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A Sustainable Procurement and Resilience Framework for Post-Pandemic Pharmaceutical Operations

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Abstract
This paper proposes a Sustainable Procurement and Resilience Framework (SPRF) for post-pandemic pharmaceutical operations, aligning environmental, social, and governance objectives with uninterrupted patient access. The framework integrates dual-sourcing and nearshoring with supplier segmentation and risk-adjusted inventory policies for active pharmaceutical ingredients, excipients, packaging, and cold-chain logistics. It embeds science-based decarbonization targets, hazard-aware sourcing, while ensuring compliance with GMP and broader GxP obligations across the product lifecycle. Technically, SPRF unifies process automation and process mining through a digital control tower. Standardized data models and API-first integration enable end-to-end traceability from tier-n suppliers to distribution hubs. Intelligent document processing accelerates onboarding, quality agreements, and batch-release dossiers, while rules engines automate three- and four-way matching, deviations, and nonconformance escalations. Scenario planning and stochastic safety-stock optimization balance service levels and waste, and IoT-enabled condition monitoring secures the temperature-controlled supply chain. Methodologically, SPRF follows a five-step cycle: assess, design, deploy, monitor, and improve. Assessment stress-tests demand variability, maps multi-tier concentration and geopolitical risk, and quantifies carbon footprints alongside GMP/GxP conformance. Design translates policy into canonical data, supplier scorecards, risk thresholds, and workflow controls with segregation of duties and exception pathways. Deployment uses low-code orchestration and secure APIs to automate due diligence, sustainability attestations, technical transfers, and quality documentation. Monitoring fuses events, conformance checking, and anomaly detection to trigger corrective and preventive actions. Improvement closes the loop through retrospectives, supplier development plans, and portfolio rebalancing. Expected outcomes include fewer stockouts, shorter cycle times, higher first-pass quality, and measurable reductions in total cost of ownership and product carbon footprint. Ethics and access are advanced via responsible sourcing in vulnerable geographies, anti-counterfeit safeguards, and affordability mechanisms. Governance is strengthened through immutable audit trails, role-based access, data minimization, and retention aligned to regulatory requirements. To support adoption, maturity metrics, training curricula, and change-management playbooks guide scaling across sites and partners. The framework is adaptable across small, mid, and large manufacturers, and supports humanitarian supply chains during emergencies and protracted crises globally.

Keywords: Sustainable Procurement, Pharmaceutical Resilience, GMP, GxP, Demand Sensing, Digital Control Tower, Traceability, Anti-Counterfeit, Scope-3 Emissions, Green Chemistry, Circular Packaging, Cold-Chain Logistics, Supplier Diversification, Risk-Adjusted Inventory, Total Cost of Ownership

1. Introduction & Context

The COVID-19 pandemic exposed structural fragilities across pharmaceutical supply chains, where sudden demand spikes for antivirals, vaccines, personal protective equipment, and critical care medicines collided with export controls, factory shutdowns, and severe logistics disruptions. Volatile lead times, port congestion, and airfreight capacity shocks propagated upstream, amplifying tier-2 and tier-3 supplier risks for active pharmaceutical ingredients, excipients, and packaging materials. Many firms discovered limited visibility beyond direct suppliers, opaque substitution rules, and brittle quality-transfer processes that slowed batch release and jeopardized continuity of patient access (Adereti, Toromade & Ogunsola, 2022, Toromade, Ogunsola & Adereti, 2022). Even as emergency waivers and ad hoc sourcing bridged shortfalls, the experience

highlighted the necessity of institutionalizing resilience measures that endure beyond crisis footing and that operate within stringent regulatory expectations for GMP, GDP, and broader GxP controls.

The recovery period has coincided with intensifying sustainability drivers that now shape procurement strategy as much as cost and service. Investors and regulators are pressing for transparent environmental, social, and governance performance; Scope-3 emissions accounting has moved from voluntary disclosure to a practical imperative; and circularity expectations are rising for primary and secondary packaging, solvent recovery, and end-of-life stewardship. At the same time, global health equity considerations have sharpened: ensuring equitable access across income settings is no longer a peripheral corporate responsibility pledge but a core dimension of license to operate (Elebe & Imediegwu, 2024, Farounbi, Oshomegie & Ogunsola, 2024). These forces converge in procurement, where supplier selection, logistics design, and quality requirements determine not only the probability of supply but also the embodied carbon, labor conditions, and affordability of the finished dose. The post-pandemic agenda therefore demands supply networks that are simultaneously robust, compliant, low-carbon, and socially responsible without compromising pharmacovigilance linkages, documentation integrity, or patient safety.

Against this backdrop, the problem is to architect a procurement operating model that absorbs future shocks while advancing sustainability and meeting regulatory obligations. The objective is a Sustainable Procurement and Resilience Framework that embeds dual/multisourcing and near-/reshoring where appropriate; codifies risk-adjusted inventory and capacity buffers; and formalizes digital traceability from tier-n suppliers to distribution nodes so deviations, temperature excursions, and quality events are detected early and resolved quickly. The framework should align category strategies with science-based emissions targets, require ESG and human-rights attestations with verifiable evidence, and integrate circular design criteria into sourcing and technical transfers (Elebe & Imediegwu, 2020, Imediegwu & Elebe, 2020). It must translate policy into automated workflows and controls that maintain GMP and GDP fidelity sanctions checks, supplier qualification, inspection readiness, and release documentation while optimizing service levels and total cost of ownership. Concretely, the goals are to lower stockout incidence and recovery time, reduce the carbon intensity of inbound materials and logistics lanes, improve first-pass quality and batch-release lead times, and expand equitable access through price-volume constructs and resilient last-mile options. By uniting resilience with sustainability and compliance by design, the framework positions pharmaceutical procurement to deliver uninterrupted, affordable therapies in normal operations and under stress, strengthening trust with patients, regulators, and partners across the global health ecosystem (Ezeh, *et al*., 2022, Imediegwu & Elebe, 2022).

2.1 Methodology

The study adopts a design-science methodology with iterative build–evaluate cycles. First, governance is established by defining scope, roles, and decision rights across procurement, quality (GxP), pharmacovigilance, ESG, finance, and cybersecurity. A charter codifies ethical standards, antitrust hygiene, DEI and access-equity commitments, and environmental guardrails for effluent control and take-back programs. Second, a privacy-preserving data fabric is built to integrate ERP/SRM/eQMS, production, logistics, market indices, and supplier disclosures. Differential access controls and homomorphic/federated analytics enable cross-organization risk insight without exposing sensitive PHI or trade secrets. Data are cleansed and harmonized to a golden supplier and item model; lineage, audit trails, and retention policies ensure inspection readiness.

Third, demand and capacity forecasts are produced using predictive analytics with uncertainty bands reflecting pandemic-era volatility, clinical trial ramp, seasonality, and cold-chain constraints. These projections feed a multi-tier supplier mapping that captures certifications (GMP/ISO 13485), cyber posture, geo-exposure, utilities dependency, and time-to-recover/time-to-survive metrics. Fourth, supplier segmentation combines spend criticality with contestability and sustainability maturity. Should-cost and index mapping decompose price into material, conversion, logistics, and risk premia tied to FX, resin/metals, and fuel indices, while ESG screens check AMR-relevant effluents, waste minimization, energy intensity, labor practices, and product stewardship. Fifth, scenario design generates resilient sourcing options: local–regional–global balancing, dual sourcing with calibrated shares, safety-stock policies for APIs and excipients, and alternates for single points of failure. Game-theoretic playbooks translate analytics into counter-offers aligned to indexation symmetry, SLAs (OTIF, quality documentation, deviation response), rebates, and reopeners.

Sixth, events are executed via e-sourcing with combinatorial lots that reflect process economies but enforce contestability and quality constraints. A robust, multi-objective optimizer selects awards that minimize total landed cost and cost-to-serve while bounding disruption and compliance risk. Contracting embeds clause logic from the model index sets with floors/caps and lags; MFN-lite notice-and-review; service credits; data-sharing obligations; cybersecurity controls; and environmental KPIs mirrored in a digital contract twin for automated price and SLA reconciliation. Seventh, execution visibility leverages BI dashboards and event-driven alerts from ERP/WMS/IoT to monitor OTIF, cold-chain excursions, lab deviations, CAPA cycle time, invoice–contract mismatches, cyber incidents, and supplier ESG signals. An early-warning layer fuses anomaly detection with external feeds (weather, labor unrest, public-health advisories) to trigger mitigations: buffer pulls, lane swaps, or alternate-site activation.

Eighth, corrective and preventive action is institutionalized through joint supplier kaizen, standard work for root-cause analysis, and capability building (PMI-aligned training, digital literacy, ethics, and quality culture). Performance is scored with a Supplier Performance & Resilience Index combining quality, delivery, cost, ESG, cyber hygiene, and transparency. Share adjustments and development plans tie future awards to measured improvement. Ninth, re-qualification and portfolio rebalancing occur on a cadence aligned to audit cycles and risk signals; dual-source thresholds, emergency buffers, and site transfers are recomputed from updated TTR/TTS and demand profiles. Finally, a continuous-improvement loop updates models, guardrails, and playbooks using post-event retrospectives,

invoice/index audits, and ESG assurance outcomes; results are reported on an integrated scorecard covering savings realization, variance reduction, OTIF, deviation closure, AMR-relevant effluent control, waste reduction, energy use, and equity of access commitments. The method is evaluated through pilot events in two categories (e.g., sterile packaging and cold-chain logistics), then scaled across plants using the same data canon and cockpit. Success criteria include realized savings net of cost-to-serve, fewer stockouts/expedites, shorter deviation-to-CAPA cycles, audit readiness, ESG uplift, and stronger supplier collaboration. Limitations such as data sparsity, varying local regulatory contexts, and supplier capability dispersion are mitigated with progressive disclosure, staged qualifications, and federated analytics. The resulting framework operationalizes sustainable procurement and resilience as a single, auditable system linking privacy-aware intelligence, rigorous award design, and continual supplier development to protect patient safety, preserve supply continuity, reduce environmental harm, and deliver durable value in post-pandemic pharmaceutical networks.

