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(REVIEW ARTICLE)

FMEA Harmonization in Global Template Revisions: Impact on Material Qualification

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Abstract

Failure Mode and Effects Analysis (FMEA) is increasingly being implemented as a globally controlled documentation framework in which centrally managed template libraries and data dictionaries are used across multi-site manufacturing networks. Harmonization of global template revisions in such settings is not a clerical task; it is a risk-governance intervention that shapes the nature of hazard framing, prioritization and translation into material qualification requirements. This review examines the impact of harmonization of FMEA in global template revisions on the material qualification, especially (i) cross-site comparability of risk ratings, (ii) traceability between identified failure mechanisms and evidence of qualification, (iii) supplier and change-control interfaces and (iv) action prioritization logic that shifts qualification workload to high-severity risks. The literature indicates several persistent obstacles: severity-occurrence-detection judgments are subjective, inconsistent taxonomies across sites, template drift over time, and the weak association of FMEA outputs with qualification protocols. Reported methodological developments, including ontology support, structured reprioritization, fuzzy and evidence-based ranking, and digital frameworks aligned with harmonized standards, partially address these limitations but also introduce additional governance burdens. The review summarizes the findings, identifies key inconsistencies and gaps, and proposes future research directions toward audit-ready, data-linked, and lifecycle-sustained FMEA-to-qualification alignment.

Keywords: Action priority; Global templates; Harmonized FMEA; Material qualification; Risk governance; Supplier change control

1. Introduction

Global production systems increasingly rely on centrally controlled template systems that standardize how process knowledge, hazards, and controls are documented across sites. In this context, FMEA is often implemented via global form sheets, shared failure-mode libraries, and organizational scoring guidance which are routinely updated to reflect changing products, processes, and regulatory expectations. This means that template revision emerges as a mode of governance that does not just dictate formatting and terminology, but also the analytical boundaries of risk assessment: which failure mechanisms will be seen, which controls will be considered as detection, which risks will require documented response. Evidence from multi-case industrial environments suggests that the more maintenance-oriented FMEA practices already entail large-scale cross-functional coordination, and that the considerations of organizational implementation highly affect the analytical fidelity and downstream behavior, such as maintenance planning and defining a maintenance control strategy [1]. With the implementation of FMEA based on templates of all the assets globally, the coordination problem is no longer confined to a single population of assets but rather to a global network, where the role of harmonization is enhanced.

A second objective of harmonization is the decades-old critique that the classical risk ranking of FMEA, specifically the simplification of risk ranking to a single composite measure, can cause unstable prioritization, and poor inter-assessor and inter-site reproducibility. The methodological literature records significant differences in the treatment of severity,

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occurrence and detection scales by organizations and reveals that a variety of risk evaluation methods have been developed in part to deal with inconsistency and ambiguity of traditional practice [2]. This lack of robustness in risk assessment logic becomes more pronounced in globally templated environments: even with the nominally identical templates, two locations can still end up making different decisions on actions because of a discrepancy in the scale anchor, taxonomy or linkage guidelines. Harmonized revision of global templates therefore acts as a control on epistemic variability by constraining how risks are interpreted across sites, so that material-related risks are prioritized in this way and transformed into the same set of standards of qualification.

It is directly related to material qualification. Material qualification, including raw materials, consumables, single-use components, packaging-contact materials and materials provided by the supplier is based on structured evidence that hazards associated with materials are identified, mitigated and verified. Multi-criteria logic is being increasingly used in conventional practice of FMEA, which has been found to be useful in addressing expert judgment of uncertainty, especially via fuzzy formulations that rephrase the judgment of severity, occurrence and detection in the form of a linguistic or graded membership scale. Initial fuzzy criticality studies show how these methods may modify the prioritization compared to crisp scoring by explicitly modelling the ambiguity, instead of coerced false precision in one-point scores [3]. The rigor and interpretability of the material qualification rationales of the international template revisions are also decided by the harmonization decisions of whether uncertainty is represented through crisp scales, fuzzy logic, or evidence-based support. Defensible limits of qualification can be based on a harmonized template that does not lose the uncertainty structure; a template that makes less of the nuance in one score can conceal the explanation as to why a material-related failure mechanism is believed to be acceptable.

The selection of the material is also inseparably intertwined with supplier selection, change control and lifecycle governance. Variants of FMEA adapted to the context of supply risks have been advocated to support structured selection of suppliers, by mapping the possible failure modes caused by supplier performance, and the control capabilities in the presence of uncertainty [4]. These studies not only demonstrate how the results of FMEA can be operationalized into procurement and qualification decisions but also demonstrate how the results are reliant on the formal structure of the FMEA method, scale calibration and prioritization rules included in the template. When a global organization revises templates, the practical question will be, will harmonize revisions improve comparability while reducing unnecessary qualification work or will they be perceived to create cascades of requalification and conflicting expectations across regions?

