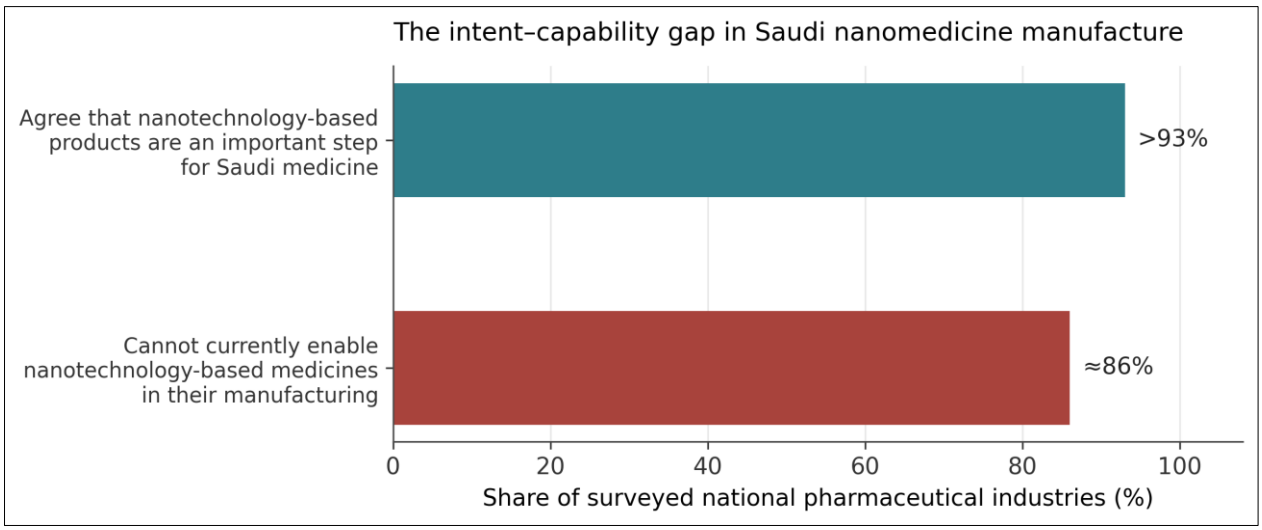

Figure 3: The intent–capability gap in Saudi nanomedicine manufacture. Data from Halwani *et al.*, (2023), survey of national pharmaceutical industries [2]

The localization opportunity is best expressed as an increase in technological depth. At the first level sit well-defined operations performed locally: packaging, labelling, conventional fill-and-finish. The second is controlled transfer of drug-product formulation and routine analytical testing.

The third is ownership of scale-sensitive platform operations — continuous granulation, hot-melt extrusion, sterile nanoparticle formulation, microsphere production, microneedle moulding. The fourth is local process development and support of post-approval change without recourse to the originator. The fifth is platform innovation. The hierarchy matters because a facility can be physically local while process knowledge, raw-material decisions, troubleshooting authority and release analytics remain outside the local organization.

Recent industrial activity has begun to populate the lower rungs. Lifera, launched by the Public Investment Fund in June 2023 as a commercial-scale contract development and manufacturing organization, is building capacity in insulins and other peptides, vaccines, monoclonal antibodies and other biologics [12]. In July 2023 it signed a memorandum of understanding with Sanofi and Arabio for local manufacture and supply of vaccines drawn from the mandatory immunization schedule, with Sanofi contributing biotechnological expertise and know-how [13]. In October 2025 it announced seven further partnerships: a contract development and manufacturing memorandum with Jamjoom Pharma; four vaccine-localization memoranda with MSD, Pfizer, Sanofi and GSK; a cell-and-gene-therapy memorandum with King Faisal Specialist Hospital and Research Centre; and a genomic sequencing memorandum between Lean Business Services and CENTOGENE [14]. Figure 4 places these commitments alongside the regulatory milestones of the same period.

