

iQM Quality Management

Quality decisions belong where the work happens.

Run change control, CAPA, deviations, complaints, risk, samples and tasks on the same orders, batches and suppliers they affect, standalone or connected to the systems you already run, with a risk file every module keeps current.



Customer overview

Solution, value model, pilot approach and detailed features

Industries

Regulated and non-regulated: pharma, biotech, devices, chemicals, food, cosmetics, semiconductors, aerospace, automotive, process, distribution and e-commerce, general manufacturing

Works with your systems

Standalone, or connected to Dynamics 365, NetSuite, SAP, Oracle and other ERP, MES and LIMS systems

Contents

What's inside.

	Who this document is for	03
	Is iQM a fit?	04
	What deciding on iQM involves	05
	Three questions every decision has to answer	06
	What changes, what doesn't, and how you stay in control	07
01	The case for ERP-native quality	12
02	What iQM does	19
03	How each industry benefits	36
04	How value is created and proven	40
05	How customers start	51
06	Features by topic	63
	Sources and definitions	89

Who this document is for

Written for everyone who has a say in a quality decision.

Quality decisions cross quality, operations, regulatory, supply chain, engineering, finance and IT, so this overview is written for all of them. Start with the pages that answer your question, then read on to see how the pieces connect.

If you lead	You will want to know	Start with
Quality and compliance VP Quality, Head of QA, QA managers	How changes, CAPAs, deviations and complaints stay controlled and connected	The case for ERP-native quality; Trust is part of the product; CAPA
Manufacturing and operations Plant directors, production managers	How quality events tie to the orders, batches and stages they affect	A connected decision; Deviations; Samples
Regulatory affairs Regulatory and compliance leads	How policies, regulations and signed records are governed	Complaints; Trust is part of the product; Questions buyers ask
Supply chain and supplier quality Procurement, supplier quality managers	How supplier-caused defects become claims and corrective action	Four ways to create value; Complaints; Samples
Risk, reliability and quality engineering Quality engineers, FMEA and risk owners	How complaints, deviations, CAPA, samples and changes keep the risk file current	Risk at the center; How a risk stays current; Risk
Finance CFO, controllers	How change cost is controlled and quality costs are recovered	A worked business case; Change Control
Industry and business-unit leaders General managers, site heads	What iQM does for your industry, module by module	How each industry benefits; Industry applications
IT and enterprise platforms CIO, ERP and platform owners	Where iQM runs, how it connects to your systems, and who can do what	Standalone, connected or both; What iQM understands from your systems; Questions buyers ask

Each chapter divider lists the pages in that chapter. Every feature, with what it does for your team and the industries it serves, is in chapter 06, Features by topic.

Is iQM a fit?

A quick, honest check before you spend time on an evaluation.

iQM works for regulated and non-regulated companies, standalone or connected to the systems you already run. **It is a strong fit when the problem is context, follow-through or cost, and a poor fit when the real gap is somewhere else.** Not every quality problem needs new software, and not every one needs AI.

Signs iQM will help

Context is re-keyed	Investigators rebuild batch, order and supplier details from other systems before they can start.
Supplier costs are absorbed	Defects caused by suppliers or carriers are found, but claims are rarely filed or recovered.
Fixes do not reach the process	CAPAs close, but the change that removes the cause is handled by email or not at all.
The risk register is out of date	Risks are reviewed in meetings, not updated by what actually happens.
Several systems, one quality picture wanted	Sites run different ERPs, or quality lives in spreadsheets beside the ERP.
An inspection, audit or customer review is coming	You need records an outsider can follow end to end.

Signs to wait, or start elsewhere

You need a LIMS, document control or training system first	iQM connects to those systems; it does not replace them. Start there, then connect iQM.
There is no one to own the process	A pilot needs a named process owner and a few hours a week from the quality team.
Your current process works and nobody feels the cost	If there is no visible cost or risk to fix, wait until there is one worth measuring.

Recognize three or more signs on the left? A one-hour walkthrough of your current process is usually enough to tell whether a pilot is worth it.

What deciding on iQM involves

Four small decisions instead of one big one, each made on evidence you can inspect.

Step	What you decide	Evidence you will have	Your commitment
1 Walkthrough One to two hours	Whether iQM addresses a real problem in your process	Your team shows us how the work runs today and what must not break	None
2 Discover About two weeks	Site, process family, owner, success and failure criteria	A pilot charter, measured baseline and one-page risk register	Your team's time only
3 Pilot About ten weeks	Whether to move up each stage of the autonomy ladder	Results on your own records against the baseline, and a backtest on your history	Pilot terms agreed in your proposal
4 Roll out Your pace	Which processes and sites come next	A readout, a value report and a rollout case Finance has reviewed	Only after the pilot result is accepted

What it takes from your team

Process owner	A few hours a week through the pilot
Quality team	A few hours a week for real records and feedback
Finance contact	Baseline agreement at the start; review at the readout
IT and platform owner	Access for read-only connection, single sign-on and roles; a test environment

You can stop after any step and keep everything you have learned. Nothing changes in your systems of record unless you decide it should.

Timings are typical and confirmed in Discover. Pricing and pilot terms are set out in your proposal.

Three questions every decision has to answer

A quality system earns its place only when it answers all three questions, for everyone who has a say.

We have learned that a good decision needs more than a strong demo. It needs proof in your own data, a real improvement for the people doing the work, and **a clear answer to what happens when something goes wrong**. This overview is written to answer all three.

What is possible?

For leaders who want to modernize and need results they can show.

What iQM gives you

- A pilot that runs real records within weeks
- Value measured in your own numbers, agreed with Finance
- A clear picture of what comes next, stage by stage

Show results on your own data before anyone commits to more.

Start with: The autonomy ladder; Four ways to create value; A pilot built around a measurable result

Will this make the work easier?

For the people who run investigations, approvals, inspections and follow-up every day.

What iQM gives you

- Batch, order, supplier and SOP filled in from your systems
- One task list across every module and system
- Capture from the floor or a phone; forms sized to the job

The context is already on the record when you open it.

Start with: What iQM does with that context; What each role sees and decides; Features by topic

What could go wrong, and who owns it?

For the people who protect your systems, your compliance and your budget.

What iQM gives you

- Your current process stays intact; iQM works alongside it
- Read-only until you say otherwise; you approve every stage
- Every action audited; your cloud; full export; a written risk register for the pilot

Read-only until you say otherwise. You decide when it acts.

Start with: What changes, what doesn't, and how you stay in control; Hard questions, answered plainly

What changes, what doesn't, and how you stay in control

Works alongside the systems you already run. Read-only until you say otherwise. You decide when it acts.

If we were in your seat, we would worry about three things: validation impact, support burden and data leaving your environment. Here is how each is handled, before you have to ask. **The process your team built is the foundation; iQM is added on top of it.**

What does not change

Your ERP and other systems stay the systems of record. Your existing quality process, including the flows your team built and maintains, keeps running. iQM is added alongside it: wrap first, replace later, if ever.

How you roll back

Any stage can be stepped back or switched off by your approver, without losing records. Write-back to your systems is enabled object by object, and can be disabled the same way.

Who approves what

A named owner on your side approves every stage gate. People accept or reject every suggestion. AI, where enabled, never approves, closes or signs a record.

What changes, stage by stage

You move up the autonomy ladder only when the criteria you set are met: Observe, then Advise, then Assist, then Act. Stopping at any stage is a legitimate outcome.

Where the data lives

In your own cloud tenant (for example your Azure subscription) or the Zeak cloud, your choice. Connected-system data stays in those systems; iQM keeps live links and a snapshot at the time of each event. Everything exports in open formats.

What it means for validation

Validation scope follows what you put live, stage by stage. A validation accelerator (requirements traceability, IQ/OQ/PQ templates, test evidence) reduces the effort.

What we will not ask you to do

- Replace your ERP or the process your team built
- Move your master data
- Sign a long commitment before the pilot result
- Accept a business case built on headcount reduction
- Turn on AI, or move past Observe, before you are ready

The autonomy ladder

Automation is a staircase you control, not a leap.

Every capability in iQM that suggests, pre-fills, automates or writes to your systems has a stage, set by you, per site. **You set the criteria for moving up. Stopping at any stage is a legitimate outcome.**

1

Observe

Read-only and in parallel. iQM watches your existing process and connected data, and changes nothing.

Your process runs exactly as today.

2

Advise

iQM suggests values, flags risks and proposes links. People accept or reject every suggestion, and every decision is logged.

Nothing is committed without a person.

3

Assist

iQM pre-fills records and drafts actions, with human approval before anything is committed or written to your systems.

You approve before anything is saved.

4

Act

Automation for routine, well-proven cases only. Exceptions route to people.

Only what you have switched on.

Your named approver signs off each move up, and can step back or switch off at any time, without losing records.

Every stage change, suggestion, acceptance and rejection is audited.

Most quality value comes at Observe and Advise. Many customers never need Act, and that is fine.

At a glance

The problems iQM solves, and how you can check each one.

These are the quality issues we hear first, regulated or not. For each, here is what changes and the measure that proves it on your own records. **Nothing here depends on trusting us: every measure comes from your data.**

1

Quality events live apart from the work

Today: Deviations and complaints sit in spreadsheets, paper or a separate system, disconnected from the order, batch and supplier.

With iQM: Raised on the same orders, batches, lots and suppliers they affect, with the context captured when it happens.

Proof you can check: Share of events linked to their order, batch or supplier

2

Investigations take too long, across too many teams

Today: Quality, production, supply chain and suppliers pass the record around by email.

With iQM: Owned tasks, due dates and escalations, one queue per stage, every team working on the same record.

Proof you can check: Deviation and CAPA cycle time

3

The same problem keeps coming back

Today: A local fix never reaches the process, the specification or the supplier.

With iQM: CAPA linked to the cause, governed change control and effectiveness checks.

Proof you can check: Repeat deviations after a CAPA

4

Proving compliance takes days

Today: Evidence for an audit or inspection is assembled by hand.

With iQM: Electronic records and signatures where required, an append-only audit trail and exportable evidence.

Proof you can check: Hours to produce evidence for a sample

5

One workflow does not fit every product

Today: Sterile and non-sterile, raw material and finished goods, all forced through the same steps.

With iQM: Every workflow configured by product category, transaction type, site and severity, without code.

Proof you can check: Workflows configured, and changed, without a release

6

A risk register nobody trusts

Today: Risk files are updated once a year, if at all.

With iQM: A risk file every module keeps current from live deviations, complaints and changes.

Proof you can check: Risks updated from live events

1

Deviation management

2

Complaints management

3

CAPA management

4

Change control

5

Risk management

6

Task management

7

Sample management

At a glance, continued

Configured to your products and your transactions.

Every iQM workflow follows the way your company works. Administrators configure each workflow by **product category**, **transaction type**, **site** and **severity**, without code, and every configuration change is versioned and approved.

Workflow	Configure by product category	Configure by transaction type	What changes with the configuration
Deviation management	Raw material, intermediate, finished good, sterile, device	Production order, batch, purchase receipt, transfer, test result	Classification, severity, investigation steps, approvers, due dates, signatures
Complaints management	By product family and market	Sales order, shipment, return, field service	Intake form, reportability check, investigation route, response deadlines
CAPA management	By product category and risk	Source record: deviation, complaint, audit, supplier	Root-cause method, action templates, effectiveness check, approval chain
Change control	By product, process, document or equipment type	Specification, BOM or formula, supplier, site, label	Impact assessment, affected items, approvers by department, implementation tasks
Risk management	By product family and process	Any linked event or change	Scoring scale, risk file template, review frequency, escalation thresholds
Task management	By process and site	Any record or transaction	Task templates, owners, due-date rules, reminders, escalation
Sample management	By material category and test plan	Purchase receipt, production, inventory, sales order	Sampling plan, quantities, stability pulls, results routing

Example. A deviation on a production order for a **sterile** product routes to QA and the production head, needs a root cause in 5 days and an electronic signature at closure. The same deviation on a **non-sterile** product routes to the area supervisor with a 10-day target. One workflow, two configurations, both on the record.

What you can configure

Forms and required fields · categories and types · numbering · approval routing · electronic signatures · due dates and service levels · task templates · effectiveness checks · risk scoring · notifications · links to documents and training.

At a glance, continued

Built to support the standards you're held to.

iQM follows your procedures and supports the external standards that apply to your industry and markets. **Compliance is your organization's obligation; iQM produces the evidence.**

Area	Frameworks and standards	How iQM supports them
Quality systems	ISO 9001 · ISO 13485 and the FDA Quality Management System Regulation · IATF 16949 · AS9100	CAPA, controlled change, document and training links, traceability
GMP and GxP	FDA cGMP (21 CFR 210/211) · EU GMP · ICH Q9 quality risk management · ICH Q10 pharmaceutical quality system	Deviations, CAPA, change control and risk on the batch
Electronic records and signatures	FDA 21 CFR Part 11 · EU GMP Annex 11 · ALCOA+ data integrity	Attributable, time-stamped records; signatures with meaning; append-only trail
Risk standards	ISO 14971 (medical devices) · AIAG and VDA FMEA (automotive)	Risk files and FMEAs kept current by live events
Food and consumer products	FSMA and food traceability rules · GFSI schemes · ISO 22716 cosmetics GMP · MoCRA adverse events	Complaints, holds and traceability on the lot
Financial controls	SOX · J-SOX, where quality events change inventory value, write-offs or supplier claims	Approvals, segregation of duties and audit evidence on financial impact
Security and privacy	SOC 2 and ISO 27001 controls · GDPR	Deployed in your cloud, under your identity and access controls

Supported through configuration; applicability depends on your industry and markets. Not a claim of certification. Regulated use requires use-case-specific configuration and validation, confirmed with your quality team. Confirm regulation names and dates with your compliance team.

01

The case for connected quality

The quality failures that cost the most, in every industry, are the ones where nobody could see what was affected in time. Keeping quality next to the transaction is how that context stays intact.



What the research says
What leading research says now
What the research says, module by module

Where quality context leaks
The cost of reconstructing context

What the research says

Quality failures stop supply, cost margin and reach customers, in every industry.

Every industry

15-20%

of sales revenue is commonly lost to the cost of poor quality.
ASQ⁶

Every industry

3.7 years

average interval between supply disruptions lasting a month or more.
McKinsey Global Institute¹⁷

Automotive and semiconductors

\$210B

in automotive revenue estimated lost in 2021 to the semiconductor shortage.
AlixPartners²⁶

Aerospace, defense and electronics

1,800+

cases of suspect counterfeit electronic parts, over one million parts, found in the US defense supply chain.
US Senate Armed Services Committee²⁵

Semiconductors

~50

points in the semiconductor supply chain where one region holds more than 65% share.
BCG and SIA¹⁹

Distribution and e-commerce

\$743B

of merchandise returned to US retailers in a single year.
NRF and Appriss Retail²⁷

Food and consumer goods

\$10M

average direct cost of a food recall, before brand damage and lost sales.
FMI and GMA³

Life sciences

\$26-36B

estimated annual cost of poor quality in medical devices.
McKinsey & Company⁵

What this means

Whether it is a wafer lot, a flight-critical part, a returned order or a drug batch, the expensive part is the same: finding out what was affected, who received it, which supplier caused it and whether the fix worked. When that context lives in a different system from the work, it is rebuilt by hand, late and inconsistently.

Where iQM fits

iQM keeps the CAPA, the complaint and the deviation on the same records as the lot, the order and the supplier, in your systems or in iQM, so the context is captured when the event happens, not reconstructed when a customer, auditor or inspector asks.

External figures describe results reported by other organizations. They are not iQM results and are not a forecast for any customer. Full sources on the last page.

What leading research says now

The leaders treat quality as connected data and risk, not as a stack of forms.

Management consultancies, standards bodies and industry groups describe the same shift: quality moves from reviewing records after the fact to managing risk with live operational data. Six findings shape how iQM is built.

Poor quality is expensive, and mostly avoidable

Cost of poor quality is commonly put at 15 to 20 percent of sales revenue in many organizations.⁶ McKinsey estimated poor quality costs the medical-device industry \$26 to 36 billion a year, much of it from non-routine events such as recalls and remediation.⁵

So iQM measures cost of poor quality from your ledger.