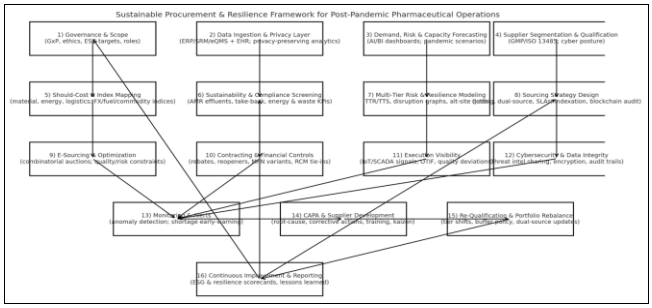

Fig 1: Flowchart of the study methodology

2.2 Industry Background & Regulatory Landscape

The pharmaceutical industry operates within one of the most stringent quality and safety regimes in the world, and procurement sits at the intersection of regulatory conformance, supply reliability, and cost stewardship. Good Manufacturing Practice and Good Distribution Practice are the cornerstone obligations within the broader GxP ecosystem, shaping how materials are sourced, qualified, transported, and released into production and market. GMP requires that active pharmaceutical ingredients, excipients, and packaging components meet validated specifications and that their suppliers are qualified through risk-based audits, quality agreements, and performance monitoring (Egemba, *et al*., 2020, Gado, *et al*., 2020). Data integrity principles (often framed as ALCOA+) apply end to end, mandating that procurement-linked records supplier change notifications, certificates of analysis, deviation reports, and batch genealogy are attributable, legible, contemporaneous, original, and accurate. GDP extends control beyond the plant gate, prescribing temperature control, segregation, and tamper-evidence during storage and transport, with route qualification and lane risk assessment to prevent excursions. Within this framework, procurement is not a transactional function but a quality-critical process: supplier selection is bound to the pharmaceutical quality system (e.g., ICH Q10), risk management (ICH Q9) informs sourcing strategies and dual-sourcing thresholds, and computerized system validation expectations (e.g., 21 CFR Part 11, EU Annex 11) govern electronic approvals, e-signatures, and audit trails used in buying and vendor management systems (Adeleke & Ajayi, 2024, Isa, 2024, Oboh, *et al*., 2024, Olufemi, *et al*., 2024, Umukoro, *et al*., 2024). Pharmacovigilance linkages further elevate expectations by tying post-market safety surveillance to lot traceability, serialization, and rapid recall capability. Serialization regimes (such as those required in the U.S. and EU) depend on accurate upstream master data and robust supplier documentation; procurement therefore curates the data and contractual mechanisms that enable safety signal investigations to trace backwards to sources and manufacturing conditions (Nwokediegwu, Bankole & Okiye, 2019, Ogunsola, 2019).

Environmental and social standards increasingly define the "license to operate" for pharmaceutical procurement alongside GxP. Environmental management systems aligned with ISO 14001 help organizations structure objectives, controls, and continuous improvement for emissions, waste, water, and chemical use across sites and supplier networks. ISO 20400 translates sustainability intent into procurement practice, offering guidance on governance, integration with category strategies, and supplier engagement, thereby operationalizing topics such as green chemistry, solvent recovery, and circular packaging (Anthony & Dada, 2020, Imediegwu & Elebe, 2020). Commitments to the United Nations Global Compact embed principles on human rights, labor, environment, and anti-corruption into supplier codes of conduct and audit criteria, informing prequalification, corrective action planning, and suspension protocols. The Science Based Targets initiative accelerates decarbonization by pushing companies to set validated targets for Scope 1, 2, and crucially Scope 3 emissions, which dominate pharma footprints through materials, logistics, contract manufacturing, and disposal (Akomea-Agyin & Asante, 2019, Awe, 2017, Osabuohien, 2019). As Scope 3 accounting matures, procurement assumes accountability for data collection (activity and supplier-specific emission factors), target deployment (category-level abatement levers such as renewable energy at suppliers, modal shifts in freight, and reduced over-specification of packaging), and contract structures that incentivize or require decarbonization. Social responsibility has also sharpened through modern slavery and human rights due diligence regimes, prompting risk-tiered supplier assessments, grievance mechanisms, and escalation pathways that are embedded into sourcing and vendor lifecycle governance (Ajakaye & Adeyinka, 2020, Bankole, Nwokediegwu & Okiye, 2020). Collectively, these frameworks move sustainability from a reporting exercise to a design constraint in procurement where choices about who to buy from, how to transport, and what technical requirements to impose directly shape environmental and social outcomes while remaining compatible with GMP and GDP.

The COVID-19 crisis provided a stress test that exposed structural vulnerabilities in global pharmaceutical supply chains and reframed resilience as a core procurement objective. One of the clearest lessons concerned active pharmaceutical ingredients: geographic concentration of API manufacturing, particularly for commoditized classes, created choke points susceptible to regional outbreaks, energy rationing, and policy shocks. Export controls and shifting national priorities disrupted accustomed flows, while capacity bottlenecks could not be alleviated quickly due to long lead times for building or transferring compliant API processes (Adereti, Toromade & Ogunsola, 2023, Nnabueze, Ogunsola & Adenuga, 2023). Procurement

learned that approved, validated second sources were often too few or non-existent, and that quality and regulatory transfer packages were not ready for rapid activation. As a result, dual or multi-sourcing strategies, earlier technical engagements with alternates, and pre-negotiated technology transfer playbooks became central to category plans, with clear triggers tied to market signals and demand variability (Adeleke & Ajayi, 2024, Davies, *et al*., 2024, Egbemhenghe, *et al*., 2024).

Cold chain fragility was another critical lesson. The rapid scale-up of temperature-sensitive products, including mRNA vaccines, collided with finite specialized transport assets, dry ice constraints, and limited lane qualifications. Many organizations found their visibility into real-time condition monitoring insufficient and their exception handling reactive rather than predictive. Post-pandemic procurement strategies now emphasize IoT-enabled temperature and shock sensors integrated with qualified shippers, dynamic lane risk scoring, and contractual arrangements that allocate liability and remediation responsibilities transparently (Anthony & Dada, 2022, Ogunsola, 2022). Investments in near-shore and regional fill-finish capacity, along with diversified packaging and cold pack suppliers, are increasingly justified not only by service risk reduction but also by Scope 3 emissions benefits from shorter routes and lower wastage.

Trade dependencies extended beyond APIs and cold chain into packaging components, sterile consumables, and single-use systems for biologics manufacturing. Shortages of stoppers, vials, filters, and bags revealed how "indirect" materials can be rate-limiting steps when demand surges. Procurement learned to treat these components as strategic categories requiring demand-capacity alignment, hedging contracts, and collaboration with suppliers on tooling and raw material security (Elebe & Imediegwu, 2021, Imediegwu & Elebe, 2021). Customs slowdowns and shifting tariff regimes added latency and unpredictability; proactive trade compliance, alternate routing, and bonded inventory arrangements emerged as risk mitigations. These lessons reinforced the importance of digital traceability from tier-n suppliers to distribution hubs: the ability to see upstream constraints, predict downstream service risk, and act before shortages manifest at the patient interface. Figure 2 shows conceptual framework for hospital sustainable supply chain management presented by Duque-Uribe, Sarache & Gutiérrez, 2019.

