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Design and Validation of a Safety Risk Assessment Checklist for Food and Drug Quality Control Labs

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ABSTRACT

***Background**: Food and drug quality control laboratories operate with complex chemical, biological, and procedural hazards that necessitate structured safety monitoring, yet validated tools tailored to these environments remain limited. A standardized risk assessment checklist can strengthen hazard identification, enhance regulatory compliance, and support safer laboratory operations. **Objective**: To design and validate a comprehensive safety risk assessment checklist specifically for food and drug quality control laboratories and evaluate its content validity, reliability, and underlying domain structure. **Methods**: A methodological cross-sectional study was conducted using expert-driven item generation, a two-round Delphi process, and psychometric evaluation across 96 checklist applications. Content validity indices (I-CVI, S-CVI/Ave) were calculated, followed by reliability testing using Cronbach's alpha, inter-rater reliability, and test–retest stability. Exploratory factor analysis assessed construct validity and domain structure. **Results**: The expert panel achieved strong consensus, yielding a final 44-item checklist with an S-CVI/Ave of 0.94. Internal consistency was high across all domains (Cronbach's alpha 0.87–0.91), with overall alpha of 0.92. Inter-rater reliability was substantial ($\kappa = 0.83$), and test–retest reliability demonstrated excellent stability (ICC = 0.89). Five domains emerged, explaining 89% of total variance. **Conclusion**: The validated checklist demonstrates strong psychometric performance and offers a reliable, domain-specific tool for improving safety assessment in food and drug quality control laboratories.*

***Keywords**: Laboratory Safety; Risk Assessment; Checklist Development; Psychometric Validation; Food and Drug Quality Control; Occupational Health*

INTRODUCTION

Quality control laboratories within the food and drug sectors play a critical role in safeguarding public health, yet they operate in environments characterized by multiple chemical, biological, physical, and ergonomic hazards that place laboratory personnel at considerable risk. Despite the availability of international laboratory safety standards, including ISO/IEC guidelines and Good Laboratory Practice (GLP) frameworks, safety compliance remains inconsistent, particularly in resource-limited settings where gaps in hazard identification, risk evaluation, and preventive controls frequently persist (1). The complexity of analytical processes, involvement of hazardous reagents, and increased automation introduce additional layers of risk that require systematic and continuous assessment. Previous studies have highlighted that laboratory accidents are often attributable to human error, inadequate training, poor infrastructure, or the absence of structured safety monitoring tools (2). Although risk assessment checklists have proven effective in improving safety culture and reducing incidents across various scientific domains, there is limited evidence regarding tools specifically tailored to the unique operational and regulatory requirements of food and drug quality control laboratories (3). This gap is significant, as these laboratories are responsible for evaluating product safety, purity, and compliance, meaning that compromised safety practices may not only endanger personnel but also affect analytical accuracy, regulatory adherence, and overall product integrity (4).

A growing body of literature emphasizes the importance of standardized risk assessment tools to guide safety audits, enhance hazard awareness, and support implementation of preventive measures. However, existing checklists often lack validation, are not context-specific, or fail to incorporate emerging risks such as nanomaterial exposure, high-throughput automation, and digitized laboratory systems (5). The absence of a validated, domain-specific risk assessment checklist limits the capacity of laboratories to identify high-priority hazards, quantify risk levels, and monitor safety improvements over time. Applying a PICO-oriented conceptualization, the population includes personnel working in food and drug quality control laboratories; the intervention is the use of a newly developed, validated risk assessment checklist; the comparator involves current or non-standardized safety practices; and the outcome reflects improved hazard detection, enhanced compliance, and reduced risk scores. Developing such a checklist is crucial for strengthening laboratory safety systems, supporting regulatory inspections, and promoting a proactive rather than reactive approach to risk management.

Accordingly, this study aims to design and validate a comprehensive safety risk assessment checklist tailored to the operational realities of food and drug quality control laboratories. The primary research objective is to

determine whether a systematically developed and expert-validated checklist can accurately identify laboratory hazards and provide a reliable tool for routine safety evaluation.

