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Self-assessment model for pharmaceutical companies based on Good Manufacturing Practices for pharmaceuticals in Brazil: A multicriteria approach

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ABSTRACT
This study presents a novel self-assessment model for evaluating organizational compliance capabilities within Brazilian pharmaceutical companies regarding the Resolution RDC 658/2022 requirements, established by the National Health Surveillance Agency (Anvisa), aligned with the World Health Organization's Good Manufacturing Practices (GMP) for pharmaceutical products. The research methodology comprised a systematic literature review and documentary analysis spanning 2010–2023, followed by the development of an analytical framework integrating the Analytic Hierarchy Process (AHP) for weighting the regulatory requirements of the aforementioned Resolution. The model's empirical validation was conducted through implementation at a Brazilian pharmaceutical company, evaluating its organizational compliance capabilities vis-à-vis the RDC 658/2022 requirements. Importance–Performance Analysis (IPA) was subsequently employed to prioritize areas that require enhanced regulatory compliance. The primary contribution of this study is a comprehensive self-assessment framework that provides pharmaceutical companies with robust decision-making support for visa certification processes. Empirical validation demonstrated the model's effectiveness in identifying critical compliance gaps and prioritizing improvement initiatives. This methodological advancement strengthens the interface between health regulatory authorities and pharmaceutical companies, potentially enhancing the effectiveness of Brazil's regulatory system.

Section: RESEARCH PAPER

Keywords: Good Manufacturing Practices; pharmaceutical sector; self-assessment model; multicriteria decision-making methods; RDC 658/2022; Brazil

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1. INTRODUCTION

In the global healthcare landscape, the pharmaceutical industry plays a pivotal role in advancing public health through the development and manufacturing of life-saving medications, in which quality and safety assurance are paramount considerations.

The industry faces rapid transformations driven by regulatory harmonization, quality standard evolution, and business consolidation, affecting manufacturers, suppliers, contractors, and distributors across the supply chain [1]–[4].

The World Health Organization's Good Manufacturing Practices (GMP) for pharmaceutical products, aligned with the Pharmaceutical Inspection Co-operation Scheme (PIC/S), represent a cornerstone in maintaining excellence within the global pharmaceutical sector [5], [6].

GMP constitutes an essential component of quality management systems, ensuring that pharmaceutical products consistently meet the quality standards mandated by marketing authorization. This comprehensive framework guides the production, control, and distribution processes.

Contemporary challenges, including the emergence of complex therapeutic modalities, supply chain globalization, and accelerated drug development imperatives, have heightened GMP's significance [5], [6]. GMP guidelines serve as a foundational paradigm for stakeholders across the pharmaceutical ecosystem, enabling risk mitigation, recall prevention, and public health protection [3].

In Brazil, the National Health Regulatory Agency (Anvisa) codified pharmaceutical GMP requirements through the Resolution of the Collegiate Board (RDC) 658/2022, establishing quality standards for pharmaceutical manufacturing [7]. It is important to note that while WHO GMP are guidelines at the international level, individual countries often transform these guidelines into mandatory standards through their national

regulations. For example, when Brazil adopts GMP principles into its Resolution RDC 658/2022, those requirements become binding standards within that jurisdiction.

The Brazilian pharmaceutical market demonstrates particular significance, maintaining positions between eighth and tenth globally [8]. The trajectory of emerging pharmaceutical markets shows improved rankings, whereas the developed markets experience a relative decline. Projections indicate Brazil's advancement to the sixth position by 2026 [8].

Achieving this projected status, as forecasted by the Research Pharmaceutical Industry Association in Brazil (Interfarma), necessitates exceptional operational excellence and innovation from domestic pharmaceutical enterprises to ensure optimal product quality, safety, and efficacy [8].

Several critical premises emerge in this context: (i) pharmaceutical GMP guidelines fundamentally underpin Brazilian pharmaceutical industry growth prospects; (ii) Anvisa's proposed harmonization with international GMP standards necessitates significant operational adaptations among domestic pharmaceutical manufacturers; (iii) domestic pharmaceutical enterprises must achieve exceptional performance standards to ensure product quality, safety, and efficacy compliance; (iv) PIC/S-aligned regulatory compliance potentially expands export opportunities for Brazilian pharmaceutical companies; and (v) literature analysis spanning 2000–2023 reveals insufficient empirical research regarding tools supporting Brazilian pharmaceutical companies' capacity assessment for RDC 658/2022 compliance.

These considerations frame the central research question: "How can pharmaceutical companies' capacity for RDC 658/2022 compliance be assessed, specifically regarding Anvisa GMP certification requirements?"

Addressing the above question, this study aims to bridge research gaps by creating and applying a conceptual multicriteria model for pharmaceutical firms based on the RDC 658/2022 framework.

This study presents the first integrated multicriteria framework specifically designed for Brazilian pharmaceutical companies' compliance assessment with the RDC 658/2022 requirements. The novelty lies in three key methodological advances: (i) the development of a hierarchical analytical structure that systematically decomposes all nine RDC 658/2022 requirements into 41 constituent items, enabling comprehensive compliance evaluation; (ii) the innovative integration of the Analytic Hierarchy Process (AHP) with Importance–Performance Analysis (IPA), specifically tailored to pharmaceutical quality management contexts; and (iii) the creation of a five-point maturity scale, adapted from established process maturity models, to provide structured progression pathways for compliance enhancement. Unlike previous approaches that rely on binary compliance verification, this model enables the quantitative prioritization of improvement initiatives through decision-making zones, representing a significant advancement over existing methodologies.

The practical significance for the metrology and quality assessment community lies in the establishment of structured measurement protocols for compliance evaluation, offering quantitative assessment methodologies that extend beyond the pharmaceutical sector to regulated industries such as medical devices, food processing, and chemical manufacturing, where systematic compliance evaluation is essential.