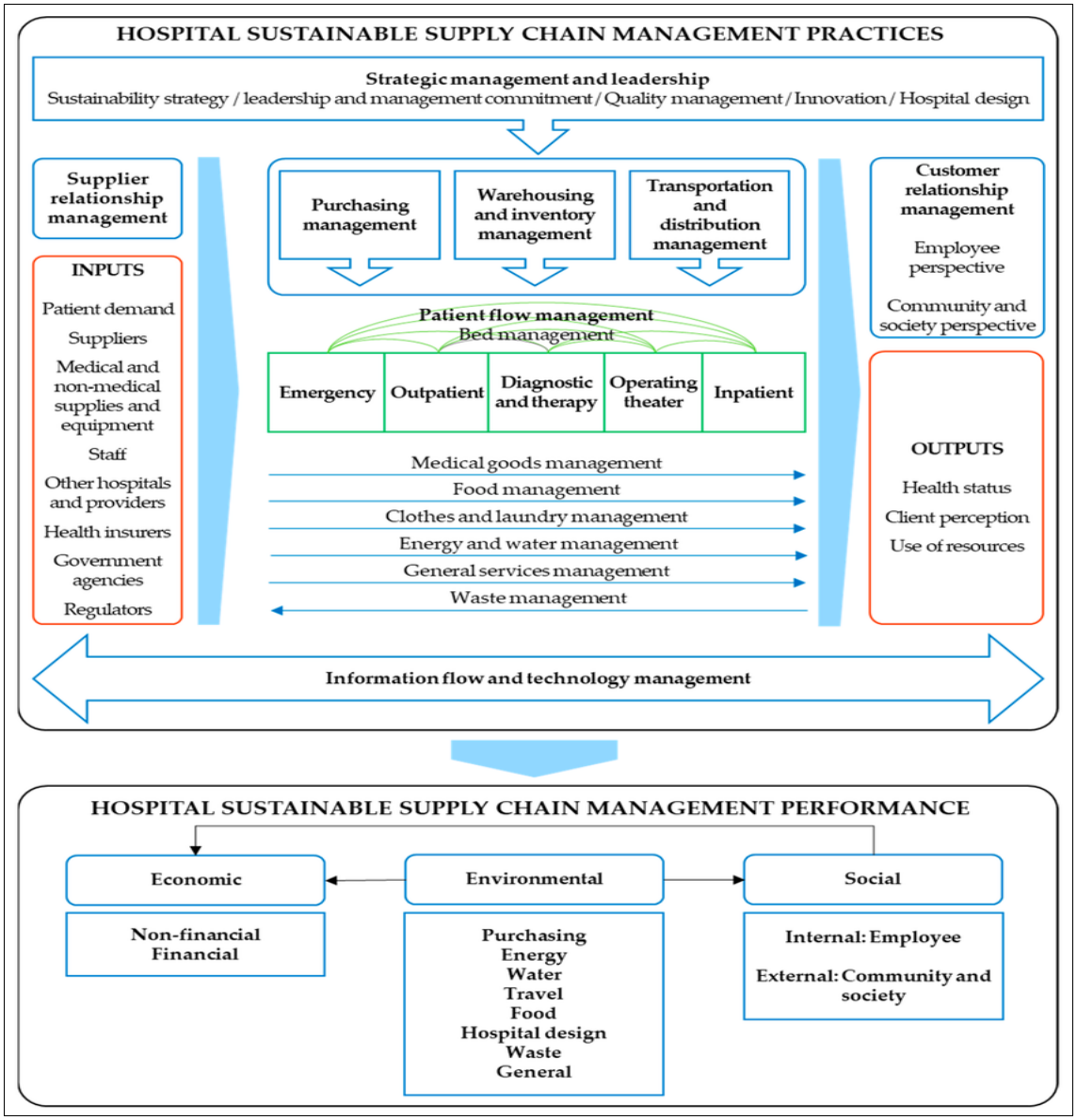

Fig 2: Conceptual framework for hospital sustainable supply chain management (Duque-Uribe, Sarache & Gutiérrez, 2019)

Crucially, resilience and sustainability are not in tension when designed coherently. Dual-sourcing and regionalization, while initially cost-intensive, can lower total risk and reduce emissions by avoiding long-haul airfreight and lowering spoilage. Green chemistry substitutions and solvent recovery can lessen both environmental impact and supply volatility for hazardous inputs. Circular packaging initiatives reduce dependency on virgin materials that proved scarce under pandemic conditions, while extended producer responsibility schemes can be integrated into logistics contracts that also enhance reverse visibility for recalls and pharmacovigilance (Ajakaye & Adeyinka, 2022, Okiye, Ohakawa & Nwokediegwu, 2022). ISO 20400's emphasis on aligning procurement with organizational strategy provides a scaffold for integrating these dimensions without losing sight of GMP/GDP compliance; for example, specifying recyclable materials while maintaining validated barrier properties, or switching transport modes only on lanes with proven temperature stability.

From a regulatory standpoint, agencies maintained and in some cases tightened expectations during the pandemic, even as temporary flexibilities were granted. The lasting implication is that resilience measures must be "compliance by design." Supplier qualifications, quality agreements, and change controls must contemplate fast activation of alternates without compromising validation; documentation systems must support remote audits and e-signatures with strong identity proofing; and GDP-compliant exception management must translate sensor alarms into documented CAPA trails (Ezeh, *et al*., 2023, Obadimu, *et al*., 2023, Oyasiji, *et al*., 2023). Pharmacovigilance systems expect rapid, accurate lot-level recall capability, which depends on procurement's stewardship of master data, serialization attributes, and contract clauses that enforce timely data sharing. As ESG and decarbonization commitments harden, auditors and investors will increasingly test whether sustainability claims are backed by procurement controls, supplier attestations, and measurable outcomes rather than aspirational statements (Adeleke, Olugbogi & Abimbade, 2024, Ikese, *et al*., 2024, Ojuade, *et al*., 2024).

In sum, the industry background and regulatory landscape dictate that pharmaceutical procurement operate as a quality-anchored, sustainability-aware, and digitally enabled discipline. GxP obligations and pharmacovigilance linkages set the non-negotiable baseline: every sourcing and logistics decision must preserve product identity, strength, quality, and purity while enabling rapid safety response. Environmental and social standards ISO 14001, ISO 20400, the UN Global Compact, and SBTi supply the governance and measurement scaffolding that turns sustainability into contractual and operational reality (Elebe & Imediegwu, 2020). The COVID-19 experience clarified where the system breaks under stress concentrated APIs, fragile cold chain, and opaque trade dependencies and illuminated practical remedies that belong in procurement design: qualifying alternates in advance, instrumenting temperature-controlled logistics, digitizing traceability, and aligning category strategies with decarbonization and equity goals. A sustainable procurement and resilience framework for the post-pandemic era therefore begins by internalizing these obligations and lessons, building capabilities that are resilient by architecture and sustainable by default, and ensuring the data and contracts exist to prove both to regulators and to society (Ogunyankinnu, *et al*., 2022, Oyeyemi, 2022).

2.3 Sustainable Procurement Principles

Sustainable procurement in post-pandemic pharmaceutical operations must be grounded in a coherent set of principles that reconcile regulatory rigor with environmental stewardship and social responsibility, while preserving continuity of patient access. A practical way to operationalize this ambition is to embed the "Avoid-Reduce-Substitute-Compensate" hierarchy into category strategies, technical specifications, and supplier contracts, complemented by green chemistry priorities and circular packaging design. "Avoid" begins upstream in the demand signal and the bill of materials: eliminate unnecessary materials, redundant secondary packaging, and over-engineered specifications that add cost and carbon without improving safety or efficacy (Nwokediegwu, Bankole & Okiye, 2021, Obadimu, *et al*., 2021). Cross-functional reviews with quality, engineering, and regulatory affairs help identify where historical requirements can be right-sized without compromising GMP or GDP. "Reduce" targets intensity per functional unit, driving leaner pack formats, lighter materials, and optimized transport modes; in logistics, that may mean shifting from expedited airfreight to qualified ocean or rail lanes where stability data allows. "Substitute" focuses on safer solvents, lower-impact excipients, and recycled or bio-based materials that meet validated barrier and sterility properties; it also encourages modular packaging components that improve reuse and refurbishability for devices or cold-chain shippers (Ajayi & Akanji, 2022, Isa, 2022). "Compensate," the least preferred option, addresses residual emissions and social impacts that cannot be engineered out in the near term, through credible offsets, insetting with supply partners, or investments in community health infrastructure tied to access commitments. Applying this hierarchy systematically ensures that decarbonization and waste minimization are treated first as design problems and only lastly as accounting exercises (Elebe & Imediegwu, 2024, Nwanko, *et al*., 2024).

Green chemistry translates substitution into concrete decision rules. Procurement, working with R&D and manufacturing science teams, can specify solvent selection guides that privilege low-toxicity, low-volatility options, encourage solvent recycling systems, and require supplier disclosure of process mass intensity and energy sources. For APIs and key intermediates, dual-sourcing strategies can favor routes with lower hazardous reagent dependency and better yield-to-waste ratios, provided quality equivalence and regulatory filings support the change. Circular packaging complements these efforts by designing for reduction, recyclability, and in some cases returnability (Ajakaye & Adeyinka, 2023, Okiye, Ohakawa & Nwokediegwu, 2023). Primary packaging must maintain integrity and compatibility, but secondary and tertiary packaging provide ample scope: right-sized cartons, mono-material laminates where feasible, recycled content targets for corrugate and plastics, and standardized footprints that improve pallet density and reduce dunnage. For temperature-controlled lanes, qualified reusable shippers with IoT sensors, coupled with take-back logistics and refurbishment SLAs, can cut both spoilage and emissions. Specifications should include end-of-life guidance that aligns with local recycling capabilities and extended producer responsibility requirements, converting

sustainability intent into enforceable vendor deliverables (Akande, *et al*., 2023, Akinbode, *et al*., 2023, Chukwuemeka, Wegner & Damilola, 2023).

