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A Conceptual Framework for Risk-Based Decision-Making in Good Manufacturing Practice Environments

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Abstract- Decision-making in Good Manufacturing Practice (GMP) environments is increasingly expected to be risk-based, yet the regulatory expectation is articulated far more clearly than the means of meeting it. Practitioners are instructed to manage risk and to allocate effort in proportion to the threat posed to product quality and patient safety, but the published guidance describes principles and tools rather than an integrated account of how risk evidence becomes a defensible decision. This paper develops a conceptual framework that links established quality risk management practice to the wider theory of decision-making under uncertainty. The framework is organized as five interacting layers. A contextual foundation grounds every decision in regulatory mandate, product and process knowledge, and organizational culture. A risk intelligence layer converts hazards into characterized, evaluated risk. A decision logic layer applies explicit criteria, tolerance thresholds, and a principle of proportionality to appraise options. A governance layer assigns decision rights, escalation routes, and documented rationale. A learning layer feeds outcomes back into knowledge and recalibrates the framework over time. The framework treats the risk matrix not as the decision itself but as one input to a structured judgement, and it incorporates well-documented limits on human reasoning so that decisions remain auditable and resistant to bias. The result is a coherent, lifecycle-oriented structure that practitioners can use to design decision processes, that quality leaders can use to evaluate the maturity of those processes, and that researchers can use as a basis for empirical study. The framework is conceptual and is offered as a foundation for subsequent validation in operating manufacturing settings.

Keywords: Quality Risk Management, Risk-Based Decision-Making, Good Manufacturing Practice, Pharmaceutical Quality System, Proportionality, Decision Under Uncertainty, Conceptual Framework

I. INTRODUCTION

The manufacture of medicines is governed by an expectation that is at once simple to state and demanding to satisfy: that quality be built into the product and that the systems producing it operate within a state of control (Ogbete et al., 2018, 2019, 2020; Aminu-Ibrahim et al., 2018, 2019, 2020). Good Manufacturing Practice (GMP) codifies this expectation as a body of requirements covering premises, equipment, materials, personnel, documentation, and the controls that bind them together (Akomolafe & Agu, 2019a; Mbonu, Iwuanyanwu, et al., 2020a). Over the past two decades the regulatory conversation around GMP has shifted from a posture of prescriptive compliance toward one that emphasizes scientific understanding and the management of risk. The United States Food and Drug Administration signaled this shift in its initiative on pharmaceutical current good manufacturing practices for the twenty-first century, which proposed a risk-based orientation to oversight and to manufacturing itself (FDA, 2004). The International Council for Harmonisation subsequently embedded the orientation in a trio of guidelines on pharmaceutical development, quality risk management, and the pharmaceutical quality system (ICH, 2005, 2008, 2009).

Within this reframed landscape, decisions are expected to be risk-based. Manufacturers are asked to decide whether a deviation affects product quality, whether a change requires revalidation, whether a supplier warrants additional oversight, and whether a batch may be released, and they are asked to make such decisions in a manner that is proportionate to the risk involved. The expectation is now routine in regulatory language. What remains comparatively underdeveloped is a clear account of how a risk-based decision is actually assembled: how evidence about hazards is converted into a characterization of risk, how that characterization is weighed against criteria, how the appropriate degree of formality is selected, and how the resulting decision is governed and revisited (Eyetsemitan et al., 2020; Obogo et al., 2020a). Guidance documents supply principles and a catalogue of tools, and the operational research literature supplies a deep theory of choice under uncertainty, but the two bodies of knowledge are seldom brought together in a way that practitioners in a regulated plant can use.

This paper addresses that gap by proposing a conceptual framework for risk-based decision-making in GMP environments. The aim is integrative rather than empirical. The contribution is to assemble, from quality risk management practice and from decision science, a coherent structure that explains how the components of a risk-based decision relate to one another and how they can be organized so that decisions are proportionate, traceable, and resistant to predictable failures of judgement. The framework is intended to serve three audiences. For practitioners it offers a template for designing decision processes. For quality leadership it offers a lens for assessing the maturity of those processes. For researchers it offers a set of constructs that can be operationalized and tested.

The remainder of the paper proceeds as follows. The next section establishes the conceptual foundations by examining GMP as a decision environment, the quality risk management paradigm associated with ICH Q9, and the theory of decision-making under uncertainty. The third section sets out the case for a dedicated framework by identifying recurrent weaknesses in current practice. The fourth section presents the framework, describing its guiding principles and its five layers. The fifth section illustrates how the framework operates across different tiers of decision. The sixth section discusses the framework in relation to existing models and to known limitations of common risk tools. The paper closes with implications for practice, a statement of limitations, and directions for future research.

II. CONCEPTUAL FOUNDATIONS

2.1 Good Manufacturing Practice as a Decision Environment

Good Manufacturing Practice is most often described as a set of requirements, but it is equally useful to view it as a decision environment. The principal guidance documents, including the European Union requirements (European Commission, 2015), the World Health Organization main principles (WHO, 2014), and the scheme operated under the Pharmaceutical Inspection Co-operation Scheme (PIC/S, 2018), share a common structure: they define the conditions under which medicines may be made, and they require that departures from those conditions be evaluated and dispositioned. Each evaluation is a decision. A deviation must be classified by significance. An out-of-specification result must be investigated and a root cause assigned or excluded. A proposed change must be approved, deferred, or rejected. A batch must be released or held. The plant is, in this sense, a near-continuous generator of decisions, many of which bear directly on patient safety (Arumosoye & Obriki, 2020; Obogo et al., 2020c).

