

Continuous-Improvement Prioritization Matrix

Approved for publication October 4, 2026.

Use this to rank an improvement backlog, choose what starts this quarter, and explain the choice to site leadership and QA. You score each idea on impact and effort, plot it on a 2x2 matrix, and leave with a short list that fits the engineering hours you actually have.

What you get: a gate that sends safety and compliance issues to your QMS first, a weighted scoring model with a written anchor for every score, a matrix with a clear cut-off rule, a worked example on a contact lens line, and an action log. A fillable PDF worksheet and an Excel calculator come with this guide.

1. Purpose and use

Who uses it. Operations, continuous-improvement, quality, and engineering leads at medical device and ophthalmic manufacturers. One person chairs the session, usually the operations or CI lead.

When to use it.

- At quarterly planning, before engineering hours are committed.
- After a reject Pareto or KPI review turns up more ideas than you can staff (see HKN-KPI-001).
- After an audit or management review, when the improvement list grows quickly.
- Any time two sponsors are arguing over the same engineering hours.

Scope. Improvement ideas for running lines and their support processes. One matrix covers one site or one value stream, with 10 to 40 ideas. Past 40, split the list by value stream.

Not in scope. These follow their own QMS or company process and are never ranked here:

- CAPA, nonconformance, and complaint actions.
- Changes to device design, labeling, or intended use (design control).
- Capital project approval. You can score a capital idea here for visibility, but the approval decision belongs to your capital process.
- EHS corrective actions required by law or by your EHS system.

Inputs to bring.

- The idea list, each with a one-line problem statement and a sponsor.
- The last 8 to 13 weeks of reject Pareto and KPI data for the area.
- The risk management file for the products made in the area.
- Rough estimates of hours and spend for each idea.
- Engineering hours available this quarter, and your site capital approval limit.

Who is in the room. The operations lead (chair), QA or validation, engineering, the production lead, and finance for the cost scores. Rule of thumb: 90 minutes for 20 ideas once people know the anchors.

2. Instructions

1. **List the ideas.** The sponsor writes each idea as the problem, the proposed change, and the owner, in one line. Merge duplicates and give each idea an ID. Output: a numbered idea list.
2. **Run the gate (Section 3.1).** QA answers the gate questions for every idea. Gated ideas leave the matrix and go to the QMS path. Subtract their hours from available capacity before you plan anything else. Output: gate result for each idea.
3. **Fix the weights and bands.** Confirm or edit the default weights and the dollar and hour bands before anyone scores. Record them on the worksheet. Don't change them after you see the results. Output: recorded weights.
4. **Score each criterion.** The named scorer (Section 3.5) gives a whole number from 1 to 5 using the written anchors and records the data source in one line. No score without evidence. Output: raw scores.
5. **Calculate.** Use the worksheet or the Excel calculator to get the weighted impact score, weighted effort score, and priority index. Output: weighted scores.
6. **Plot and sort.** Place each idea in a quadrant using the cut-off rule (Section 3.4). Discuss any idea within 0.25 of a cut-off before accepting its quadrant. Output: quadrant for each idea.
7. **Check capacity and decide.** Take Quick Wins in priority-index order until planned hours reach available hours. Pick at most one or two Major Projects to scope. Output: the start list for the quarter.
8. **Log the actions.** Record each started idea in the action log with owner, due date, acceptance criterion, and effectiveness check. Output: action log.
9. **Re-score each quarter.** Re-score ideas whose inputs changed, close completed ones, and add new ones. Output: updated matrix.

3. Working section

3.1 Gates before ranking

Answer these for every idea before anyone scores it. QA owns the answers.

Gate	Question	If yes
G1	Does the idea respond to an open nonconformance, complaint trend, CAPA, audit finding, or a risk in the risk management file that is not acceptable under your risk acceptability criteria?	Route to the QMS path: CAPA, risk management, and change control. Don't score it. Staff it first and take its hours off the top.
G2	Would it change device design, labeling, or intended use?	Route to design control and change control, including a regulatory assessment. Don't score it here.
G3	Would spend exceed the site capital approval limit?	Score it here for visibility and flag it Capital. The approval decision is made in the capital process.

