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Measuring Operational Performance in the Pharmaceutical Industry: Key Metrics and Best Practices

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Abstract
The pharmaceutical industry operates under a combination of pressures that is unusual in manufacturing: strict regulatory oversight, long product qualification cycles, high gross margins that historically masked operational inefficiency, and a growing public expectation that medicines will be available without interruption. Together these forces have moved operational performance measurement from a back-office accounting exercise to a strategic capability. This paper reviews the literature and industry practice on operational performance measurement in pharmaceutical manufacturing and supply, and proposes an integrative framework organised around six dimensions: quality and compliance, delivery reliability, asset and labour productivity, cost efficiency, inventory and working capital, and organisational health including safety and sustainability. For each dimension the paper identifies the metrics most commonly used, specifies their calculation, and discusses their known limitations and gaming risks. The paper then synthesises best practices in measurement system design, covering metric selection and cascading, data governance and definitional discipline, tiered daily management, external benchmarking, leading versus lagging indicator balance, and the role of digital manufacturing technologies. A four-stage maturity model is offered to help organisations sequence improvement. The central argument is that the value of a performance measurement system in this sector derives less from the sophistication of any individual metric than from definitional consistency, the visible linkage between shop floor indicators and patient level outcomes, and the behavioural response the system provokes. Poorly designed systems in regulated environments are not merely uninformative; they can actively degrade quality culture by encouraging metric management in place of process improvement.

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1. Introduction

1.1. Background

For much of the second half of the twentieth century, pharmaceutical manufacturing was not a primary source of competitive advantage. Gross margins on patented products were high enough that the cost of goods sold represented a modest fraction of revenue, and the dominant operational objective was regulatory compliance rather than efficiency. Manufacturing organisations were evaluated on whether they avoided regulatory citations and whether they supplied the commercial plan. How efficiently they did so attract comparatively little executive attention.

Several developments have changed this. The expiry of a large cohort of blockbuster patents shifted volume toward generic and

biosimilar competitors whose business models depend on cost leadership. Payer consolidation and reference pricing compressed realised prices in many markets. Product portfolios fragmented as therapies became more targeted, replacing a small number of very high-volume products with a larger number of lower volumes, higher complexity ones, including biologics, cell and gene therapies, and combination devices. Meanwhile, a sustained pattern of drug shortages in the United States and Europe drew regulatory and legislative attention to the reliability and resilience of pharmaceutical supply, and the disruption associated with the COVID-19 pandemic made supply continuity a matter of public and political concern rather than a purely commercial one. Work on early warning and regulatory response for essential medicines (Eze *et al*., 2022a) and on last mile distribution to underserved populations (Asiedu & Asiedu, 2022) illustrates how far the consequences of manufacturing performance now extend beyond the factory gate.

The consequence is that manufacturing and supply performance is now scrutinised by internal executives, investors, customers, and regulators simultaneously, and each of these audiences asks different questions of the same operations. Executives ask about cost and capital efficiency. Customers ask about delivery reliability. Regulators, particularly through the United States Food and Drug Administration's quality metrics initiative and the International Council for Harmonisation's Q10 pharmaceutical quality system framework, ask whether the manufacturer can demonstrate a state of control and continual improvement. Answering these questions coherently requires a measurement system, not a collection of reports.

1.2. The Measurement Problem in A Regulated Setting

Performance measurement in pharmaceutical operations is complicated by features that generic operations management literature does not always anticipate.

First, the output of a pharmaceutical process is not fully characterised at the point of production. Quality is partly established through validated process control and partly confirmed through analytical testing that may take days or weeks. Metrics that assume immediate knowledge of conformance, such as conventional first pass yield measured at the machine, translate imperfectly.

Second, change is constrained. In most manufacturing sectors an engineer who identifies a better set point simply implements it. In a regulated pharmaceutical environment, changes to validated processes may require change control, comparability assessment, and in some cases regulatory variation filings across dozens of markets with different review timelines. Improvement cycle time is therefore structurally longer, and metrics that reward rapid iteration can mislead.

Third, the consequences of failure are asymmetric. A shortfall in efficiency costs money. A shortfall in quality can harm patients and can result in consent decrees, import alerts, or site closure. Any measurement system that implicitly trades quality against throughput is dangerous, and there is credible evidence from regulatory inspection findings and from academic work on quality culture that badly designed incentive linked metrics do exactly that.

Fourth, the industry has historically lacked common definitions. Two sites within the same company may compute right first time differently, and two companies almost certainly do. This has made external benchmarking difficult and has slowed the diffusion of practice compared with automotive or semiconductor manufacturing, where standardised measures such as overall equipment effectiveness and defects per million opportunities are more consistently applied.

1.3. Research Questions and Contribution

This paper addresses three questions:

1. Which operational performance metrics are actually used in pharmaceutical manufacturing and supply, and how should they be defined and calculated?
2. How should these metrics be organised into a coherent system that serves shop floor, site, network, and regulatory audiences without fragmenting into unmanageable proliferation?
3. What practices distinguish organisations that derive improvement from measurement from those that merely produce reports?

The contribution is threefold. The paper consolidates dispersed guidance from regulatory documents, industry association publications, benchmarking consortia, and academic operations management literature into a single framework. It provides explicit calculation conventions and a discussion of failure modes for each major metric, including the ways each can be gamed. And it proposes a maturity model that sequences implementation, on the argument that many organisations fail not because they chose the wrong metrics but because they attempted advanced measurement before establishing the data discipline that makes it meaningful.

1.4. Scope and Structure

The scope is operational performance in small molecule and biologic drug substance and drug product manufacturing, packaging, quality control laboratories, and the associated supply chain through to customer delivery. Research and development productivity, commercial performance, and clinical supply are outside scope except where they interface with commercial manufacturing.

Section 2 reviews the relevant literature. Section 3 sets out the methodology. Section 4 presents the conceptual framework. Section 5 details metrics by dimension. Section 6 synthesises best practices. Section 7 presents the maturity model and an implementation sequence. Section 8 discusses limitations and open questions. Section 9 concludes.

2. Literature Review

2.1. Foundations in Performance Measurement Theory

The modern literature on performance measurement systems begins with the critique that financial accounting measures are lagging, aggregated, and poorly aligned with operational decision making. Johnson and Kaplan's argument that management accounting had lost relevance to manufacturing decisions prompted a generation of alternative frameworks. Kaplan and Norton's balanced scorecard proposed measurement across financial, customer, internal process, and learning and growth perspectives, explicitly linking operational indicators to strategy through cause and effect chains. Neely and colleagues subsequently formalised the design of performance measurement systems, introducing the performance measurement record sheet, which requires each metric to have a stated purpose, formula, owner, data source, frequency, and defined improvement action. Bititci and

others extended this into work on the dynamics of measurement systems, noting that systems decay when they are not periodically reviewed against changing strategy.

Three propositions from this literature are directly relevant to pharmaceutical operations. Measures should be derived from strategy rather than from data availability. Measures should be few enough to direct attention. And measures should be paired with an explicit theory of how improvement in the indicator produces improvement in the outcome, without which the indicator becomes an end in itself. Applied work extending these principles into operational settings, including frameworks for data driven operations management and performance improvement (Efobi *et al*., 2021), reaches the same conclusion from practice.

2.2. Lean, Six Sigma, and Total Productive Maintenance In Pharmaceutical Operations

The transfer of Toyota Production System concepts into pharmaceutical manufacturing accelerated during the 2000s and 2010s. Nakajima's formulation of total productive maintenance introduced overall equipment effectiveness as the product of availability, performance, and quality, and this measure has become the most widely adopted asset productivity indicator in pharmaceutical packaging and solid dose manufacturing. Empirical studies of lean adoption in pharmaceutical settings report improvements in changeover time, work in process, and lead time, but also report distinctive barriers: validation requirements that constrain rapid experimentation, deviation documentation burden, and organisational separation between quality and operations functions. Adaptations of Lean Six Sigma for resource constrained organisations (Ambali *et al*., 2021), studies of process redesign aimed at cycle time reduction (Oyeleye *et al*., 2022), and models of data driven lean supply chain optimisation in manufacturing (Efobi *et al*., 2022b) describe comparable barriers outside the pharmaceutical sector, suggesting that the constraint is partly organisational rather than purely regulatory.

The literature is divided on whether classical lean metrics transfer cleanly. Several authors argue that takt time and continuous flow logic are poorly suited to campaign-based production with long cleaning and changeover requirements, and that pharmaceutical operations more closely resemble process industries where constraint management and yield stability dominate. Others report successful application of pull systems in packaging and distribution, which are structurally closer to discrete manufacturing. Research on governance alignment across organisational boundaries in highly regulated environments (Eyetsemitan *et al*., 2020) further indicates that coordination structure, rather than technique selection, frequently determines whether such transfers succeed.

2.3. Regulatory Perspectives on Quality Metrics

A distinct strand originates from regulators rather than academia. The International Council for Harmonisation guideline Q10 on pharmaceutical quality systems established management review and performance monitoring as expectations of a modern quality system, and introduced the concepts of a state of control and continual improvement across the product lifecycle. The United States Food and Drug Administration subsequently pursued a quality metrics programme, publishing draft guidance in 2015 and a revised draft in 2016, proposing a small set of measures including lot acceptance rate, product quality complaint rate, and invalidated out of specification rate, with associated optional measures on the effectiveness of the pharmaceutical quality system. Industry response, channelled through associations including the International Society for Pharmaceutical Engineering and the Parenteral Drug Association, raised concerns about definitional ambiguity, comparability across dosage forms, and the risk that regulatory reporting of metrics would discourage the very transparency that quality culture requires.

The initiative subsequently moved toward a voluntary and iterative approach, and the emphasis shifted from mandatory reporting to the maturity of the quality management system as a whole. Parallel work by the International Society for Pharmaceutical Engineering on advancing pharmaceutical quality developed assessment approaches for quality system maturity across elements such as change management, deviation management, corrective and preventive action, and knowledge management. Related maturity-based approaches to regulatory readiness for firms pursuing global market entry (Eze *et al*., 2022b) apply a similar staged logic to the wider compliance system. The unresolved question in this literature is whether externally reported metrics can measure quality culture without distorting it, a question with clear parallels in healthcare performance measurement and in education.

2.4. Drug Shortages and Supply Reliability

Analyses of drug shortages consistently identify manufacturing and quality problems as a leading proximate cause, with economic factors that discourage investment in ageing facilities as a structural contributor. This literature connects operational performance measurement to public health outcomes: sites with weak process capability generate deviations, deviations generate investigations and rejected lots, and in markets served by few suppliers with thin inventory buffers, rejected lots become shortages. Work on supply chain resilience distinguishes robustness, the ability to withstand disruption, from agility, the ability to recover, and argues that conventional service level metrics measure neither because they capture performance only under normal conditions. The proposed remedies include time to recover and time to survive measures, single source and single site exposure indices, and stress testing of the supply network. Analogous resilience frameworks developed for critical infrastructure and process plant supply chains (Agbabiaka *et al*., 2019; Ogunwole *et al*., 2021) offer transferable structure, since those settings share the combination of long qualification lead times, few qualified suppliers, and severe consequences of unplanned outage.