Three features distinguish this decision environment. First, the consequences are asymmetric. The harm associated with releasing a defective medicine is generally far greater than the cost of withholding a sound one, and this asymmetry shapes the burden of proof that a decision must satisfy. Second, decisions are made under regulatory observation, which means that the rationale for a decision is itself a deliverable: a conclusion that cannot be reconstructed and defended is, for practical purposes, a deficient conclusion (Akomolafe & Agu, 2018; Dogbatsey et al., 2019). Third, the environment is knowledge-intensive. The quality of a decision depends on the depth of product and process understanding available to the decision-maker, a point made central by the emphasis on knowledge management within the pharmaceutical quality system (ICH, 2008) and elaborated in the literature on knowledge excellence in biopharmaceutical operations (Calnan, Lipa, Kane, & Menezes, 2017).

These features explain why the move to risk-based decision-making is more than a stylistic preference. Where requirements cannot anticipate every situation, and where resources are finite, some principle is needed to direct attention and effort toward the situations that matter most (Agbabiaka et al., 2019; Akomolafe & Agu, 2019b). Risk supplies that principle. The difficulty is that risk is a contested and easily misused construct, and converting it into sound decisions requires more discipline than the appealing simplicity of the term suggests.

2.2 Quality Risk Management and the ICH Q9 Paradigm

The reference point for risk management in pharmaceutical manufacturing is the guideline on quality risk management issued by the International Council for Harmonisation (ICH, 2005), commonly cited as Q9. The guideline defines risk as the combination of the probability of occurrence of harm and the severity of that harm, and it organizes risk management into a process of assessment, control, communication, and review. Risk assessment is further divided into identification, analysis, and evaluation. The guideline is deliberately tool-agnostic, listing methods such as failure mode and effects analysis, hazard analysis and critical control points, fault tree analysis, and the risk ranking and filtering approaches that underlie many risk matrices (Obogo et al., 2020b; Obriki & Arumosoye, 2018). The World Health Organization adopted a closely aligned position in its own guidance on the subject (WHO, 2013).

Two principles from Q9 are foundational for the present framework. The first is that the level of effort, formality, and documentation of the risk management process should be commensurate with the level of risk (Akomolafe & Agu, 2019b; Dosunmu & Ogundele, 2019). This principle of proportionality is the engine of a risk-based approach, because it licenses the allocation of scarce attention. The second is that the evaluation of risk should ultimately be linked to the protection of the patient. These principles are widely endorsed, and the broader literature on quality risk management has explored their application across development and manufacturing (Charoo & Ali, 2013; Vesper, 2006; O'Donnell & Greene, 2011).

Q9 also reflects a wider, generic theory of risk management that is not specific to pharmaceuticals. The international standard on risk management (ISO, 2018) frames risk as the effect of uncertainty on objectives and situates assessment within a cycle of establishing context, treating risk, and monitoring (Adegbite et al., 2020; Mbonu, Iwuanyanwu, et al., 2020a), supported by a companion standard on assessment techniques (ISO/IEC, 2019). Foundational work in risk analysis has long held that a complete description of risk must answer what can go wrong, how likely it is, and what the consequences would be (Kaplan & Garrick, 1981), and more recent scholarship has stressed that any such description carries an irreducible component of uncertainty and strength of knowledge that the bare probability and severity figures conceal (Aven, 2016; Aven & Renn, 2009). The pharmaceutical paradigm inherits both the strengths and the unresolved tensions of this wider field (Dosunmu & Ogundele, 2020).

2.3 Decision-Making Under Uncertainty

Risk management produces an assessment; it does not, by itself, produce a decision. The step from assessment to decision is the province of decision theory, and it is here that quality risk management has the most to gain from a wider literature. Classical decision theory models choice as the maximization of expected value across uncertain outcomes, and probabilistic risk analysis provides the machinery for combining likelihoods and consequences in a defensible way (Bedford & Cooke, 2001). This normative account remains useful as a benchmark, but it is an incomplete description of how decisions are actually made in organizations.

The behavioral tradition supplies the necessary correction. Simon argued that real decision-makers are boundedly rational: they operate with limited information, limited time, and limited cognitive capacity, and they satisfice rather than optimize, accepting an option that is good enough rather than searching exhaustively for the best (Simon, 1955, 1979). The heuristics and biases program demonstrated that human judgements of probability and risk are systematically distorted, for example by availability, anchoring, and overconfidence (Tversky & Kahneman, 1974; Kahneman, 2011). Perceptions of risk are further shaped by qualitative features such as dread and unfamiliarity that have no place in a probability calculation but powerfully influence how risk is weighed (Slovic, 1987).

A complementary line of work shows that expertise changes the character of decision-making. In naturalistic settings, experienced practitioners often recognize a situation as typical and act on a workable option without comparing alternatives, a pattern documented in the naturalistic decision-making literature (Klein, 2008). Such expert intuition is valuable but fallible, and it is most reliable in stable, well-structured domains. The Cynefin framework offers a useful way to match decision approach to situation, distinguishing ordered contexts in which good practice or expert analysis suffices from complex contexts in which cause and effect can be understood only in retrospect and a more exploratory posture is required (Snowden & Boone, 2007). For GMP, the implication is that no single decision style is universally appropriate: a routine, well-characterized deviation calls for rule-based judgement, while a novel failure with unclear mechanism calls for a more deliberate, evidence-gathering response.

