

Redefining Quality: Transforming Internal Reviews into Team Development Tools

Company: STATECS

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Agenda

- ≡≡≡ Why Traditional QA Reviews Miss Real Performance Drivers
- ≡≡≡ Limitations of Traditional Quality Review Models
- ≡≡≡ A People-Focused Quality Review Framework
- ≡≡≡ Performance Improvement After People-Focused QA Framework
- ≡≡≡ From Framework to Practice
- ≡≡≡ Case Study: Junior Programmer Development Cycle
- ≡≡≡ Visual Summary of The Evaluation Results For a Junior Employee
- ≡≡≡ Measured Results and Visual Evidence
- ≡≡≡ Key Takeaways and Conclusion

≡ Why Traditional QA Reviews Miss Real Performance Drivers

Traditional QA reviews are designed to:

- Confirm Compliance
- Error Detection

But they fail to consistently assess:

- Communication and escalation quality
- Decision-making under real project pressure
- Underlying behavioral and capability drivers

Result: Compliance achieved, but performance variability persists

≡ Limitations of Traditional Quality Review Models

Inspection-style, pass/fail reviews

Root causes remain largely unexamined

Focus on outputs over behaviors

Recurring issues across studies

Corrective actions without capability development

Outcome

Compliance achieved

- SOPs followed
- Audits passed
- CAPAs closed
- Deliverables technically acceptable

Performance variability persists

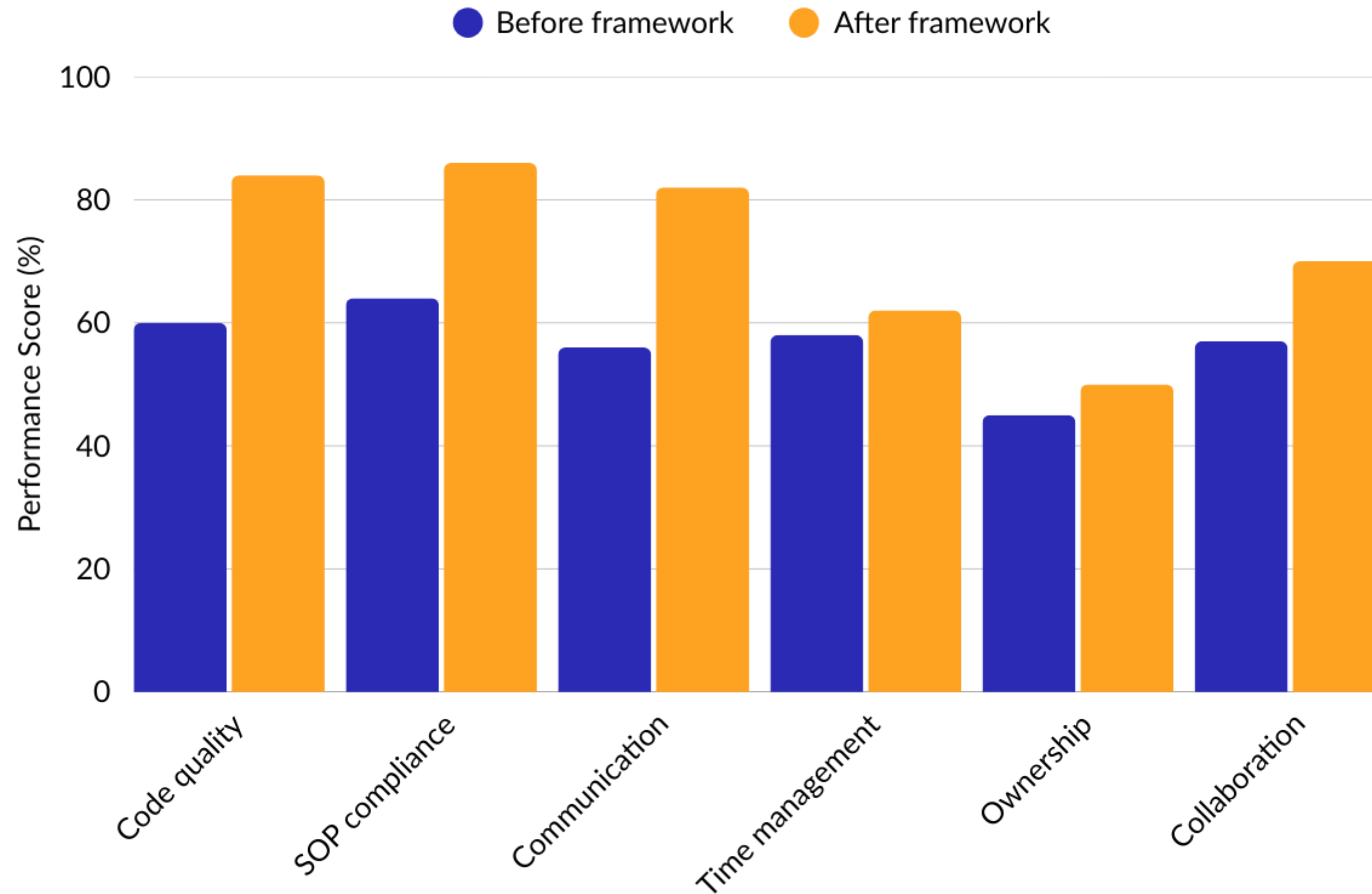
- Some teams perform well, others struggle
- Same types of issues keep appearing
- Quality depends on who is working, not on a stable system

≡ A People-Focused Quality Review Framework

- Quality reviews as a development tool
- Behavioral and technical assessment
- Leadership engagement and accountability