MATERIAL AND METHODS

The study employed a methodological, cross-sectional design to develop and validate a safety risk assessment checklist specific to food and drug quality control laboratories, a design appropriate for instrument development and psychometric evaluation (6). The study was conducted across multiple food and drug quality control laboratories operating under national regulatory oversight, where safety practices, infrastructure, and workflows reflect typical analytical environments. Laboratory personnel with at least one year of experience were eligible to participate in the expert review and validation phases. Individuals not directly involved in laboratory activities or lacking familiarity with laboratory safety protocols were excluded to ensure content validity. Participants were recruited through formal invitations sent to laboratory managers, and informed consent was obtained from all respondents in accordance with institutional ethical guidelines.

Checklist development followed a multi-stage process incorporating literature review, hazard mapping, and item generation. Initial checklist items were derived from international laboratory safety standards, national regulatory requirements, and documented laboratory incident reports. A structured Delphi technique was used to refine item content, where expert reviewers independently rated each item for relevance, clarity, and essentiality using a 4-point scale. Content validity indices (I-CVI and S-CVI) were calculated to quantify expert agreement, with items scoring below 0.78 undergoing revision or removal based on established instrument development criteria (7). The revised checklist was subsequently piloted across participating laboratories. Trained observers used the tool to evaluate real-time laboratory practices, equipment use, chemical handling, documentation, and environmental controls. Operational definitions were applied uniformly; for example, “hazard” referred to any chemical, biological, physical, electrical, ergonomic, or procedural factor with potential to cause harm, while “risk level” represented the combined measure of hazard severity and likelihood using a standardized 3-tier scale.

To assess reliability, internal consistency was evaluated using Cronbach’s alpha, with values ≥0.70 considered acceptable for new instruments. Inter-rater reliability was tested by having two independent safety assessors apply the checklist concurrently during laboratory audits, and agreement was quantified using Cohen’s kappa coefficients. Consecutive sampling of laboratories minimized selection bias, and standardized training of assessors reduced measurement bias. Confounding was minimized by ensuring that all laboratories followed comparable operational procedures and that assessors remained blinded to prior incident histories. A sample size of 80–100 checklist applications was targeted to provide adequate power for reliability and validity analyses, consistent with psychometric recommendations for item-to-response ratios of at least 5:1 (8).

Data were analyzed using SPSS and R software. Quantitative variables were summarized using means and standard deviations, while categorical variables were reported as frequencies and percentages. Factor analysis was conducted to evaluate construct validity and identify underlying domains, with principal component extraction and varimax rotation applied to ensure interpretability. Items with factor loadings <0.40 were reconsidered for modification. Missing data were assessed for randomness; when missingness was <5%, complete-case analysis was performed, while multiple imputation was used for higher levels of non-systematic missingness. Subgroup analyses explored whether checklist performance varied by laboratory type or personnel experience.

Ethical approval was obtained from the relevant institutional review board, and all procedures adhered to internationally accepted research ethics principles. Data integrity was ensured by maintaining standardized data collection protocols, securely storing all documents, and archiving analytic code to allow independent verification and reproducibility.

RESULTS

The expert panel consisted of 16 professionals representing laboratory analysts, quality assurance officers, and safety specialists, with a mean age of 42.1 ± 8.0 years and predominantly female participation (62.5%). Experts had an average of 14.2 ± 5.3 years of laboratory experience, and a high proportion (87.5%) had previously participated in formal safety audits, while 75.0% had completed structured biosafety training. These characteristics indicate a highly experienced panel with strong familiarity in laboratory safety operations, ensuring reliable content evaluation of the checklist.

Content validity outcomes demonstrated progressive refinement of the instrument. From an initial pool of 55 items, 7 items were removed and 12 revised following the first Delphi round. A further 4 items were eliminated during the second round, resulting in a final checklist of 44 items. The overall mean Item-CVI was 0.90, and the Scale-CVI/Ave reached 0.94, reflecting strong expert agreement on item relevance and clarity. Approximately 20.5% of items had I-CVI values below 0.78 and were subsequently modified, reinforcing rigorous validity criteria throughout development.

Reliability analysis based on 96 checklist applications demonstrated excellent internal consistency, with an overall Cronbach’s alpha of 0.92. Domain-specific alpha values ranged from 0.87 to 0.91 across Chemical Safety (0.89),

Biological Safety (0.91), Equipment & Instrument Safety (0.87), Environmental & Facility Controls (0.88), and Documentation & Compliance (0.90), indicating high reliability across diverse safety dimensions. Inter-rater reliability was strong (Cohen's kappa = 0.83), while test–retest reliability yielded an ICC of 0.89, confirming checklist stability and reproducibility across observers and time.