2.5. Benchmarking and Cross Company Comparison

Benchmarking in this industry has been advanced largely by consortia rather than by open publication. Structured benchmarking programmes collect standardised operational data across participating sites and report distributions for measures such as cost per unit, overall equipment effectiveness, deviation rates, batch record review cycle time, and quality control laboratory testing lead time. Published summaries of such programmes have repeatedly reported wide dispersion, often several fold, between upper and lower quartile sites performing comparable operations, suggesting that a large share of performance variation is attributable to management practice rather than to technology or product mix. The methodological caution is that self-reported data

with heterogeneous definitions overstates dispersion, and that normalisation for product complexity, batch size, and regulatory market coverage is essential before drawing inferences.

2.6. Digital Manufacturing and Measurement

The Pharma 4.0 discourse, which adapts the industry 4.0 concept to regulated pharmaceutical production, treats data integrity, digital maturity, and connected systems as prerequisites for advanced performance management. Contributions here address process analytical technology, real time release testing, continuous manufacturing, and the use of manufacturing execution systems and historians to automate metric capture. The measurement relevant claim is that manual data collection imposes a ceiling on both the frequency and the trustworthiness of performance indicators, and that automated capture changes the economics of measurement enough to alter which metrics are practical.

2.7. Evidence from Adjacent Regulated and Asset Intensive Sectors

Peer reviewed empirical work on operational performance measurement inside pharmaceutical manufacturing is thin relative to the sector's economic weight, and much of what exists consists of single site case descriptions. A broader evidence base is available in adjacent settings that share the defining structural features of pharmaceutical operations: statutory regulation of the process rather than only of the product, severe and sometimes irreversible consequences of failure, long asset qualification cycles, and a requirement to demonstrate control to an external authority. High hazard process and construction operations, civil aviation, energy and utility infrastructure, regulated healthcare facilities, and audited financial control environments each generate measurement literature that transfers with care. This subsection reviews that literature by theme, because several of the framework dimensions developed in Section 4, particularly leading indicator design, data integrity, and organisational health, are more thoroughly evidenced outside the pharmaceutical sector than within it.

2.7.1. Safety Measurement and The Leading Indicator Problem In High Hazard Operations

Occupational safety measurement faces a version of the problem identified in Section 1.2 in an especially acute form. Injury outcome rates are lagging, statistically sparse at site level, and suppressible, so a literature has developed around indicators that precede harm. Studies of near miss and hazard observation data argue that reporting volume, treated correctly, is a measure of system health rather than of system failure (Arumosoye & Obriki, 2019; Obogo *et al*., 2021a), and that the value of the data lies in its use in analysis rather than in its collection (Obriki & Arumosoye, 2018). Related work links the frequency and coverage of management safety walkthroughs to cultural outcomes (Obriki & Arumosoye, 2019), and positions leadership behaviour as a measurable antecedent of workforce practice (Obogo *et al*., 2019a).

The causal structure that this literature describes closely parallels the quality investigation dynamics discussed in Section 5.1.3. Analyses of human error causation in high risk activities argue that attributing incidents to individual error terminates inquiry prematurely and conceals systemic antecedents (Obriki & Arumosoye, 2020), and work on the recurrence of unsafe behaviour identifies the mechanisms by which corrected conditions re-emerge when only the proximate act is addressed (Obriki & Arumosoye, 2022a). Both findings are directly analogous to the repeat deviation and human error attribution diagnostics proposed in this paper. Maturity based approaches to continuous safety improvement (Arumosoye & Obriki, 2021) and models for institutionalising practice across project based organisations (Obriki & Arumosoye, 2021) provide the staged logic later applied in Section 7.

A further body of work addresses measurement across organisational boundaries, which matters for pharmaceutical networks that depend heavily on contract manufacturing and contracted services. Governance oriented models of contractor safety performance in multi contract environments (Arumosoye & Obriki, 2020), reviews of contractor compliance systems (Obogo *et al*., 2021c), and risk governance models for multi-party projects (Obogo *et al*., 2019b) all conclude that performance measured only within the principal organisation systematically understates exposure. Internal audit systems for quality, health, safety and environment functions (Obogo *et al*., 2020a) and critical reviews of safety management systems in maintenance intensive operations (Obogo *et al*., 2020c) address the reliability of the assurance layer itself. Complementary studies cover incident prevention in maintenance environments (Obogo *et al*., 2021b), risk modelling for specific high consequence activities (Obogo *et al*., 2020b; Arumosoye & Obriki, 2022), safety governance in large facility operations (Obogo *et al*., 2022), hazard identification and control practice (Obogo *et al*., 2019c), environmental stressors as a measurable risk factor (Arumosoye & Obriki, 2018), workforce training as an operational risk control (Obriki *et al*., 2022b), and emergency preparedness capability (Obriki *et al*., 2022c).

Civil aviation provides the closest institutional analogue to pharmaceutical regulation, in that a state authority certifies an operator's system rather than inspecting each output. Work on safety management system implementation in resource constrained contexts (Adeyelu, 2019), predictive compliance monitoring built from complaint and report data (Adeyelu, 2018), quantified risk modelling for specific hazard classes (Adeyelu, 2020), and regulatory evidence frameworks supporting enforcement decisions (Adeyelu, 2022a; Adeyelu, 2021) all address how a regulator and an operator can share a measurement basis. Comparative benchmarking of certification compliance across jurisdictions (Adeyelu & Dagodzo, 2022b) confronts the same normalisation difficulty discussed in Section 6.6, and reaches a similar conclusion: comparison is informative only where the underlying definitions and scope are demonstrably aligned.

2.7.2. Procurement, Supplier Performance, And Supply Network Measurement

Because a substantial share of pharmaceutical cost and risk originates upstream, supplier and procurement measurement is part of operational performance rather than adjacent to it. Frameworks for strategic procurement optimisation (Okonkwo *et al*., 2018a) and for cost reduction through contract negotiation and vendor governance (Okonkwo *et al*., 2019) establish the basic measurement categories of price, total cost, and supplier capability. Later work adds data driven vendor evaluation and bid selection (Ahiaeke Patrick *et al*., 2021), procurement process automation directed at efficiency and transparency (Akinleye & Adeyoyin, 2021),

negotiation optimisation applied to manufacturing input costs (Akinleye & Adeyoyin, 2022a), and profitability analysis built from transactional procurement data (Akin-Oluyomi *et al*., 2020).

Supplier relationship measurement has moved from transactional scoring toward capability and continuity assessment. Frameworks positioning supplier relationships as strategic assets (Akinleye & Adeyoyin, 2022b; Ike *et al*., 2021) argue that measures of qualification depth, responsiveness, and joint improvement predict continuity better than price variance does. This aligns directly with the single source exposure and time to recover measures proposed in Section 5.2.4. Resilience oriented work in critical infrastructure and process plant supply (Agbabiaka *et al*., 2019; Ogunwole *et al*., 2021) and end to end visibility frameworks (Nnabueze *et al*., 2021) address the network level question of whether an organisation can see far enough upstream to measure its exposure at all. Predictive approaches to supplier performance (Aifuwa *et al*., 2020) and real time risk dashboards applied to health system supply (Filani *et al*., 2022) illustrate the transition from periodic scorecards to continuous monitoring, while lean supply chain practice (Ike *et al*., 2022; Efobi *et al*., 2022b) and materials readiness models (Okonkwo *et al*., 2021a) connect upstream measurement to plant level availability and uptime (Okonkwo *et al*., 2018b).

Regulatory and sustainability constraints add measurement dimensions that conventional procurement scorecards omit. Models for regulatory compliant procurement in high risk environments (Okonkwo *et al*., 2021b), sustainable procurement frameworks for manufacturing enterprises (Efobi *et al*., 2022a), decision frameworks reconciling chemical safety with circular economy targets (Okojie & Abioye, 2020), and data driven operations management frameworks that treat performance improvement as a measurement problem (Efobi *et al*., 2021) all extend the measurement boundary beyond cost and delivery. Logistics execution measures, including port and inbound flow efficiency (Okonkwo *et al*., 2020) and geospatially enabled procurement processes (Ahiaeke Patrick *et al*., 2020), address the segment between supplier and site where lead time variability frequently originates. Programmatic delivery strategy work in large capital contexts (Yeboah & Ike, 2020) provides a comparable view of measurement at portfolio rather than transaction level.

2.7.3. Asset Reliability, Condition Monitoring, And Maintenance Measurement

The maintenance metrics discussed in Section 5.4.4 rest on a substantial engineering literature. Work on the transition from reactive to predictive maintenance in mechanical systems (Sunday *et al*., 2020) establishes the planned to reactive ratio as a system state rather than a resourcing outcome, and sensor-based fault detection in building and utility systems (Sunday & Omoegun, 2022) demonstrates the instrumentation dependency that makes the transition possible. Studies of thermodynamic efficiency and control strategy (Sunday *et al*., 2019b), electrical load distribution optimisation (Sunday & Omoegun, 2019a), and integration of distributed generation into industrial supply (Sunday & Omoegun, 2018) show how equipment level measurement aggregates into facility level energy performance, which Section 5.6.4 treats as an operational rather than a peripheral metric.

Inspection and integrity measurement form a second strand with direct pharmaceutical parallels, since both domains rely on nondestructive verification of conditions that cannot be observed in normal operation. Reviews of nondestructive testing-based integrity management and corrosion risk assessment (Atta *et al*., 2020), advances in weld integrity evaluation (Atta *et al*., 2021), inspection standards and quality assurance practice in large capital projects (Atta *et al*., 2022), and materials protection strategies (Atta *et al*., 2018) collectively describe how inspection frequency, coverage, and method sensitivity are chosen and reported. The methodological question they address, namely how much verification is enough given the consequence of undetected failure, is the same question that underlies sampling and testing strategy in pharmaceutical quality control.

Remote and automated condition monitoring extends measurement coverage to assets that cannot be inspected economically by conventional means. Work on unmanned aerial inspection of transmission and distribution infrastructure (Dagodzo, 2018a; Dagodzo, 2018b), corridor and pipeline monitoring (Dagodzo & Ahiaeke Patrick, 2020), integrated aerial, LiDAR and geospatial frameworks (Dagodzo & Ahiaeke Patrick, 2021b), geospatial asset management (Dagodzo & Ahiaeke Patrick, 2021a), encroachment and deviation detection (Dagodzo & Ahiaeke Patrick, 2022a), and machine learning based classification of monitored conditions (Dagodzo *et al*., 2022b) describe a progression from periodic manual inspection to continuous automated assessment. This is the same progression that Section 6.7 describes for manufacturing data capture, and the reported constraint is likewise data quality and interpretation capability rather than sensing hardware. Equipment design and performance evaluation studies (Bello *et al*., 2022a; Bello *et al*., 2022b) illustrate the standard experimental approach to establishing a machine's design rate, which is the reference value on which the performance component of overall equipment effectiveness depends. Loss modelling in electrical machines (Amayo, 2017a; Amayo & Popoola, 2017b; Amayo *et al*., 2015) and studies of network and power quality (Amayo & Popoola, 2017c; Oshevire *et al*., 2017) provide the analytical treatment of efficiency losses that the overall equipment effectiveness loss taxonomy expresses in operational terms.

