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Review Article

Digital Transformation of Pharmaceutical Production Planning in Saudi Arabia Using Integrated ERP Systems

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Abstract: Saudi Arabia is pursuing pharmaceutical localization, industrial diversification, health security, and digital transformation under Vision 2030. Yet local manufacturing capacity alone does not guarantee reliable medicine supply. Pharmaceutical plants must convert volatile demand, imported-material constraints, validated process capacity, quality-release requirements, and regulatory obligations into executable production plans. Enterprise resource planning (ERP) systems can provide the digital backbone for this task, but value depends on integration with manufacturing execution, quality, laboratory, warehouse, maintenance, supplier, and advanced planning systems. This integrative review examines how ERP-enabled digital transformation can strengthen pharmaceutical production planning in Saudi Arabia. Recent pharmaceutical and Industry 4.0 literature is synthesized with Saudi policy and regulatory sources to identify planning capabilities, integration requirements, governance risks, and implementation priorities. The review argues that ERP should be treated not as an administrative transaction platform but as the controlled planning layer connecting demand, master production scheduling, material requirements planning, finite capacity, procurement, inventory, manufacturing execution, and batch release. A six-domain framework is proposed covering master-data integrity, integrated planning, execution visibility, quality-by-design information flows, analytics, and governance. The paper also presents an architecture for ERP-MES-QMS-LIMS-WMS-APS integration, a balanced KPI framework, and a phased 2026–2030 roadmap. For Saudi pharmaceutical manufacturers, the expected strategic value is improved schedule reliability, material readiness, capacity utilization, traceability, technology-transfer readiness, and resilience. The central conclusion is that digital transformation of planning should be built around validated processes, standardized data, cross-functional governance, and progressive integration rather than isolated technology deployment.

Keywords: Saudi Vision 2030, Pharmaceutical Manufacturing, Digital Transformation, Enterprise Resource Planning, ERP, Production Planning, MRP, SAP PP/MM, Pharma 4.0, Manufacturing Execution Systems.

1. INTRODUCTION

Saudi Arabia's pharmaceutical sector is being reshaped by a combination of health-system transformation, industrial policy, localization, biotechnology development, and supply-chain resilience. Vision 2030 and the National Industrial Strategy position manufacturing capability as an economic and strategic asset, while the National

Industrial Development and Logistics Program links domestic industrial growth with logistics performance and localization. In pharmaceuticals, the policy logic is especially important because local production affects not only economic diversification but also continuity of medicine supply. Saudi research has highlighted the Kingdom's continued reliance on imported medicines and the need to deepen domestic pharmaceutical capabilities, diversify product portfolios, strengthen technology transfer, and develop more resilient supply chains (Tawfik *et al*., 2022; Alshehri *et al*., 2023; Halwani *et al*., 2023). The SFDA has also expanded digital regulatory infrastructure, including drug registration services and the national drug track-and-trace system, while its industrial initiatives support local manufacturing and advanced therapies. Together, these developments create a strong policy case for digitally mature manufacturing operations rather than capacity expansion alone.

Production planning is a critical operating mechanism within this transformation. Pharmaceutical plants must translate commercial demand into feasible schedules while respecting long manufacturing lead times, cleaning and changeover constraints, equipment and labor availability, process validation ranges, imported-material lead times, shelf-life considerations, quality-control queues, batch-release rules, and regulatory commitments. A schedule that is commercially attractive but operationally infeasible creates expediting, excess work-in-process, frequent changeovers, delayed release, and service instability. Conversely, overly conservative planning can leave expensive validated assets underused and weaken the economics of localization. This tension is particularly relevant in multiproduct plants producing solid, liquid, and semi-solid dosage forms, where shared equipment and campaign sequencing generate complex dependencies between production, packaging, quality, warehouse, procurement, and commercial functions.

Enterprise resource planning systems provide a foundation for coordinating these dependencies. In pharmaceutical operations, ERP typically supports demand management, master production scheduling (MPS), material requirements planning (MRP), bills of material, routings, inventory, procurement, production orders, batch management, costing, and enterprise reporting. However, an ERP system cannot deliver digital transformation merely because it is installed. Its planning outputs are only as reliable as the master data, transaction discipline, integration architecture, governance model, and operational feedback feeding the system. Recent research on pharmaceutical digitalization emphasizes that transformation depends on interoperability, data quality, organizational readiness, cybersecurity, workforce capability, and integration of information technology with operational technology (Hole *et al*., 2021; Arden *et al*., 2021; McDermott *et al*., 2024; Phiri *et al*., 2025).

This paper therefore asks: how can integrated ERP systems transform pharmaceutical production planning in Saudi Arabia in a manner that supports Vision 2030 localization, regulatory compliance, and manufacturing resilience? The objective is not to promote a specific software vendor. Rather, the paper develops a journal-neutral operating framework in which ERP becomes the governed planning backbone connecting demand, materials, capacity, execution, quality, and release. The study synthesizes recent pharmaceutical manufacturing literature, Saudi strategic and regulatory sources, and production-planning research to identify the digital capabilities that matter most, the system interfaces required, the main risks, and a practical implementation sequence for 2026–2030.

2. Saudi Pharmaceutical Digitalization and the Planning Imperative

Saudi pharmaceutical localization is increasingly defined by depth of capability rather than by the physical presence of a factory. A sustainable local manufacturer must repeatedly source compliant materials, maintain validated processes, plan and execute batches, test and release product, trace distribution, respond to shortages, and introduce new products. This operating capability is consistent with the National Industrial Strategy's emphasis on industrial competitiveness and the NIDLP's role in strengthening manufacturing and logistics. SFDA initiatives supporting pharmaceutical manufacturing and the national biotechnology strategy further extend localization toward complex therapies and biomanufacturing. Such products generally impose even higher requirements for controlled data, synchronized planning, cold-chain coordination, specialized capacity, and quality-release visibility.