Figure 4: Policy, regulatory and industrial milestones shaping advanced-manufacturing localization in Saudi Arabia, 2020–2025. Compiled from references [4–14]

Readiness at the receiving site means something more specific than signed agreements. It means engineers who understand scale-dependent mass transfer, formulation scientists who can interpret material variation, analysts capable of orthogonal characterization, quality staff who can handle comparability and change control, and qualified suppliers of pharmaceutical-grade lipids, polymers, sterile single-use components, filters and sensors. Localization programmes should therefore measure domestic value not by spend or headcount, but by the proportion of critical decisions, investigations, analytical methods and process improvements executed independently inside the Kingdom.

4. The Technology-Transfer Architecture

Technology transfer is most reliable when it begins with a knowledge map rather than a document handover. The sending site should establish the relationships between the quality target product profile, the critical quality attributes, the critical material attributes, the critical process parameters and the control strategy. For a conventional product, a manufacturing formula and a validated analytical procedure may capture most of the operational knowledge. For an advanced delivery system, much of the knowledge is tacit and resides in start-up sequences, order of addition, hold-time sensitivity, equipment geometry, shear environment, filter behaviour, sampling technique and the interpretation of in-process signals.

A receiving site in Saudi Arabia should therefore require a package that explains why each parameter matters, what failure modes are expected, which variables interact, how deviations have historically been resolved, and which ranges are supported by development data. This is consistent with the lifecycle perspective set out in current quality-risk-management and analytical-development guidance [8, 9].

A practical transfer package resolves into six connected layers. Product knowledge covers composition, physicochemical properties, release mechanism, degradation pathways and clinical performance. Material knowledge covers supplier history, grade sensitivity, particle-size distribution, polymer or lipid variability and substitution rules. Process knowledge covers unit-operation mechanisms, scale-independent and scale-dependent parameters, residence time, heat and mass transfer, and hold conditions. Analytical knowledge covers method robustness, reference standards, in-process sensors, multivariate models and method-transfer acceptance criteria. Operational knowledge covers cleaning, sterilization, environmental classification, changeover and deviation patterns. Governance covers responsibilities between sites, change-control thresholds, data ownership, intellectual-property boundaries and the duration of technical support.

Comparability must be designed before engineering batches begin. The receiving site should know which attributes must be equivalent, which may deviate with justification, and which require monitoring across batches. For modified-release products, dissolution profiles and mechanical properties dominate. For nanoparticles, particle-size distribution, polydispersity, encapsulation efficiency, potency, impurity profile and release behaviour all matter. For PLGA microspheres, attention falls on polymer characteristics, residual solvent, particle morphology, burst and sustained release. For microneedles, drug content must be assessed together with geometry, insertion force, fracture resistance and packaging integrity. An effective protocol therefore combines release specifications with process-performance evidence, so that localization is demonstrated by mechanistic comparability rather than by pass-or-fail testing.

Analytical method transfer is a frequently unrecognized bottleneck. Advanced platforms often depend on methods sensitive to sample handling, dispersion state, instrument configuration, chemometric calibration or analyst technique. ICH Q14 promotes a science- and risk-based approach to analytical procedure development, its companion Q2(R2) sets out the corresponding validation expectations, and Q9(R1) emphasizes formality proportionate to risk and knowledge [8–10]. Transfer to a receiving laboratory should therefore include training data, a system-suitability rationale, defined robustness boundaries, instrument-equivalence studies and pre-defined investigation rules. Where process analytical technology is used, the calibration model must be treated as a controlled manufacturing asset, with versioning, applicability ranges and drift monitoring defined before routine production.

5. Scale-Up Mechanics across Delivery Platforms

Scale-up is not the production of a larger batch. The correct scaling factor depends on the physical mechanism that determines product quality, and that mechanism differs by platform.

Continuous solid-dosage manufacture illustrates the point with unusual clarity. Moving from batch high-shear granulation to twin-screw wet granulation may require different operating conditions to reach equivalent end-point properties, because material experiences mixing and wetting through a continuous residence-time distribution rather than a single batch history. Kotamarthy and colleagues demonstrated performance-based translation between the two for an extended-release metoprolol succinate product, achieving dissolution profiles comparable to the reference tablets with a similarity factor above 50 [15]. Their data also show how sensitive the outcome is: raising screw speed from 200 to 800 rpm reduced metoprolol released at 20 hours from 94.4% to 80.6%, a shift attributed to reduced residence time and altered axial shear mixing (Figure 5). Nothing in the formulation changed. The localization lesson is that scale-up criteria must be founded on conserved product and material states, not on replicated machine settings.

