

Redefining Quality: Transforming Internal Reviews into Team Development Tools

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ABSTRACT

In CRO environments, quality is often equated with compliance and deliverable accuracy. However, true performance lies in how teams operate, communicate, escalate issues, apply domain knowledge in real time. This paper introduces a people-focused framework that redefines internal quality reviews as developmental tools rather than process checks, fostering high-performing programming teams. By evaluating not only code, but also team dynamics, communication, and understanding of project context, internal reviews become opportunities to identify growth areas and implement structured, targeted action plans. Tools such as communication scorecards, code quality rubrics, and learning dashboards provide measurable, actionable insights. A CRO case study illustrates how this approach transformed a struggling team into a reliable, results-driven group capable of consistently delivering high-quality outputs and engaging proactively with sponsors. Geared toward quality and programming leaders, this paper demonstrates how internal team development, anchored in thoughtful review practices, can become a strategic asset beyond traditional quality control.

INTRODUCTION

In contract research organizations (CROs), quality is traditionally defined through compliance, audit readiness, and the accuracy of deliverables such as analysis datasets, tables, listings, and figures. While these elements remain essential for regulatory acceptance and sponsor confidence, they do not fully capture how effectively teams operate in real project environments. True performance also depends on how programmers communicate, escalate issues, interpret clinical context, and apply domain knowledge under pressure. The CRO industry is currently facing increasing study complexity, accelerated development timelines, growing regulatory scrutiny, and rising sponsor expectations for transparency and responsiveness. Programming teams are often required to manage multiple studies simultaneously, adapt quickly to changing specifications, and communicate clearly across global, cross-functional environments. In this context, technical accuracy alone is no longer sufficient. Strong communication, proactive risk escalation, and a deep understanding of clinical and regulatory requirements have become critical components of sustainable quality performance.

A robust Quality Management System (QMS) provides the structural foundation for ensuring consistency, compliance, and regulatory alignment across operational processes. Standard Operating Procedures, quality controls, and audit mechanisms define what must be done to meet regulatory expectations. However, the effectiveness of a QMS ultimately depends on how well these standards are translated into daily team behaviors, decision-making, and communication practices. Quality systems are only as strong as the people who apply them. From a Chief Quality Officer perspective, quality must be embedded not only in formal systems and documentation, but also in how teams think, collaborate, and respond to challenges. Leadership plays a key role in shaping a culture where quality reviews are viewed not as fault-finding exercises, but as opportunities for learning, alignment, and continuous improvement. When internal reviews focus on both technical outputs and behavioral performance, they become powerful tools for strengthening team capability and accountability.

The purpose of this paper is to demonstrate how internal quality reviews can be redesigned as structured team development tools that support both regulatory compliance and operational excellence. Through a people-focused review framework, supported by standardized assessment tools and leadership engagement, this approach enables CROs to identify growth areas, implement targeted action plans, and build high-performing programming teams. A practical case study illustrates how this model can improve communication, consistency, and overall team effectiveness in real-world project environments.

LIMITATION OF TRADITIONAL QUALITY REVIEW MODELS

Traditional quality assurance (QA) models in contract research organizations (CROs) primarily focus on compliance with Standard Operating Procedures (SOPs), regulatory requirements, and the technical accuracy of deliverables such as analysis datasets, tables, listings, and figures. Internal reviews are often structured around identifying deviations, documenting findings, and implementing corrective and preventive actions (CAPAs). While this approach ensures procedural consistency and regulatory alignment, it does not always address the broader performance factors that

influence long-term team effectiveness. In many organizations, quality reviews are perceived as inspections rather than development opportunities. Feedback is frequently limited to technical issues, such as programming errors, missing documentation, or formatting inconsistencies. Less attention is given to how teams communicate, escalate risks, interpret study context, or collaborate under time pressure. As a result, recurring issues may persist despite repeated audits and corrective actions, as the underlying behavioral and process-related causes are not fully addressed.

