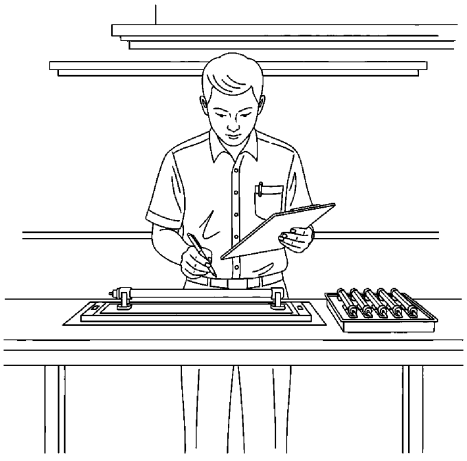
SPECIFIC-CASE

WORKSHEET 9 OF 9

New SKU Requires a Sampling Plan from Scratch

Scenario: you are launching a product line not previously manufactured. No historical defect data exists for this SKU. You need to establish IQC specs for incoming materials, an IPQC control point for the critical process stage, and a final inspection sampling plan — all before the first production run.



Complementary worksheet for
Quality Control Systems

SECTION 1

What This Is For

Launching a new SKU without a quality plan means the first three production runs will teach you what defects are possible — at the cost of rework, scrap, and potentially customer returns if any of those runs are shipped. This worksheet builds the minimum viable quality plan before the first run: one IQC parameter, one IPQC binary question, one final inspection AQL — enough to catch the most likely failures without requiring a complete quality system the business does not yet have for this product.

The constraint that makes this specific to new SKUs: no historical defect data exists. Every number in this plan starts as an informed assumption based on the product's end-use requirements, the supplier's datasheet, or analogous products already in production. The plan is built once, used for the first ten runs, and reviewed against actual data before being treated as permanent.

SECTION 2

Benefits

What you get when you actually run this worksheet on a real situation:

- Establishes IQC spec derivation in writing — so when a supplier dispute arises about which lot caused the defect, the basis for the incoming material standard is on record, not in someone's memory.
- Row 5 (the IPQC binary question) forces precision about what 'good' means at the most critical process stage before operators start producing — rather than discovering what 'bad' means from the first batch of rejects.
- The 100% IQC inspection for the first three lots (row 3) builds the defect baseline that makes subsequent AQL sampling statistically meaningful, instead of applying AQL to a supplier whose actual quality level is unknown.
- Row 12 (10-run review date) is the only mechanism that prevents the initial assumptions from becoming permanent standards regardless of what the real production data shows.
- The complete plan on one sheet creates a cross-functional handoff document: purchasing knows what to inspect on receipt, production knows where the IPQC point is, QC knows what AQL applies to final inspection, and management knows where the records are stored.

SECTION 3

Framework To Use

— IQC → IPQC → Final Inspection Stack

Three inspection layers, each catching what the previous one cannot — the stack is only as strong as its weakest link, and the weakest link on a new SKU is always the one that was not designed before the first production run.

1	IQC: incoming material received — measure the one critical parameter before material enters the process
▼	
2	If IQC fails: quarantine lot, contact supplier, do not start production on that lot
▼	
3	IPQC: at the most irreversible stage — operator answers one binary yes/no question
▼	
4	If IPQC fails: stop, hold units, notify QC lead before continuing
▼	
5	Final inspection: AQL sampling on completed lot — accept/reject by documented criteria
▼	
6	If final inspection fails: quarantine lot, open NCR, management disposition decision
▼	
7	After 10 runs: review IQC spec, IPQC question, and AQL level against actual defect data

SECTION 4

How To Use

Follow these steps in order. Each one builds on the previous.

1. Start with row 1 (main incoming material) and row 4 (most critical in-process stage). These two decisions determine everything else. If you cannot name one main material and one critical stage, the product launch readiness question is not yet answered.

2. For row 2 (IQC spec), use the supplier datasheet if available. If no datasheet exists, measure ten samples of the material you intend to use and set the tolerance to the range you find. Document which method you used — datasheet reference or sample measurement — in the Rationale column.

3. Row 3 (sample size for IQC): default to 100% inspection for the first three lots. AQL sampling requires a baseline to be meaningful. For the first three lots, the baseline does not exist.

4. Row 5 (IPQC binary question): write it as a yes or no sentence that an operator can answer with available tools. 'Does the stitching tension meet the specification?' is not binary if the operator has no tension gauge. 'Is the seam within 2mm of the pattern line?' is binary with a ruler.

5. Rows 6 and 7 (measuring tool and operator training): both must be in place before the first production run, not during it. Name the specific tool and its current calibration status. Name the training method — verbal instruction is not sufficient; simulation with a passing and failing sample is the minimum.

6. Row 9 (final inspection AQL): use the ns-1 worksheet (AQL Sampling-Plan Design) to derive the correct level for this product's risk category. Do not carry over the AQL from an existing product without checking that the risk category matches.

7. Row 12 (10-run review date): enter it as a calendar event today. Name the person who will run the review and who will sign off on any spec changes that result. Without a named reviewer and a calendar date, the review will not happen.

SECTION 5

Example Use

A food manufacturer is adding a new chili paste in 250g glass jars to their existing line. No previous glass jar product. The filling process, sealing method, and incoming material (glass jars) are all new to this facility.

Row 1: Main incoming material — glass jars (250ml). Critical parameter: rim flatness and chip-free status (determines whether the heat seal will be airtight).

