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Post-Merger IT Compliance Harmonization in Life Sciences Organizations

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Abstract: Life sciences mergers and acquisitions pose unique challenges in harmonizing diverse IT systems while meeting regulatory requirements under international laws and frameworks, including FDA 21 CFR Part 11, EU GMP Annex 11, HIPAA, and SOX. This paper describes the challenges of harmonizing all aspects of IT for compliance after the merger, including system heterogeneity, audit-trail discontinuity, and conflicting standard operating procedures. The study design employed a blended methodology, combining case-study analysis of key pharmaceutical and medical device mergers with practitioner survey questions. The study proposes a four-phased harmonization process that includes compliance gap assessment, development of a unified control framework, system rationalization, and continual monitoring. It can be established that regulatory inspection readiness is achieved much faster for organizations that use a structured harmonization approach than for those that opt for an ad hoc integration approach. This research offers a viable governance process for computerized health-care compliance officials and CIOs who face the regulatory uncertainty accompanying life sciences mergers and acquisitions.

Keywords: IT compliance harmonization, post-merger integration, life sciences regulatory frameworks, validated systems, audit trail continuity, IT governance.

INTRODUCTION

Over the past two decades, Merger & Acquisition (M&A) transactions have grown at an accelerating rate, particularly in the life sciences, in response to the need to develop pipelines, build stronger intellectual property (IP) portfolios, and achieve economies of scale [McDowall, R. D. 2016]. However, more often than not, when two life science organizations merge, they don't just experience a seamless integration of their IT systems; it's really a compliance issue. In comparison, life sciences companies face some of the world's most rigorous regulations to protect their electronic records and electronic signatures (EU GMP Annex 11, controls over the use of computer systems; FDA 21 CFR Part 11; Financial data integrity as per the Sarbanes-Oxley Act [SOX]; and also healthcare privacy regulations/HIPAA). Each of these frameworks demands system validation, system integrity (with break-free audit trails), access control, and defensible change control, and, unfortunately, these requirements do not go away during the turmoil of a corporate merger. IT environments are also usually mixed after the merger: the two companies use different architectures in their Laboratory Information Management System (LIMS), Electronic Document Management System (EDMS), Enterprise Resource Planning (ERP) and Quality Management System (QMS), or different architectures that have to meet different standards and that are used differently in the two companies, even if those standards are the same [Peklaj, K., & Cerovšek, M. 2025]. But the challenge is not just getting to the desired technical consolidation; it also needs to be compliant with regulations without compromising data integrity or putting the newly formed system at risk should regulators trawl through it midway or at the end of the process. There have been Warning Letters, consent decrees, and monumental monetary fines for several of these companies, among others, and it is a very different ball game if they don't manage to do it after they have merged [Chitraju, S. *et al*., 2025; Weed, B. *et al*., 2025].

Numerous examples exist of implementing IT compliance in M&A deals, but there is limited academic literature or industry guidance on how to achieve more structured IT compliance harmonization in these deals. The literature focuses on the enterprise perspective on M&A IT integration [Burke, R. J. 1987] and the business domain of regulation [Bowen, P. L. *et al*., 2007], with little attention to the potential synergies and links between the two areas. IT frameworks such as ITIL 4 and COBIT 2019 offer governance guidelines for information technology management, but fail to address the specific considerations of GxP-regulated environments, which involve extensive documentation and validation efforts [Information Systems Audit and Control Association, 2018]. Similarly, FDA regulatory communication, such as Data Integrity and Compliance with Drug CGMP Guidance (2018) and the reflection paper from the EMA on the Expectations for Electronic Source Data, includes primarily operational compliance points, but not exclusively the points related to transition

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to migration issues and the consideration of organizational change in the context of system change [Integrity, D. 2018]. There are some anecdotal structures and integration checklists available in the practitioner literature. Still, they have not been tested and do not account for the variety and complexity of mergers beyond those involving Western entities or those with Western entities in a different country/region, nor for the maturity of the banking system involved [Wilson, Z. J. 2024]. This is particularly meaningful since the time between a pharmaceutical merger and full IT integration is 18-36 months, and it entails two compliance challenges: maintaining current systems and converging them to a desired "after the merge" state. In practice, the incongruity between the Harmonization model used to validate the concept within a specific compliance environment in Life Sciences (LS) has been observed. It is considered a significant area of scholarship [Kohli, R., & Kettinger, W. J. 2004].