2.7.4. Data Governance, System Architecture, And the Integrity Of Operational Data

Section 6.7 argues that measurement quality is bounded by data quality, and that data integrity in a regulated setting is a compliance obligation rather than a technical preference. A substantial information systems literature addresses how that obligation is met architecturally. Work on identity and access management in hybrid environments (Mbonu *et al*., 2020a), cloud identity and access governance at scale (Mbonu *et al*., 2022c), identity centric zero trust models (Ogbole *et al*., 2021), and privacy centric security design (Okoruwa *et al*., 2020) addresses attributability, which is the first requirement of a defensible data record.

The completeness and traceability of records depend on architecture and change control. Studies of enterprise log analytics and automated incident response (Mbonu *et al*., 2019b), infrastructure as code governance (Mbonu *et al*., 2020c), version control and code review governance in regulated platform environments (Badmus *et al*., 2022a), continuous integration and delivery pipeline practice

(Badmus *et al*., 2018), comparative evaluation of deployment tooling (Badmus *et al*., 2020), and integration patterns across multi cloud estates (Badmus *et al*., 2022b) describe the mechanisms by which a computed metric can be traced back to a source record and a system state. Extraction, transformation and loading design (Badmus *et al*., 2019a) and platform governance frameworks for regulated healthcare environments (Badmus *et al*., 2019b) address the specific risk identified in Section 6.2, namely that the same named indicator computed in different systems will diverge unless the transformation logic is itself governed. Risk based business intelligence architecture (Mbonu *et al*., 2021a) and agile supply chain digital transformation with embedded control (Mbonu *et al*., 2020b) treat governance as a design input rather than a subsequent addition.

Operational technology security is directly relevant because manufacturing execution systems, historians, and process control networks are both the source of performance data and a regulated part of the manufacturing system. Reviews of operational technology network security in utilities (Adegbite *et al*., 2020), architectures for information and operational technology convergence in regulated networks (Adegbite *et al*., 2022), zero trust applied to critical infrastructure control systems (Ahmed *et al*., 2021), and adversarial machine learning threats to critical infrastructure (Adebayo *et al*., 2022) all address the integrity of the data path between process and report. Enterprise security work on audit and risk assessment frameworks (Dosunmu & Ogundele, 2019), intrusion detection (Dosunmu & Ogundele, 2020), incident response and forensics (Dosunmu & Ogundele, 2021), threat intelligence integration (Dosunmu & Ogundele, 2022), and lessons from offline assessment of security critical systems (Ladapo *et al*., 2018) describes the assurance layer around that path. Related contributions address enterprise directory and access administration (Ladapo *et al*., 2019), cloud migration practice (Ladapo *et al*., 2022b), automated and intelligent software testing (Borah *et al*., 2022; Mbonu *et al*., 2021b), human in the loop machine learning (Ladapo *et al*., 2022a), legal and ethical risk modelling in enterprise systems (Mbonu *et al*., 2018), comparative data protection regulation and secure cloud implementation (Mbonu *et al*., 2019a), data protection impact assessment in regulated multi cloud settings (Mbonu *et al*., 2022b), cross border data privacy governance (Annan, 2022), automated controls testing and audit automation (Mbonu *et al*., 2022a), forensic analytics for transaction integrity (Mbonu *et al*., 2021c; Ekechi *et al*., 2022), automated settlement and payment control (Akomolafe *et al*., 2022), the financial consequences of security investment in healthcare (Ozowara *et al*., 2022), and predictive capacity planning across multi stakeholder programmes (Edivri & Oteri, 2022). Taken together this literature supports the sequencing argument of Section 6.7: definition, then governed source systems, then automation, then analytics.

2.7.5. Financial Control, Audit, And the Measurement of Operational Cost

The cost and working capital metrics in Sections 5.4 and 5.5 sit at the interface between operations and finance, and their credibility depends on control quality in the underlying accounting system. Work on technology enabled internal audit quality (Akomolafe & Agu, 2018), risk based internal control models (Akomolafe & Agu, 2019a), data driven risk evaluation (Akomolafe & Agu, 2019b), and integrated governance and compliance strategy (Akomolafe & Agu, 2019c) addresses the assurance layer beneath reported operational cost. Reconciliation control and financial workflow redesign (Dogbatsey *et al*., 2019), budget compliance and statutory reporting practice (Dogbatsey & Ebhojie, 2018), and comprehensive financial reporting models directed at organisational accountability (Medon & Oduleye, 2022) address the reliability of the figures that operational metrics are normalised against.

Strategic finance contributions connect operational measures to enterprise outcomes. Capital allocation decision models built on financial analytics (Lawal & Oduleye, 2021a), frameworks aligning financial planning analytics with corporate strategy (Lawal & Oduleye, 2021b), data driven executive decision systems (Lawal & Oduleye, 2019b), and enterprise value creation models (Lawal & Oduleye, 2018a) describe the mechanism through which conversion cost and inventory performance influence investment decisions. Treasury and cash management work on multinational cash flow consolidation (Dada *et al*., 2021a) and cross border partnership finance (Isiekwu *et al*., 2021) provides the enterprise context for the cash to cash cycle measure. Analytical and compliance-oriented contributions on transfer pricing risk (Lawal & Oduleye, 2019a) and cross border tax governance (Lawal & Oduleye, 2018b) are relevant to any multinational manufacturing network where internal transfer prices distort site level cost comparison, a normalisation issue noted in Section 6.6. Forecasting applied to commercial pipelines (Dada *et al*., 2021b) and detection-oriented analytics in regulated financial operations (Atakpa, 2021; Atakpa & Abetoh, 2022a) illustrate the same measurement principle applied to different data, while privacy preserving analytics architecture for regulated industries (Atakpa & Abolaji, 2022b) addresses how such analysis is performed within legal constraint.

2.7.6. Analytics, Forecasting, and Dashboard-Based Performance Visibility

The tiered management and visual management practices in Section 6.3 depend on the timely presentation of reliable indicators, and a distinct literature addresses how such presentation succeeds or fails. Business intelligence dashboard frameworks developed to resolve executive visibility gaps (Sanni & Atima, 2021b) and real time analytics frameworks for performance dashboards (Orise & Niniola, 2022) address the design question of what belongs on a dashboard at each organisational level. Evidence oriented platform frameworks (Orise & Niniola, 2020) address the prior question of whether the underlying data supports the inference being drawn.

Measurement validity is the recurring theme. Analytical work on return on investment measurement in regulated contexts (Sanni *et al*., 2020a) and on attribution modelling under multi touch conditions (Sanni *et al*., 2022a) confronts the general problem of assigning outcome to intervention when several causes act simultaneously, which is the same difficulty encountered when attributing operational improvement to a specific initiative. Segmentation and targeting models (Atima *et al*., 2022; Basnet *et al*., 2021), positioning frameworks in regulated markets (Sanni *et al*., 2020b), analytics driven strategy frameworks addressing compliance and sustainability complexity (Sanni & Atima, 2021a), product management practice in complex rollouts (Sanni *et al*., 2020c), and adaptive control models for automated decision

systems (Sanni *et al*., 2022b) all address the operating conditions under which analytical output can safely drive action.

Forecasting and optimisation work links directly to the planning and cost metrics developed earlier. Demand forecasting method comparisons (Tonoyan *et al*., 2021a), predictive cash flow and working capital modelling (Tonoyan *et al*., 2021b), simulation based process optimisation with financial impact assessment (Tonoyan *et al*., 2022b), predictive cost optimisation (Tonoyan *et al*., 2022c), geospatial predictive analysis for network decisions (Tonoyan *et al*., 2022a), and resilient logistics frameworks integrating predictive analytics with sensing (Anene & Clement, 2022) collectively support the argument in Section 6.4 that operational data should be interpreted through models of variation rather than through single period comparison.

2.7.7. Regulated Facility Design, Capital Delivery, And Health System Context

Manufacturing performance is bounded by facility design decisions taken years earlier, and a literature on regulated laboratory and healthcare facility delivery addresses this constraint directly. Regulatory compliant design systems for molecular and pathology laboratories (Ogbete *et al*., 2019), spatial planning strategies directed at diagnostic accuracy and throughput (Ogbete *et al*., 2018), design standards and operational planning for scalable collection and processing facilities (Ogbete *et al*., 2022), and sustainable infrastructure models for diagnostic capacity (Aminu-Ibrahim *et al*., 2018) describe how layout, segregation, and flow decisions determine achievable operational performance. Because pharmaceutical facilities face equivalent segregation, containment, and cleanliness constraints, this work identifies the design variables that later appear as changeover time, cleaning duration, and contamination risk in operational metrics.

Capital delivery and risk management in regulated construction (Aminu-Ibrahim *et al*., 2019; Ogbete *et al*., 2021), sustainable materials selection and energy efficiency in facility design (Ogbete *et al*., 2020), and infrastructure driven expansion of service access (Aminu-Ibrahim *et al*., 2020) address the tradeoff between capital cost and lifecycle operational performance that Section 5.4 treats through conversion cost and maintenance ratios. Health system contributions provide the outcome context that Section 4.1 requires: analyses of financing and provider payment reform (Ilodigwe & Adesemoye, 2019a), explanations of why scientific innovation fails to reach populations (Ilodigwe & Adesemoye, 2019b), pharmacy led delivery and access models (Ilodigwe & Adesemoye, 2020), and governance and architecture frameworks for integrated health data (Ilodigwe & Adesemoye, 2021) connect manufacturing output to the systems through which patients actually receive medicines.

Environmental and energy performance work completes the sustainability dimension. Lifecycle risk assessment in industrial effluent management (Falegan & Aniebonam, 2022), smart grid architecture for high renewable penetration (Adenuga, 2022), forecasting for variable generation (Komi, 2021a), interpretable early failure prediction in distributed energy assets (Komi & Adamolekun, 2021b), control architecture comparisons for distributed resources (Komi & Adamolekun, 2022a), storage degradation and lifecycle assessment in demanding operating conditions (Komi & Ganiu, 2022b), and co-optimisation of technical performance with affordability (Komi & Adeniji, 2020) provide both the measurement methods and the tradeoff framing that Section 5.6.4 applies to energy intensity, emissions, and process mass intensity.

2.7.8. Transferability and Its Limits

The evidence reviewed in this subsection is analogical rather than direct, and three limits apply. First, consequence structures differ: an aviation or construction safety failure is typically immediate and locally observable, whereas a pharmaceutical quality failure may be latent, distributed across a distributed lot, and detected only in post market surveillance, which lengthens every feedback loop. Second, change control regimes differ in severity, so measurement practices that assume rapid iteration transfer poorly, a point already made in Section 1.2. Third, most of the cited work is conceptual or review based rather than experimental, and shares the general weakness of the practitioner-oriented literature identified in Section 2.7 and Section 8.2. These sources are therefore used here to identify measurement constructs and known failure modes, not to establish effect sizes.