Template harmonization may change not only risk ranking but also action prioritization, especially when moving towards action-priority conceptualizations, which are commonly used in harmonized implementations, rather than the purely multiplicative logic of scoring, is also supported by the recent literature that supports harmonized standards. Digital models of implementing harmonizing FMEA standards highlight the role of action prioritization to provide more informative cues to decisions and reduce unequal ranking, as well as to append new requirements to structured data models and controlled templates [5]. This review focuses on how harmonization mechanisms such as taxonomy alignment, scoring guidance, action priority logic and digital enablement on the material qualification results such as evidence quality, auditability, test planning, supplier control strategy and change impact assessment.

The purpose of the review is to evaluate peer-reviewed evidence on (i) operationalization of global FMEA template harmonization in reported studies, (ii) methodological tools to stabilize prioritization and improve consistency, and (iii) how the choices would affect material qualification activities, such as analytical validation, single-use system risk controls, and supplier-driven risk governance. The sections that follow give a thematic literature evaluation, a conceptual framework and methodological typology, an analytical discussion of findings reported, future directions and a synthesized conclusion.

2. Literature Review

The literature relevant to template-based FMEA harmonization cuts across a number of overlapping themes: (a) prioritization of actions and convergence via a standard, (b) structured knowledge representation, which limits terminology drift, (c) application studies, which establish links between FMEA outputs and qualification evidence, and (d) critical assessments, which remind us of resource burden and inadequately controlled decision value. The main fact is that harmonization is not frequently referred to as a single intervention but emerges as a constellation of different controls: standardized taxonomies of failure modes and causes, shared scale anchors, defined relationships between failure mechanisms and controls and disciplined practices of controlled update practices that prevent template drift. According to the action-priority work, the action numbers and types needed under the new prioritization logic can change compared to the old ways of operating and the consequences can be found in the ways of distributing qualification workload, and documentation workload [6]. In global environments, such approaches can rebalance effort

toward high-severity failure modes in qualification testing and supplier control but may require tight control in order to prevent local workarounds.

The second theme has to do with representational infrastructure. FMEA has been suggested to be supported by ontology to formalize the concept of domains, reuse them, and decrease their ambiguity in terminology and relationships between teams [7]. Ontology support can serve as a semantic underpinning in global template revisions, to offer inter-site mapping of failure-mode catalogues, material types, and control strategy descriptions, and reduce translation loss during template updates. Applications in related areas show that FMEA can be extended by adjusting the inappropriate terminology without undermining the analytical intent, but it is this flexibility which also indicates a harmonization tension: it does not weaken the cross-site comparability, but it is more likely to do so when it is over-adapted [8]. This tension can be addressed in part by using global template revisions that use controlled vocabularies and explicit mapping rules, to allow localized phrasing, but still a common underlying taxonomy.

A third theme is related to the interrelationship between the output of FMEA and qualification evidence. The FMEA-based risk analysis has been reported within the framework of analytical validation because it is an obvious part of the validation planning since it enables revealing the previously unknown risks, and assists in selecting corrective measures, lowering the risk priority indicators [9]. This relationship is directly linked to the material qualification, because validation and qualification procedures can provide the evidence base of the material acceptance criteria, sampling plan and test method control. The proposed validation logic can be different when a global template update occurs, which alters the scoring of detection controls, or the scoring of causes of classification, which can lead to a requalification decision, or can raise the defensibility of legacy qualification packages. This shifts template governance from a document-control function to an operational quality risk management function.

Another methodological advancement is related to the alternative ranking methods which strive to minimize subjectivity, more effectively deal with linguistic judgment and enhance the strength of prioritization. Linguistic operator based and fuzzy priority logic based improved prioritization techniques have been reported to be better prioritized in situations where there is discretization of scales and equal weighting skews action choices, and simple multiplicative scoring is less refined in ranking behavior [10]. At the same time, the skeptical views warn that FMEA can turn out to be resource-consuming, and offer a minimal marginal value, when introduced in a mechanistic form, when the process is executed with too much granularity or when it is not connected to decision-making paths in an explicit manner [11]. The subsequent critique applies to global template revisions: harmonization can create more complex procedures, i.e. introduction of columns, structured analyses or data requirements; absence of corresponding value of decisions can cause global adoption to become burdensome and superficial.