Digital regulatory infrastructure reinforces this direction. The SFDA's Drug Track and Trace System (RSD) monitors human pharmaceutical products manufactured in Saudi Arabia and imported into the Kingdom, creating an external requirement for accurate product, batch, and movement information. The SFDA's electronic drug-registration services and digital regulatory systems also demonstrate that the surrounding ecosystem is becoming increasingly data driven. The 2025 SFDA annual report indicates continued development of RSD infrastructure, while the 2026 Saudi GMP guideline maintains strong expectations for

traceability, documentation, computerized systems, and controlled manufacturing. For manufacturers, the implication is that internal planning data cannot remain fragmented across spreadsheets, disconnected departmental tools, and manually reconciled records if the broader regulatory and supply ecosystem is digital.

The planning challenge is amplified by the structure of pharmaceutical supply. Active ingredients, excipients, primary packaging, printed components, and specialized spare parts may have long or variable international lead times. Some materials require quality testing before use, and some products share equipment, rooms, tooling, or packaging lines. Demand can shift because of tenders, seasonal disease patterns, hospital consumption, regulatory actions, product launches, or shortages elsewhere in the market. A production planner therefore operates across multiple clocks: commercial demand timing, supplier lead time, quality-release time, manufacturing cycle time, campaign duration, shelf life, and regulatory deadlines. The digital transformation of planning must connect these clocks into one consistent decision model.

This requirement changes how ERP value should be assessed. Conventional ERP success is often measured by transaction completion, financial integration, or basic inventory control. For pharmaceutical localization, a more demanding standard is needed: does the system create a feasible, traceable, and responsive plan that reflects demonstrated capacity, material status, quality constraints, and current execution? The answer depends on closed-loop integration. Production orders created in ERP need reliable confirmation from manufacturing execution; laboratory status should influence availability and release; warehouse movements must update inventory; procurement should reflect actual demand and lead-time risk; maintenance events should inform capacity; and commercial changes should be translated into controlled replanning. The planning imperative is therefore not simply 'digitize more' but 'connect the right decisions with trustworthy data.'

Table 1: Saudi strategic and regulatory context for ERP-enabled pharmaceutical production planning

Strategic / regulatory driver	Planning implication	ERP-enabled response
Vision 2030 / National Industrial Strategy	Localization must be economically competitive and scalable	Connect demand, capacity, materials, costing and performance through one governed planning model
NIDLP and supply-chain development	Manufacturing resilience depends on logistics and supplier coordination	Integrate procurement, lead-time risk, inventory and production priorities
SFDA local-manufacturing initiatives	Domestic products require repeatable GMP execution and release	Link production orders, batch status, quality and release planning
SFDA Drug Track & Trace (RSD)	Batch and product movements require reliable traceability data	Synchronize ERP batch master, warehouse movements and serialization/traceability processes
National Biotechnology Strategy	Complex products raise requirements for data, capacity and quality coordination	Extend controlled planning architecture to specialized materials, testing and biomanufacturing capacity

3. REVIEW APPROACH AND ANALYTICAL FRAME

This study uses an integrative review and conceptual-framework design. That approach is appropriate because the research question spans operations management, pharmaceutical manufacturing, digital transformation, ERP, Industry 4.0, supply-chain resilience, quality systems, and Saudi industrial policy. The evidence base was structured around peer-reviewed literature published mainly from 2020 onward, complemented by authoritative Saudi Vision 2030, SFDA, WHO, ICH, and FDA sources. Earlier regulatory principles are referenced where they remain foundational to computerized pharmaceutical systems. Search concepts included pharmaceutical manufacturing digitalization, Pharma 4.0, ERP integration, production planning, MRP, manufacturing execution systems, digital twins, supply-chain traceability, Industry 4.0 readiness, data governance, continuous manufacturing, and Saudi pharmaceutical localization.

The synthesis was organized around six analytical questions. First, which planning decisions should remain within the ERP core and which require specialized systems? Second, what data dependencies determine the reliability of MPS, MRP, and capacity planning? Third, how should ERP connect with manufacturing execution, quality, laboratory, warehouse, maintenance, and supplier

systems? Fourth, what digital capabilities improve responsiveness without weakening GMP control? Fifth, which governance, validation, cybersecurity, and workforce risks can undermine the transformation? Sixth, how can a phased roadmap align plant-level digital maturity with Saudi localization and resilience objectives? These questions guided the evidence matrix and the proposed architecture.

The paper deliberately avoids presenting invented plant performance data. Figure 3 is a conceptual maturity trajectory, not an observed Saudi industry dataset. Quantitative relationships reported in cited studies are used only where the underlying publication supports them. The proposed framework is therefore normative: it defines how a regulated pharmaceutical manufacturer could structure ERP-enabled planning, while recognizing that system configuration, validation, product mix, technology platform, and organizational design will differ among firms. This distinction is important for journal integrity because digital transformation claims should not be presented as empirical outcomes without primary operational data.

4. ERP as the Digital Backbone of Pharmaceutical Production Planning

The strongest role for ERP in pharmaceutical manufacturing is to provide a controlled enterprise planning truth. Demand, inventory, recipes and bills of material, routings, standard lead times, procurement parameters, batch sizes, production versions, work-center calendars, and product status must converge into one planning model. Master production scheduling converts demand and inventory policy into planned supply. Material requirements planning explodes that supply plan into component needs and timing. Capacity planning translates routing quantities and standards into load on work centers. Procurement converts shortages into purchasing signals, while inventory and batch management control the availability and traceability of materials. When these functions share consistent master data, the ERP system links commercial priorities with execution constraints.

The first digital-transformation priority is therefore master-data integrity. In pharmaceuticals, small data errors can create disproportionate planning effects. An incorrect yield can understate raw-material requirements; an outdated setup time can overload a packaging line; a missing alternate resource can create a false bottleneck; an incorrect procurement lead time can trigger shortages; a wrong shelf-life parameter can increase obsolescence; and inconsistent units of measure can disrupt inventory reconciliation. Digitalization literature repeatedly identifies data quality and interoperability as foundational challenges (Hole *et al*., 2021; Miozza *et al*., 2024; Fitzgerald *et al.,* 2026). A reliable ERP program should assign business ownership for each critical master-data object, establish controlled change workflows, audit high-impact planning parameters, and monitor exception rates.