Supplier ESG due diligence becomes the mechanism for translating these principles into everyday purchasing behavior. Pharmaceutical companies bear responsibility not only for product quality but also for the human rights and environmental practices embedded in upstream operations. Effective diligence starts with risk segmentation: geography, sector, and material criticality inform depth and frequency. On human rights, procurement should require verifiable policies prohibiting forced and child labor, freedom of association, non-discrimination, and safe working conditions; where risk is elevated, third-party social audits, worker voice mechanisms, and corrective action plans are prerequisites for qualification (Ajakaye & Lawal, 2024, Egemba, *et al*., 2024). Waste management expectations must cover hazardous and non-hazardous streams, with permits, manifests, and treatment certificates tied to batch genealogy for materials that contact product or environment. Water stewardship is critical in solvent-intensive and biotech processes: suppliers report withdrawal volumes, stress basin context, discharge quality parameters, and reuse rates; high-risk geographies trigger tighter thresholds and improvement projects. Energy disclosures include fuel mix, electricity sourcing, and efficiency programs; long-term agreements for renewable power or onsite generation at key suppliers can be enshrined in contracts with shared economics (Adeshina & Ndukwe, 2024, Isa, 2024, Joeaneke, *et al*., 2024, Olufemi, *et al*., 2024). To make diligence actionable, procurement integrates these ESG attributes into vendor master data and scorecards, weighting them alongside service and quality. Gate conditions such as valid environmental permits, grievance mechanism evidence, or renewable energy milestones become operational privileges: inability to demonstrate compliance suspends PO issuance or invoice acceptance until remediation is verified. This approach prevents ESG from becoming a parallel paperwork stream and instead fuses it with the transactional system of record. Figure 3 shows Supply Chain Resilience Framework presented by Hanke & Krumme, 2012.

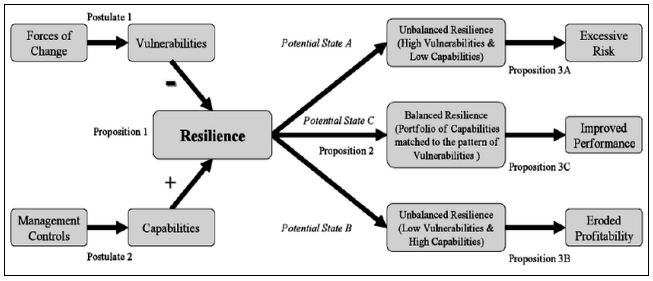

Fig 3: Supply Chain Resilience Framework (Hanke & Krumme, 2012,)

Balancing Total Cost of Ownership with lifecycle carbon and social impact reframes value in a way that aligns CFO scrutiny with sustainability outcomes. Traditional TCO captures price, logistics, inventory, quality failures, and administrative burden across the lifecycle of a purchase; in pharmaceuticals, it should also include regulatory change costs, batch release delays, and risk capital for single-source dependencies. Extending TCO to incorporate lifecycle carbon anchored in supplier-specific emission factors where possible and social externalities reveals trade-offs that unit price obscures (Alade, *et al*., 2024, Obadimu, *et al*., 2024). For example, a cheaper vial from a distant supplier might carry higher freight emissions, longer lead times, and increased buffer stock, eroding working capital and resilience; a regional source with recycled glass content could lower Scope 3 emissions and spoilage risk while improving agility, even at a higher unit cost. Social impact, while harder to monetize directly, influences regulatory and reputational risk and can be proxied through audit findings, remediation success rates, and community engagement metrics in vulnerable geographies. Decision frameworks can weight these dimensions explicitly, with category councils setting guardrails for instance, a maximum lifecycle carbon per delivered dose, or a minimum social compliance score for award eligibility. Contracts can incorporate outcome-based incentives: price escalators tied to renewable energy adoption at supplier sites, shared savings for packaging weight reductions, or bonuses for validated improvements in waste or water intensity (Ajayi & Akanji, 2023, Oyeyemi & Kabirat, 2023).

Operationalizing these principles requires data, governance, and change management. Data pipelines collect ESG attributes and carbon factors at the supplier and product levels; where primary data is unavailable, category averages are used with a plan to improve specificity over time. Governance bodies adjudicate material substitutions to ensure GMP and pharmacopoeial compliance, and quality agreements incorporate sustainability clauses alongside traditional change control (Adeleke & Baidoo, 2022, Oyeyemi, 2022). Procurement technology supports guided buying that nudges requesters toward lower-impact options within validated catalogs, while workflow rules enforce ESG gate checks during onboarding and at renewal. Supplier development programs pair expectations with capability building, offering templates for water audits, energy efficiency playbooks, and packaging redesign sprints. Where the hierarchy recommends Avoid or Reduce, the business unit's planning and forecasting processes must adapt demand smoothing, order consolidation, or alternative pack sizes may be needed to capture benefits without stockouts (Aniebonam, 2024, Ogunsola, 2024, Udensi, Akomolafe & Adeyemi, 2024). Figure 4 shows Conceptual Framework presented by Aigbogun, Ghazali & Razali, 2014.

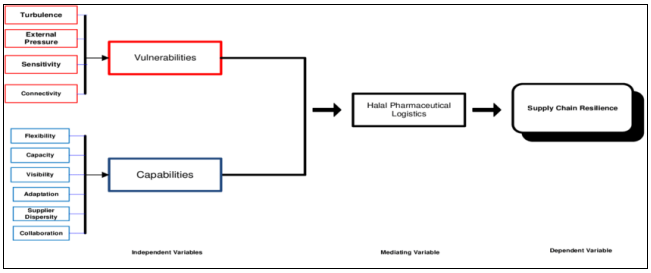

Fig 4: Conceptual Framework (Aigbogun, Ghazali & Razali, 2014)

These principles also strengthen resilience rather than trade against it. Avoiding non-value-adding complexity simplifies supply and reduces failure points. Reducing weight and volume improves freight flexibility and lowers the risk that capacity shocks strand orders. Substituting hazardous or rare inputs with safer or more abundant ones lowers exposure to regulatory crackdowns and geopolitical scarcity. Circular

approaches create reverse visibility that can double as recall channels, enhancing pharmacovigilance responsiveness. When lifecycle carbon and social performance are baked into TCO, category strategies naturally favor closer, cleaner, and better-governed supply nodes features that also shorten recovery times and improve inspection readiness (Elebe & Imediegwu, 2020, Imediegwu & Elebe, 2020). In practice, the same data and controls used to qualify suppliers on ESG metrics feed risk scoring for business continuity planning, making resilience and sustainability facets of one governance system.

There are constraints and trade-offs. Some green chemistry substitutions demand lengthy validation and regulatory filings; certain circular packaging innovations may be limited by sterilization compatibility or recyclability infrastructure; and supplier ESG data quality can be uneven, particularly among small and medium enterprises in emerging markets. Mitigations include tiered roadmaps that pilot changes in low-risk products first, regulatory engagement to pre-clear acceptable ranges of materials, and pooled industry programs that standardize disclosures and audit protocols to lower supplier burden (Nwokediegwu, Bankole & Okiye, 2022, Okiye, Ohakawa & Nwokediegwu, 2022). Contracts can share transition costs where long-term benefits are clear, while internal capital allocation recognizes that early investments in tooling, return logistics, or renewable energy PPAs at strategic suppliers unlock recurring operating benefits.

Ultimately, sustainable procurement principles become durable when they inform daily trade-offs under real constraints. The "Avoid-Reduce-Substitute-Compensate" hierarchy disciplines design choices; green chemistry and circular packaging translate ideals into specifications that survive audits; supplier ESG due diligence ties social and environmental accountability to operational privileges; and an expanded TCO lens ensures that lifecycle carbon and social impact are counted alongside cash costs. When embedded into systems, contracts, and metrics, these principles produce medicines that reach patients reliably with a smaller footprint and stronger social license an outcome worthy of the lessons learned in the post-pandemic era (Ezeh, *et al*., 2022, Gado, *et al*., 2022, Imediegwu & Elebe, 2022).

2.4 Resilience Design & Risk Management

Resilience in post-pandemic pharmaceutical procurement is the disciplined capability to absorb shocks, adapt operations, and recover swiftly without compromising patient safety, regulatory compliance, or affordability. Designing for resilience begins with supply architecture and extends through quantitative risk models, inventory policies, and action playbooks that are rehearsed not just written. The structural backbone is dual and multi-sourcing, near- or reshoring where it makes sense, and rigorous mapping of supplier tiers beyond immediate counterparties. For active pharmaceutical ingredients and critical excipients, pre-qualified alternates with validated analytical methods and aligned quality agreements reduce single-point fragility; for sterile packaging and single-use systems, secondary suppliers with tooled capacity and raw-material commitments prevent rate-limiting shortages (Ajakaye & Lawal, 2024, Sidney, 2024). Nearshoring and reshoring are evaluated not as ideology but as portfolio options: when total delivered cost, service risk, and lifecycle carbon are modeled together, regional fill-finish or packaging lines can outperform distant sources, especially for temperature-controlled products where lane stability and spoilage dominate. Tier mapping looks past tier-1 to sub-tier chemical producers, film and resin makers, stopper elastomer suppliers, and logistics subcontractors. The map is a living graph with attributes country exposure, transport nodes, critical utilities, and substitution constraints so that when a port closes or a region faces power rationing, exposure is immediately quantifiable and mitigations are triggered.