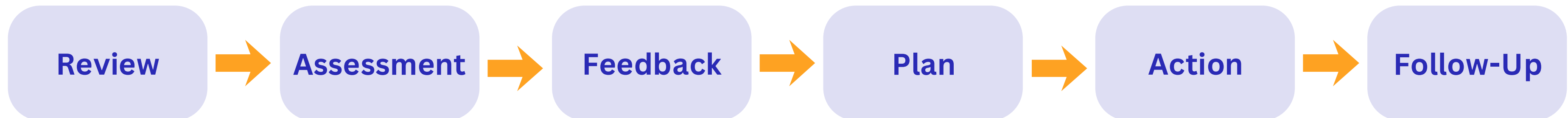


≡ Performance Improvement After People-Focused QA Framework



≡ From Framework to Practice

- Embedded into existing QA and review processes
- Aligned with SOPs, GPP, and regulatory expectations
- Structured technical, behavioral, and process assessment
- Review findings translated into targeted development actions
- Leadership involvement to drive accountability and consistency



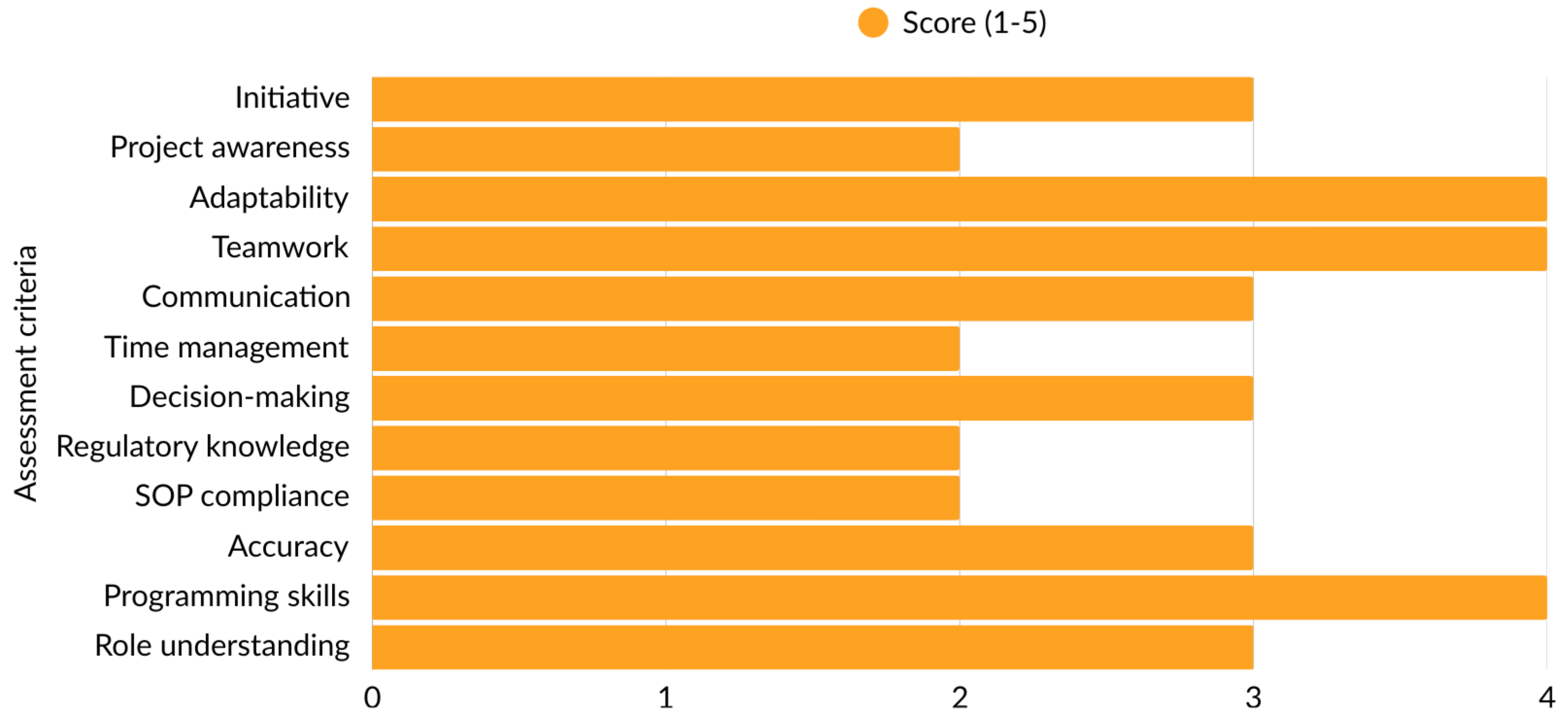
≡ Case Study: Junior Programmer Development Cycle

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

Criteria	Key Findings	Individual Action Plan	Team/Manager Action Plan	Timeline	Owner
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



Visual Summary of The Evaluation Results For a Junior Employee



Measured Results and Visual Evidence

Focus Area	Key Observations	QA Recommendations / Actions
Strengths	• Structured and mindful task execution • Responsive communication • Flexible when instructions are clear • Good coding logic and • Sstructure 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

≡ Measured Results and Visual Evidence

Focus Area	Key Observations	QA Recommendations / Actions
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.

≡ Key Takeaways and Conclusion

Quality goes beyond compliance

Human factors are essential to sustainable quality and performance.

Quality reviews enable development

A people-focused approach turns QA into a performance improvement tool.

Structured reviews drive consistency

Standard processes support measurable and repeatable improvement.

Leadership enables performance gains

Leadership and mentorship strengthen ownership and communication.

Quality culture is reinforced

The framework aligns with ICH E6 principles of prevention and transparency.

The model is scalable across CROs

The approach can be applied across CROs to strengthen outcomes and trust.



Thank You!

Let's keep in touch!



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