Caution: The matrix never overrides the QMS. A low score does not close a quality or safety concern, and a high score does not approve a change. Every change to a validated process still goes through your change-control procedure (ISO 13485:2016, clauses 4.1.4 and 7.5.6).

3.2 Scoring model

Each idea gets nine scores from 1 to 5: five for impact and four for effort. Weights turn them into one impact score and one effort score, each still on a 1 to 5 scale because the weights in each group add up to 100%.

Group	Criterion	Question it answers	Default weight
Impact	I1 Safety and compliance risk reduction	How much does it widen the margin on a known risk or compliance weakness?	20%
	I2 Quality and yield	How much of the area's current reject and rework loss does it remove?	30%
	I3 Delivery and throughput	How much does it add at the constraint, or cut from lead time?	25%
	I4 Cost	What is the annual recurring hard saving?	15%
	I5 People and ergonomics	Does it remove a hard, risky, or single-person task?	10%
Effort	E1 Engineering hours	Total hours across all functions, QA and validation included.	25%
	E2 Capital or spend	Money out the door, including outside services.	20%
	E3 Time to result	Calendar time until the benefit shows up on the line.	20%
	E4 Validation and change-control burden	Does it trigger revalidation, a regulatory assessment, or customer notification?	35%

Impact score = (I1 x 0.20) + (I2 x 0.30) + (I3 x 0.25) + (I4 x 0.15) + (I5 x 0.10)

Effort score = (E1 x 0.25) + (E2 x 0.20) + (E3 x 0.20) + (E4 x 0.35)

Priority index = Impact score minus Effort score. It runs from -4 to +4 and orders ideas inside a quadrant.

Why these weights. Validation burden carries the most effort weight because in a regulated plant it is what usually decides whether a "small" change takes three weeks or six months. I1 carries 20%, not more, because real safety and compliance exposure has already been sent to the QMS by gate G1. I1 scores the proactive gains: more margin on a process that is already in control.

Heron practice, not a requirement. The criteria, weights, anchors, and bands are Heron's starting point. Edit them to fit your site, record what you used, and keep them fixed for the quarter so the ranking can be compared over time.

3.3 Score anchors

Use whole numbers only. If an idea sits between two anchors, score the lower one and write down why. The dollar, hour, and time bands are examples for a mid-size line. Set your own before scoring.

