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Quality governance and risk management in compounding pharmacies: integration between good practices, traceability, and sanitary compliance.

Quality governance and risk management in compounding pharmacies: integrating good practices, traceability, and regulatory compliance

Quality governance and risk management in formulation pharmacies: integrating good practices, transparency and regulatory compliance

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Summary

This article examines how compounding pharmacies can integrate risk management, a system of Quality, traceability, and health compliance within a single governance architecture. Through a structured narrative review of standards and technical-scientific literature, process criticality, supplier qualification, change control, deviation investigation, documentation, and indicators are discussed. A conceptual cycle is proposed in which decisions are proportional to risk and linked to patient protection. The study does not present primary data, a validated protocol, or an evaluation of a specific organization.

Keywords: compounding pharmacy; quality management; health risk; traceability; compliance; patient safety.

Abstract

This article examines how compounding pharmacies can integrate risk management, pharmaceutical quality systems, traceability, and regulatory compliance within a unified governance architecture. A structured narrative review of standards and technical-scientific literature addresses process criticality, supplier qualification, change control, deviation investigation, documentation, and indicators. A conceptual cycle is proposed in which decisions are proportional to risk and linked to patient protection. The study presents no primary data, validated protocol, or assessment of a specific organization.

Keywords: pharmaceutical compounding; quality management; health risk; traceability; compliance; patient safety.

Introduction

Compounded preparations occupy a unique position in pharmaceutical care because they allow

Individualize concentrations, pharmaceutical forms, excipients, and presentations when products

Industrialized products do not adequately meet a prescribed need. This flexibility, however,

transfers a significant portion of the responsibility for interpreting the prescription to the operation.

Select inputs, control the process, and demonstrate that each preparation was produced within the established guidelines.

Defined requirements. Quality cannot be assumed from the team's experience; it needs to be...

to be built using verifiable controls.

In small and medium-scale operations, the challenge increases because of the variety of formulas and batches.

Reduced resources and frequent changes coexist with limited resources. The same environment can

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processing substances with distinct risk profiles, requiring segregation, cleaning, qualification, records and release criteria compatible with criticality. Within the adopted time frame, Resolution RDC No. 67/2007, which expires on December 31, 2025, constitutes the Brazilian regulatory reference. of good practices for compounded and officinal preparations, while chapters of the USP distinguish risks of non-sterile, sterile and dangerous drug preparations (ANVISA, 2007; USP, 2023a; 2023b; 2023c).

The managerial response should not be the indiscriminate multiplication of forms. ICH Q9(R1) It links effort, formality, and documentation to the level of risk and acknowledges that uncertainty, Complexity and available knowledge alter the decision (ICH, 2023). This principle allows Focus robust controls on critical steps without trivializing requirements. The condition is that... proportionality must be justified by scientific knowledge, oriented towards patient protection and submitted for review.

The objective of this article is to organize an educational approach to quality governance in compounding pharmacies. The proposal articulates responsibilities, processes, evidence and Learning without reporting personal experiences or evaluating a specific company. It is argued that Effective health compliance is not an external layer to the operation: it is achieved when criteria Technical decisions, management analysis, and record-keeping form a coherent chain capable of preventing failures. detect deviations and demonstrate an appropriate response.

Methodology

A structured narrative review of regulatory documents, standards, guidelines, and literature was conducted. pharmaceutical quality management. The choice stems from the integrative nature of the question, which involves The study did not address normative requirements, risk principles, and heterogeneous organizational practices. classified as a systematic review and did not calculate aggregate effect. The transparency of the rationale, The search, scientific reasoning, and referencing process was guided by the domains of SANRA. (BAETHGE; GOLDBECK-WOOD; MERTENS, 2019).

The search prioritized primary and institutional sources: RDC No. 67/2007 and official materials from Anvisa; ICH Q9(R1) and ICH Q10; general chapters USP <795>, <797> and <800>; ISO 31000; and documents international guidelines on good pharmaceutical practices were excluded. Commercial pages and materials were also excluded. Promotional and non-authored statements, or statements without identifiable source code, were used. The standards were applied within their scopes, without presuming legal equivalence between countries. The survey adopted as a limit Temporary date: December 31, 2025; documents, regulatory changes, or publications subsequent to This date is not included in the summary.