This paper aims to address this recognized gap and to present and discuss a five-part framework to harmonize IS rules across life sciences organizations following the merger. To provide such market conditions, a case study analysis was used to select major M&A transactions in the pharmaceutical and medical device sectors and subsequently analyze them. The analysis of key cases in pharmaceutical and medical device acquisition processes was conducted, and the practitioner survey was subsequently used to contextualize the proposed business model. This paper sets several boundaries for its scope:

- The main impact of Harmonization concerns (FDA 21CFR Part 11, EU GMP Annex 11, HIPAA, SOX) on GxP-regulated computer systems in areas such as LIMS, EDMS, QMS, and ERP.
- Organizational scope: The paper focuses on mid to large life sciences organizations, such as pharmaceutical manufacturers, biotechnology companies, and medical device companies, going through full mergers or majority acquisitions.
- Coverage during integration Phase: The framework supports the whole integration value chain from the compliance gap through to system rationalization, deployment of a unified control and compliance monitoring during the integration.
- Geographic applicability: Regulatory frameworks analyzed primarily included those from North America and Europe, and the harmonization model attempts to apply to other geographic areas, like APAC and LA, with the ICH Q10 harmonized markets.
- The paper does not consider cases where investments were made in minority equity or in the form of licensing or compliance harmonization as a result of divestments, spin-offs, and joint ventures, because these offer different regulatory and integration scenarios that may be out of scope.

Related Work

The existing research on post-merger IT integration and regulatory compliance in the life sciences shows how technology integration aligns with organizational alignment to meet GxP regulatory requirements. The research shows that organizational factors, including governance misalignment, cultural incompatibility, and inadequate stakeholder coordination, drive IT integration failures during mergers and acquisitions more than technical constraints do [Buono, A. F., & Bowditch, J. L. 2003]. Research on IT integration strategies shows that different integration methods have varying effects on implementation duration and on operational and system stability risks [Wijnhoven, F. *et al*., 2006]. The pharmaceutical industry faces these challenges because its strict validation and compliance standards demand complete adherence to requirements. The research shows that organizations require formal revalidation processes when moving or replacing their validated systems, which makes IT rationalization take longer and become more complex than in industries without regulations [MCKEEN, J. D. *et al*., 2012]. According to regulatory compliance research, data integrity problems, together with FDA warning letters, emerge from deficiencies in IT governance, audit controls, and quality management systems [Rogers, C. A. *et al*., 2020].

The newly validated cloud platforms, together with their SaaS quality systems, pose three new challenges that organizations must address through continuous validation, cybersecurity protection, and vendor monitoring. Organizations use risk-based Computer Software Assurance (CSA) methods to support their compliant system migration and validation processes in accordance with their respective compliance requirements. The literature indicates that business process harmonization, organizational learning, and knowledge transfer are essential to successful post-merger integration. Research on pharmaceutical mergers shows that successful technology

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consolidation, together with cross-functional coordination, is essential. Existing research shows that GxP-compliant pharmaceutical mergers and acquisitions require organizations to establish a structured IT harmonization framework to support compliance.

Table 1: Summary of Related Literature

Ref	Focus Area	Key Contribution	Relevance to This Paper
[Buono, A. F., & Bowditch, J. L. 2003]	Human side of mergers & acquisitions	Examined cultural collisions, employee resistance, and organizational integration challenges during M&A processes	Supports the organizational and cultural dimensions of IT harmonization and stakeholder alignment in post-merger pharmaceutical environments
[Wijnhoven, F. *et al*., 2006]	Post-merger IT integration strategies	Developed an IT alignment perspective for selecting integration approaches based on organizational fit and strategic objectives	Provides the strategic IT integration framework applied to harmonization, sequencing, and integration-mode selection
[MCKEEN, J. D. *et al*., 2012]	IT development and governance	Highlighted governance structures and management controls required for enterprise IT development in complex organizations	Anchors governance and validation control requirements within regulated pharmaceutical IT harmonization initiatives
[Rogers, C. A. *et al*., 2020]	Data integrity in pharmaceutical regulation	Analyzed FDA Bioresearch Monitoring inspections and warning letters related to data integrity failures from 2007 to 2018	Informs compliance-risk assessment, audit trail continuity, and regulatory oversight considerations during system migration
[Chien, M., & Jain, A. 2019]	Data quality tools and governance	Evaluated enterprise data quality platforms and established comparative criteria for governance, validation, and integration capabilities	Supports the data governance and master-data harmonization components of post-merger IT integration
[Davidson, J. K. 2023]	Computer Software Assurance (CSA)	Examined FDA draft guidance promoting risk-based Computer Software Assurance approaches over traditional CSV methods	Directly relevant to reducing validation burden and enabling efficient, compliant system rationalization during harmonization
[Yazdani, F. 2025]	Business process harmonization in M&A	Investigated operational and cultural dimensions influencing successful process harmonization after mergers	Provides conceptual grounding for business process standardization and cross-functional alignment in pharmaceutical integrations
[Schönreiter, I. M. 2018]	Process harmonization methodologies	Reviewed methodologies and frameworks for post-merger process harmonization across organizations	Informs the structured harmonization methodology and phased integration approach proposed in this study
[Peppiatt, J. 2025]	Technology integration in pharma acquisitions	Identified critical success factors for integrating technology firms acquired by large pharmaceutical organizations	Supplies contemporary insights into technology consolidation, digital integration, and strategic post-merger transformation
[Azan, W., & Huber Sutter, I. 2010]	Knowledge transfer in post-merger integration	Explored mechanisms of knowledge sharing and organizational learning in a multinational healthcare merger case	Supports the knowledge-management and organizational learning dimensions necessary for sustainable IT harmonization

