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Conversion Readiness and Gap Analysis in SAP S/4HANA Migrations in Regulated Life Sciences Environments

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ABSTRACT

The article examines conversion readiness and gap analysis in SAP S/4HANA migrations across regulated life sciences organizations. ERP conversion in this sector affects transactional design, master data, custom code, validation evidence, and compliance control within the same program. The aim is to formulate an analytical model that connects gap analysis, readiness evaluation, and solution architecture. The study uses comparative source analysis, source criticism, conceptual synthesis, typologization, and analytical generalization across ten recent academic, regulatory, and SAP technical sources. The analytical part defines three results: a readiness logic shaped by brownfield and greenfield migration choices; a regulated life sciences gap taxonomy; and a decision path that links identified gaps to architecture. The model supports earlier separation of conversion risks, validation obligations, and design choices before realization work begins. The argument advances conversion readiness as an architectural control discipline, grounded in regulated process use and evidence requirements.

Keywords: SAP S/4HANA, conversion readiness, gap analysis, brownfield migration, greenfield implementation, life sciences, GxP validation, ERP modernization, custom code, solution architecture

INTRODUCTION

SAP S/4HANA migration in life sciences organizations follows a different risk logic from a routine ERP modernization program. Pharmaceutical, biotechnology, medical device, healthcare, and molecular diagnostics companies use ERP processes to control regulated data, product release dependencies, customer authorization checks, batch-sensitive distribution, pricing rules, billing evidence, and country-specific order execution. An ECC-to-S/4HANA move changes the technical core and alters the conditions under which business transactions remain traceable, validated, and acceptable for regulated operation.

Brownfield and greenfield choices set the initial risk boundary for readiness work. A brownfield path carries forward much of the inherited ECC landscape. Project teams need to know which configurations, custom code, interfaces, master data structures, and validation records still support safe operation in S/4HANA. A greenfield path offers greater design flexibility, but it places greater pressure on process reconstruction, data migration, user adoption, and validation of new control logic. Gap analysis is where business continuity, compliance evidence, and architecture meet.

The research aim is to formulate an analytical model for conversion readiness and gap analysis in SAP S/4HANA migrations within regulated life sciences environments. The article defines how brownfield and greenfield migration choices shape readiness evaluation and risk, classifies the gap types that matter most in regulated life sciences SAP landscapes, and

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develops a decision logic that connects identified gaps with solution architecture before realization work begins.

The novelty lies in treating conversion readiness as an architectural control process. SAP technical materials describe simplification items, readiness checks, custom-code adaptation, and fit-to-standard workshops. Life sciences validation guidance addresses risk-based assurance, data integrity, and computerized system control. ERP implementation literature examines success factors, organizational readiness, and legacy modernization. The proposed model links these streams through one sequence: gap analysis, readiness judgment, and architecture decision. The hypothesis states that SAP S/4HANA migration in regulated life sciences environments gains stronger conversion control when project teams organize gap analysis as a risk-ranked architectural discipline that separates brownfield retention risks from greenfield redesign risks.

MATERIALS AND METHODOLOGY

The source corpus consists of ten recent academic, regulatory, and SAP technical sources selected through narrative screening. The first group covers ERP readiness in life sciences and the organizational demands of ERP implementation, with attention to regulatory requirements, data integrity, change management, and post-implementation success factors [1, 3, 10]. The second group covers legacy-system modernization and migration decision logic, where preservation of business knowledge and technical debt shape modernization choices [2]. The third group covers regulated computerized-system assurance through FDA guidance on computer software assurance, ISPE GAMP 5 Second Edition, and a pharmaceutical quality-assurance review linking GAMP 5, data integrity, and Quality by Design [4, 5, 6]. The fourth group consists of SAP technical materials on S/4HANA conversion, custom-code migration, readiness checks, simplification items, and fit-to-standard workshops [7, 8, 9]. The selected sources cover three linked question groups: readiness assessment, regulated gap severity, and architecture decisions after gap identification.

The study applies comparative source analysis, source criticism, conceptual synthesis, typologization, and analytical generalization. A comparative analysis separates the logic for brownfield and greenfield readiness. Source criticism differentiates SAP technical guidance, regulatory guidance, and academic ERP research by purpose and evidentiary weight. Typologization classifies gaps by process, data, custom code, integration, validation, and governance. Conceptual synthesis converts these classifications into an architecture-oriented decision model.