Impact criteria

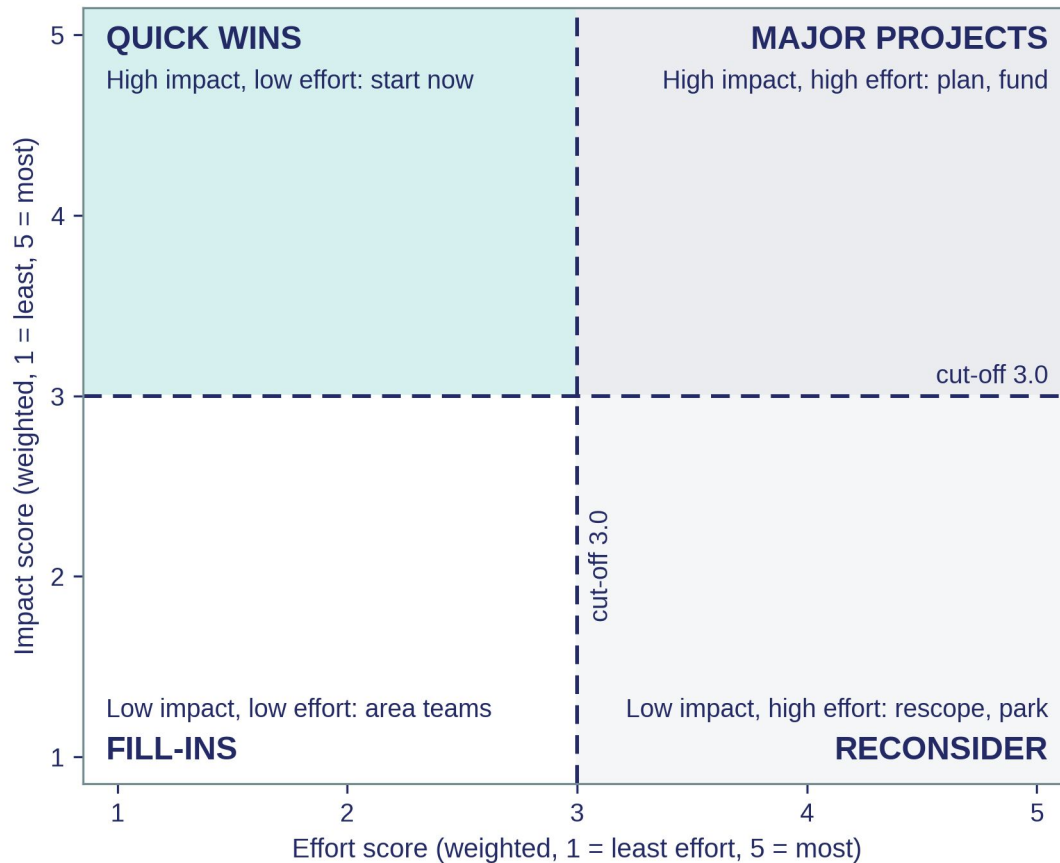
Criterion	Score	Anchor
I1 Safety and compliance	1	No effect on product risk or compliance.
	2	Fixes a documentation or housekeeping weakness with no product effect.
	3	Lowers the likelihood of a known low-severity failure mode, or an audit observation type you have had before.
	4	Adds margin on a process linked to a medium-severity hazard in the risk file, or replaces a check that depends on operator attention.
	5	Designs out, or adds automatic detection for, a failure mode linked to a high-severity hazard in the risk file.
I2 Quality and yield	1	No measurable change in yield, scrap, or rework.
	2	Addresses less than 5% of the area's current reject and rework loss.
	3	Addresses 5% to 15% of that loss.
	4	Addresses 15% to 30% of that loss.
	5	Addresses more than 30% of that loss.
I3 Delivery and throughput	1	No effect on the constraint or on lead time.
	2	Helps a non-constraint step only.
	3	Up to 5% more output at the constraint, or up to 1 day off lead time.
	4	5% to 15% more output at the constraint, or 1 to 3 days off lead time.
	5	More than 15% more output at the constraint, more than 3 days off lead time, or removes a recurring backorder cause.
I4 Cost (annual, recurring, hard)	1	Less than \$10k.
	2	\$10k to \$25k.
	3	\$25k to \$75k.
	4	\$75k to \$200k.
	5	More than \$200k.
I5 People and ergonomics	1	No change.
	2	Removes a minor nuisance task.
	3	Removes a repetitive manual task on one shift, or shortens training for a role.
	4	Removes a documented ergonomic risk, or the task operators rate hardest on the line.
	5	Removes an injury risk, or a single-person skill dependency across all shifts.

Effort criteria (5 = most effort)

Criterion	Score	Anchor
E1 Engineering hours (all functions)	1	Less than 40 hours.
	2	40 to 120 hours.
	3	120 to 300 hours.
	4	300 to 800 hours.
	5	More than 800 hours.
E2 Capital or spend	1	Less than \$5k.
	2	\$5k to \$25k.
	3	\$25k to \$100k.
	4	\$100k to \$250k.
	5	More than \$250k, or above the site capital approval limit.
E3 Time to result	1	Less than 1 month.
	2	1 to 2 months.
	3	2 to 4 months.
	4	4 to 9 months.
	5	More than 9 months.
E4 Validation and change-control burden	1	No change to a validated process, specification, or controlled document beyond a minor edit.
	2	Controlled document change with a documented impact assessment. No revalidation.
	3	Partial revalidation (for example OQ or PQ on one parameter or one machine), or a test method change that needs a new MSA.
	4	Full IQ/OQ/PQ, or a process change that needs an updated risk file and a documented regulatory assessment (for example a 510(k) change decision).
	5	Likely needs a regulatory submission or notified body notification, or customer notification or approval under a supply agreement.