The second priority is finite and constraint-aware planning. Basic MRP is often time-phased but may assume that planned orders can be executed within available capacity. Pharmaceutical plants require stronger logic because cleaning, campaign sequencing, room occupancy, quality-control capacity, utilities, and labor can all constrain feasible output. Advanced planning and scheduling tools can complement ERP by applying finite-capacity logic, sequence-dependent setup times, campaign rules, and optimization. Lindahl *et al*., (2023, 2024) show the importance of integrated capacity and production-planning models for pharmaceutical supply networks, particularly under uncertainty. The practical implication is that ERP should remain the enterprise record of demand, materials, orders, and inventories, while finite scheduling engines may generate more detailed resource-feasible sequences that are returned to ERP under controlled interfaces.

The third priority is event-driven replanning. Traditional planning cycles can become stale quickly when materials are delayed, equipment fails, quality testing extends, or commercial priorities change. A digital ERP environment should receive timely status from connected systems and convert exceptions into decisions. This does not mean continuously rescheduling the factory, which can create nervousness and instability. Instead, organizations need planning fences, exception thresholds, and governance rules defining when a new signal justifies replanning. The value of digital integration is not the maximum number of alerts; it is the ability to distinguish actionable exceptions from normal variability and to coordinate responses across supply chain, production, quality, warehouse, procurement, and commercial teams.

5. INTEGRATING ERP WITH MES, QMS, LIMS, WMS, APS, AND DIGITAL OPERATIONS

ERP becomes transformational when it is connected to the systems that observe and control execution. Manufacturing execution systems (MES) or electronic batch record platforms can provide granular information on order status, equipment use, quantities, process steps, downtime, and electronic records. ERP answers what should be produced, in what quantity, and by what business date; MES answers what is currently happening on the shop floor and whether execution is progressing according to the approved process. A controlled interface can

send production orders and relevant master data downward while returning confirmations, consumption, yield, and status upward. This reduces manual transcription and shortens the time between physical events and planning visibility.

Quality management systems (QMS) and laboratory information management systems (LIMS) are equally important because pharmaceutical output is not commercially available until quality requirements are satisfied. A batch may be physically complete yet remain unavailable because samples are pending, deviations are open, documentation requires review, or release testing is incomplete. If ERP inventory is treated as fully usable before quality status is accurately represented, MRP can create misleading supply signals. Integrating quality and laboratory status with ERP therefore allows planners to distinguish unrestricted, quality-inspection, blocked, quarantined, or pending-release stock and to model realistic release timing. Fitzgerald *et al*., (2026) identify digital innovations such as data management, process modelling, IoT, AI, and real-time monitoring as opportunities to improve pharmaceutical quality and batch release, while also emphasizing validation, cybersecurity, and capability risks.

Warehouse management systems and serialization or track-and-trace systems connect physical inventory with planning and regulatory traceability. In a high-volume pharmaceutical plant, the planning system must know not merely the aggregate quantity of a material but its batch, status, expiry, storage location, and usability. Warehouse digitalization can support first-expiry-first-out logic, controlled staging, line-side material availability, and rapid reconciliation. In Saudi Arabia, the external RSD track-and-trace environment increases the strategic importance of accurate product and batch data. Internal ERP and warehouse records should therefore be designed as part of a traceability chain rather than as separate administrative systems.

Maintenance and equipment data add another layer. Planned preventive maintenance, calibration, qualification work, and unplanned failures directly affect capacity. Doyle *et al*., (2024) examine digitalization for predictive failure modelling in regulated pharmaceutical environments, highlighting the potential for condition monitoring while recognizing validation and implementation challenges. ERP capacity calendars should not assume that every theoretical hour is available. Where computerized maintenance-management or asset systems are used, planned outages and critical equipment status should inform scheduling. IoT data may eventually support predictive maintenance and dynamic risk assessment, but the transformation should proceed only when asset data are reliable and governance is defined.

Finally, advanced analytics and digital twins can expand decision support beyond transactional visibility. Chen *et al*., (2020) describe digital twins in pharmaceutical and biopharmaceutical manufacturing as a way to connect process models and data for monitoring, simulation, and optimization. Recent reviews similarly show growing interest in digital twins, predictive analytics, AI, and continuous manufacturing (Arden *et al*., 2021; Gong *et al*., 2025; Maharjan *et al*., 2025). For production planning, the most practical near-term use cases include demand-scenario analysis, inventory-risk prediction, schedule-risk scoring, capacity simulation, deviation trend analysis, and predictive maintenance. ERP should provide governed enterprise data to these tools, while analytical recommendations should be returned through controlled workflows rather than bypassing validated business processes.

6. Evidence Synthesis: How Digital Transformation Improves Planning Performance

The literature suggests that digital transformation affects production planning through information quality, integration, visibility, responsiveness, and decision speed. Hole *et al*., (2021) argue that pharmaceutical digitalization should focus on process understanding, data management, people, and implementation discipline rather than technology alone. Arden *et al*., (2021) similarly position Industry 4.0 technologies as enablers of smart pharmaceutical factories while recognizing the need for regulatory alignment. McDermott *et al*., (2024) find that Pharma 4.0 readiness depends on organizational understanding, leadership, skills, infrastructure, and clear implementation priorities. These findings support an ERP-centered view in which the core value is not automation by itself but reliable coordination across functions.

Supply-chain research reinforces this point. Ma *et al*., (2023) show that information sharing and traceability mediate the relationship between digital transformation and sustainable pharmaceutical supply-chain performance. Wong *et al*., (2023) demonstrate how digitalization can strengthen pharmaceutical supply-network risk management, while Kyeremeh *et al*., (2025) find positive relationships between technology integration, collaboration, trust, and supply-chain performance. In planning terms, these findings indicate that ERP benefits should be measured through the quality and timeliness of shared decisions: procurement sees the same priorities as production; quality understands

the release consequences of delays; commercial teams see feasible promise dates; and warehouse operations stage materials according to the current sequence.