Application evidence based on the material qualification is prevalent in biopharmaceutical manufacturing, where materials, in particular, single-use parts and contact plastics, add leachable, impurities and variability issues, which need to be managed by means of formalized risk management. The multi-stakeholder quality risk management multi-single use system report recognizes control measures and concentrates on systematic examination of impurities and system influences and provides a basis to the qualification planning using all component lifecycles [12]. The upstream single-use implementation in continuous processing environments by complementary case evidence with the use of FMEA reveals that the intensified operations have distinct risk profiles that can be advantageously identified by using the structured identification of failure mechanisms and mitigation planning [13]. This work confirms that harmonized template revisions can have a powerful impact on the scope of material qualification: a template that explicitly specifies that mapping material-related hazards to critical quality attributes is mandatory can focus the qualification goals, but a template which is not explicit in so doing may allow critical gaps.

Lastly, the literature on industrial safety and recall analysis shows that a systematic organization of the failure mode data can facilitate the large scale learning of defects and recall data, such as classification of defective parts and types of defects and conversion into FMEA statements [15]. In case of global template update, it means that cross-site learning can be facilitated by harmonization in case failure-mode catalogues, material failure classes and root-cause taxonomies are open to external evidence streams. On the other hand, conflicting catalogues or lack of uniformity of classification principles can inhibit worldwide learning and compel local re-invention.

Table 1 Summary of key findings

Ref	Focus	Key Findings
[6]	Action priority versus legacy prioritization	Action-priority logic can reduce total improvement actions while preserving emphasis on high-severity conditions; highlights governance value of consistent action rules within shared templates.
[7]	Ontology support for FMEA	Formalized domain concepts enable structured querying and reuse of failure knowledge; reduces ambiguity in failure-mode catalogues and supports consistent terminology across distributed teams.
[8]	Risk assessment workflow adaptation within structured FMEA	Terminology tailoring can improve usability in specialized contexts while retaining core ranking logic; underscores need for controlled mappings to maintain cross-site comparability.
[9]	FMEA as input to analytical validation	Risk analysis identifies previously unrecognized analytical risks and supports targeted corrective actions; demonstrates direct linkage between FMEA outputs and qualification evidence planning.
[10]	Linguistic operator and fuzzy priority for improved ranking	Linguistic aggregation improves prioritization behaviour under vague judgments; supports more stable action focus when severity, occurrence, and detection are expressed in qualitative terms.
[11]	Critical assessment of FMEA effort-value balance	Resource intensity can outweigh benefits when FMEA is applied mechanistically; suggests that harmonization should focus on decision-relevant structure rather than expanded documentation.
[12]	Quality risk management for single-use systems	Structured evaluation of impurity and system impacts supports control strategy definition; emphasizes lifecycle and change management considerations relevant to material qualification.
[13]	FMEA case study for upstream single-use continuous processing	Intensified upstream processing introduces distinct risk mechanisms; structured FMEA supports mitigation planning for material-related and operational failure modes.
[14]	Analytical validation risk analysis using FMEA	Demonstrates how corrective actions can reduce risk indicators and improve method robustness; illustrates how FMEA structure influences qualification decisions and documentation traceability.
[15]	Classification and translation of recall evidence into FMEA statements	Systematic categorization of defects and components supports scalable learning; aligns with harmonized taxonomies that enable cross-site comparison and template library updates.

According to Table 1, the most empirical connections between harmonization and material qualification can be observed when FMEA results are directly related to validation or risk-control evidence [9], [14] and when risks associated with materials are at the focus of the process design such as the implementation of single-use systems [12], [13]. Developments in methodology to stabilize ranking and minimize ambiguity facilitate harmonization by limiting interpretation [7], [10], and critical views warn that harmonization needs to be decision-focused to minimize procedural overload [11]. Across these themes, a recurring gap is the limited documentation of how global template revisions are managed over time: versioning, legacy FMEA migration, and practical management of template drift are not well described in peer-reviewed literature but are of prime importance in the impact of multi-site qualification.

3. Methodology

The harmonization of FMEA in the context of global template revisions can be conceptualized as a four-layer intervention comprising semantic alignment, scoring alignment, decision alignment, and evidence alignment. The literature suggests that instability frequently occurs when a single layer is considered such as when scale anchors are standardized and taxonomies are fragmented, when action rules are standardized and qualification evidence mapping is optional. A template update to bring all four layers into agreement allows a model path between the known mechanisms of failure related to materials to qualification requirements like test plans, supplier controls and acceptance rationale. Figure 1 shows a conceptual model that connects the global template governance with the local FMEA

implementation and downstream material qualification results, with a strong focus on feedback activities to continuously better the templates based on lessons learned and qualification results.