2.9. Gaps Addressed by This Paper

Three gaps are apparent. First, regulatory quality metrics literature and operations management productivity literature have developed largely in parallel, with limited integration despite measuring the same underlying processes. Second, published guidance rarely specifies calculation conventions in enough detail to support comparability, which is precisely the deficiency practitioners report. Third, there is little work sequencing implementation, so organisations frequently attempt network wide benchmarking before achieving intra site definitional consistency. This paper addresses each.

3. Methodology

This is a conceptual paper based on a structured review of four bodies of source material, followed by synthesis into a framework.

Search period. The review covers material published to the end of 2022, which is the date of this paper. No source dated later than 2022 is cited, and the reference list spans 1931 to 2022.

Source identification. Four source categories were reviewed. Peer reviewed operations management and pharmaceutical engineering literature was searched for combinations of the term's performance measurement, key performance indicators, operational excellence, lean, overall equipment effectiveness, and quality metrics with pharmaceutical, biopharmaceutical, and drug manufacturing. Regulatory and guidance documents were reviewed, principally International Council for Harmonisation guidelines Q8 through Q12, United States Food and Drug Administration quality metrics guidance and associated docket comments, and European Medicines Agency guidance on shortage prevention. Industry association outputs from the International Society for Pharmaceutical Engineering and the Parenteral Drug Association were reviewed, including drug shortage prevention and quality system maturity work. Finally, publicly available summaries of benchmarking programmes and consultancy analyses were

reviewed for descriptive statistics on metric distributions, treated as indicative rather than as evidence of comparable quality to peer reviewed work.

A fifth category was added after initial screening. Because pharmaceutical specific empirical work proved sparse for several framework dimensions, the review was extended to measurement literature from adjacent regulated and asset intensive sectors, comprising occupational safety and high hazard process operations, civil aviation regulatory oversight, energy and utility infrastructure, procurement and supply network management, enterprise data governance and operational technology, financial control and audit, applied analytics, and regulated facility delivery. Sources in this category were retained only where they addressed the design, calculation, governance, or behavioural consequences of performance indicators, and they are used analogically rather than as direct evidence about pharmaceutical operations. Section 2.7 presents this material and Section 2.7.8 states the limits of the analogy.

Inclusion criteria. Sources were retained if they defined, evaluated, or reported on operational metrics applied to commercial pharmaceutical manufacturing or supply, or if they met the adjacent sector criterion described above. Sources concerned exclusively with research and development productivity, clinical trial operations, or commercial performance were excluded.

Synthesis approach. Metrics identified across sources were catalogued and grouped inductively. Grouping converged on six dimensions after redundant and near duplicate measures were consolidated. For each retained metric, a calculation convention was specified, drawing on the most explicit available definition and, where sources conflicted, selecting the convention that minimised ambiguity in denominator construction. Known failure modes and gaming behaviours were identified from regulatory inspection observations, practitioner commentary, and the general literature on performance measurement dysfunction.

Limitations of method. The review is not a systematic review in the formal sense; no protocol was registered, and grey literature was included deliberately because much practice relevant material in this field is not published in peer reviewed venues. Benchmarking figures cited from consultancy and consortium sources cannot be independently verified and are used only to illustrate dispersion, not to establish specific values. The framework is proposed on analytical grounds and has not been empirically validated through field testing, which is identified in Section 8 as the principal avenue for further research.

4. A Conceptual Framework for Pharmaceutical Operational Performance

4.1. Design Principles

The framework rests on five principles derived from the literature reviewed above.

Patient primacy. Every operational metric should be traceable, through an explicit logic, to patient outcome: the right medicine, of the right quality, available when needed, at a cost the health system can sustain. Metrics that cannot be traced in this way are candidates for elimination. Work on why scientific innovation fails to reach populations (Ilodigwe & Adesemoye, 2019b) and on delivery and access models at the point of care (Ilodigwe & Adesemoye, 2020) makes the endpoint of that chain concrete, and health financing analysis (Ilodigwe & Adesemoye, 2019a) shows why affordability belongs in the same chain as availability.

Definitional precedence. A metric with an ambiguous definition is worse than no metric, because it produces false confidence and unproductive argument. Definition precedes measurement, which precedes target setting, which precedes incentive linkage. Platform governance work in regulated environments (Badmus *et al*., 2019b; Badmus *et al*., 2019a) treats definitional and transformation logic as a controlled artefact for the same reason. Organisations that invert this sequence generate dysfunction.

Balance of tension. Metrics should be deployed in sets that create productive tension rather than singly. Throughput without quality invites corner cutting. Cost without service invites stockouts. Service without inventory discipline invites working capital inflation. The set, not the individual measure, is the unit of design. Maturity based safety improvement models reach the same conclusion about indicator sets in high hazard operations (Arumosoye & Obriki, 2021).

Level appropriateness. An operator needs a small number of indicators visible within their span of control and refreshed within their shift. A site head needs aggregated performance across value streams. A network executive needs comparability across sites. These are different measures derived from the same data, not the same measure viewed at different aggregations. Dashboard design research addresses this level dependence directly (Sanni & Atima, 2021b; Orise & Niniola, 2022).

Asymmetric treatment of quality. Quality and compliance indicators are treated in this framework as constraints rather than as one objective among several. Performance on other dimensions is meaningful only within a maintained state of control. The parallel argument in industrial safety is that treating harm prevention as one objective among several predictably erodes it (Obriki & Arumosoye, 2020; Obriki & Arumosoye, 2021).

4.2. The Six Dimensions

Dimension 1: Quality and compliance. Measures whether the process reliably produces conforming product and whether the quality system detects, investigates, and prevents failure. Includes right first time, deviation and investigation performance, corrective action effectiveness, complaint and recall rates, and process capability.

Dimension 2: Delivery and supply reliability. Measures whether product reaches customers and patients when required. Includes customer service level, schedule adherence, lead time, and forward-looking supply risk exposure.

Dimension 3: Asset and labour productivity. Measures how effectively capacity and people are converted into output. Includes overall equipment effectiveness and its components, changeover performance, laboratory throughput, and output per full time equivalent.

Dimension 4: Cost efficiency. Measures the resource consumed per unit of output. Includes conversion cost per unit, cost of poor quality, maintenance cost ratios, and yield loss valuation.

Dimension 5: Inventory and working capital. Measures the capital tied up to achieve service. Includes days of inventory on hand, inventory turns, slow moving and obsolete write off, and cash to cash cycle time.

Dimension 6: Organisational health, safety, and sustainability. Measures the durability of the operating system. Includes recordable injury rates, training compliance, turnover and absenteeism, improvement idea participation, energy and water intensity, waste generation, and greenhouse gas emissions.

4.3. Structural Relationships Between Dimensions

The dimensions are not independent, and their causal relationships determine how the system should be read.

Quality performance drives delivery performance with a lag. A rise in deviation rate typically precedes a rise in batch rejection, which precedes a fall in supply. Where inventory buffers are healthy, the delivery effect may be invisible for a quarter or more, which means delivery metrics alone provide late warning of a deteriorating process. Materials readiness and inventory availability studies describe the same buffering effect from the upstream side (Okonkwo *et al*., 2021a; Okonkwo *et al*., 2018b).

Productivity and quality are complementary over the medium term and can appear antagonistic over the short term. Unplanned downtime, rework, and investigation effort consume capacity. Sites with strong process capability typically show both higher overall equipment effectiveness and lower deviation rates, contradicting the intuition that quality is purchased with throughput. The apparent antagonism arises when short term throughput pressure is applied to an incapable process.

Inventory substitutes for capability. A site with unstable yield can maintain service by holding more stock. This makes joint interpretation essential: service level improvements achieved through inventory build are qualitatively different from those achieved through variability reduction, and a measurement system that does not distinguish them will reward the wrong behaviour.

Organisational health is leading for everything else. Training compliance gaps, high turnover in experienced operators, and low improvement participation reliably precede deterioration in quality and productivity, though the lag can be long enough that the connection is not perceived without deliberate analysis. Workforce capability and institutionalisation research in project based organisations documents this lag explicitly (Obriki *et al*., 2022b; Obriki & Arumosoye, 2021).

4.4. Leading and Lagging Indicators

The framework classifies metrics on a leading to lagging spectrum. Lagging metrics, including batch rejection rate, complaint rate, and cost per unit, describe outcomes that have already occurred and are typically the metrics of interest to external audiences. Leading metrics, including process capability indices, trend signals in in process control data, deviation recurrence, overdue corrective actions, training currency, and preventive maintenance completion, describe conditions that predict future outcomes. The corresponding safety constructs, namely hazard observation volume, walkthrough coverage, and near miss reporting, are among the better evidenced leading indicators in any industrial setting (Arumosoye & Obriki, 2019; Obogo *et al*., 2021a; Obriki & Arumosoye, 2019).

A practical diagnostic is the ratio of leading to lagging metrics in routine management review. Reviews dominated by lagging metrics tend to produce explanation of the past; reviews with a meaningful proportion of leading metrics tend to produce intervention in the present. The framework recommends that leading indicators constitute a substantial share of shop floor and site level review content, with lagging indicators dominating only at governance and external reporting levels.

5. Key Metrics by Dimension

This section specifies the principal metrics in each dimension. For each, a calculation convention is given along with interpretation guidance and known failure modes. Calculation conventions are stated explicitly because the review found definitional ambiguity to be the dominant obstacle to comparability.

5.1 Quality and Compliance Metrics

5.1.1. Right first time

Definition. The proportion of batches that proceed from initiation through to disposition without a deviation, unplanned event, or documentation error requiring investigation or correction.

Calculation. Right first time equals batches completed without any recorded deviation or error, divided by total batches completed, expressed as a percentage.

Interpretation. Right first time is the most informative single measure of process and documentation control because it captures both technical process performance and the human and system factors surrounding it. It is deliberately unforgiving: a batch with one minor documentation error fails.

Failure modes. The measure is only as honest as the deviation reporting culture. A site that raises the threshold for what constitutes a reportable deviation will show improving right first time while its actual control deteriorates. This is the single most commonly gamed metric in pharmaceutical operations. Countermeasures include monitoring deviation rate and right first time together, tracking the distribution of deviation classifications over time, and treating a simultaneous fall in deviation count and rise in complaint or out of specification rate as a signal for audit rather than for celebration. The analogous suppression dynamic in incident reporting is documented in high hazard operations (Arumosoye & Obriki, 2019; Obriki & Arumosoye, 2022a).

A second failure mode is scope inconsistency: whether documentation errors caught and corrected at the point of entry count as failures is a decision that must be made explicitly and applied uniformly. Treating procedural documentation as a governed asset rather than as administrative overhead makes such decisions durable (Eyetsemitan *et al*., 2022).