Finally, the organizational dimension cannot be ignored. Decisions in a regulated plant are embedded in structures of authority, accountability, and culture. The literature on organizational accidents shows that serious failures usually arise not from a single error but from the alignment of latent weaknesses across multiple defenses (Reason, 1990, 1997; Obriki & Arumosoye, 2020), and the literature on risk governance emphasizes that the legitimacy of a risk decision depends on the process by which it is reached and on the inclusion of appropriate perspectives (Renn, 2008; Rasmussen, 1997). A framework for risk-based decision-making in GMP must therefore address not only the analysis of risk but the human and organizational conditions under which that analysis is converted into action (Akomolafe & Agu, 2019c; Obogo, Uduokhai, & Ozobu, 2019).

III. THE CASE FOR A DEDICATED FRAMEWORK

If the principles of risk-based decision-making are already established in guidance, it is reasonable to ask why a further framework is needed. The answer lies in a set of recurrent weaknesses that arise when those principles are applied without an integrating structure. These weaknesses are observable across the published commentary on quality risk management and are familiar to practitioners, even where they are not always named.

Tool substitution. A persistent problem is the treatment of a risk tool as if it were the decision. The risk matrix is the most common instance. A matrix that multiplies a severity score by a probability score, and perhaps a detectability score, produces a number that is easily mistaken for an answer (Akomolafe & Agu, 2018). Yet the analytical limitations of such matrices are well documented. They can assign identical scores to risks of very different character, can reverse the true ordering of risks under plausible conditions, and depend heavily on arbitrary choices of category boundaries (Cox, 2008; Duijm, 2015). The score is an input to a decision, not the decision itself, and a framework must keep the two distinct.

Disproportion. The principle that effort should match risk is widely endorsed and unevenly practiced. In some organizations every change, however trivial, is subjected to the same heavyweight assessment, which exhausts the very attention that proportionality is meant to conserve. In others, high-consequence decisions receive only cursory analysis because they have become routine (Agbabiaka et al., 2019; Okonkwo et al., 2019). Without an explicit mechanism for selecting the level of effort, the proportionality principle remains an aspiration.

Opaque rationale. Because a risk-based decision must be defensible, the reasoning behind it is part of the output (Dogbatsey et al., 2019; Mbonu et al., 2018). In practice the reasoning is frequently compressed into a score and a conclusion, leaving the assumptions, the evidence considered, and the judgement of uncertainty unrecorded (Mbonu, Iwuanyanwu, et al., 2019). When the decision is later questioned, whether internally or by a regulator, it cannot be reconstructed. The strength of knowledge underlying the assessment, emphasized in modern risk scholarship (Aven, 2016), is precisely the element most often lost.

Unmanaged bias. The behavioral literature shows that risk judgements are systematically distorted, yet most quality risk management procedures contain no countermeasures against bias (Akomolafe & Agu, 2019a, 2019c). Severity and probability are scored by the same individuals who may be invested in a particular outcome, anchored on prior assessments, or subject to optimism about familiar processes. A framework that ignores these tendencies inherits them.

Static assessment. Risk is dynamic but assessments are often treated as one-time artifacts produced at qualification or at the time of a change and then archived (Dosunmu & Ogundele, 2020). The review element of the quality risk management cycle is the most frequently neglected, with the result that decisions rest on a picture of risk that may no longer be accurate. The lifecycle orientation now expected of product and process management (ICH, 2019) has not consistently extended to the management of the underlying risk decisions.

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Inconsistent criteria. A further weakness is variation in the standard applied to similar decisions across a site or a network. When criteria are not defined in advance and held in common, two comparable deviations may be dispositioned differently by different individuals or on different days, depending on workload, recent events, or the confidence of the person deciding. Such inconsistency is corrosive twice over: it undermines the defensibility of any single decision, since the standard cannot be articulated, and it erodes confidence in the quality system as a whole. The remedy is not to remove judgement but to anchor it in shared, pre-established criteria, so that judgement is exercised within a common frame rather than reinvented case by case (Eyetsemitan et al., 2020).

These weaknesses are not arguments against risk-based decision-making; they are arguments for doing it well. Each can be traced to the absence of an integrating structure that connects the assessment of risk to the logic of decision, the governance of authority, and the discipline of review. The framework presented below is designed to supply that structure.

IV. THE PROPOSED CONCEPTUAL FRAMEWORK

4.1 Overview and Guiding Principles

The framework conceives of a risk-based decision as the output of five interacting layers, illustrated in Figure 1. The layers are arranged so that context and constraints flow downward into each decision while knowledge and outcomes flow upward to refine the system over time. The contextual foundation establishes what a sound decision must respect. The risk intelligence layer converts hazards into characterized risk. The decision logic layer applies criteria and proportionality to appraise options. The governance layer assigns authority and records rationale. The learning layer captures outcomes and recalibrates the whole. The layers are conceptual rather than sequential; in any given decision they operate together, but separating them clarifies the distinct work each performs (Arumosoye & Obriki, 2019; Mbonu, Iwuanyanwu, et al., 2019).

Four principles guide the framework as a whole. The first is the primacy of the patient: every criterion and threshold is ultimately referred to the protection of the patient, consistent with the foundational commitment of the quality risk management paradigm (ICH, 2005). The second is proportionality: the formality, rigor, documentation, and seniority of a decision scale with the assessed risk, so that scarce attention is concentrated where the stakes are highest. The third is transparency of reasoning: a decision is not complete until its basis, including the evidence weighed and the uncertainty acknowledged, can be reconstructed by an independent party. The fourth is adaptivity: the framework is a living system that learns from outcomes rather than a fixed procedure applied unchanged.

Figure 1. The five-layer conceptual framework for risk-based decision-making in GMP environments.