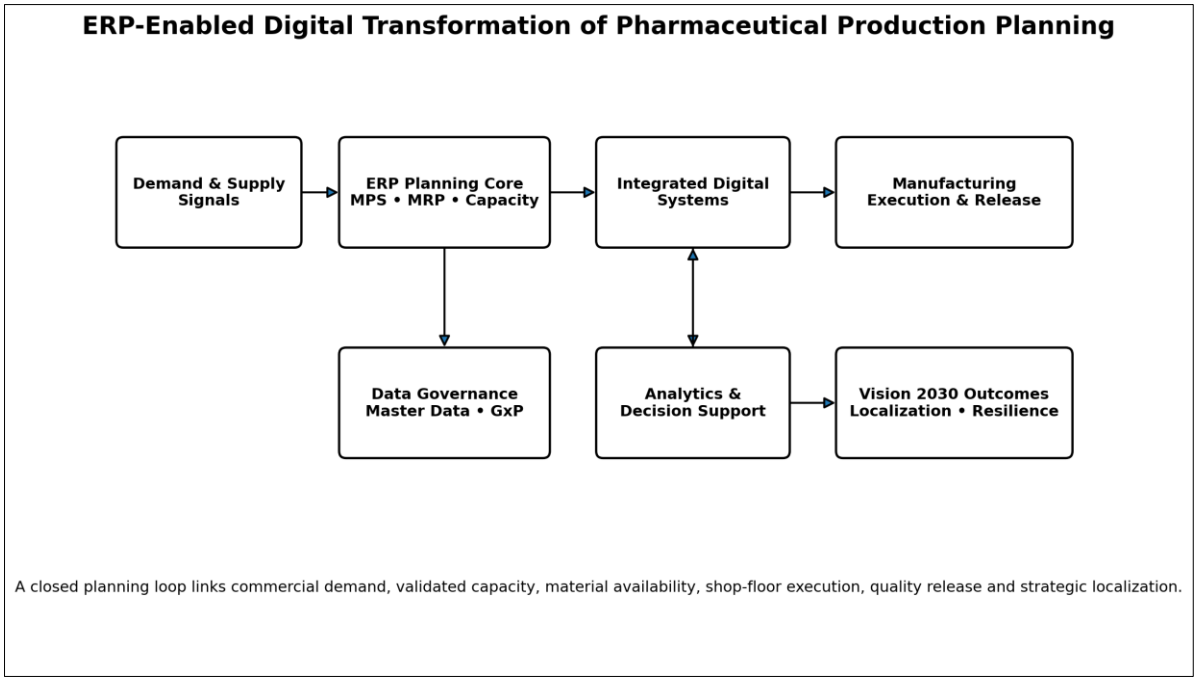

Figure 1: Graphical abstract: ERP-enabled closed-loop digital production planning for Saudi pharmaceutical manufacturing (author synthesis)

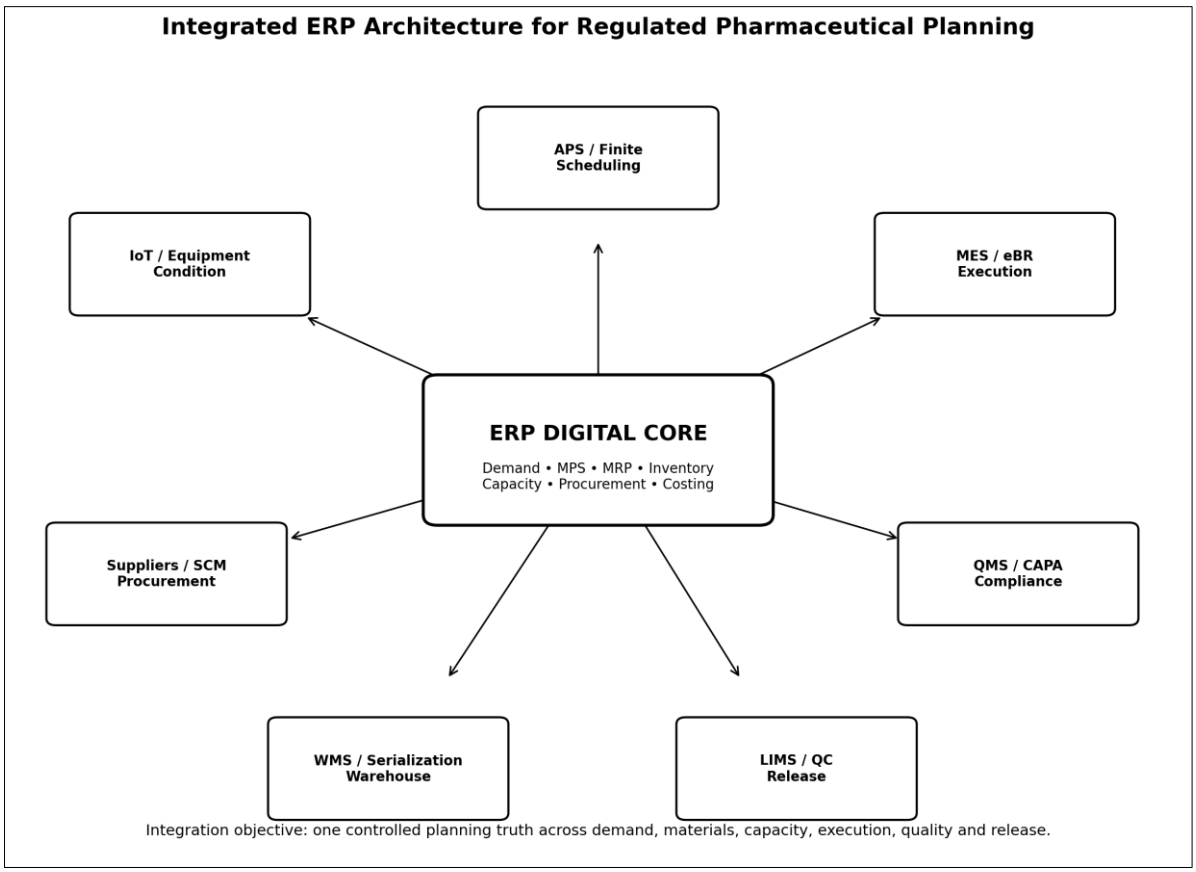

Figure 2: Integrated digital architecture with ERP as the enterprise planning core and bidirectional interfaces to execution, quality, laboratory, warehouse, supplier, maintenance and scheduling systems (author synthesis)

Manufacturing research adds an execution perspective. Digitalization is most effective when connected to operational excellence rather than used to automate unstable processes. Tetteh *et al*., (2024) emphasize top-management commitment in Lean 4.0 implementation, and McDermott *et al.,* (2024) identify readiness and cultural factors that influence Pharma 4.0 adoption. This suggests a sequencing principle for Saudi plants: standardize and stabilize the process, establish trustworthy data, integrate critical systems, and then apply advanced analytics. Automating poor master data or inconsistent planning rules can make errors travel faster through the organization rather than improving performance.