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The synthesis was structured around six axes: governance and responsibility; design and criticality of processes; inputs and suppliers; in-process control and release; deviations and changes; and Indicators with learning. In each axis, three questions were examined: what risk needs to be... to be controlled, what evidence demonstrates the control, and who has the authority to decide. This triad It prevented requirements from being treated merely as lists of documents.

Figure 1 represents a conceptual elaboration based on the principles of ICH Q9(R1) and ICH Q10. It is not a regulatory flowchart, decision algorithm, or validated instrument. The arrows indicate functional relationships between identification, evaluation, control, communication, and review; implementation It requires adaptation to the legal scope, types of preparation, and capabilities of each organization.

1. Governance, accountability and quality culture

Quality governance begins with defining authority. Technical responsibility.

The pharmaceutical company does not eliminate management's responsibility for resources, infrastructure, personnel, and Priorities. When financial goals or deadlines clash with requirements.

In sanitary facilities, there must be an explicit rule for escalation and decision-making. ICH Q10 addresses this. managerial commitment, quality policy, planning and performance review as components of the pharmaceutical quality system (ICH, 2008).

A policy only produces an effect when it translates into observable routines. Roles need to be distinguished. Who executes, who verifies, who approves, and who can interrupt the process. Matrices of Responsibility helps, but it doesn't replace competence or professional judgment.

Segregation of duties should be proportional to the risk and size of the operation, while preserving review. independent in stages where failure could compromise identity, content, sterility, or safety. occupational.

A culture of quality doesn't mean the absence of error, but rather the ability to make problems visible. Before they turn into harm. Punitive environments encourage concealment; tolerance.

Indiscriminate normalization of deviations is necessary. Leadership needs to differentiate between human error, systemic conditions, and... Deliberate conduct, choosing appropriate responses. Reports, near misses, and complaints should To foster learning, without shirking accountability when conscious procedures violate essential requirements.

Management review connects operations and strategy. Data on deviations, rework, complaints, Qualification, training, maintenance, and suppliers should be analyzed together. Meetings Simply confirming numbers does not constitute governance. The purpose is to decide on priorities, to accept

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or reduce risks, allocate resources, and monitor the effectiveness of the measures. The minutes must record this.
Reasoning and accountability, not just the presentation of indicators.
In short, governing quality means making explicit who decides, and based on what evidence.
and within what limits. This clarity reduces improvisation and protects technical autonomy. Also
It prevents compliance from being delegated exclusively to the responsible pharmacist or the department.
quality, when its causes and solutions encompass purchasing, finance, technology, people and
maintenance.

2. Process mapping and criticality classification

The magistral process should be described from the receipt of the prescription to its dispensation and to the end.
Complaint tracking. Process maps reveal interfaces that isolated procedures...
They conceal: transcription, calculation, separation, weighing, mixing, encapsulation, packaging, labeling.
Conference and release. Every transfer of information or material creates an opportunity for loss.
Changes or ambiguities are not allowed. The description should reflect the actual work, including exceptions and returns.
Criticality doesn't depend solely on the frequency of an activity. A rare step can have...
serious consequence; a frequent failure can be detected before reaching the patient. The ICH
Q9(R1) recommends assessing risk based on scientific knowledge and patient protection.
Tools such as FMEA, HACCP, and hazard analysis can support the discussion, provided that scores
Do not substitute justification or create false accuracy.
Sterile preparations, non-sterile preparations, and hazardous drugs require distinct control architectures.
USP <795> addresses non-sterile preparations; USP <797>, sterile preparations; and USP <800>,
Occupational exposure to hazardous medications (USP, 2023a; 2023b; 2023c). The use
The academic understanding of these benchmarks does not automatically make them a legal obligation outside of their...
jurisdiction, but it offers useful language for recognizing risks.
Critical points need to have predefined limits and responses. Temperature, humidity, time of
Mixing, calibration, cleaning, reconciliation, and verification may require monitoring as needed.
The product and the process. A boundary without a reaction plan is incomplete. The team must know when
segregate material, suspend production, repeat testing, investigate, or forward a decision to
technical manager.
The classification should be revised when new inputs, equipment, formulas, or volumes become available.
or performance data. Risk is not a fixed attribute of a spreadsheet. Seemingly simple changes
They can alter exposure, detectability, or complexity. Therefore, the process map
It should function as a living document, connected to change control, training, and...