RESULTS AND DISCUSSION

Recent life sciences ERP readiness research gives the article its sector-specific starting point. A 2025 framework for ERP readiness assessment in life science companies identifies regulatory compliance, data migration, change management, operational integration, and data integrity as evaluation dimensions that require sector-specific treatment [1]. This position matters for SAP S/4HANA migration because technical convertibility gives only one part of readiness evidence. A regulated organization needs confidence that process behavior, master-data logic, auditability, and validation evidence will remain under control after ERP core changes.

Legacy-system modernization research adds another layer. Contemporary software modernization studies frame legacy renewal as a task of preserving business knowledge while organizations adopt newer technologies [2]. ECC landscapes often contain years of configuration, user exits, reports, forms, interfaces, and local operating decisions. Some objects reflect accumulated technical debt. Other objects carry business knowledge that supports validated order processing, restricted distribution, customer eligibility checks, returns

handling, pricing exceptions, credit controls, or intercompany movement. Brownfield conversion attracts life sciences companies because it preserves much of this knowledge. The same preservation path carries obsolete design forward unless project teams examine each retained element in terms of business use and regulatory impact.

SAP conversion guidance supports this risk distinction by treating simplification items and readiness checks differently. The SAP Conversion Guide for SAP S/4HANA 2025 describes simplification items as conversion-relevant changes that require action from business and technical viewpoints [8]. SAP guidance for converting to S/4HANA Cloud Private Edition links preparation to the Simplification Item Check, custom-code checks, the Simplification Item Catalog, and the SAP Readiness Check [8]. The readiness baseline begins with the real source system, including usage, configuration, data, and active objects. In a regulated life sciences landscape, a simplification item may affect a process that quality teams have already validated, trained, and controlled through change records. Architects need to translate technical output into business and validation language before they turn it into a conversion decision.

Custom code sharpens the same issue. SAP's custom-code migration guidance for S/4HANA 2025 describes a tool-supported process that identifies code requiring adaptation through S/4HANA simplification knowledge and usage-based scoping [7]. In a standard commercial environment, teams often treat this work as cleanup. In a pharmaceutical or medical-device environment, custom code may include approval gates, controlled distribution rules, serialization-related checks, special document statuses, customer license restrictions, or regulated reporting paths. A readiness review needs to decide whether the object deserves retention, remediation, replacement with standard S/4HANA behavior, redesign as a controlled extension, or decommissioning.

Greenfield implementation produces a different readiness profile. SAP learning material on fit-to-standard analysis workshops describes workshops where line-of-business experts compare selected standard processes with the organization's needs and collect configuration information for the implementation phase [9]. This practice gives migration teams a disciplined way to test the fit between business requirements and S/4HANA standard design. In life sciences, fit-to-standard work still needs a regulated lens. A new standard process requires mapped intended use, data ownership, test strategy, access control, audit-trail handling, and evidence logic. The greenfield gap concerns future-state completeness: the team needs proof that redesigned processes can support regulated execution.

Brownfield and greenfield paths create two readiness logics. Brownfield readiness centers on inherited system reality. Teams examine ECC elements that remain technically compatible, custom developments that still serve a regulated purpose, interfaces that require remediation, and validation evidence that may survive change impact assessment. Greenfield readiness centers on future-state design. Teams test whether standard S/4HANA processes meet regulatory requirements, where justified extensions belong, how legacy data will be migrated into the target model, and how new control logic will be included in validation evidence. Both paths depend on gap analysis, but each path searches for a different failure mode.

Figure 1 presents the resulting readiness logic. It adapts SAP's conversion-readiness structure around simplification items, Readiness Check, custom-code checks, and fit-to-standard preparation to a life sciences migration setting [8].