At the process level, continuous manufacturing and digital quality systems illustrate the direction of travel. ICH Q13 provides an international regulatory framework for continuous manufacturing, while Gong *et al*., (2025) describe how digitalization supports process development, monitoring, control, and more integrated pharmaceutical manufacturing. The FDA's discussion on artificial intelligence in drug manufacturing also recognizes potential applications in process control, pharmaceutical quality, and advanced manufacturing while raising questions about model lifecycle and governance. These developments imply that planning systems will increasingly need to exchange data with more automated manufacturing environments. ERP architecture should therefore be designed for interoperability and controlled extension rather than as a closed monolith.

The evidence also identifies constraints. Digital transformation can fail because of legacy systems, inconsistent data, high integration costs, cybersecurity risk, weak ownership, limited workforce capability, and unclear business cases (Debnath *et al.,* 2023; Miozza *et al*., 2024; Phiri *et al*., 2025; Fitzgerald *et al*., 2026). In regulated environments, changes may require validation and documented assessment. A Saudi manufacturer pursuing rapid localization can therefore face a paradox: pressure to scale digital capability quickly, but a regulatory need for controlled implementation. The correct response is not to slow transformation indefinitely; it is to modularize the roadmap, prioritize high-value interfaces, validate in proportion to risk, and establish strong data governance from the beginning.

Table 2: Selected evidence streams informing ERP-enabled digital pharmaceutical planning

Evidence stream	Representative literature	Implication for ERP-enabled planning
Pharma 4.0 / smart manufacturing	Arden *et al*., (2021); McDermott *et al*., (2024); Phiri *et al*., (2025)	Digital value depends on integration, readiness, data and governance—not isolated technology
Digitalization strategy	Hole *et al*., (2021); Miozza *et al*., (2024); Mariani *et al*., (2024)	Establish roadmap, common data language, cross-functional ownership and measurable use cases
Supply-chain digitalization	Ma *et al*., (2023); Wong *et al*., (2023); Kyeremeh *et al*., (2025)	Information sharing and traceability improve coordination and resilience
Digital twins / advanced analytics	Chen *et al*., (2020); Maharjan *et al*., (2025)	Use simulation and prediction after transactional and process data are stable
Digital quality and release	Fitzgerald *et al*., (2026); Gong *et al*., (2025)	Integrate process, laboratory and quality information to improve release visibility
Regulated predictive maintenance	Doyle *et al*., (2024)	Connect asset condition and maintenance windows to demonstrated capacity with risk-based controls

7. A Six-Domain ERP-Enabled Digital Planning Framework

The framework proposed in this paper contains six mutually reinforcing domains. Domain 1 is master-data governance. The plant should define controlled ownership for material masters, bills of material, routings, work centers, production versions, yields, lead times, minimum order quantities, safety stocks, calendars, inspection settings, and procurement parameters. High-impact fields should be reviewed using risk-based rules, and changes should be traceable. A useful principle is that every planning parameter must have a clear business owner, source of truth, review frequency, and approval path. Without this foundation, subsequent integration only propagates inconsistent assumptions.

Domain 2 is integrated demand, supply, and capacity planning. Sales and operations planning or an equivalent cross-functional process should reconcile commercial demand with inventory policy, material constraints, demonstrated manufacturing capacity, technology-transfer commitments, and quality-release capability. The MPS should be stable enough to protect execution but flexible enough to respond to material shortages and critical demand changes. MRP should be run using realistic lead times and quality-release assumptions. Capacity should be represented at the resources that actually constrain output, not only at high-level line names. Where

product mix is complex, APS tools can generate finite schedules using sequence-dependent changeover rules and campaign logic.

Domain 3 is closed-loop execution. ERP production orders should connect to MES or controlled shop-floor systems so that actual start, completion, consumption, yield, and status are captured with minimal delay. Plan-versus-actual variance should be visible at batch, line, and product-family level. The closed loop matters because planning parameters should learn from execution. If actual cycle times, yields, or changeovers consistently differ from standards, the system should trigger review rather than allowing inaccurate values to persist. This converts ERP from a static planning database into a learning operating system.

Domain 4 is integrated quality and release planning. Quality constraints should be modelled as part of capacity, not as an afterthought. LIMS and QMS status should support realistic estimates of when materials and finished goods become usable. Deviations, investigations, and repeated documentation corrections should be analyzed for schedule impact. Products with long or variable QC release should be visible in the supply plan so that customer commitments do not assume immediate availability. This domain is especially important for local manufacturing of strategic medicines, where supply continuity depends on released stock rather than on physical production alone.

Domain 5 is analytics and decision support. Once transactions and interfaces are stable, plants can develop dashboards and predictive models for shortage risk, schedule adherence, capacity overload, material aging, supplier delay, equipment reliability, and batch-release lead time. Advanced models should complement, not replace, accountable planners. Their purpose is to improve scenario evaluation and exception prioritization. A strong digital planning function therefore combines process expertise with data literacy: planners understand manufacturing and GMP constraints while also using analytics to test alternatives.

Domain 6 is governance, validation, cybersecurity, and workforce capability. Digital planning spans GxP and non-GxP information, so organizations should classify interfaces and functions by risk, document intended use, control access, maintain audit trails where required, manage changes, and test critical functions. Cybersecurity must be integrated because connected systems expand the attack surface. Workforce development is equally central. Fitzgerald *et al*., (2026) identify digital skills as a major adoption challenge, and Mariani *et al*., (2024) show the value of cross-functional coordination, common data language, roadmaps, and KPIs in pharmaceutical digital transformation. Saudi manufacturers should therefore build multidisciplinary teams combining production planning, quality, IT, engineering, supply chain, validation, and data expertise.