4.2 Layer One: Contextual Foundation

Every risk-based decision rests on a foundation of context that determines what a sound decision must respect and what knowledge is available to inform it. Four elements compose this foundation. The regulatory mandate establishes the non-negotiable requirements within which any decision must fall; risk-based reasoning operates inside the boundary of compliance, not as a substitute for it (Aminu-Ibrahim et al., 2019). Product and process knowledge supplies the substantive understanding on which the quality of risk assessment depends, drawing on development data, the established design space where one exists, and accumulated manufacturing experience (ICH, 2008, 2009). Quality culture conditions whether problems are surfaced honestly and whether the discipline of the framework is genuinely applied (Aifuwa et al., 2020; Okonkwo et al., 2018b); the literature on organizational accidents shows that a culture which suppresses bad news erodes every defense built upon it (Reason, 1997), a dependency reinforced by conceptual work linking safety oversight to culture outcomes. Organizational context, including the maturity of the quality system and the resources available, determines what the organization can realistically execute (Eyetsemitan et al., 2020).

The practical role of this layer is to prevent decisions from being made in a vacuum. A risk assessment conducted without adequate process knowledge is a structured form of guessing, and a decision logic applied in an organization that punishes the reporting of deviations will be subverted regardless of its technical merit. Establishing context is therefore the first act of any risk-based decision, a point on which the pharmaceutical guidance and the generic risk management standard agree (ICH, 2005; ISO, 2018).

4.3 Layer Two: Risk Intelligence

The risk intelligence layer performs the analytical work of converting hazards into characterized, evaluated risk. It corresponds to the assessment stage of the quality risk management cycle but is framed here to emphasize that its product is intelligence for a decision rather than a score for a file. The layer comprises four activities. Hazard identification asks what can go wrong, drawing on systematic techniques appropriate to the situation, from failure mode and effects analysis for well-understood processes (Stamatis, 2003) to broader hazard reviews for less structured problems, informed by the practices consolidated in systematic reviews of hazard identification and risk control. Risk analysis estimates the likelihood and severity associated with each hazard using the evidence assembled in the contextual foundation (Akomolafe & Agu, 2019b). Risk evaluation compares the analyzed risk against the criteria established in the decision logic layer. Characterization of uncertainty, the activity most often omitted, makes explicit how strong the underlying knowledge is and where the assessment is most fragile.

Two design choices distinguish this layer from common practice. First, it treats the output of any scoring tool as evidence to be interpreted rather than as a verdict to be applied, in direct response to the documented failures of mechanical reliance on risk matrices (Cox, 2008; Duijm, 2015). Second, it requires that uncertainty be reported alongside the central estimate, so that a decision-maker can distinguish a high risk that is well understood from a moderate risk that rests on weak evidence. This reflects the argument in contemporary risk analysis that the strength of knowledge behind a risk figure is itself decision-relevant information (Aven, 2016; Aven & Renn, 2009; Dosunmu & Ogundele, 2019).

4.4 Layer Three: Decision Logic

The decision logic layer is the analytical heart of the framework, for it is here that characterized risk becomes a decision. It contains four elements. Risk criteria define, in advance, what levels of risk are acceptable, tolerable subject to controls, or unacceptable, expressed wherever possible in terms referred to patient safety (Aifuwa et al., 2020; Ahiaeke Patrick et al., 2020). Tolerance thresholds translate these criteria into the specific boundaries against which a given assessment is judged. Proportionality rules determine the level of effort, formality, and seniority that the decision warrants, operationalizing the principle that effort should match risk (ICH, 2005). Option appraisal compares the available courses of action, including the option of gathering further information before deciding, against the criteria and the characterized uncertainty.

The decision logic layer is also where the framework matches its approach to the nature of the problem. For ordered, well-characterized situations, the appraisal can rely on established rules and expert judgement, the mode in which experienced practitioners reliably perform well (Klein, 2008). For complex or novel situations where cause and effect are unclear, the layer prescribes a more deliberate posture that favors reversible actions, additional evidence, and explicit treatment of uncertainty, consistent with the guidance that decision approach should be matched to context (Snowden & Boone, 2007). Defining criteria and thresholds in advance, before a specific case arises, serves a further purpose: it reduces the influence of the biases that distort case-by-case judgement, since the standard against which a risk is measured is set when no particular outcome is at stake (Tversky & Kahneman, 1974; Kahneman, 2011).

4.5 Layer Four: Governance and Accountability

A technically sound decision that is made by the wrong person, without the right oversight, or without a recoverable record is not a sound decision in a regulated environment (Dogbatsey et al., 2019; Mbonu, Iwuanyanwu, et al., 2019). The governance layer supplies the structures that make decisions authoritative and defensible. It defines decision rights, specifying who is empowered to decide at each level of risk so that routine matters are dispositioned efficiently while consequential ones reach appropriate seniority. It defines escalation paths, ensuring that a decision exceeding a given threshold of risk or uncertainty is elevated rather than absorbed at a level that lacks the authority to own it (Ladapo et al., 2019; Mbonu, Aliliele, et al., 2020). It requires documented rationale, capturing not only the conclusion but the evidence, assumptions, and uncertainty that support it, so that the decision can be reconstructed and defended. It provides for independent oversight separating, where the stakes warrant, the party that assesses a risk from the party that benefits from a particular disposition.