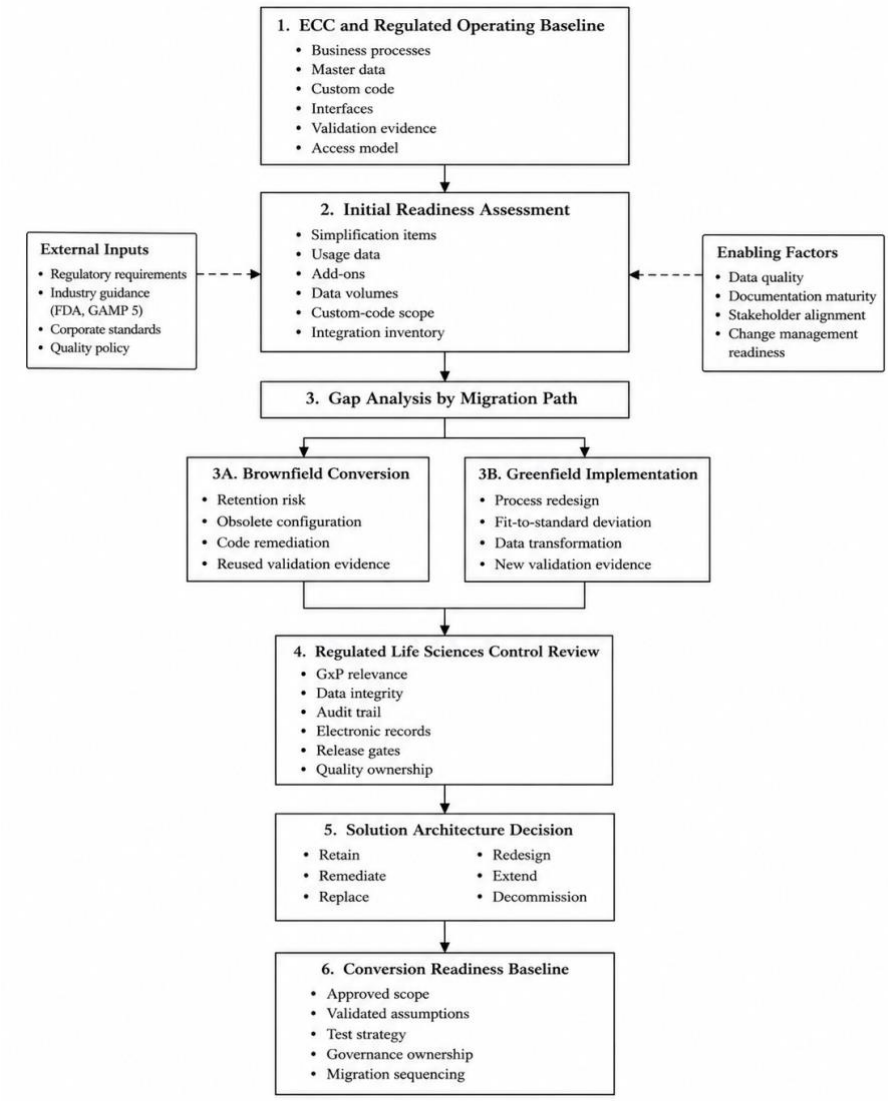

Figure 1. Conversion-readiness logic for SAP S/4HANA migration in regulated life sciences environments, adapted from SAP conversion guidance [8]

The second result concerns gap taxonomy. The reviewed sources support six groups that require separate treatment in regulated life sciences SAP landscapes. Process gaps arise when ECC transactions no longer match S/4HANA process behavior, or when a greenfield template omits regulated steps. Data gaps concern business partners, materials, batches, units of measure, customer authorization attributes, pricing records, plant assignments, and historical documents. Custom-code gaps arise when development depends on changed tables, obsolete transactions, inactive logic, or untested assumptions. Integration gaps affect external manufacturers, logistics providers, quality systems, warehouse tools, labeling systems, tax engines, trade-compliance tools, and document repositories. Validation gaps concern traceability between user requirements, configuration, test evidence, and change control. Governance gaps arise where IT, quality, business process owners, and external partners lack a shared owner for remediation.

Regulatory and quality sources define how teams need to rank these gaps. FDA's guidance on computer software assurance for production and quality management system software describes a risk-based route for establishing confidence in automation used in medical-device production or quality management systems [4]. ISPE GAMP 5 Second Edition

gives a risk-based approach to compliant GxP computerized systems, with a focus on patient safety, product quality, and data integrity [5]. Pharmaceutical quality research links GAMP 5, data integrity, and Quality by Design as connected elements of quality assurance [6]. These sources support a direct rule for S/4HANA readiness: teams should rank a gap by its effect on regulated process control.

A cross-reading of ERP readiness, regulatory guidance, and pharmaceutical quality research makes the rule more concrete. Life sciences ERP readiness research identifies regulatory compliance, complex product life cycles, and data integrity requirements as sector-specific conditions [1]. FDA and ISPE guidance place assurance efforts around intended use, risk, and documented confidence in system behavior [4, 5]. Pharmaceutical quality research links data integrity to the broader assurance framework that protects product quality [6]. A pricing-field gap, an availability-check gap, a customer-license gap, or an interface-status gap needs to be evaluated using regulated use, the evidence chain, and failure consequences. Configuration effort alone gives an incomplete severity rating.