8. KPI Architecture for ERP-Enabled Production Planning

A digital transformation program needs performance measures that reflect both planning quality and pharmaceutical control. Traditional service and inventory metrics remain important, but they should be linked to the causes that planners can influence. The first KPI group is planning reliability: forecast accuracy at the appropriate horizon, master schedule stability, schedule adherence, plan-versus-actual quantity, and replanning frequency. Excessive schedule changes can indicate unstable demand management or poor constraint visibility. Conversely, a perfectly stable schedule is not automatically good if it ignores genuine shortages or high-priority patient needs. Governance should therefore distinguish necessary from avoidable changes.

The second KPI group is material readiness. Measures can include percentage of scheduled batches with all materials released before the planning fence, supplier on-time delivery, purchase-order confirmation reliability, shortage incidence, batch expiry risk, and emergency procurement. ERP enables these metrics because it links demand dates, purchase orders, inventory, quality status, and reservations. Material readiness is particularly relevant in Saudi Arabia because imported inputs can expose local manufacturers to global transport and supplier disruption. A localization strategy that depends on imported critical inputs still requires digitally mature risk visibility.

The third KPI group is capacity and execution. Demonstrated capacity utilization, bottleneck load, queue time, changeover duration, right-first-time execution, yield variance, and order completion against schedule help planners understand whether system assumptions reflect reality. Manufacturing execution data can improve timeliness and granularity, while ERP provides the business context. The fourth group is quality-release performance: QC lead time, batch-review duration, deviation closure impact, percentage of finished batches released by planned date, and inventory days in quality status. These measures prevent the organization from declaring success when production is complete but product remains unavailable.

The fifth group is digital-system health. Interface failure rate, master-data error rate, manual planning overrides, transaction latency, percentage of orders electronically confirmed, user adoption, data-quality exceptions, and system-related deviations reveal whether the digital backbone is reliable. A high-value KPI is 'manual reconciliation hours' between ERP, spreadsheets, warehouse records, and departmental trackers. Persistent manual reconciliation is a signal that integration or data governance is incomplete. The objective is not to eliminate every spreadsheet, but to ensure that critical production-planning decisions do not depend on uncontrolled shadow systems.

Table 3: Decision-to-data integration matrix for pharmaceutical production planning

Planning decision	Key data	Primary digital systems	Example KPI
Master production schedule	Demand, inventory policy, campaign rules, release timing	ERP + S&OP/IBP	MPS stability; schedule attainment
Material requirements	BOM, inventory status, lead time, yield, safety stock	ERP + WMS + supplier portal	Material readiness; shortage rate
Finite scheduling	Routing, calendars, changeover rules, constraints	ERP + APS + MES	Bottleneck load; changeover adherence
Execution control	Order status, consumption, yield, downtime	MES/eBR + ERP	Plan vs actual; order cycle time
Quality release	Sampling, testing, deviations, batch review	LIMS + QMS + ERP	Release lead time; % released by plan date
Maintenance-capacity alignment	PM plan, equipment condition, qualification/calibration	CMMS/EAM + IoT + ERP	Capacity lost to maintenance; predictive alerts
Scenario analytics	Historical demand, constraints, supplier risk, execution data	Data platform / BI / AI + ERP	Scenario response time; forecast risk accuracy

9. GOVERNANCE, VALIDATION, DATA INTEGRITY, AND CYBERSECURITY

Pharmaceutical digital transformation operates within a different risk environment from ordinary enterprise IT. Planning data can affect material availability, production sequence, batch status, traceability, and ultimately medicine supply. Where computerized functions influence GxP records or regulated decisions, validation and data-integrity expectations apply. The 2026 SFDA GMP guideline, international GMP principles, and established computerized-system guidance reinforce the need for controlled access, traceability, accuracy, and lifecycle management. Organizations should therefore classify ERP functions and interfaces according to intended use and patient/product risk rather than treating the entire system as either fully GxP or entirely administrative.

Data integrity begins with ownership and context. A production planner may legitimately change a planned date, but an uncontrolled change to a material status, batch record, or released inventory can create regulatory and operational risk. Role design should apply segregation of duties where appropriate, with auditability for critical actions. Interfaces should be monitored so that failed or duplicated messages are detected quickly. Backup, disaster recovery, business continuity, and periodic access review are also essential because manufacturing can become highly dependent on integrated systems. Digital transformation creates efficiency, but it can also create new single points of failure if resilience is not engineered.

Cybersecurity should be considered at the architecture stage. ERP, MES, laboratory systems, warehouse devices, IoT sensors, and industrial networks may span different technology generations and security models. The more connected the plant becomes, the more important network segmentation, identity management, patch governance, endpoint protection, vendor-access controls, logging, incident response, and recovery testing become. Pharma 4.0 literature consistently identifies cybersecurity as a critical adoption factor (Debnath *et al.,* 2023; Phiri *et al.,* 2025; Fitzgerald *et al*., 2026). For Saudi plants, cyber resilience supports not only corporate continuity but also national medicine-security objectives.

Governance should finally address artificial intelligence and advanced analytics. Predictive recommendations can be valuable for planning, but models can drift as demand patterns, suppliers, products, or process conditions change. The FDA's AI manufacturing discussion highlights the need to consider model development, performance monitoring, data quality, and lifecycle controls. A practical rule is that high-impact recommendations should remain explainable enough for accountable human review, especially during early adoption. Over time, automation can increase where data, validation evidence, and organizational confidence justify it.

10. VISION 2030 IMPLEMENTATION ROADMAP, 2026–2030

A phased roadmap can prevent Saudi pharmaceutical manufacturers from attempting a technically impressive but operationally fragile transformation. Phase 1, during 2026, should establish digital foundations. Plants should map planning processes, clean high-impact master data, define KPI baselines, document system ownership, identify shadow spreadsheets, and assess ERP configuration against actual planning requirements. Critical interfaces should be inventoried and classified by business and GxP risk. The immediate objective is trusted data and a stable monthly-weekly-daily planning cadence rather than advanced analytics.