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RESEARCH DESIGN & METHODOLOGY

The present research employs a mixed-methods research design to study how post-merger IT compliance harmonization becomes established in life sciences companies because both quantitative and qualitative research methods fail to measure this complex phenomenon. The researchers selected this methodology to compare actual merger data with operational experience from compliance and IT professionals who had worked on these integrations. The research consists of four interconnected research components, which include a systematic case study analysis of recorded post-merger IT integration activities in the pharmaceutical and medical device industries and a structured practitioner survey which targets IT compliance specialists, quality assurance managers and Chief Information Officers in life sciences companies; a regulatory document analysis which investigates FDA, EMA and ICH guidance regarding computerized system validation and data integrity for system transitions; and a comparative framework analysis which assesses existing IT governance models against GxP-regulated environments. The unit of analysis for this study is the entire post-merger IT harmonization program, rather than individual system migrations or independent compliance events, enabling a comprehensive view of governance, implementation sequencing, and compliance continuity throughout the integration lifecycle. Data collection occurred over a period of twelve months, with the case(s) selected using purposive sampling based on the following criteria: completion date of the merger; regulatory geography; complexity of the systems in question; and availability of publicly available compliance outcome documentation (e.g., inspection reports, Warning Letters, or consent decrees). Thematic Analysis (drawing liberally on existing IT Governance and Pharmaceutical Compliance literature) was used to analyze all qualitative data through an iterative coding framework. In contrast, descriptive statistics and correlation analyses were used to examine all quantitative survey data to identify patterns in harmonization timing, resource allocation, and inspection readiness outcomes.

Case Study Selection & Design

The twelve post-merger IT integration programs for life sciences analyzed in this research use a case-study approach. This case study incorporates IT integration programs regulated by multiple regulatory agencies from 2010 to 2021. Each case reflects the evolution of the regulatory environment over time through the adoption of new FDA data integrity standards and the proliferation of cloud-based validated systems. These cases were selected because of the regulatory relevance of the subject matter, the availability of relevant public documents, a merit-based or otherwise diverse range of merger cases, and the need to include GxP regulatory associations. All cases also include incidents of non-compliance related to the selected case. All twelve cases were evaluated using a consistent, rigorous structure that examines the complexity of the IT systems; the governance structure of the merger; the strategy for harmonizing the IT systems within the merged organization; and the compliance outcomes of the integrated organization.

- Summary of 12 life sciences post-merger IT integration case studies from 2010 to 2021;
- Selection based on: GxP regulations, regulatory relevance, availability of relevant public records, and the inclusion of GxP violations;
- US, cross-Atlantic, and Asia/Pacific GxP case studies considered;
- Report on 4 areas of analysis for cases: (1) IT complexity; (2) governance structure; (3) harmonization strategies; and (4) post-integration compliance outcomes.

Practitioner Survey Methodology

The practitioner survey was designed to complement the case study analysis by capturing the lived experience of IT compliance professionals who have managed post-merger harmonization programs. The survey instrument was developed through an iterative process involving two rounds of expert review of 60 questions derived from themes identified in the literature review. The final instrument contained forty-two items, divided into six thematic domains: organizational readiness for IT harmonization and regulatory gap assessment practices, system validation and revalidation approaches, data integrity management during migration, governance and decision-making structures, and overall inspection readiness at key integration milestones. The survey was administered electronically to a targeted sample of 280 professionals who were recruited through three channels, which included direct outreach to members of the Parenteral Drug Association (PDA) Technology Special Interest Group and the Drug Information Association (DIA) Data

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Management Community, and a LinkedIn-based purposive sampling approach that targeted individuals with verifiable post-merger IT integration experience in life sciences roles. Survey respondents were required to meet three eligibility criteria, including at least 5 years of experience in life sciences, IT quality, and compliance. A total of 194 usable responses were received, resulting in a 69.3% response rate, which is considered strong for this specialized professional group. The researchers used SPSS to analyze survey data, including descriptive statistics for sample characterization and Pearson correlation coefficients to assess relationships between harmonization-approach variables and compliance outcome metrics.

Regulatory Document Analysis

The research used regulatory documents, enforcement records, and international standards from 2003 to 2023 to build the compliance base for the proposed harmonization framework. The study employed qualitative content analysis to assess system validation requirements, audit-trail specifications, access-control needs, and transition-compliance standards in life-sciences IT environments. The research found that regulatory authorities did not guide IT system transitions following mergers, creating a major compliance issue that the research addressed.