The structure of the manuscript encompasses five sections, beginning with the introduction. Section 2 synthesizes relevant literature from 2000 to 2023, examining global pharmaceutical GMP harmonization and adoption, process maturity models, and applicable decision-making methodologies. Section 3 describes the research design and methodology. Section 4 presents an RDC 658/2022-based self-assessment model for Brazilian pharmaceutical companies that incorporates two decision-support methodologies: (i) the Analytic Hierarchy Process (AHP) and (ii) the Importance–Performance Analysis (IPA). Section 5 examines the synergistic benefits of combining these decision-making approaches for enhancing pharmaceutical companies' self-assessment processes in pursuit of the Anvisa certification and concludes with final remarks.

2. LITERATURE REVIEW

A literature review was conducted focusing on the central research subjects, namely: (i) harmonization and adoption of GMP for pharmaceutical products worldwide, (ii) process maturity models, and (iii) decision-making methods applicable to the intended modelling. This review was complemented with a documental analysis of resolutions by Anvisa and regulatory bodies in other countries, to consolidate the theoretical and normative framework of this research [5]–[7], [9]–[13].

In the initial phase of our literature review, we conducted a comprehensive examination of GMP fundamentals in pharmaceutical production [5]–[7], analyzing the core theoretical principles that form the foundation of these regulatory guidelines, their multifaceted implications across pharmaceutical manufacturing domains, and the complex interplay of implementation challenges and opportunities that emerge in practical applications.

GMP guidelines constitute a regulatory and technical framework that ensures that pharmaceuticals are consistently manufactured and controlled according to predetermined quality standards. The primary objective is to manage and minimize the risks inherent in pharmaceutical manufacturing, thereby ensuring the quality, efficacy, and safety of the finished product.

They emerged at the global level through the World Health Organization's (WHO) initiative in 1967, aimed at supporting member states' efforts to enhance the quality of commercialized pharmaceuticals. That year, the document approved at the XXI World Health Assembly, titled "Draft Requirements for Good Manufacturing Practices in the Manufacture and Quality Control of Drugs and Pharmaceutical Specialities", represented the first official text addressing pharmaceutical manufacturing regulations utilizing the term GMP.

Within this framework, WHO recommends the development of international standards and instruments to ensure pharmaceutical quality, whether produced and commercialized nationally or transnationally. Consequently, regulatory bodies across various nations have begun to develop increasingly stringent GMP guidelines, seeking to accommodate pharmaceutical sector innovations, while facilitating the market entry of products with enhanced quality, efficacy, and safety profiles.

To achieve these objectives, pharmaceutical companies must implement GMP protocols in their manufacturing facilities and routinely verify that their operations comply with regulatory requirements established within their respective jurisdictions. It is noteworthy that this research, seeking to provide a self-assessment model to assist Brazilian pharmaceutical companies in complying with the regulatory requirements of Resolution

RDC 658/2022, encompasses all nine requirements, including self-inspection.

The term 'self-inspection' has been consistently present in WHO guidelines since the publication of the WHO Technical Report No. 32 in 1992. The PIC/S Guide, internalized by the Anvisa in Brazil, also employs this terminology.

The self-assessment model proposed in Section 4 comprehensively addresses all nine requirements of Resolution RDC 658/2022, including the requirement of self-inspection.

According to Resolution RDC 658/2022, self-inspection must be conducted to monitor the implementation and compliance with GMP principles and propose necessary corrective measures.

Self-inspection must examine key areas, including personnel, facilities, equipment, documentation, production, quality control, pharmaceutical distribution, complaint management procedures, recalls, and self-inspection processes, at regular intervals, following a pre-established program to verify compliance with Quality Assurance principles. The complete text of this requirement can be found in Resolution 658/2022 [7].

The second literature search covered peer-reviewed scholarly publications indexed in the Scopus bibliographic database of process maturity model frameworks. Seminal works in this domain [14]–[16] provided the theoretical foundation for establishing a maturity assessment scale incorporated into the conceptual framework.

Process maturity models have emerged as frameworks for organizational development and process improvement, representing significant advancements in management theory and practice. The literature demonstrates their evolution from simple quality assessment tools to comprehensive frameworks for organizational transformation. The conceptual foundation of maturity models stems from the understanding that organizations need structured approaches to systematically evaluate and enhance their processes These models have progressed beyond mere assessment tools to become strategic instruments for organizational development [14].

Jochem et al. [15] presented a sophisticated framework specifically designed for knowledge-intensive business processes, emphasizing the importance of systematic measurement and evaluation methodologies in contemporary organizational contexts.

The strategic implementation of maturity models, as Dufry [16] articulated, serves as a blueprint for organizational evolution. This perspective emphasizes the dynamic nature of organizational development and the necessity for structured progression through defined maturity levels. The implementation framework provides organizations with clear pathways for advancement, while maintaining flexibility for adaptation to specific organizational contexts.

De Bruin et al. [16] proposed a framework for developing maturity assessment models through six distinct phases: scope definition, design, population, testing, deployment, and maintenance. The authors emphasized the importance of stakeholder involvement and iterative refinement throughout the development process. The framework provides methodological rigor for creating maturity models that can be applied across different domains while maintaining domain specificity.

The methodological rigor of maturity models has increased significantly by incorporating sophisticated measurement techniques and evaluation criteria. This evolution reflects a deeper understanding of organizational complexity and the need for nuanced approaches to process improvement.

The literature emphasizes the importance of contextual adaptation, and the need for organizations to customize these models to their specific requirements, while maintaining the fundamental principles of systematic assessment and improvement. It also emphasizes the use of structured assessment criteria, measurable outcomes, and clear developmental pathways [14].

This analysis of seminal works on maturity models [15]–[16] reveals their significant contributions to organizational development theory and practice. In this regard, the application of maturity models in Brazilian pharmaceutical companies, when tailored to measure and evaluate their manufacturing processes, quality systems, and compliance levels with the GMP standards and Resolution RDC 658/2022 requirements, enables a systematic progression from basic regulatory compliance to advanced quality management.