Quality 4.0 is a data and process problem first

BCG and ASQ found that Quality 4.0 programs stall on people, process and data more than on technology, and progress where quality is tied to business outcomes.⁷

So iQM starts with one process, one site and one measure Finance agrees.

Smart quality runs on connected records

McKinsey describes "smart quality" in pharma and medtech as connected, structured data with automation and analytics replacing manual review.⁸ Deloitte's smart-manufacturing research puts data foundations and integration ahead of tools.⁹

So iQM keeps every record on live records in your ERP, MES and LIMS, through connectors for any vendor.

Close the loop from field to process

Accenture's digital-thread work connects field and service experience back to engineering, process and supply.¹⁰ ISO 14971 and ICH Q10 ask the same of the risk file and CAPA.¹²

So iQM lets complaints, deviations and CAPA results update risk.

Supplier risk is quality risk

Bain's supply-chain research treats supplier concentration, notably in semiconductors, as a structural risk.¹¹ ICH Q9(R1) now names product availability as a quality-risk concern.¹²

So iQM brings supplier scores and supply-continuity risk into the same register.

Rigor should match risk

ICH Q9(R1) asks for formality proportionate to risk; ISO 9001 builds risk-based thinking into every process; IATF 16949 and the AIAG-VDA FMEA tie process risk to control plans.¹²¹³¹⁵

So iQM scales change classes, approvals and evidence to the risk.

Findings are summarized from the cited publications and standards and describe direction, not iQM results. Full sources on the last page.

What the research says, module by module

Each module addresses a cost or a risk that research has put a number on.

Module	Metric	What the research found
Change Control	90 days	minimum advance notice JEDEC JESD46 expects before a semiconductor supplier implements a major product or process change ²⁴
CAPA Management	Top 2	CAPA and complaint handling: the two most-cited quality-system sections in FDA device inspections ²
CAPA Management	\$26-36B	estimated annual cost of poor quality in the medical-device industry (McKinsey) ⁵
Deviation Management	\$210B	automotive revenue estimated lost in 2021 when semiconductor supply failed (AlixPartners) ²⁶
Deviation Management	62%	of US drug shortages studied followed manufacturing or product-quality problems (FDA) ¹
Deviation Management	15-20%	of sales revenue: common cost of quality in many organizations (ASQ) ⁶
Complaints Management	\$743B	of merchandise returned to US retailers in a single year (NRF and Appriss Retail) ²⁷
Complaints Management	5% to 25-95%	a 5% rise in customer retention can lift profits by 25% to 95% (Bain & Company) ¹⁶
Complaints Management	\$10M	average direct cost of a food recall, before brand damage (FMI and GMA) ³
Task Management	28%	of a knowledge worker's week spent on email, and 19% searching for and gathering information (McKinsey Global Institute) ¹⁸
Risk Management	3.7 years	average interval between supply disruptions lasting a month or longer (McKinsey Global Institute) ¹⁷
Risk Management	40%+	of a year's profits companies can expect to lose to disruptions over a decade (McKinsey Global Institute) ¹⁷
Risk Management	~50	points in the semiconductor supply chain where one region holds more than 65% share (BCG and SIA) ¹⁹
Sample Management	1,800+	cases of suspect counterfeit electronic parts found in the US defense supply chain, the kind incoming inspection exists to stop (US Senate Armed Services Committee) ²⁵
Sample Management	24 hours	to give FDA sortable traceability records on request under the Food Traceability Rule ²³
Platform, compliance and connectivity	10-12%	gains in output, capacity utilization and labor productivity reported by smart-factory adopters (Deloitte and MAPI) ²⁰
Platform, compliance and connectivity	94%	of Fortune 1000 companies saw supply-chain disruption early in the COVID-19 pandemic (Accenture research, as reported) ²¹

Figures are reported by the organizations cited and are not iQM results or forecasts for any customer. Full sources on the last page.

Where quality context leaks

A quality event is only closed when the fix works, and context leaks at every step on the way.

Quality issues travel through seven steps. At each one, context slips away quietly: into an inbox, a spreadsheet or a system the next person cannot see. Nobody is careless. The leaks happen because the quality record and the operational record live apart.

1 Detect An issue is noticed and reported.	2 Record The event is captured with its context.	3 Investigate The cause and scope are found.	4 Decide The right people approve a response.	5 Act The fix is made and governed.	6 Verify The fix is proven to work.	7 Learn The same issue does not return.
Stage	Where it leaks	How you'd spot it		How iQM catches it		
1 Detect	Complaints counted in service but not in quality.	- Complaints arrive by phone and email and wait to be logged - Supplier defects found at receiving are handled informally		- Complaint intake with category and owner - Samples from purchase orders at receiving - Intake from service and web channels		
2 Record	Records that name batches the ERP has never heard of.	- Product, batch and order typed in by hand, or not at all - The SOP version in force is not recorded		- ERP transaction, product and batch on deviations - SOP number and revision in force - Products linked to complaints		
3 Investigate	Investigations measured in weeks.	- Investigators rebuild context across systems - Supplier involvement found late		- Dedicated investigation details - Vendor and carrier on the complaint - Structured root-cause analysis		
4 Decide	Decisions that exist only in an inbox.	- Approvals by email, by whoever is available - Change cost unknown at approval		- Department approval routing - E-signature on CAPA approval - Budget control on changes		

Where quality context leaks, continued

A quality event is only closed when the fix works, and context leaks at every step on the way.

Stage	Where it leaks	How you'd spot it	How iQM catches it
5 Act	CAPAs closed before the change is made.	■ CAPA completed, but the process change never governed ■ Follow-up tasks in personal lists	■ CAPA, deviation and risk linked to Change Control ■ Shared, source-aware task list ■ Tasks for every quality process
6 Verify	Recurring events with closed CAPAs.	■ Closed without checking the fix worked ■ Supplier costs never claimed	■ Verify step before change closure ■ Vendor, transport and third-party claims ■ CAPA effectiveness verification
7 Learn	Repeat findings in consecutive inspections.	■ The same deviation recurs at another site ■ Trends invisible until an audit	■ Queues and keyword search across records ■ Complaint trending ■ Recurrence detection ■ Signals that update the risk file

Every leak on these pages sits in data you already own in your ERP and plant systems. iQM keeps the quality record on the same transactions, so the context is captured once and travels with the case.

Capabilities are described in chapter 06. Availability by release is confirmed in your proposal.

The cost of reconstructing context

Context rebuilt by hand is the slowest step in most quality investigations.

Time spent finding information

19%

of a knowledge worker's week goes to searching for and gathering information.

McKinsey Global Institute¹⁸

Disruption cost

40%+

of a year's profits companies can expect to lose to supply disruptions over a decade.

McKinsey Global Institute¹⁷

Customers kept

25-95%

profit increase from a 5% rise in customer retention, which depends on resolving problems well.

Bain & Company¹⁶

What slows the response

Nobody can answer quickly which lots, orders and customers an event touches, which revision or specification applied, whether the supplier has been told, and whether a change is already under way. Each answer lives in a different place, whether that is an ERP, a MES, a spreadsheet or an inbox.

What changes with iQM

The transaction, product, lot, revision, supplier and related change are already on the record. The first question becomes "what do we approve?" rather than "what does this affect?"

02

What iQM does

A quality-management suite that runs standalone or connected to your systems. It answers four questions on the record itself: what happened, what it touched, what we are doing about it, and who approved it.



The right tool for each problem

When you don't need AI

What iQM covers

Standalone, connected or both

What iQM understands from your systems

What iQM does with that context

A connected decision

Risk at the center

How a risk stays current

Seven capabilities, seven answers

What each role sees and decides

Industry applications

What each industry needs

The right tool for each problem

Most quality problems are solved by connected records, controlled values and governed decisions.

Quality findings rarely come from a lack of software. They come from gaps: a deviation that doesn't name its batch, a complaint whose supplier cost is never claimed, a fix that is never governed as a change.

1

Connect the record

Put the quality event on the transaction it affected.

Deviation on the batch

Production order, product, batch and stage on the deviation.

Complaint on the product

Item, group and type linked, not typed.

Sample on the order

Quality, production, purchase, inventory or sales order.

Use it when: The context exists in your ERP but is re-keyed into quality.

2

Control the values

Let people choose from lists you govern.

Reason and cause codes

Trendable from day one.

Approved policies and regulations

Referenced only once approved.

Defaults and required fields

Title, reason, category and quantity where they matter.

Use it when: Reports disagree because people describe things differently.

3

Govern the decision

Route each decision to the right approver and record it.

Department routing

Single or multi-stage, with named approvers.

Signed CAPA decisions

E-signature on approval and closure.

Budget control

Overrun policy and override groups.

Use it when: Approvals happen by email, or by whoever is available.

4

Close the loop

Connect the event to the fix and the follow-up.

Into Change Control

From CAPA, deviation and risk.

CAPA from complaints

With the source recorded.

Shared tasks

Owned, dated and tied to the source.

Use it when: The issue is known, but the fix is not governed.

Not every quality problem needs AI. Connected records, controlled values and governed decisions are where most of the value is. Where you enable AI assistance, it only suggests, and a named person reviews every suggestion before anyone acts.

When you don't need AI

Not every quality problem needs AI. Most need connected records, controlled values and clear decisions.

Problems iQM solves without AI

The problem	What solves it
Context re-keyed between systems	Connect the record to the transaction. No AI needed.
Reports that disagree	Controlled reason codes, categories and required fields. No AI needed.
Approvals by email or by whoever is free	Department routing, change classes and signatures. No AI needed.
Fixes that never reach the process	CAPA linked to governed change, with effectiveness checks. No AI needed.
Supplier costs absorbed	Claims recorded on the complaint with the evidence attached. No AI needed.
Follow-up that slips	One task list with owners, due dates and reminders. No AI needed.

Where AI can help, with a person deciding

The situation	What AI does
Sorting a high volume of free-text complaints, reviews and returns	Suggested classification and duplicate grouping, reviewed by a person
Finding similar past cases for an investigator	Ranked suggestions with the reasoning shown
Spotting weak patterns across many records	Emerging-risk suggestions for a risk owner to accept or reject

AI is off until you switch it on. It starts at Observe or Advise on the autonomy ladder, shows its reasoning, and never approves, closes or signs a record.

What iQM covers

Seven modules and one platform layer, for any industry and any system.

Modules	Features	Industries	Systems	Into change	Audit
7 quality processes, plus a shared platform layer	197 described in chapter 06	12 regulated and non-regulated, with starter configurations	Any standalone or connected ERP, MES, LIMS, PLM	3+ CAPA, deviation and risk raise governed change	Every transaction and update is audited
Module	What it is for				
Change Control	A quality change process separate from engineering change: request, review by the right department, implement, verify and close, with change classes for regulated and non-regulated sites and budget control where you need it.				
CAPA Management	Every CAPA carries its source, the transaction behind it and the controlled change that delivers the fix, with 8D and other methods, containment and effectiveness checks.				
Deviation Management	Deviations, nonconformances, OOS results and excursions recorded against the real transaction, product and batch, dispositioned and connected to the change that removes the cause.				
Complaints Management	External, internal and other complaints linked to products, suppliers, carriers, regulations, corrective action and tasks, with claims, reporting clocks and recalls.				
Task Management	Tasks on any iQM record or any transaction in a connected system, such as a batch, sales order or purchase order, each showing where it came from.				
Risk Management	One living risk file on items, processes, sites and suppliers: matrix, FMEA, ISO 14971 or HACCP methods, fed by signals from every module and raising governed change.				
Sample Management	Samples from quality, production, purchase, inventory and sales orders on one lifecycle, sample orders with or without cost and shipping, environmental monitoring and certificates of analysis.				
Platform, compliance and connectivity	Standalone or connected; an audit trail on every transaction; e-signatures, data integrity and validation; traceability, cost of poor quality and industry packs.				

Availability of each feature by release is confirmed in your proposal and verified during the pilot.

Standalone, connected or both

Use iQM on its own, or connect it to the systems you already run. Change your mind later without starting over.

Zeak is platform and system independent. iQM is not an add-on to one ERP: it is a complete quality system that can stand alone, and it becomes context-aware the moment you connect it to Dynamics 365, SAP, NetSuite, Oracle or whatever else you run.

Start standalone

iQM holds its own items, lots, suppliers, customers, sites and orders. A team can be running in days, with no integration project.

For: a first site, a non-regulated team, a business without an ERP, or a pilot that must not touch production systems.

Connect to what you run

iQM links live to the records in your ERP, MES, LIMS, PLM, CRM or commerce platform. Start read-only; switch on write-back object by object when you approve it.

For: plants and distribution centers that already run on an ERP and want the context on every quality record.

Mix across the enterprise

One quality system across sites that run different systems: a plant on D365, a distribution center on NetSuite, an acquired business on SAP, a small site standalone.

For: multi-site, multi-ERP and acquisitive companies that want one quality picture.

Want to start now? Begin this month, standalone, and show results before any integration is approved.

Responsible for your systems? Your ERP stays the system of record; connect read-only first; every write-back needs your approval.

Doing the work? Connected or not, the screens and the work are the same; connected, the context fills itself in.

What iQM understands from your systems

If your system holds it and you authorize it, iQM can use it.

iQM can work with any record, field or transaction your systems expose, including your custom fields and custom objects. The examples below are common starting points, not limits. New or custom data is added by configuring the connector, not by changing iQM.

The questions context answers

What was affected?	Items, formulas and BOMs, lots and serials, genealogy, routes and operations, equipment and resources
Who was involved?	Suppliers, customers, carriers, marketplaces, sites, warehouses, people
What happened?	Purchase, production, sales, transfer, return, shipment and inventory transactions; inspections, test results, holds and status
What did it cost?	Scrap, rework, credits, refunds, claims and their financial postings
What governs it?	Specifications, approved supplier lists, certifications, SOP and document references, engineering changes
Whatever else you rely on	Custom fields, custom objects, attachments and records from other business systems

For example, in your system

Dynamics 365	released products, batches, production and batch orders, quality orders, purchase and sales orders, vendors, and more
SAP S/4HANA	materials, batches, process and production orders, inspection lots, quality notifications, business partners, and more
NetSuite	items, lot and serial numbers, work orders, purchase and sales orders, item receipts and fulfillments, and more
Oracle Cloud SCM	items, lots, work orders, receipts, inspection plans, quality issues, suppliers, and more
Any other system	Infor, Acumatica, Epicor, Sage, MES, LIMS, PLM, CRM, e-commerce and marketplace platforms, through the same connector approach

iQM reads and writes through each system's own interfaces, within the access you grant. Record names are examples of each vendor's terminology.

What iQM does with that context

Context turns a quality record from a form someone fills in into a case that already knows what it touched.

A deviation fills itself in

Pick the batch; the product, order, stage, supplier and SOP revision arrive from your systems.

A complaint finds every customer

Trace the lot forward to every customer, order and shipment that received it.

A task lives on the transaction

Create a task on a NetSuite sales order, an SAP purchase order or a D365 batch, or on any iQM record.

A failed inspection teaches risk

A rejected incoming sample updates the supplier's risk and can tighten its sampling.

A change reaches the ERP

Once approved, the change launches the BOM, formula or route update in your ERP and waits for it.

A return becomes evidence

Marketplace returns and reviews arrive as complaint signals with the order and product attached.

Beyond the ERP

MES, SPC and IoT

excursions, alarms, batch-record exceptions

LIMS

samples, results, stability pulls

PLM and documents

BOMs, specifications, SOP revisions

CRM and service

cases that become complaints

E-commerce and marketplaces

orders, returns, reviews, claims

Identity

single sign-on, roles, signatures

Zeak Supplier Intelligence

supplier responses and scores

iQM links to the record live and keeps a snapshot of what it showed when the event happened. It does not copy your master data.

A connected decision

From a customer complaint to a governed fix, with the supplier paying its share.

1 Record

Log the complaint with product, severity and owner

A customer reports foreign material in a finished product. The complaint is logged against the product and batch, severity high.

2 Understand

Add the supplier, related SOP and regulations

The material traces to one supplier's lot. The vendor is notified; the claim is recorded on the complaint the same day.

3 Act

Create the CAPA and assign tasks

A CAPA is created from the complaint with the complaint as its source; containment tasks go to receiving and production.