Phase 2, during 2027, should integrate core planning and execution. Priority interfaces are ERP with warehouse, procurement, production execution, and quality status. Plants should improve electronic order confirmation, material staging visibility, shortage alerts, and released-versus-unreleased inventory logic. Finite-capacity methods can be introduced for the most constrained resources. Change management should focus on planner, production, warehouse, procurement, and quality roles so that digital transactions replace—not duplicate—manual workflows.

Phase 3, during 2028, should extend closed-loop planning. MES/electronic batch records, LIMS/QMS, maintenance, and supplier information can be connected more deeply. Actual cycle-time, yield, downtime, and release-time data should feed periodic review of ERP planning standards. Technology-transfer and new-product-introduction projects should reserve capacity and materials within the same planning environment as commercial production. This phase is especially relevant to localization because transferred products often fail operationally when project schedules are managed separately from routine manufacturing constraints.

Phase 4, during 2029, should introduce predictive and scenario-based decision support. Plants with stable data can develop models for material-shortage risk, capacity overload, supplier variability, batch-release delay, and equipment reliability. Digital twin or simulation approaches can evaluate campaign sequences and capacity expansion before capital is committed. The objective is not autonomous scheduling for its own sake; it is faster, better-informed decisions under uncertainty. Model governance, validation, and human oversight should mature in parallel.

Phase 5, during 2030, should connect plant planning with the wider localization ecosystem. Mature manufacturers can integrate strategic suppliers, contract manufacturers, logistics partners, and enterprise-level demand planning through standardized data and collaborative planning. Network visibility can support national resilience by identifying dependence on single-source materials, critical capacity, and vulnerable products. At this stage, ERP-enabled planning contributes directly to Vision 2030 by turning localization investments into a coordinated industrial capability that is measurable, scalable, and resilient.

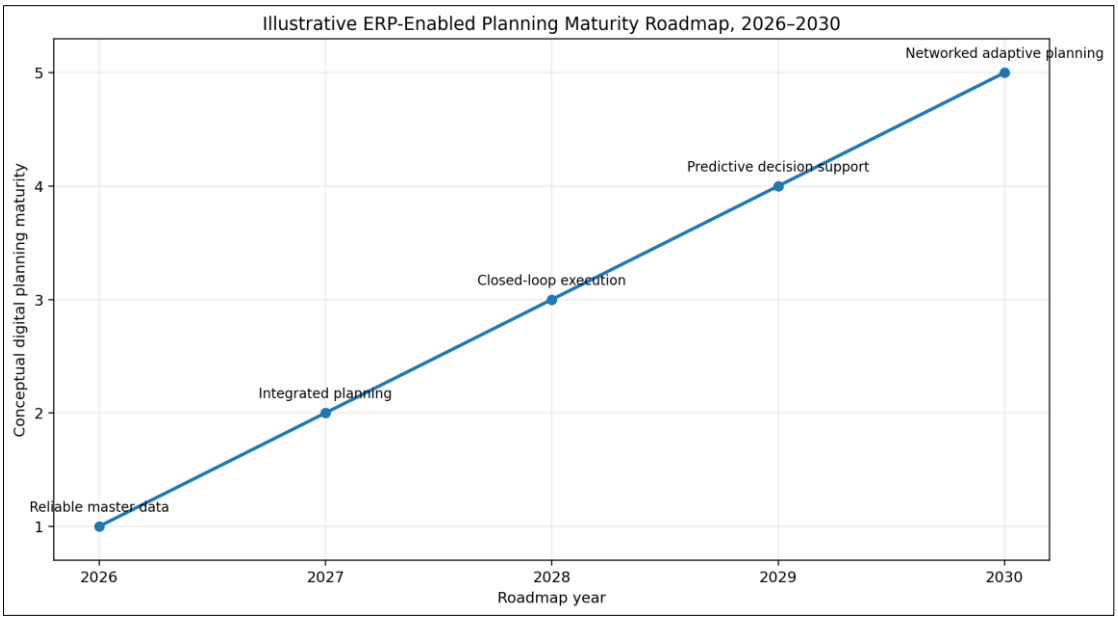

Figure 3: Illustrative ERP-enabled digital planning maturity trajectory, 2026–2030. The chart is conceptual and does not represent measured Saudi industry data

Table 4: Proposed 2026–2030 implementation roadmap for ERP-enabled pharmaceutical production planning

Phase	Year	Primary objective	Key deliverables	Governance gate
1. Foundation	2026	Reliable data and planning discipline	Master-data cleanup; process map; KPI baseline; interface inventory	Data ownership and risk classification approved
2. Core integration	2027	Connect material, warehouse, production and quality status	Electronic confirmations; shortage visibility; finite planning on critical resources	Validated critical interfaces and user adoption
3. Closed loop	2028	Use execution and release data to improve plans	MES/LIMS/QMS integration; actual standards review; NPI integration	Performance review and controlled master-data feedback
4. Predictive	2029	Scenario and predictive decision support	Shortage risk, capacity simulation, maintenance and release-risk analytics	Model governance, monitoring and human oversight
5. Networked	2030	Collaborative localization and resilience planning	Supplier/partner integration; network risk visibility; scalable planning standards	Enterprise and ecosystem resilience governance

11. DISCUSSION

The central argument of this review is that ERP should be repositioned from a back-office transaction system to the governed digital backbone of pharmaceutical production planning. This reframing matters because many digital-transformation programs prioritize visible technologies—AI, dashboards, IoT, digital twins—before resolving basic planning inconsistencies. In a regulated manufacturing environment, advanced technologies create sustainable value only when demand, material status, capacity, quality, and execution data are reliable. The sequence proposed here is therefore deliberately conservative in architecture but ambitious in outcome: build a trustworthy ERP core, integrate the systems that constrain plan feasibility, and then layer analytics and predictive decision support.

For Saudi Arabia, the framework has three strategic implications. First, it strengthens localization economics. Better planning can reduce avoidable inventory, emergency procurement, idle validated capacity, and schedule disruption, improving the cost competitiveness of domestic manufacturing. Second, it strengthens medicine security. Digital visibility can reveal material shortages, release delays, and capacity constraints earlier, giving organizations more time to respond. Third, it strengthens technology absorption. When multinational or local firms transfer products into Saudi plants, mature ERP and planning processes provide a controlled platform for bills of material, routings, batch sizes, procurement parameters, validation campaigns, and launch inventory.

