

**9 x 9 =
IMPACT**

9 x 9 = Impact

**9 Levels
9 Use Cases
9 Industry
Problems Solved**

RRL-P™ & RRL-QMS[®]

The New Standard in Regulatory Maturity

1. FAIL FIRST-CYCLE

Pharma: Only ~24% of NDAs/BLAs require multiple review cycles; 76% succeed in first (FDA CDER, 2023).


MedTech: ~67% of 510(k)s receive AI requests in first cycle (FDA CDRH FY2022).

✅ **RRL-Solution: Target RRL-6+ to achieve >70% first-pass approval odds; each level ↑ approval odds 1.4–3.4×.**

2. CRLs & QMS GAPS

Pharma: ~30% of CRLs cite CMC/Quality gaps as primary reason (BioSpace, 2024).


MedTech: CAPA, design, production controls = ~35% of 483 citations (FDA FY2020).

 **RRL-Solution: Apply 50-point checklist to proactively close QMS/CMC compliance gaps.**

3. NO READINESS METRIC

Pharma: No numeric metric is used by most sponsors to assess approval readiness (FDA 2022).

MedTech: 90%+ of device firms lack QMS maturity rating (MDIC, Deloitte 2022).

 **RRL-Solution: Assign 1–9 RRL + Success Prob + Stability Index as quantified readiness KPIs.**

4. INTERNAL MISALIGNMENT

Pharma: ~40% of submissions fail/delay due to RA-QA-R&D misalignments (McKinsey, 2021).

MedTech: ~40% of device projects miss timelines due to cross-functional miscoordination.

✓ **RRL-Solution: Use joint RRL milestones with signoffs across RA/QA/R&D to catch gaps early.**

5. PREMATURE DELAYS

Pharma: Premature filings trigger ~6–12 month delays via CRLs and clock-stops (EMA 2022).


MedTech: Early 510(k)s extend to ~5–12 months due to AI loops (FDA 2022).

 **RRL-Solution: Predictive RRL risk score flags >40% risk → smart deferral before submission.**

6. INVESTOR SIGNAL MISSING

Pharma: No clear KPI exists for boards to monitor readiness/maturity before a failure.


MedTech: 18% of health startups cite regulatory/legal as reason for failure (CB Insights, 2023).

 **RRL-Solution: Use RRL dashboard to quantify de-risking and signal maturity progress to investors.**

7. STARTUP FAILURES

Pharma: 75%+ of biotechs fail to reach approval with first product (CB Insights, 2023).


MedTech: Most MedTech startups face QMS surprises; 18% fail due to regulatory/legal issues.

 **RRL-Solution: Use lean RRL stages with de-risked regulatory milestones per startup phase.**

8. NO BENCHMARK

Pharma: No benchmark system across CMOs or global sites for quality maturity (PharmaExec, 2022).


MedTech: Lack of maturity ratings for internal vs contract manufacturing (MDIC, 2022).

 **RRL-Solution: Rate each site/product via RRL scale → enable cross-site and CMO maturity comparisons.**

9. CHANGE CONTROL RISKS

Pharma: Poor change control causes compliance regression, triggers warning letters (FDA, 2022).

MedTech: Design/software changes often bypass QMS controls → drops maturity (IMDRF 2023).

 **RRL-Solution: Recalculate RRL after changes;
drops in score → trigger revalidation & QA review.**

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RRL-P™ (Pharma): First-Pass Drug Approval Model

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RRL-QMS® (MedTech): Device Clearance Predictive Model

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