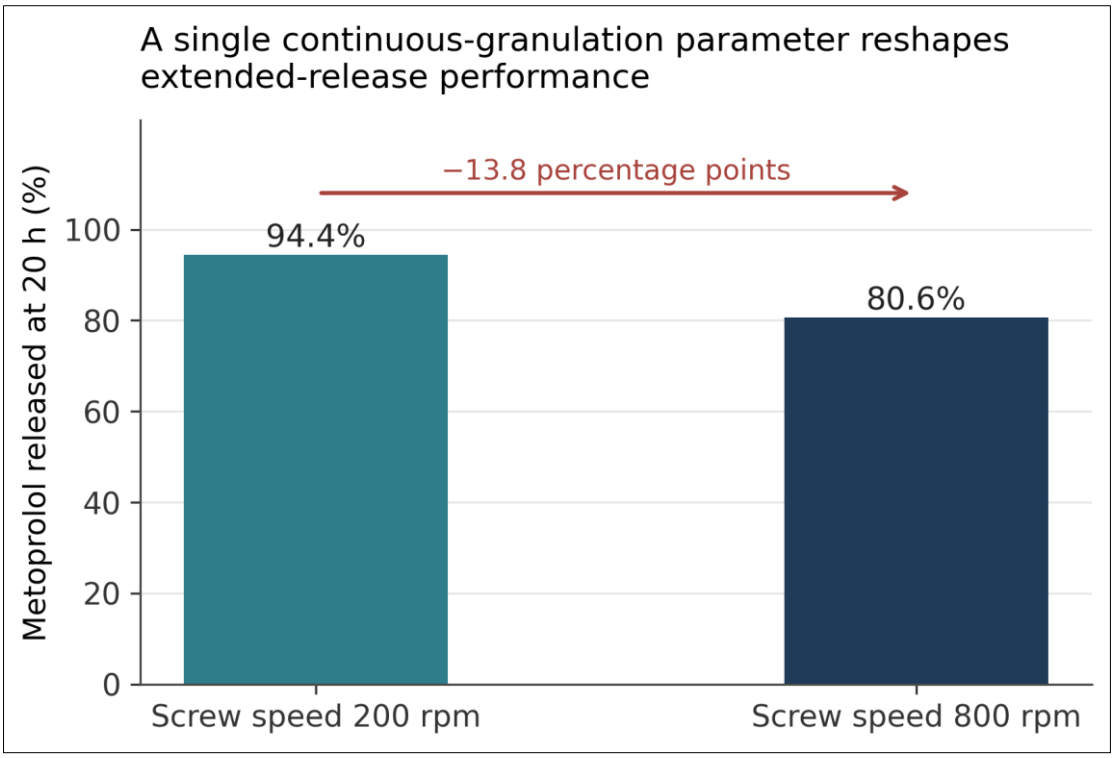

Figure 5: Effect of twin-screw granulator screw speed on extended-release performance of metoprolol succinate tablets. Data from Kotamarthy *et al.*, (2022), Table 6 [15]. Dissolution profiles of tablets from optimized twin-screw granules were comparable to the high-shear reference (similarity factor above 50)

Continuous lines also change how traceability and disturbance management are handled. The residence-time distribution describes how an incoming material disturbance propagates through feeders, blenders, granulators and presses; models of this kind define diversion windows and prevent unnecessary rejection after transient events. ICH Q13 provides the regulatory framework for continuous manufacturing and is directly relevant when a Saudi project deploys a technology different from the sending site's batch configuration [7].

Hot-melt extrusion is an attractive localization platform because it combines mixing, thermal processing and shaping in one continuous operation and supports amorphous solid dispersions, modified-release systems and films. Its apparent simplicity misleads. Quality depends on specific mechanical energy, melt temperature, residence time, feed uniformity, screw design, die pressure, cooling, and the thermal stability of drug and excipients. Current reviews stress that meaningful scale-up demands attention to energy input, geometry, throughput and in-line monitoring rather than proportional increases in batch size [16].