Variants. Right first time may be computed separately for manufacturing, packaging, quality control testing, and batch

record review, which is generally more diagnostic than a composite figure, because the improvement levers differ substantially across these areas.

5.1.2. Batch Rejection Rate and Lot Acceptance Rate

Definition. Lot acceptance rate is the proportion of lots manufactured that are accepted for distribution. Batch rejection rate is its complement.

Calculation. Lot acceptance rate equals the number of lots accepted for distribution during the period, divided by the number of lots that started or were completed in the period, depending on the convention adopted. The convention must be fixed, as start based and completion-based denominators diverge materially for long cycle processes such as biologics.

Interpretation. This is the headline outcome measure of manufacturing quality and appears in regulatory quality metrics proposals. It is directly linked to supply risk, since a rejected lot is lost capacity and lost supply.

Failure modes. The measure is insensitive at high performance levels; a site rejecting one lot in three hundred will show almost no period to period signal, so it should be supplemented by leading measures. Rework and reprocessing treatment must be defined: a lot reworked and subsequently accepted is not equivalent to a lot accepted first time, and conflating them conceals problems. Inspection and integrity literature apply the same distinction to verified versus repaired condition (Atta *et al*., 2020; Atta *et al*., 2022). For low volume, high value products such as autologous cell therapies, a single lot represents a single patient, which changes the interpretation entirely and argues for absolute event tracking rather than rate reporting.

5.1.3. Deviation and Investigation Metrics

Several related measures are used together.

Deviation rate is the number of deviations recorded per batch, per unit of output, or per thousand production hours. Normalisation choice matters and should reflect the dominant exposure driver in the operation.

Investigation cycle time is the elapsed time from deviation identification to investigation closure, typically reported as the proportion closed within the procedurally defined period, for example thirty days, and as the median and ninetieth percentile of the distribution. Reporting only the on-time percentage conceals a tail of chronic open investigations, which is frequently where the most serious issues sit.

Overdue investigation count and age track the backlog. A growing backlog is one of the most reliable early indicators of a site under stress and is a common inspection focus.

Repeat deviation rate is the proportion of deviations that match a previously investigated root cause. This is the closest available proxy for corrective action effectiveness and therefore for whether the quality system is learning. A high repeat rate indicates that investigations are terminating at symptom level rather than reaching actionable root cause. Studies of human error attribution in industrial incident investigation describe the same terminating mechanism and its consequences (Obriki & Arumosoye, 2020; Obriki & Arumosoye, 2022a).

Failure modes. Investigation cycle time is readily gamed by closing investigations with superficial root cause attribution, frequently to human error. A site showing rapid closure with a high proportion of human error root cause and a rising repeat rate is exhibiting a well-documented dysfunction pattern rather than good performance. Human error attribution rate is therefore worth tracking as a diagnostic in its own right.

5.1.4. Invalidated Out of Specification Rate

Definition. The proportion of out of specification laboratory results that are invalidated as attributable to laboratory error rather than to the product.

Calculation. Invalidated out of specification rate equals the number of out of specification results invalidated, divided by the total number of out of specification results, or alternatively divided by the total number of tests performed. Both conventions appear in practice and give very different numbers, so the denominator must be stated.

Interpretation. This measure, included in regulatory quality metrics proposals, is a proxy for laboratory control. A high rate indicates a laboratory generating unreliable results. Laboratory design and spatial planning research shows that a share of this variation originates in facility layout and workflow rather than in analyst practice (Ogbete *et al*., 2019; Ogbete *et al*., 2018).

Failure modes. The metric creates a perverse incentive if read naively, because the way to improve it is to invalidate fewer results, which could mean either genuinely improving laboratory performance or failing to invalidate results that should be invalidated. It should always be read alongside total out of specification rate and laboratory right first time.

5.1.5. Process Capability Indices

Definition. Process capability index and process performance index quantify the relationship between process variation and specification limits.

Calculation. The capability index compares the specification width to six standard deviations of within subgroup variation. The performance index uses overall variation and accounts for centring by taking the minimum of the distances from the process mean to each specification limit, each divided by three standard deviations.

Interpretation. These indices are the primary quantitative expression of a state of control for critical quality attributes and feed directly into annual product quality review and continued process verification. Unlike attribute measures such as rejection rate, they are sensitive at high performance levels and therefore provide early warning.

Failure modes. The indices assume stability and approximate normality; computing them for an out of control or non-normal process produces meaningless values. They are

also frequently computed on release testing data alone, which reflects only a small sample of the batch. Where in process and process analytical data are available, capability computed on those data is more informative. Loss and efficiency modelling in equipment engineering provides the analytical treatment of variation on which such computation rests (Amayo, 2017a; Bello *et al*., 2022a).

5.1.6. Complaints, Recalls, and Field Actions

Definition and calculation. Product quality complaint rate is typically expressed per million units distributed. Recall and field alert counts are tracked as absolute numbers with severity classification, alongside time from awareness to notification.

Interpretation. These are the most lagging quality measures and the closest to patient experience. Their value lies less in period to period comparison, which is statistically noisy at typical rates, than in trend analysis and in the categorisation of complaint types as an input to improvement prioritisation. Predictive compliance monitoring built from aviation consumer complaint data demonstrates how a noisy, self-selected complaint stream can nonetheless yield systemic risk signals when categorised and trended (Adeyelu, 2018).

Failure modes. Complaint rate is confounded by reporting propensity, which varies by market, distribution channel, and product type. Cross product and cross market comparison is therefore unreliable without careful adjustment.

5.2. Delivery and Supply Reliability Metrics

5.2.1. Customer Service Level

Definition. The proportion of customer demand satisfied within the committed timeframe.

Calculation. Several conventions exist and are not interchangeable. Line fill rate is order lines delivered complete on time divided by total order lines. Case fill rate uses units rather than lines. On time in full is the proportion of orders delivered both complete and within the delivery window, and is the most demanding of the common conventions because a single late or short line fails the whole order.

Interpretation. This is the primary external facing operational measure. Best practice is to report against the original requested date rather than a renegotiated date, as measurement against revised commitments allows performance to be improved by moving the commitment.

Failure modes. Date basis manipulation is pervasive. So is scope exclusion, where allocated or short supply products are removed from the calculation, which removes precisely the products the measure exists to monitor. Any exclusions should be reported alongside the headline figure. End to end visibility frameworks (Nnabueze *et al*., 2021) and inbound logistics efficiency models (Okonkwo *et al*., 2020) address the upstream and downstream segments where the excluded failures typically originate.

5.2.2. Schedule Adherence and Attainment

Definition. Schedule adherence measures whether production executed what was planned, in the planned sequence and quantity, in the planned period.

Calculation. A rigorous convention counts a scheduled batch as adherent only if it was produced in the scheduled period in the scheduled quantity, with over production counted as non-adherent rather than as a positive offset. Adherence equals adherent batches divided by scheduled batches.

Interpretation. Schedule adherence is a strong leading indicator for both service and cost. Low adherence generates expediting, unplanned changeovers, overtime, and elevated deviation risk from working outside the planned rhythm.

Failure modes. If the schedule is revised frequently, adherence measured against the latest revision approaches one hundred percent while the operation remains chaotic. Adherence should be measured against a frozen schedule established at a defined horizon, and schedule change frequency within the frozen period should be tracked as a separate metric. Predictive capacity planning across competing programmes (Edivri & Oteri, 2022) and demand forecasting accuracy (Tonoyan *et al*., 2021a) determine how realistic that frozen schedule can be in the first place.

5.2.3. Manufacturing Cycle Time and Total Lead Time

Definition. Manufacturing cycle time is elapsed time from batch start to batch completion. Total lead time extends from material availability through disposition and release to availability for shipment.

Calculation. Report the median and the ninetieth percentile rather than the mean, as the distribution is typically right skewed and the tail is where supply risk concentrates. Decomposition into value adding processing time, waiting time, testing time, and review and release time is more actionable than the aggregate.

Interpretation. In most pharmaceutical operations, a large share of total lead time is quality control testing and batch record review rather than physical processing. This decomposition frequently redirects improvement effort from the shop floor, where it is instinctively applied, to the laboratory and the documentation review process, where the larger opportunity usually sits. Structured redesign of administrative and handoff intensive processes has been shown to yield substantial cycle time reduction in other service and professional contexts (Oyeleye *et al*., 2022), and the mechanism is similar. Reconciliation and financial workflow redesign studies report the same concentration of elapsed time in review and approval steps (Dogbatsey *et al*., 2019). Reducing lead time reduces the inventory required to achieve a given service level and shortens the exposure window between a process problem and its detection.

Failure modes. Clock start and stop definitions vary widely. Whether the clock starts at dispensing, at first processing step, or at order release changes the number materially.

5.2.4. Forward Looking Supply Risk Measures

Conventional service metrics describe past performance under normal conditions and say little about resilience. Supplementary measures include:

Time to survive, the period a network could continue supplying at required levels if a specified node failed, given current inventory and alternative capacity.

Time to recover, the estimated period required to restore supply after a specified node failure.

Single source exposure, the proportion of revenue or of volume dependent on a single supplier, single site, or single qualified line, with particular attention to active ingredient and critical excipient sourcing and to geographic concentration. Supplier relationship frameworks that treat qualification depth as a strategic rather than a transactional variable (Akinleye & Adeyoyin, 2022b), and procurement models designed for regulatory constrained environments (Okonkwo *et al*., 2021b), provide practical approaches to reducing this exposure.

Inventory coverage against risk profile, comparing days of cover held to the assessed recovery time for each product, which identifies products where buffers are inadequate relative to their exposure.

These measures are considerably harder to compute than service level and require network modelling, but they address the questions that regulators and health systems increasingly ask about shortage prevention. Resilience frameworks for critical infrastructure supply (Agbabiaka *et al*., 2019; Ogunwole *et al*., 2021) and predictive, sensing enabled logistics models (Anene & Clement, 2022) provide the modelling approaches this requires. The 2020 and 2021 period demonstrated that organisations able to answer these questions quickly responded materially better to disruption than those that could not.

5.3. Asset and Labour Productivity Metrics

5.3.1. Overall Equipment Effectiveness

Definition. Overall equipment effectiveness is the product of availability, performance, and quality for a defined asset over a defined period.

Calculation. Availability equals run time divided by planned production time. Performance equals actual output divided by the output theoretically achievable at design rate during run time. Quality equals conforming output divided by total output. Overall equipment effectiveness is the product of the three.

Interpretation. The measure's principal value is diagnostic decomposition rather than the headline figure. Two lines at sixty percent, one constrained by availability and the other by rate performance, require entirely different interventions. The associated loss taxonomy, distinguishing breakdown, setup and adjustment, minor stoppage, reduced speed, startup, and defect losses, is the practical mechanism through which the metric drives action. Equivalent loss decomposition approaches are long established in equipment engineering (Amayo, 2017a; Bello *et al*., 2022a).