Risk scoring translates mapped exposure into prioritized action. A composite score blends geopolitical, quality, capacity, cyber, and climate dimensions, each with measurable indicators. Geopolitical risk covers export controls, sanctions dynamics, tariff volatility, and conflict probability; ingestion of external indices is combined with internal trade compliance events to keep the signal fresh. Quality risk arises from audit findings, CAPA effectiveness, deviation frequency, and data-integrity maturity; suppliers with chronic repeat observations or sluggish CAPA closure see elevated thresholds for order release and tighter inspection sampling plans (Anthony, *et al*., 2019, Ogunsola, 2019). Capacity risk measures effective throughput versus demand variability, tooling changeover times, and reliance on scarce inputs; leading indicators include order acceptance lag and forecast bias. Cyber risk considers third-party security posture, incident history, and connectivity into shared portals; in a world of e-signatures and serialized traceability, ransomware upstream can cascade into batch-release delays. Climate risk integrates acute hazards (flood, wildfire, storm surge) at supplier sites and along logistics lanes with chronic stresses such as heat trends affecting cold chain reliability; facility-level geolocation tied to hazard maps enables precise mitigation planning. Scores are not static: they adjust with event feeds, inspection outcomes, and macro signals, and they directly inform operating privileges such as requiring pre-ship inspections, raising safety stocks, or constraining order concentration.

Inventory and buffer strategies provide temporal resilience when structural mitigations cannot fully remove risk. Pharmaceutical portfolios span stable generics, seasonally spiking therapies, and launch products with uncertain uptake; a single safety-stock rule will either waste capital or leave patients exposed. Stochastic safety stock based on service level targets explicitly models demand and lead-time distributions rather than point averages (Aniebonam, 2024, Ogunsola, Oshomegie & Farounbi, 2024). For APIs with long and variable lead times, safety stock incorporates supplier capacity curves and yield variability; for cold-chain biologics, it factors temperature excursion risk and lane delay distributions. Multi-echelon optimization spreads buffers where they are most protective per unit of capital placing inventory at regional hubs for fast demand capture while maintaining upstream raw material reserves for rapid replenishment. Time buffers complement stock: regulatory-ready technical transfer packages, pre-approved label variants for alternate pack sites, and flexible quality agreements reduce the calendar time to activate alternates (Elebe & Imediegwu, 2023, Imediegwu & Elebe, 2023, Udensi, Akomolafe & Adeyemi, 2023). Contractual buffers matter as well: option clauses for surge capacity, committed logistics space during known seasons of stress, and hedged allocation for scarce components like filters or stoppers. To

keep buffers from complacency, target service levels are reviewed quarterly against observed variability and patient impact, with process mining linking stockouts and near-misses to upstream events so parameters evolve with reality.

Pandemic playbooks institutionalize response under extreme uncertainty. They define triggers, roles, and rehearsed actions for waves of demand spikes, workforce constraints, and border closures. Triggers can include WHO declarations, regional ICU occupancy thresholds, or vendor absenteeism rates; crossing a trigger escalates governance from business-as-usual to crisis cadence with daily tiered stand-ups. The playbook pre-positions supplier development squads to accelerate alternate qualification, deploys mobile audit kits for remote quality assessment, and activates emergency logistics (chartered lanes, military corridors where permitted) with pre-negotiated rates (Ajakaye, *et al*., 2023, Bankole, Nwokediegwu & Okiye, 2020). It also outlines ethical frameworks for allocation when supply is constrained, integrating equitable access commitments with regulatory obligations and public health guidance. Crucially, the playbook is not procurement-only: it binds manufacturing, quality, regulatory affairs, pharmacovigilance, and commercial so that changes to sourcing routes, pack formats, or distribution priorities remain compliant and traceable. Post-event retrospectives feed a continuous improvement loop what signals were early and reliable, where did documentation stall, which buffers proved most cost-effective and the lessons become updates to rules, contracts, and training.

Execution mechanisms knit these strategies into daily operations. Dual-source policies are encoded in rules no more than a specified concentration with a single supplier unless a waiver is signed at a defined executive level and purchase allocation automatically rebalances with score shifts. Near/reshoring decisions are embedded in category strategies with TCO plus lifecycle carbon and service risk modeled side by side; approved playbooks specify when to switch modes (ocean to air) or nodes (regional DCs) based on detected disruption bands (Aniebonam & Aniebonam, 2023, Okiye, Nwokediegwu & Bankole, 2023). Supplier tier mapping is maintained through onboarding disclosures, periodic attestations, and third-party data enrichment; any change in a tier-2 critical input triggers a mini change-control process to reassess risk and documentation impacts. Composite risk scoring is computed per supplier, site, and lane, and is visible in buyer workbenches and supplier scorecards; thresholds drive automatic holds or escalated approvals for POs, receipt acceptance, or payment release when risk exceeds appetite. Cyber and climate elements feed vendor lifecycle stages high cyber risk may restrict portal access to read-only and impose manual verification of bank changes; elevated climate risk may require alternate routes or seasonal inventory uplifts.

Quantitative rigor is balanced with human judgment through structured reviews. Monthly risk councils examine outliers and trends, adjudicating investments such as secondary tooling, renewable energy PPAs at strategic suppliers, or installing additional IoT telemetry on fragile lanes. These forums connect risk spend to resilience outcomes by reviewing key indicators: supplier on-time in full, cold-chain excursion rates, deviation recurrence, and service levels during micro-disruptions like port strikes (Ajakaye, *et al*., 2023, Okiye, Ohakawa & Nwokediegwu, 2023). Where models show persistent over-conservatism excess inventory without commensurate risk the council authorizes parameter relaxation; where near-misses cluster, it tightens controls or accelerates sourcing of alternates. The council also aligns resilience with sustainability, approving shifts that lower both risk and emissions, such as moving to rail on validated corridors or adopting reusable shippers with managed reverse logistics.

People and process readiness are as vital as models. Training equips buyers and quality liaisons to interpret risk dashboards, understand when a waiver is defensible, and when a hold is mandatory. Supplier engagement transforms transparency from a compliance demand into a shared advantage: joint risk assessments, tabletop exercises for pandemic scenarios, and co-funded projects to eliminate shared bottlenecks build trust and shorten reaction times. Contracts codify the spirit of collaboration with clear data-sharing obligations, cyber incident notification windows, climate-hazard disclosures, and penalties or incentives tied to resilience metrics. Communication plans ensure that during disruption, suppliers and internal stakeholders receive concise, role-specific guidance what has changed, how to operate, and where to escalate reducing noise and decision paralysis (Okiye, 2021).

Measurement closes the loop. Resilience cannot be asserted; it must be evidenced. Dashboards track concentration by category and critical material, the proportion of spend dual-sourced, activation time for alternate suppliers, and the percentage of supplier sites with climate and cyber risk remediations in place. Inventory health reports show stochastic safety-stock adherence, stockout and backorder rates, and write-off trends to ensure buffers are right-sized. During incidents, leading indicators lane delay percentiles, sensor alarm frequencies, supplier acceptance lag are monitored against predefined bands that map to playbook actions (Aniebonam & Aniebonam, 2024, Udensi, Akomolafe & Adeyemi, 2024). Post-incident, the factual narrative is reconstructed from immutable logs: when scores shifted, which gates held, who overrode with what justification, and how long each stage took. These facts support both regulatory defensibility and internal learning.

The most important insight from the pandemic is that resilience is a system property, not a single tactic. Dual and multi-sourcing without tier visibility still leaves hidden choke points. Nearshoring without demand modeling can strand capacity. Safety stock without playbooks decays into expensive comfort blankets. A sustainable resilience design binds architecture, analytics, and action: diversified, transparent networks; composite risk scoring that updates with the world; buffers calculated from variability and validated against patient impact; and rehearsed, ethical responses when uncertainty spikes (Elebe & Imediegwu, 2021, Gado, *et al*., 2021). When these elements are embedded in procurement governance and quality systems, pharmaceutical organizations can face the next shock be it geopolitical, climatic, cyber, or epidemiological with speed, compliance, and a steady commitment to patient access.

2.5 Digital Architecture & Data Foundations

A sustainable procurement and resilience framework for post-pandemic pharmaceutical operations depends on a digital architecture that unifies visibility, evidence, and action across quality, logistics, and sourcing. The organizing concept is a digital control tower that ingests multi-tier signals, reasons over them with process mining and

conformance checking, and orchestrates responses through secure, policy-aware integrations. Rather than a single application, the control tower is a federated layer that sits above enterprise systems and partner platforms, converting disparate transactions into coherent, risk-aware decisions. It renders end-to-end status from tier-n suppliers to distribution nodes, exposes impending bottlenecks, and proposes mitigations aligned to GMP/GDP constraints and sustainability targets (Bankole, Nwokediegwu & Okiye, 2021, Egemba, *et al*., 2021). In practical terms, it provides role-specific workspaces buyers, quality leaders, logistics planners, pharmacovigilance analysts on top of the same canonical truth, so escalation and remediation are based on consistent facts, not reconciled spreadsheets.

Process mining and conformance checking give this tower its evidence engine. Event logs from ERP, quality management, laboratory information, warehouse, and transportation systems are normalized and stitched along correlation keys so the "as executed" flows can be reconstructed for APIs, excipients, packaging, and finished goods. Mining quantifies cycle times, rework loops, and variance hotspots; conformance checking compares these traces against validated procedures and standard operating workflows, flagging deviations such as invoices posted without corresponding goods receipts, temperature excursions not acknowledged within required windows, or supplier changes applied outside change-control gates (Awe, Akpan & Adekoya, 2017, Osabuohien, 2017). In a resilience context, the same analytics are used predictively: if lead-time distributions drift or inspection queues grow beyond control bands, the system raises risk posture for affected categories, invites pre-ship inspections, or pre-allocates alternate lanes. Because each alert carries the exact event lineage and rule evaluation that produced it, quality and regulatory teams can act quickly without compromising documentation fidelity.

