REDICA WEBINAR • APRIL 2026

Quality Intelligence

What's new in the Redica Intelligence Cloud: connected site intelligence for decisions that matter.

Alison Sathe
SVP, Quality Intelligence

Yelena Ionova, PharmD
Sr. Manager, Data Strategy & Analytics

REDICA Systems

WHO WE ARE → WHO WE'RE BECOMING

REDICA Systems

Dashboards Are Done

Static, backwards-looking data is limited.

Redica built the most comprehensive database of inspection outcomes, enforcement actions, and regulatory compliance signals in the world. We are now transforming that unmatched data foundation into a living intelligence layer for quality teams, connecting every site, supplier, inspector, and product in a single knowledge graph. AI summaries and predictive signals power the decisions your teams make every day for supplier benchmarking, audit planning, portfolio monitoring, enforcement risk, embedded directly in the workflows where work happens.

01 VISIBILITY

Every site, every signal, one model

Inspections, enforcement, documents, observations and severity connected to one site identity across 10 health authorities

02 EXPLANATION

AI that interprets, not just counts

Plain-language narratives that connect interlinked events into a coherent risk picture.

03 PREDICTION

Leading risk indicators

Single-variable and convergent signals that anticipate enforcement and disruption.

WHAT'S NEW

What's powering the intelligence

Three layers of signal feeding scores, surfacing risk, supporting workflows.

Scored Risk Events

Critical, major, and minor event identification with threshold alerts. Risk scores based on confirmed inspection outcomes, enforcement actions, and post-inspection documents in real time.

Key Signals:

- Inspection outcomes (OAI, VAI, NAI)
- Warning Letters & Import Alerts
- 483 observation count & severity
- Temporal decay weighting

Risk Indicators

Signals detectable during or immediately after a site visit, before the outcome is classified. Based on observable inspection characteristics — who shows up, how long they stay, how quickly it closes.

Key Signals:

- Inspector expertise & career WL/OAI rate
- Inspection team size
- Inspection duration (days on-site)
- Time to close an inspection

Predictive Risk Models

Increasing probability of a specific negative outcome based on combinations of multiple variables, metadata, and leading indicators over time. Models produce an actionable risk score per inspection.

Key Signals:

- Warning Letter Risk Model
- CRL Risk Model
- Time to Next Inspection (in development)

New Data

From U.S.-centric inspection events to a globally normalized signal foundation.

FROM

Regulatory data, retrieved

- FDA, MHRA, EMA, Health Canada inspection and enforcement events and documents
- Document content provided, not analyzed
- First generation risk score
- Predictive signals bundled with retrospective outcomes

TO

A normalized intelligence foundation

- Expanded coverage: FDA, EMA, MHRA, Health Canada, MEB, MFDS, PMDA, WHO, Swissmedic, NDA
- Additional data: MRA, RRA, announced/unannounced
- Severity-classified observation text via Redica AI: 483 documents, MHRA, MEB severities from HA
- Predictive signals separated from score

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New Risk Scores

A credit score for site regulatory risk — interpreted, normalized, decayed.

FROM

Inspection Driven

V1 Risk Score

- Uncapped risk score limited benchmarking
- Strongest coverage on FDA; other authorities included at lower depth
- Limited document scoring
- Leading indicators bundled with retrospective outcomes
- No decay; events weighted equally regardless of recency

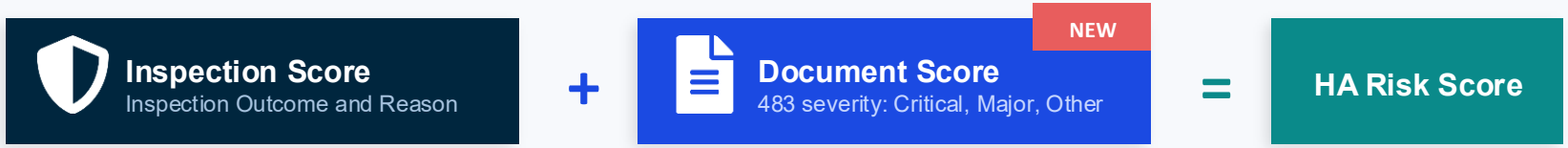
TO

Intelligence Driven

New Risk Score

- 0–100 scale, lower score indicates worse performance
- 10 health authorities, normalized to one scale
- Redica AI severity classification on observation text; interpreted, not counted
- Weighting and decay balances heavily inspected sites
- Predictive signals separated from the score; each does its job
- Linear decay after 2-yr grace; events negligible after ~7 years

How the Health Authority Risk Score is Now Composed



WHAT'S NEW

New Observation Severity

Every 483 observation, classified with Redica models grounded in PIC/S and validated by GMP experts.