Nanoparticle production presents a different class of problem, because product attributes are established within milliseconds of mixing. For lipid nanoparticles and comparable self-assembling systems, total flow rate, flow-rate ratio, solvent composition, temperature, lipid concentration, channel geometry and mixing intensity all influence particle size and encapsulation. Microfluidic approaches are attractive because they can be scaled by parallelizing mixing units rather than by enlarging a single mixer. Shepherd and colleagues built a silicon-and-glass platform incorporating 1×, 10× and 256× nanoparticle-generating units, varying production from 0.1 to 17 litres per hour — the upper figure equivalent to roughly 8.5 g of mRNA, or some 34,000 vaccine doses, per hour — while demonstrating that particle physical properties and in vivo potency were unchanged as throughput scaled [17]. (Figure 6). This is direct evidence for preserving microscale hydrodynamics rather than scaling a mixer geometrically.

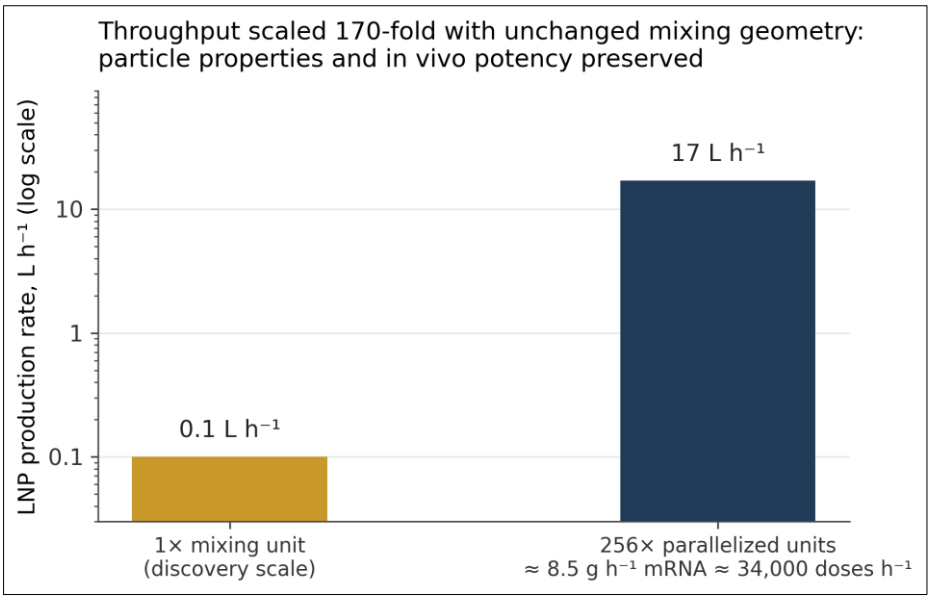

Figure 6: Throughput scaling of lipid nanoparticle production on a parallelized silicon–glass microfluidic platform. Data from Shepherd *et al.*, (2023) [17], the platform also includes a 10× configuration, and mixing geometry and flow conditions are unchanged across all three scales

The receiving-site challenge extends well beyond the mixer. Downstream steps include solvent removal, buffer exchange, filtration, concentration, sterile handling, aseptic filling and cold-chain storage, and each can alter particle size, aggregation state, encapsulation, potency or impurity level. A Saudi programme should therefore define the boundary of the platform being transferred — formulation only, formulation plus fill-and-finish, or full drug-substance and drug-product manufacture. Partial localization can be strategically sound, but interface risks must be made explicit, because quality accountability fragments when plasmid, RNA, lipids, formulation, filling and testing sit with different organizations.

Long-acting injectables show how much excipient knowledge and microstructure matter. PLGA microspheres can release drug over weeks to months, but performance depends on polymer molecular weight, lactide-to-glycolide ratio, end groups, solvent system, emulsification, extraction, drying, particle-size distribution, porosity and drug localization within the particle. A receiving site must not treat a polymer grade as a commodity input: a change of supplier, or minor variation in polymer characteristics, can alter release kinetics even when compendial identity is unchanged. Scale-up should therefore include polymer fingerprinting, mixing-energy equivalence, solvent-transfer analysis and discriminating in vitro release methods.