This structured approach allows organizations to assess their current state, identify gaps, and plan improvements through well-defined maturity levels. By providing clear developmental pathways and measurable criteria, these models help companies align their quality management efforts with both regulatory requirements and operational excellence goals, while optimizing resource allocation for continuous improvement initiatives.

The third search focused on decision-making methods applicable to model design, concentrating specifically on two frameworks selected a priori by the authors based on their alignment with the intended modeling objectives: the Analytic Hierarchy Process (AHP) method [18] and the Importance–Performance Analysis (IPA) framework [19], [20].

Saaty [18] introduced the Analytic Hierarchy Process (AHP) method as a structured mathematical framework for organizing and analyzing complex decisions. This method enables decision-makers to decompose intricate problems into hierarchical structures and make pairwise comparisons between elements. The author outlined the fundamental scale of absolute numbers for comparing alternatives and demonstrated how to calculate consistency ratios to validate the coherence of judgments. AHP's key innovation lies in its ability to convert subjective assessments into numerical values that can be processed and compared across the entire decision scope.

In turn, Martilla and James [19] developed the Importance–Performance Analysis (IPA) as a marketing research technique to identify key attributes requiring managerial attention. Their framework plots perceived importance against performance ratings on a two-dimensional grid divided into four quadrants: "Keep up the good work", "Concentrate here", "Low priority", and "Possible overkill". This visual representation helps prioritize improvement efforts by identifying attributes that are highly important but underperforming. The authors demonstrated the practical utility of IPA through a case study of an automobile dealer's service department.

Years later, Slack [20] advanced the IPA methodology by refining the importance–performance matrix specifically for the operation strategy. His key contribution was the introduction of a more nuanced zonal approach than the original quadrant model. Slack proposed a boundary line between acceptable and unacceptable performance levels that varies with importance ratings, creating zones of "urgent action", "improve", "appropriate", and "excess". This modification reflects the reality that acceptable performance standards should be higher for more important attributes. This study includes detailed guidelines for determining the importance and performance measures in operational contexts.

Together, these complementary methodological approaches provide pharmaceutical companies with a comprehensive framework for improving performance assessments based on the RDC 658/2022 requirements, which are aligned with the GMP guidelines.

Although AHP offers a rigorous mathematical framework for multicriteria decision analysis, the Importance–Performance Analysis [19] and its subsequent refinement by Slack [20] provide practical tools for prioritizing improvement initiatives, based on the relationship between importance and performance regarding the GMP guidelines. Their enduring influence is evidenced by extensive citations and adaptations across various fields from quality management to strategic planning.

The interest in developing a comprehensive self-assessment framework for pharmaceutical manufacturing certification in Brazil was verified in [21]–[29]. Reviewing these previous works, two significant research gaps were revealed regarding both empirical investigations and methodological frameworks for self-assessment: (i) the absence of empirical investigations or methodological frameworks that could facilitate Brazilian pharmaceutical enterprises in identifying critical compliance factors and optimization opportunities necessary for visa certification under the Resolution RDC 658/2022 requirements, and (ii) limited application of integrated multi-criteria decision-making methodologies combined with the Importance–Performance Analysis (IPA) in pursuit of the aforementioned objectives.

These research gaps present a compelling opportunity to advance our theoretical and practical understanding of the mechanisms through which Brazilian pharmaceutical enterprises can systematically identify critical compliance factors and optimization opportunities essential for obtaining Anvisa certification under the promulgated Resolution RDC 658, enacted on March 30, 2022.

Table 1. Research design.

Phase	Stage	Research questions [Section]
Motivation (Why?)	Problem definition and the rationale for the research.	Why should we develop a self-assessment model for pharmaceutical companies based on the Good Manufacturing Practices (GMP) for pharmaceuticals in Brazil? [Section 1].
Development (What and How?)	State of research on central themes and identification of research gaps and unsolved problems.	What are the significant gaps in empirical investigations and methodological frameworks regarding adoption of the GMP for pharmaceuticals in Brazil, particularly concerning compliance assessment tools and integrated decision-making approaches under Resolution RDC 658/2022? [Section 2].
	Definition of the research methodology.	What methodological framework can effectively assess the organizational compliance capacity of Brazilian pharmaceutical companies pursuing the Anvisa GMP certification in accordance with Resolution RDC 658/2022? [Section 3].
	Development of a self-assessment model for pharmaceutical companies in Brazil based on the RDC 658/2022.	What hierarchical analytical structure best aligns with the requirements established in Resolution RDC 658/2022? How should requirement weights for RDC 658/2022 be determined within the context of pharmaceutical companies seeking an Anvisa certification? [Section 4] What structural framework and measurement scale should be incorporated into a self-assessment instrument for evaluating organizational compliance capacity with the RDC 658/2022 requirements? [Section 4] To what extent can the Importance–Performance Analysis (IPA) method assist Brazilian pharmaceutical companies in identifying and prioritizing critical requirements for an Anvisa certification? [Section 4]
Analysis of managerial implications (What do the results mean regarding actions?)	Discussion of the results and implications of this research.	What distinctive features characterize this self-assessment framework in comparison to existing methodologies for pharmaceutical GMP compliance assessment across global contexts? [Section 5] What are the practical and managerial implications derived from the implementation of this methodological framework? [Section 5]

3. RESEARCH DESIGN AND METHODOLOGY

Table 1 presents a methodological framework adapted from Correia et al. [30], comprising three sequential phases and five distinct stages, establishing a systematic procedural structure that guides the investigative trajectory of this research: (i) motivation, which establishes the research imperative; (ii) development, which encompasses the constructive elements; and (iii) validation, which provides empirical verification of the proposed framework.

In the first phase, stage one addresses the problem definition and rationale for the research (Section 1).

The subsequent stage involves a comprehensive synthesis of the extant literature on the core research themes, aimed at identifying lacunae in scholarly knowledge and unresolved theoretical constructs within the specified domain (Section 2).

