



## Quality as a number. *Continuous Quality Signals*

From reactive compliance to *measurable, predictable, AI-driven quality.*

### THE CHALLENGE

## Why quality leaders are reaching for AI solutions now.

**62%**

#### OF U.S. DRUG SHORTAGES

trace back to manufacturing quality issues. Traditional monitoring fails to catch drift. FDA's QMM initiative is the response.

**Largest**

#### OVERHEAD IN QUALITY

Thousands of audits run on schedule — fear of non-compliance overpowers a risk-based, predictive approach.

**AI Adoption**

#### NARROW & FRAGMENTED

AI is used as point tools for short-term productivity. Enterprise-scale AI that finds, predicts, and solves quality issues is still missing.

**Continuous**

#### QUALITY GAPS

Quality needs continuous monitoring — near real-time signals so teams act fast, not after the issue surfaces.

### THE REGLLER PLATFORM

## Four pillars. One AI engine. One quality number.

**01**

#### Regller Quality Score

Continuous AI-driven asset monitoring with a live score—across every site, building, lab, and asset.

**02**

#### Regller Audits

AI pre-checks, automated audits, and drillable risk dashboards. Aligned with regulatory and industry frameworks.

**03**

#### Regller Intelligence

Toolbox of fully trained, private, non-token-based AI models. Plug and play for continuous quality signals.

**04**

#### Regller Lab Optimizer

Lab resource management, qualification, scheduling and dynamic AI-driven rescheduling for resource productivity.

### THE BENEFITS

## Outcomes you will measure on the first cycle.

**5x Faster**

*Issue Detection*

**Up to 80%**

*Cost Reduction*

**50–60%**

*Productivity Gain*

**Always**

*Inspection Ready*

### REGLLER IS ENTERPRISE-GRADE AI SOFTWARE — NOT AN AI TOOL

Most AI products are tools, depend on user prompting. Regller's AI is pre-trained, runs in the background — reading documents, comparing systems, monitoring data, surfacing risks against the regulatory corpus. **Quality team fixes issues.**

## Regler Quality Score

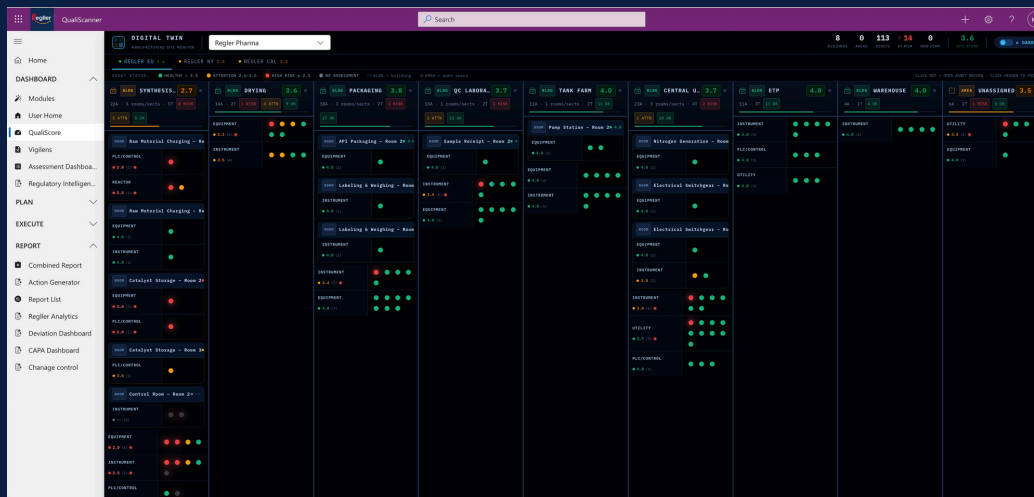
Continuous AI signals across every asset, site, and quality system.