This layer translates the proportionality principle into the social structure of the decision. The seniority and independence of the decision-maker, and the depth of the record, all scale with risk. The design draws on the insight from the organizational accidents literature that defenses must be layered and that no single individual or check should be relied upon for high-consequence outcomes (Reason, 1990, 1997), and on the risk governance principle that the legitimacy of a decision rests on the adequacy of the process that produced it (Renn, 2008), an emphasis echoed in governance-oriented conceptual models of safety performance across complex multi-party project settings.

4.6 Layer Five: Learning and Adaptation

The final layer closes the loop between decisions and the system that produces them. Risk is dynamic, and a framework that does not learn will gradually drift out of alignment with reality. This layer performs four functions. Knowledge capture records the outcomes of decisions and feeds them back into the product and process knowledge of the contextual foundation, strengthening future assessments. Periodic risk review revisits prior assessments on a schedule proportionate to their consequence, recognizing that the review element of the quality risk management cycle is the most commonly neglected. Signal detection scans accumulating data, including deviations, complaints, and monitoring results for evidence that a previously accepted risk has changed, an approach that parallels the documented use of near-miss and hazard observation data in industrial safety management (Arumosoye & Obriki, 2019). Framework recalibration uses this evidence to adjust criteria, thresholds, and proportionality rules so that the system improves over time.

This layer gives the framework its lifecycle character, aligning it with the broader expectation that risk be managed across the entire life of a product rather than fixed at a single point (ICH, 2019). It also makes the framework adaptive in the sense required by complex environments, where the consequences of a decision cannot be fully known in advance and learning from outcomes is the principal means of improvement (Snowden & Boone, 2007; Rasmussen, 1997). Table 1 summarizes the five layers, their core questions, and their principal outputs.

Table 1. The five layers of the framework, their guiding questions, and their outputs.

Layer	Guiding question	Core activities	Principal output
1. Contextual foundation	What must this decision respect, and what do we know?	Regulatory mandate, product and process knowledge, quality culture, organizational context	A bounded, informed basis for the decision
2. Risk intelligence	What can go wrong, how likely, how severe, how certain are we?	Hazard identification, analysis, evaluation, characterization of uncertainty	Characterized risk with explicit uncertainty

3. Decision logic	Is the risk acceptable, and which option is best?	Risk criteria, tolerance thresholds, proportionality rules, option appraisal	A reasoned, proportionate decision
4. Governance and accountability	Who decides, with what oversight, and on what record?	Decision rights, escalation paths, documented rationale, independent oversight	An authoritative, defensible decision
5. Learning and adaptation	What did we learn, and has the risk changed?	Knowledge capture, periodic review, signal detection, recalibration	Updated knowledge and an improved framework

4.7 Interactions Among the Layers

The five layers are presented separately for clarity, but the framework's value emerges from how they interact. Context flows downward: the knowledge and constraints established in the foundation set the terms on which risk is analyzed, the analyzed and characterized risk becomes the raw material of the decision logic, and the resulting decision is exercised within the authority defined by governance. Knowledge flows upward in return: the outcomes captured by the learning layer revise the product and process understanding of the foundation and recalibrate the criteria and thresholds of the decision logic. The layers are therefore coupled rather than merely stacked, and several of these couplings are decision-relevant (Dosunmu & Ogundele, 2020; Sunday et al., 2020). Weak knowledge in the foundation, for instance, widens the uncertainty reported by the risk intelligence layer, which the decision logic must answer by favoring information-gathering or reversible action, while a high level of characterized uncertainty is itself a trigger for escalation within the governance layer (Akomolafe & Agu, 2019a, 2019c).

The coupling also explains how the framework fails. A weakness in any single layer degrades the others, in the manner of the layered defenses described in the study of organizational accidents (Reason, 1997). A culture that discourages the honest reporting of problems corrupts the risk intelligence built upon it, however sound the analytical method. An assessment that omits the characterization of uncertainty deprives the decision logic of the basis for proportionality, so that effort can no longer be matched to risk. Weak governance allows a careful analysis to be overridden by expedience and an absent learning layer freezes the framework in place while the underlying risks move (Arumosoye & Obriki, 2020; Eyetsemitan et al., 2020). Designing a sound decision process therefore means attending not only to each layer in isolation but to the integrity of the connections between them.

Communication is the medium through which these connections operate, and it deserves explicit attention. Risk that is well characterized but poorly communicated cannot inform a decision made elsewhere in the organization, and a decision that is well reasoned but poorly recorded cannot inform the learning that should follow it (Dogbatsey et al., 2019). The quality risk management paradigm treats communication as one of its core activities for this reason (ICH, 2005), and within the present framework communication is best understood not as a sixth layer but as the connective tissue that allows the other five to function as a system rather than as a set of isolated steps.

V. OPERATIONALIZING THE FRAMEWORK ACROSS DECISION TIERS

The value of the framework lies in its application, and its application is governed by the principle of proportionality. The same five layers operate in every decision, but the intensity with which each layer is exercised varies with the consequence of the decision (Akomolafe & Agu, 2019b; Obogo et al., 2020b). It is useful to describe three tiers, recognizing that real decisions occupy a continuum rather than discrete categories.

Operational decisions are frequent, low-consequence dispositions made close to the process, such as the classification of a minor, well-understood deviation with no plausible product impact. Here the contextual foundation and decision logic are largely pre-established in procedures, the risk intelligence required is modest, governance rests with appropriately trained operational staff, and the learning contribution is the accumulation of cases that confirm or challenge the standing rules (Arumosoye & Obriki, 2018; Obogo et al., 2020c). The framework is satisfied with a light touch, which is precisely what proportionality demands.