4 Change

Govern the fix through Change Control

An incoming-inspection change is raised from the CAPA, routed to Quality and Procurement approvers, and implemented within budget.

5 Verify

Verify, close and keep the history

The change is verified and closed, the CAPA closed with e-signature, and the complaint's history shows every step.

Scenario is illustrative.

WITHOUT THE CONNECTED VIEW

Customer service logs a case, quality opens a spreadsheet, procurement learns about the supplier issue weeks later, and the claim window has closed. The fix is a memo, not a change.

With it

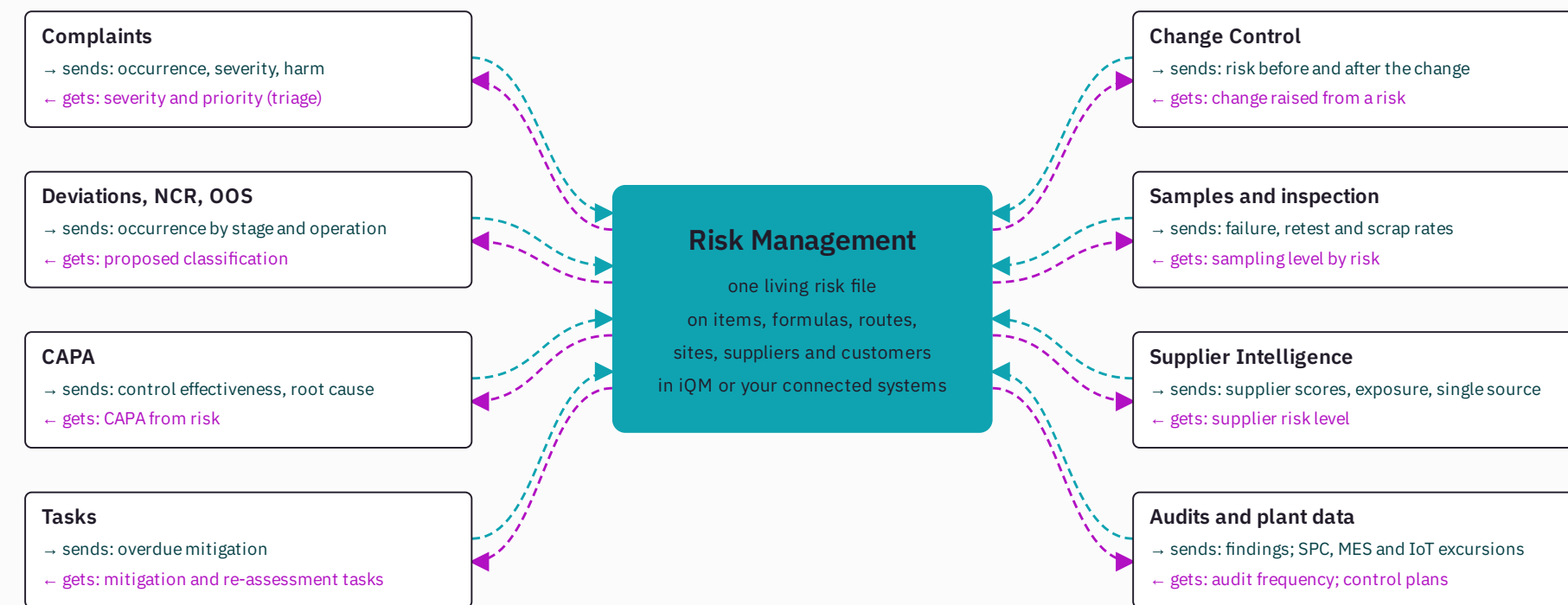
One complaint carries the product, the supplier claim, the CAPA, the tasks and the change. The supplier is claimed against in time, and an inspector can follow the record end to end.

And the risk file learns

The complaint also posts a signal to the supplier-material risk; the risk owner re-assesses, incoming sampling for that supplier tightens, and the change shows the risk before and after.

Risk at the center

Every module already knows something about risk. iQM is connecting all of it to one living risk file.



--> signals into risk --> what risk drives Modules and connected systems can be any vendor's; iQM can also run standalone.

The register

Controlled scales, clear ownership, separate risk and approval status, and pluggable methods. A risk raises a governed change with its owner and department carried across.

The signals

Complaints, deviations, CAPA results, sample failures, overdue mitigations, supplier scores and changes post signals to the risks they touch; the owner re-assesses with the evidence in front of them.

Why it matters

ISO 14971, ICH Q9(R1) and IATF 16949 expect a risk file kept current by what actually happens. iQM sees the orders, batches and suppliers those signals come from, in whichever system holds them.

How a risk stays current

Signals propose. People decide. Every rating can be explained from evidence.

1 Identify Risks on real items, processes, sites and suppliers	2 Assess Matrix, FMEA, ISO 14971 or HACCP	3 Control Each control tied to a test, sampling plan or control-plan line	4 Detect Complaints, deviations, samples and plant data post signals	5 Re-assess Thresholds ask the owner to re-rate; every version kept	6 Treat CAPA or change, sized to the risk	7 Verify Effectiveness re-rates residual risk
When this happens	The risk receives			What follows		
A customer complaint names harm on a product	Occurrence and severity evidence on the product risk			Owner asked to re-assess severity		
The same mixing deviation recurs three times in a quarter	Occurrence evidence on the process risk for that step			Re-assessment; classification proposed for the next one		
A CAPA is verified effective	Control effectiveness recorded			Residual risk re-rated; if ineffective, the risk reopens		
A supplier's incoming samples start failing	Detection evidence on the supplier-material risk			Sampling tightened for that supplier		
A major change is submitted	Risk before and after on the change			Approval waits until the assessment is complete		
A mitigation task goes overdue	Control-not-in-place flag			Escalation to the risk owner		
Nothing changes silently. A signal never re-rates a risk on its own; a named person re-assesses, and the version is kept.		Rigor matches risk. Change classes, approvals and due dates scale with the risk a record touches.		Your methods. A simple matrix, AIAG-VDA FMEA, ISO 14971 hazard analysis or HACCP, in one register.		

Thresholds and actions are configured with your team; examples are illustrative.

Seven capabilities, seven answers

Each module exists to answer one question the business asks every week.

Change Control

“Who approved this change, what did it cost, and did it work?”

Department routing, change classes, budget control and separate implement and verify steps.

- Department approval routing
- Change classes and profiles
- Customer and supplier change notices

CAPA

“Where did this action come from, and what did it change?”

Source, transaction and Change Control on every CAPA.

- Source and transaction traceability
- 8D and problem-solving methods
- Effectiveness verification

Deviations

“Which batch, which stage, which SOP version?”

Operational context recorded with the event.

- Product, batch and stage
- Material review and disposition
- OOS and OOT investigations

Complaints

“Who pays for this, and what do we owe the regulator?”

Claims, regulations and reporting clocks on the complaint.

- Vendor, transport and other claims
- Regulatory reports on the clock
- Recalls and mock recalls

Tasks

“What do I need to do, and for which case?”

Every task shows its source record, in iQM or a connected system.

- Source-aware tasks
- Tasks on any record, in any system
- Reminders and escalation

Risk

“Which risks are rising, and who owns them?”

Signals from every module keep the risk file current.

- Risk signals
- Risk assessed on every change
- FMEA, ISO 14971 and HACCP

Samples

“Which order is this sample for, and who has it?”

One framework across five order sources.

- Quality order and test context
- Sample orders with or without cost
- Environmental monitoring

Platform

“Can an inspector follow every record, in any system?”

Audited, connected and signed.

- Audit trail on every transaction
- Connects to your systems
- Works standalone

What each role sees and decides

One quality record. Eight roles, each with a decision to make.

Role	What they see	What they decide	What they are measured on
Head of Quality	Open CAPAs, deviations and complaints by status and age; changes waiting for approval	Where to intervene, what to escalate	Overdue CAPAs; repeat findings
QA manager	Department queues, approvals, tasks due, complaint deadlines	Approve, return, close or reopen	Cycle time; on-time closure
Investigator	Batch, stage, SOP revision, supplier and related change on the record	Cause, scope and response	Investigation time; recurrence
Plant / production	Deviations and samples on their orders and batches	Containment and release readiness	Batches held; deviations per batch
Supplier quality	Vendor claims, vendor samples and supplier-caused complaints	Claim, request samples, escalate	Claims filed and recovered
Risk owner / quality engineer	Risks, ratings, controls and the change raised from each risk	Treatment, re-assessment and when to raise a change	Open high risks; mitigations on time
Regulatory	Approved policies and regulations; complaint history	Which obligations apply	Response deadlines met
Administrator	Masters, defaults, sequences, routing and workflow switches	How the process is configured	Consistent configuration across sites

Views shown are the standard work queues and lists; a cross-module quality dashboard and risk portfolio complete the picture.

Industry applications

Different industries, the same need: the quality record has to know what it affected.

Pharmaceuticals

A planned deviation on a granulation step is approved for one batch. Six weeks later an inspector asks which SOP revision applied, and the answer is on the record.

Measures: Deviations per batch, CAPA on-time closure

Context: GMP, SOP revision control, signed decisions

Biotech and cell and gene therapy

A cell-therapy batch moves from the clinical site to a contract manufacturer. The transfer runs as a governed change, and every hand-off of patient material is checked against its chain of identity.

Measures: Transfer readiness, custody exceptions

Context: GMP, chain of identity, tech transfer

Medical devices

Three complaints about the same housing arrive from two distributors. They share a product and a supplier, and one CAPA covers them.

Measures: Complaint cycle time, CAPA effectiveness

Context: Complaint handling, CAPA, supplier controls

Chemicals and specialty materials

An incoming raw-material sample fails. The vendor sample, purchase order and claim are on one record.

Measures: Incoming sample failures, claims recovered

Context: Vendor samples, quality orders, claims

Food and beverage

Foreign material in a finished lot: the complaint, the supplier claim, the CAPA and the inspection change move together.

Measures: Complaints per volume, recall readiness

Context: Lot traceability, supplier claims

Cosmetics and consumer goods

A packaging change is raised as an emergency, approved by Quality and Regulatory in one stage, and verified before launch.

Measures: Change cycle time, launch readiness

Context: Regulatory references, change governance

Scenarios are illustrative. Configuration and regulated-workflow design are scoped to each customer environment.

Industry applications, continued

The same record serves the fab, the hangar, the reactor and the warehouse.

Semiconductors and electronics

A wafer lot fails incoming inspection at the assembly site. The vendor sample, purchase order and claim sit on one record, and the CAPA links to the change that tightens incoming inspection.

Measures: Incoming ppm, customer escapes, 8D on time

Context: Lot genealogy, change notification, 8D

Aerospace and defense

A special-process supplier's certification lapses. Purchases of affected parts stop, a renewal task opens, and the FOD finding on the last lot is already linked to the supplier.

Measures: Escapes per part, supplier approval lapses

Context: AS9100, first article, export-controlled data

Automotive and discrete manufacturing

A recurring machining deviation becomes a risk, the risk raises a change, and the owner and department carry across automatically.

Measures: Repeat deviations, change on-time completion

Context: Risk-driven change, budget control

Process manufacturing

A viscosity deviation on a resin batch is recorded against the production order with its stage and SOP revision; a risk on the raw material raises a change to the supplier specification.

Measures: Deviations per batch, off-spec rework

Context: Batch context, specifications, supplier certificates

Distribution and e-commerce

Returns for one SKU spike with the same reason on a marketplace. The returns arrive as complaint signals with the order and lot, the supplier is charged back, and the product is held across warehouses.

Measures: Return rate by SKU, chargebacks recovered

Context: Returns, marketplaces, carrier claims, recalls

General manufacturing and services

A machine shop with no regulator starts with the quick-start profile: complaints, CAPA and tasks running in days, ISO 9001 audit findings recorded where they lead.

Measures: Repeat complaints, on-time CAPA

Context: ISO 9001, light controls

Configured, not customized

Each industry names its events differently and audits against different standards, and some are not regulated at all. iQM ships industry starter packs and a quick-start profile for non-regulated teams, so every pilot starts close to how you already work.

Scenarios are illustrative. Configuration and regulated-workflow design are scoped to each customer environment.

What each industry needs

Which iQM capabilities matter most to each industry.

Capability	Pharma	Biotech	Med devices	Chemicals	Food and bev.	Cosmetics, CPG	Semicon.	Aero and defense	Auto and discrete	Process mfg.	Distrib. and e-com.	General mfg.
Change												
Governed change with department routing and budget control	•	•	•	•	•	•	•	•	•	•	•	•
Change classes; regulated and non-regulated profiles	•	•	•	•	•	•	•	•	•	•	•	•
Affected-object impact and changes executed in the ERP	•	•	•	•	•	•	•	•	•	•	•	•
Customer and supplier change notices (PCN / SCN)	-	-	-	•	-	-	•	•	•	•	•	-
Regulatory filing impact	•	•	•	-	-	•	-	-	-	-	-	-
CAPA and investigation												
CAPA with source, ERP transaction and e-signature	•	•	•	•	•	•	•	•	•	•	•	•
Root cause, 8D and problem-solving methods	•	•	•	•	•	•	•	•	•	•	•	•
Containment across inventory and effectiveness verification	•	•	•	•	•	•	•	•	•	•	•	•
Events												
Deviations with batch, stage and SOP revision	•	•	•	•	•	•	•	•	•	•	•	•
Nonconformance, MRB disposition and batch hold	•	•	•	•	•	•	•	•	•	•	•	-
OOS and OOT investigations	•	•	-	•	•	•	-	-	-	•	-	-
Excursions from SPC, MES and temperature loggers	•	•	-	•	•	-	•	-	-	•	•	-
Complaints and field actions												
Complaints with vendor, transport and third-party claims	•	•	•	•	•	•	•	•	•	•	•	•
Reportability and regulatory reporting workflows	•	•	•	-	-	•	-	-	-	-	•	-

What each industry needs, continued

Capability	Pharma	Biotech	Med devices	Chemicals	Food and bev.	Cosmetics, CPG	Semicon.	Aero and defense	Auto and discrete	Process mfg.	Distrib. and e-com.	General mfg.
Recalls, market withdrawals and mock recalls	●	●	●	●	●	●	●	●	●	●	●	●
Return failure analysis	●	●	●	●	●	●	●	●	●	●	●	●
Risk												
Risk register that raises governed change	●	●	●	●	●	●	●	●	●	●	●	●
Risk signals from every module; living risk file	●	●	●	●	●	●	●	●	●	●	●	●
FMEA with Action Priority and control-plan linkage	●	●	●	●	●	●	●	●	●	●	●	●
ISO 14971 hazard analysis	●	●	●	●	●	●	●	●	●	●	●	●
HACCP and food-safety hazard analysis	●	●	●	●	●	●	●	●	●	●	●	●
Supply-continuity risk	●	●	●	●	●	●	●	●	●	●	●	●
Samples												
Samples across five ERP sources; sample orders with or without cost	●	●	●	●	●	●	●	●	●	●	●	●
Retained samples and environmental monitoring	●	●	●	●	●	●	●	●	●	●	●	●
Supplier certificates of analysis and risk-based sampling	●	●	●	●	●	●	●	●	●	●	●	●
Enterprise and compliance												
Audit trail, e-signatures on every approval, validation package	●	●	●	●	●	●	●	●	●	●	●	●
Audits and inspections	●	●	●	●	●	●	●	●	●	●	●	●
Trace forward and back	●	●	●	●	●	●	●	●	●	●	●	●
Part approval (PPAP) and first-article inspection	●	●	●	●	●	●	●	●	●	●	●	●
Cost of poor quality, measured	●	●	●	●	●	●	●	●	●	●	●	●
Industry starter packs and quick-start profile	●	●	●	●	●	●	●	●	●	●	●	●
Export-controlled data protection	●	●	●	●	●	●	●	●	●	●	●	●
Supplier certifications and special processes	●	●	●	●	●	●	●	●	●	●	●	●

What each industry needs, continued

Capability	Pharma	Biotech	Med devices	Chemicals	Food and bev.	Cosmetics, CPG	Semicon.	Aero and defense	Auto and discrete	Process mfg.	Distrib. and e-com.	General mfg.
Industry-specific												
Returns, reviews and marketplace signals; returns grading	·	·	·	·	●	●	·	·	·	·	●	●
Chain of identity for patient-specific products	·	●	·	·	·	·	·	·	·	·	·	·
Technology transfer and scale-up	●	●	●	·	·	·	·	·	·	·	·	·
FOD and special-process events	·	·	·	·	·	·	·	●	●	·	·	·
Private-label and new-product approval	·	·	·	·	●	●	·	·	·	·	●	●

● a primary need in this industry · available, but not usually a primary need. How each industry benefits, module by module, is in chapter 03.