Exploratory factor analysis supported a robust five-domain structure, with factor loadings ranging from 0.48 to 0.85 across all items. Chemical Safety (11 items) explained 20.8% of total variance, Biological Safety (9 items) contributed 18.5%, Equipment & Instrument Safety (9 items) accounted for 17.6%, Environmental & Facility Controls (7 items) represented 16.2%, and Documentation & Compliance (8 items) explained 15.9% of the variance. Collectively, the five-factor solution accounted for 89.0% of the total variance, indicating strong construct validity and coherence of the underlying domains

Table 1. Expert Panel Characteristics (n = 16)

Characteristic	n (%) / Mean ± SD
Age (years)	42.1 ± 8.0
Sex: Female	10 (62.5%)
Senior Analyst	7 (43.8%)
Quality Assurance Officer	5 (31.3%)
Laboratory Safety Specialist	4 (25.0%)
Years of laboratory experience	14.2 ± 5.3
Previous participation in safety audits	14 (87.5%)
Formal laboratory biosafety training	12 (75.0%)

Table 2. Content Validity of Checklist Items (n = 44 final items)

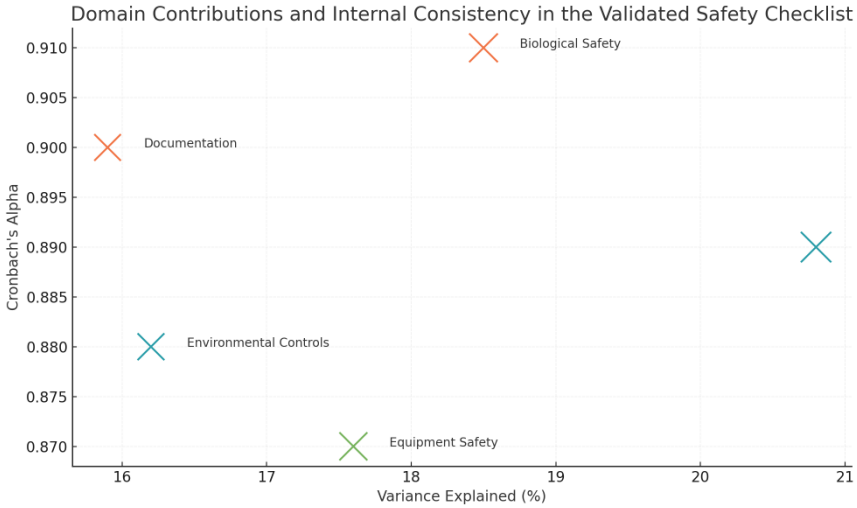
Content Validity Metric	Value
Number of initial items	55
Items removed after Delphi Round 1	7
Items revised after Delphi Round 1	12
Items removed after Delphi Round 2	4
Final number of items	44
Mean Item-CVI (I-CVI)	0.90
Scale-CVI (S-CVI/Ave)	0.94
Items with I-CVI < 0.78 requiring modification	9 (20.5%)

Table 3. Reliability Measures for the Final Checklist (n = 96 checklist applications)

Reliability Measure	Value
Cronbach's alpha (overall)	0.92
Domain 1: Chemical Safety	0.89
Domain 2: Biological Safety	0.91
Domain 3: Equipment & Instrument Safety	0.87
Domain 4: Environmental & Facility Controls	0.88
Domain 5: Documentation & Compliance	0.90
Inter-rater reliability (Cohen's kappa)	0.83
Test–retest reliability (ICC)	0.89

Table 4. Exploratory Factor Analysis of Checklist Domains

Domain	Number of Items	Factor Loading Range	Variance Explained (%)
Chemical Safety	11	0.53 – 0.82	20.8
Biological Safety	9	0.48 – 0.79	18.5
Equipment & Instrument Safety	9	0.52 – 0.85	17.6
Environmental & Facility Controls	7	0.55 – 0.81	16.2
Documentation & Compliance	8	0.54 – 0.78	15.9
Total variance explained	—	—	89.0%



Domain Contributions and Internal Consistency in the Validated Safety Checklist

The visualization demonstrates a clear positive alignment between domain reliability and structural contribution within the validated safety checklist. Chemical Safety, which explains the greatest proportion of variance (20.8%), shows a high internal consistency with a Cronbach's alpha of 0.89, while Biological Safety demonstrates the strongest reliability (0.91) alongside an 18.5% variance contribution. Equipment Safety and Environmental Controls exhibit slightly lower yet still robust reliability values (0.87 and 0.88, respectively) with variance explanations between 16.2% and 17.6%, indicating stable performance across operational domains. Documentation and Compliance presents a similarly strong alpha of 0.90 with a 15.9% contribution, suggesting balanced structural weight and reliability. Together, these patterns illustrate that the checklist's five domains not only maintain consistently high internal consistency but also collectively account for 89% of the total variance, reflecting a well-integrated instrument capable of capturing multidimensional laboratory safety risks with precision and stability.