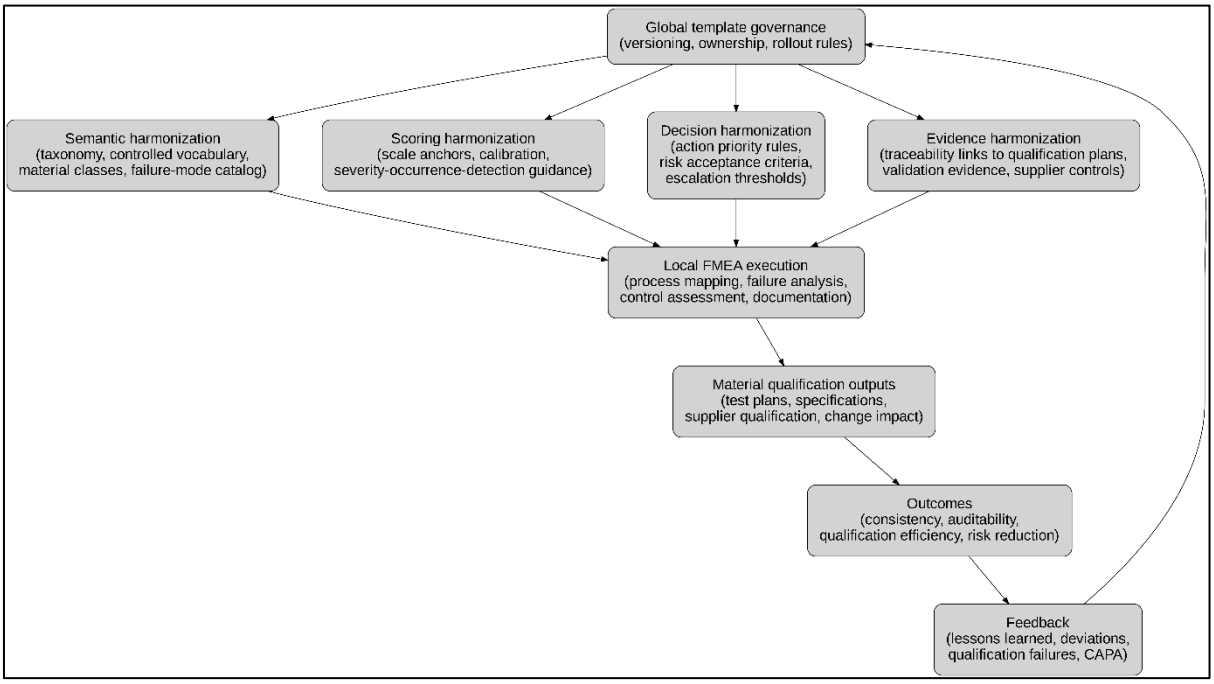

Figure 1 Conceptual framework linking global FMEA template harmonization to material qualification outcomes

Literature operationalizes these layers in various mechanisms using methodological approaches. Approximate reasoning methods are attempts to alter the traditional FMEA to include reasoning frameworks that are more capable of approximating uncertain expert judgment, but which are practical to use [16]. Approximate reasoning can also be viewed in the context of template harmonization as a way to structure the conversion of qualitative expert inputs to consistent ranking results, which may reduce cross-site variation in the training and interpretation of scale when training and interpretation are inconsistent across sites. Nevertheless, these methods enhance the complexity of methods and might demand further governance to make sure that the reasoning parameters are similar across locations and template versions.

The other approach that stands out is how to deal with interdependencies of failure mechanisms and cause and effect of risk. The relationship between influence among failure causes and modes is explicitly modelled in reprioritization based on decision-making trial and evaluation laboratory (DEMATEL) techniques which generate a reprioritized ranking that displays causal centrality, as opposed to isolated risk scores [17]. In the case of global template revisions, it applies in material qualification since failure mechanisms associated with materials tend to spread to several steps in the process, as well as quality properties. A standardized template which allows causal linkage representation, as opposed to the linear tabular listing, can enhance the reasonableness of qualification scope decisions, but the increased modelling cost imposes additional implementation costs in standard manufacturing environments.

Assessment methods based on fuzzy criticality are trying to capture the ambiguous severity, occurrence and detection rating descriptions by modelling the inputs as fuzzy numbers or membership functions and generate criticality assessment that is more resilient to linguistic judgment [18]. These strategies are consistent with semantic and scoring levels of harmonization: harmonized linguistic features and membership variables have the potential of minimizing cross-site interpretive drift. However, the demands of governance are not trivial: parameter calibration, training and tool support become a part of template changes, and inconsistent calibration can provide variability again in another form.