At the heart of the architecture is a canonical data model that stabilizes semantics across organizations and partners. The supplier entity encompasses corporate identity, beneficial ownership where required, site-level attributes, banking coordinates, certifications, audit history, ESG attestations, sanctions screening status, and lifecycle states such as approved, probation, or suspended. The API batch entity links process route, lot genealogy, critical process parameters, deviation references, and batch-level release status, making it possible to trace how upstream variability propagates into lead time and quality risk (Akpan, Awe & Idowu, 2019, Ogundipe, *et al*., 2019). Certificates of Analysis and Certificates of Conformity are modeled as first-class artifacts rather than attachments: their test panels, methods, specifications, signatories, and validity periods are structured to support automated checks, selective redaction for sharing, and rapid recall investigations. The lane entity represents a point-to-point path including mode, carriers, handoff nodes, qualified packaging, and stability constraints while lane-risk captures dynamic attributes such as delay percentiles, excursion frequency, weather and climate hazards, labor unrest signals, and regulatory choke points. Together, these canonical objects provide the substrate for both operational execution issuing POs only to active, screened suppliers on validated lanes and analytics prioritizing decarbonization initiatives by lane emissions intensity or identifying suppliers whose batch variability drives inspection backlog.

Traceability is the connective tissue that makes the model actionable. IoT devices on cold-chain shippers and in storage areas stream temperature, humidity, shock, and tilt readings with cryptographic device identity and clock synchronization so GDP evidence stands up in audits. Serialization at the unit or aggregation level, aligned with jurisdictional requirements, binds physical product to digital tokens; QR or 2D DataMatrix codes anchor rapid verification at handoffs and accelerate downstream pharmacovigilance when safety signals surface (Akinola, *et al*., 2024, Bobie-Ansah, Olufemi & Agyekum, 2024, Ikese, *et al*., 2024, Osabuohien, 2024). For upstream materials, QR-linked CoA/CoC allow receiving teams and quality to resolve ambiguities without email ping-pong, and they enable rule-driven acceptance in-tolerance lots flow, out-of-tolerance lots auto-create CAPA cases with all requisite attachments. Immutable logs implemented via append-only storage with hash chaining or ledger technologies record every status change, rule decision, override, and signature. This creates non-repudiation across procurement and logistics while decoupling audit evidence from operational databases, preserving performance and discovery integrity.

Secure APIs are the arteries of the architecture, offering stable, versioned contracts for partners and internal systems. Authentication uses phishing-resistant methods for people and mutual TLS with short-lived certificates for services; authorization mixes role-based and attribute-based policies so access can depend on context risk score, spend amount, data sensitivity, or geography. Payloads are schema-validated at the edge, personally identifiable and bank data are field-encrypted or tokenized, and idempotency keys prevent duplicates during retries (Odezuligbo, Alade & Chukwurah, 2024, Oyeyemi, Orenuga & Adelakun, 2024, Taiwo, Akinbode and Uchenna, 2024). For legacy endpoints, mediation services or an ESB translate canonical payloads to system-specific formats while preserving correlation identifiers and policy metadata. Webhooks and event topics let suppliers subscribe to order and status updates and publish signals advanced shipping notices with embedded telemetry, dispute creation, document updates back into the core flow. Observability spans traces, metrics, and structured logs; dashboards surface latency, error budgets, data quality, and control health so reliability is managed explicitly.

Data quality and stewardship are embedded, not afterthoughts. Golden-record management de-duplicates suppliers and sites using deterministic keys and probabilistic match, with survivorship rules and lineage that explain which source won each attribute. Validation services enforce business invariants no PO to a supplier lacking a current CoA or ESG attestation, no lane assignment without active qualification and generate remediation tasks when rules fail. Reference data currencies, units, tax codes, stability classes is centrally governed and cached close to where decisions occur (Ayobami, *et al*., 2024, Davies, *et al*., 2024, Eyo, *et al*., 2024, Isa, 2024). Where primary emission factors or water/waste data are unavailable from suppliers, category averages are used with confidence scores, and contracts define a glidepath to supplier-specific data to improve Scope-3 precision. The result is a data foundation that is both pragmatic and progressive, fit for immediate control needs and able to mature as partners' capability improves.

The control tower's intelligence improves as it learns from its own operations. Process mining insights feed rule tuning: if three-way match failures cluster around certain invoice layouts, IDP models are retrained and suppliers receive format guidance; if approvals systematically breach SLAs at a threshold, parallelization or delegation rules are introduced. Lane-risk models incorporate IoT histories, weather forecasts, and geopolitical signals to produce time-varying risk scores that drive packing choices, mode switches, or temporary safety-stock uplifts (Awe & Akpan, 2017). Batch-level variability seen in CoA trends can trigger targeted supplier development, route changes to greener or more robust processes, or revision of sampling plans. All of these adjustments are deployed like software: versioned, tested against masked production data, and rolled out with feature flags and rollback paths to protect GMP compliance.

Sustainability is not bolted on but encoded in the same primitives. Supplier objects carry renewable energy commitments and progress; lane objects carry emissions factors by mode and route; API batch objects carry solvent use and recovery rates. The tower can therefore calculate lifecycle carbon alongside cycle time and service risk for any sourcing or logistics choice, making it possible to optimize for patient access, cost, and footprint simultaneously. When the system recommends nearshoring a fill-finish step, it can show not just lead-time and spoilage benefits but also emissions reductions; when it flags a high-risk lane, it can propose a rail alternative that lowers both delay probability and carbon intensity, contingent on validated stability (Ogunyankinnu, *et al*., 2024, Okon, *et al*., 2024, Olulaja, Afolabi & Ajayi, 2024).

Security and compliance flow through this fabric. Every rule evaluation produces an explainability payload inputs used, policies fired, tolerances applied hashed and linked to the transaction so auditors can replicate decisions. E-signatures bind approvals to identities and policy versions; retention schedules ensure GDP/GMP evidence persists for statutory windows while personal data is minimized. Segregation of duties is enforced by policy at the API layer as well as the user interface, preventing back-channel circumvention. Cyber hygiene is verified through supplier security disclosures tied to their API credentials; elevated cyber risk can dynamically restrict a partner to read-only flows or force out-of-band verification for bank detail changes (Akinbode, *et al*., 2024, Folorunso, *et al*., 2024, Orenuga, Oyeyemi & Olufemi John, 2024).

Crucially, the architecture is designed to evolve. The canonical model is versioned with backward-compatible extensions; the event catalog grows as new sensors or regulatory regimes demand fresh signals; and partner integration kits lower the barrier for smaller suppliers by offering templates, test sandboxes, and gradual pathways from portal uploads to full API participation. Because every change is instrumented and reversible, innovation does not compromise stability, and resilience improves with each cycle (Ajayi & Akanji, 2021, Ejibenam, *et al*., 2021, Osabuohien, Omotara & Watti, 2021).

In total, a digital control tower powered by process mining and conformance checking, grounded in canonical models for suppliers, API batches, CoA/CoC, lanes, and lane-risk, and reinforced by IoT telemetry, serialization, QR verification, immutable logs, and secure APIs, provides the digital backbone for a sustainable and resilient pharmaceutical procurement function. It replaces anecdote with telemetry, hindsight with foresight, and paper trails with cryptographic evidence, enabling organizations to deliver uninterrupted, compliant, and lower-carbon access to medicines even as shocks continue to test global supply networks (Akanji & Ajayi, 2022, Francis Onotole, *et al*., 2022).

2.6 Operating Model & Controls

An operating model for a sustainable procurement and resilience framework in post-pandemic pharmaceutical operations must turn written policy into reliable, repeatable workflows that satisfy GMP/GDP expectations while advancing environmental and social goals. The backbone is policy→workflow translation: each rule who can create or modify suppliers, which materials require dual sourcing, what documentation is mandatory at each gate must be rendered as explicit steps, timers, decision points, and evidence requirements inside an orchestrated process (Awe, 2021, Halliday, 2021). Rather than relying on training alone, the model embeds controls where work happens. Approval matrices, tolerance bands, and exception pathways are configured in a rules service, while the workflow engine enforces sequence and segregation so that critical actions cannot occur out of order or without proof. This "policy as code" approach ensures that changes to regulation or corporate standards become versioned configurations with auditable effective dates, not ambiguous memos.

Segregation of duties is encoded as an unbreakable constraint across request, approve, receive, and pay, and further extended to vendor lifecycle changes and bank detail updates. Role-based access control provides coarse partitioning (requesters, buyers, quality, AP, supplier admins), while attribute-based access control adds contextual granularity based on spend amount, risk score, material criticality, or geography (Babalola, *et al*., 2024). A senior approver might view price clauses for high-risk categories, while bank account fields remain masked unless acting within a payment authorization context; a supplier manager can initiate onboarding but cannot approve both ESG attestations and sanctions resolution for the same entity. All approvals and acknowledgments use e-signatures compliant with Part 11/Annex 11, binding identity, policy version, and timestamp to the record. Retention schedules are automated: procurement and quality artifacts are held for statutory windows with legal holds honored, while personal data is minimized and deleted per privacy commitments. These identity, signature, and retention primitives create a defensible audit posture where decisions are explainable and artifacts are discoverable.