Tactical decisions involve moderate consequence and some genuine uncertainty, such as the evaluation of a change to a process parameter or the qualification of a new supplier (Agbabiaka et al., 2019; Ahiaeke Patrick et al., 2020). These decisions exercise the risk intelligence and decision logic layers more fully, require an explicit appraisal of options, and call for governance at a supervisory or cross-functional level with a documented rationale that an auditor could follow (Akomolafe & Agu, 2018; Dogbatsey et al., 2019). The characterization of uncertainty becomes material, because the evidence base is rarely complete.

Strategic decisions carry high consequence, often under substantial uncertainty, such as the disposition of a batch implicated in an unexplained failure or the response to a newly detected quality signal across a product family (Arumosoye & Obriki, 2019; Dosunmu & Ogundele, 2020; Mbonu, Iwuanyanwu, et al., 2019). These decisions demand the full weight of every layer: deep contextual knowledge, rigorous risk intelligence with honest treatment of what is not known, deliberate option appraisal that favors reversible and information-gathering actions where cause and effect are unclear, senior and independent governance, and a thorough contribution to organizational learning. The matching of a deliberate, exploratory posture to high uncertainty reflects the guidance that decision approach should track the nature of the problem (Snowden & Boone, 2007).

Table 2 sets out how the layers scale across these tiers. The table is not a procedure to be applied mechanically but a description of how proportionality shapes the exercise of the framework. Its purpose is to make explicit a judgement that is often left implicit, namely how much process a given decision deserves.

Table 2. Proportional exercise of the framework across three decision tiers.

Dimension	Operational	Tactical	Strategic
Typical example	Classifying a minor, well-understood deviation	Approving a process change or qualifying a supplier	Dispositioning a batch under an unexplained failure
Risk intelligence	Pre-defined; minimal new analysis	Structured analysis with stated uncertainty	In-depth analysis; uncertainty made central
Decision logic	Rule-based against standing criteria	Explicit option appraisal	Deliberate appraisal favoring reversible actions
Governance	Trained operational staff	Supervisory or cross-functional	Senior and independent oversight
Documentation	Concise record against procedure	Auditable rationale	Full reconstruction of reasoning

To make the operation of the framework concrete, the following vignettes trace a representative decision through the five layers at each tier. They are stylized illustrations intended to show the pattern of reasoning rather than to prescribe specific thresholds, which any organization must set in its own context.

5.1 An Operational Decision: A Minor Deviation

Consider a line operator who observes that a routine in-process check was recorded a few minutes outside its scheduled window, in a process that is well characterized and for which the parameter in question carries ample margin. The contextual foundation supplies a standing procedure and established product knowledge indicating that timing variation of this magnitude has no plausible effect on quality. The risk intelligence layer requires little new analysis: severity is negligible, occurrence is understood, detectability is high, and so the characterized risk is low and the uncertainty around it is small. The decision logic layer resolves the case against pre-defined criteria, placing it below the threshold that would call for a formal investigation. Governance rests with the operator and the immediate supervisor, and the record is a concise note against the procedure (Mbonu, Iwuanyanwu, et al., 2019). The learning layer logs the event so that, should such timing deviations accumulate, the pattern would surface for review. The framework is satisfied with a light touch, which is exactly what proportionality requires, and the speed of the disposition does not come at the cost of traceability.

5.2 A Tactical Decision: A Change to a Process Parameter

Consider a proposal to widen the operating range of a mixing step in order to improve throughput. Here the contextual foundation is invoked more fully: development data, the established understanding of the step, and prior manufacturing experience are assembled, and any gaps in that knowledge are noted. The risk intelligence layer conducts a structured analysis, for example a failure mode and effects review, estimating how the proposed change could affect the relevant quality attributes and stating the confidence in each estimate. Because the evidence base is incomplete, the characterization of uncertainty becomes material to the outcome. The decision logic layer then appraises options rather than simply scoring the change, weighing approval with additional controls against deferral pending a small confirmatory study, and applying the proportionality rule to decide how much assurance the change warrants (Ahiaeke Patrick et al., 2020; Akomolafe & Agu, 2019a). Governance is cross-functional, drawing in quality and technical functions, and the rationale is documented so that an independent reviewer could follow the reasoning from evidence to conclusion. The learning layer specifies the monitoring that will confirm, after implementation, whether the predicted effect holds, closing the loop between the decision and its consequences.

5.3 A Strategic Decision: Disposition Under an Unexplained Result

Consider a batch implicated by a confirmed out-of-specification result whose cause cannot be established after investigation. This is the most demanding case, and it exercises every layer at full intensity. The contextual foundation is searched deeply, and, crucially, the limits of the available knowledge are made explicit rather than papered over. The risk intelligence layer produces an in-depth analysis in which uncertainty is the central feature: the severity of a quality failure to the patient may be high, the probability is genuinely unknown, and the strength of the underlying knowledge is weak (Aifuwa et al., 2020; Okonkwo et al., 2018b). The decision logic layer responds to this profile by giving weight to the asymmetry of consequences and by favoring reversible, precautionary action, such as withholding the batch and gathering further evidence, over an irreversible release that the evidence cannot support. Governance is senior and independent: the disposition is owned by the quality function with authority separate from the pressure to supply and the decision is documented in full, including the reasoning, the assumptions, and the acknowledged uncertainty, so that it can be reconstructed and defended (Arumosoye & Obriki, 2019; Mbonu, Iwuanyanwu, et al., 2019). The learning layer treats the event as a signal feeding the investigation into the organization's knowledge and, where warranted, recalibrating the criteria and thresholds that will govern similar decisions in future. The matching of a deliberate, evidence-seeking posture to high uncertainty is precisely what the framework prescribes for situations in which cause and effect are not yet understood.