Every observation, classified

CRITICAL

Significant risk to patients, or fraud / data integrity failure. ~5–10% of cited deficiencies.

OAI likely; may trigger WL or import alert

MAJOR

Non-critical but indicates major GMP deviation, or QP/QC duty failure. May produce non-compliant product.

Elevated enforcement risk; comprehensive action required.

OTHER

Departure from GMP not classified as Critical or Major. Requires investigation and correction but carries lower immediate risk of escalation.

Investigation and correction required; accumulation may escalate

WHAT THIS ENABLES

- **Triage at scale** — Surface Critical and Major findings across sites and networks without reading every page.
- **Risk benchmarking** — Compare severity profiles across sites, inspection cycles, and GMP systems.
- **Score input** — What feeds the HA Risk Score is interpretation, not just counts.
- **Document-level severity** — Critical/Major/Other classifications roll up to a document-level risk profile per inspection.

Observation severity is now available on 483s, MHRA and MEB inspection reports. Expansion to additional documents in process.

Leading Risk Indicators

Predictive signals separate from the score, ahead of enforcement events.

The risk score tells you where a site is today. Leading risk indicators surface from patterns indicative of risk.

SINGLE-VARIABLE

One signal, strong on its own.

Inspection Duration: Inspections lasting more than 6 days produce a significantly higher rate of critical and major findings

Time to Close: Time between an inspection's site-visit end date and its official closure is an emerging risk signal

Inspector Expertise: Investigators high rates of OAI and WL outcomes are systematically deployed to complex, targeted, or high concern inspections

Multi-Inspector: Inspections with larger teams reflects FDA resource allocation decisions – potentially indicating concern about a site's complexity or compliance posture

Time Since Last Inspection: Long gaps between FDA visits raise the risk of compliance drift over time.

Unannounced Visit: Regulator's choice to forgo notice often signals concern triggered by complaints, whistleblowers, or escalation.

MULTI-VARIABLE • CONVERGENT

Multiple signals, aligning.

WL Risk Model: A model combining multiple variable classes to produce an inspection-level risk score for Warning Letter issuance before the WL is issued. Includes site level metadata, inspection metrics and document contents to enable identification of WL risk.

CRL Risk Model: A model combining multiple variable classes to produce an inspection-level CRL risk score for a PAI inspection. Includes site level metadata, inspection metrics and document contents to enable identification of CRL risk.

CASE STUDY

Quality Intelligence

In the Real World

REDICA Systems

What this connected intelligence reveals when applied to a supplier portfolio and what teams do with it.

Site A

Human Drugs • Biologics • CMO

Agencies	FDA, HC, EMA, PMDA
Total Inspections	53
Form 483s Issued	17
App 1.0 Score	**Very Good**

Based on inspection metadata only

What the metadata shows: On paper, this site looks exemplary. Across recent inspection cycles, every inspection resolved as Minor risk — no OAIs, mostly Compliant or VAI outcomes. The App 1.0 framework rated this site "Very Good." But is that the full picture?

Date	Agency	Reason	Outcome	Risk
Sep 2025	FDA	Pre-Approval	483 + VAI / NAI	Minor
Apr 2025	PMDA	Pre-Approval	Compliant	Positive
Feb 2025	PMDA	Routine	Compliant	Positive
Jan 2025	EMA, HC	--	GMP Certificate Issued	Positive
Dec 2024	PMDA	Routine	Compliant	Positive
Nov 2024	FDA	Pre-Approval / Routine	No 483	Positive
Nov 2024	PMDA	Pre-Approval	Compliant	Positive
Sept 2024	PMDA	Routine	Compliant	Positive
Jul 2024	PMDA	Routine	Compliant	Positive
Jun 2024	PMDA	Routine	Compliant	Positive
May 2024	FDA, HC	Post-Approval	483 + Compliant	Minor
Feb 2024	PMDA	Pre-Approval	Compliant	Positive
Feb 2024	FDA	Routine	483 + VAI	Minor
Oct 2023	PMDA	Pre-Approval	Compliant	Positive
Jul 2022	FDA, HC	Routine	483 + Compliant + VAI	Minor
Jun 2022	EMA, HC	--	GMP Certificate Issued	Positive
Apr 2022	FDA	Pre-Approval	No 483	Positive
Nov 2021	FDA	Pre-Approval / Routine	No 483	Positive
Aug 2020	FDA	Pre-Approval	483	Minor
May 2019	FDA, HC	Routine	No 483 + NAI	Positive
Oct 2018	EMA	--	GMP Certificate Issued	Positive

