



**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 1.4–3.4x.

## 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.

# Author & Contact

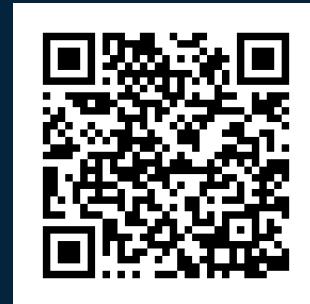
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**RRL-P™ (Pharma): First-Pass Drug Approval Model**

DOI: [10.5281/zenodo.1548664](https://doi.org/10.5281/zenodo.1548664)

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

DOI: [10.5281/zenodo.1546850](https://doi.org/10.5281/zenodo.1546850)