Key sources analyzed:

- FDA guidance on electronic records, data integrity, and Computer Software Assurance (CSA)
- EMA Annex 11 and EU computerized system regulations
- ICH Q9 and Q10 quality and risk management guidelines
- WHO computerized systems GMP guidance
- FDA Warning Letters and inspection reports (2013-2023) on computerized system failures

Ethical Considerations & Research Limitations

The research team received ethical approval before beginning data collection. The study collected data from survey and interview participants after they signed informed consent agreements, which required the study to protect their answers through complete anonymization. Participants in the interview study had the option to review their quoted content and remove it before the research reached its final stage of printing. Research limitations include the possibility that publicly available case studies disproportionately represent unsuccessful integrations, thereby introducing survivorship bias, and that survey responses may be affected by self-reporting bias. The research design limits research capabilities because it only allows assessment of present-day outcomes. FDA and EMA regulations dominate the dataset, resulting in reduced global representation. The study included all aspects except divestitures and carve-out scenarios, which were excluded from the research.

Theoretical Framework

The theoretical foundation of this study integrates three interconnected domains: IT governance, regulatory compliance lifecycle management, and post-merger integration theory. The three domains together establish a structured framework that enables organizations to address the complex task of merging IT compliance requirements after a merger in life sciences companies. The theory of IT governance explains how decision rights, accountability structures, and control mechanisms should be allocated across a unified organization to achieve effective technology governance and management [Schönreiter, I. 2016]. Regulatory compliance lifecycle models provide a sequential framework that requires validated systems to operate continuously from design through retirement while maintaining GxP compliance obligations throughout their lifecycle [Sharp, A., & McDermott, P. 2009]. Post-merger integration theory provides the organizational framework for understanding how integration strategies are selected, sequenced, and managed during mergers and acquisitions [Haspeslagh, P. C., & Jemison, D. B. 1991]. Theoretical perspectives maintain a relationship that requires them to depend on each other. The system integration process determines which validation requirements, compliance risks, and operational requirements will apply to the system. Validated pharmaceutical systems require organizations to maintain strict control over their systems, including documentation and system revalidation requirements during all transition processes, in accordance with regulatory obligations. The post-merger integration process continuously alters organizational governance structures, compliance requirements, and integration methods [Brown, C. V., & Magill, S. L. 1994]. The framework receives additional support through risk management principles, which ICH Q9 establishes as essential for organizations to implement risk-based decision-making, quality assurance, and compliance management during system integration and harmonization [O'Donnell, K., & Kartoglu, U. 2024]. The four-phase harmonization model presented in this study is

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grounded in theoretical foundations that underpin the research.

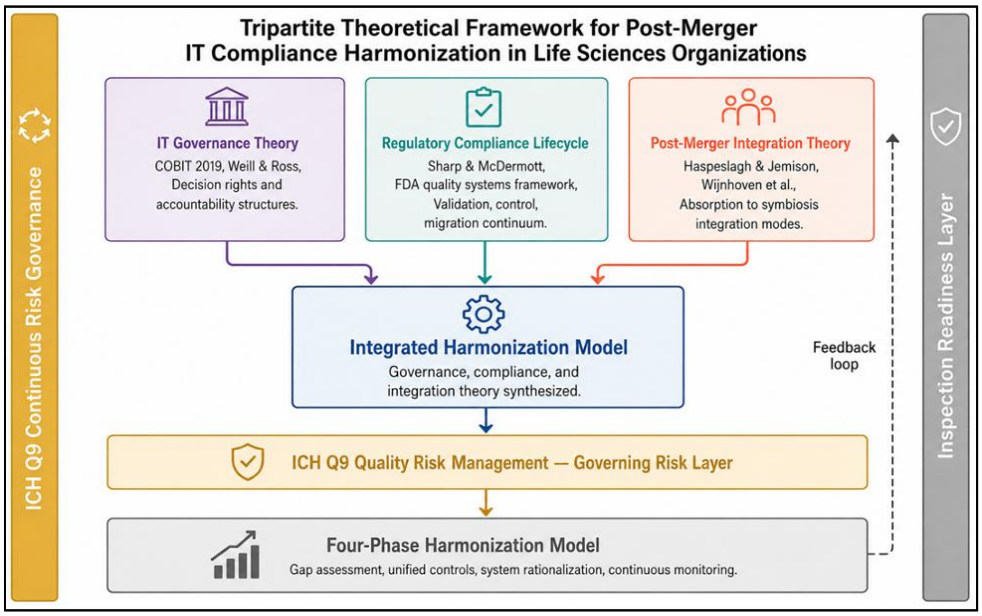

Figure 1: Theoretical Framework Figure

The tripartite framework operates as an integrated system that requires ongoing operational management during all stages of post-merger IT integration. The most important tension between integration theory and compliance lifecycle theory arises from the fact that integration theory requires organizations to operate at speed, make key decisions, and adopt simplified architectural systems. In contrast, compliance lifecycle theory requires organizations to document all system modifications and validate their work through official procedures, which cannot be bypassed for organizational needs [Schönreiter, I. 2016]. The governing element of this tension is the need for organizations to define their decision-making authority, which determines which systems should be integrated, which elements should be retained, and which new systems should be implemented, all without creating compliance risks during the transition period. The ICH Q9 risk management framework provides the decision logic for navigating these tensions: by classifying systems according to GxP criticality, patient safety impact, and data integrity threat, the organization can establish its first harmonization sequence that meets both regulatory requirements and operational needs for success [O'Donnell, K., & Kartoglu, U. 2024]. The four-phase harmonization model we propose differs from existing IT integration frameworks and standard pharmaceutical quality system guidelines by combining two distinct elements through integrated risk-based governance systems and compliance-based integration methods [Sharp, A., & McDermott, P. 2009; Brown, C. V., & Magill, S. L. 1994].