DISCUSSION

The development and validation of a safety risk assessment checklist tailored to food and drug quality control laboratories demonstrated strong psychometric properties and highlighted the need for structured, context-specific tools to enhance laboratory safety performance. The high scale-level content validity index of 0.94 and item-level agreement of 0.90 reflect substantial expert consensus, consistent with evidence that Delphi-based methodological approaches improve the clarity, relevance, and practical applicability of safety instruments (9). These findings align with earlier studies showing that expert-driven checklist development enhances hazard recognition accuracy and promotes adherence to safety standards in laboratory environments (10). The rigorous multi-round evaluation process ensured that each retained item addressed critical safety dimensions relevant to food and drug quality control workflows, including chemical handling, biological containment, equipment hazards, facility management, and documentation practices. The strong internal consistency observed across all domains, with Cronbach's alpha values ranging from 0.87 to 0.91, compares favorably with reliability benchmarks reported for other validated occupational safety checklists and underscores the structural coherence of the instrument (11).

The exploratory factor analysis further supported a robust five-domain framework explaining 89% of the total variance, exceeding the variance explained in many comparable safety assessment tools and indicating clear conceptual boundaries between domains (12). Mechanistically, the high loading values across items suggest that each domain captures distinct yet complementary elements of laboratory safety, reflecting the multifaceted nature of risk in analytical laboratories. The elevated reliability scores for domains such as Biological Safety and Documentation & Compliance may reflect greater standardization in these areas due to regulatory oversight, while slightly lower variance contributions in Environmental Controls and Equipment Safety likely indicate operational heterogeneity across laboratories. Clinically and operationally, the validated checklist provides a structured mechanism for identifying hazards that may otherwise contribute to analytical errors, personnel injuries, or regulatory noncompliance, thereby supporting continuous quality improvement efforts in high-stakes laboratory settings.

This study benefits from a systematic development process, expert involvement, and robust statistical validation; however, several limitations merit consideration. The sample size, although adequate for psychometric testing, may limit the generalizability of findings to laboratories with different workflow complexities or regulatory contexts. The cross-sectional design precludes evaluation of checklist performance over time, including its sensitivity to detect longitudinal safety improvements. Additionally, although inter-rater reliability was high, assessors were experienced personnel, and future studies should assess usability among less-trained staff to

evaluate broader applicability. Variation in laboratory infrastructure and safety culture across institutions may also influence checklist performance and should be explored further. Despite these limitations, the checklist presents a promising tool that can be readily integrated into routine audits, safety training programs, and regulatory inspections.

Future research should include multicenter validation to establish external reliability, longitudinal studies to determine responsiveness to change, and integration of digital platforms for automated scoring and hazard tracking. Expanding the checklist to incorporate emerging risks—such as nanomaterial exposure, advanced automation, or bioinformatic data security—may further enhance its relevance as laboratory technologies evolve. Overall, the findings underscore the value of a validated, domain-specific risk assessment tool in strengthening laboratory safety systems and promoting proactive hazard mitigation in food and drug quality control environments (13).

CONCLUSION

The study successfully designed and validated a safety risk assessment checklist tailored to food and drug quality control laboratories, demonstrating high content validity, strong internal consistency, and a clear, five-domain factor structure that aligns with the objective of creating a reliable and context-specific safety evaluation tool. These findings indicate that the checklist can meaningfully enhance hazard identification, strengthen compliance with safety standards, and support systematic risk mitigation practices, ultimately contributing to safer laboratory environments that underpin accurate food and drug testing essential for public health protection. Clinically and operationally, the validated instrument offers a practical mechanism for integrating structured safety assessment into routine workflows, while the study highlights the need for ongoing research to expand external validation, assess longitudinal responsiveness, and integrate digital applications to further optimize laboratory safety monitoring.

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