Microneedles and digitally manufactured dosage forms introduce a product–device interface. Microneedle quality is influenced by mould fidelity, polymer viscosity, casting or printing conditions, drying, demoulding, needle geometry, drug distribution and mechanical strength; large-scale manufacture and reproducibility remain the principal barriers to adoption. Three-dimensional printing offers flexible production and intricate geometry but requires control of feedstock properties, layer deposition, print parameters and dose uniformity. For now, localization should concentrate on standardized designs with validated materials under centralized quality control, building device-manufacturing capability without relaxing pharmaceutical controls.

Table 1: Localization matrix for advanced drug-delivery platforms

Platform	Scale-sensitive features	Transfer-critical controls	Saudi localization implication
Modified-release oral / continuous solids	Granule density; residence time; feeder dynamics; screw configuration	Material attributes; liquid-to-solid ratio; screw speed and configuration; residence-time distribution; tablet strength; dissolution	Strong early platform where demand is stable; builds reusable engineering and PAT capability
Hot-melt-extruded systems	Specific mechanical energy; melt temperature;	Rheology; thermal stability; feed uniformity; torque;	Compact continuous platform with portfolio potential; requires polymer

Platform	Scale-sensitive features	Transfer-critical controls	Saudi localization implication
	residence time; die pressure; cooling history	temperature profile; degradation markers	and thermal-process expertise
Lipid and polymeric nanoparticles	Mixing time; flow-rate ratio; total flow; solvent composition; downstream buffer exchange and filtration	Particle size and polydispersity; encapsulation; potency; impurities; morphology; sterile integrity	High strategic value, but should follow maturation of advanced analytics and sterile handling
PLGA long-acting injectables	Polymer variability; emulsification energy; solvent extraction; drying; particle formation	Polymer fingerprint; residual solvent; particle size; burst and sustained release; morphology	Suitable once sterile and complex-product analytics mature; supplier control is decisive
Microneedle and device-associated delivery	Mould or print fidelity; drying; geometry; material mechanics; dose distribution	Needle geometry; insertion and fracture force; content uniformity; release; packaging integrity	Build standardized device-manufacturing capability first; avoid highly customized early production
mRNA and biologic delivery	Drug-substance purity; sensitive formulation; aseptic interfaces; cold chain	Identity and potency; RNA integrity; encapsulation; sterility; particulates; temperature history	Best approached as a staged network: formulation and fill-and-finish first, then drug-substance ownership

6. Quality By Design, Process Analytical Technology and Digital Control

Quality by design supplies a common language across these platforms. Before transfer, the sending and receiving teams should agree a risk-ranked map of how material attributes and process variables affect product quality. The purpose is not an exhaustive risk register but a decision about which sources of variability must be controlled directly, which can be monitored, and which are already constrained by supplier specification or equipment design. ICH Q9(R1) is directly relevant here, emphasizing appropriate formality, effective knowledge management and reduced subjectivity in quality-risk decisions [8]. In a localization programme the highest risks combine high product impact with low familiarity at the receiving site: a raw material never characterized locally, a parameter controlled differently on the new equipment, or a method whose robustness depends on informal technique.

Process analytical technology converts some of these risks into observable process states. Near-infrared spectroscopy has been studied extensively for blend monitoring, but results are affected by probe location, powder density, sampling volume, flow behaviour and calibration robustness. The lesson is that the physical basis of an in-line signal must be understood rather than assumed, since a chemometric model is not universally portable. A method transferred to a Saudi line should be challenged against the expected variation in raw materials, humidity, throughput, equipment condition and product concentration, and calibration transfer deserves the same rigour as method transfer.

Digital models add a further degree of transferability. Model-predictive control and digital-twin approaches allow disturbances to be simulated, control actions tested and operating envelopes established without exposing commercially sensitive information. Model governance is then essential: the quality system must address model structure, parameter provenance, training data, assumptions, uncertainty, software version and revalidation criteria. Digitalization should not conceal weak process understanding; its function is to make that understanding explicit and transferable.