The third stage focuses on methodological framework selection, whereas the fourth stage focuses on the development of a systematic self-assessment paradigm for Brazilian pharmaceutical enterprises, predicated on RDC 658/2022 [7].

The research methodology incorporated a structured modelling process to develop a self-assessment framework. The identified research gaps informed the selection of Analytic Hierarchy Process (AHP) and IPA methodologies, considering the contextual parameters and regulatory characteristics of RDC 658/2022, supported by a preliminary analysis of decision-making frameworks [31].

Additionally, the formal modelling process encompasses the development of a maturity assessment scale to evaluate organizational capabilities regarding regulatory requirement fulfilment.

The AHP implementation comprises three distinct phases: (i) evaluation objective formulation and hierarchical structure development aligned with the RDC 658/2022 requirements, (ii) systematic value judgment assessment regarding regulatory requirement significance through pairwise comparisons at dual hierarchical levels, and (iii) algebraic computation to derive requirements and item weightings. A comprehensive explanation of the AHP methodology is available in [18].

The selection of AHP was based on its capacity to decompose complex evaluation paradigms into analytical hierarchies, facilitating a systematic comparison of the RDC 658/2022 requirements. Furthermore, the methodology enables internal judgment consistency analysis during weight assignment through the consistency ratio (C.R.) evaluation of pairwise comparison matrices, allowing expert judgment refinement when inconsistencies emerge.

In addition to AHP implementation, the methodology incorporates a five-point maturity scale derived from widely adopted process maturity models identified in [14]–[16].

Within individual pharmaceutical companies, assessment data acquisition from organizational leadership and subject matter experts facilitates a comprehensive evaluation of their regulatory requirement–fulfilment capabilities.

The methodological framework included the development of an assessment instrument structured according to the RDC 658/2022 parameters, incorporating the aforementioned five-point maturity scale. Expert validation was conducted through instrument pre-testing by professionals with extensive experience in compliance assessment, health surveillance, and pharmaceutical quality systems.

The final modelling phase employed the IPA methodology [19]–[20], which has been extensively utilized to improve opportunity identification within organizational systems. This approach facilitates priority action identification through the concurrent analysis of factor significance and performance metrics. IPA integration enables pharmaceutical enterprises to develop action plans systematically, to enhance regulatory compliance capabilities under Resolution RDC 658/2022 [7].

Table 2. Elements of the self-assessment model based on the structure of the RDC 658/2022 [7].

Requirements	Items
R1 – Pharmaceutical quality system	R11 – Good Manufacturing Practices (GMP) for pharmaceuticals
	R12 – Quality control
	R13 – Product quality review
	R14 – Quality risk management
R2 – Personnel	R21 – Key personnel
	R22 – Training
	R23 – Personal hygiene
	R24 – Consultants
R3 – Facilities and equipment	R31 – Facilities
	R32 – Production areas
	R33 – Storage area
	R34 – Quality control areas
	R35 – Auxiliary areas
	R36 – Equipment
R4 – Documentation	R41 – Generation and control of documentation
	R42 – Good documentation practices
	R43 – Documentation retention
	R44 – Specifications
	R45 – Manufacturing formula and process instructions
	R46 – Procedures and records
R5 – Production	R51 – Prevention of cross-contamination in production
	R52 – Validation
	R53 – Raw materials
	R54 – Manufacturing operations for intermediates and bulk products
	R55 – Packaging materials
	R56 – Packaging operations
	R57 – Finished products
	R58 – Rejected, recovered, and returned materials
	R59 – Shortage of products due to manufacturing restrictions
R6 – Quality control	R61 – Good manufacturing practices and quality control
	R62 – Ongoing stability program
	R63 – Technical transfer of analytical methods
R7 – Outsourced activities	R71 – Contracting party
	R72 – Contracted party
	R73 – Contract
R8 – Complaints and product recall	R81 – Personnel and organization
	R82 – Procedures for handling complaint investigations, including possible quality deviations
	R83 – Investigation and decision-making
	R84 – Root cause analysis and corrective and preventive actions
	R85 – Product recall and other risk reduction actions
R9 – Self-inspection	R91 – Self-inspection

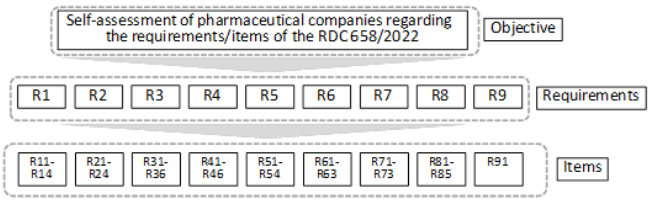
4. SELF-ASSESSMENT MODEL FOR BRAZILIAN PHARMACEUTICAL FIRMS BASED ON THE RDC 658/2022 REQUIREMENTS

This section presents the five-stage self-assessment model, developed according to the methodology described in Section 3. The stages are detailed in subsections 4.1 through 4.5.

4.1. Stage 1: Development of an analytical hierarchical structure based on Resolution RDC 658/2022 requirements

This first stage refers to identifying the constituent elements of the self-assessment model for pharmaceutical companies based on the structure of Resolution RDC 658/2022 (Table 2).

Figure 1 presents the hierarchical analytical structure for assessing pharmaceutical manufacturers' operational capabilities vis-à-vis their adherence to the regulatory requirements under Resolution RDC 658/2022 [7].



Subtitles: R1 – Pharmaceutical quality system; R2 – Personnel; R3 – Facilities and equipment; R4 – Documentation; R5 – Production; R6 – Quality control; R7 – Outsourced activities; R8 – Complaints and product recall; R9 – Self-inspection

Figure 1. Analytical hierarchical structure for assessing pharmaceutical manufacturers' organizational compliance capabilities.

This structural representation delineates the multi-tiered assessment criteria employed in determining organizational compliance capacities.

