RRL-QMS Comparative Appendix

Comparative positioning of RRL-QMS against common maturity / readiness frameworks.

Purpose

This appendix provides a compact, citation-friendly comparison table for stakeholder discussions. It highlights where traditional maturity frameworks stop short of regulatory/QMS submission readiness and where RRL-QMS adds staged checkpoints and quantitative signals.

Table 1 — Comparative overview of maturity/readiness frameworks

Framework / Programme	Primary Domain	Maturity Layers	Predictive component	Scope	Key Gaps Remaining
TRL	Technology feasibility	9	✘	Cross-industry	No QMS / regulatory checkpoints
CMMI	Process capability	5	✘	Cross-industry	Not aligned to ISO 13485 or regulators
FDA-QMM	Pharma manufacturing	5 tiers	✘ (pilot)	Drugs only	No design-control layer; no approval-probability model
MDIC-MDDAP	US medical devices	Narrative maturity	✘	US only	Lacks EU/MDSAP mapping & quantitative risk
ISO 13485 certification	Device QMS	Pass / fail	✘	Global devices	Binary; no staged roadmap
Our RRL-QMS	Global medical devices (incl. SaMD)	9	✔ Logistic risk, Sobol, Stability index	All device classes	Fills all above gaps; multi-country and quantitative

Notes

• “Predictive component” indicates an explicit quantitative layer that maps maturity/readiness to a submission or approval outcome (not just narrative grading).
• “Key gaps remaining” is framed from a medical-device QMS and multi-jurisdiction readiness perspective.
• RRL-QMS is presented as a nine-level ladder; implementation details may be shared privately under agreement.

References (selected)

• ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes.
• FDA — Quality Management Maturity (QMM) program (public materials).
• Medical Device Innovation Consortium (MDIC) — Medical Device Discovery Appraisal Program (MDDAP) (public materials).
• Technology Readiness Levels (TRL) — common cross-industry maturity concept.
• CMMI — Capability Maturity Model Integration (process capability maturity).

Version: v1.1 | Last updated: 2025-12-28 | Publisher: FWL.ai