Real-time release testing should be treated as an outcome of maturity rather than an entry requirement. A receiving site needs stable feeders, qualified sensors, robust calibrations, a functioning deviation system and demonstrated process understanding first. Once those are in place, continuous data reduce end-product sampling and shorten feedback cycles. ICH Q13 and the FDA's Advanced Manufacturing Technologies Designation Program, finalized in December 2024 under section 506L of the Federal Food, Drug, and Cosmetic Act, both indicate a regulatory climate increasingly willing to engage with advanced manufacturing where the evidence supports it [7-11]. For Saudi projects, early scientific dialogue with the SFDA can establish which changes are justifiable on comparability grounds and which require broader development or clinical bridging — a distinction that

matters most when a site change and a technology change occur together.

7. A Staged Pathway for Saudi Localization

A localization initiative should proceed in stages, each designed to establish durable capability rather than to complete a single batch. The first phase establishes governance, qualifies suppliers, sets document control and conducts local testing for products still manufactured abroad. The second adds secondary packaging, device assembly and selected sterile fill-and-finish, building competence in environmental control, line clearance, container-closure systems, visual inspection and batch release. The third transfers full drug-product formulation, but only for platforms whose materials and process mechanisms are well understood — continuous oral solids, hot-melt-extruded products, or established sterile formulations with strong development packages. The fourth adds nanoparticles, microspheres and complex combination products, together with dedicated characterization and process-development laboratories. The fifth targets platform ownership, lifecycle optimization, local supplier development and export.

Product selection should be guided by a localization readiness score rather than by market size alone. Priority products should combine public-health importance, stable demand, a technically transferable process, available or developable local talent, acceptable intellectual-property terms and a realistic route to qualified raw materials. A complex platform dependent on a single proprietary lipid supplier, a fragile cold chain and analytical competencies that do not yet exist locally may deliver symbolic localization with little real resilience. Portfolio planning should therefore maximize learning spillovers, so that each transfer makes the next one easier by broadening shared analytical, engineering, validation and supplier capability.

Workforce development belongs in the technology-transfer contract, because training limited to equipment operation is insufficient. Saudi scientists and engineers should participate in development batches at the source site, in deviation investigations, in design-of-experiments studies, in analytical method development and on change-control boards. Competence should be assessed by problem-solving capability rather than by attendance certificates. The insulin programme run through Lifera's subsidiary SaudiBio illustrates the model: the 2024 agreement with Novo Nordisk covers local formulation, filling and finishing [18], and the company reports having trained sixty staff at Novo Nordisk facilities abroad while building that capability [19]. Saudi localization studies consistently identify human capital as the binding constraint [1–3], advanced delivery manufacture intensifies it, because troubleshooting requires interdisciplinary reasoning across chemistry, materials, mechanics, biology, analytics and automation.

Supplier localization should be staged as well. Localizing every excipient at once is unrealistic, and forced substitution can raise quality risk. The first objective is supply visibility and dual sourcing; then local testing and technical agreements; then selective development of domestic suppliers for high-volume or strategically important materials. For complex delivery systems, supplier qualification must extend beyond compendial compliance wherever functional properties matter — polymer molecular characteristics, lipid impurity profiles, membrane properties or device-resin moisture content can all affect performance. Local suppliers should be included in change notification and trend monitoring. This builds resilience without confusing geographical proximity with equivalence.

A formal technology-transfer scorecard should be reviewed after engineering, after validation, at launch and after the first commercial year. It must distinguish equipment readiness from knowledge readiness, because a qualified machine does not demonstrate that the receiving organization can diagnose unexpected process behaviour. Evidence of maturity includes independent interpretation of process trends, timely closure of deviations and documented decisions on material variability. A lessons-learned review after each transfer should update platform standards, training modules, supplier requirements and model assumptions for the next product.

Regulatory strategy and economics determine whether a technically successful transfer becomes sustainable manufacturing. Site change, equipment change, scale increase, raw-material change and analytical change interact; bundling many of them into one submission raises the comparability burden. Sequencing changes so that causal interpretation remains possible is a practical risk-reduction measure [7–9]. Stability programmes should account for Saudi distribution conditions, excursion risk and cold-chain dependence.