03

How each industry benefits

The same seven modules, configured for the way each industry works, regulated or not. Here is what each module does for each industry.

Pharmaceuticals

Biotech and cell and gene therapy

Medical devices

Chemicals and specialty materials

Food and beverage

Cosmetics and consumer goods

Semiconductors and electronics

Aerospace and defense

Automotive and discrete manufacturing

Process manufacturing

Distribution and e-commerce

General manufacturing and services



How each industry benefits

What each module does for your industry.

Pharmaceuticals

Change Control	Changes classified by risk, with regulatory filing impact and implementation held until approval
CAPA	CAPAs traced to the batch and transaction, closed only when effectiveness is shown
Deviations	Deviations and OOS results with the batch, stage and SOP revision; batch review by exception
Complaints	Product quality complaints with reportability and recall readiness
Tasks	Every investigation and change step owned and dated against the batch
Risk	ICH Q9(R1) risk kept current by deviations, complaints and CAPA results
Samples	Retained, environmental-monitoring and stability samples on one framework
Platform	Audit trail on every transaction, e-signatures, data integrity and annual product reviews

Biotech and cell and gene therapy

Change Control	Technology transfer and scale-up between sites and CDMOs as governed changes
CAPA	Investigations tied to the batch, the patient-specific lot and the site
Deviations	Process and custody deviations with batch and SOP context
Complaints	Product complaints with reportability and pharmacovigilance hand-off
Tasks	Owned actions on every batch, shipment and transfer
Risk	ICH Q9(R1) risk kept current by every deviation and change
Samples	Chain of identity and custody from collection to administration
Platform	Audit trail on every transaction, signatures and data integrity

Medical devices

Change Control	Design-transfer and process changes with risk before and after
CAPA	8D or 5 Whys investigations with effectiveness checks inspectors accept
Deviations	Nonconformances with MRB disposition and product impact
Complaints	MDR and vigilance clocks, IMDRF coding and UDI on every complaint
Tasks	Owned actions for every complaint, CAPA and field action
Risk	An ISO 14971 risk file fed by post-market complaints
Samples	Incoming inspection and retained samples tied to lots and serials
Platform	QMSR-ready records, audit trail, signatures and recalls by UDI

Chemicals and specialty materials

Change Control	Formula and supplier changes that flag SDS, labels and customer specifications; process-safety MOC
CAPA	Supplier corrective actions from failed incoming lots
Deviations	Off-spec batches with regrade, rework and disposition posted to inventory
Complaints	Customer complaints with claims against suppliers and carriers
Tasks	Actions tied to batches and orders in your ERP
Risk	Raw-material and supply-continuity risk with risk-based sampling
Samples	Supplier CoA verification and customer CoAs against each customer's specification
Platform	COPQ measured from scrap, rework and claims

How each industry benefits, continued

Food and beverage

Change Control	Recipe, supplier and packaging changes that update labels and allergen profiles
CAPA	Containment that blocks every affected lot
Deviations	CCP breaches and environmental excursions as events on the batch
Complaints	Foreign-material and allergen complaints escalated with supplier claims
Tasks	Sanitation, changeover and recall tasks with checklists
Risk	HACCP and allergen cross-contact risk by line
Samples	Environmental monitoring, retained samples and supplier CoAs
Platform	Trace forward and back within hours; mock recalls timed

Cosmetics and consumer goods

Change Control	Formula and packaging changes with label and safety-substantiation triggers
CAPA	Root-cause and effectiveness on product and packaging defects
Deviations	Batch deviations with SOP revision and review by exception
Complaints	Serious adverse events reported on the MoCRA clock
Tasks	Launch and change tasks owned across teams
Risk	Product safety and allergen risk linked to formulas
Samples	Stability pulls and retained samples by batch
Platform	Complaint trends and warranty cost in one view

Semiconductors and electronics

Change Control	PCN to every customer who bought the part, with acknowledgment and requalification triggers
CAPA	8D on customer timelines with containment across sites and in transit
Deviations	Excursions from SPC and MES with OCAP and MRB disposition
Complaints	Return failure analysis and ppm by customer
Tasks	8D and FA steps assigned against lots and orders
Risk	PFMEA with Action Priority linked to control plans; concentration risk in the supply base
Samples	Incoming wafer and component sampling by supplier risk
Platform	Lot genealogy, qualification tracking and counterfeit-part controls

Aerospace and defense

Change Control	Engineering and process changes with first-article and customer approval triggers
CAPA	8D and corrective action on customer timelines
Deviations	FOD findings, special-process escapes, NCR and MRB
Complaints	Field returns and counterfeit-part reports with quarantine
Tasks	Containment and inspection actions on parts, lots and work orders
Risk	PFMEA linked to control plans and key characteristics
Samples	First-article and receiving inspection by supplier risk
Platform	Export-controlled data protection, supplier certifications and audit findings

How each industry benefits, continued

Automotive and discrete manufacturing

Change Control	Engineering and process changes with PPAP re-approval and customer notification
CAPA	8D with containment and customer-format reports
Deviations	NCR and MRB with customer concessions
Complaints	Warranty and field failures linked to cost
Tasks	Layered-audit and containment actions on the shop floor, from a phone
Risk	DFMEA and PFMEA tied to control plans and inspection
Samples	First-article and incoming inspection samples on purchase orders
Platform	PPAP, first-article inspection, calibration impact and audit findings in one place

Process manufacturing

Change Control	Specification and route changes executed in the ERP once approved
CAPA	Recurring process deviations driven to permanent fixes
Deviations	Batch deviations from SPC and historians with regrade and rework
Complaints	Off-spec complaints with claims and CoA evidence
Tasks	Actions on production orders and batches in any connected ERP
Risk	Process risk updated by real deviation frequency
Samples	In-process and customer CoA samples against specifications
Platform	Cost of poor quality by plant, product and supplier

Distribution and e-commerce

Change Control	Supplier, packaging and listing changes absorbed without disrupting customers
CAPA	Corrective action from carriers, suppliers and private-label factories
Deviations	Temperature excursions and damaged receipts with disposition
Complaints	Return reasons, reviews and marketplace claims as signals; carrier and vendor claims recovered; DSCSA where it applies
Tasks	Return, quarantine and recall tasks on sales and purchase orders in your ERP or commerce platform
Risk	Carrier, supplier, SKU and cold-chain risk scored from real returns and claims
Samples	Vendor and customer samples with charged or free shipping; product approval before listing
Platform	Returns grading and chargebacks; recalls cascaded to every customer; carrier and 3PL scorecards

General manufacturing and services

Change Control	Simple change requests with one-step approval, more rigor when needed
CAPA	Corrective action that closes the loop on repeat complaints
Deviations	Nonconformances with rework, scrap and supplier return
Complaints	Customer complaints with claims against suppliers and carriers
Tasks	One list of quality work tied to the order or job
Risk	A risk register that raises change, sized to the business
Samples	Supplier and customer samples, charged or free
Platform	Quick-start profile, ISO 9001 audit findings, cost of poor quality

Benefits describe the intended use of iQM capabilities; each is configured and confirmed for your environment during Discover and the pilot. Feature detail by module is in chapter 06.

04

How value is created and proven

Four levers create measurable value. A measurement method agreed with Quality and Finance up front proves it in your own numbers, and shows how quickly it pays back.



Four ways to create value

A worked business case

What a better decision looks like

Why the approach is different

The cost of poor quality, part by part

How to quantify it

Worked example: a manual quality process

The cost of customizing your ERP

Rapid ROI: build, keep manual, or switch on Zeak

A value case for everyone who has a say

Four ways to create value

Four levers, each with an example Quality and Finance would recognize.

1

Recover what others cost you

Record vendor, transport and third-party claims on the complaint, with the evidence already attached.

Forty complaints trace to one supplier lot. The claim is filed from the first one, with batch and PO evidence: **\$85K recovered** instead of written off.

Measured by: Claims filed, value recovered

2

Stop repeat failures

Link deviations and complaints to CAPA, and CAPA to governed change, so the fix reaches the process.

The same mixing deviation recurs three times a quarter. The CAPA drives an SOP change; **recurrence stops, and about \$60K a year of rework with it.**

Measured by: Repeat deviations, rework and scrap

3

Release with confidence

Start investigations with batch, stage, SOP revision and supplier on the record.

An investigation that took two weeks to scope is scoped in a day; **held batches are released a week sooner.**

Measured by: Investigation cycle time, batch hold time

4

Stay inspection-ready

Numbered, routed and signed records that an inspector can follow end to end.

A pre-inspection review finds every open CAPA, its source and its change in one queue, **with no overdue items left unexplained.**

Measured by: Overdue CAPAs, repeat findings

Examples are illustrative. No single percentage is assumed; your baseline and Finance validation determine the value case.

A worked business case

Quality value counts only when it shows up in cost, not in a count of closed records.

Cost of poor quality = internal failure (scrap, rework, retest) + external failure (complaints, returns, claims absorbed) + appraisal effort spent rebuilding context

Illustrative case: one site with \$5M annual cost of poor quality

Source of value	Illustrative basis	Annual	% of COPQ
Recover cost	Vendor and transport claims filed on complaints previously absorbed	\$180K	3.6%
Stop repeat failures	Rework, scrap and retest on three recurring deviations removed by governed change	\$220K	4.4%
Release with confidence	Shorter batch holds; investigation hours redeployed	\$140K	2.8%
Stay inspection-ready	Avoided remediation effort on repeat observations	\$60K	1.2%
Less: overlap	A benefit counted in one lever only	(\$40K)	
Gross annualized opportunity	Before implementation and run cost	\$560K	11.2%

Illustration only. Figures depend entirely on your baseline, volumes and the levers that apply.

The four rules we apply

- 1. Baseline first:** twelve months of deviations, complaints, claims and rework, agreed before the pilot.
- 2. Attributable only:** count savings only where the iQM record shows the link.
- 3. Recovered means received:** a claim counts when the credit arrives, not when it is filed.
- 4. No double counting:** each benefit sits in one lever.

Quality and Finance agree the baseline before the pilot starts. Nothing is reported as value until both have accepted it.

What a better decision looks like

Same event, different outcome: the difference is having the context on the record.

Situation	Typical response today	With iQM
A customer complaint Foreign material in a finished lot	Logged in service, re-keyed into quality days later; the supplier is told after the claim window closes.	Complaint on the product and batch; vendor claim recorded the same day; CAPA created from the complaint; containment tasks assigned.
A production deviation A mixing time exceeded on one batch	Paper form; the SOP version is assumed; the permanent fix waits for the next review meeting.	Deviation on the production order and batch with stage and SOP revision; New Change Control raised from the deviation and routed to the department.
A risk in review A single-source critical ingredient	Recorded in a spreadsheet; the action owner is agreed verbally.	Risk with impact, likelihood and owner; a change raised from it with owner and department copied across and budget control applied.

Scenarios are illustrative.

Why the approach is different

The ERP knows what happened. A separate QMS knows what was decided. iQM keeps both on one record.

The question	ERP alone	A standalone eQMS	iQM
Which batches and orders does this deviation touch?	Has the data but no deviation record.	Typed in, or depends on an integration.	Referenced live on the deviation.
Who pays for this defect?	Credit notes without a quality case.	A complaint record; claims vary by product.	Vendor, transport and third-party claims on the complaint.
Is the fix governed?	Engineering change for product versions.	Change control, separate from the ERP.	Change Control routed by department, with budget control, fed by CAPA, deviation and risk.
Which order is this sample for?	Quality orders and sampling.	Usually through a LIMS or ERP integration.	One sample framework across five ERP sources.
Is the risk file current?	No risk register.	A register updated in review meetings, often from exported data.	Signals from every module re-assess risk on live records, and risk raises governed change.
Does it work with our systems?	Only with itself.	Through custom integrations.	Standalone, or connected to any ERP, MES and LIMS through connectors.

From a quality event to a governed, verified fix, on the same records as the batch, the order and the supplier, in whichever system holds them.

Describes typical approaches. Capabilities of specific products vary by vendor, version and licensing.

The cost of poor quality, part by part

Poor quality costs money in six places. The quality budget shows only some of them.

Scrap and rework are visible. The hours spent re-keying records, the days batches wait, the claims never filed and the evidence rebuilt for every audit sit in other budgets, so nobody connects them to how quality is managed. Here is where the money goes, and how each part is measured.

1 Record admin and re-keying

Quality records typed, copied and chased across email, spreadsheets, paper and a separate system.

Measured as: Records a year × hours of admin each × loaded rate

2 Held batches and slow release

Investigations that start without the batch, stage, SOP revision and supplier on the record take longer, and stock waits.

Measured as: Held batches × extra hold days × cost of a hold day

3 Repeat failures

A deviation or complaint fixed locally comes back, because the fix never reached the process through governed change.

Measured as: Recurring events × rework, scrap and retest per event

4 Cost absorbed instead of recovered

Supplier, transport and third-party claims not filed in time, or filed without the evidence.

Measured as: Claims not filed or lost × average claim value

5 Inspection and audit effort

Evidence assembled by hand for every audit and inspection; repeat observations to remediate.

Measured as: Audits a year × hours to prepare × rate, plus remediation

6 External failures

Complaints, returns, recalls and lost customers when a quality problem leaves the plant.

Measured as: Events traced to quality × cost per event

What the research says

Every industry

15-20%

of sales revenue is commonly lost to the cost of poor quality.

ASQ

Life sciences

\$26-36B

estimated annual cost of poor quality in medical devices.

McKinsey and Company

Food

~\$10M

average direct cost of a food recall, as widely cited in trade press (secondary).

FMI and GMA

Every industry

Two-thirds

of the cost of bad data can be identified and eliminated permanently by removing root causes.

MIT Sloan Management Review, 2017

External figures describe results reported by other organizations; they are not results of iQM and not a forecast. Full references in Sources and definitions; MIT figure: Redman, Seizing Opportunity in Data Quality, MIT Sloan Management Review, 27 November 2017.

How to quantify it

Six steps, two weeks, your own numbers.

We don't rely on industry averages for your business case. In Discover we measure each part with your team, using records you already have, and Quality and Finance sign the baseline.

1

Count the records

Deviations, CAPAs, complaints, change controls and samples a year, by site.

Data: Your quality system, logs and spreadsheets

2

Measure the admin

For 10 to 20 recent records: who touched each one, for how long, and how often data was re-keyed.

Data: Record history plus short interviews

3

Measure hold and cycle time

Days from event to closure, and days batches waited for a quality decision.

Data: Batch status and record time stamps

4

Count repeats and recoveries

Events that recurred; claims filed, lost or never raised; credits received.

Data: Quality records, credit notes, finance

5

Price audit and external failure

Hours to prepare each audit or inspection; complaints, returns and recalls traced to quality.

Data: Quality, customer service and finance records

6

Agree it with Quality and Finance

Sign the baseline before anything changes. Every result is measured against it.

Data: Quality head, process owner, Finance contact

Recovered means received

A claim counts when the credit arrives, not when it is filed, and a saving counts only where the iQM record shows the link. That is what makes the number defensible.

Count each benefit once

A shorter investigation can shorten a batch hold too. We assign each benefit to one part only, and show the overlap we removed.

Worked example: what a manual quality process costs

An illustrative site: 1,500 quality records a year, 60 held batches, 12 recurring deviations.

All figures are illustrative assumptions to show the arithmetic. They are not a forecast or a measured result. External failures (complaints, returns, recalls) are left out to keep the example conservative.