Read together, the three vignettes display the single pattern that the framework is designed to produce. The same five layers operate in each, but the intensity of each layer, the seniority of the governance, and the depth of the record all rise with the consequence and the uncertainty of the decision. Proportionality is not a separate rule applied on top of the framework; it is the variable that tunes the framework's intensity from one decision to the next, and the vignettes show that tuning in operation.

VI. DISCUSSION

The framework advances the practice of risk-based decision-making in GMP environments in three respects. It separates the assessment of risk from the making of the decision, it builds proportionality and governance into the structure rather than leaving them to discretion and it incorporates the management of uncertainty and bias that the conventional approach neglects (Eyetsemitan et al., 2020). Each of these deserves to be located in relation to existing work.

The framework does not displace the quality risk management cycle of ICH Q9; it embeds it. The assessment, control, communication, and review activities of the guideline map onto the risk intelligence, decision logic, governance, and learning layers respectively, while the contextual foundation makes explicit the establishment of context that the generic risk management standard places at the head of its own process (ISO, 2018). The contribution is not a new vocabulary of risk but an account of how the familiar activities combine to produce a decision, an account that the guidance documents, by design, leave to the implementer. Integrative conceptual models in adjacent high-hazard industrial domains, which consolidate dispersed risk considerations into a single structure, lend support to this consolidating approach as do enterprise-level risk assessment frameworks oriented toward system resilience (Arumosoye & Obriki, 2018),

On the contested question of risk matrices, the framework takes a deliberate position. The documented failures of these tools, including their capacity to mis-rank risks and to obscure differences in the strength of underlying knowledge (Cox, 2008; Duijm, 2015), do not justify abandoning them, since they remain a useful means of organizing and communicating a first pass over many risks. The framework instead confines them to the risk intelligence layer as one input to be interpreted, and it requires the decision logic layer to weigh that input against explicit criteria and characterized uncertainty. The matrix informs the decision; it does not constitute it. This positioning is consistent with the broader argument that quantitative and semi-quantitative tools should support rather than replace structured judgement (Apostolakis, 2004).

The treatment of human judgement is a further point of distinction. By defining criteria and thresholds in advance, by requiring uncertainty to be reported, and by separating assessment from disposition in high-consequence cases, the framework builds in countermeasures against the biases that the behavioral literature has shown to distort risk judgements (Tversky & Kahneman, 1974; Kahneman, 2011). At the same time, by matching decision style to context, it preserves a role for the expert intuition that performs reliably in well-structured situations (Klein, 2008) while constraining it where the situation is novel or complex (Snowden & Boone, 2007). The aim is neither to mechanize judgement nor to trust it uncritically, but to structure the conditions under which it is exercised.

Finally, the learning layer responds to the most neglected element of current practice. By treating each decision as a source of knowledge and by scheduling the review of prior assessments in proportion to their consequence, the framework gives operational meaning to the lifecycle management of risk that the guidance now expects (ICH, 2019). This adaptive character is also what allows the framework to remain useful in the complex situations where the consequences of a decision cannot be fully foreseen and learning from outcomes is the principal route to improvement (Rasmussen, 1997).

6.1 A Structured Comparison with Established Models

Locating the framework against established models clarifies what it adds. Table 3 maps the five layers onto the quality risk management process of ICH Q9, the generic risk management process of ISO 31000, and the conceptual models developed for adjacent high-hazard industrial settings. The comparison reveals substantial overlap in the analytical core, since all three reference points address the establishment of context, the assessment of risk, and the importance of review. The distinctive emphases of the present framework lie in three places. It elevates decision logic to an explicit layer, whereas the established pharmaceutical and generic models tend to compress the move from assessment to decision into a brief notion of risk acceptance. It gives governance and accountability the same structural standing as analysis, reflecting the lesson from industrial safety scholarship that the legitimacy and durability of a decision depend on who makes it and how it is recorded. And it treats the characterization of uncertainty as a first-class output rather than an afterthought, consistent with both contemporary risk theory (Aven, 2016) and the

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resilience orientation of enterprise risk frameworks. The framework is therefore best understood not as a competitor to the established guidance but as an account of the decision architecture within which that guidance operates.

Table 3. The five layers mapped against ICH Q9, ISO 31000, and adjacent industrial safety conceptual models.

Framework layer	ICH Q9 (2005)	ISO 31000 (2018)	Adjacent industrial models
Contextual foundation	Establish context; link risk to the patient	Scope, context, and criteria	Safety culture and oversight context
Risk intelligence	Risk assessment: identify, analyze, evaluate	Risk identification and analysis	Hazard identification and near-miss observation
Decision logic	Risk acceptance and proportionate effort	Risk evaluation and treatment	Resilience-oriented enterprise appraisal
Governance and accountability	Roles, responsibilities, communication	Leadership and integration	Governance of multi-party performance
Learning and adaptation	Risk review	Monitoring, review, and improvement	Learning from human error and field data

6.2 Implications for Practice

Several implications follow for organizations seeking to strengthen risk-based decision-making. First, the framework can be used as a diagnostic. An organization can examine its existing decision processes layer by layer and ask whether each is adequately exercised: whether context is genuinely established, whether uncertainty is characterized rather than hidden, whether criteria are set in advance, whether governance scales with risk, and whether learning is captured. Gaps revealed by this examination point directly to improvement.

Second, the framework clarifies what proportionality requires. Rather than treating proportionality as a slogan, an organization can define, for each tier of decision, the expected intensity of each layer, as illustrated in Table 2, and can hold its processes to that standard. This guards equally against the waste of subjecting trivial decisions to heavyweight analysis and against the danger of dispositioning consequential matters too lightly.