Economic assessment should cover capability formation, not unit cost alone. Early local batches may cost more because of lower utilization, imported inputs, training, validation and duplicated testing. Those costs are justified if the programme reduces shortage risk or enables portfolio expansion. The stronger business case is usually a platform case: a continuous oral solid line, a microfluidic nanoparticle suite or a long-acting injectable capability should support several products over time.

Contracts must allow technical latitude for local optimization, since a plant able to execute only one licensed recipe without process authority remains externally dependent even while producing the finished dose domestically.

8. Research Gaps and Future Priorities

Future work should move from descriptive localization metrics towards measurable manufacturing capability. Useful indicators include the proportion of critical analytical methods executed locally; deviations resolved without originator intervention; local ownership of process models; the time required to introduce a second product on the same platform; qualified local or regional suppliers for critical materials; first-pass scale-up success; and the ability to support regulatory variations using locally generated evidence. Comparative case studies across Saudi transfers would help identify which contract structures, training models and regulator interactions best retain tacit knowledge. Research is also needed on climate-resilient packaging and stability strategies for complex products, particularly cold-chain-sensitive nanomedicines and biologics.

A second priority is platform testbeds where universities, manufacturers, hospitals and regulators can study scale-up before a commercial programme is committed. Pilot continuous-manufacturing lines, microfluidic formulation skids, sterile development suites and advanced characterization laboratories would reduce the cost of learning for individual companies, especially where equipment is expensive but demand does not yet justify full utilization. The long-term objective is an ecosystem in which Saudi teams formulate, scale, characterize, transfer and regulate advanced products as an integrated domestic activity.

9. CONCLUSION

Localization of advanced drug-delivery manufacturing in Saudi Arabia should be treated as a transfer of capability rather than of production volume. The most valuable asset is the causal knowledge connecting materials, process conditions, analytical signals and final product performance. Continuous manufacturing, hot-melt extrusion, nanoparticle formulation, long-acting injectables, microneedles and digitally manufactured products each expose different scale-up sensitivities, yet all can be managed through the same disciplined architecture: define the quality target, identify critical variables, transfer both tacit and documented knowledge, establish discriminating analytics, demonstrate mechanistic comparability, and retain learning through the quality system. Given a domestic manufacturing share of 22.55% of registered items, and roughly 86% of national manufacturers reporting no current nanomedicine capability against more than 93% who consider it important, the phased pathway proposed here — beginning with lower-risk operations and progressing towards formulation ownership, advanced platform manufacture, lifecycle optimization and export — is realistic rather than conservative. Where workforce development, supplier qualification, digital process understanding and regulatory engagement are built into each transfer, localization can produce resilient domestic manufacturing rather than geographically relocated dependence.

REFERENCES

1. Tawfik EA, Tawfik AF, Alajmi AM, Badr MY, Al-jedai A, Almozain NH, Bukhary HA, Halwani AA, Al Awadh SA, Alshamsan A, Babhair S, Almalik AM. Localizing pharmaceuticals manufacturing and its impact on drug security in Saudi Arabia. Saudi Pharm J. 2022;30(1):28–38. doi:10.1016/j.jsps.2021.12.002.
2. Halwani AA, Balkhi B, Alamoudi AA, Almozain NH, Alajmi AM, Noorwali A, Badr MY, Noor AO, Bagalagel A, Tawfik EA. Current status and vision of local pharmaceutical industries in Saudi Arabia: the focus on nanomedicines. Saudi Pharm J. 2023;31(8):101674. doi:10.1016/j.jsps.2023.06.007.
3. Alshehri S, Alshammari R, Alyamani M, Dabbagh R, Almalki B, Aldosari O, Alsowayigh R, Alkudeer A, Aldosari F, Sabr J, Shakeel F. Current and future prospective of pharmaceutical manufacturing in Saudi Arabia. Saudi Pharm J. 2023;31(4):605–616. doi:10.1016/j.jsps.2023.03.001.
4. Kingdom of Saudi Arabia. National Biotechnology Strategy. Launched by HRH the Crown Prince, Riyadh, 25 January 2024. Saudipedia, Saudi Press Agency. Available from: https://saudipedia.com/en/national-biotechnology-strategy
5. World Health Organization. Saudi Arabia regulatory system becomes third to reach WHO Maturity Level 4. Geneva: WHO; 30 October 2023. Available from: https://www.who.int/news/item/30-10-2023-saudi-arabia-regulatory-system-becomes-third-to-reach-who-maturity-level-4
6. Local Content and Government Procurement Authority. Al-Hay'ah tutliq mubadarat "al-tafdil al-si'ri al-idafi" li-208 muntajat wataniyyah [The Authority launches the Additional Price Preference initiative for 208 national products]. Riyadh: LCGPA; 21 September 2020. Arabic. Available from: https://lcgpa.gov.sa/ar/mediacenter/MediaMaterial/news/Pages/News-007.aspx
7. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q13: Continuous Manufacturing of Drug Substances and Drug Products. Step 4