At the transactional core, automated three- and four-way matching converts policy into pre-payment control. Invoices are algorithmically compared to purchase orders and goods receipt notes and, where required, to contracts or batch release documentation using explicit tolerance tables for price, quantity, tax, and freight. Line-level discrepancies trigger targeted holds with evidence attached: the specific lines, the mismatched fields, the rule invoked, and a recommended resolution (Afolabi, Ajayi & Olulaja, 2024, Ilemobayo, *et al*., 2024, Selesi-Aina, *et al*., 2024). Low-risk variances within micro-tolerances auto-clear to preserve flow, while high-risk anomalies price increases above thresholds, mismatched units of measure, or mismatched serial/batch identifiers route to an exception workspace with segregation enforced between investigators and approvers.

The same rigor applies to services: milestone-based acceptance replaces vague attestations, with e-signed service receipts acting as the functional equivalent of GRNs to support matching and audit.

Deviation and CAPA workflows give the operating model its quality spine. Any departure from specification supplier process change notices, out-of-spec CoAs, packaging integrity failures, or missed stability sampling creates a deviation case automatically linked to lots, POs, and shipments. The workflow captures immediate containment, impact assessment (including batch genealogy and market status), root-cause analysis, and corrective/preventive actions with due dates and effectiveness checks (Adeshina, 2021, Isa, Johnbull & Ovenseri, 2021, Wegner, Omine & Vincent, 2021). Ownership is clear: procurement manages commercial consequences and supplier development actions, quality leads technical investigation, and logistics ensures recall or rework when needed. KPI dashboards surface deviation age, recurrence by supplier and category, and CAPA effectiveness so that chronic issues are addressed structurally (e.g., route changes, supplier requalification) rather than patched transaction by transaction. Because deviations and CAPAs live in the same system that runs procurement, their outcomes influence operational privileges repeat deviations can tighten match tolerances, enforce pre-ship inspections, or temporarily suspend auto-approval.

Temperature excursion handling exemplifies how GDP discipline is operationalized. IoT sensors on qualified shippers and storage locations stream telemetry to the control plane; when readings breach validated ranges, the system opens an excursion case, links affected lots and lanes, and freezes further process steps for those items. A triage workflow verifies sensor integrity, correlates with logger redundancy, and applies product stability data to classify the event. For classed excursions, the system enforces evidence collection (charts, courier logs, chain-of-custody records), triggers quality review and QP/QRPs sign-off where applicable, and decides on disposition (release, re-test, rework, or destruction) (Ajayi & Akanji, 2023, Halliday, 2023). Supplier and carrier responsibilities are explicit in contracts and reflected in workflow routing so costs and CAPAs land with the right parties. The same apparatus handles shock, tilt, or light exposure where relevant, ensuring that sustainability moves (e.g., modal shifts or reusable packaging) never compromise patient safety.

Operating controls extend to the supplier lifecycle. Onboarding requires structured identity and compliance evidence: corporate registrations, beneficial ownership declarations as required, bank verification, quality certifications, environmental permits, human rights policy statements, and verifiable ESG attestations. Sanctions and PEP screenings are performed at onboarding and on a schedule, with TTLs that force re-checks at renewal or prior to payment. Workflow gates are non-negotiable: no PO to a supplier lacking current screening and required attestations; no invoice acceptance if a critical certificate has lapsed; no payment release if bank changes lack dual control review (Akinbode, *et al*., 2023, Onibokun, *et al*., 2023, Osabuohien, *et al*., 2023). Changes to master data are governed by dual-control and time-boxed just-in-time access; every change is e-signed and stored immutably with before/after states for forensic traceability.

To make sustainability a daily reality, supplier scorecards combine service, quality, risk, and ESG metrics in one pane of glass, weighted by category strategy. Service captures on-time in full, lead-time adherence, responsiveness to expedites, and forecast collaboration. Quality includes first-pass CoA acceptance, deviation rates, CAPA closure timeliness, data integrity maturity, and audit performance. Risk reflects composite scores across geopolitical exposure, capacity headroom, cyber posture, and climate hazard at the site and lane levels. ESG integrates energy mix, renewable adoption trajectory, water withdrawal relative to basin stress, waste intensity and treatment routes, labor findings and remediation, and progress against science-based targets (Asonze, *et al*., 2024, Davies, *et al*., 2024, Odezuligbo, 2024, Wegner, 2024). Each metric carries a definition, data lineage, and confidence score; thresholds drive operational consequences such as tighter inspection plans, allocation limits, or eligibility for strategic programs. The scorecard is not merely evaluative it drives action. Underperforming suppliers receive development roadmaps with milestones tied to commercial incentives; high performers gain preferred status, longer-term agreements, and co-innovation access.

The operating model depends on continuous measurement and governance. A cross-functional design authority owns the configuration of rules, workflows, and data standards, adjudicating changes based on risk and value. Monthly control reviews examine unmatched invoice rates, SoD violations prevented, sanctions rechecks, ESG coverage, and temperature excursion handling times. Process mining compares "as executed" traces to the approved workflow, flagging shortcuts and rework loops for remediation (Akande & Chukwunweike, 2023, Awe, *et al*., 2023, Ogundipe, *et al*., 2023). Anomaly detection augments deterministic controls by surfacing weak signals clusters of approvals just below thresholds, sudden spikes in tolerance overrides, or atypical payment routing each opening a case with explainable features and assigned owners. Change control treats rules and workflows like software artifacts: versioned, tested against masked production data, released via feature flags, and rolled back if unintended behavior emerges.

People and communications make the controls humane and adopted. Role-based training teaches requesters guided buying and sustainability nudges, approvers how to interpret policy rationales and provide justifications, AP analysts how to triage exceptions with evidence, and supplier users how to submit complete documents and respond to CAPAs. Communications follow a steady cadence: "what's changing and why," "how to succeed," and "what we learned this month," with real examples of avoided stockouts, emissions reductions, or audit praise. Hypercare windows after major changes provide rapid support, while telemetry identifies where refresher training is needed high override rates, recurring onboarding defects, or frequent temperature alerts on specific lanes (Ajayi & Akanji, 2022, John & Oyeyemi, 2022, Osabuohien, 2022).

Finally, the model recognizes trade-offs and encodes them transparently. Efficiency gains must never erode control; sustainability advancements must hold GMP/GDP lines. Therefore, the system favors "hold and review" when risk is ambiguous, but allows risk-based sampling for low-risk segments to preserve throughput. It rewards demonstrated capability suppliers with pristine quality and ESG records

can enjoy lighter touch within guardrails while ensuring rapid tightening when signals worsen (Adeshina, 2023, Onyedikachi, *et al*., 2023, Wegner & Ayansiji, 2023). By turning policy into workflow, enforcing SoD and contextual access with e-signatures and retention, automating 3/4-way match and quality pathways for deviations and temperature excursions, and managing suppliers through balanced scorecards that unite service, quality, risk, and ESG, the operating model makes compliance and sustainability inseparable from everyday execution. It produces a living control system where evidence is automatic, accountability is clear, and continuous improvement is built in so that essential medicines reach patients reliably, responsibly, and with the trust of regulators and society.

2.7 Implementation & Value Realization

Implementing a sustainable procurement and resilience framework after the pandemic requires a disciplined, phased roadmap that converts intent into measurable operational change while meeting GMP/GDP obligations and advancing ESG goals. The journey begins with assess, where the organization establishes a factual baseline. Event logs from ERP, QMS, WMS, and TMS systems are mined to quantify stockout incidence, on-time-in-full performance, first-pass quality acceptance of CoAs and incoming inspections, total cost of ownership per category, Scope-3 emissions intensity across lanes and suppliers, and the pattern of audit findings (Akpan, *et al*., 2017, Oni, *et al*., 2018). Supplier landscapes are mapped beyond tier-1 to capture API and excipient dependencies, packaging resin and elastomer sources, and lane-level risks. Maturity diagnostics gauge data stewardship, traceability, and cold-chain telemetry coverage. The assess phase also generates a value hypothesis linking root causes to targets such as reducing stockouts by a set percentage, lifting OTIF above a defined threshold, improving first-pass quality for targeted categories, cutting TCO through waste removal and modal shifts, lowering Scope-3 intensity per delivered dose, and halving repeat audit observations.

Design translates the hypothesis into an executable blueprint that can withstand regulatory scrutiny. Canonical data models for supplier, API batch, CoA/CoC, lane, and lane-risk are finalized; policy is codified into workflow and rules: dual/multi-sourcing thresholds, ESG gate checks, sanctions screening TTLs, three- and four-way match tolerances, and temperature excursion handling. Digital control tower views, supplier scorecards, and lane-risk dashboards are prototyped with the exact KPIs to be tracked post-go-live (Adeleke & Ajayi, 2023, Adeshina, Owolabi & Olasupo, 2023, Oyeyemi, 2023). Contracts are templated to include renewable energy milestones, water stewardship commitments in stressed basins, take-back obligations for reusable shippers, and allocation clauses for surge events. Critically, change management is designed in: a RACI matrix clarifies ownership of policy, data, integrations, validation, and training; communications articulate the "why," the "how," and the "help" channels for each role; and supplier development playbooks are prepared to close ESG and quality gaps uncovered in diligence.