Caution: E4 anchors 4 and 5 describe regulatory change assessment in general terms, using the US 510(k) change decision as the example. Other markets have their own rules. Whether a given change needs a submission or notification is a decision for your RA function, made under your own procedures.

3.4 The 2x2 matrix



Quadrant	Rule	What to do
Quick Wins	Impact 3.0 or more, effort below 3.0	Start this quarter in priority-index order, up to available hours.
Major Projects	Impact 3.0 or more, effort 3.0 or more	Write a one-page case, then plan, fund, and phase it. Start one or two per quarter at most (rule of thumb).
Fill-ins	Impact below 3.0, effort below 3.0	Give to area teams. No dedicated engineering hours.
Reconsider	Impact below 3.0, effort 3.0 or more	Rescope for less effort, or park and re-score next quarter.

Cut-off rule. The cut-off is 3.0 on both axes, the midpoint of the 1 to 5 scale. A score of exactly 3.0 counts as high. That is deliberate on the effort axis: when in doubt, assume the work is bigger.

Near the line. Discuss any idea 0.25 or less from a cut-off before you accept its quadrant. Look at which single score put it there and check that score's evidence.

Order inside a quadrant. Highest priority index first. For ties, higher impact first, then lower E4, then lower idea number.

3.5 Starter criteria table

Who scores what, from which data, and how each score tends to get pushed. Name the scorer before the session, not during it.

Criterion	Data source	Who scores	How it gets gamed
I1 Safety and compliance. Margin gained on a known risk or compliance weakness.	Risk management file, audit history, process capability data	QA or RA	Everything gets called "safety" to jump the queue. Ask for the risk file line item. No line item, no score above 2.
I2 Quality and yield. Share of current reject and rework loss addressed.	Reject Pareto, 8 to 13 weeks (HKN-KPI-001)	Quality engineer	The same reject category is claimed by two ideas. Assign each Pareto bar to one idea.
I3 Delivery and throughput. Gain at the constraint or in lead time.	Capacity model, OEE by step, schedule attainment	Production or planning lead	Throughput is claimed at a step that is not the constraint. Name the constraint first.
I4 Cost. Annual recurring hard saving.	Standard cost, scrap cost, labor rates	Finance or site controller	Soft savings (avoided cost, hours freed but not removed) are counted as hard. Finance signs the number.
I5 People and ergonomics. Hard, risky, or single-person tasks removed.	Ergonomic assessments, skills matrix, operator input	Production lead with operators	Rarely inflated. More often skipped and scored 1 by default. Ask the operators.
E1 Engineering hours. Total hours, all functions.	Similar past projects, owner estimate	Engineering lead	QA, validation, and document hours are left out. Pet projects get optimistic estimates.
E2 Capital or spend. Money out the door.	Quotes, purchasing	Engineering with purchasing	A purchase is split to stay under an approval limit. Score the whole idea.
E3 Time to result. Calendar time to benefit.	Supplier lead times, validation queue	Idea owner	Only engineering time is quoted. Add equipment lead time and the wait for validation resources.
E4 Validation and change control. Revalidation, regulatory, customer notice.	Validation master plan, change-control procedure, supply agreements	QA or validation lead	A change is called "like for like" to skip revalidation. QA scores E4, never the sponsor.

Decision or output: a ranked start list for the quarter that fits available hours, with gated items routed to the QMS and one or two Major Projects chosen for scoping.

Caution: Scores are structured estimates, not measurements. The ranking supports a management decision. It is not a business case, a risk assessment, or approval of a change.