Traditional QA models also tend to focus on outcomes rather than the processes that lead to those outcomes. When a deliverable does not meet expectations, the emphasis is often placed on correcting the final output rather than examining how the issue arose. Factors such as unclear communication, misinterpretation of specifications, or delayed risk escalation may remain unexamined, even though they significantly affect quality and efficiency.

Furthermore, QA activities are frequently separated from team development and leadership processes. Findings are documented, but they are not always systematically translated into targeted training plans, mentoring strategies, or performance improvement initiatives. This separation limits the ability of QA functions to contribute to sustainable skill development and cultural change within programming teams. As CROs face increasing study complexity, tighter timelines, and greater regulatory and sponsor expectations, these limitations become more pronounced. A quality approach that focuses only on compliance and technical checks is no longer sufficient. To support consistent performance in modern project environments, quality review processes must evolve to incorporate communication effectiveness, clinical understanding, and team behavior as core components of quality.

This need for a more integrated approach forms the basis for the people-focused quality review framework described in the following sections.

A PEOPLE-FOCUSED QUALITY REVIEW FRAMEWORK

To enhance both compliance and team performance, a people-focused quality review framework was developed. This approach expands the scope of internal reviews beyond technical verification to include evaluation of communication, clinical understanding, and professional behaviors that directly impact project outcomes.

The framework is built on three core principles:

QUALITY AS A DEVELOPMENT TOOL

Internal quality reviews are designed not only to identify issues, but also to highlight growth opportunities. Feedback is structured to support learning, accountability, and continuous improvement rather than solely documenting deficiencies. By linking review findings to targeted development actions, quality activities become part of an ongoing performance improvement cycle within the QMS framework.

BEHAVIORAL AND TECHNICAL ASSESSMENT

In addition to reviewing code, datasets, and outputs, the framework evaluates how team members communicate, escalate risks, manage timelines, and demonstrate clinical trial knowledge. This dual focus ensures that both technical accuracy and professional behavior are considered essential components of quality performance.

LEADERSHIP ENGAGEMENT

Quality reviews are aligned with leadership objectives and team development plans. Review outcomes are used to guide mentoring, training priorities, and performance discussions. Active leadership involvement reinforces accountability and ensures that quality feedback is translated into meaningful improvement actions.

Through this model, quality assurance becomes an active contributor to team capability, not just a compliance function.

People-Focused Quality Review Framework



Figure 1: People-Focused Quality Review Framework

Figure 1 illustrates the three core principles of the people-focused quality review framework - quality as a development tool, behavioral and technical assessment, and leadership engagement - integrated within a Quality Management System to support enhanced team performance.

IMPLEMENTATION OF THE FRAMEWORK: FROM ORGANIZATIONAL DESIGN TO SCALABLE PRACTICE

The people-focused quality review framework was designed and implemented at STATECS LLC as a structured initiative to enhance both technical quality and team development. While the framework was initially developed to address internal organizational needs, its structure and principles are intentionally scalable and adaptable for use across different CROs and programming environments.

The model was built to complement existing Quality Management Systems (QMS) rather than replace them, ensuring that regulatory compliance, audit readiness, and documentation standards remain fully supported. At the same time, it expands the purpose of internal quality reviews to include professional growth, communication effectiveness, and accountability.

FRAMEWORK DESIGN AND ORGANIZATIONAL INTEGRATION

The framework was created to integrate seamlessly into routine quality and review processes. It aligns with:

- Standard Operating Procedures (SOPs)
- Good Programming Practice (GPP) principles
- Regulatory expectations (e.g., GCP and data integrity)
- Internal documentation and audit requirements

This alignment ensures that the framework supports both compliance objectives and workforce development goals. Although initially implemented at STATECS, the same structure can be applied in any CRO or statistical programming organization with minimal customization.

DEVELOPMENT OF A STRUCTURED QA ASSESSMENT MODEL

A standardized QA Audit Template was developed to evaluate individual performance using a combination of technical, behavioral, and process-oriented criteria. Each criterion is weighted according to its relevance to project success and team effectiveness.