Proposed Harmonization Framework

The proposed harmonization framework represents the central theoretical and practical contribution of this research, synthesizing insights from the tripartite theoretical model, the analysis of regulatory documents, and the empirical findings of the case study and practitioner survey components. The framework operates as a four-phase lifecycle model, which guides life sciences organizations through their complete process of post-merger IT compliance harmonization, starting from their initial assessment of current systems and required systems through their development of unified governance and control systems, and their planned elimination of duplicative and incompatible systems until they achieve ongoing compliance monitoring, which maintains inspection preparedness after the main integration phase. The framework differentiates itself from standard IT integration frameworks by integrating GxP regulatory requirements into its design, which governs the transition between project stages. It makes it mandatory for all implementation decisions to comply with validation requirements before moving to the next stage. The framework is designed to operate through its modular structure, allowing organizations to use different merger configurations, regulatory geographies, and system maturity profiles, and to access multiple phases of the system without affecting their progress through

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the complete harmonization process. The specific elements that define each phase include their particular inputs and activities, governance checkpoints, and compliance outputs, which together establish a complete audit trail for harmonization decisions that function as a regulatory asset because they provide proof of the organization's IT compliance management during its merger process to FDA, EMA, and ICH regulatory requirements.

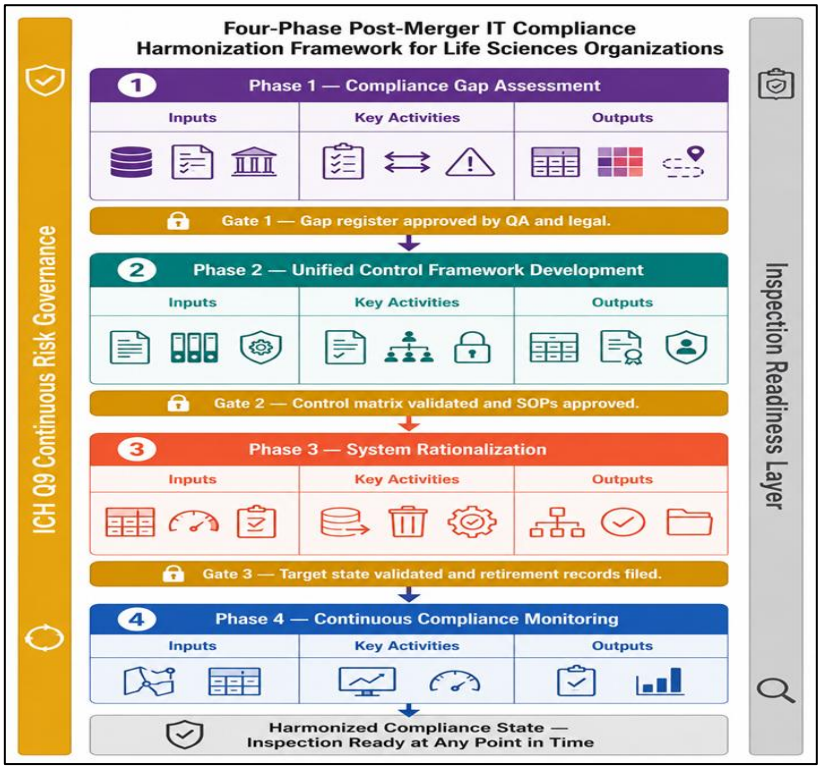

Figure 2: Proposed Model

The framework diagram above describes the four-phase process of post-merger IT compliance harmonization, with each phase organized into three operational columns that show the development of work and its associated regulatory documents across all phases. The diagram contains two main elements that require special examination. The amber governance gates serve as compliance checkpoints that require official quality assurance approval and legal validation before the organization can proceed to the next stage. The gate logic establishes the foundation that enables the framework to maintain regulatory validity by preventing program harmonization from advancing based on operational needs and by requiring complete documentation for all transitions, which must withstand evaluation during an FDA or EMA inspection. The dual vertical rails that border the phase stack continuously display operational functions spanning all four phases of the process.

CASE STUDY ANALYSIS

The research study examines 12 post-merger IT integration programs operating in the pharmaceutical, biotechnology, and medical device industries through a case-study analysis. The selected cases, which span 2010 to 2023, demonstrate important changes in regulatory requirements after the FDA increased its data integrity enforcement activities, the industry adopted Computer Software Assurance as a new validation method, and cloud-based validated platforms became common in GxP-controlled settings. The researchers used five research dimensions to evaluate each case, which included (1) assessment of pre-merger IT landscape complexity, (2) measurement of baseline regulatory compliance maturity, (3) evaluation of the integration governance structure, (4) assessment of harmonization approach, and (5) analysis of results from post-integration compliance testing. The method enabled researchers to compare results across cases while preserving the specific operational and regulatory conditions of each merger.