4.2. Stage 2: Assignment weights of the elements of the self-assessment model through the Analytic Hierarchy Process (AHP)

The second stage encompasses expert evaluations conducted by qualified professionals possessing formal credentials or substantive experience in compliance assessment protocols, health surveillance mechanisms, or pharmaceutical quality systems. The comparative analysis employs Saaty's scale to quantify the relative significance of the RDC 658/2022 requirements and their constituent subordinate elements (Table 3).

The assessment protocol requires the development of ten discrete evaluation instruments for expert completion, structured as follows: the primary instrument addresses the nine foundational requirements, while the subsequent instruments systematically evaluate the subordinate elements within each major requirement domain: Pharmaceutical Quality System (R1), Personnel (R2), Facilities and Equipment (R3), Documentation (R4), Production (R5), Quality Control (R6), Outsourced Activities (R7), and Complaints and Product Recall (R8). It warrants notation that the Self-Inspection requirement (R9) comprises a singular element, thus precluding the necessity for paired comparative analysis within the Analytic Hierarchy Process (AHP) framework.

The comparative assessment of requirements and their constituent elements within Resolution RDC 658/2022 employs Saaty's nine-point scale as the foundational measurement instrument (Table 3), facilitating the systematic quantification of relative significance through pairwise analytical protocols.

The distribution of elements across the nine regulatory requirements specified in Resolution RDC 658/2022 exhibits significant heterogeneity, with individual requirements encompassing varying quantities of constituent items. This distribution ranges from minimal complexity (three items in R6 and R7) to moderate (four items in R1 and R2; six items in R3 and R4) and substantial complexity (nine items in R5).

This structural asymmetry necessitates an initial normalization protocol, utilizing the IPÊ® analytical framework [32] for each requirement classification. The normalization procedure ensures that the aggregated weights of constituent items within any given requirement converge to unity (1.0). This methodological approach facilitates the identification of critical elements within each requirement domain, as determined through expert evaluation protocols.

For requirements characterized by limited constituent elements (R6, R7, and R9), the primary normalization procedure provides sufficient discriminatory power to elucidate relative importance hierarchies. However, in cases of requirements with numerous constituent elements (exemplified by R5), the distributed nature of importance metrics introduces potential analytical challenges regarding discriminatory capacity. A proposed methodological solution involves the comparative analysis of normalized importance coefficients against theoretical equidistribution values (calculated as the reciprocal of the total number of items per requirement), designated as the equimportant value.

The calculation of relative importance metrics, achieved through the quotient of normalized values and equimportant values, yields quantitative indicators of item significance. Values exceeding unity indicate enhanced relative importance within the requirement framework, while values below unity suggest diminished relative significance. In theoretical boundary conditions, items with null normalized importance retain null relative importance, while dominant items with unity-normalized importance achieve relative importance equal to the total number of constituent items (N). Consequently, while the theoretical range of relative importance extends from 0.0 to N, empirical observations suggest typical clustering within the interval of 0.5 to 2.5.

4.3. Stage 3: Development of a maturity scale and an assessment instrument

This stage encompasses two distinct steps. The initial step entails establishing a standardized scale for pharmaceutical companies to evaluate their compliance with the Resolution RDC 658/2022 requirements and constituent items, as detailed in Section 3. A five-point maturity scale was developed to assess each of the nine requirements and 41 items within the Resolution.

The subsequent step involves the development of an assessment instrument aligned with the analytical hierarchical structure schematically represented in Figure 1.

The preliminary version of this instrument underwent validation through pre-testing with three domain experts: a senior organizational management consultant with over ten years of experience in the pharmaceutical sector; an Anvisa professional with more than eight years of expertise in pharmaceutical compliance evaluation; and a professor from PUC-Rio's Graduate Program in Metrology. Their recommendations were subsequently incorporated into the finalized instrument.

Table 4 presents the five-level assessment scale integrated into the self-assessment instrument for evaluating pharmaceutical companies' compliance with the RDC 658/2022 requirements.

Table 3. Saaty's nine-point scale [18].

Scale	Linguistic scale
1	Equally important
2	Equally to moderately more important
3	Moderately more important
4	Moderately to strongly important
5	Strongly important
6	Strongly to very strongly more important
7	Very strongly more important
8	Very strongly more important to absolutely important
9	Absolutely important

Table 4. Maturity scale integrated into the self-assessment instrument.

Maturity level	Scale	Description
Nothing, informal, or *ad hoc*	1	Organizational compliance capabilities regarding the RDC 658/2022 requirements are either undefined or implemented through informal, reactive, or ad hoc processes.
Managed at the basic level	2	Organizational compliance capabilities regarding the RDC 658/2022 requirements are established at a fundamental level, with basic management processes in place.
Defined and managed	3	Organizational compliance capabilities regarding the RDC 658/2022 requirements are proactively established but require systematic and continuous improvement protocols.
Systematically managed	4	Organizational compliance capabilities regarding the RDC 658/2022 requirements are systematically established and subject to continuous improvement processes, though not yet optimized.
Optimized	5	Organizational compliance capabilities regarding the RDC 658/2022 requirements are systematically established, continuously improved, and optimized through active monitoring, feedback mechanisms, and organizational learning processes.

4.4. Stage 4: Evaluation of organizational compliance capabilities vis-à-vis Resolution RDC 658/2022 requirements

The implementation of the self-assessment instrument with designated manager(s) responsible for internal compliance evaluation regarding Resolution 658/2022 requirements can be conducted either through consensus meetings or individual assessments [18]. In cases where individual assessments are selected, the application of fuzzy logic is recommended for aggregating collective outcomes [33].

The implementation protocol encompasses three sequential steps: (i) introduction of the self-assessment instrument to managers responsible for internal compliance evaluation; (ii) individual completion of assessment protocols followed by evaluator consensus meetings; and (iii) systematic organization of consensus data for subsequent analysis utilizing the Importance–Performance Analysis (IPA) methodology, which is to be executed in the fifth stage of model implementation.