Failure modes. The definition of planned production time is the dominant source of non-comparability. Excluding planned maintenance, cleaning, changeover, validation activity, and unstaffed shifts from the denominator can move the reported figure by tens of percentage points. Cross site or cross company comparison of overall equipment effectiveness without a shared time model is essentially meaningless, and this is one of the most common errors in pharmaceutical benchmarking. Design rate definition is a second source of drift, since rates are sometimes reset to recently achieved performance, which flatters the measure and destroys the historical series.

Complementary measures. Total effective equipment performance uses calendar time as the denominator and is more appropriate for capacity and capital investment decisions. Overall equipment effectiveness applied to a non-constraint asset can drive local optimisation and inventory build; the measure should be applied primarily to constraints, with non-constraint assets measured on responsiveness instead. Condition based monitoring research shows how availability data for both constraint and non-constraint assets can be captured without additional manual effort (Sunday *et al*., 2020; Sunday & Omoegun, 2022).

5.3.2. Changeover and Cleaning Performance

Definition. Elapsed time from last conforming unit of one product to first conforming unit of the next, including cleaning, line clearance, verification, and documentation.

Interpretation. As portfolios fragment, changeover frequency rises and changeover time becomes a primary determinant of both capacity and minimum economic batch size. Reduction of changeover time directly enables smaller batches, which reduces inventory and improves responsiveness. Cleaning validation strategy, line clearance procedure, and documentation practice are usually larger contributors than physical equipment changeover in pharmaceutical settings, which distinguishes this from the classical single minute exchange of die context. Facility layout and flow decisions taken at design stage bound what changeover performance is subsequently achievable (Ogbete *et al*., 2018; Ogbete *et al*., 2022).

5.3.3. Quality Control Laboratory Productivity

Laboratory operations frequently constrain overall lead time yet are measured less rigorously than production. Relevant metrics include testing cycle time by test type reported as median and ninetieth percentile, analyst utilisation, instrument utilisation, laboratory right first time, sample backlog and ageing, and method transfer and validation cycle time. Laboratory right first time, defined as the proportion of tests completed without repeat, invalidation, or documentation error, is generally the most actionable of these. Regulatory compliant laboratory design work identifies the physical and procedural antecedents of these failures (Ogbete *et al*., 2019; Ogbete *et al*., 2021).

5.3.4. Labour Productivity

Definition and calculation. Output per full time equivalent, expressed in units, batches, or standard hours earned, depending on portfolio homogeneity. Where product mix is heterogeneous, standard hours earned divided by hours worked is more meaningful than physical unit counts.

Failure modes. Physical unit measures are distorted by mix shift and reward long runs of simple products. Standard hour measures depend on the currency of the standards, which decay if not maintained. Neither measure should be used for cross site comparison without normalisation for automation level and vertical integration. Training and qualification depth is a further normalisation variable, since qualified coverage determines how much of the nominal workforce is actually deployable (Obriki *et al*., 2022b).

5.4. Cost Efficiency Metrics

5.4.1. Conversion Cost Per Unit

Definition. Total manufacturing cost excluding materials, divided by output.

Calculation. Conversion cost includes direct labour, indirect labour, quality function cost, maintenance, utilities, depreciation, and allocated site overhead. Output should be normalised, since units of different complexity are not comparable. Standard hour or complexity weighted unit denominators are preferable to raw unit counts where portfolios are mixed.

Interpretation. This is the primary financial expression of operational efficiency and the metric most commonly used in external benchmarking. Its trend within a site, holding scope constant, is more reliable than its level compared across sites.

Failure modes. Overhead allocation methodology drives large differences that have nothing to do with operational performance. Volume effects dominate short term movement, since fixed cost absorption means the measure improves with volume regardless of efficiency. Separating volume, mix, and efficiency effects through variance analysis is necessary for the measure to inform management action. Simulation based approaches to process optimisation and financial impact assessment (Tonoyan *et al*., 2022b) offer one route to isolating these effects before committing to change, and negotiated input cost reduction (Akinleye & Adeyoyin, 2022a) addresses the material component that conversion cost deliberately excludes. In multinational networks, internal transfer pricing introduces a further distortion that must be removed before site level cost is comparable (Lawal & Oduleye, 2019a), and capital allocation models describe how the resulting figures are then used (Lawal & Oduleye, 2021a).

5.4.2. Cost of Poor Quality

Definition. The total cost attributable to failure to achieve quality first time, conventionally decomposed into prevention, appraisal, internal failure, and external failure costs.

Calculation. Internal failure includes rejected and reworked material, investigation labour, and lost capacity valued at contribution margin where capacity is constrained. External failure includes complaint handling, recall execution, and regulatory response. Appraisal includes testing and inspection. Prevention includes training, validation, and improvement activity.

Interpretation. The measure translates quality performance into financial terms and is unusually effective at securing investment for quality improvement, because it makes visible costs that are otherwise dispersed across departmental budgets. The valuation of lost capacity is often the largest single component and the one most frequently omitted.

Failure modes. Boundary definition is difficult and the resulting figure is an estimate. It should be used for prioritisation and trend, not for precise financial reporting. Its credibility depends on the control environment beneath it, which internal audit and risk-based control research addresses directly (Akomolafe & Agu, 2018; Akomolafe & Agu, 2019a). There is also a risk that appraisal cost reduction is pursued as an efficiency gain in a regulated context where testing serves a control function.

5.4.3. Yield and Material Loss

Definition and calculation. Process yield is output divided by theoretical output based on input. Report at each major process step rather than only in aggregate, as aggregate yield conceals where loss occurs.

Interpretation. For high value materials, particularly biologics where drug substance can dominate cost of goods, yield improvement is often the single largest cost lever available. Yield variability matters as much as yield level, since variable yield forces conservative planning and inventory buffering. Material efficiency framing that connects yield loss to environmental as well as financial cost (Okojie & Abioye, 2020) strengthens the case for treating yield as a cross dimensional metric.

5.4.4. Maintenance Cost and Effectiveness

Relevant measures include maintenance cost as a percentage of asset replacement value, the ratio of planned to reactive maintenance work, preventive maintenance schedule compliance, mean time between failures, and mean time to repair. The planned to reactive ratio is the most diagnostic, as a reactive dominated maintenance organisation cannot sustain equipment reliability and will generate both downtime and deviation risk. Preventive maintenance compliance is additionally a compliance expectation, not merely an efficiency measure. Evidence from the transition to condition based and predictive maintenance in mechanical systems (Sunday *et al*., 2020) indicates that the shift is enabled by instrumentation and data availability rather than by additional maintenance labour, and materials readiness has been shown to be a binding constraint on maintenance driven performance (Okonkwo *et al*., 2021a). Interpretable early failure prediction (Komi & Adamolekun, 2021b), nondestructive integrity assessment (Atta *et al*., 2020), and incident prevention practice in maintenance environments (Obogo *et al*., 2021b) together describe the capability set required.

5.5. Inventory and Working Capital Metrics

5.5.1. Days of Inventory on Hand and Inventory Turns

Definition and calculation. Days of inventory on hand equals average inventory value divided by average daily cost of goods sold. Inventory turns equals annual cost of goods sold divided by average inventory value. Report separately for raw material, work in process, and finished goods, as the improvement levers differ.

Interpretation. Pharmaceutical inventory levels are typically high relative to other manufacturing sectors, reflecting long lead times, testing and release cycles, regulatory market specific packaging, and deliberate buffering against supply interruption. Interpretation must therefore be relative to lead time and demand variability rather than against generic cross industry norms. A useful supplementary measure is inventory coverage relative to replenishment lead time, which distinguishes justified buffer from excess. The relationship between spares and materials availability and plant uptime is well established in asset intensive sectors (Okonkwo *et al*., 2018b), and the same logic

applies to the qualified materials that constrain pharmaceutical production.

Failure modes. Aggregate inventory measures conceal simultaneous excess and shortage. A site can hold six months of cover in aggregate while stocking out of specific presentations. Segmented reporting by product and by inventory purpose, whether cycle stock, safety stock, strategic buffer, or excess, is more useful than an aggregate figure. This segmentation depends on visibility that many networks lack (Nnabueze *et al*., 2021).

5.5.2. Slow Moving and Obsolete Inventory

Definition and calculation. Inventory value with no movement beyond a defined threshold period, or with remaining shelf life below the minimum acceptable at the point of sale, expressed as a proportion of total inventory value, alongside write off value as a proportion of cost of goods sold.

Interpretation. Shelf life gives pharmaceutical obsolescence a hard deadline that most sectors do not face. Remaining shelf life on hand, measured against market specific minimum acceptance requirements, is a valuable forward-looking complement to the retrospective write off figure. Forecasting driven working capital models provide the projection basis for this measure (Tonoyan *et al*., 2021b).

5.5.3. Cash to Cash Cycle Time

Definition and calculation. Days inventory outstanding plus days sales outstanding minus days payables outstanding.

Interpretation. The measure connects operational decisions to enterprise cash generation and is the principal bridge between operations and finance functions. It is included here because operational lead time reduction is the most durable lever on the inventory component. Predictive approaches to working capital and cash flow modelling (Tonoyan *et al*., 2021b) allow the operational consequences of lead time and inventory decisions to be expressed in financial terms that finance functions act on. Treasury structures for consolidating cash across entities (Dada *et al*., 2021a; Isiekwu *et al*., 2021) determine how far such improvements are visible at group level.

5.6. Organisational Health, Safety, and Sustainability Metrics

5.6.1. Safety

Total recordable incident rate and lost time injury frequency rate remain standard, supplemented by leading indicators including near miss reporting rate, safety observation completion, and corrective action closure. A rising near miss reporting rate alongside a falling injury rate indicates a maturing reporting culture rather than deteriorating safety, and this pattern parallels the relationship between deviation reporting and quality culture closely enough that the two should be interpreted with the same logic. This interpretation is well supported in the occupational safety measurement literature (Arumosoye & Obriki, 2019; Obogo *et al*., 2021a; Obriki & Arumosoye, 2019), which also warns that leadership behaviour and training currency are measurable antecedents rather than background conditions (Obogo *et al*., 2019a; Obriki *et al*., 2022b).

5.6.2. People and Capability

Training compliance, defined as the proportion of personnel current on required qualifications for the tasks they perform, is both a compliance requirement and a leading indicator of quality performance. Supplementary measures include voluntary turnover, particularly among experienced operators and technicians where tacit process knowledge concentrates, absenteeism, vacancy duration for critical roles, and skills matrix coverage expressed as the proportion of critical tasks with adequate qualified depth. Work on workforce capability as an operational risk control reaches the same conclusion from the safety side (Obriki *et al*., 2022b; Obriki & Arumosoye, 2021). Where work is performed by contractors, coverage must extend to them as well, since measurement confined to direct employees understates exposure (Arumosoye & Obriki, 2020; Obogo *et al*., 2019a).

5.6.3. Continuous Improvement Engagement

Improvement suggestions submitted and implemented per employee, participation rate in improvement events, and benefits realised from closed projects together measure whether an improvement system is genuinely operating. Implementation rate matters more than submission rate: a high submission rate with low implementation actively erodes engagement. Organisational learning models of continuous improvement treat implementation follow through as the defining maturity variable (Arumosoye & Obriki, 2021; Obriki & Arumosoye, 2021).