The assessment areas include:

- Understanding of role, expectations, and responsibilities
- Programming skill proficiency
- Accuracy of work output
- Compliance with internal SOPs
- Regulatory and industry knowledge
- Problem-solving and decision-making skills

- Time management and task prioritization
- Communication skills (written and verbal)
- Collaboration and teamwork
- Adaptability to project changes
- Awareness of project processes and accountability
- Initiative and self-motivation

This structure allows organizations to assess not only what is delivered, but how it is delivered.

INDIVIDUAL ASSESSMENT AND FEEDBACK PROCESS

Using the framework, employees are evaluated through a structured review of recent project work, communication practices, and overall engagement. Each assessment includes:

- A performance rating for each criterion
- A weighted score reflecting its importance
- Written qualitative feedback
- A personalized action plans

Technical performance is reviewed through code quality, documentation, and adherence to specifications. Communication effectiveness is assessed through written updates, meetings, and escalation practices. Process awareness is evaluated through understanding of study design, timelines, and deliverable expectations.

This approach ensures that feedback is constructive, consistent, and focused on development rather than fault-finding.

TRANSLATING REVIEW OUTCOMES INTO DEVELOPMENT ACTIONS

One of the key strengths of the framework is the direct link between quality review findings and development actions. Identified gaps are converted into structured improvement plans, such as:

- Targeted technical training
- Mentorship and coaching
- Independent programming assignments
- Study onboarding refreshers
- Communication and time-management guidance

This ensures that internal reviews lead to measurable improvements rather than static documentation.

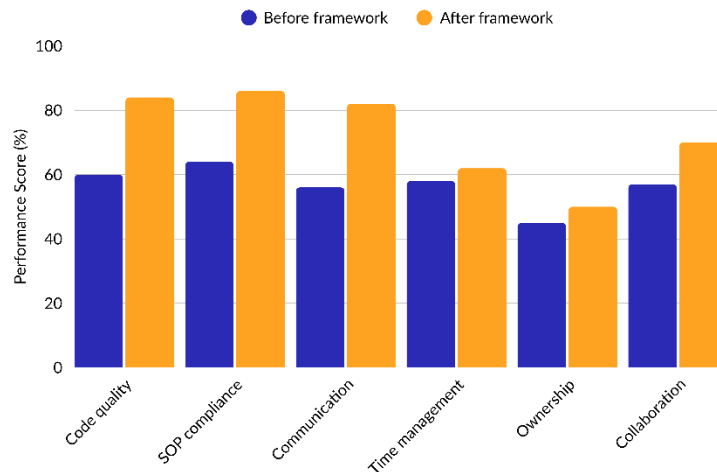


Figure 2: Performance improvement across key technical and behavioral dimensions following implementation of the people-focused QA review framework.

LEADERSHIP INVOLVEMENT AND ACCOUNTABILITY

Leadership engagement is essential to the success of the framework. Managers and team lead participate in review discussions to:

- Reinforce expectations
- Support accountability
- Align development plans with performance goals
- Promote a culture of continuous improvement

This shared responsibility ensures that quality and development are embedded into everyday operations rather than isolated within QA functions.

SCALABILITY AND APPLICABILITY ACROSS ORGANIZATIONS

Although the framework was initially developed and piloted at STATECS LLC, its design is not organization-specific. The principles, assessment criteria, and feedback mechanisms can be adapted to:

- Small or large CROs
- Global programming teams
- Different therapeutic areas
- Various regulatory environments

By adjusting weighting, terminology, and documentation formats, the framework can be tailored to meet local organizational needs while preserving its core purpose: transforming quality reviews into tools for team development and performance optimization.

CASE STUDY: IMPLEMENTING A PEOPLE-FOCUSED QUALITY REVIEW CYCLE

At STATECS, the people-focused quality review framework was applied through a structured, cyclical quality assessment process designed to evaluate individual performance, identify development needs, and implement targeted improvement actions.

When a quality review is initiated, each individual presents their recent work, deliverables, and communication outputs to the Quality Check Team. Over an observation period of approximately one to two months, the QA team evaluates both technical performance and behavioral competencies using standardized assessment criteria.