Site A | Document Severity Reveals Hidden Risk

Human Drugs • Biologics • CMO

App 1.0

Very Good

Metadata only

▼ 2 levels

App 2.0

Average

+ document severity

Score Decomposition

Inspection Score: 100

Document Score: 51

Form 483 Observation Severity

483 Date	Critical	Major	Other	Doc Level
Sep 2025	0	1	0	Major
May 2024	1	3	0	Critical
Feb 2024	0	0	1	Minor
Aug 2022	1	3	0	Critical
Aug 2020	0	2	0	Major
Jul 2018	0	0	2	Minor
Nov 2016	0	2	2	Major
Dec 2015	0	0	3	Minor

Why the Score Shifted

Inspection Score = 100

No OAIs. Mostly compliant outcomes from FDA, HC, PMDA, and EMA. A few citations and VAIs from FDA.

Document Score = 51

Recent 483s contain Critical and Major observations — repeated across cycles.

The gap tells the story

Without reading the 483, this site appeared top-tier. The observation content reveals a fundamentally different risk profile.

Site A | What the 483 Observations Say

Why was the document classified as Critical or Major? Because of what the investigators noted during the inspection.

Major **Sept 2025 • Observation 1 • Facilities & Equipment > Equipment**

Equipment used in manufacturing isn't appropriately designed or maintained. Controls for Process Analytical Technology (PAT) system modifications and validation procedures for the spectroscopy system are inadequate. This led to the abortion of a PPQ batch due to out-of-limits predictions and critical deficiencies, including inadequate validation and change control.

"Your firm failed to establish adequate controls for Process Analytical Technology (PAT) system modifications and validation procedures for the spectroscopy system used in continuous manufacturing tablets. PPQ batch was aborted. Your firm's investigation documented critical deficiencies."

Critical **May 2024 • Observation 2 • Production > Sterile Products**

Procedures to prevent microbiological contamination of sterile drug products are not established or followed. Indirect product-contact parts aren't sterilized before assembly. Sterilized parts are exposed to lower-grade environments before installation. Operators contaminate sterilized parts with non-sterile gloves and equipment during filling operations, including interventions performed by maintenance.

"A. Indirect product-contact parts are not sterilized prior to assembly. B. Sterilized indirect product-contact parts are removed and exposed to the environments outside prior to loading and installation... C. The operator blocked (b)(4) to the stoppers with a non-sterile glove... the glove made direct contact with the stoppers... D. ... E. ... F. ... G. ...

Critical **Aug 2022 • Observation 1 • Production > Sterile Products**

Procedures to prevent drug product contamination are not followed. On <DATE>, personnel were observed not spraying gloved hands, inadequately disinfecting surfaces, and failing to properly sanitize their hands within the aseptic processing area. These deviations compromise the sterility assurance of drug products.

"An employee did not spray gloved hands prior to opening the unit. Although a sterile wipe was used in the left hand to grasp the forceps, the forceps were switched to the right hand to retrieve the stoppers. Prior to closing the door, an employee used a sterile wipe to clean the inside of the door. The wiping down did not ensure full coverage. An employee did not clean the entire hand."

The pattern: Repeated sterile processing failures directly observed by investigators across multiple cycles. Without reading the 483, this site appeared "Very Good." The observation content tells a fundamentally different story.

Observation text from FDA Form 483s • Site identifiers redacted • (b)(4) redactions are FDA's

Site B

Agencies	FDA, HC, EMA, PMDA
Total Inspections	39
Form 483s Issued	13
App 1.0 Score	**Poor**
	Metadata already flagged risk

What the metadata shows:

Unlike Site A, inspection metadata already raised alarms here. A **CRL was issued in Sep 2023** — a Critical risk indicator. A **For-Cause inspection in 2019** signals regulatory concern. 483s were issued in every FDA cycle since 2016.