5.6.4. Environmental Performance

Energy intensity per unit of output, water consumption intensity, waste generated and proportion diverted from landfill, solvent recovery rate, and greenhouse gas emissions across the relevant scopes have moved from peripheral reporting to material operational metrics, driven by corporate commitments, investor requirements, and procurement criteria in public tenders. Process mass intensity, the ratio of total material input to product output, has become a standard measure in pharmaceutical green chemistry and connects environmental and cost performance directly, since material efficiency improvement usually reduces both. Sustainable procurement frameworks developed for manufacturing enterprises (Efobi *et al*., 2022a) extend the same measurement logic upstream into the supply base, where a substantial share of environmental impact originates. Facility level energy and materials strategy (Ogbete *et al*., 2020), effluent lifecycle risk assessment (Falegan & Aniebonam, 2022), and generation and storage decisions on the supply side (Adenuga, 2022; Komi & Adeniji, 2020) complete the measurement boundary.

6. Best Practices in Measurement System Design and Use

Identifying metrics is the easier half of the problem. The review indicates that the difference between organisations that improve and those that merely report lies in a set of practices governing how measurement is designed, governed, and used.

6.1. Select Few Metrics and Cascade Them Deliberately

Metric proliferation is the most common pathology observed. Sites routinely maintain hundreds of indicators, of which a small minority influence any decision. The remedy is a deliberate hierarchy.

A workable structure uses a small set of site level indicators, typically between eight and twelve, spanning all six dimensions, each owned by a named executive. These decompose into value stream or department level indicators that are within the span of control of the owning manager, which in turn decompose into shift and line level indicators visible at the point of work.

The cascade must be logical rather than merely arithmetic. A packaging line does not improve site conversion cost per unit directly; it improves it through overall equipment effectiveness and right first time. Making this logic explicit, in the form of a driver tree, is what converts a reporting hierarchy into a management system. Where a driver tree cannot be constructed, the metric at the lower level is probably not connected to anything that matters. Frameworks for data driven operations management make the same point in different language: measurement architecture should follow the structure of the decisions it supports (Efobi *et al*., 2021). Executive decision system design research reaches the same conclusion from the strategy side (Lawal & Oduleye, 2019b), and dashboard research from the presentation side (Sanni & Atima, 2021b).

A practical test for retention is whether anyone can name the decision the metric informs and the action that would follow a deterioration. Metrics that fail this test should be retired, and periodic retirement should be scheduled, since measurement systems accrete indicators unless actively pruned.

6.2. Establish Definitional Discipline Before Comparability

Definitional inconsistency is the most frequently cited obstacle to useful measurement in this industry. The remedy is a metric definition catalogue holding, for each indicator, a unique name and identifier, business purpose, precise numerator and denominator definitions, inclusion and exclusion rules, unit of measure, calculation frequency, data source system and field, named owner, target and target basis, and revision history.

Two disciplines make this catalogue effective. First, the exclusions must be enumerated exhaustively, because exclusions are where comparability is lost and where gaming occurs. Second, definition changes must be controlled and dated, with historical series either restated or clearly annotated at the break point, so that trend analysis is not silently corrupted. This treats metric definitions as controlled documents in the same sense that standard operating procedures are controlled, an approach that has been argued for explicitly in work treating procedural documentation as a strategic rather than an administrative asset (Eyetsemitan *et al*., 2022). Where the computation happens inside data pipelines, the transformation logic itself requires equivalent control (Badmus *et al*., 2019a; Mbonu *et al*., 2021a).

The sequencing implication is significant: intra site consistency should precede intra network comparability, which should precede external benchmarking. Organisations that attempt cross site league tables before achieving definitional consistency generate disputes about data rather than improvement, and consume credibility that is difficult to recover.

6.3. Build Tiered Daily Management Around the Metrics

Metrics produce improvement only when embedded in a management routine. Tiered daily management, adapted from lean production systems, provides the mechanism.

A typical structure operates four tiers. At tier one, shift teams meet briefly at the line at shift start, reviewing safety, quality events, output against schedule, and constraints, and escalating what cannot be resolved locally. At tier two, department leadership meets daily, reviewing aggregated performance and escalated issues. At tier three, site leadership meets daily or several times weekly, addressing cross functional issues and resource conflicts. At tier four, network leadership meets weekly or monthly on network level performance, capacity, and supply risk.

Three design features determine whether the structure works. Escalation criteria must be defined in advance rather than negotiated in the moment, so that issues move up predictably. Each tier must resolve or escalate within a defined period, so that escalation does not become deferral. And the review must focus on abnormality rather than on comprehensive reporting: the purpose is to identify deviation from expected condition and to trigger response, not to narrate performance.

Where operations span organisational boundaries, whether internal functions, joint ventures, or contract partners, escalation design must also reconcile differing governance structures (Eyetsemitan *et al*., 2020), since an escalation path that stops at an organisational boundary will not resolve issues that cross it. Management walkthrough frequency and coverage (Obriki & Arumosoye, 2019) and internal audit systems for operational functions (Obogo *et al*., 2020a) provide the assurance that escalation is functioning as designed rather than merely documented.

Visual management supports this. Performance boards, physical or digital, showing plan against actual by hour or by shift, with abnormalities annotated and countermeasures visible, make the state of the operation legible without a meeting. The critical distinction is between boards that display data and boards that display data alongside the response to it.

6.4. Distinguish Signal from Noise Using Statistical Thinking

A widespread failure is the treatment of routine variation as if it were meaningful change. Monthly comparisons against target, with explanations demanded for every adverse movement, generate substantial effort explaining common cause variation and frequently provoke interventions that increase variability.

Statistical process control logic addresses this. Plotting metrics as time series with control limits derived from the data, rather than as single period comparisons against target, allows a distinction between a process that is stable but not capable, which requires system change, and a process disturbed by a special cause, which requires investigation of that cause. The two require opposite responses, and confusing them is a well-documented source of degraded performance.

Simulation and predictive modelling approaches (Tonoyan *et al*., 2022b; Komi & Adamolekun, 2021b) and attribution methods developed for multi cause settings (Sanni *et al*., 2022a) extend the same reasoning to cases where several interventions act at once.

The practical implications are that management review should be organised around charts rather than tables, that explanation should be demanded only for signals rather than for every movement, and that targets should be understood as expressions of desired system capability rather than as thresholds whose breach requires an excuse.

6.5. Balance Leading and Lagging Indicators Explicitly

Because the most credible pharmaceutical outcome metrics are heavily lagging, a review that uses only these will be permanently retrospective. Deliberate inclusion of leading indicators is required.

Useful leading indicators for quality outcomes include process capability trends on critical quality attributes, in process control result trends within specification, deviation rate by category, repeat deviation rate, overdue corrective and preventive actions, training currency, and preventive maintenance compliance. Useful leading indicators for delivery outcomes include schedule adherence, supplier on time delivery, raw material quality performance, and forward inventory projection against demand plan. Where demand signals are volatile, forecasting accuracy itself becomes a measurable input to operational performance rather than a purely commercial concern (Tonoyan *et al*., 2021a).

An explicit ratio target helps. Review agendas at site level and below should contain a meaningful majority of leading content, with lagging outcome measures reviewed less frequently at governance level. Where a review consists entirely of last month's outcomes, the organisation is managing history. The safety literature offers the clearest demonstration of the alternative, since reporting volume and observation coverage there are treated as primary indicators rather than as supporting detail (Arumosoye & Obriki, 2019; Adeyelu, 2018).

6.6. Benchmark Externally with Methodological Care

External benchmarking is valuable because internal trend analysis cannot reveal what is achievable. Organisations improving steadily against their own history may remain far from the achievable frontier without knowing it. Published summaries of pharmaceutical benchmarking consortia consistently report severalfold dispersion between upper and lower quartile performers on measures such as conversion cost per unit, overall equipment effectiveness, deviation rate, and release cycle time, indicating that management practice rather than technology explains much of the gap.

Methodological caution is nonetheless essential. Comparisons require normalisation for product complexity, dosage form, batch size, regulatory market coverage, degree of vertical integration, and automation level, since a site producing a single high-volume solid dose product for one market is not comparable to a multiproduct sterile site supplying fifty markets. Definitional alignment must be verified rather than assumed. And the object of benchmarking should be the identification of practice differences that explain performance gaps rather than the production of a ranking, since a rank without a mechanism is not actionable and tends to provoke defensiveness rather than learning.

Internal benchmarking across a network is often more productive than external benchmarking, because definitions can be genuinely controlled, underlying practice can be examined directly, and transfer of practice between sites of the same organisation is administratively feasible. Comparative compliance benchmarking in civil aviation reaches a similar conclusion about the primacy of definitional alignment over breadth of participation (Adeyelu & Dagodzo, 2022b). Structured vendor and site evaluation methods provide a workable basis for the normalisation this requires (Ahiaeke Patrick *et al*., 2021).

6.7. Treat Data Integrity and Automation as Prerequisites

Manual data collection places a hard ceiling on measurement quality. Data collected by transcription is delayed, sampled rather than complete, and vulnerable to error and to unconscious adjustment. In a regulated environment it also carries data integrity risk, since regulators expect data to be attributable, legible, contemporaneous, original, and accurate, with completeness, consistency, endurance, and availability as extensions of that expectation.

Automated capture from manufacturing execution systems, historians, laboratory information management systems, enterprise resource planning systems, and quality management systems changes the economics of measurement. The governance requirements that make such capture defensible, covering access control, change control, and traceability from report to source record, are addressed extensively in the enterprise systems literature (Mbonu *et al*., 2020a; Mbonu *et al*., 2020c; Mbonu *et al*., 2019b; Badmus *et al*., 2022a; Badmus *et al*., 2019b). It permits complete rather than sampled data, near real time rather than periodic refresh, consistent computation across sites, and audit traceability from reported figure back to source record.

The practical sequence matters. Automating a badly defined metric produces a fast-wrong answer. Definition, then source system alignment, then automation, then advanced analytics is the productive order. Organisations that begin with dashboard technology typically find within a year that the dashboards are not trusted, because different systems produce different values for the same named indicator. Comparable sequencing conclusions appear in work on process automation for transactional efficiency and transparency (Akinleye & Adeyoyin, 2021) and on data driven optimisation of supply operations (Efobi *et al*., 2022b), where automation delivered value only after the underlying process was standardised.

Where automated data are available at high frequency, the analytical options expand considerably: multivariate analysis of process data to identify predictors of deviation, model based soft sensing of quality attributes, and predictive maintenance based on equipment condition data. Comparable predictive approaches are established in distributed asset monitoring (Komi & Adamolekun, 2021b; Sunday *et al*., 2020) and in remote infrastructure inspection (Dagodzo & Ahiaeke Patrick, 2021b; Dagodzo *et al*., 2022b). Sensor based condition monitoring in building and utility systems provides a mature analogue (Sunday & Omoegun, 2022), and the pharmaceutical application differs mainly in the validation burden attached to acting on model output. These techniques depend entirely on data foundations and cannot compensate for their absence.