What the current process costs a year

Part	Calculation	Cost a year
1 Record admin	1,500 records × 4 hours of admin × \$85 an hour	\$510,000
2 Held batches	60 held batches × 5 extra hold days × \$1,500 a day	\$450,000
3 Repeat failures	12 recurring deviations × \$20,000 rework, scrap and retest	\$240,000
4 Cost absorbed	40 claims not filed × \$4,500 each	\$180,000
5 Audit and inspection	4 audits × 120 hours × \$120 an hour	\$57,600
Total cost of the current process	About \$120,000 a month	\$1,437,600 a year

If your measured improvement matched these assumptions

Part	Assumed reduction	Value a year
Record admin	Half	\$255,000
Held batches	Half	\$225,000
Repeat failures	Half	\$120,000
Cost absorbed	3 in 4 recovered	\$135,000
Audit and inspection	60% less	\$34,560
Value a year		\$769,560
Value a week		about \$14,800

Not in these numbers: a single recall, an inspection finding that stops shipments, or a lost customer, any one of which can outweigh everything above.

Replace every assumption with your measured baseline. We don't publish a saving for iQM until it has been measured with a customer.

The cost of customizing your ERP, or building a quality system

Building quality processes into your ERP is a project, and then it is a product you maintain.

Customizing an ERP for quality means building or enhancing workflows for change control, CAPA, deviations, complaints, risk and samples, then paying people to build, test, validate and keep them working. Hours are illustrative. Partner resource costs are averaged to \$150 an hour, including onshore and offshore resources; your own people (line 13) are costed at \$85 an hour.

#	Build line item	Hours	Cost
1	Process discovery and design workshops (quality, production, supply chain, IT)	160	\$24,000
2	Functional specification for seven processes	120	\$18,000
3	Data model and forms: change control, CAPA, deviations, complaints, risk, samples, tasks	400	\$60,000
4	Workflows and approvals, including electronic signatures	360	\$54,000
5	Integrations: ERP orders, batches and suppliers; MES; LIMS	320	\$48,000
6	Audit trail, reports and dashboards	160	\$24,000
7	Risk register and links between records	160	\$24,000
8	Testing: unit, integration, user acceptance	280	\$42,000
9	Computer system validation (IQ/OQ/PQ), where regulated	320	\$48,000
10	Migration of open records	120	\$18,000
11	Training, documentation and deployment	120	\$18,000
12	Project management (about 15%)	378	\$56,700
13	Your own people: workshops, testing, validation sign-off	600	\$51,000
	Build: six to nine months	3,498	\$485,700

Then, every year

Ongoing line item	Cost
Regression testing at each ERP service update (assumed 4 a year × 60 hours)	\$36,000
Changes to forms, workflows and rules (150 hours)	\$22,500
Support and fixes (160 hours)	\$24,000
Re-validation of changes, where regulated (120 hours)	\$18,000
Every year after go-live	\$100,500

What the research says

Whole ERP projects: a median cost of \$450,000 and a median timeline of 9 months, with timelines depending on the degree of customization (Panorama Consulting, 2025 ERP Report, 172 organizations). Cloud ERPs ship regular service updates that can be paused for at most one consecutive update (Microsoft Learn), so custom quality workflows are retested, and in regulated settings re-validated, on the vendor's schedule.

A standalone quality system avoids the ERP build but adds licences, integrations to keep orders and batches in sync, and a second place to look.

Rapid ROI: build it, keep it manual, or switch on Zeak

Rapid ROI. Payback measured in weeks, against your own baseline.

Two comparisons, both from the worked example. **Against your manual process:** the weeks until the measured value (about \$14,800 a week) repays iQM's first-year cost. **Against building it in your ERP:** how much less iQM's first-year cost is than the build it replaces (about \$486,000), before any saving is counted.

Level	iQM first-year cost (illustrative)	Weeks to pay back from measured value	Compared with building it
A	\$25,000	About 2 weeks	\$460,700 less than the build
B	\$50,000	About 3 weeks	\$435,700 less than the build
C	\$100,000	About 7 weeks	\$385,700 less than the build

Compared with building it, you are ahead before the first record is raised: the build you don't commission, and the \$100,500 a year of upkeep and re-validation you don't carry, cost more than any of these levels.

A, B and C are illustrative levels to show the arithmetic, not iQM pricing. Your proposal sets the real cost; your pilot measures the real value. Payback in weeks = first-year cost ÷ measured weekly value.

	Customize the ERP	Zeak iQM
Time to first value	6 to 9 months of build and validation	Weeks: read-only alongside your process, on real records
Build cost	About \$486,000 in the example	No workflow, form, integration or audit-trail code to write
Connected records	Built and maintained by your project	Orders, batches, suppliers and SOP revisions referenced live
Validation	Every custom change re-validated	Validation accelerator: traceability, IQ/OQ/PQ templates, test evidence
ERP updates	Your custom code is retested every cycle	iQM sits outside your ERP code; connectors are maintained by Zeak
Changing the process	A change request to IT	Configured by your administrator

A value case for everyone who has a say

Rapid ROI means something different to each person in a quality decision.

The same numbers answer four different questions. Here is what each person should be able to see before they say yes.

If you want results you can show

Operations and site leaders

- Value in weeks, measured on your own records
- A business case Quality and Finance have signed
- A clear next step at every stage of the autonomy ladder

If you do the work every day

Quality engineers, investigators, supervisors

- Records that start with the batch, order and supplier already on them
- Less re-keying and chasing from the first week
- CAPA and change linked, so fixes stop coming back

If you protect the systems and the controls

QA heads, validation, IT, audit

- Nothing to build in your ERP, nothing to re-validate at every update
- Read-only first; nothing written to your ERP unless you switch it on
- Signatures, audit trail and validation evidence built in

If you sign off the numbers

Finance

- Every line tied to a measured baseline
- Recovered means received; each benefit counted once
- Costs and value reviewed at the readout, before any expansion

The value case is never built on fewer people. It is built on fewer repeat failures, faster release, cost recovered instead of absorbed, and no quality build to fund, validate and maintain. If the pilot does not show value on your own records, you stop, and you keep everything you learned.

05

How customers start

Start where the quality pain is visible. Prove one process family at one site with your own records, then extend by process and site.



A pilot built around a measurable result
What a pilot delivers
A controlled path to production
Trust is part of the product
Who delivers iQM

Delivery and support
A pilot designed around your team
How iQM is delivered
Questions buyers ask
Hard questions, answered plainly

A pilot built around a measurable result

One site. One process family. One measure Quality and Finance agree.

A focused pilot puts a real quality process on iQM, makes better decisions with it, and proves the result before any larger commitment.

Weeks 1-2

Discover

Pick the site, process family and owner; agree baseline and measures with Quality and Finance.

Weeks 3-5

Configure

Masters, defaults, departments, approvers, number sequences and connectors set in your test environment.

Weeks 6-9

Run

Live records on real events; first CAPAs, changes and claims through the process.

Weeks 10-12

Prove

Results reviewed against the baseline; readout with the rollout case.

We need from you

A named process owner; a test environment (standalone, or connected to a test copy of your ERP); twelve months of the records in scope; a Finance contact; a few hours a week from the quality team.

Good first candidates

A site with recurring deviations, a complaint backlog with unclaimed supplier costs, changes still managed on paper, a risk register nobody updates, or an inspection on the horizon.

Timeline is indicative and confirmed during Discover; it depends on scope and validation needs.

A pilot designed around your team

We design the pilot around how your team works today, and around the people who have to say yes.

We learn your process first

Before we show anything, your team walks us through how the work runs today and what must never break. Your process is the foundation; iQM is added on top.

You define failure

We ask what would make the pilot a failure in your eyes, and write your answer into the pilot charter as a success criterion.

We backtest on your own history

iQM runs against the last six to twelve months of your records and shows what it would have flagged against what actually happened, before anything goes live.

We measure the baseline before we build

Cycle times, effort, claims and rework are measured with your team, so the numbers argue instead of us.

You get the risk register first

A one-page pilot risk register, handed over before you ask: data access, validation impact, rollback plan, support model, and what happens when iQM is wrong.

Your owner approves every gate

A named owner on your side approves each move up the autonomy ladder and can stop the pilot at any point.

A free pilot is never free to the people who run it. It costs your team's time and puts names on a decision. So the pilot starts at Observe or Advise, keeps your process intact, and uses your criteria to decide whether it succeeded.

What a pilot delivers

Prove value before you scale.

A pilot is not a demo. It ends with results in your own records and a clear case for what to do next.

What you have at the end of a pilot

- 1 A live quality process on your data**
Your process family running in iQM on your own records, in use by your team.
- 2 A configured, documented setup**
Masters, defaults, departments, approvers and sequences, written down.
- 3 A baseline Quality and Finance agreed**
The starting point and how it is measured, set before the pilot begins.
- 4 Decisions made on the new records**
Real CAPAs, changes or claims taken through the process, and what they changed.
- 5 A validation approach**
For regulated sites, the scope and evidence plan for production.
- 6 A readout and rollout case**
What was found, what was realized, and a plan for the next sites or processes.

A GOOD FIT

What we look for

You see the value in your own records before you commit to more.

- A clear quality problem with a visible cost
- A process owner and an executive sponsor
- A test environment available in the first weeks
- Finance involved from the baseline onward
- A path to rollout if the value is proven

A controlled path to production

Each phase ends with evidence you can inspect, not a date on a plan.

1 Discover	Choose the site, process family, owner and measures. Confirm the records and validation needs.	Exit evidence: Signed pilot charter: owner, baseline, measures	Your team: Process owner, Finance, IT
2 Configure	Set masters, defaults, departments, approvers, number sequences, connectors and workflow switches.	Exit evidence: Configuration record, reviewed	Your team: Quality systems, ERP or platform admin
3 Validate	Test the configured process with users. For regulated sites, execute the agreed validation scope.	Exit evidence: User acceptance; validation evidence where required	Your team: Quality, validation
4 Go live	Move the approved configuration to production and run real events.	Exit evidence: Go-live checklist; first records closed	Your team: Process owner, IT
5 Expand	Extend to further process families and sites, measured against the baseline.	Exit evidence: Value report; next site case approved	Your team: Sponsor, Finance

Exit criteria are proposed defaults and are agreed with each customer during Discover.

Trust is part of the product

Six controls that let a quality head, a regulator and an IT owner say yes.

Every record is numbered

Changes, CAPAs, deviations, complaints, risks, tasks and samples draw identifiers from configured number sequences, never reused.

Approvals follow your organization

Changes route to each department's named approvers, in one stage or several, scaled by change class. Lifecycle actions are limited to authorized users.

Signatures where they matter

Electronic signatures with a recorded meaning on approvals and closures, where your procedures require them.

Reference data is controlled

Reason codes, categories and scales are maintained centrally; policies and regulations must be approved before use.

Every transaction is audited

Every create, update, approval, signature and system transaction is recorded with who, what, when, old and new values and why.

In your environment

iQM runs in the Zeak cloud or your own cloud tenant, under the identity and security your IT team operates, standalone or connected.

Regulated workflows, including electronic records and signatures, require use-case-specific configuration and validation. No blanket compliance claim is made here.

Who delivers iQM

Built and delivered by people who have run enterprise systems in regulated industries for decades.

iQM is built and delivered by XcelPros. Each of our co-founders brings more than 25 years of experience leading SAP, Oracle and Microsoft Dynamics ERP, CRM and systems integration programs for complex, global organizations.

25+ years each

Enterprise platforms

ERP, CRM and systems integration across SAP, Oracle and Microsoft Dynamics, from strategy and design through go-live and support.

Regulated by design

Industry depth

Pharmaceuticals and life sciences, chemicals, food and beverage, cosmetics and consumer goods, and the many industries where quality, traceability and control matter even without a regulator.

Platform independent

Any system

iQM runs standalone or connects to Dynamics 365, NetSuite, SAP, Oracle and other systems, built by a team that has implemented them for decades.

One accountable team

Product and delivery

The people who build iQM implement and support it, so decisions are made by those who know the product best.

Leadership

Kiran Bhavaraju

Co-founder, XcelPros

More than 25 years leading SAP, Oracle and Microsoft Dynamics ERP, CRM and systems integration programs across many industries, including highly regulated ones, and releasing complex software products for regulated industries.

Bindu Bhavaraju

Co-founder, XcelPros

More than 25 years leading SAP, Oracle and Microsoft Dynamics ERP, CRM and systems integration programs across many industries, including highly regulated ones, and releasing complex software products for regulated industries.

You work with senior people who have done this before: in your industry, on your platform, under the controls your auditors expect.

Delivery and support

One team, one method, from the first workshop to long-term support.

A unified delivery approach

Product, implementation and support sit in one team under one method, so nothing is lost in hand-offs between vendors.

Outcome first. Every engagement starts from a process, an owner and a measure, not a feature list.

Prove before scale. One site or process family first; expansion once the result is accepted.

In your environment. Configured standalone or connected to your systems, under your security and change management.

Validated where required. Testing and evidence aligned with your quality system in regulated settings.

Knowledge transfer. Your administrators are trained to run iQM day to day.

Ongoing success

A named customer success lead, periodic value reviews with your sponsor, and releases tested in your test environment before production.

A tiered support model

Tier	Who	What
Tier 1	Your administrators	Trained on masters, defaults, departments, approvers and day-to-day configuration
Tier 2	iQM support desk	Functional and configuration questions, how-to guidance, connector and integration issues
Tier 3	iQM product engineering	Defects and product fixes, with root cause and release notes

Response targets

Severity	Definition	First response
Severity 1	Production quality process stopped	In your agreement
Severity 2	Major function impaired; no reasonable workaround	In your agreement
Severity 3	Function impaired with a workaround	In your agreement
Severity 4	Question, minor issue or enhancement request	In your agreement

Response targets, coverage hours and escalation contacts are set in your support agreement.

How iQM is delivered

Prove it first, then extend, in the order your priorities set.

Phase 1

Foundation

The base every module stands on.

Representative features

- Seven modules configured for your process family
- Audit trail on every transaction
- Standalone or connected to your ERP
- E-signatures and data integrity

Phase 2

Connected quality

Every module feeds and draws on risk.

Representative features

- Risk signals from every module
- Risk assessed on every change
- Root cause, 8D and effectiveness
- Tasks on any record, in any system

Phase 3

Industry depth

Configured for the way your industry works.

Representative features

- Industry starter pack
- MRB disposition, OOS and excursions
- Recalls and regulatory reports
- PCN, PPAP and qualification where needed

Phase 4

Insight and reach

See patterns and bring partners in.

Representative features

- Quality dashboard and risk portfolio
- Cost of poor quality, measured
- AI assist you can audit
- Supplier collaboration

Phases are a typical sequence. The order, scope and release of each feature are agreed per customer and confirmed in your proposal. Every feature is described in chapter 06.

Questions buyers ask

The questions we hear first, answered plainly.

Will iQM replace our ERP's quality management?

No. iQM works alongside it. Where your ERP has quality orders, inspection or sampling, iQM uses them; iQM adds change control, CAPA, deviations, complaints, risk, samples and tasks on the same records.

Is iQM 21 CFR Part 11 compliant?

Compliance is a property of a validated system and your procedures, not of software alone. iQM is designed with an audit trail on every transaction, e-signatures with a recorded meaning, data-integrity controls and a validation package. Validation scope is agreed per customer.

Where does our data live?

In the Zeak cloud or your own cloud tenant. Records in your connected systems stay there; iQM keeps a live link and a snapshot of what they showed at the time of the event.

How soon will we see something real?

The pilot is designed to run real records through iQM within weeks of configuration, and to end with results reviewed against an agreed baseline.

We run Dynamics 365, and Microsoft ships Advanced Quality Management. Why iQM?

AQM adds native CAPA, sampling plans and e-signatures, and it is part of current D365 releases.⁴ iQM adds general Change Control with department routing and budget control, complaint handling with claims and regulations, connected risk, and one task list. Where both apply, the boundary is agreed in Discover.

Does it work with SAP, Oracle or NetSuite?

Yes. Zeak is platform and system independent. iQM runs standalone or connects to Dynamics 365, NetSuite, SAP, Oracle, Infor, Acumatica and other systems through connectors.

What happens when our ERP is upgraded?

Connectors are versioned and tested against supported releases, and updates are tested in your test environment before production.

What do you need from IT?

A test environment or cloud tenant, access for the connectors in scope, single sign-on, and roles for the pilot users.

Questions buyers ask, continued

And the questions we hear as the conversation goes deeper.

Can we start without connecting our ERP?

Yes. iQM runs standalone with its own items, lots, suppliers and customers, and connects later without re-keying.