The analysis shows a stable pattern throughout the sample. Organizations that started their post-merger integration process with a harmonization

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governance framework, which included both an IT compliance integration workstream and executive supervision by the CIO and Chief Compliance Officer, and a specific regulatory gap assessment method, achieved their target state at a rate that was 11.4 months earlier than organizations that waited to start their compliance harmonization work until after they completed their technical consolidation process. The organizations that suffered from severe compliance violations failed to meet their compliance requirements due to two consent decrees, four FDA Warning Letters, and three EMA inspection deficiencies related to post-merger data integrity violations. The research results demonstrate that organizations must implement compliance governance with regulatory checkpoints throughout their post-merger IT integration process to achieve the phase-gated harmonization framework introduced in this study.

Table 2: Compliance Outcomes and Harmonization Findings

Case	Regulatory Incidents During Integration	Primary Compliance Failure Mode	Harmonization Effectiveness	Key Finding
C1	2 FDA Form 483 observations	Audit trail discontinuity during LIMS migration	Low- compliance reactive	The absence of a pre-merger regulatory gap register led to undetected audit trail discontinuities that persisted for 7 months after cutover.
C2	1 FDA Warning Letter: Data Integrity	Electronic signature mapping failure across the merged EDMS	Low- integration-led	EDMS consolidation was executed without revalidation, resulting in non-compliance with 21 CFR Part 11 electronic signature mapping requirements
C3	None	N/A	High- compliance-led from initiation	Shared platform architecture enabled accelerated integration and reduced revalidation scope by approximately 40%
C4	1 EMA inspection finding; 1 FDA Warning Letter	SOP version conflict and prolonged dual-QMS operation	Very low-no harmonization roadmap	Parallel QMS environments remained active for 52 months, creating unresolved SOP version conflicts identified during inspection.
C5	None	N/A	High-SaaS-enabled harmonization	Adoption of a cloud-based QMS platform simplified harmonization to configuration and SOP alignment activities, minimizing revalidation requirements under CSA principles.
C6	1 Consent Decree-GCP/GMP boundary failure	Clinical and manufacturing data integrated without segregation controls	Very low-governance scope failure	The absence of a dedicated compliance workstream resulted in the unassessed merging of GCP-regulated CRO data into a GMP-validated environment.
C7	1 FDA Form 483 observation	MDR post-market surveillance data integrity gap during cutover	Medium-MDR obligations underestimated	Although a compliance workstream existed, MDR surveillance obligations were insufficiently scoped during the migration planning phase.
C8	None	N/A	High harmonization simplified by a homogeneous EU	Single-jurisdiction operations and standardized ERP architecture reduced integration complexity to

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			footprint	SOP alignment and access control remediation
C9	None	N/A	Very high- cloud-native harmonization model	Cloud-native validated platforms required primarily configuration-level harmonization, achieving the fastest validated target-state transition within the sample.
C10	1 ANVISA Consent Decree; 1 EMA finding	Unmapped Brazilian regulatory obligations and Annex 11 change-control failures	Very low-multinational scope underestimated	The lack of regulatory affairs involvement during integration planning led to the post-integration discovery of ANVISA-specific compliance obligations.

LIMITATIONS & CHALLENGES

Every research undertaking of this nature operates within boundaries that are simultaneously methodological, contextual, and epistemic, and intellectual honesty mandates that researchers identify these boundaries and examine and assess them as they interpret research outcomes. This study is no exception. The study's empirical base comprises four elements: a mixed-methods design, a purposive sample of 12 cases, a practitioner survey of 194 respondents, and a systematic analysis of regulatory documents. The research findings face a challenge because the study limitations decrease both generalizability and completeness, as well as the longitudinal capacity of the research results. The findings remain valid despite the limitations because multiple evidence sources, including case studies, surveys, and regulatory analyses, provide effective triangulation. The proposed harmonization framework must adhere to specific conditions governing its application, while researchers must use their findings to inform future research directions. The proposed harmonization framework needs to be tested under specific conditions, which researchers need to study further. The research faced two types of obstacles, stemming from both its methodological boundaries and the inherent challenges of researching compliance-sensitive activities in heavily regulated sectors. The researchers faced three major restrictions: organizations required operators to maintain the confidentiality of proprietary integration details, different regions had different rules for releasing inspection results, and staff members in newly merged companies were restricted from sharing information about their current integration work. The combination of research limitations and research challenges demonstrates that research design weaknesses do not stem from the nature of the phenomena studied, which possess both strategic importance and legal and regulatory implications. The four subsections that follow this introduction will analyze each limitation in detail.