Each employee operates within a defined support structure that includes a direct Manager and an assigned Mentor. During the quality review process, the QA team assesses not only the individual's strengths and weaknesses, but also the broader support environment influencing performance.

When performance gaps are identified, the QA team conducts a root cause analysis to determine contributing factors. These may include:

- Gaps in mentoring support
- Misalignment between assigned tasks and individual competency levels
- Inappropriate mentor–employee pairing
- Workload or task allocation challenges
- Communication or expectation-setting issues

This approach ensures that performance concerns are evaluated within the full organizational context rather than being attributed solely to the individual.

Following this analysis, a comprehensive Final Audit Report is prepared. The report documents performance findings, root causes, and development priorities. Based on these findings, structured Action Plans are created at two levels:

TEAM / MANAGEMENT ACTION PLAN

Focused on improvements in mentoring quality, task allocation, communication structure, and leadership support.

INDIVIDUAL EMPLOYEE ACTION PLAN

Focused on targeted skill development, training needs, communication improvement, and accountability goals.

Each Action Plan Includes defined objectives, responsible parties, and clear timelines. The Final Audit Report and

associated Action Plans are formally reviewed by the Team Manager, who is required to read, acknowledge, and sign off on the findings and development commitments.

CASE STUDY ASSESSMENT SUMMARY

The following table presents an anonymized example of a quality review conducted for a junior-level statistical programmer using the people-focused QA framework. The assessment reflects the individual's performance across technical, behavioral, and process-related criteria during a structured observation period. All personal identifiers have been removed to ensure confidentiality.

Each criterion was evaluated using weighted scoring, and findings were documented alongside targeted individual and team/management action plans. This approach allowed the QA team to systematically link performance observations to concrete development actions, ensuring both accountability and continuous improvement.

Table 1 illustrates how the framework translates qualitative performance observations for a junior employee into structured recommendations for both the employee and the responsible manager.

Table 1. Example of a Structured Quality Review Assessment and Action Planning Framework

Criteria	Key Findings	Individual Action Plan	Team/Manager Action Plan	Timeline	Owner
Understanding of Role, Expectations, and Responsibilities	Role expectations were not clearly understood; reliance on informal guidance observed.	Review role responsibilities with mentor; attend onboarding refresher.	Provide structured role description and onboarding checklist.	1 month	Team Lead
Programming Skill Proficiency	Strong logical coding but limited independent ADaM/TLF development.	Targeted ADaM and TLF training sessions.	Assign supervised independent programming tasks.	2 months	Mentor
Accuracy of Work Output	Outputs are not self-reviewed before Updating the status to 'Ready for QC'.	Reinforce ownership of Output quality	Provide clear guidance and training on proper self-QC steps Beyond Visual checks.	1 month	QA Team
Compliance with Internal SOPs	SOP awareness present but inconsistently applied.	Review SOP sections related to TLF production.	Conduct SOP refresher training.	1 month	QA Lead
Regulatory Knowledge	Gaps in SDTM/ADaM concepts and regulatory terminology.	Attend regulatory training sessions.	Provide regulatory knowledge materials.	2 months	Mentor
Problem-Solving and Decision-Making	Hesitant to make independent decisions; frequent mentor consultation required.	Practice independent problem-solving exercises.	Gradually reduce mentor dependency.	2 months	Mentor
Time Management and Task Prioritization	Difficulty estimating timelines; delays in task completion.	Apply task planning tools and weekly goal setting.	Improve task allocation based on skill level.	1 month	Manager

Communication Skills (Written & Verbal)	Clear verbal communication, but written documentation lacked structure.	Technical writing practice.	Provide documentation templates.	1 month	QA Team
Collaboration and Teamwork	Positive collaboration, but limited mentoring confidence.	Participate in peer mentoring.	Provide mentor support training.	2 months	Manager
Adaptability to Project Changes	Adapted well to new tasks when guidance was provided.	Continue exposure to varied project tasks.	Monitor adaptation progress.	Ongoing	Manager
Awareness of Project Processes	Limited understanding of end-to-end study workflow.	Study lifecycle overview training.	Improve onboarding process.	1 month	QA Lead
Initiative and Self-Motivation	Motivation present, but confidence limited.	Set personal development goals.	Provide structured feedback sessions.	Ongoing	Mentor

To complement the detailed assessment presented in Table 1, Figure 3 provides a visual summary of the same evaluation results for an anonymized junior employee. The figure highlights relative strengths and development gaps across technical, behavioral, and project-related performance criteria, allowing for rapid identification of priority areas for improvement.