How does risk connect to the rest of iQM?

Complaints, deviations, CAPA results, samples, tasks, changes and Zeak Supplier Intelligence post signals to the risks they touch; the owner re-assesses with the evidence attached, and a risk raises a governed change.

Can we run regulated and non-regulated sites on one system?

Yes. Change classes and regulated or non-regulated profiles let a GMP plant and a distribution center use the same product with different rigor.

Will AI make quality decisions?

No. AI makes suggestions only: each shows its basis and is accepted or rejected by a named person. AI never approves, closes or signs a record.

Does iQM fit semiconductor, automotive or distribution operations?

Yes. Beyond the seven modules, iQM covers 8D, material review, change notices to customers, part approval and qualification, recalls, carrier scorecards and FMEA linked to control plans, configured through industry starter packs.

Is audit management a separate module?

No. Audit is part of every transaction: every create, update, approval and system event is recorded. Audit and inspection findings are recorded on the CAPAs, deviations, risks and changes they lead to.

What if we want to leave?

You can export every record, file, audit entry and setting in open formats at any time, and receive a complete archive at contract end.

Hard questions, answered plainly

The questions a careful buyer should ask us, with the limitations stated up front.

Is every feature in this document available today?

No. This overview describes the full iQM capability set. Which features are available in which release is confirmed in your proposal and verified in the pilot before you rely on it.

Does iQM make us compliant?

No software does. Compliance comes from a validated system used under your procedures. iQM provides audit trail, signatures, data-integrity controls and a validation accelerator; validation remains your decision and your responsibility.

What will this cost our team?

Time: a process owner, a Finance contact, a few hours a week from the quality team, and IT for access. We say so up front because a free pilot is never free to the people running it.

What if we run iQM standalone?

Then iQM holds your items, lots, suppliers and customers, and your team maintains them until a connector is switched on.

What happens when iQM is wrong?

Rules and suggestions can be wrong. That is why iQM advises before it acts, shows the reasoning and source records behind every flag, logs every accept and reject, and lets you step back a stage at any time.

Will it work with our version of our ERP?

Connectors are versioned and tested per system and release. We confirm your system, version and customizations in Discover, and start read-only.

Is iQM a LIMS, a document-control or a training system?

No. iQM orchestrates samples and references documents and training; where you run those systems, iQM connects to them rather than replacing them.

Can we stop?

Yes, at any stage, and keep every record. You can also export everything in open formats at any time.

06

Features by topic

Every iQM feature, grouped by the job it does for your team: what it does, what you get, and the industries it serves. Availability by release is confirmed in your proposal.

Change Control
CAPA Management
Deviation Management
Complaints Management

Task Management
Risk Management
Sample Management
Platform, compliance and connectivity



Topic 1 of 8

Change Control

Every change governed, routed and verified, with its cost in view.

A quality change process inside the connected ERP, separate from engineering change: request, review by the right department, implement, verify and close, with budget control where you need it.

At a glance

- Change requests with reason, category, type, impact, priority, emergency and planned or unplanned flags
- Draft, submit, approve or reject, implement, verify and close, with recall and revise along the way
- A work queue for every stage, from Draft to Closed
- Approval by department: single or multi-stage, with a primary approver plus second and third approvers
- Budget control with overrun policy, currency, exchange-rate type and named override groups
- Defaults for every intake field, and numbering by department if you want it

What the research says

90 days minimum advance notice JEDEC JESD46 expects before a semiconductor supplier implements a major product or process change²⁴

23 features (9 core, 14 advanced and industry)

Core features

Change requests

Your team raises a change with a reason, description, category, type, overall impact, priority, an emergency flag and a planned or unplanned classification. Requester, department, request date and estimated completion are recorded, and the system stamps who created it and when.

What you get: Every change starts as one controlled, attributable record instead of an email.

All industries

Work queues by stage

Separate views for Draft, Submitted, Approved, Implemented, Verified, Rejected and Closed changes, each with filtering.

What you get: Owners and approvers see exactly what is waiting at their stage.

All industries

Controlled lifecycle

Submit for approval, recall, approve, reject, revise the proposal, implement, verify and close. Each step is a deliberate action by an authorized user.

What you get: Approval, execution and verification are recorded as separate control points, which is what auditors look for.

All industries

Department approval routing

Choose Standard or Custom workflow. Each department can approve in one stage or several, with a primary approver and second and third approvers, and its own member list.

What you get: Changes reach the people who understand them, without a central bottleneck.

All industries

Topic 1 of 8, continued

Change Control

Budget and currency control

Switch budget control on where change cost matters: set the overrun policy, default and budget currency, exchange-rate type, and the user groups allowed to override.

What you get: Quality change and financial governance meet in one record.

All industries

Numbering your way

Assign the change number sequence, or number changes by department to match existing conventions.

What you get: Identifiers your organization already recognizes.

All industries

Impact assessment types

Maintain the impact-assessment types your changes are assessed against.

What you get: Assessments use one controlled vocabulary.

All industries

Advanced and industry features

Affected-object impact

List the items, formulas, routes, resources, vendors and SOPs a change affects, with the impact on each, before approval.

What you get: Reviewers approve knowing exactly what the change touches.

All industries

Implementation task plan

Break an approved change into owned, dated tasks in the shared task list.

What you get: Execution between approval and verification is visible.

All industries

Post-change effectiveness check

Plan and record a check that the change achieved its intent before closure.

What you get: Proof that the change worked, not just that it was done.

All industries

Intake defaults

Set default category, type, priority, impact, emergency and planned values, and default completion days from which target dates are calculated.

What you get: Faster, more consistent intake with fewer keying errors.

All industries

Formal change reports

Change or remove the report logo and choose whether approver signatures print on the report.

What you get: Change records that are ready to file or hand to an auditor.

All industries

Reasons on reject and revise

Capture a reason code and comment whenever a change is rejected or sent back.

What you get: Requesters know why, and the history explains itself.

All industries

Linked-records view

See every CAPA, deviation and risk that points at a change, with its status.

What you get: Change owners see what depends on their change.

All industries

Document and training impact

Flag SOPs to revise and roles to retrain, through your document and training systems.

What you get: Procedures and people catch up with the change.

All industries

Topic 1 of 8, continued

Change Control

Change classes and profiles

Minor, major and critical changes each get the rigor they need, with separate regulated and non-regulated profiles that can run in the same company.

What you get: One change process that fits a GMP plant and a distribution center.

All industries

Customer and supplier change notices

Notify the customers who bought an affected item, track their acknowledgments, and turn every supplier change notice into a reviewed change.

What you get: Customers hear about changes on time, and supplier changes never slip in unreviewed.

Chemicals Semicon. Aero and defense Auto and discrete Process mfg. Distrib. and e-com.

Changes that update ERP

Approved changes launch the BOM, formula, route and vendor updates they need, and the change cannot close until those are effective.

What you get: What was approved is what the ERP runs.

Pharma Biotech Chemicals Food and bev. Semicon. Aero and defense Auto and discrete Process mfg.

Label, SDS and registration triggers

A formula or packaging change flags every safety data sheet, label, registration and customer specification it touches.

What you get: Regulated content never lags the product.

Chemicals Food and bev. Cosmetics, CPG Process mfg.

Regulatory filing impact

Record what each change means for your registrations in each market, and hold implementation until the approval it needs arrives.

What you get: No change goes live ahead of its approval.

Pharma Biotech Med devices Cosmetics, CPG

Multi-site rollout

Follow one approved change through every site that must implement it, each with its own date and verification.

What you get: Nothing is closed while a site is still on the old process.

All industries

Process-safety management of change

A management-of-change variant with hazard review and a pre-startup safety review before anything restarts.

What you get: Quality and process-safety change in one governed record.

Chemicals Process mfg.

Technology transfer and scale-up

Run transfers between sites and contract manufacturers as governed changes with comparability and readiness by site.

What you get: Transfers that arrive ready to run.

Pharma Biotech Med devices

Topic 2 of 8

CAPA Management

Corrective action that remembers where it came from and what it changed.

Every CAPA carries its source, the ERP transaction behind it and the controlled change that delivers the fix, with electronic signatures where your procedures require them.

19 features (8 core, 11 advanced and industry)

Core features

CAPA records

Open a CAPA with a required title and reason code, severity, process status (for example Problem Identification) and the responsible department. Reporter, reported date, creator and creation time are recorded.

What you get: Every corrective or preventive action is a controlled record with clear ownership.

All industries

Link to Change Control

When raising a CAPA, link an existing change or choose New Change Control; the change number, description, requester, category and department show on the CAPA.

What you get: The fix is governed as a change, and the link is on the record.

All industries

At a glance

- CAPA records with reason code, severity, process status and responsible department
- Source of the CAPA, the source document and the ERP reference transaction on every record
- A link to an existing Change Control, or a request for a new one, from the CAPA itself
- Approve, return for update, reopen and close, with optional e-signature on approval and closure
- Separate numbering for corrective, preventive and other actions
- Preview, print and email of the formal CAPA document

What the research says

Top 2 CAPA and complaint handling: the two most-cited quality-system sections in FDA device inspections²

\$26-36B estimated annual cost of poor quality in the medical-device industry (McKinsey)⁵

Source and ERP traceability

Each CAPA shows where it came from, such as a complaint, with the source document number, and the ERP reference transaction type and transaction.

What you get: A CAPA can always be traced back to the issue and the transaction that triggered it.

All industries

Approval and closure with e-signature

Approve, return for update, reopen and close. Administrators can require an electronic signature on approval, on closure, or both.

What you get: Signed decisions at the two points inspectors check most.

All industries

Topic 2 of 8, continued

CAPA Management

Work queues and search

All, Favorites, Draft, Reopened, Approved, Needs Update and Closed views, with status filtering and keyword search.

What you get: Owners find their work, and investigators find similar past cases.

All industries

Controlled values

Maintain reason codes, CAPA categories with impact and probability, and disposition comments. Workflow can be switched on or off.

What you get: Consistent classification that can be trended.

All industries

Advanced and industry features

Root-cause analysis

Capture structured root cause with cause codes and link each action to the cause it addresses.

What you get: Actions aimed at causes, not symptoms.

All industries

CAPA from deviations and risks

Raise a CAPA directly from a deviation or a risk, with the source recorded.

What you get: Fewer re-keyed records and a complete source trail.

All industries

Action plan roll-up

See corrective, preventive and other actions together, with completion rolled up to the CAPA.

What you get: One view of progress on every CAPA.

All industries

Typed action numbering

Corrective, preventive and other CAPA tasks each draw from their own number sequence, alongside shared sequences for related quality records.

What you get: Corrective and preventive actions stay distinguishable in every report.

All industries

Formal CAPA outputs

Preview, print or email the CAPA document, with your report logo.

What you get: Records ready for review boards and auditors.

All industries

Effectiveness verification

Plan an effectiveness check with criteria and a due date; closure waits for the result.

What you get: Evidence that the CAPA worked.

All industries

Recurrence detection

Flag new deviations and complaints that match a closed CAPA's product, cause or source.

What you get: Repeat failures surface before the next inspection.

All industries

Phase due dates and escalation

Set due dates per CAPA phase and escalate overdue phases.

What you get: CAPAs keep moving.

All industries

Topic 2 of 8, continued

CAPA Management

8D and problem-solving methods

Run 8D, 5 Whys, fishbone, is / is-not, A3 or DMAIC on the CAPA, and send customers an 8D in the format they expect.

What you get: Investigations that are consistent inside and accepted outside.

Med devices Chemicals Semicon. Aero and defense Auto and discrete Process mfg.
Distrib. and e-com.

Supplier corrective actions

Send a corrective action request to the supplier and see its response, due date and acceptance on the CAPA.

What you get: Supplier fixes are tracked like your own.

All industries

Cost on every CAPA

See what the failure cost and what the fix cost on the CAPA, from your ERP transactions.

What you get: Corrective action that Finance can value.

All industries

Containment that finds every unit

Block affected batches and serials on hand, in transit, at other sites and at customers, from the CAPA.

What you get: Suspect product stops moving the day the problem is found.

All industries

More ways into CAPA

Raise a CAPA from an audit finding, an OOS result, a failed sample or a supplier event, with the source recorded.

What you get: Every source of nonconformity reaches corrective action.

All industries

Topic 3 of 8

Deviation Management

Every deviation arrives with the batch, the stage and the SOP revision already attached.

Planned and unplanned deviations recorded against the real ERP transaction, product and batch, classified for trending, and connected to the change that removes the cause.

20 features (6 core, 14 advanced and industry)

Core features

Deviation records

Record a deviation with a required title, its type (including Planned), category or risk level, structured cause, source (for example Human Error) and controlled reason codes.

What you get: Deviations classified the same way every time, ready to trend.

All industries

Link to Change Control

Link an existing change or choose New Change Control; the change number, description, requester, category and department show on the deviation.

What you get: Deviations that need a permanent fix lead straight into governed change.

All industries

At a glance

- Deviation type (including planned), category or risk, cause and source, such as human error
- ERP reference transaction, product and batch on the record
- Processing stage, SOP number and the SOP revision in force
- A link to an existing Change Control or a request for a new one
- Approve, return for update, reopen and close, plus controlled removal of an approval
- Queues, keyword search, preview, print and email

What the research says

\$210B automotive revenue estimated lost in 2021 when semiconductor supply failed (AlixPartners)²⁶

62% of US drug shortages studied followed manufacturing or product-quality problems (FDA)¹

15-20% of sales revenue: common cost of quality in many organizations (ASQ)⁶

Operational context

Each deviation carries the ERP reference transaction, affected product and batch, processing stage (for example Raw Material), SOP number and SOP revision, and start and end dates.

What you get: Investigators start with the facts instead of rebuilding them from three systems.

All industries

Approval lifecycle

Approve, return with Needs Update, reopen and close. An approval-maintenance view lets authorized users remove an approval made in error.

What you get: Clear dispositions, and a controlled way to correct them.

All industries

Topic 3 of 8, continued

Deviation Management

Queues, search and list context

All, Favorites, Submitted, Approved and Rejected views, status filter and keyword search; lists show status, type, category, cause and transaction without opening the record.

What you get: Faster triage across the whole deviation population.

All industries

Advanced and industry features

Investigation and root cause

Record the investigation, root cause, impact assessment and conclusion on the deviation.

What you get: A complete case from event to conclusion.

All industries

Multiple products and batches

Link one deviation to several products and batches.

What you get: Real events recorded at their real scope.

All industries

Deviation tasks

Raise deviation tasks in the shared task list.

What you get: Follow-up work is owned and dated.

All industries

Material review and disposition

Decide use as is, rework, repair, regrade, return to vendor or scrap for each affected quantity, and post it to the connected ERP.

What you get: Dispositions that are approved, complete and already in inventory.

Chemicals Food and bev. Semicon. Aero and defense Auto and discrete Process mfg.
Distrib. and e-com.

Formal deviation outputs

Preview, print and email the deviation report.

What you get: Records ready for batch documentation and audits.

All industries

Batch hold and disposition

Hold affected ERP batches while a deviation is open and record the disposition at release.

What you get: No batch leaves while its deviation is unresolved.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG Semicon.
Process mfg. Distrib. and e-com.

Planned-deviation validity

Give planned deviations an approved window and flag use outside it.

What you get: Planned deviations stay within what was approved.

All industries

One module, every kind of event

Deviations, nonconformances, OOS and OOT results, excursions and CCP breaches each get the fields and lifecycle they need.

What you get: Industries use their own vocabulary without a second system.

All industries

Out-of-specification investigations

Run phase I and phase II OOS and OOT investigations on the quality order, test and sample, with controlled retests.

What you get: Laboratory results investigated the way inspectors expect.

Pharma Biotech Chemicals Food and bev. Cosmetics, CPG Process mfg.

Topic 3 of 8, continued

Deviation Management

Who received it?

Trace a deviation's batches to the customers who received them and the suppliers behind them, and record the impact on each.

What you get: Impact assessed in hours, with the trace on file.

All industries

Excursions captured automatically

Out-of-control SPC points, MES alarms and temperature-logger excursions open an event with its reaction plan.

What you get: Containment starts when the signal does.

Pharma Biotech Chemicals Food and bev. Semicon. Process mfg. Distrib. and e-com.