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periodic evaluation of the system.

3. Inputs, suppliers and traceability

The quality of a preparation begins before handling. Specifications for ingredients must...
To define identity, purity, transport conditions, storage, packaging and documentation.
Certificates of analysis are relevant elements, but they do not eliminate the need to qualify the...
supplier and verify the consistency between the document, the material received, and the performance history. A
Trust needs to be built through accumulated evidence.
Supplier qualification combines initial assessment and monitoring. Documentary compliance,
Technical skills, change management, delivery deviations, packaging integrity, and results.
Analytics can contribute to the profile. The decision to approve, restrict, or disqualify should consider the
The criticality of the input and the available alternatives. Dependence on a single source also represents
There is a risk to continuity and this needs to be acknowledged.
Traceability should allow for reconstructing the history of the batch without relying on the memory of individuals.
Prescription, handling order, supplies, batches, quantities, equipment, responsible parties,
Results, labels, and destination need to remain linked. Digital records can expand this.
readability and searchability are important, but they introduce risks related to access, modification, availability, and migration.
Integrity controls should accompany the information lifecycle.
Reconciliation verifies whether entries, exits, losses, and returns are plausible. Differences may
To signal weighing errors, incomplete records, material mix-ups, spills, or diversions. The objective
It's not about pursuing impossible mathematical equality, but rather about defining justified tolerances and investigating.
Relevant surpluses. Controlled or high-potency substances require criteria compatible with
its legal and health risks.
Traceability also supports external response. When there is a complaint, recall, or alert of...
The supplier, the organization needs to quickly locate affected preparations and recipients.
The longer it takes to rebuild connections, the greater the exposure. Simulated traceability tests.
They allow you to measure completeness and response time, transforming a document requirement into...
demonstrable operational capability.

4. In-process controls, release and evidence

In-process control reduces reliance on final inspection. Independent conferences,
Container identification, standardized sequencing, cleaning, and calculation verification are all factors that come before...

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that the product be released. The choice of control should consider the failure mode and its Detectability. Adding redundant checks without purpose can lead to fatigue and transfer...
Pay attention to critical steps for bureaucratic tasks.
Release is a technical decision based on a body of evidence. Complete records, results within criteria, reconciliation, environmental conditions and absence of deviations not Resolved issues need to be evaluated. A signature shouldn't function as a retroactive formality. Who liberation requires time, competence, independence, and access to the information that supports it. decision.

Equipment and environments must remain suitable for their intended use. Qualification, Calibration, maintenance, and monitoring need to be related to process risk. One Calibrated equipment may be unsuitable for the range used; an environment within the average limit. It can present relevant excursions. Trends and context are more informative than isolated certificates.

Contemporary documentation reduces the need for reconstructions. Records should be kept at the time. of the activity, with traceable and justified corrections. Data integrity includes attribution, Readability, contemporaneity, originality, and accuracy. In electronic systems, access profiles, Audit trails, backups, and usage-proportional validation need to be considered.
The evidence produced needs to be sufficient, not excessive. Too many records can obscure signs. Relevant and consume capacity without reducing risk. Management should review whether each form, An indicator or approval has a clear purpose. Controls that do not detect, prevent, or clarify Decisions should be simplified or replaced, while preserving mandatory requirements.

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Figura 1 — Ciclo de governança da qualidade orientado por risco.
Fonte: elaborado pela autora com base em ICH (2008; 2023).

5. Deviations, investigation, CAPA, and change control.

Deviation is the difference between what is expected and what is observed, not an automatic synonym for damage. The response
The initial goal is to protect the patient, the product, and the evidence: stop when necessary, isolate.
materials, preserve records, and assess scope. Preliminary classifications help prioritize, but
Occurrences should not be minimized before investigation. Criticality may change as new information emerges.
Information emerges.

Investigations need to explain how the conditions allowed the event to occur. Attributing the cause to distraction,
Lack of attention or non-compliance prematurely ends the reasoning process. Questions about
Process design, workload, training, interface, maintenance, environment, and supervision.
They broaden the analysis. Root cause analysis methods are helpful; completed diagrams are not a guarantee.
causal explanation.

Corrective action eliminates or reduces the cause of an event that occurred; preventive action addresses a condition capable of...
To produce a future event, both need to have a responsible party, a deadline, priority, and effectiveness criteria.
Generic training is a weak solution when the problem involves an ambiguous process or
An inadequate tool. Its effectiveness must be verified after sufficient time to observe.
Recurrence and side effects.