4. Illustrative worked example (synthetic data)

Illustrative example only. All data here is synthetic. Line 3 is an invented line, not a Heron client or a verified result.

Setup. Line 3 makes lathe-cut hydrogel specialty contact lenses: lathing, hydration and extraction, inspection, blister sealing, and terminal sterilization. The team has 10 ideas and 200 engineering hours for the quarter. Default weights and bands are used.

Step 1: Gate

CIM-10 (particulate found in three packaged lots, with a complaint trend) answers yes to G1. It goes to CAPA, which is estimated at 60 hours. That leaves 140 hours for the matrix. The other nine ideas pass the gate. None exceeds the capital limit except CIM-07, which is flagged Capital under G3.

Step 2: Raw scores

ID	I1	I2	I3	I4	I5	E1	E2	E3	E4
CIM-01	2	3	5	4	3	2	2	2	2
CIM-02	3	4	3	3	2	2	1	2	2
CIM-03	2	4	3	4	1	3	1	2	4
CIM-04	2	4	2	3	3	3	3	3	3
CIM-05	4	3	3	2	1	4	3	4	4
CIM-06	1	2	2	1	3	1	1	1	1
CIM-07	3	3	4	4	4	5	5	5	4
CIM-08	1	1	3	2	2	1	1	2	1
CIM-09	2	2	2	1	5	2	1	2	1
CIM-10	Gated to CAPA (G1). Not scored.								

ID	Idea	Est. hours
CIM-01	Lathe changeover SMED (preset tooling, external setup)	80
CIM-02	Lathe tool-life SPC and planned tool change	50
CIM-03	Inspection vision tuning to cut false rejects	140
CIM-04	Hydration fixture redesign to cut edge tears	160
CIM-05	Blister seal parameter window study (DOE)	400
CIM-06	Tier 1 board and daily huddle at hydration	20
CIM-07	Robotic lens transfer at packaging	900
CIM-08	Kanban for blister foil and saline	16
CIM-09	Inspection cross-training matrix	45
CIM-10	Particulate in three packaged lots (open complaint trend)	60