App 1.0 rated this site "Poor." Does document severity confirm or change that picture?

Recent Inspection History

Date	Agency	Reason	Outcome	Risk
Jun 2025	PMDA	Post-Approval	Compliant	Positive
May 2025	FDA	Routine	483	Minor
Feb 2025	PMDA	Pre-Approval	Compliant	Positive
Nov 2024	PMDA	Pre-Approval	Compliant	Positive
Sep 2024	EMA	--	GMP Certificate Issued	Positive
Jul 2024	FDA, HC	Pre-Approval	483 + Compliant	Minor
Jun 2024	EMA, HC	--	GMP Certificate Issued	Positive
Sep 2023	EMA, HC	--	GMP Certificate Issued	Positive
Sep 2023	FDA, HC	Pre-Approval	**483 + CRL + Compliant + VAI**	Critical
Feb 2023	FDA	Routine	483 + VAI	Minor
Oct 2022	EMA, HC	--	Compliant + GMP Cert.	Positive
Jun 2022	FDA	Pre-Approval	483	Minor
Aug 2021	FDA, HC	Pre-Approval	483 + Compliant	Minor
Nov 2019	FDA, HC	Routine	483 + CFR + Compliant + VAI	Minor
Sep 2019	FDA	For-Cause	483	Minor
Jun 2018	FDA	Pre-Approval	483 + CFR + VAI	Minor
Jun 2016	FDA	Pre-Approval	483	Minor

Site identifiers redacted • Showing 17 of 39 inspections • Data from Redica platform

Site B | Document Severity Deepens the Signal

App 1.0

Poor

Metadata only

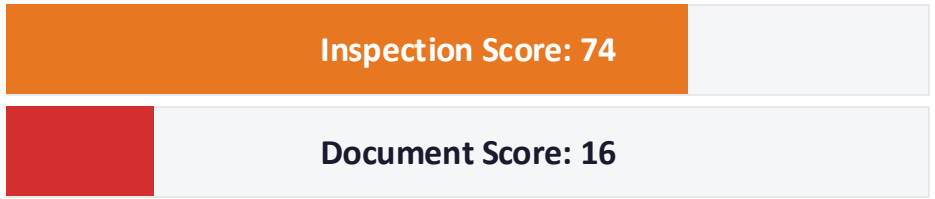
▼ 1 level

App 2.0

Well Below Avg

+ document severity

Score Decomposition



Form 483 Observation Severity

483 Date	Critical	Major	Other	Doc Level
May 2025	1	2	1	Critical
Jul 2024	2	5	1	Critical
Sep 2023	0	5	1	Major
Feb 2023	0	3	0	Major
Jun 2022	1	2	0	Critical
Aug 2021	0	1	1	Major
Nov 2019	0	1	0	Major
Sep 2019	0	0	3	Minor

Why the Score Shifted

Inspection Score = 74

Already flagged: CRL in 2023, For-Cause in 2019, persistent 483s. Metadata caught the pattern.

Document Score = 16

3 of the last 5 cycles classified as Critical. Jul 2024 alone had 2 Critical + 5 Major observations.

Severity confirms depth

The 483 content shows the risk isn't just frequent — it's severe. Critical findings across sterility, data integrity, and quality systems.

Site B | What the 483 Observations Say

Three recent 483s — three different facets of critical and major risk. This is what document severity scoring captures.

Critical **May 2025 • Observation 2 • Quality Unit > Inadequate | Data Integrity**

The Quality Control Unit's responsibilities and procedures were not followed, as evidenced by ongoing data integrity deficiencies since last inspection. Issues include falsification of documentation related to equipment and testing data, as well as the alteration of batch records without proper verification These deficiencies occurred despite the implementation of numerous CAPAs and change controls.

"Since the conclusion of the previous inspection, data integrity deficiencies have continued...during the investigation, it was revealed that the falsification was instructed by the manufacturing shift leader...the Quality Systems Director attempted to identify an employee who had anonymously reported a data integrity violation...a shift supervisor instructed manufacturing operators to change the documented lot and serial number without verification that the changed lot and serial numbers were correct."