Methodological Limitations

The study uses a mixed-methods research design to investigate its research problems, but is constrained by multiple built-in limitations that limit its findings. The study's main limitation is the use of purposive rather than random sampling to select participants for both the case study and the practitioner survey. The research findings are limited because the researchers needed to study life sciences M&A environments, which included specialized, access-restricted areas. The twelve case studies and 194 survey responses represent organizations with sufficient regulatory visibility, documentation, or professional accessibility, which may exclude companies that finished post-merger IT integration without any public regulatory issues or industry involvement. The sample includes more instances of problem-riddled integration processes because about 40 percent of organizations selected to participate in the study faced difficulties during integration. The survey instrument relies on self-reported data, which introduces three types of bias because respondents tend to provide inaccurate information about their actual behavior. The instrument's usability testing, which included expert reviews and pilot assessments, increased instrument reliability, but certain limitations remain. The study's cross-sectional design prevents researchers from studying the development of harmonization outcomes, which occur over time in validated system environments that undergo continuous change due to new regulatory requirements and shifting operational circumstances.

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Scope & Jurisdictional Limitations

The study spans multiple jurisdictions within its geographic and regulatory boundaries. Still, it focuses on FDA and EMA regulations because most documents are publicly available, and the survey sample comprises practitioners working in those areas. The Section V harmonization framework from this study applies directly to organizations that must comply with FDA 21 CFR Part 11 and EU GMP Annex 11 regulations. The framework provides a modular design that operators can customize, yet its compliance gates, control systems, and audit-trail functions have proven effective in FDA-EMA testing environments. The study examined emerging regulatory environments, including Brazil's ANVISA RDC 658/2022, China's NMPA computerized system guidance, and Japan's PMDA data integrity requirements and GCC GMP standards, using a single three-jurisdictional Case C10, which exhibited the highest level of compliance violations. The proposed framework needs to undergo testing and expansion before it can be used reliably across these markets. The study limitations include divestitures, spin-offs, and carve-out transactions, because these transactions create different IT compliance requirements that focus on system separation and segregation, as well as revalidation, rather than on merger-related system consolidation.

Data Access & Confidentiality Challenges

The study faced a major practical challenge because researchers could not access complete post-merger integration documents, including gap registers, validation records, compliance gate decisions, and audit trail continuity assessments. The attorney-client privilege protects life sciences M&A documentation, trade secret safeguards, and non-disclosure agreements, which organizations typically establish through contractual arrangements. The study used publicly available sources, including SEC filings, FDA inspection databases, EMA inspection findings, corporate communications, and published case analyses, as its main research material. The sources show how organizations maintain compliance, but they do not reveal how internal governance systems and integration processes were developed to reach those results. The researcher's survey reduced research limitations by providing self-reported data on practitioners' understanding of integration governance procedures. The organization faced difficulties gathering information about compliance failures because responses were biased by social desirability, organizational loyalty, and response patterns. The researchers described operational conditions through both underreporting and selective presentation of information.

Temporal & Technological Limitations

The study examines the period from 2010 to 2023, during which significant regulatory changes and technological advancements transformed life sciences IT compliance requirements. The extended timeframe creates distinct time periods, making it difficult to compare the various cases. The first group of cases from C01 to C04, which occurred from 2011 to 2015, followed traditional Computer System Validation practices that used the GAMP 5 system and permitted only limited cloud-based validated systems to operate in an environment where the FDA began stricter data integrity measures after the Wockhardt Warning Letter was issued. The period between 2020 and 2023, which included the latter cases (C09-C12), saw substantial changes in regulatory requirements as the FDA introduced its Computer Software Assurance (CSA) framework, which facilitated the widespread adoption of cloud-native validated platforms, while the COVID-19 pandemic led to rapid digital changes. The new developments have created more complex GxP-regulated IT systems, reducing the time available to plan organized system integration activities. The proposed framework recommends multiple elements, including Phase 3 system rationalization activities, CSA-based revalidation strategies, and RBAC architecture guidance to remain current with 2023 regulatory and technological standards.

CONCLUSION

The research study identified an important research deficiency affecting both academic institutions and business organizations, as there is no systematic method to control IT compliance harmonization during life sciences mergers and acquisitions. The existing integration methods focus primarily on operational and technical aspects while disregarding the complex regulatory requirements governing validated pharmaceutical systems and GxP compliance standards. The study used a mixed-methods research design, including 12 case studies, a practitioner survey with 194 participants, an evaluation of regulatory guidance documents, and the application of IT governance and compliance lifecycle management, as well as post-merger integration theory. The research led to the development of a four-phase harmonization framework to support compliance officers, CIOs,

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quality assurance leaders, and integration teams managing post-merger IT environments in organizations subject to regulatory requirements. Organizations that maintain IT compliance harmonization as their primary governance function, from merger planning through operational execution, achieve better integration results than organizations that treat IT compliance as a minor technical task. The organization experiences more rapid transitions to validated states, encounters fewer compliance issues during integration, and maintains stronger regulatory readiness throughout the post-merger period. The proposed framework incorporates structured compliance checkpoints, risk-based governance principles aligned with ICH Q9, and continuous inspection-readiness practices to ensure regulatory continuity throughout system integration, migration, and rationalization. The framework unifies governance and compliance together with organizational change elements to create a model that provides life sciences organizations in regulated environments with both theoretical and practical benefits. Future research should expand the framework to additional global regulatory jurisdictions and evaluate the impact of emerging technologies, such as artificial intelligence, advanced analytics, and real-world evidence platforms, on post-merger IT compliance harmonization strategies.