Newer multi-criteria models combine state-of-the-art fuzzy sets and formal causal analysis. Intuitionistic fuzzy set approaches with systematic assessments offer an approach to include both levels of membership and non-membership, which increases expressiveness in the face of uncertain or conflicted experts [19]. Such expressiveness can be used to record defensible qualification rationales of material in global template revisions by recording the uncertainty explicitly, but doing so can be challenging to describe in audit, unless the tool outputs are clearly associated with qualification

decisions. Methods employing D numbers with ranking techniques like TOPSIS also resolve uncertainty and missing information by generalizing evidence theory models to FMEA risk prioritization [20]. Such strategies imply a route to harmonized templates to capture missing or mismatched evidence, which is common during supplier changes and the adoption of new material - without imposing artificially sharp scores. Simultaneously, a higher level of mathematical complexity may introduce interpretability gaps that need to be dealt with by governance and design of documentation.

In all techniques, the prevalent trend is a trade-off between consistency and usability. Unified templates with elaborate ranking logic can enhance cross-site comparability and minimize arbitrary prioritization, yet may also increase the training needs, reliance on tools and documentation overhead. The conceptual framework thus situates global template governance as a needed overlay to maintaining integrity of the methods over time, averting local drift, and assuring material qualification evidence to be connected to the ever-changing FMEA logic as opposed to being stagnated in the archaic rating conventions.

4. Discussion

The published studies reveal a cumulative impact of the harmonization of FMEA in the revisions of global templates on the material qualification in three key aspects: redistribution of priorities, the enhancement of the traceability of the evidence, and the capacity to learn on the site. Prioritization redistribution happens when harmonized templates modify the way actions are activated either by new thresholds, action-priority logic or by methods of ranking that are uncertain. Action-priority evidence indicates that new priority structure can decrease the amount of improvement actions as compared to old scoring regulations, but high-severity conditions are still prioritized [6]. This can help target qualification resources, such as testing depth and supplier oversight, toward risks with the greatest potential consequences rather than those inflated by composite scores. The operational qualification burden may be reduced; the governance risk is that the emphasis on some of the detection-based improvements which have assisted to sustain robustness in the past, especially in the analytical and material variability dimensions, can be diminished.

A recurring limitation in FMEA-to-qualification alignment is weak evidence traceability. Analytical validation studies reveal that risk analysis using FMEA can reveal previously unknown risks and that the risk indicators can be reduced by corrective actions which can be quantified, contributing to more robust validation outcomes [14]. This is one of the important harmonization implications: the revised templates that render the relationship between the failure mechanisms and the qualification evidence (validation tests, acceptance criteria, control measures) visible will improve the auditability and will reduce the risk of orphan risks, which are depicted in FMEA tables, but they cannot be verified downstream. This principle is supported by ontology support which allows querying and connecting failure knowledge to process and control data in a structured way [7]. In global template revisions, there are ontology-like structures that can be used as controlled dictionaries that guarantee that material classes, supplier characteristics and failure modes are uniformly mapped into qualification artifacts in different locations.

Applications in biopharmaceutical single-use systems are especially instructive for understanding how harmonized template requirements influence qualification scope. Quality risk management work of single-use systems focuses on risk assessment of impurity risks and system effects and includes life cycle and change management requirements much like the material qualification requirements [12]. Single-use adoption in an intensified upstream continuous processing environment using FMEA will be used to identify risks associated with configuration and operational needs of the system that will provide a structured basis on mitigation planning [13]. These insights can be aligned in template revision by creating a mandatory classification of the material-related hazards, systematic distribution of the detection controls, and uniform escalation criteria for supplier or component changes. However, there is a challenge set by the literature: a problem of site-specific risks of single-use and over-generic templates may exist, but the local context may only be represented by site-specific detail unless site-specific detail is forced to be comparable to global comparability via controlled mappings.

The cross-site learning enablers are reliant on consistent taxonomies and classification schemes. A classification of defective parts and defects type can be converted into FMEA statements and implemented to offer prevention data in case of their repeat in the future, as demonstrated in the work of recall analysis [15]. In the case of global template governance, it is proposed that compatibility of templates can be used as a repository of lessons learned, except in cases where failure-mode catalogues and material failure classes remain constant between revisions and can be associated with external sources of evidence, like field failure databases or recall reports. Learning becomes fragmented when template revisions are organized to repeatedly alter taxonomy structure, without support by a reverse mapping, and qualification decision making can ping-pong between template revisions.

Contradictions and limitations in the literature are also pointed out. It has been frequently criticized that FMEA may be resource-intensive and have limited incremental value with expansion beyond the scope of the decision [11]. Under global harmonization, the revisions of templates may accidentally cause work to be burdened with structured analysis and linkage columns or even with obligatory mappings which are not explicitly related to qualification decisions. This poses a danger of shallow accomplishment, and the very purpose of harmonization is jeopardized. A case in point of adaptation is the application studies that tailor's terminology to be utilized locally; it is obvious that adaptation might be necessary but in the absence of controlled mapping the divergence may repeat [8]. The harmonization strategies should thus be able to maintain a balance between standardization and a flexible extensible form driven by control.