Pilot establishes proof with real transactions and live controls in a contained scope. One or two high-volume, moderate-complexity categories such as MRO or selected packaging are run end-to-end using the new workflows, secure APIs, and exception handling. Suppliers are onboarded in cohorts; telemetry captures OTIF, first-pass quality, and invoice match rates; cold-chain telemetry is validated on defined lanes; and Scope-3 signals are collected using supplier-specific factors where available and credible proxies where not (Ajayi & Akanji, 2022, Leonard & Emmanuel, 2022). Daily triage refines rules, adjusts IDP templates, tunes lane qualifications, and clarifies escalation thresholds. Pilot exit criteria are objective: a statistically significant reduction in stockouts within the cohort, sustained OTIF improvement, first-pass quality gains on incoming lots, reduced TCO from rework and expedites avoided, measurable declines in emissions per delivered unit on the piloted lanes, and fewer audit findings tied to procurement records and GDP documentation.

Scale extends capability across categories, regions, and partners in controlled waves. Each wave bundles a sensible mixture of categories (e.g., an API family with a related excipient and corresponding packaging) to exercise multi-party coordination. Training is role-specific and layered: requesters learn guided buying nudges toward validated low-impact options; buyers practice interpreting lane-risk and supplier ESG scores alongside price and service metrics; quality and logistics teams rehearse deviation/CAPA and temperature excursion workflows; finance teams reconcile TCO components and carbon accounting. RACI ensures that change requests flow to accountable owners and that policy updates are versioned and validated before release (Adeleke & Olajide, 2024, Awe, *et al*., 2024, Davies, *et al*., 2024). Supplier development accelerates scaling: joint workshops on document completeness, serialization data quality, and packaging right-sizing reduce mismatches at source; energy and water improvement roadmaps are co-authored, with milestone-based commercial incentives.

Optimize makes improvement a habit rather than a project closeout slide. Process mining continuously compares "as executed" traces to the approved workflows, exposing rework loops and approval bottlenecks; conformance checking highlights policy drift; anomaly detection surfaces weak signals such as clusters of approvals near thresholds or sudden spikes in temperature alarms on specific lanes. Quarterly reviews recalibrate safety stocks and lane choices as lead-time distributions shift; semiannual supplier business reviews incorporate ESG and resilience metrics alongside service and quality; and annual control attestations replay critical paths to validate that evidence remains complete and discoverable. Technical debt is retired deliberately: RPA bridges are replaced with native integrations; schema contracts are tightened; and variant complexity is reduced to increase touchless flow without weakening control (Abdulkareem, *et al*., 2023, Adeleke & Ajayi, 2023, Halliday, 2023).

Change management sustains momentum across the roadmap. Training blends micro-learning, in-app guidance, and sandbox exercises, with certification gates for high-risk roles such as approvers, vendor masters, and temperature excursion triage. The RACI matrix is visible and enforced policy owners sign off on rules; data stewards own golden-record quality; the design authority approves new variants; product teams own service level objectives for workflow latency, rules evaluation time, extraction accuracy, and exception resolution. Communications follow a steady drumbeat: pre-wave "what's changing and why," go-live day "how to succeed," and post-wave "what we learned,"

sharing hard metrics and candid lessons (Ogunyankinnu, *et al*., 2022, Onibokun, *et al*., 2022). Supplier development pairs expectations with enablement: templates for water audits, renewable energy contracting guides, packaging redesign sprints, and remote-audit readiness checklists. Escalation paths are agreed in advance for sanctions hits, labor findings, or repeated CoA deviations, linking commercial consequences with corrective action ownership.

Value realization is engineered through clear KPIs that trace to economic, compliance, and sustainability outcomes. Stockout rate is measured at item-location and patient-criticality levels, distinguishing upstream shortages from distribution issues; improvement equates to patient access protected and revenue preserved. OTIF is tracked by supplier, lane, and mode, with lane-risk overlays that explain variance and justify modal shifts or buffer recalibration. First-pass quality captures CoA acceptance and incoming inspection pass rates, directly cutting rework, delays, and write-offs; improvements tie to supplier process capability or greener chemistry routes with fewer impurities (Afolabi, Ajayi & Olulaja, 2024, Joeaneke, *et al*., 2024, Olulaja, Afolabi & Ajayi, 2024). TCO is decomposed into unit price, freight, duties, inventory carrying, quality failures, expedites, and administrative burden; reductions come from right-sized specs, reusable shippers, modal shifts, duplicate vendor removal, and touchless processing. Scope-3 intensity is calculated per delivered unit using supplier-specific factors for materials and carrier-specific factors for transport, with confidence scores; decarbonization is attributed to nearshoring, ocean/rail substitutions, packaging weight reductions, renewable energy adoption at suppliers, and reduced spoilage. Audit findings are tracked by clause and root cause data integrity, incomplete documentation, GDP chain-of-custody so remediation is systemic; a decreasing trend demonstrates that compliance has moved from inspection to design.

To turn numbers into decisions, dashboards show baselines and deltas with control limits and annotations for rule changes or supplier milestones. Business reviews link KPI movement to financials and reinvestment choices: savings from reduced expedites fund IoT telemetry expansion; carbon reductions justify reusable shipper pools; improved first-pass quality supports faster batch release and lower working capital (Akinbode, Taiwo & Uchenna, 2023, Onotole, *et al*., 2023). Where KPIs lag, the framework does not hunt for culprits it hunts for signals. Process mining pinpoints the queues where approvals age; scorecards reveal suppliers whose CAPA effectiveness is weak; lane-risk shows corridors where climate hazards are rising, warranting seasonal inventory lifts or alternate routing. Corrective actions are bounded by time and owner, and their outcomes are made visible to maintain credibility.

Several pitfalls can derail value realization if unaddressed. Data quality gaps undermine Scope-3 and TCO calculations; mitigation includes progressive disclosure requirements tied to commercial incentives, supplier-specific factor pilots, and robust survivorship rules for golden records. Over-reliance on RPA can ossify fragile integrations; an explicit API backlog and retirement plan prevents technical debt from eroding reliability. Change saturation can breed workarounds; pacing waves, providing hypercare, and celebrating role-level wins help adoption. A myopic focus on unit price can crowd out resilience and sustainability; TCO and carbon-intensity dashboards must sit next to P&L views in leadership routines (Akinbode, *et al*., 2024, Isa, 2024, Olufemi, Anwansedo & Kangethe, 2024).

The endpoint of a well-run program is not an IT system but a management system that reliably delivers medicines with fewer surprises and a smaller footprint. The phased roadmap ensures that each stage funds the next with realized benefits; change management ensures that people and partners evolve with the process; and KPIs ensure that outcomes are observable, attributable, and durable. When stockout rates decline even as demand varies, when OTIF rises on validated lower-carbon lanes, when first-pass quality improves due to greener processes, when TCO drops without pushing risk downstream, when Scope-3 intensity falls and audit findings recede, the organization has proof not a promise that resilience and sustainability can advance together (Ajayi, *et al*., 2024, Bamigbade, Adeshina & Kemisola, 2024, Taiwo and Akinbode, 2024). That proof earns permission to scale the framework across more categories and geographies, compounding value and strengthening the sector's most important commitment: uninterrupted, equitable access to safe, effective therapies (Ajayi & Akanji, 2022, Isa, 2022).

2.8 Conclusion

The Sustainable Procurement and Resilience Framework demonstrates that uninterrupted patient access and a smaller environmental footprint are not competing goals but mutually reinforcing outcomes of disciplined design. By hardwiring dual/multi-sourcing, validated alternates, and lane qualification into policy-driven workflows then instrumenting cold-chain movements, batch documentation, and supplier performance with real-time telemetry the framework shortens recovery time from shocks, prevents stockouts, and accelerates batch release without relaxing GMP/GDP guardrails. At the same time, green chemistry criteria, circular packaging, and lane choices that privilege lower-carbon modes reduce Scope-3 intensity while also curbing spoilage and emergency airfreight, turning sustainability into a practical lever for reliability and cost.

The strategic payoff is a supply network that is adaptive, compliant, and transparent by default. Adaptive, because composite risk scoring across geopolitical, capacity, cyber, and climate signals continuously rebalances orders, buffers, and routes before disruptions reach the patient. Compliant, because every threshold, tolerance, and segregation rule is executed as code, with e-signatures, immutable logs, and explainable decisions that make regulatory scrutiny routine rather than exceptional. Transparent, because suppliers, quality, logistics, finance, and pharmacovigilance consume the same canonical truth supplier status, API batch lineage, CoA/CoC validity, lane risk through role-specific workspaces and scorecards that convert data into accountable action. These properties compound: as conformance improves and exceptions decline, working capital falls, audit findings recede, and credibility with regulators and health systems grows.

Future work will deepen foresight and circularity. AI-enabled demand sensing that fuses epidemiological signals, prescription trends, and lead-time drift can set buffers dynamically and prioritize scarce capacity toward the highest patient value. Climate-risk scenarioing combining downscaled hazard models with site geocoding and lane telemetry will move seasonal playbooks from heuristics to quantified triggers, informing near/reshoring decisions and

surge contracts. Circular reverse logistics, anchored in serialization and QR-verified chain of custody, can enable safe returns, component refurbishment, and material recovery at scale, shrinking waste while improving recall responsiveness. As these capabilities mature, the framework will continue to convert insight into assurance: medicines arriving when and where they are needed, with verifiable quality and ever-lower environmental impact, under a governance model that the public and regulators can trust.

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