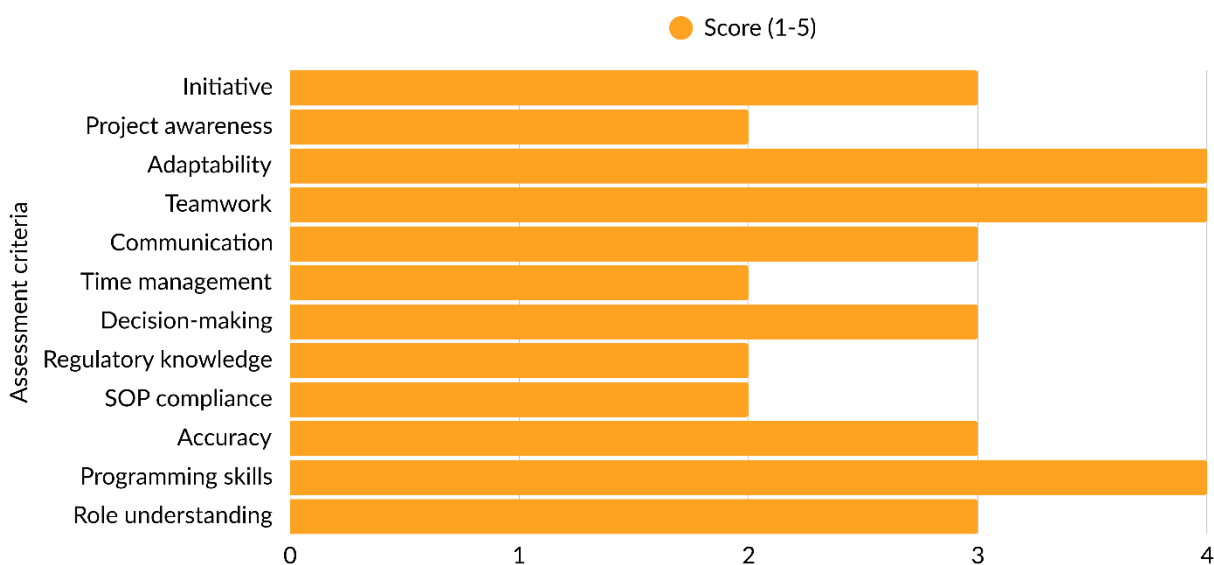


Figure 3: Visual summary of initial assessment scores for an anonymized junior employee across technical, behavioral, and project-related criteria.

The lower-scoring domains informed the targeted recommendations and structured development actions presented in Table 2.

INTERPRETATION OF FINDINGS AND MANAGEMENT RECOMMENDATIONS

The assessment revealed that the employee demonstrated strong logical coding practices, responsiveness within the project environment, and adaptability when instructions were clearly defined. The individual showed a structured and mindful approach to tasks, maintained good communication within assigned responsibilities, and was willing to support team members despite limited experience.

However, several development gaps were identified. These included difficulties with time estimation and task prioritization, limited confidence in independent decision-making, and insufficient understanding of study design, deliverable objectives, and regulatory frameworks. Written communication and technical English skills also required further development.

Based on these findings, the QA team issued targeted recommendations to the Team Manager to support both individual growth and overall team effectiveness.

The QA team summarized the assessment findings into structured development recommendations for both the employee and the responsible manager. Table X presents the key strengths, improvement areas, and targeted actions derived from the review.