The framework also clarifies the relationship between ERP and Pharma 4.0. Pharma 4.0 is not a replacement for ERP. Rather, ERP can serve as the enterprise coordination layer within a broader digital ecosystem that includes MES, QMS, LIMS, WMS, APS, IoT, digital twins, and AI. Phiri *et al.*, (2025) emphasize enterprise-wide adoption, system integration, cybersecurity, data management, and continuous improvement; Fitzgerald *et al.,* (2026) identify similar needs from a pharmaceutical quality perspective. The architecture proposed in this review translates those themes into production-planning decisions: demand and supply must remain synchronized with execution and quality through controlled interfaces.

A further implication is that digital planning is organizational transformation. The most difficult interfaces are often not technical APIs but decision boundaries between functions. Commercial teams may optimize service, procurement may optimize order economics, production may optimize campaign efficiency, quality may optimize compliance, and finance may optimize working capital. ERP creates a shared data environment but cannot resolve conflicting objectives without governance. A mature planning process therefore requires cross-functional decision rights, escalation rules, planning horizons, frozen periods, and agreed definitions of service, inventory, capacity, and risk.

Finally, digital transformation should preserve human expertise. Pharmaceutical planners routinely interpret signals that are difficult to encode completely: a supplier's credibility, the practical effect of a complex changeover, the likelihood of a quality delay, or the urgency of a market shortage. AI and analytics can improve pattern recognition and scenario evaluation, but accountable professionals should remain central to high-impact decisions. This human-centered direction is consistent with emerging Industry 5.0 thinking and with the need to build Saudi technical capability rather than merely import software. The long-term competitive

advantage is not the ERP license; it is the organization's ability to combine regulated manufacturing knowledge, reliable data, digital tools, and disciplined decision making.

12. RESEARCH IMPLICATIONS AND LIMITATIONS

The proposed framework creates several opportunities for empirical research in Saudi Arabia. Plant-level studies could test whether ERP master-data improvement reduces shortages and schedule changes, whether MES integration improves plan-versus-actual visibility, and whether quality-system integration reduces the gap between production completion and commercial availability. Longitudinal research could examine how digital maturity changes capacity utilization, inventory, schedule adherence, and service over multiple years. Comparative studies across local manufacturers, multinational affiliates, and contract manufacturers could identify which organizational and technology factors most strongly predict successful transformation.

Future research should also investigate planning for advanced therapies and biologics, which are increasingly relevant to Saudi biotechnology strategy. These products may require different batch structures, cold-chain constraints, specialized testing, patient-linked demand, and high-value materials. ERP architecture may therefore need different integration and risk controls than conventional oral solid-dose manufacturing. Another research opportunity is national-level pharmaceutical supply visibility: aggregated, appropriately governed data could help identify systemic dependencies while protecting commercial confidentiality and cybersecurity.

This paper has limitations. It is an integrative review and conceptual synthesis rather than a systematic meta-analysis. It does not use proprietary operational data from Saudi pharmaceutical plants, so the proposed KPI effects and maturity roadmap should be tested empirically. ERP products differ in functionality and configuration; the framework is intentionally vendor-neutral and does not prescribe a specific technical stack. Regulatory expectations also evolve, particularly for AI, cloud systems, and advanced manufacturing, so implementation should be checked against current SFDA and applicable international guidance at the time of deployment. Figure 3 is illustrative and should not be interpreted as a measured industry benchmark.

13. CONCLUSION

Saudi Arabia's pharmaceutical localization agenda requires more than new facilities and registered products. It requires a planning system capable of converting demand into released medicine through coordinated materials, capacity, manufacturing, quality, and logistics. Integrated ERP systems can provide that backbone when they are built on trustworthy master data, constraint-aware planning, closed-loop execution, quality integration, analytics, and disciplined governance. The proposed six-domain framework and 2026–2030 roadmap offer a practical sequence for manufacturers seeking to move from transactional ERP use toward digitally integrated pharmaceutical operations.

The most important implementation principle is progressive integration. Plants should first stabilize master data and planning rules, then connect execution and quality, then develop predictive capabilities. This sequence reduces the risk of automating inconsistent processes and supports validation in manageable stages. For Saudi manufacturers, the expected strategic benefits include stronger schedule reliability, material readiness, capacity utilization, traceability, technology-transfer execution, inventory control, and supply resilience. In that sense, ERP-enabled production planning is not merely an IT modernization project. It is operational infrastructure for Vision 2030: a mechanism for converting pharmaceutical investment, digital capability, and regulatory control into reliable local medicine supply.

Declarations

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

Ethics Approval: Not applicable to the review design.

Data Availability: No new empirical dataset was generated. Figure 3 is a transparent conceptual maturity illustration.

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Abbreviations

AI – Artificial Intelligence; APS – Advanced Planning and Scheduling; BOM – Bill of Materials;

CAPA – Corrective and Preventive Action; CMMS – Computerized Maintenance Management System; eBR – Electronic Batch Record; ERP – Enterprise Resource Planning; GMP – Good Manufacturing Practice; GxP – Good Practice requirements; ICH – International Council for Harmonisation; IoT – Internet of Things; KPI – Key Performance Indicator; LIMS – Laboratory Information Management System; MES – Manufacturing Execution System; MPS – Master Production Schedule; MRP – Material Requirements Planning; NIDLP – National Industrial Development and Logistics Program; NPI – New Product Introduction; QMS – Quality Management System; RSD – Saudi Drug Track and Trace System; SFDA – Saudi Food and Drug Authority; WMS – Warehouse Management System.

Highlights

- Repositions ERP as the governed digital planning backbone linking demand, materials, capacity, execution, quality and release.
- Proposes a six-domain framework for master data, integrated planning, closed-loop execution, quality integration, analytics and governance.
- Defines an ERP-MES-QMS-LIMS-WMS-APS architecture suitable for regulated pharmaceutical manufacturing.
- Provides a balanced KPI system covering planning reliability, material readiness, capacity, release and digital-system health.
- Presents a phased 2026–2030 roadmap aligned with Saudi pharmaceutical localization, resilience and Vision 2030.

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