Batch review by exception

Exceptions from electronic batch records and MES arrive as events on the batch, so reviewers see only what needs a decision.

What you get: Faster batch release without skipping a check.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG

Classified, with deadlines

Each event is classified by your rules and gets a closure target by class; extensions need approval.

What you get: Fewer late investigations and consistent classification.

All industries

Customer concessions

Ask a customer to accept nonconforming product and keep the approval, limits and expiry on the record.

What you get: Nothing nonconforming ships without the customer's yes.

Semicon. Aero and defense Auto and discrete Process mfg.

FOD and special-process events

Record foreign object debris and special-process escapes against the part, operation and supplier certification.

What you get: Aerospace escapes handled the way customers expect.

Aero and defense Auto and discrete

Topic 4 of 8

Complaints Management

From the first call to the recovered claim, one complaint record.

External, internal and other complaints move through a clear lifecycle, linked to products, suppliers, carriers, regulations, corrective action and follow-up tasks, with alerts before deadlines slip.

26 features (11 core, 15 advanced and industry)

Core features

Complaint intake

Record a complaint with title and description, an ID numbered by category, the External, Internal or Other category, owner, severity and priority; mark favorites.

What you get: Every complaint is owned and classified from the first minute.

All industries

Products and context

Link affected products, map complaint types to ERP transaction types, and add keywords, notes and related SOPs.

What you get: Product-level trending and the procedural context on one record.

All industries

Vendor, transport and third-party claims

Record the vendor or carrier, notification dates, and each claim's flag, number, date, comments and response, including claims against other external parties.

What you get: Costs caused by others are claimed, not absorbed.

All industries

At a glance

- External, Internal and Other complaints with owner, severity, priority and a nine-status lifecycle
- Affected products with item number, name, group and type
- Vendor, transport and other third-party claims on the complaint
- Create a CAPA from the complaint and track its status there; add owned, dated tasks
- Approved policy and law or regulation references
- Target dates, advance alerts, extra recipients, report previews and a full history

What the research says

\$743B of merchandise returned to US retailers in a single year (NRF and Appriss Retail)²⁷

5% to 25-95% a 5% rise in customer retention can lift profits by 25% to 95% (Bain & Company)¹⁶

\$10M average direct cost of a food recall, before brand damage (FMI and GMA)³

Nine-status lifecycle

Register, request more information, accept, reject, close and reopen. Workspace tiles show how many complaints sit in each of nine statuses.

What you get: Managers see the shape of the workload at a glance.

All industries

Investigation details

A dedicated, numbered investigation area separate from intake.

What you get: Investigation and intake each stay readable.

All industries

CAPA and tasks from the complaint

Create a new CAPA from the complaint's resolution and see its number, status and date there. Add tasks with owner, status and due date.

What you get: Systemic issues reach corrective action, and follow-up gets done.

All industries

Topic 4 of 8, continued

Complaints Management

Policies and regulations

Maintain policies and laws or regulations as approved reference data, then reference them, with notes, on complaints.

What you get: Handlers know which obligations apply, from a controlled list.

All industries

Deadlines and alerts

Set a target resolution date, an alert a chosen number of days ahead or on a custom date, and extra recipients by email.

What you get: Deadlines are met because people are told in time.

All industries

Administration

Switch complaint workflow on or off, set the report logo and number sequences for complaints, investigations, policies, regulations and tasks.

What you get: The process fits your organization without custom code.

All industries

Advanced and industry features

Reportability assessment

Record whether a complaint must be reported to a regulator, the basis and the due date.

What you get: Reporting obligations are decided and evidenced on every complaint.

Pharma Biotech Med devices Cosmetics, CPG Distrib. and e-com.

Claim value and recovery

Record claimed and recovered amounts on every claim.

What you get: Finance sees what quality recovered.

All industries

Customer correspondence

Send templated acknowledgment and closure letters and keep a log.

What you get: Consistent, provable customer communication.

All industries

Rejection with reasons

Reject with a controlled reason code and description.

What you get: Every rejection is explainable to the customer and the regulator.

All industries

Reports, history and workspace

Preview and email complaint reports, see who previewed last, review the full status history, and work from ten views plus an Analytics tab.

What you get: A complete, retrievable record of how each complaint was handled.

All industries

Return and credit link

Link complaints to the connected ERP return orders and credit notes.

What you get: Customer remedies and quality cases in one place.

All industries

Complaint trending

Complaint rates by product, batch, customer and vendor against volume shipped, with threshold alerts.

What you get: Rising rates are seen before they become recalls.

All industries

Intake from service channels

Create complaints from Customer Service cases or a web form.

What you get: No re-keying between service and quality.

All industries

Topic 4 of 8, continued

Complaints Management

Regulatory reports on the clock

Each reportable complaint follows the workflow and deadline of its regime, with the submission reference kept on the record.

What you get: Reports made on time, and proof that they were.

Pharma Biotech Med devices Cosmetics, CPG Distrib. and e-com.

Return failure analysis

Take returned parts through failure analysis, keep the results with the complaint and link them to the 8D.

What you get: Returns explained with evidence.

Med devices Semicon. Aero and defense Auto and discrete

Warranty and service link

See warranty claims and service work orders on the complaint, with their cost.

What you get: Field cost and field signals in the quality record.

Cosmetics, CPG Semicon. Aero and defense Auto and discrete

Counterfeit and suspect parts

Report, quarantine and trace suspect or counterfeit parts, and block their source.

What you get: Counterfeits stopped before they reach a product.

Semicon. Aero and defense Auto and discrete Distrib. and e-com.

Returns grading and recovery

Grade every return, decide its disposition and charge the supplier back, with inventory updated in your system.

What you get: Returns margin protected and supplier cost recovered.

Cosmetics, CPG Distrib. and e-com. General mfg.

Recalls and mock recalls

Run recalls and market withdrawals from the affected lots to every customer notice and return, and time your mock recalls.

What you get: Recall readiness you can demonstrate.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG Distrib. and e-com.

Standard complaint coding

Code complaints by problem, component, cause and harm, including IMDRF terms for devices.

What you get: Complaints that trend and report cleanly.

All industries

Customer-specific rules

Each customer's response times, report formats and contacts apply automatically to its complaints and notices.

What you get: Customer requirements met without a spreadsheet.

Semicon. Aero and defense Auto and discrete Distrib. and e-com.

Returns and reviews as quality signals

Return reasons, reviews and marketplace claims arrive as complaint signals with the order, product and supplier attached.

What you get: Product problems caught at the first return, not the hundredth.

Food and bev. Cosmetics, CPG Distrib. and e-com. General mfg.

Topic 5 of 8

Task Management

One list of quality work, every task tied to the record that needs it.

Tasks from CAPAs and complaints land in one shared list. Each one shows the process it came from, the source record's number and its title, so nobody works a task without context.

12 features (3 core, 9 advanced and industry)

Core features

Source-aware tasks

Every task carries its number, description, owner, status, due date and creation time, plus its source process, source document number and source title.

What you get: Assignees see what the task is for without opening another record.

All industries

Status views and filters

Not Started, In Process and Completed views, with filters by status, by source and on any column.

What you get: Slippage shows up early, and completed work is evidence.

All industries

Advanced and industry features

Tasks for every process

Raise tasks from Change Control, deviations and risks as well.

What you get: One task list for all quality work.

All industries

At a glance

- Every task with number, description, owner, status, due date and creation time
- The source process, source document number and source title on each task
- All Tasks, plus CAPA and complaint task views
- Not Started, In Process and Completed views
- Filters by status, by source and on any column

What the research says

28% of a knowledge worker's week spent on email, and 19% searching for and gathering information (McKinsey Global Institute)¹⁸

One consolidated list

An All Tasks view across quality processes, with dedicated views for CAPA tasks and complaint tasks.

What you get: One place to see and manage quality work.

All industries

Reminders and escalation

Remind owners before due dates and escalate overdue tasks.

What you get: Fewer overdue actions.

All industries

Topic 5 of 8, continued

Task Management

Completion evidence

Require a comment or attachment to complete a task where needed.

What you get: Completed tasks prove what was done.

All industries

Delegation with history

Reassign or delegate with a recorded reason.

What you get: Accountability survives absences.

All industries

Task templates and checklists

Start a recall, a containment or a change implementation from a template of owned, dated tasks.

What you get: Repeatable work done the same way every time.

All industries

Tasks on any record, in any system

Create a task on any iQM record or on a batch, sales order or purchase order in your ERP; the task shows where it came from.

What you get: Quality work tied to the transaction that needs it, wherever it lives.

All industries

My tasks

A personal queue for each user.

What you get: Everyone starts the day with their own list.

All industries

Teams and mobile

Update and complete tasks from Microsoft Teams or a mobile browser.

What you get: Shop-floor owners close tasks where they work.

All industries

Dependencies and service levels

Tasks wait for the step before them and show how long they have left.

What you get: Hand-offs that do not stall.

All industries

Topic 6 of 8

Risk Management

Risks that turn into governed change, not entries in a register.

A configurable risk register with controlled scales, clear ownership and separate risk and approval status, where a risk can raise a change with its owner and department carried across.

At a glance

- Risk statement, impact, likelihood, category, mitigation strategy, owner and department
- Risk status and workflow status kept separately, with start and end dates
- A related Change Control from the risk, with owner and department copied across when enabled
- Defaults for impact, likelihood, mitigation, category and change category
- Controlled masters for category, likelihood, effectiveness and mitigation, with audit columns

What the research says

3.7 years average interval between supply disruptions lasting a month or longer (McKinsey Global Institute)¹⁷

40%+ of a year's profits companies can expect to lose to disruptions over a decade (McKinsey Global Institute)¹⁷

~50 points in the semiconductor supply chain where one region holds more than 65% share (BCG and SIA)¹⁹

32 features (6 core, 26 advanced and industry)

Core features

Risk register

Record a risk with title, statement, impact, likelihood, a required category, mitigation strategy, department, owner and date identified.

What you get: Every risk has a statement, a rating, a treatment and an owner.

All industries

Risk to Change Control

Capture a related change with its category, requester, department and description. Administrators can copy the risk owner and department into the change and set its default category.

What you get: Mitigation that needs a change goes straight into governed change.

All industries

Controlled scales

Maintain categories, likelihoods, effectiveness values and mitigation strategies with description, display order and active state; changes are attributed.

What you get: One rating vocabulary, maintained without breaking history.

All industries

Risk and workflow status

Risk status (for example Open) and workflow status (for example Draft) are tracked separately, with risk start and end dates.

What you get: Whether a risk is live and whether it is approved are both clear.

All industries

Assessment defaults

Set default impact, likelihood, mitigation strategy and category for new risks.

What you get: Consistent starting points across assessors.

All industries

Numbering and oversight

Configure sequences for risks and related records, and see every risk in one view with its ratings, owner and both statuses.

What you get: Leadership sees the whole risk population in one place.

All industries

Topic 6 of 8, continued

Risk Management

Advanced and industry features

Risk score and heatmap

Compute a priority from impact and likelihood with a configured matrix and show it on a heatmap.

What you get: Risks ranked, not just listed.

All industries

Risks on real objects

Link risks to items, resources, sites and vendors in the connected ERP.

What you get: Risk tied to the thing it is about.

All industries

FMEA and hazard analysis

Severity, occurrence and detection analysis for process and product risks, with AIAG-VDA Action Priority.

What you get: Structured analysis where regulators expect it.

All industries

Risk signals

Every complaint, deviation, CAPA result, sample failure, overdue mitigation and change that touches a risk is logged on it, with a link back.

What you get: Ratings explained by evidence, not memory.

All industries

Deviations that update process risk

Link a deviation to the process risk for its stage; its classification is proposed from that risk, and recurrence updates the rating.

What you get: Consistent classification and process risk that reflects what happens.

All industries

Risk assessed on every change

Each change carries a risk assessment sized to its class, with risk before and after.

What you get: Approvers see what a change does to risk before they sign.

All industries

Residual risk and controls

Record controls, their effectiveness and the residual rating.

What you get: Proof that mitigation reduced the risk.

All industries

Periodic review

Set review cadence, reviewer and outcome for each risk.

What you get: The register stays current.

All industries

Risk from quality trends

Propose a risk when deviation or complaint trends cross a threshold.

What you get: Reactive signals feed proactive risk.

All industries

Complaints that update risk

Link a complaint to the risk it proves; the risk's occurrence and severity evidence update.

What you get: Field experience reaches the risk file the day it arrives.

All industries

CAPA results that re-rate risk

When a linked CAPA is verified, its control and effectiveness update the residual risk; if it did not work, the risk reopens.

What you get: Proof that corrective action reduced the risk.

All industries

Topic 6 of 8, continued

Risk Management

Sample results that inform risk

Failed, retested and scrapped samples update the material and supplier risks they relate to.

What you get: Supplier and material risk measured, not guessed.

All industries

Risk-based triage

New events start with severity and priority from the risk they touch, and high-risk events route to more reviewers.

What you get: Effort goes where the risk is.

All industries

Living risk file

When signals cross a threshold the owner is asked to re-assess, and every assessment is kept as a version with what changed and why.

What you get: A risk file that stays current and shows its history.

All industries

Medical-device hazard analysis

Hazard, hazardous situation and harm, with control measures, verification and overall residual risk, structured as ISO 14971 describes.

What you get: A device risk file linked to the products and events it covers.

Med devices

Risks linked to control plans

Each control on a risk points to the test, sampling plan or control-plan line that detects it.

What you get: Process risk and inspection stay aligned.

Chemicals Food and bev. Semicon. Aero and defense Auto and discrete Process mfg.

Supply-continuity risk

Record single-source, lead-time and concentration risks on the items and suppliers they affect.

What you get: Shortage risk seen before it stops supply.

Pharma Biotech Med devices Chemicals Food and bev. Semicon. Distrib. and e-com.

Supplier risk from Supplier Intelligence

Supplier scores, audits and exposure from Zeak Supplier Intelligence update supplier risk, and quality events flow back.

What you get: One supplier risk picture across quality and procurement.

All industries

Risk-based sampling

A supplier's or material's risk sets how much incoming inspection it gets: tightened, normal, reduced or skip-lot.

What you get: Inspect more where it matters and less where it is proven.

All industries

Risk acceptance rules

Your criteria decide which risks are acceptable; accepting one above the line needs a recorded rationale and an authorized signer.

What you get: Consistent, defensible risk decisions.

All industries

Food-safety hazard analysis (HACCP)

Hazards, critical control points, limits and monitoring, with limit breaches raised as events.

What you get: Food-safety plans tied to the batches and lines they protect.

Food and bev. Cosmetics, CPG

Risk portfolio

See risk by product, site, process and supplier, with trends and open mitigations.

What you get: Leadership sees exposure, not just entries.

All industries

Mitigation plans that finish

Mitigation actions are owned, dated tasks, and a risk only closes when they are done and the control is verified.

What you get: Mitigation done and proven, not promised.

All industries

Topic 6 of 8, continued

Risk Management

Risk-informed audit plans

Audit frequency and scope follow the risk of the process or supplier.

What you get: Audit time spent where the risk is.

All industries

Allergen control

Allergen profiles, cross-contact risk and cleaning verification by line, with allergen complaints escalated at once.

What you get: Allergen risk managed line by line.

Food and bev. Cosmetics, CPG

Emerging-risk suggestions

Patterns across complaints, deviations and CAPAs are suggested as possible new risks for review.

What you get: Patterns surface before they become findings.

All industries

Topic 7 of 8

Sample Management

One sample framework from the receiving dock to the customer's lab.

Samples from quality orders, production, purchasing, inventory and sales share one lifecycle and one set of queues, with vendor and customer samples handled from the same list and sample orders that ship with or without cost.

23 features (11 core, 12 advanced and industry)

Core features

Sample intake

Create a sample with its reference context, a required quantity, a configured type, an assignee and, where relevant, a destructive date.

What you get: Every physical sample is numbered, owned and accounted for.

All industries

Production and purchase context

Select a production order (status, quantity, type) or purchase order (approval and order status, type, vendor), with source line, item and product.

What you get: Samples trace to the order and line they represent.