Step 3: Weighted scores and quadrants

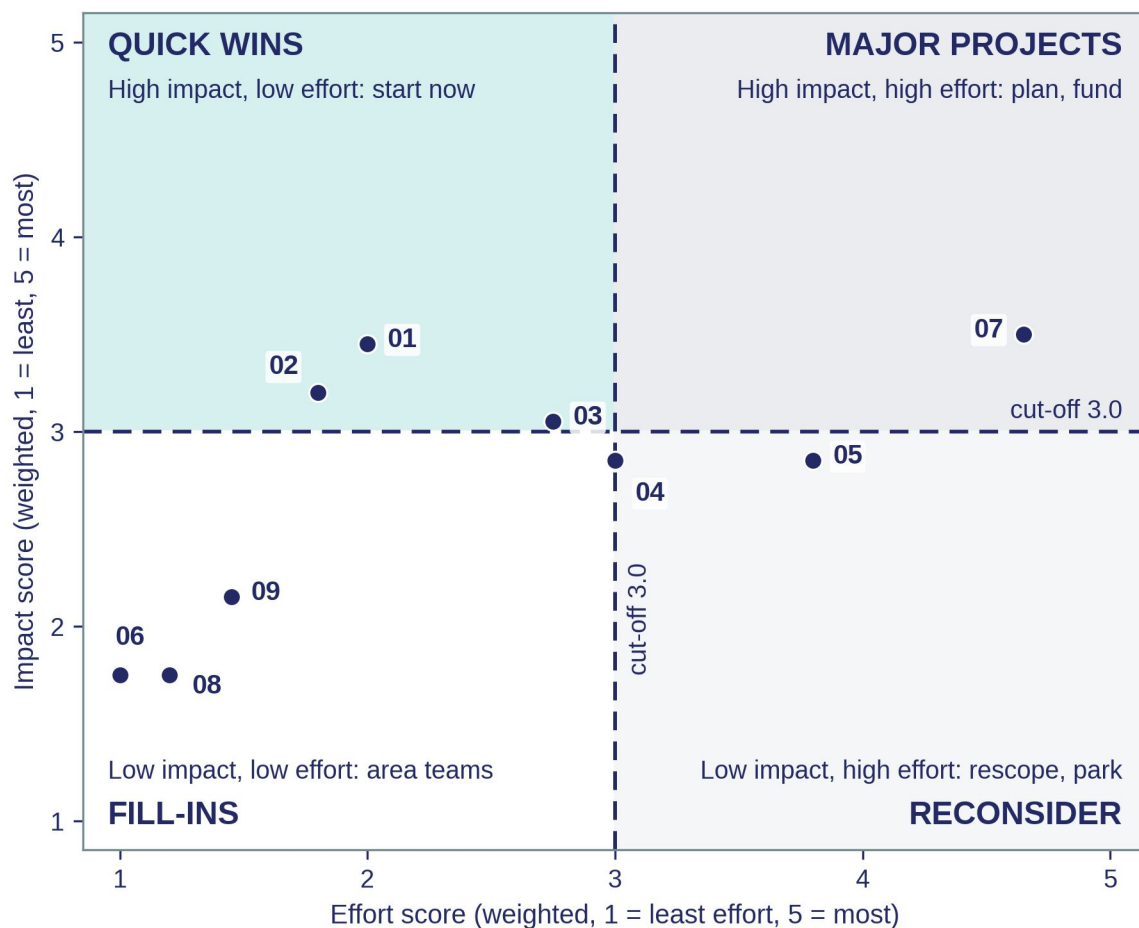
Rank	ID	Impact	Effort	Index	Quadrant
1	CIM-01	3.45	2.00	+1.45	Quick Win
2	CIM-02	3.20	1.80	+1.40	Quick Win
3	CIM-03	3.05	2.75	+0.30	Quick Win
4	CIM-07	3.50	4.65	-1.15	Major Project
5	CIM-06	1.75	1.00	+0.75	Fill-in
6	CIM-09	2.15	1.45	+0.70	Fill-in
7	CIM-08	1.75	1.20	+0.55	Fill-in
8	CIM-04	2.85	3.00	-0.15	Reconsider
9	CIM-05	2.85	3.80	-0.95	Reconsider

Hand check, CIM-01

Impact = $(2 \times 0.20) + (3 \times 0.30) + (5 \times 0.25) + (4 \times 0.15) + (3 \times 0.10) = 3.45$

Effort = $(2 \times 0.25) + (2 \times 0.20) + (2 \times 0.20) + (2 \times 0.35) = 2.00$

Index = $3.45 - 2.00 = +1.45$



Step 4: Decision

- **Start now: CIM-01 lathe changeover SMED (80 h) and CIM-02 tool-life SPC (50 h).** Both are Quick Wins at the constraint and together use 130 of the 140 hours. CIM-02 is flagged Discuss because its impact (3.20) is 0.20 above the cut-off. The team checked its I2 score of 4 against the reject Pareto: tool-wear defects are 22% of the loss, so the score stands.
- **Hold: CIM-03 vision tuning (140 h).** A Quick Win, but exactly 0.25 inside the effort cut-off, so it is flagged Discuss. E4 is 4 because the vision system is validated inspection equipment and a recipe change means requalification. If the hour estimate grows past 300 ($E1 = 4$), effort reaches 3.00 and it becomes a Major Project. QA and engineering confirm the scope first. It doesn't fit this quarter's hours either way, so it goes first next quarter.
- **Scope: CIM-07 robotic lens transfer.** Major Project, flagged Capital. The owner writes a one-page case for next year's capital plan.
- **Area teams: CIM-06, CIM-09, CIM-08.** Fill-ins with no engineering hours. Production and materials leads own them.
- **Rescope: CIM-04 hydration fixture.** Flagged Discuss: effort sits exactly on the cut-off (3.00) and impact is 0.15 below it. The owner brings a cheaper fixture concept to the next scoring.
- **Park: CIM-05 seal window study.** Flagged Discuss on impact (2.85). Raising I1 or I2 by one point would still leave effort at 3.80, so it would only move to Major Projects, not Quick Wins. Seal strength is in control, so widening the window buys flexibility, not safety, and it costs a full revalidation. If seal data starts to trend, gate G1 applies and it goes to the QMS path.
- **Gated: CIM-10 particulate.** Handled as CAPA with its 60 hours taken off the top.