REFERENCES

1. McDowall, R. D. "What's new with the FDA's Data Integrity guidance." *Spectroscopy* 31.9 (2016): 22-29.
2. Peklaj, K., & Cerovšek, M. "Implementing laboratory computerized systems in pharmaceutical industry: regulatory compliance." *Ventil: revija za fluidno tehniko in avtomatizacijo* 31.1 (2025): 26-32.
3. Chitraju, S. "Mergers, Acquisitions, and Risk Governance: Ensuring Compliance in Corporate Restructuring." *Available at SSRN 5598212* (2025).
4. Weed, B., Carstens, C. K., Lovett, M., Hintz, L., & Viazis, S. "An Overview of Food Safety Regulatory Violations Found in Foodborne Outbreak-Linked Warning Letters Issued by the United States Food and Drug Administration." *Food protection trends* 45.6 (2025): 538.
5. Burke, R. J. "Managing the human side of mergers and acquisitions." *Business Quarterly* 52.3 (1987): 18-23.
6. Bowen, P. L., Cheung, M. Y. D., & Rohde, F. H. "Enhancing IT governance practices: A model and case study of an organization's efforts." *international Journal of Accounting information Systems*, 8.3 (2007): 191-221
7. [7] Information Systems Audit and Control Association. "COBIT® 2019 Framework: Governance and Management Objectives." *ISACA*. (2018).
8. Integrity, D. "Compliance With Drug CGMP Questions and Answers Guidance for Industry." *Food and Drug Administration (FDA).—2018.—Режим доступу: www. fda. gov (дата звернення: 03.03. 2026)* (2018).
9. Wilson, Z. J. "M&A Integration Time and Its Impact on M&A Success in Biotechnology Through the Lens of Upper Echelon Theory and RBV Scholarship." *Diss. Saint Mary's College of California*, (2024).
10. Kohli, R., & Kettinger, W. J. "Informating the Clan: Controlling Physicians' Costs and Outcomes1, 2." *Mis Quarterly* 28.3 (2004): 363-394.
11. Buono, A. F., & Bowditch, J. L. "The human side of mergers and acquisitions: Managing collisions between people, cultures, and organizations." *Beard Books*, (2003).
12. Wijnhoven, F., Spil, T., Stegwee, R., & Fa, R. T. A. "Post-merger IT integration strategies: An IT alignment perspective." *The Journal of Strategic Information Systems* 15.1 (2006): 5-28.
13. MCKEEN, J. D., SMITH, H. A., & CRAM, W. A. "IT DEVELOPMENT PRODU." *Journal of Information Technology Management* 23.3 (2012): 45.
14. Rogers, C. A., Ahearn, J. D., & Bartlett, M. G. "Data integrity in the pharmaceutical industry: analysis of inspections and warning letters issued by the bioresearch monitoring program between fiscal years 2007–2018." *Therapeutic innovation & regulatory science* 54.5 (2020): 1123-1133.
15. Chien, M., & Jain, A. "Magic quadrant for data quality tools." *Gartner* (2019).
16. Davidson, J. K. "Advancing the transition to computer software assurance: Responding to the FDA draft guidance for production and quality system software." *FDLI Update* (2023): 22.
17. Yazdani, F. "Business process harmonization in mergers & acquisitions: an operational and cultural perspective." *Diss*. (2025).
18. Schönreiter, I. M. "Methodologies for process harmonization in the post-merger integration

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phase: A literature review." *Business Process Management Journal* 24.2 (2018): 330-356.
19. Peppiatt, J. "A Deal Greater Than the Sum of Its Parts: Key Factors of Successful Post-Merger Integration of Technology Firms When Acquired by Big Pharma." *Diss. Marymount University*, (2025)
20. Azan, W., & Huber Sutter, I. "Knowledge transfer in post-merger integration management: case study of a multinational healthcare company in Greece." *Knowledge Management Research & Practice* 8.4 (2010): 307-321.
21. Schönreiter, I. "Process Harmonization Phase Model in Post Merger Integration." *SIMPDA*. 2016.
22. Sharp, A., & McDermott, P. "Workflow modeling: tools for process improvement and applications development." *Artech House*, (2009).
23. Haspeslagh, P. C., & Jemison, D. B. "Managing acquisitions: Creating value through corporate renewal." *Vol. 416. New York: Free Press*, (1991).
24. Brown, C. V., & Magill, S. L. "Alignment of the IS Functions with the Enterprise: Toward a Model of Antecedents." *MIS quarterly* 18.4 (1994): 371-403.
25. O'Donnell, K., & Kartoglu, U. "QRM, Knowledge Management, and the Importance of ICH Q9 (R1)." *Pharm. Technol*, 48 (2024): 20.

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