Change control anticipates risks before modifying formula, supplier, equipment, system, etc.

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installation or procedure. The change must state the reason, scope, impact assessment, testing,
Training and return-to-work plan. Emergency changes may require an abbreviated procedure, never absence.
registration. Subsequently, the decision needs to be reviewed and incorporated into the authorized status of
operation.

Deviations and changes form a single learning system. Occurrences reveal weaknesses;
Changes introduce new conditions. When records remain in separate databases, they are lost.
The ability to observe patterns. Conjoint analysis allows for the identification of recurrences, effects of
Interventions and areas where variability grows before becoming a critical event.

6 Indicators, management review and continuous improvement

Indicators should answer management questions. Deviation rate, rework, complaints,
Rejected deliveries, expired training, and delayed maintenance can be helpful, but each measure...
It needs definition, denominator, and source. Raw counts confuse volume with performance.
The comparison should consider the mix, complexity, and changes in production.
Outcome measures come too late; process measures help to anticipate them. Complaints
Confirmed cases and recalls are results, while adherence to controls, completion of CAPA and
Supplier performance can signal antecedent conditions. A balanced panel
It combines both. Goals should not encourage underreporting, premature closure, or exclusion of
difficult cases.

Management review should interpret trends, not just colors. Change of definition, loss of
Data and seasonality can alter apparent performance. Warning thresholds need to be reviewed accordingly.
In light of the process and criticality, when there is an adverse signal, the central question is what decision will be made.
The decision and how its effectiveness will be verified.

Continuous improvement does not mean changing everything. Stable and appropriate processes should be...
Preserved; changes must respond to relevant risk, evidence, or opportunity. The cycle of
Improvement includes selection, testing, implementation, monitoring, and standardization. Interventions
Simultaneous actions make it difficult to attribute the effect and may exceed the team's absorption capacity.
The proposed model integrates governance, risk, traceability, and learning. Its usefulness depends
from translation into local responsibilities and evidence. This is not about certification, a scale of
maturity or validated regulatory protocol. Future studies may test relationships between
indicators, recurrence of deviations, and responsiveness, without assuming causality from
observational associations.

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Conclusion

Compounding pharmacies combine personalized therapy with operational responsibility.
high. The diversity of formulas and the variable scale make management based on [specific factors] insufficient.
only in experimentation or final inspection. Quality needs to be incorporated into the design of
A process supported by evidence that allows us to understand what was done, by whom, and with what means.
materials and under what conditions.

Clear governance distributes authority without fragmenting responsibility. Leadership, accountability.
Technical, quality, and support areas need to recognize that financial, technological, and...
People affect health risks. Management review creates the space where priorities are made explicit.
Resources are linked to the most relevant weaknesses.

The risk-based approach offers proportionality. Not every activity requires the same degree of risk.
formality is important, but all simplification needs to be justifiable. Scientific knowledge, protection of
Patient care, uncertainty, and complexity guide the effort. Scores and matrices support the decision, never...
They replace a judgment or legal requirement.

Traceability transforms records into responsiveness. When the history of a preparation
It can be rebuilt quickly; investigations, complaints, and recalls become more...
precise. Digital systems can expand this capability, provided that integrity, access,
Availability and migration are governed.

In-process controls and releases need to act as coherent barriers. Conferences,
Monitoring, qualification, and documentation are valuable when related to failure modes.
identified. The accumulation of pointless checks can unnecessarily increase cognitive load.
To increase security.

Deviations, CAPA, and changes should form a single learning cycle. Fragile investigations.
They blame individuals and preserve the conditions that allowed the event. Robust responses examine
The system verifies its effectiveness and incorporates knowledge into the authorized routine.

Indicators only support governance when they have definition, context, and decisional consequence.
Extensive panels can simulate control. A few well-chosen measures, associated with questions and
Responsibilities tend to produce more useful analysis and reduce perverse incentives.

It is concluded that sustainable health compliance emerges from the integration of leadership, science,
processes and evidence. The model presented offers a teaching and planning framework, not
An empirical validation. Its application requires reading the current regulatory framework, competence.
pharmaceutical and adaptation proportional to the risk of each operation.

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