ERP implementation literature provides the organizational side of readiness. A systematic review of ERP post-implementation success factors identifies management commitment, project management, communication, user involvement, training, and business-process alignment as recurring determinants of ERP outcomes [3]. A 2024 reassessment of ERP success factors for the digital era links ERP outcomes with configuration choices, digital integration, cloud operation, and organizational readiness [10]. These studies matter for S/4HANA migration because a readiness report has limited operational value until governance turns findings into owned decisions. A gap without a process owner, quality owner, technical owner, target disposition, and evidence requirement remains unresolved, even if the project team records it in a formal workbook.

The third result concerns the movement from gap identification to solution architecture. SAP sources provide technical evidence in the form of simplification impacts, custom-code findings, usage data, fit-to-standard outputs, and conversion preparation steps [7–9]. Life sciences and quality sources define why regulated use changes assurance effort [1, 4–6]. ERP success-factor studies explain why governance and business-process alignment decide whether technical programs reach stable adoption [3, 10]. The proposed model treats the gap register as an architectural input.

Each significant gap needs a disposition category. A retain decision aligns with inherited ECC behavior that remains compatible with S/4HANA and has a valid regulatory purpose. A remediate decision fits code, configuration, data, or documentation that standard conversion can carry forward after controlled correction. A replace decision aligns with custom ECC behavior that duplicates standard S/4HANA functionality. A redesign decision fits a future process that requires a new control pattern. An extended decision meets a justified regulatory requirement that standard S/4HANA cannot address in the target design. A decommission decision fits an object with no current business use, no compliance need, and no future-state value.

This disposition logic addresses two recurring migration risks. Brownfield programs may retain familiar ECC objects because teams lack evidence to support retirement. Greenfield programs may remove legacy complexity during design and rebuild it later under validation pressure. A readiness model built around gap severity, regulated use, and architecture disposition gives both paths a shared decision language.

Table 1: Readiness logic for brownfield and greenfield SAP S/4HANA migration in regulated life sciences environments

Readiness area	Brownfield conversion	Greenfield implementation	Architecture disposition
Legacy process logic	Teams test existing behavior for S/4HANA compatibility and regulated relevance	Teams design future behavior against selected S/4HANA standard processes	Retain, remediate, or redesign
Custom code	Usage, simplification impact, and compliance purpose guide scope	Every rebuilt custom behavior requires fresh justification	Replace, extend, or decommission
Validation evidence	Quality and process owners review existing evidence after the change impact assessment	Teams create new evidence for redesigned process behavior	Reuse with control or rebuild
Master data	Cleansing targets conversion blockers and regulated attributes	Target data design follows the new template and migration rules	Correct, harmonize, or transform
Integrations	Engineers remediate, retire, or wrap existing interfaces	Architects rebuild interface ownership around the target process model	Stabilize, replace, or redesign
Governance ownership	Ownership often follows inherited module and support structures	Program leadership assigns ownership through the target operating model	Reassign or formalize

The table shows that brownfield and greenfield paths differ in the location of uncertainty. Brownfield uncertainty sits in inherited objects whose current use, compliance purpose, and technical compatibility require proof. Greenfield uncertainty sits in the completeness of the future design. A regulated company can choose either path, but a single checklist will not serve both paths with the same level of accuracy.

The decision sequence then needs to move from classification to architecture. A gap register should contain regulated use, business owner, quality owner, technical owner, affected process, affected evidence, target disposition, testing implication, and release dependency. This structure keeps technical issues connected to compliance obligations. It also gives the team a way to address a regulated concern through an architectural remedy.

Figure 2 presents the proposed gap-to-architecture model, separating discovery, evaluation, decision-making, and controlled implementation, and placing quality review before final architecture disposition.