Table 2. Summary of QA Findings and Development Recommendations for a Junior-Level Programmer

Focus Area	Key Observations	QA Recommendations / Actions
Strengths	- Structured and mindful task execution - Responsive communication - Flexible when instructions are clear - Good coding logic and structure - Willingness to support teammates	Maintain strengths through continued exposure to independent tasks and peer collaboration opportunities.
Areas for Improvement	- Weak time estimation - Low confidence in independent decisions - Limited study design understanding - Written English needs improvement - Unclear mentorship expectations	Implement targeted training, clarify mentorship structure, and align task complexity with competency level.
Training Needs	- Technical English - SDTM/ADaM structures - CT usage - Deliverable types (CSR, DSUR, IEMT) - TLF review techniques - Time planning	Use estimation tools and templates
Mentorship / Coaching	- Needs support in ADaM/TLF reviews - Needs time management guidance - Supports juniors but feels overloaded	Encourage decision-making with guidance
Process Improvements	- Onboarding lacks structure - Task estimates not standardized - No formal code review checklist	Introduce onboarding framework, task breakdown templates, and standardized code review checklists.
Final Management Recommendations		Assign a dedicated mentor, prioritize regulatory training, improve task planning processes, clarify roles and deliverables, and encourage independent problem-solving with structured support.

These recommendations ensured that performance feedback was translated into actionable development steps, reinforcing accountability and continuous improvement

At the end of the defined action period, a follow-up quality review is conducted to reassess performance against the original criteria. This allows the QA team to evaluate measurable improvements in:

- Communication effectiveness

- Accountability
- SOP adherence
- Issue escalation practices
- Ownership of deliverables
- Consistency of feedback implementation
- Reduction of repeated issues

This cyclical review process demonstrates how internal quality reviews can function as structured development tools rather than one-time compliance checks.

To ensure consistency and transparency, the QA review process at STATECS follows a structured, cyclical model. The approach begins with an observation and assessment phase, followed by root cause analysis, targeted action planning, focused development activities, and formal re-evaluation. This cycle allows performance gaps to be addressed systematically and ensures that improvement efforts are measurable and accountable.



Figure 4: People-focused QA review cycle illustrating assessment, root cause analysis, targeted action planning, development interventions, and re-evaluation of individual and team performance.

As shown in Figure 4, the QA review cycle begins with a structured assessment phase, during which the QA team evaluates individual performance across technical, communication, and process-related criteria. This is followed by a root cause analysis to determine whether observed gaps originate from individual skill limitations, mentoring effectiveness, or managerial task allocation.

Based on these findings, targeted action plans are developed at both the individual and team levels, with defined responsibilities and timelines. Development activities may include focused technical training, mentoring adjustments, communication coaching, or workflow changes.

The final stage of the cycle involves re-evaluation against the original assessment criteria to measure improvement. The results are documented in a formal QA audit report, which is reviewed and signed by the responsible team manager to ensure accountability and continuous performance improvement.

CONCLUSION

Traditional quality review models in CRO environments often focus primarily on compliance, error detection, and deliverable accuracy. While these elements remain essential, they do not fully address the human factors that drive sustainable performance, such as communication, accountability, and continuous skill development. This paper demonstrates how a people-focused quality review framework can transform internal QA activities from reactive control mechanisms into proactive development tools.

By integrating structured performance assessments, root cause analysis, targeted action plans, and formal re-evaluation cycles, the framework enables organizations to systematically identify gaps, strengthen team capabilities, and promote consistent improvement. The case study presented illustrates how leadership engagement, mentor alignment, and individualized development plans contribute to measurable gains in technical quality, process adherence, communication effectiveness, and ownership of deliverables.

Importantly, the framework supports the principles of quality culture outlined in ICH E6 by emphasizing prevention, transparency, accountability, and continuous improvement rather than relying solely on retrospective error correction. The use of standardized review criteria, documented action plans, and formal sign-off processes ensures traceability, consistency, and audit readiness while simultaneously fostering professional growth.

Although this framework was developed and implemented within a specific organizational context, its core principles are adaptable and scalable across CROs of varying sizes and structures. By repositioning internal quality reviews as development-driven processes, organizations can strengthen both compliance outcomes and team performance, ultimately enhancing sponsor confidence and the reliability of clinical study deliverables.

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