Table 2 Method comparison

Ref	Method	Strengths	Limitations
[16]	Approximate reasoning modification of FMEA	Captures uncertain expert judgment without forcing rigid point estimates; supports more consistent ranking under ambiguous evidence.	Adds modelling complexity; requires governance of reasoning parameters to prevent cross-site drift.
[17]	DEMATEL-based reprioritization	Models causal influence among failure mechanisms; improves prioritization where material-related causes propagate across steps.	Data and expertise intensive; causal matrices can be difficult to maintain across template revisions.
[18]	Fuzzy criticality assessment	Represents linguistic uncertainty explicitly; can stabilize ranking when scale interpretation varies across sites.	Requires calibration of membership functions; interpretability can be challenging for audit narratives.
[19]	Intuitionistic fuzzy set-based risk assessment	Encodes hesitation and conflicting judgment; supports qualification decisions under incomplete evidence.	Higher computational and communication burden; requires tool support and standardized parameter governance.
[20]	D numbers with TOPSIS ranking	Handles incomplete and non-exclusive information; supports prioritization when supplier or material evidence is heterogeneous.	Method transparency may be limited for non-specialists; governance needed to preserve comparability across deployments.
[6]	Action-priority driven decision logic	Shifts action focus toward high-severity conditions; can reduce total actions while preserving risk focus.	Requires consistent scale anchoring; may reduce attention to certain detection-driven improvements if poorly contextualized.

As shown in Table 2, harmonization is not necessarily linked to a single method, but rather harmonization relies on the existence of method assumptions, parameters, and taxonomies controlled among template versions. State-of-the-art uncertainty-conscious techniques can enhance consistency but increase interpretability and governance costs. Action-priority approaches may enhance the clarity of decisions but still base on disciplined scale calibration and stable definitions across locations.

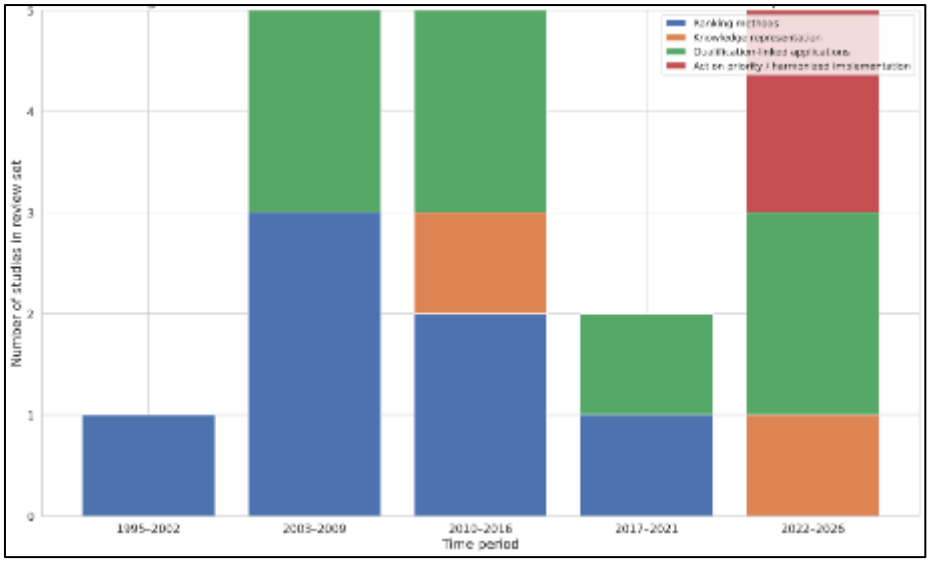

Figure 2 Trend graph of reviewed studies by theme across time periods

Figure 2 visualizes the reviewed peer-reviewed studies by thematic emphasis across time periods using counts based on the set of references used in this review. The plot backs the discussion that the previous work was based on a ranking-method innovation, and subsequent work started to concentrate more on the digital implementation and material-qualification-attached applications.