Critical **Jul 2024 • Observation 1 • Production > Sterile Products**

Procedures to prevent microbiological contamination of sterile drug products are not adequately established or followed. Airflow visualization studies for the vial filling line failed to meet acceptance criteria, showing turbulence. Poor aseptic techniques were observed, including improper handling of equipment and materials, and deficiencies in environmental monitoring.

"A. Air flow visualization studies (smoke study) did not meet the acceptance criteria…Video footages show air turbulence... B. Poor aseptic techniques were observed during manufacturing…C. Aseptic processing system and procedures are not designed to prevent microbial contamination… D. Environmental monitoring of aseptic processing areas is deficient.

Critical **Jul 2024 • Observation 2 • Quality Unit > Reviews & Approvals | Data Integrity**

Deviation investigations into discrepancies from June 2022 to June 2024 for a drug substance, attributed mostly to human error, lacked thorough root-cause analysis of processes, equipment and systems. Recurring deviations, such as personnel and air viable monitoring excursions, were inadequately addressed, with insufficient CAPA.

"A. During 2022 to 2024, there were 181 deviations initiated. Your investigations attributed the root-cause for 95 (52.5%) out of these to human errors. Your firm failed to conduct adequate root-cause analysis. B. Deviation was initiated for an action level excursion of personnel monitoring (PM) samples. The deviation was deemed 'recurring', but classified as 'minor.' Only an 'awareness training' was given to the operator. C. No CAPA was taken to address the significant deviation from fundamental principle of GMP. D. EM OOT investigation was initiated...and was concluded with no root-cause identified. No CAPA was initiated. E. … F. …"

The pattern: Persistent data integrity issues, sterile processing failures, and systemic investigation breakdowns drive a 'well below average' document score.

Observation text from FDA Form 483s • Site identifiers redacted • (b)(4) redactions are FDA's

Leading Risk Indicators

Major & Critical Signals
FDA Inspections Since 2023

These signals suggest the regulator anticipated elevated risk before or during the inspection — and are associated with increased likelihood of adverse outcomes.

Site A	
May 2024 — 483 + CFR Citation + Compliant — Critical 483	
Critical	23 months to close inspection
Critical	Inspector with 30% OAI / 16% WL rate
Major	3 investigators assigned
Major	Inspector with 12% OAI/WL rate

Site B	
Sep 2023 — 483 + CRL Issued + VAI — Major 483	
Critical	6 investigators assigned
Critical	Inspector with 22% OAI / 12% WL rate
Critical	Inspector with 13% OAI / 23% WL rate

Other LRI Categories We Monitor

Signals not present in these particular inspections but monitored across every FDA inspection

Unannounced Visit

Major

No prior notice given to the facility

The facility had no opportunity to prepare. Operations are observed in their natural state — and the regulator's choice to forgo notice often signals concern triggered by complaints, whistleblowers, or escalation.

Long Duration on Site

Major Critical

Major: 11–14 days • Critical: 15+ days

An inspection that runs long signals the investigators are finding more issues to dig into. Extended on-site duration correlates with broader scope of findings and a higher likelihood of an adverse final outcome.

Time Since Last Inspection

Major Critical

Major: 3–4 years • Critical: 4+ years

Long gaps between FDA visits raise the risk of compliance drift over time. A site that has never been inspected carries inherent risk — there is no documentation of practices or facility state to baseline against.