The integrated self-assessment instrument comprises nine distinct sections, corresponding to Resolution RDC 658/2022 requirements. The evaluation of organizational compliance capacity for each requirement is predicated upon the assessment of its constituent items, aligned with the analytical hierarchical structure illustrated in Figure 1. For visual representation of self-assessment outcomes, the construction of requirement-specific radar charts is recommended, following the methodology proposed in [34].

4.5. Stage 5: Analysis and prioritization of compliance initiatives using the Importance–Performance Analysis (IPA)

The final stage of the proposed model encompasses the analysis of stage 4 outcomes and the development of a comprehensive self-assessment report regarding organizational compliance with Resolution RDC 658/2022 requirements. This stage aims to delineate decision-making zones that facilitate the establishment of strategic action plans for enhancing compliance capabilities, as illustrated in Figure 2.

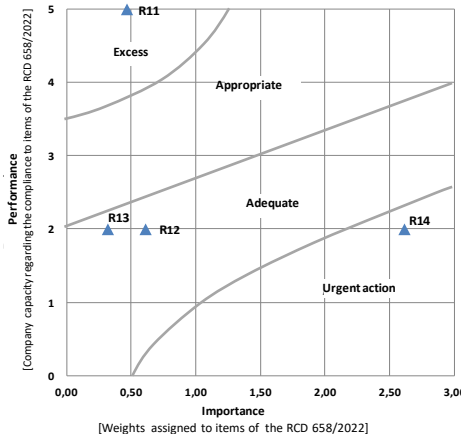


Figure 2. An illustrative example of an IPA matrix for the 'Pharmaceutical quality system' items.

Through the application of the Importance–Performance Analysis (IPA) [19], [20], a two-dimensional analytical space is generated for each of the nine Resolution requirements.

The horizontal axis represents the attributed importance of each requirement/item, while the vertical axis indicates organizational compliance capacity for subordinate items within each requirement. The importance scales are defined by the intervals between the maximum and minimum values of the final weights, calculated for items within each Resolution RDC 658/2022 requirement (derived from stage 2 of the model). The resulting IPA matrices enable pharmaceutical quality management system stakeholders to identify four distinct strategic zones for maturity enhancement initiatives.

As depicted in Figure 2, these decision-making zones comprise the following: (i) 'Excess zone', characterized by low importance and high performance metrics, necessitating the evaluation of resource allocation efficiency; (ii) 'Adequate zone', exhibiting balanced importance–performance relationships in short and medium terms, though requiring attention for long-term sustainability; (iii) 'Improvement zone', containing elements of intermediate importance and performance metrics; and (iv) 'Urgent action zone', encompassing high-importance, low-performance elements requiring immediate organizational intervention.

The culmination of this stage involves the development of a comprehensive assessment report integrating all organizational evaluation outcomes and incorporating targeted action plans designed to enhance the pharmaceutical company's compliance capabilities vis-à-vis the Resolution RDC 658/2022 requirements.

5. DISCUSSION

This study advances the field of pharmaceutical GMP compliance assessment through a novel integrated methodological framework that addresses critical gaps in existing literature. The following discussion examines these methodological advances, acknowledges limitations, and explores managerial implications at multiple organizational levels.

The proposed model demonstrates significant advancement over existing approaches in four key dimensions. First, regarding assessment methodology, the examination of the literature from 2000 to 2023, particularly works by Geyer [21] and Vogler et al. [24], reveals that prior approaches primarily emphasized

compliance verification through conventional checklist-based methods. In contrast, our model integrates a systematic maturity assessment approach with multicriteria decision-making methods, enabling both the evaluation and the strategic prioritization of improvement initiatives.

Second, concerning the analytical framework, while a previous work by Nwokike et al. [22] treated the GMP guidelines with equal weightage, the proposed model employs the AHP method to establish relative importance among the different requirements and their constituent items. The model's analytical hierarchy structure, derived from the Resolution RDC 658/2022 requirements, offers a more comprehensive evaluation framework than earlier studies, such as Ravinetto et al. [25] and Linna et al. [29], which emphasized implementation challenges without providing structured assessment frameworks.

Third, the integration of process maturity models represents a significant advancement over existing literature. While Jochem et al. [15] and Dufry [16] developed maturity frameworks for general business processes, the proposed model specifically adapts these concepts to pharmaceutical quality management, providing a structured progression path from basic compliance to optimized performance.

Fourth, the incorporation of the IPA method distinguishes this model from previous approaches documented by Scott and Wilcock [25] and Yu et al. [26]. This feature enables the visualization of performance gaps through decision-making zones, allowing pharmaceutical companies to optimize resource allocation—a capability notably absent from earlier studies.

Despite its contributions, the study acknowledges several important limitations that warrant consideration. The model's effectiveness depends significantly on expert judgment quality during the AHP weighting process, a challenge also noted by Carmo et al. [2] in their work on pharmaceutical quality systems. While consistency ratio analysis helps mitigate subjective bias, inherent variability in expert opinions could influence the final weights assigned to different requirements.

The single-company application, while providing valuable insights, limits generalizability across different pharmaceutical market segments and organizational contexts. Future validation studies should encompass multiple companies across various scales (small, medium, large enterprises) and therapeutic areas (generic, innovative, biological products) to establish broader applicability.

Implementation challenges include resource requirements for comprehensive assessment, potential resistance to organizational change, and the need for trained personnel to conduct evaluations. The five-point maturity scale, though comprehensive, may not capture nuanced variations in compliance levels existing between the defined maturity stages. Future research should explore more granular assessment scales or adaptive scaling based on organizational context.

Scalability considerations reveal that while the framework applies effectively to individual companies, industry-wide implementation would require the standardization of the expert evaluation protocols and the development of automated assessment tools. Machine learning techniques could potentially enhance consistency in weight assignment and reduce subjectivity in future model iterations.

The model's generalizability across different pharmaceutical market segments and regulatory contexts also requires further validation.

The implications of this research extend across multiple organizational levels, advancing beyond those identified in previous studies by Haleem et al. [3] and Woodcock [4].