Table 3 Results comparison

Ref	System	Metric	Outcome
[6]	Automotive-oriented action prioritization logic	Action volume under prioritization rule	Reduced number of improvement actions under action-priority focus while retaining emphasis on high-severity scenarios.
[14]	Analytical method validation context	Risk indicator reduction after corrective actions	Corrective actions reduced risk indicators and improved method robustness; supports risk-driven qualification planning.
[12]	Single-use systems in biologics manufacturing	Control strategy completeness for impurity/system risks	Structured QRM guidance supports lifecycle control strategies and change management aligned with material qualification needs.
[13]	Upstream intensified continuous processing with single-use	Identification and mitigation coverage of operational/material risks	FMEA-based evaluation supports structured mitigation planning for intensified operations with material-contact system risks.
[15]	Passenger vehicle recall evidence translation	Defect classification-to-FMEA mapping utility	Classification enables scalable conversion of defect evidence into FMEA statements, supporting preventive learning and catalogue updates.
[4]	Supplier selection in supply chain risk context	Supplier prioritization under structured FMEA logic	Modified FMEA supports supplier selection decisions under risk environment, linking failure mechanisms to supplier-related controls.
[8]	Scientific process risk assessment in non-regulated labs	Process variability and error reduction potential	Structured FMEA supports improvement proposals and repeatability, illustrating template adaptation and maintenance needs.

Table 3 supports the idea that the impact of material qualification is greatest when the outputs of FMEA are directly converted to qualification evidence or control measures, and not as independent risk tables. The comparative evidence as well indicates that harmonization in template revisions could strengthen or weaken these translations based on the degree to which traceability is enforced.

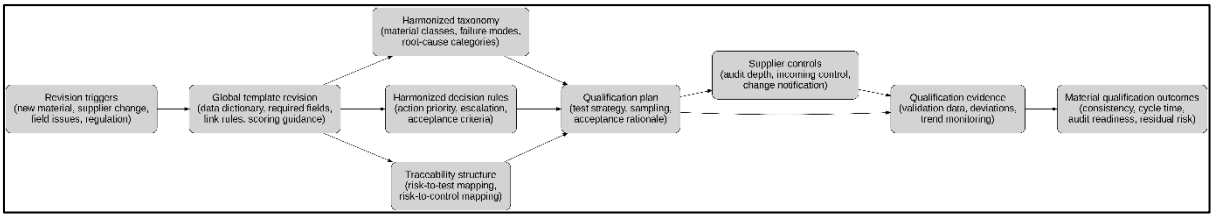

Figure 3 Relationship diagram between template revision elements and material qualification impacts

Figure 3 illustrates causal and dependency relationships documented or suggested by the literature and how harmonized taxonomies and action rules spur qualification planning and supplier controls. The diagram justifies the discussion that template revisions are a form of governance lever that have direct downstream implications.

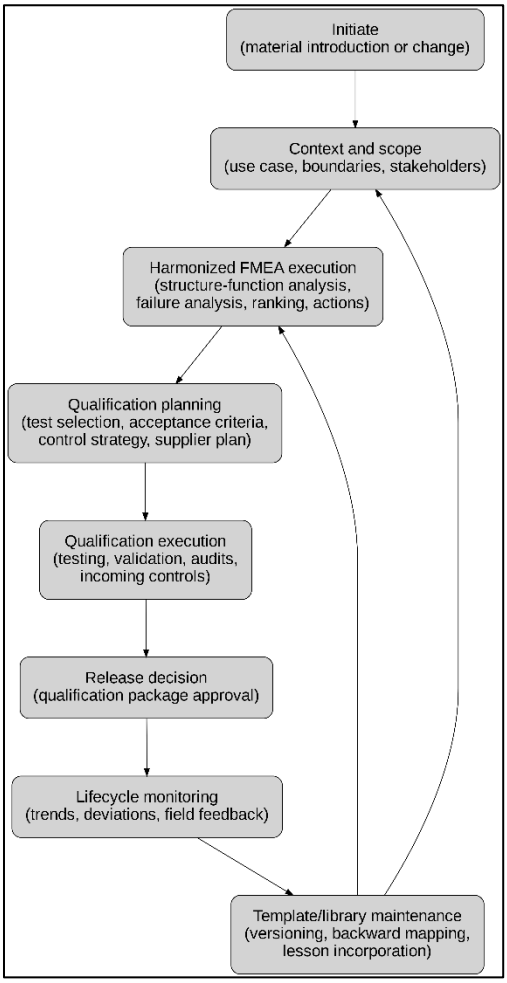

Figure 4 Integrated model for harmonized FMEA-driven material qualification lifecycle

Figure 4 combines lifecycle steps and feedback loops to give an idea of how harmonized template governance can be used to keep FMEA libraries and qualification evidence aligned. The model helps in supporting the argument that template revisions need to be considered as lifecycle risk governance events, which need to be backwardly mapped and have a controlled migration.