Third, the framework draws attention to documentation as reasoning rather than as record-keeping. The requirement that a decision be reconstructable shifts the purpose of the record from demonstrating that a process was followed to demonstrating that a conclusion was warranted, including the evidence weighed and the uncertainty acknowledged (Sunday et al., 2020). This is a more demanding standard, but it is the standard that the defensibility of a regulated decision actually requires.

Fourth, the framework underscores that risk-based decision-making is a cultural undertaking as much as a technical one. The honesty of risk reporting, the willingness to escalate, and the discipline of review all depend on an organizational environment that rewards the surfacing of problems. Without that environment, the most elegant decision structure will be quietly subverted, a lesson long established in the study of organizational failure (Reason, 1997).

A further implication concerns competence. A framework of this kind presumes that those who exercise it can assess risk, characterize uncertainty, and recognize when a decision exceeds their authority and must be escalated. These are skills rather than mere procedures, and they develop through training, calibration against worked examples, and feedback on past decisions. An organization that invests in the framework without investing in the judgement of the people who operate it will find the structure present on paper but absent in practice. The learning layer has a role here as well, since the record of past decisions and their outcomes is among the most effective materials for developing the judgement that future decisions will require.

6.3 Toward a Maturity Assessment

Because the framework decomposes a decision into distinct layers, it offers a natural basis for assessing how well an organization performs each of them. A maturity perspective describes a progression from ad hoc practice toward a self-improving system, allowing an organization to locate its current state and to identify the next increment of improvement rather than treating capability as simply present or absent (Obogo et al., 2020a). Table 4 sketches four illustrative levels, from decisions made without explicit structure, through documented and then consistently proportionate practice, to a state in which outcomes systematically refine the framework itself.

The levels are descriptive rather than prescriptive, and the boundaries between them are not sharp. An organization may sit at different levels for different layers, exercising rigorous risk intelligence, for example, while neglecting the learning that would keep its criteria current. The value of such an assessment lies less in assigning a single label than in revealing these imbalances and directing improvement toward the weakest connection. As with the framework as a whole, the maturity sketch is offered as a conceptual aid that would itself require empirical development before it could support formal benchmarking across sites.

Table 4. An illustrative maturity progression for risk-based decision-making.

Maturity level	Hallmarks across the five layers
1. Ad hoc	Decisions are made without explicit structure. Context and criteria are implicit, uncertainty is left unstated, and governance and review occur inconsistently.
2. Defined	Criteria and decision rights are documented and risk assessment follows a standard method, but proportionality and review are applied unevenly.
3. Managed	Proportionality is enforced across decision tiers, uncertainty is characterized, escalation and documentation scale with risk, and periodic review is scheduled.
4. Optimizing	Outcomes feed back systematically into knowledge and recalibrate criteria, signal detection is active, and the framework itself is reviewed and improved.

6.4 Limitations and Future Research

This paper offers a conceptual framework, and its limitations follow from that status. The framework is synthesized from established guidance and from the decision-science literature rather than derived from primary observation of decision-making in operating plants, and it has not been empirically validated. Its constructs, while grounded in the literature, are proposed rather than measured, and the relationships among the layers are argued rather than tested.

These limitations define an agenda for future work. The framework invites empirical study of how decisions are actually made in GMP environments and of whether organizations whose practices align with the framework produce decisions that are more defensible, more proportionate, or better calibrated than those that do not. The constructs of each layer could be operationalized into a maturity instrument and tested across sites. The treatment of uncertainty in the risk intelligence layer could be developed into specific methods for reporting strength of knowledge alongside conventional scores, building on the conceptual advances in the wider risk field (Aven, 2016). The interaction between the framework and emerging approaches to manufacturing, including the growing use of data and automation in quality systems, also merits investigation, building on conceptual work on data-driven occupational safety risk control and on technology-enabled risk assessment frameworks in adjacent industrial domains (Mbonu, Iwuanyanwu, et al., 2020b; Dosunmu & Ogundele, 2020), Each of these directions would move the framework from a structure for organizing thought toward a tested basis for practice.

VII. CONCLUSION

Risk-based decision-making has become the expected mode of operation in Good Manufacturing Practice environments, but the expectation has outrun the means of meeting it. Practitioners are asked to manage risk and to act in proportion to it, while the guidance supplies principles and tools rather than an integrated account of how risk evidence becomes a defensible decision. This paper has proposed such an account in the form of a five-layer conceptual framework. A contextual foundation grounds each decision in regulatory mandate, knowledge, and culture. A risk intelligence layer converts hazards into characterized risk with honest treatment of uncertainty. A decision logic layer applies pre-defined criteria and a principle of proportionality to appraise options. A governance layer assigns authority and records reasoning. A learning layer feeds outcomes back into knowledge and recalibrates the system over time.

The framework separates assessment from decision, builds proportionality and accountability into its structure, and confronts the uncertainty and bias that conventional practice tends to ignore. It treats the risk matrix as an input rather than a verdict, matches the intensity of each decision to its consequence, and gives operational meaning to the lifecycle management of risk. As a conceptual contribution it is offered not as a finished procedure but as a foundation: a structure that practitioners can use to design and assess their decision processes and that researchers can use as a basis for the empirical work that the field still needs. The quality of medicines depends, in the end, on the quality of the countless decisions made in the course of producing them, and the disciplined improvement of those decisions is a goal worth the structure this framework attempts to supply.

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