## THE PROBLEM TODAY

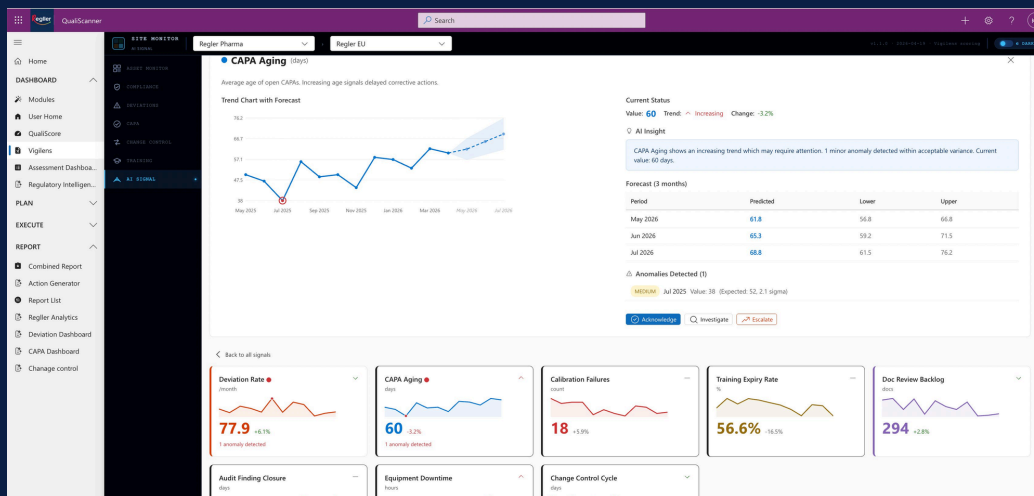
Quality is described in narrative, assembled through inspections. There is no live, comparable, quantitative score across sites that is measurable, and trackable. Drift between formal reviews goes undetected until next inspection.

## WHAT REGLER DELIVERS

A live 1–5 score per asset, lab, building, and site — updated from operational data, documents, systems, and historical audit information. Regler shows real-time quality signals, forecasts trends, detects anomalies, and predicts risks.



**PRODUCT VIEW:** Site Monitor — 8 buildings, 113 assets, 14 at-risk surfaced in real time. Drilldown views identify the exact issues dragging the quality score down.



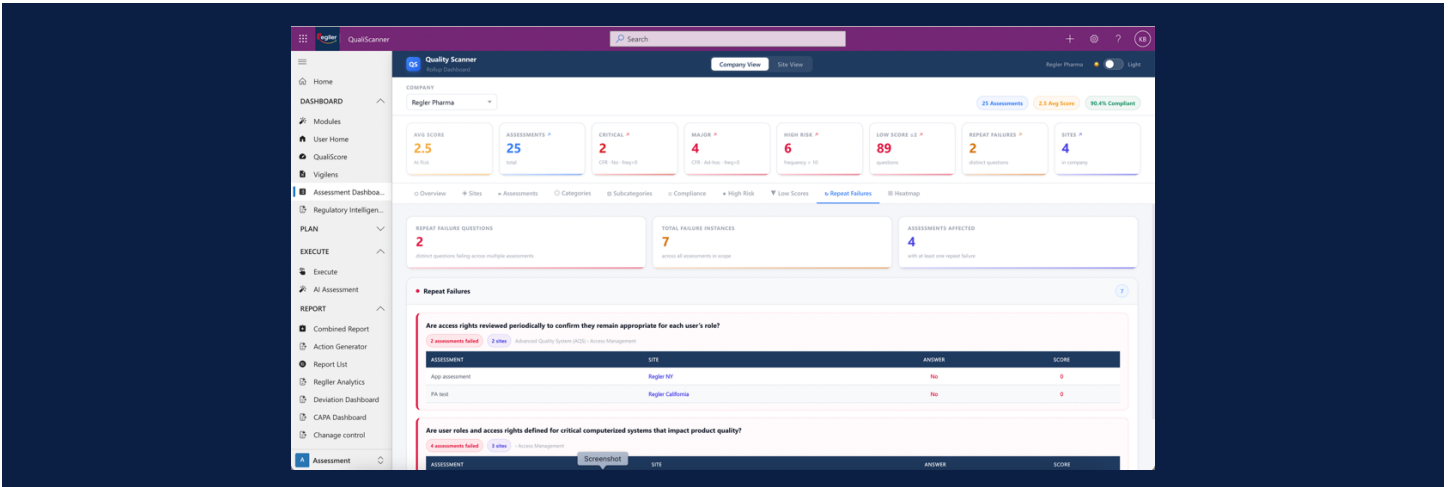
**PRODUCT VIEW:** Regler AI Signal — CAPA aging trended, 3-month forecast, anomaly flagged for triage. Similar views for deviation, change control, non-conformances, repeat issues, documentation gaps, and more.