Overall, the reviewed evidence suggests that harmonization is more likely to ensure that material qualification decisions are comparable, traceable, and efficiently targeted, as long as explicit template revisions exist that directly govern semantics, scoring, decision rules and evidence linkages. The principal gaps are associated with longitudinal governance: few peer-reviewed articles provide a break-down report on the versioning of template libraries, the re-location of legacy FMEAs, and backward compatibility in case of a revision. A gap exists in the measurement of the effect of qualification as well; action volumes reduction [6] and risk indicator reduction in the context of validation [14] provide partial measures, but there are few systematic measures of the qualification cycle time, audit results, or supplier performance improvement using harmonized templates.

Future Directions

Future studies would benefit from shifting the focus of FMEA application from individual projects to the lifecycle management of global template ecosystems. Strong versioning and backward-mapping policies to maintain interpretability of old qualification packages in the event of a change in template scoring rules or taxonomies are one priority. The gap would be filled by empirical studies to measure the impact of backward mapping on requalification rates, audit findings, and the cross-site comparability. Monitored migration schemes - covering old failure modes to updated catalogues and old risk rankings into new action rules would need strict testing within industries where material qualification is a high-stakes context.

A second direction is the evidence-linked digital FMEA architectures which relate risk statements to repositories of qualification evidence. Ontology structures suggest a pathway of systematic relationship of failure modes, material and control classes to test reports and supplier reports [7]. The evaluation of practical implementations in preserving usability and allowing the automated completeness checks should be evaluated in research, which could involve detecting risks with no qualification evidence or detecting qualification tests with no associated risk rationales. The architectures can also reduce audit effort as they enable tracing a risk that is attributed to a material to the associated supporting quality evidence for that assessment.

A third direction is the uncertainty-aware decision support that is sensitive to material qualification situations. More advanced and evidence-based fuzzy techniques can be used to improve prioritization when the information about suppliers is not complete and when adopting an unfamiliar material as well as when there is a dispute in the judgment of the experts [18], [20]. The interpretation and audit narrative design should be studied: techniques that generate transparent intermediate outputs, such as explicit belief ranges or structured hesitation, can be adopted without compromising the rigor. The judgments need to be comparative in terms of the outcomes of the decisions (suitability of qualification extent, efficiency of the supplier control) and not in terms of the action of the strictly mathematical ranking.

The fourth direction is on harmonized action rules which explicitly account for qualification workload and residual risk. Action-priority logic suggests that prioritization has the potential to decrease the amount of action without losing focus on high severity situations [6]. Future work would be the testing of the hypothesis that action-priority-based templates qualification plans are more effective in minimizing risks in material qualification programs especially in cases where there is limited testing resources. These studies can establish metrics beyond the number of actions, including qualification period, decrease in the occurrence of defects and the performance of corrective actions of suppliers.

There are also interdisciplinary opportunities on the interface of reliability engineering, supply chain risk management and regulated quality system. The examples of the applications to supplier selection show that it can be possible to apply structured FMEA reasoning in order to make procurement decisions under risky conditions [4]. Future research should examine how supplier performance data, change-notification histories, and material-variability indicators can be incorporated into harmonized templates to support timely qualification updates. Cross-domain learning models that can be used to correlate recall evidence classification with FMEA catalogues can also facilitate global learning as far as compatibility of both taxonomies and controlled revision control are put in place [15].

5. Conclusion

The harmonization of FMEA in the context of global template revision is a risk-governance intervention which influences the naming, ranking, and transformation of failure mechanisms to material qualification evidence. The reviewed literature indicates that harmonization is the most effective when semantic alignment, scoring calibration, decision-rule consistency, and traceability between risk statements and qualification artifacts are addressed together.

The methodological advances can offer partial means to fulfil these purposes. Action-priority logic has the ability to redistribute workload of qualification to high-severity conditions and can reduce the amount of action in general under

certain prioritization policies but requires strict scale anchoring and control to avoid accidental failure to address detection-driven improvements in robustness. The structured representation and ontology improve terminological consistency and enables reuse and querying failure knowledge, improving cross-site comparability and making it easier to have more reliable links to qualification evidence.

Application studies show that the impact of material qualification is most pronounced in cases where FMEA outputs directly inform validation and control strategies, as is the case with analytical validation risk analysis and biopharmaceutical single-use system risk management. These studies demonstrate that harmonized templates can aid in defensible definition of qualification scope and more auditable rationales, when template changes preserve backward compatibility and make evidence linkage explicit rather than optional.

Persistent gaps remain. There is limited longitudinal reporting on template governance versioning, backward mapping, legacy FMEA migration and taxonomy drift management in peer-reviewed literature. Quantitative assessment of qualification outcomes under harmonized templates also remains limited and very few studies claim to have systematic measures such as time required to complete the qualification process, audit performance or requalification rates following template revisions. To address these gaps research designs are required that are aware of global template revisions as lifecycle events, the operation and quality impact of which can be measured.

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