At the operational level, the model provides managers with a structured framework to: (i) systematically evaluate their organization's GMP compliance status; (ii) identify specific areas requiring improvement through quantitative assessment; (iii) develop targeted action plans based on the IPA matrix analysis; (iv) optimize resource allocation for compliance initiatives; and (v) monitor progress through periodic self-assessments.

At the strategic level, the model addresses the gaps identified by Ravinetto et al. [28] regarding decision-making in quality system investments. For the Brazilian pharmaceutical industry specifically, this model offers a standardized approach to prepare for Anvisa certification, potentially reducing certification-related costs and timelines—a benefit not addressed in previous studies.

At the industry level, the framework provides a standardized methodology for benchmarking and comparative analysis across organizations. This enables industry associations to identify common challenges and share best practices more effectively.

At the regulatory level, the model offers potential benefits for oversight bodies. It provides a framework that could be adapted to evaluate industry-wide compliance trends and identify systematic challenges in GMP implementation, addressing the need for systematic assessment tools highlighted by early works in the field.

This discussion demonstrates that the proposed model not only builds upon previous research but also addresses significant gaps in the literature regarding the systematic assessment and improvement of GMP compliance in pharmaceutical companies. The integration of multiple methodological approaches provides a more robust and practical framework than those previously available, while acknowledging limitations that could guide future research efforts.

6. CONCLUSIONS

This research successfully addressed the challenge of developing a comprehensive self-assessment model for Brazilian pharmaceutical companies to evaluate their compliance with the Resolution RDC 658/2022 requirements.

The study's outcomes effectively responded to the primary research objective through the development of a structured methodological framework that integrates multicriteria decision-making methods with maturity-based evaluation protocols.

The study addressed two significant research gaps identified during literature review. First, it resolved the absence of empirical studies and methodological approaches for Brazilian pharmaceutical companies by developing a comprehensive analytical framework based on the Resolution RDC 658/2022 requirements. Second, it advanced the field through the novel integration of the AHP and IPA methods, providing a systematic methodological approach for prioritizing compliance improvement initiatives not found in existing pharmaceutical compliance literature.

The model's five-stage framework offers a systematic approach to compliance assessment, encompassing: (i) hierarchical element definition; (ii) expert evaluation protocols; (iii) maturity scale development; (iv) capability assessment; and (v) result analysis.

This structured methodological approach enables Brazilian pharmaceutical companies to: (i) systematically evaluate their current compliance status regarding each Resolution RDC

658/2022 requirement; (ii) identify and prioritize areas that need improvement; (iii) optimize resource allocation for compliance initiatives; (iv) monitor progress through quantifiable metrics; and (v) develop targeted action plans based on objective data.

The integration of the AHP methodology for weight assignment and the IPA analysis for gap identification provides pharmaceutical companies with robust decision-making tools. Furthermore, the model's maturity scale, derived from established process maturity frameworks, offers a clear progression path for enhancing compliance capabilities.

Looking forward, several promising directions for future research emerge from this study:

(i) Refinement of maturity scales to capture intermediate progression levels;
(ii) Integration of machine learning techniques for compliance data analysis;
(iii) Development of automated assessment tools;
(iv) Integration with broader quality management systems;
(v) Application across varied pharmaceutical company profiles;
(vi) Comparative analysis of assessment outcomes;
(vii) Longitudinal studies tracking compliance improvement over time;
(viii) Development of industry-specific benchmarking capabilities;
(ix) Development of standardized approaches for regulatory bodies.

These research directions could significantly advance pharmaceutical quality management and regulatory compliance assessment methodologies, while supporting regulatory decision-making processes and industry-wide quality improvement initiatives.

In conclusion, this self-assessment model represents a significant contribution to both academic literature and practical applications in pharmaceutical quality management. Its structured approach and the integration of established methodologies provide a foundation for future research, while offering immediate practical value to pharmaceutical companies seeking to enhance their GMP compliance capabilities.

AUTHORS' CONTRIBUTION

Conceptualization: A. S. N, M. F. L. A; methodology: A. S. N, M. F. L. A, D. R. L; writing—original draft preparation: A. S. N, D. R. L; writing—review and editing: M. F. L. A. All authors have read and agreed to the published version of the manuscript.

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REFERENCES

[1] G. P. Bunn, Good Manufacturing Practices for Pharmaceuticals, 7th ed. Boca Raton, FL, USA: CRC Press, 2019. ISBN: 978-0367023454.

[2] A. C. M. Carmo, M. S. S. Cunha-Filho, G. M. Gelfuso, T. Gratieri, Quality management systems in drug testing laboratories, Accreditation Qual. Assur. vol. 22 (2017) no. 4, pp. 199–205. DOI: 10.1007/s00769-017-1270-z

[3] R. M. Haleem, M. Y. Salem, F. A. Fatahallah, L. E. Abdelfattah, Quality in the pharmaceutical industry - A literature review, Saudi Pharm. J. vol. 23 (2015) no. 5, pp. 463–469. DOI: 10.1016/j.jsps.2013.11.004

[4] Woodcock, The concept of pharmaceutical quality, Am. Pharm. Rev. vol. 7 (2004) no. 6, pp. 10–15. Online. https://www.americanpharmaceuticalreview.com/

[5] World Health Organization, Good manufacturing practices for pharmaceutical products: main principles, WHO Technical Report Series, Annex 2, Geneva, Switzerland, 2014. ISBN: 978-9241209861.

[6] Pharmaceutical Inspection Co-operation Scheme, Guide to good manufacturing practice for medicinal products, PE 009-14, Geneva, Switzerland, 2018. Document ID: PE 009-14.

[7] Agência Nacional de Vigilância Sanitária, Resolução nº 658 de 30 de março de 2022, Diário Oficial da União, Brasília, Brazil, Mar. 30, 2022. Document ID: RDC 658/2022.

[8] Interfarma, Guia Interfarma 2022. Online. https://www.interfarma.org.br/guia/

[9] European Medicines Agency, Good Manufacturing Practice, EMEA/INS/GMP/23022/2007, London, UK, 2007. Document ID: EMA/572454/2014 Rev 17.

