

KaizenEdge Validation Summary Report v1

This document summarizes the verification and validation-adjacent activities performed to ensure the KaizenEdge Lifestyle Meal Planner system is safe, reliable, and FDA-grade in its current Phase 1 configuration.

1. Defined Product Inputs & Outputs

User needs (allergens, medical conditions, budget, cultural filters) were translated into design inputs. Expected outputs were meal plans, recipes, grocery lists, and fitness guidance validated against these inputs.

2. Built Deterministic Guardrails

Hard safety rules were encoded based on FDA/USDA/NIH thresholds. These act as the oracle for pass/fail decisions, ensuring safety regardless of model behavior.

3. Guardrail Test Suite Execution

A comprehensive 45-case test suite was executed, spanning allergens, diet restrictions, medical conditions, and food safety. Final result: 45/45 PASS.

4. Validation-Adjacent Activity

Simulation of real-world user scenarios confirmed that the system's outputs were safe and aligned with user constraints. While not formal FDA validation (which requires user trials), this provides strong pre-validation evidence.

5. Quality & FDA-Grade Hardening

Outputs enforced via JSON schema, signed SHA-256 reports, ruleset v1 pinning, pre-commit guards, and CI/CD staging. All artifacts are reproducible and auditable.

Conclusion

KaizenEdge has verified its Phase 1 lifestyle system to be FDA-grade in process rigor, with validation simulation showing outputs meet intended use. This sets the foundation for full FDA validation in Phase 2.