**THE PROBLEM TODAY**

Audits are time-boxed; document review is sampled. Every audit lives in a different system. Repeat findings are hard to trace. Audits are people-dependent — no insight into FDA focus areas. Am I asking the right questions? Am I ready for the next agency audit?

**WHAT REGLER DELIVERS**

AI reviews documents against FDA, EMA, ICH Q10, and GAMP 5 guidelines before the audit. Every assessment uses a question library mapped to regulatory codes — the same references agencies use. High-risk areas, repeat findings, and FDA audit insights in every report.



**PRODUCT VIEW:** Regler Assessment- agency guideline driven questionnaires. Overall score, high risk areas, repeat findings, FDA inspection insights, action plans

**WHAT REGLER ASSESSES — EVERY AUDIT YOUR ORGANIZATION RUNS**

<p><b>FDA QMM</b> Quality Management Maturity across 5 FDA practice areas</p>	<p><b>FDA Pre-Inspection</b> Audit readiness, mock inspections, CFR gap analysis</p>	<p><b>21 CFR Part 11</b> Electronic records, signatures, computer systems validation</p>	<p><b>Vendor Qualification</b> Supplier audits, third-party risk, qualification packages</p>
<p><b>IT Security</b> Cybersecurity posture, controls, vulnerability assessment</p>	<p><b>SOX</b> Financial controls, Sarbanes-Oxley compliance assessments</p>	<p><b>Project Audits</b> Project stage-gate audits. Internal audits for projects</p>	<p><b>Internal Audit</b> Enterprise internal audit programs, control testing</p>

**THE DIFFERENTIATOR — RISK PREDICTION, REGULATORY INTELLIGENCE**

Most audit tools show you what you did. Regler shows what you're missing — with risk predictions powered by FDA data

▲ **CFR-CODE RISK HEATMAP**

See which CFR codes have most findings across the industry — and whether your assessments cover them.

■ **HIGH RISK MITIGATION**

Flag questions and categories with repeated FDA findings — areas at high risk of citation during inspections.

● **INSPECTION INTELLIGENCE**

Search FDA historical findings by CFR section, segment, or company type. Know what inspectors cite at companies like yours.

◆ **REPEAT-FINDING DETECTION**

Identify findings recurring across sites, business units, or audit cycles — the pattern regulators watch for.

03

P I L L A R

# Regler Intelligence

Plug-and-play AI toolbox. Built & validated once. Use everywhere without any prompts.

## Regler Army of Quality AI

A toolbox of fully trained, private, non-token-based AI models.

Plug and play — pick the tools your team needs today, layer in more as you scale.



### PROTOCOL DRAFTING

One-click generation of documents — SOP, URS, FS, IQ, OQ, PQ and other quality documents.



### DEVIATION PATTERN

Finds all deviations, performs trend analysis and predictions across sites.



### COMPLIANCE

Finds all non-conformances and OOS, with trend analysis and predictive insight.



### SCHEDULE INTELLIGENCE

Predictive schedule analysis and prediction of completion. Risk heat-map and what-if analysis.



### RISK SCORING

Risk assessment with predictive analytics. Weighted factor breakdown and FMEA support.



