WHITE PAPER

Quality Management System (QMS): How Clinix QM Works

The QA review process, feedback incorporation, model versioning, output monitoring, and continuous improvement protocols.

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Author:	ClinixSummary Research Team

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1. Executive Summary

In clinical AI, output quality is a patient safety issue. A single inaccurate medication dosage, a missed diagnosis, or an incorrect procedure code can have real clinical consequences. The Clinix Quality Management System (Clinix QM) is a systematic framework ensuring that every ClinixSummary output meets clinical documentation standards.

This white paper describes the processes, metrics, and governance structures that constitute Clinix QM, providing the detail needed by quality officers, clinical leaders, and compliance teams evaluating ClinixSummary for deployment.

2. QMS Framework Overview

Clinix QM operates across four pillars:

- Proactive Quality — Preventing errors through model design, training methodology, and output validation rules.
- Reactive Quality — Detecting and correcting errors through clinician feedback, automated monitoring, and manual QA review.
- Continuous Improvement — Systematically incorporating quality findings into model updates (the Kai-zen loop).
- Governance — Oversight structures, documentation, and accountability mechanisms.

3. Proactive Quality Controls

3.1 Model Validation Gates

Every model update must pass through a series of validation gates before deployment:

- Automated regression testing against a curated test suite of 10,000+ clinical scenarios.
- Specialty-specific accuracy benchmarks that must meet or exceed the previous model version.
- Clinical review by specialty advisors for any changes affecting clinical reasoning or terminology.
- A/B testing on a subset of production traffic before full rollout.

3.2 Output Validation Rules

Generated notes are checked against a rule engine that flags potential issues before the clinician sees the output: missing mandatory sections, medication dosages outside normal ranges, contradictory clinical findings, and incomplete procedure documentation. Flagged items are highlighted for clinician review.

4. Reactive Quality Processes

4.1 Clinician Feedback Integration

Every clinician edit, correction, or rating is captured and fed into the quality pipeline. Feedback is categorised (terminology error, section misclassification, missing information, incorrect clinical reasoning, etc.) and prioritised for remediation.

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4.2 Manual QA Reviews

A dedicated clinical QA team conducts regular manual reviews of model outputs. Review samples are stratified by specialty, note type, and complexity to ensure comprehensive coverage. QA reviewers are licensed clinicians with specialty expertise in the areas they review.

4.3 Automated Monitoring

Production outputs are continuously monitored for statistical anomalies: sudden changes in note length, section distribution, terminology frequency, or clinician edit rates. Anomalies trigger automated alerts and investigation by the QA team.

5. Continuous Improvement: The Kai-zen Loop

Quality findings from all three reactive channels (clinician feedback, manual QA, automated monitoring) are aggregated weekly into a prioritised improvement backlog. The top priorities are addressed in the next model update cycle, creating a continuous improvement loop that makes ClinixSummary more accurate with every iteration.

Key metrics tracked over time:

- Clinician Acceptance Rate (target: >95% by end of 2025).
- Clinical Accuracy Score per specialty.
- Mean edits per note (trending toward zero).
- Critical error rate (medication, allergy, procedure — target: <0.1%).
- Time from error detection to model fix deployment.

6. Governance & Documentation

Clinix QM is governed by a Quality Steering Committee comprising the Chief Medical Officer, Head of AI, Head of Quality, and external clinical advisors. The committee meets monthly to review quality metrics, approve model releases, and set quality targets.

All QMS processes are documented in a controlled document system with version tracking, approval workflows, and periodic review cycles. Documentation is available for review by customers and regulators upon request.

7. Conclusion

Quality management in clinical AI requires the same rigour applied to medical devices and pharmaceuticals. Clinix QM provides the systematic framework to ensure that ClinixSummary's outputs are not just technically impressive, but clinically safe, accurate, and continuously improving. Our commitment to quality is not aspirational — it is operational, measurable, and governed.

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