What leadership hears. "We are fixing the particulate issue first through CAPA. With the remaining 140 hours we're doing the two changes that add the most at the lathe for the least validation work. Vision tuning goes next quarter once QA sizes the revalidation, and the robot goes into the capital plan."

5. Interpretation and follow-up

What the ranking means. It is a defensible order for spending discretionary improvement hours, based on weights you recorded and evidence for each score. You can show anyone why one idea came before another.

What it does not mean. It is not a business case, a risk assessment, a savings forecast, or approval of a change. The quadrant of an idea near a cut-off can flip with one score. A Fill-in is not a bad idea; it's an idea that doesn't need engineering hours.

Who acts. The operations lead owns the list and the quarterly re-score. Each started idea has one named owner. QA confirms gate results and E4 scores. Finance confirms I4 before an idea is reported as a saving.

Action log

Action	Owner	Due date	Acceptance criterion	Effectiveness check

Acceptance criterion: what must be true to call the action done (for example, changeover under 25 minutes on 10 consecutive changeovers). Effectiveness check: when and how you confirm the benefit held (for example, 8 weeks after closure, from the KPI board).

30-60-90 day plan (Heron practice)

Window	What to do	Evidence it's done
Days 1 to 30	Pick one line or value stream. Build the idea list, agree the weights and bands, run the gate, score the first matrix, and start the top Quick Wins that fit capacity.	Recorded weights, gated list, first matrix, action log with owners
Days 31 to 60	Review started items weekly in 15 minutes. Compare estimated hours with actual. Fix any anchor that caused an argument during scoring.	Weekly review notes, estimate vs actual, updated anchors
Days 61 to 90	Close finished items and set their effectiveness checks. Re-score the backlog at quarterly planning. Decide whether to extend the method to the next line.	Closed actions, re-scored matrix, decision on next line

6. References and control

Primary references were checked in September 2026. Check clause text against your own licensed copies. The criteria, weights, anchors, bands, cut-off, tie rule, 0.25 discussion band, priority index, and 30-60-90 plan are Heron practice, not requirements.

Reference	Used for
ISO 13485:2016, Medical devices: Quality management systems. Clauses 4.1.4 (changes to QMS processes), 7.5.6 (validation of processes, including revalidation criteria), 8.4 (analysis of data), 8.5 (improvement).	Gates, E4 anchors, caution on change control
ISO 14971:2019, Medical devices: Application of risk management to medical devices (3rd edition).	Gate G1, I1 anchors
21 CFR Part 820, Quality Management System Regulation (QMSR), effective February 2, 2026. Incorporates ISO 13485:2016 by reference.	US regulatory context for change control
21 CFR 807.81(a)(3), and FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device" (final, October 25, 2017).	E4 anchors 4 and 5 (US). Other markets have their own change-notification rules.
Shingo, S. (1985). A Revolution in Manufacturing: The SMED System. Productivity Press.	Worked example, idea CIM-01
Heron HKN-KPI-001, KPI Field Guide.	Reject Pareto and baseline window used for I2

Control	Value
Resource ID	HKN-CIM-001
Version	0.1
Status	Approved for publication October 4, 2026.
Approval Heron - October 4, 2026	Approval Heron - October 4, 2026
Related resources	HKN-KPI-001 KPI Field Guide; HKN-TRF-001 Process Transfer Readiness Checklist; HKN-CIM-001 Worksheet (fillable PDF) and Calculator (Excel)
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