All industries

At a glance

- Sample intake with reference, required quantity, type, assignee and destructive date
- Quality order, test and test sequence on the sample
- Production order, purchase order, vendor and source line details
- Request vendor samples and ship customer samples from the sample list
- Sample orders with one or more sample items, charged or no-charge, with shipping details
- Personal, unassigned, lifecycle and source queues
- Scrap, history and test sample logs, using native ERP quality-order and item-sampling setup

What the research says

1,800+ cases of suspect counterfeit electronic parts found in the US defense supply chain, the kind incoming inspection exists to stop (US Senate Armed Services Committee)²⁵

24 hours to give FDA sortable traceability records on request under the Food Traceability Rule²³

Quality order and test context

Select the quality order and see its status, quantity, reference, test and test sequence on the sample.

What you get: Testers know exactly which test step each sample serves.

All industries

Vendor and customer samples

Request a vendor sample or ship a customer sample directly from the sample list.

What you get: Supplier and customer sampling run in the same framework.

All industries

Topic 7 of 8, continued

Sample Management

Personal and lifecycle queues

All Samples, My Assigned, My Pending Approvals and Unassigned, plus New, Approved, Testing in Progress, In Review, On Hold, Rejected, Retest Required and Scrapped.

What you get: Nothing waits on a shelf without an owner.

All industries

Disposition and history

Scrap samples, open their history, read test sample logs, and triage from lists that show the key fields.

What you get: Sample handling that can be reconstructed.

All industries

Sample orders with sample items

Trigger a sample order to a customer or from a vendor from the sample framework, with one or more sample items, quantities and units, and the batch where it matters.

What you get: Every sample sent or requested is an order you can track.

All industries

Sample shipping

Capture ship-to, carrier and shipping method on the sample order, so samples move with a shipment record.

What you get: Samples shipped and traceable like any order.

All industries

Advanced and industry features

Retained samples

Track retention period, storage location and destruction due date.

What you get: Retention that meets GMP expectations.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG

Chain of custody

Record every transfer between people and locations.

What you get: Custody that holds up in an investigation.

All industries

Source views

Sales order, quality order, inventory, production order and purchase order sample views.

What you get: Receiving, production and sales each see their own samples.

All industries

Native test setup

Sampling setup links to the connected ERP quality orders, item sampling and sample types.

What you get: Test rules are defined once, in the connected ERP.

All industries

With or without cost

Issue a sample order with an associated cost or as a no-charge sample, with the choice recorded on the order.

What you get: Sample cost decided and recorded, not assumed.

All industries

Results on the sample

Show quality-order test results on the sample record.

What you get: Sample and result in one view.

All industries

Labels and barcodes

Print labels and scan to find or update samples.

What you get: Fewer handling errors.

All industries

Topic 7 of 8, continued

Sample Management

Turnaround measures

Time from New to Approved by source and type.

What you get: Lab and receiving performance made visible.

All industries

Environmental monitoring

Plan and track environmental samples by location and schedule, trend the results and raise excursions as events.

What you get: A contamination-control program in the same system as your batches.

Pharma Biotech Med devices Food and bev. Cosmetics, CPG

Sample cost visibility

See what samples cost by customer, vendor and item, charged or free.

What you get: The cost of sampling, finally visible.

All industries

Stability sample pulls

Plan and track stability pulls by condition and time point, with results from your LIMS and trends flagged.

What you get: Stability programs that run on time.

Pharma Biotech Med devices Food and bev. Cosmetics, CPG

LIMS integration

Exchange samples and results with your LIMS.

What you get: Integrate where a LIMS is the system of record.

Pharma Biotech Chemicals Food and bev. Semicon. Process mfg.

Supplier certificates of analysis

Check supplier CoA values on the incoming sample and earn reduced testing from a proven record.

What you get: Less incoming testing, with evidence.

Pharma Biotech Chemicals Food and bev. Cosmetics, CPG Process mfg. Distrib. and e-com.

Customer certificates of analysis

Produce a CoA for each shipment against the customer's own specification, and stop the shipment if a result is outside it.

What you get: The right certificate with every lot.

Pharma Biotech Chemicals Food and bev. Process mfg. Distrib. and e-com.

Chain of identity

Track patient-specific material from collection to administration with identity checks at every hand-off.

What you get: Whose material it is, proven at every step.

Biotech

Topic 8 of 8

Platform, compliance and connectivity

The layer every module stands on: connected to your systems, audited on every transaction, ready for inspection.

iQM runs on its own or connected to the ERP, MES, LIMS, PLM and CRM systems you already use. Every transaction is audited, records are signed where your procedures require, and quality is measured across sites and in cost.

42 features (0 core, 42 advanced and industry)

Advanced and industry features

Audit trail on every transaction

Every create, update, approval, signature and system transaction in iQM is recorded with who, what, when, old and new values and why.

What you get: An audit trail inspectors can open on any record.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG Semicon.

Validation accelerator

Traceability matrix, IQ/OQ/PQ templates, risk-based test scripts and vendor test evidence for each release, scoped to what you put live.

What you get: Lower validation effort, and a smaller scope to validate.

Pharma Biotech Med devices Cosmetics, CPG

Attachments and evidence

Versioned evidence files on every quality record.

What you get: Evidence lives with the record.

All industries

At a glance

- Standalone, or connected to the systems you already run: Dynamics 365, SAP, NetSuite, Oracle and others
- Live links to batches, orders, items and suppliers in those systems
- Audit trail on every create, update, approval and system transaction
- E-signatures, data integrity controls and a validation package
- Cost of poor quality, traceability, management review and industry packs

What the research says

10-12% gains in output, capacity utilization and labor productivity reported by smart-factory adopters (Deloitte and MAPI)²⁰

94% of Fortune 1000 companies saw supply-chain disruption early in the COVID-19 pandemic (Accenture research, as reported)²¹

E-signatures on every approval

Signatures with recorded meaning on change, deviation, complaint, risk and sample decisions.

What you get: Signed decisions across the whole quality system.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG

Security roles

Documented ERP security roles per module, with no self-approval.

What you get: Access your IT and QA reviewers can verify.

All industries

Quality dashboard

Volume, aging, cycle time and recurrence across all modules.

What you get: One view of quality performance.

All industries

Topic 8 of 8, continued

Platform, compliance and connectivity

Conditional routing

Route by severity, product or site, with delegation and escalation.

What you get: Approvals that adapt to the case.

All industries

Document and training integration

Connect to your document control and training systems.

What you get: Change, procedures and training stay in step.

All industries

Audit and inspection findings, everywhere

Audit and inspection findings are recorded as the source of CAPAs, deviations, risks and changes, with references and due dates.

What you get: Findings handled in the same records as everything else.

All industries

Cost of poor quality, measured

Scrap, rework, retest, returns and recovered claims are measured from your ledger by site, product and supplier.

What you get: A value case Finance can audit.

All industries

Part approval and first articles

Track PPAP, first-article inspection and APQP status for each part and supplier.

What you get: No new or changed part ships without its approval.

Semicon. Aero and defense Auto and discrete

Trace forward and back

Trace any quality event to the customers who received the product and the suppliers behind it, and keep the result.

What you get: The fastest trace is the one your ERP already knows.

All industries

AI assist

Suggested classification, similar past cases and likely causes on new events.

What you get: Faster, more consistent triage.

All industries

Supplier collaboration

Suppliers respond to claims, sample requests and corrective actions through Zeak Supplier Intelligence.

What you get: Supplier follow-up without email chains.

All industries

Management review pack

The management-review inputs assemble themselves from every module; decisions and actions are recorded.

What you get: Management review in hours, not days.

All industries

Industry starter packs

Start from a configuration built for your industry: codes, event types, change classes, risk methods and reports.

What you get: A faster start that already speaks your industry's language.

All industries

Calibration out-of-tolerance impact

A failed calibration opens an event that shows which products were measured since the last good check.

What you get: Measurement problems contained, not discovered at audit.

All industries

Data integrity by design

Controlled fields need a reason to change, approved records lock, and nothing controlled is ever deleted.

What you get: Records that hold up to a data-integrity review.

Pharma Biotech Med devices Chemicals Food and bev. Cosmetics, CPG

Topic 8 of 8, continued

Platform, compliance and connectivity

AI you can audit

Every AI suggestion shows why it was made and who accepted it; AI never approves or signs.

What you get: AI help without losing control of the record.

All industries

Capture on the shop floor

Raise an event from a terminal or phone with a photo and a scanned batch or serial.

What you get: Problems recorded where and when they are found.

Chemicals Food and bev. Semicon. Aero and defense Auto and discrete Process mfg.
Distrib. and e-com.

Annual product quality review

Every product's annual review assembles itself from the year's deviations, CAPAs, changes, complaints and results.

What you get: Annual reviews in days, not weeks.

Pharma Biotech Cosmetics, CPG

Carrier and 3PL scorecards

Score carriers and logistics providers on damage, excursions and claims recovered.

What you get: Carrier performance you can negotiate with.

Pharma Biotech Food and bev. Distrib. and e-com.

Connects to the systems you already run

Connect iQM to your ERP, MES, LIMS, PLM, CRM and e-commerce systems, whichever vendors you use, and use any record or field they expose that you authorize.

What you get: Quality on your records, whatever system holds them.

All industries

Live links to records in your systems

Any quality record can point to a batch, order, item or supplier in your systems, with live status and a snapshot of what it showed at the time.

What you get: ERP context without copying ERP data.

All industries

Built for many sites

Share masters globally, configure locally, and see quality across sites and legal entities.

What you get: One quality system across the enterprise.

All industries

Open to your other systems

MES, LIMS, PLM and SPC systems can create and read quality records, and quality events notify the systems that need them.

What you get: Quality connected to the rest of the plant.

All industries

Device identifiers on every record

UDI device and production identifiers on complaints, events, CAPAs and recalls.

What you get: Device records that match how regulators search.

Med devices

Product qualification

Track qualification and reliability testing per part and site, and requalify when a change requires it.

What you get: Qualification evidence ready when customers ask.

Semicon. Aero and defense Auto and discrete

Works standalone

Run iQM on its own, with its own items, lots, suppliers and customers, and connect systems later.

What you get: Start with quality now; integrate when ready.

All industries

Your cloud or ours

Run iQM in the Zeak cloud or in your own cloud environment.

What you get: Your data stays where your policies require.

All industries

Topic 8 of 8, continued

Platform, compliance and connectivity

Controlled-data protection

Classify records and files, and keep export-controlled and confidential data away from people and systems not cleared for it.

What you get: Controlled technical data stays controlled.

Semicon. Aero and defense Auto and discrete

Product approval before launch

Approve private-label and new products, with supplier, test and label evidence, before they are listed.

What you get: Products you sell are products you have checked.

Food and bev. Cosmetics, CPG Distrib. and e-com. General mfg.

A workspace for every role

People doing the work see their tasks and records, quality and IT owners see controls and exceptions, and leaders see value and trends.

What you get: Everyone opens iQM to what they care about.

All industries

Your data, always exportable

Export every record, file, audit entry and setting in open formats whenever you want.

What you get: No lock-in, by design.

All industries

The autonomy ladder

Choose for each capability whether iQM observes, advises, assists or acts, and move between stages only when your criteria are met.

What you get: Change at the pace you approve, reversible at every step.

All industries

Reasons behind every flag

Every flag and suggestion shows the rule or model, the data and the source records behind it.

What you get: No black boxes.

All industries

Supplier certifications and approvals

Track each supplier's certifications and approved processes, and stop purchases when one lapses.

What you get: Only approved suppliers, for approved work.

Med devices Food and bev. Semicon. Aero and defense Auto and discrete General mfg.

Quick start

A simple setup with short forms and one-step approvals, running in days and ready to grow.

What you get: Quality running this week, with room to grow.

All industries

Value you can show

See value against the agreed baseline, traced to the records that created it.

What you get: A business case that keeps proving itself.

All industries

Read-only first, write-back by approval

Connect read-only first; switch on each write-back to your systems only when you approve it.

What you get: You decide what iQM may change in your systems.

All industries

Backtest on your own history

See what iQM would have flagged on your last six to twelve months of records, compared with what actually happened, before anything goes live.

What you get: Proof from your own data, not our claims.

All industries

Your pilot charter, in iQM

Your success and failure criteria, baseline, risk register and stage-gate approvals kept in one place.

What you get: The plan is yours, in your words.

All industries

Sources and definitions

Research cited in this document.

#	Source	Link
1	U.S. Food and Drug Administration, Drug Shortages: Root Causes and Potential Solutions (2019)	fda.gov/media/131130/download
2	Med Device Online, Trends in FDA Quality System Inspections (analysis of FDA inspection observation data)	meddeviceonline.com/doc/trends-in-fda-quality-system-inspections-takeaways-to-ensure-future-success-0001
3	Food Marketing Institute and Grocery Manufacturers Association recall cost study, as reported by Food Dive, 'More than money: What a recall truly costs' (2016)	fooddive.com/news/more-than-money-what-a-recall-truly-costs/426855
4	Microsoft Learn, Advanced quality management overview (Dynamics 365 Supply Chain Management), accessed October 2026	learn.microsoft.com/en-us/dynamics365/supply-chain/inventory/advanced-quality-management-overview
5	McKinsey & Company, Capturing the value of good quality in medical devices (2017)	mckinsey.com
6	ASQ (American Society for Quality), Cost of quality resources	asq.org
7	Boston Consulting Group and ASQ, Quality 4.0 Takes More Than Technology (2019)	bcg.com
8	McKinsey & Company, smart-quality and digital-quality research for pharma and medtech	mckinsey.com
9	Deloitte, smart-factory and smart-manufacturing research, with the Manufacturers Alliance (MAPI)	deloitte.com
10	Accenture, Industry X and digital-thread research	accenture.com
11	Bain & Company, supply-chain resilience and semiconductor research (Technology Report)	bain.com
12	ICH Q9(R1) Quality Risk Management (2023); ICH Q10 Pharmaceutical Quality System; ISO 14971:2019	ich.org ; iso.org
13	ISO 9001:2015 Quality management systems: requirements	iso.org
14	FDA Quality Management System Regulation (21 CFR 820), effective 2 February 2026	fda.gov
15	IATF 16949:2016; AIAG and VDA FMEA Handbook (2019)	iatfglobaloversight.org ; aiag.org
16	Bain & Company (Frederick F. Reichheld), The Loyalty Effect and related customer-retention research	bain.com
17	McKinsey Global Institute, Risk, resilience, and rebalancing in global value chains (2020)	mckinsey.com
18	McKinsey Global Institute, The social economy: unlocking value and productivity through social technologies (2012)	mckinsey.com
19	Boston Consulting Group and Semiconductor Industry Association, Strengthening the Global Semiconductor Supply Chain in an Uncertain Era (2021)	bcg.com ; semiconductors.org

Sources and definitions, continued

#	Source	Link
20	Deloitte and MAPI, 2019 Deloitte and MAPI Smart Factory Study	deloitte.com
21	Accenture, supply-chain disruption research (2020), as reported in Fortune	accenture.com
22	US Code of Federal Regulations, 21 CFR 211.170, Reserve samples	ecfr.gov
23	FDA, Food Traceability Rule (21 CFR Part 1, Subpart S)	fda.gov
24	JEDEC, JESD46 Customer notification of product/process changes by semiconductor suppliers	jedec.org
25	US Senate Committee on Armed Services, Inquiry into Counterfeit Electronic Parts in the Department of Defense Supply Chain (2012)	armed-services.senate.gov
26	AlixPartners, automotive semiconductor-shortage revenue forecast (2021)	alixpartners.com
27	National Retail Federation and Apriss Retail, Consumer Returns in the Retail Industry (2023)	nrf.com

Definitions

CAPA is corrective and preventive action. A deviation is a departure from an approved procedure; a planned deviation is approved in advance. COPQ is the cost of poor quality. FMEA is failure mode and effects analysis. A risk signal is an event, such as a complaint or failed sample, recorded on the risk it bears on. A connected system is an ERP, MES, LIMS, PLM or CRM that iQM links to. Core features are the base of each module; advanced and industry features extend it. Availability by release is confirmed in each customer proposal.

How to read the numbers

External figures are results reported by other organizations and are not iQM results. Illustrative figures are labeled as such. Realized value requires a baseline and customer validation.

Zeak iQM

Bring us your quality problem.

Choose a process, a site, a recurring issue or a risk register nobody trusts. We will define the scope, the records and the measure with your team, and prove the result before you commit to more.