6.8. Set Targets That Motivate Without Corrupting

Target setting is where measurement systems most often generate dysfunction. Four practices reduce the risk.

Targets should be derived from a combination of process capability analysis, benchmark evidence, and improvement roadmap rather than from arbitrary uplift on last year, since arbitrary targets communicate that the number matters more than the mechanism.

Targets should be set in balanced sets, so that no single metric can be improved without visible consequence elsewhere. Cost targets without service and quality targets are an instruction to degrade service and quality.

Incentive linkage should be applied with particular caution to quality reporting metrics. Linking individual or site compensation to deviation counts or to right first time creates direct pressure to suppress reporting, which is the opposite of what a mature quality system requires. Where incentives touch quality, they are better attached to leading behaviours such as investigation quality, corrective action effectiveness, and reporting completeness than to the count of adverse events. Research on the recurrence of unsafe behaviour and on premature attribution to individual error explains why count based incentives fail in the analogous safety case (Obriki & Arumosoye, 2022a; Obriki & Arumosoye, 2020).
Improvement trajectories are frequently more useful than fixed thresholds, since a site improving rapidly from a weak base and a site sustaining excellent performance both deserve recognition, and a single threshold reward only one of them.

6.9. Connect Operational Metrics to Patient and Business Outcomes Visibly

The final practice concerns meaning rather than mechanics. Operators asked to improve overall equipment effectiveness on a packaging line are being asked to improve an abstraction. Operators shown that the line supplies a specific therapy, that a given number of patients depend on it, and that a rejected batch represents a specific quantity of treatment that will not reach them, are being asked to do something intelligible.
The evidence on quality culture suggests that this connection is not merely motivational decoration. Sites where personnel understand the patient consequence of their work report higher deviation identification rates, greater willingness to stop production when uncertain, and more substantive investigation participation. Since the most damaging failure mode of a pharmaceutical measurement system is suppression of adverse information, practices that increase the willingness to surface problems have measurement value in the strict sense: they improve the accuracy of the data. The health system literature supplies the content of that connection, describing how manufacturing output translates into access, affordability, and coverage (Ilodigwe & Adesemoye, 2019b; Ilodigwe & Adesemoye, 2020; Aminu-Ibrahim *et al*., 2020).

7. Maturity Model and Implementation Sequence

The review indicates that failure is more often a sequencing error than a selection error. The following four stage model provides a sequence.

Stage 1: Foundational
Characteristics. Measurement is retrospective and largely financial and compliance driven. Data are collected manually and reported monthly. Definitions vary between departments. Reviews explain past performance. Improvement is project based and driven by external triggers such as inspection findings.

Priorities. Establish the metric definition catalogue. Fix a minimum viable metric set covering all six dimensions. Establish reliable monthly reporting from agreed sources. Assign named owners. Do not attempt benchmarking or incentive linkage at this stage.

Exit criteria. A defined, owned metric set producing consistent numbers that participants do not dispute. Staged assessment logic of this kind is well established in adjacent regulatory readiness models (Eze *et al*., 2022b).

Stage 2: Systematic
Characteristics. Metrics are consistently defined across the site and cascaded to department level. Daily and weekly review routines operate. Some leading indicators are in use. Data are partly automated. Improvement activity is linked to metric performance.

Priorities. Implement tiered daily management with defined escalation. Introduce visual management. Establish driver trees linking levels. Begin statistical process control on key indicators. Start internal cross site comparison on the most robustly defined metrics.

Exit criteria. Escalation operating reliably, abnormality-based review functioning, and demonstrable improvement traceable to the routine rather than to standalone projects. Comparable stage two markers appear in audit and walkthrough-based assurance models (Obogo *et al*., 2020a; Obriki & Arumosoye, 2019).

Stage 3: Integrated
Characteristics. Metrics are automated from source systems and available in near real time. Leading indicators dominate operational review. Cross functional metrics span the value stream rather than stopping at departmental boundaries. Internal and external benchmarking inform target setting. Statistical thinking is embedded.

Priorities. Complete automation of core metric capture. Extend measurement across functional interfaces, particularly the manufacturing to laboratory to release chain where most lead time and most handoff loss reside. Introduce supply risk and resilience measures. Establish structured external benchmarking with normalisation.

Exit criteria. Cross functional value stream performance managed as a unit, with end to end lead time and right first time visible and owned. Achieving this depends on visibility and traceability infrastructure spanning the functions involved (Nnabueze *et al*., 2021; Mbonu *et al*., 2019b).

Stage 4: Predictive
Characteristics. Process data are used to anticipate rather than to describe. Multivariate models identify conditions preceding deviation. Equipment condition data drive maintenance intervention. Supply models simulate disruption scenarios. Where process analytical technology and real time release are implemented, quality is measured during production rather than confirmed afterward.

Priorities. Develop analytical capability and governance for model-based decision making in a regulated context, including model validation and lifecycle management. Extend measurement upstream into supplier operations and downstream toward patient level supply outcomes.

Realistic assessment. Few organisations operate fully at this stage across a network in 2022, and elements of it are typically implemented for specific high value products or new facilities rather than universally. Interpretable failure prediction (Komi & Adamolekun, 2021b), human in the loop

model governance (Ladapo *et al*., 2022a), and the security of the data path feeding such models (Adebayo *et al*., 2022) are the principal capability constraints. Attempting stage four capability without stage two discipline is a recognisable and expensive failure pattern.

7.1. Sequencing guidance

Three sequencing rules follow from the model. Definition precedes automation, because automating an ambiguous metric industrialises the ambiguity. Internal consistency precedes external comparison, because benchmarking against uncontrolled definitions produces disputes rather than insight. And review routine precedes technology investment, because a dashboard without a management routine is a display, not a system. Infrastructure and pipeline governance research support the same ordering from the systems side (Mbonu *et al*., 2020c; Badmus *et al*., 2019a).

8. Discussion, Limitations, and Future Research

8.1. The Central Tension

The paper's recurring theme is that measurement in a regulated, safety critical industry carries risks that measurement in other contexts does not. The information a pharmaceutical quality system most needs is information about failure: deviations, near misses, anomalous results, uncertainty. Any measurement practice that raises the cost of reporting such information degrades the system it is intended to monitor. This produces a genuine design tension, because the same metrics that provide accountability create suppression pressure. The occupational safety literature has confronted this tension for longer and has converged on similar mitigations, namely separating reporting systems from performance appraisal and treating reporting volume as a positive signal (Arumosoye & Obriki, 2019; Obogo *et al*., 2021a; Obriki & Arumosoye, 2022a).

The framework's response is to separate metrics used for learning from metrics used for accountability, to attach incentives to the quality of response rather than to the count of events, and to monitor for suppression signatures, notably falling deviation counts alongside rising escaped defects, rapid investigation closure alongside rising recurrence, and high human error attribution. This is a mitigation rather than a resolution, and the tension is unlikely to be eliminated.

8.2. Limitations of This Study

The framework is analytically derived and has not been empirically validated. No field study tested whether organisations adopting it outperform those that do not, and the maturity model in particular is a synthesis of observed patterns rather than a validated instrument.

The evidence base is uneven. Regulatory guidance and industry association material is abundant but normative rather than empirical. Benchmarking data are proprietary and self-reported, and cannot be independently verified. Peer reviewed empirical work on pharmaceutical operational performance measurement remains thin relative to the sector's economic and public health significance, and much of it consists of single site case studies with limited generalisability. The adjacent sector literature drawn on in Section 2.7 partly compensates for this, but it introduces its own limitation: transferring a measurement construct across sectors imports the assumptions of the originating setting, and this paper has argued only that the constructs are informative, not that reported relationships hold at equivalent magnitude in pharmaceutical operations.

The scope excludes several settings where the framework may transfer poorly. Contract manufacturing organisations face different metric priorities, since their customer service and capacity utilisation dynamics differ from those of integrated manufacturers. Measurement across organisational boundaries is known to understate exposure where the principal organisation measures only its own operations (Arumosoye & Obriki, 2020; Obogo *et al*., 2021c; Obogo *et al*., 2019b). Advanced therapy manufacturing, where a batch may correspond to a single patient, breaks the statistical assumptions underlying rate-based metrics. Small manufacturers may find the recommended infrastructure disproportionate.

8.3. Future Research

Four directions appear productive. Empirical testing of the relationship between measurement system maturity and objective outcomes, using inspection findings, shortage incidence, and recall history as dependent variables, would establish whether the practices recommended here have the effects attributed to them. Work on metric standardisation, potentially through industry consortia, addressing the calculation conventions this paper has had to specify from first principles, would materially improve comparability. Cross jurisdiction compliance benchmarking in aviation offers a partial model for how such standardisation can be organised (Adeyelu & Dagodzo, 2022b), as do maturity assessment approaches that fix definitions before comparing scores (Arumosoye & Obriki, 2021; Eze *et al*., 2022b). Investigation of the suppression effect, quantifying how measurement and incentive design affects reporting propensity, would inform the central tension identified above. And development of measurement approaches suited to personalised and advanced therapies, where existing rate-based metrics are structurally inapplicable, is increasingly urgent as these modalities move to commercial scale.

9. Conclusion

Operational performance measurement in the pharmaceutical industry has moved from a compliance and accounting function to a strategic capability, driven by margin compression, portfolio complexity, and a public and regulatory expectation of reliable supply. This paper has reviewed the relevant literature and practice, and proposed a framework organising measurement across six dimensions: quality and compliance, delivery and supply reliability, asset and labour productivity, cost efficiency, inventory and working capital, and organisational health, safety, and sustainability.

Three conclusions stand out.

First, the metrics themselves are largely settled. Right first time, lot acceptance rate, deviation and investigation performance, on time in full, schedule adherence, overall equipment effectiveness, conversion cost per unit, cost of poor quality, days of inventory on hand, and training compliance recur across sources. The differentiator between organisations is not which metrics they choose but how precisely they define them, how coherently they cascade them, and how disciplined the routine is that surrounds them.

Second, definitional rigour is the binding constraint on progress. The industry's slower diffusion of measurement practice relative to automotive and semiconductor manufacturing is attributable in substantial part to the

absence of shared calculation conventions. This is a solvable problem, and its solution is a precondition for meaningful benchmarking rather than a refinement of it.

Third, measurement system design in this industry carries an obligation absent in most others. Because the information the system most needs concerns failure, and because failure in this sector can harm patients, the behavioural consequences of measurement deserve as much design attention as the analytical content. A system that produces accurate numbers by encouraging honest reporting of problems is more valuable than a sophisticated system that produces flattering numbers by discouraging it.

The practical implication for organisations is to begin with definitional discipline and a small owned metric set, build the management routine before the technology, extend measurement across functional boundaries where most loss accumulates, and connect operational indicators visibly to the patients who depend on the output. The sophistication can follow. Without those foundations, it will not deliver.

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