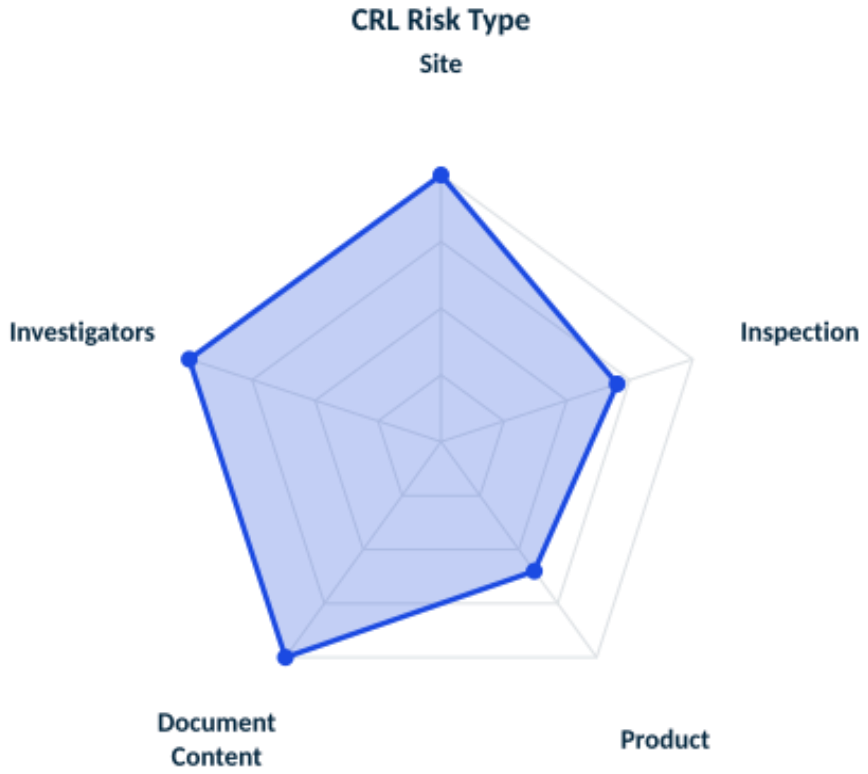
LRIs are predictive signals — they do not feed into the composite HA Risk Score

CRL Risk Prediction • Site B

Sep 2023 Pre-Approval Inspection

CRL Risk Score

1	Very High
	Moderate to High
	Moderate
	Low to Moderate
	Very Low



CRL Risk Factors

Risk Type	Risk Factors
Site	Redica HA Score – Well Below Average CMO / CDMO
Inspection	483 Issued
Product	NDA / BLA | Parenteral
Document Content	More Than 5 Observations Critical or Major Observations
Investigators	> 3 Investigators > 2 CRLs Investigator

Outcome: This Pre-Approval inspection — with 6 investigators, 5+ Major observations, a Well Below Average site score, and CMO / CDMO status — scored **Very High CRL Risk.** A Complete Response Letter was subsequently issued to the applicant. The CRL Risk model correctly predicted this outcome based on signals at the time of the inspection.

CRL Risk model evaluates Pre-Approval inspections for NDA/BLA applications

Two Sites. Two Stories. One Framework.

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Site A

Very Good → **Average**

Inspection metadata saw no problems.
Document severity uncovered repeated Critical and Major 483 observations hidden behind compliant outcomes.

Site B

Poor → **Well Below Avg**

Metadata already flagged risk — CRL issued, For-Cause inspection, persistent 483s.
Document severity confirmed: the findings aren't just frequent, they're severe.

It's not just whether a 483 was issued or whether the outcome was OAI, it's what the observations said and how critical they were.

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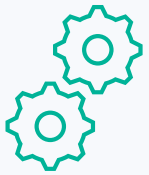
A New Way to Consume Intelligence

Four views. Same data. Different decisions. Different use cases.



Space

All Sites, All Risk Areas

Portfolio-level view. Start here to see your network.

Site Profile

Single Site, All Risk Areas

Every risk lens on one facility: snapshot, score, drill down.

Risk Area

All Sites, Single Lens

Compare sites through one risk lens: HA today, Post-Market and HSE in Q3.

Risk Area: Single Site

Single Site, Single Lens

Every event driving one score on one site for full visibility.

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LIVE

In the Application

WHAT'S NEXT

Where we go from here.

Three directions in flight. Hand-raisers welcome on any of them.

01

Veeva Vault Integration

Site intelligence lives where work happens: on the supplier record in your QMS. Redica ID ↔ Vault ID.

We're talking to early partners. Let us know if this fits your roadmap.

02

Bring Your Own Data

Pull your audits, deviations, CAPAs, and OTIF data into the same intelligence layer. Advanced insights using Redica and internal data.

Active implementations underway.

03

Self-Service AI Reports

Audit plans, supplier briefs, inspection prep generated on demand from the same connected data foundation.

Pilots in process.

If any of these resonate, your Redica account team can connect you with the right person on our side.

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Quality intelligence

at the point of decision.

Questions & Discussion

Follow up directly: your Redica account team • redica.com

Thank you