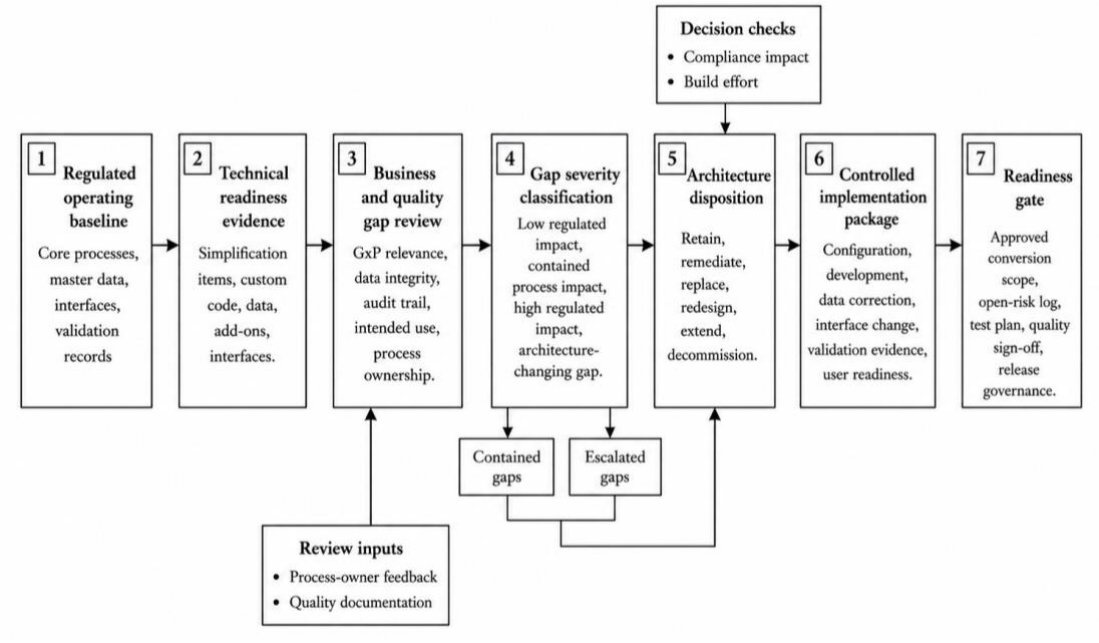

Figure 2. Gap-to-architecture decision model for SAP S/4HANA conversion in regulated life sciences environments

A quality review should occur before the architecture decision. Late quality participation often leaves the project team with technically acceptable changes that lack evidence, training alignment, access-control review, or traceability to requirements. Earlier quality participation gives architects a clearer distinction between a low-risk technical adaptation and a regulated design change.

A practical readiness sequence contains six steps. The team first defines the regulated operating baseline at the process level. It then runs SAP-readiness and custom-code assessments with sufficient production usage history to distinguish live objects from obsolete ones. Process owners and quality representatives join fit-to-standard and gap workshops by process family. The team classifies gaps by severity and target disposition. Architects convert disposition categories into implementation packages with named owners and evidence requirements. Each package passes through a readiness gate before realization.

Review signals should focus on evidence quality, clarity of ownership, and open-architecture decisions. The strongest warning signs are gaps without owners, custom objects without stated business purpose, interfaces without target ownership, regulated processes without mapped evidence, and design deviations without approval. These signals reveal readiness weakness with greater precision than a general completion percentage.

The proposed approach has limits. It depends on reliable system inventories, experienced process owners, and early quality participation to influence architecture. It also leaves room for organizational conflict where business teams prefer inherited process behavior and technical teams prefer simplification. Its value lies in exposing those conflicts before late-stage build or validation work turns them into defects.

For a functional architect, the practical task is translation. SAP tools produce technical findings. Business teams describe operating needs. Quality teams interpret regulated risk. Architects convert these inputs into a target design. Conversion readiness reaches maturity when this translation produces decisions that engineers can build, users can operate, and quality stakeholders can defend through evidence.

CONCLUSION

SAP S/4HANA migration readiness in regulated life sciences environments depends on the chosen migration path. Brownfield conversion concentrates risk in inherited ECC configuration, custom code, interfaces, master data, and validation evidence. Greenfield implementation shifts risk toward process reconstruction, fit-to-standard deviations, data transformation, and new evidence generation. The readiness method needs separate evaluation logic for each path.

Gap analysis in life sciences SAP landscapes requires a regulated taxonomy. Process, data, custom code, integration, validation, and governance gaps carry different consequences when they affect GxP-relevant flows, data integrity, audit trails, customer authorization controls, release logic, or external regulated communication. Gap severity follows the effect on controlled business use and evidence.

The architecture-oriented decision path links each significant gap with a disposition: retain, remediate, replace, redesign, extend, or decommission. This path confirms the hypothesis stated in the introduction. SAP S/4HANA migration gains stronger conversion control when project teams treat gap analysis as a risk-ranked architectural discipline that separates brownfield retention risks from greenfield redesign risks and connects readiness evidence with solution design before realization begins.

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