### DOCUMENT REVIEW & GAP DETECTOR

Document completeness analysis, comparison and risk against agency frameworks — FDA, EU, ICH, GAMP.



### TRAINING INTELLIGENCE

Training deviations, gaps, and correlations between training records and deviations.



### QUALITY SIGNAL MONITORING

Continuous score monitoring, anomaly detection, CAPA forecast and deviation forecast.

**AI PROTOCOL DRAFTING**

**AI RISK SCORING**

**AI DEVIATION PATTERN ANALYSIS**

**AI TRAINING INTELLIGENCE**

## IMPACT

INTELLIGENCE IN ACTION — Pre-trained, private AI tools. Pick what your team needs. Scale as you grow. Each AI tool can be used standalone or composed across workflows. Regler Intelligence scales with your team — not against your roadmap.

## Regler Lab Optimizer

Lab resources, qualified. Schedules, AI-driven. Capacity, unlocked.

### THE PROBLEM TODAY

Lab leaders report that operational overhead — not science — limits productivity. Reagents, equipment, consumables, calibrations tracked in silos. One disruption cascades across dependent tasks, costing days.

### WHAT REGLER DELIVERS

Every resource on one platform: equipment, reagents, operators, suppliers. AI-powered scheduling that maximizes utilization. Disruptions recovered in minutes — not days. GXP audit trails built in.

#### 1 MANAGE

*Every resource, one platform.*

- Equipment, reagents, samples, operators, consumables
- Lot-level inventory with expiry alerts and auto-reorder
- Calibration, maintenance, qualification, training lifecycle

#### 2 SCHEDULE

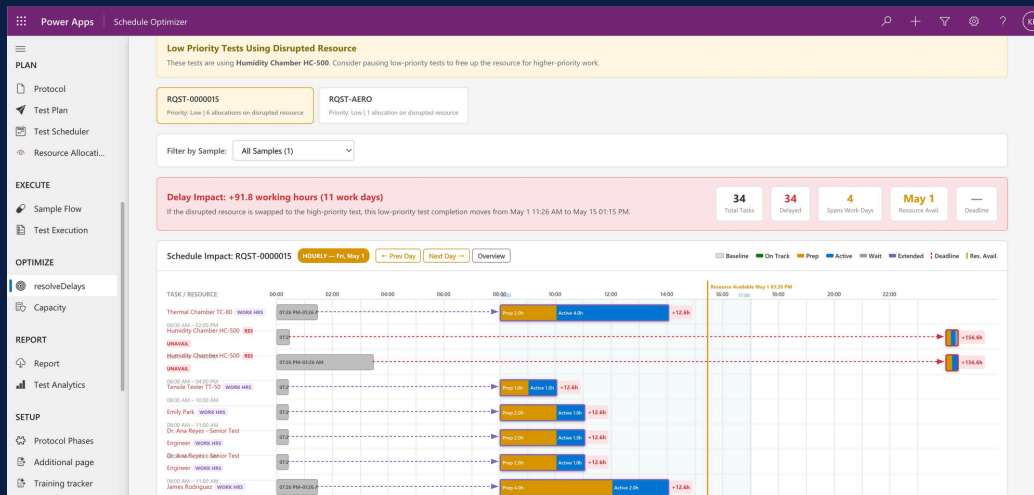
*AI-powered, always optimized.*

- Dynamic scheduling that maximizes resource utilization
- AI rescheduling when disruptions hit — recover in minutes
- Scenario analysis with quantified trade-offs

#### 3 OPTIMIZE

*More capacity. Always compliant.*

- Utilization dashboards reveal idle capacity
- GxP audit trails and chain of custody built in
- Continuous improvement: every cycle feeds smarter scheduling
- Time tracking to optimize protocols and task estimation



**PRODUCT VIEW:** Schedule Optimizer — AI finds best resources; flags low-priority tasks for swap; finds time saving opportunities; extended hours optimizations.

LET'S HAVE A CONVERSATION

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