Guideline. Geneva: ICH; adopted 16 November 2022.
8. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q9(R1): Quality Risk Management. Step 4 Guideline. Geneva: ICH; adopted 18 January 2023.
9. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q14: Analytical Procedure Development. Step 4 Guideline. Geneva: ICH; adopted 1 November 2023.
10. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Q2(R2): Validation of Analytical Procedures. Step 4 Guideline. Geneva: ICH; adopted 1 November 2023.
11. United States Food and Drug Administration. Advanced Manufacturing Technologies Designation Program: Guidance for Industry. Silver Spring, MD: CDER and CBER; December 2024. Notice of availability: Fed Regist. 2 January 2025. Statutory basis: section 506L, Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356l), added by section 3213 of the Food and Drug Omnibus Reform Act of 2022.
12. Saudi Biotechnology Manufacturing Company (SaudiBio). Media. Riyadh: SaudiBio. Available from: https://saudibio.com/media/ [accessed 20 August 2026].
13. Lifera, Sanofi, Arabio. LIFERA, SANOFI and ARABIO sign MoU to manufacture and supply vaccines in Saudi Arabia, boosting local production with a new state-of-the-art manufacturing facility. Riyadh; 5 July 2023. Available from: https://tamergroup.com/newsroom/lifera-sanofi-arabio-sign-mou
14. Saudi Press Agency. Alkhorayef commends Lifera's partnerships to localize pharmaceutical manufacturing. Riyadh: SPA; 28 October 2025. Available from: https://spa.gov.sa/en/N2430065
15. Kotamarthy L, Feng X, Alayoubi A, Bolla PK, Ramachandran R, Ashraf M, O'Connor T, Zidan A. Switching from batch to continuous granulation: a case study of metoprolol succinate ER tablets. Int J Pharm. 2022;617:121598. doi:10.1016/j.ijpharm.2022.121598.
16. Patil H, Vemula SK, Narala S, Lakkala P, Munnangi SR, Narala N, Aleti MR, Karnati VVR, Repka MA. Hot-melt extrusion: from theory to application in pharmaceutical formulation — where are we now? AAPS PharmSciTech. 2024;25:37. doi:10.1208/s12249-024-02749-2.
17. Shepherd SJ, Han X, Mukalel AJ, El-Mayta R, Thatte AS, Wu J, Padilla MS, Alameh MG, Srikumar N, Lee D, Weissman D, Issadore D, Mitchell MJ. Throughput-scalable manufacturing of SARS-CoV-2 mRNA lipid nanoparticle vaccines. Proc Natl Acad Sci U S A. 2023;120(33):e2303567120. doi:10.1073/pnas.2303567120.
18. Lifera. Lifera (a PIF company) to localize over 50% of Saudi Arabia's insulin needs with Novo Nordisk Saudi Arabia. Riyadh: Lifera; 21 October 2024. Available from: https://lifera.com.sa/lifera-to-localize-over-50-of-saudi-arabias-insulin-needs-with-novo-nordisk/
19. BioProcess International. Saudi Arabia's big biotech bet: from regional player to global leader. 2026. Available from: https://bioprocessintl.com/global-markets/saudi-arabia-s-big-biotech-bet-from-regional-player-to-global-leader [accessed 20 August 2026].