[10] Pharmaceutical Inspection Co-operation Scheme, A recommended model for risk-based inspection planning in the GMP environment. Online. Document ID: PI 037-1. http://www.picscheme.org

[11] Pharmaceutical Inspection Co-operation Scheme, Guide to good manufacturing practice for medicinal products, PE 009-14 Part I, Geneva, Switzerland, 2018. Document ID: PE 009-14 (Part I).

[12] Pan American Health Organization, Resolution CD50.R9. Online. Document ID: CD50.R9. http://new.paho.org/hq/dmdocuments/2010/CD50.R9-e.pdf.

[13] International Conference on Harmonisation, Quality Guidelines. Online. https://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

[14] R. Wendler, The maturity of maturity model research: A systematic mapping study, Inf. Softw. Technol. vol. 54 (2012) no. 12, pp. 1317–1339. DOI: 10.1016/j.infsof.2012.07.007

[15] R. Jochem, D. Geers, P. Heinze, Maturity measurement of knowledge-intensive business processes, TQM J. vol. 23 (2011) no. 4, pp. 377–387. DOI 10.1108/17542731111139464

[16] J. Duffy, Maturity models: Blueprints for e-Volution, Strategy Leadersh. vol. 29 (2011) no. 6, pp. 19–24. DOI: 10.1108/EUM0000000006530

[17] T. de Bruin, R. Freeze, U. Kulkarni, M. Rosemann, Understanding the main phases of developing a maturity assessment model, in Proc. 16th Australasian Conf. Inf. Syst., Sydney, Australia, 2005, p. 109. Online [Accessed 31 July 2026] https://aisel.aisnet.org/acis2005/109/

[18] T. L. Saaty, Decision making with the analytic hierarchy process, Int. J. Services Sciences vol. 1 (2008) no. 1, pp. 83–98. DOI: 10.1504/IJSSCI.2008.017590

[19] J. A. Martilla, J. C. James, Importance–performance analysis, J. Marketing vol. 41 (1977) no. 1, pp. 77–79. DOI: 10.1177/002224297704100112

[20] N. Slack, The importance-performance matrix as a determinant of improvement priority, Int. J. Oper. Prod. Manag. vol. 14 (1994) no. 5, pp. 59–75. DOI: 10.1108/01443579410056803

[21] A. R. C. Geyer, Boas Práticas de Fabricação de Medicamentos no Brasil: estabelecimento, situação atual e desafios, Ph.D. dissertation, Fac. Health Sciences, Univ. Brasília, Brasília, Brazil, 2019. Handle: 10482/35533.

[22] J. Nwokike, A. Clark, P. P. Nguyen, Medicines quality assurance to fight antimicrobial resistance, Bull. World Health Organ. vol. 96 (2018) no. 2, pp. 135–137. DOI: 10.2471/BLT.17.199562

[23] M. Vogler, Boas Práticas de Fabricação de Medicamentos: uma análise sobre suas determinantes e o cenário brasileiro de cumprimento de seus requisitos, Ph.D. dissertation, Health Sciences, Univ. Brasília, Brasília, Brazil, 2018. Handle: 10482/34977.

[24] M. Vogler, T. Gratieri, G. Gelfuso, M. S. Cunha Filho, Boas práticas de fabricação de medicamentos em Brasil: cenário atual, Vig. Sanit. Debate vol. 5 (2017) no. 2, pp. 34–43. DOI: 10.22239/2317-269X.00918

[25] R. Ravinetto, W. Pinxten, L. Rägo, Quality of medicines in resource-limited settings: need for ethical guidance?, Glob Bioeth. 2018 Sep 18; 29(1), pp. 81–94. DOI: 10.1080/11287462.2018.1522991

[26] B. Scott, A. Wilcock, Process analytical technology in the pharmaceutical industry: A toolkit for continuous improvement. PDA J. Pharm Sci Technol., vol. 60 (2006), pp. 17-53. Online [Accessed 31 July 2026] https://pubmed.ncbi.nlm.nih.gov/17089677/

[27] L. Yu, G. Amidon, M. Khan, S. Hoag, J. Polli, G. Raju, J. Woodcock, Understanding pharmaceutical quality by design, AAPS J. vol. 16 (2014) no. 4, pp. 771–783. DOI: 10.1208/s12248-014-9598-3

[28] R. M. Ravinetto, M. Boelaert, J. Jacobs, C. Pouget, C. Luyckx, Poor-quality medical products: Time to address substandards, not only counterfeits, Trop. Med. Int. Health vol. 17 (2012) no. 11, pp. 1412–1416. DOI: 10.1111/j.1365-3156.2012.03076.x

[29] A. Linna, M. Korhonen, J. Mannermaa, M. Airaksinen, A. M. Juppo, Developing a tool for the preparation of GMP audit of pharmaceutical contract manufacturer, Eur. J. Pharm. Biopharm. vol. 69 (2008), pp. 786–792. DOI: 10.1016/j.ejpb.2007.12.002

[30] E. Correia, R. Calili, J. F. Pessanha, M. F. Almeida, Definition of regulatory targets for electricity non-technical losses: proposition of an automatic model-selection technique for panel data regressions, Energies vol. 16 (2023) no. 6, pp. 2519. DOI: 10.3390/en16062519

[31] D. Verma, Study and analysis of various decision making models in an organization, IOSR J. Business Manag. vol. 16 (2014) no. 2, pp. 171–175, 2014.

[32] H. G. Costa, IPÊ Version 1.0, 2006.

[33] L. A. Zadeh, Fuzzy sets, Inf. Control vol. 8 (1965) no. 3, pp. 338–353. DOI: 10.1016/S0019-9958(65)90241-X

[34] H. Mosley, A. Mayer, Benchmarking national labour market performance: a radar chart approach, Wissenschaftszentrum Berlin für Sozialforschung, Discussion Paper, March 1999, ISSN 1011-9523.