Row 2: IQC spec for rim flatness — supplier datasheet specifies rim runout max 0.3mm. No prior measurement data for this supplier. Rationale: use supplier datasheet value, verify with first-lot measurement on 20 samples before committing.

Row 3: IQC sample size for first three lots — 100% visual inspection for chips and cracks, 100% rim runout measurement with dial gauge. Switch to AQL 1.0 after three lots establish baseline.

Row 4: Most critical in-process stage — filling and heat sealing. Once sealed, leaks can only be detected by the customer opening the jar. Irreversible.

Row 5: IPQC binary question at sealing stage — "Does the vacuum indicator (button on jar lid) depress and return to flat position when tested by hand within 60 seconds of sealing?" This is a binary yes/no test that any operator can run with no tools.

Row 6: Measuring tool — dial gauge (calibration current; last calibrated 3 weeks ago). For IPQC vacuum test: no tool required, tactile test.

Row 7: Operator trained on IPQC — production lead trained via live simulation (5 passing seals + 3 intentionally failed seals demonstrated). Sign-off record in training log dated [launch date minus 3 days].

Row 8: Final inspection parameter — net weight (250g ±5g) and visual for label alignment and lid deformation. Different parameter from IPQC (IPQC tests seal integrity; final inspection tests weight and appearance).

Row 9: Final inspection AQL — AQL 1.0 at Level II. Lot size 400 jars per run. Sample size 80. Ac=2, Re=3. Food product risk category justifies tighter AQL.

Row 10: Disposition for rejected units — rework allowed for weight off-spec (add or reduce fill quantity if still within tolerance, reseal) and for label misalignment (relabel). Scrap for lid deformation or failed vacuum test — no rework path exists for seal integrity failure.

Row 11: Records stored — IQC log in receiving folder (physical binder, receiving dock). IPQC form posted at sealing station (one row per production hour). Final inspection log in QC folder (digital, shared drive + physical backup).

Row 12: 10-run review date — set for 10 production runs from launch date. Reviewer: QC lead and production lead jointly. Sign-off required from owner for any spec changes. Calendar event created.

First run outcome: 3 jars failed vacuum test at IPQC (1 per approximately 130 units). All three held and scrapped. Root cause: sealing temperature 2°C below spec during first 40 minutes of run (machine warm-up). Temperature spec added to IPQC form as second binary check.

SECTION 6

The Worksheet

Tear this out, copy it onto a fresh sheet, or fill it in directly.

New SKU Requires a Sampling Plan from Scratch

Scenario: you are launching a product line not previously manufactured. No historical defect data exists for this SKU. You need to establish IQC specs for incoming materials, an IPQC control point for the critical process stage, and a final inspection sampling plan — all before the first production run.

SETUP ELEMENT	DECISION REQUIRED	YOUR ANSWER	RATIONALE

SECTION 6 (CONTINUED)

Reflection Prompts

After filling in the worksheet on the previous page, work through these.

1. Twelve setup elements: (1) Main incoming material — name and critical parameter to inspect. (2) IQC spec for that parameter: acceptable range, source of the number (supplier datasheet / sample measurement / regulatory minimum). (3) Sample size for IQC receiving inspection: 100% for first three lots, then AQL after baseline established? (4) Most critical in-process stage — where an undetected defect becomes irreversible. (5) IPQC binary question at that stage: write it as a yes/no sentence an operator can answer with available tools. (6) Measuring tool needed for IPQC: name and current calibration status. (7) Operator trained on IPQC: name and training method (live simulation, written SOP, both). (8) Final inspection parameter and tolerance: same or different from IPQC parameter? (9) Final inspection AQL: chosen level and lot size it applies to. (10) Disposition procedure for rejected units: rework / scrap / hold for management decision — which applies to this SKU? (11) Where will IQC, IPQC, and final inspection records for this SKU be stored? (12) Planned review date for all three specs after first 10 production runs: who reviews and adjusts tolerances based on actual data?

---

2. Row 2 priority: if no supplier datasheet exists and no sample measurement is possible before launch, the IQC spec must be sourced from the product's end-use requirement working backwards. What parameter value at the output is required for the product to function or be accepted? That value, minus reasonable process variation, is the incoming material floor. Document the derivation method so it can be reviewed after real data arrives.

---

3. Row 12 is the most important row in this worksheet. A sampling plan built on assumptions rather than data must be reviewed after the first 10 runs. Without a planned review, the initial assumptions become permanent defaults regardless of what the real defect distribution looks like.

SECTION 7

Tips and Traps

TIPS

- Run this worksheet 10 business days before the first production run, not 2. Rows 6 and 7 (tool calibration and operator training) take time. Discovering on launch day that the dial gauge is out of calibration means either delaying the run or launching without IQC.
- If the supplier provides a datasheet with tighter tolerances than what your process can achieve, the incoming material spec may be tighter than your process stability. This is a design problem to resolve before launch, not an IQC problem to work around after.
- For row 5, test the binary question on three colleagues who are not familiar with the product. If they answer it differently, it is not yet binary — the question is ambiguous and needs rewriting with a concrete measurement or observable criterion.
- Keep the completed worksheet as a permanent record. When the 10-run review happens, update this same sheet rather than creating a new document. The version history of spec changes is its own quality record.

TRAPS

- Carrying over the AQL from an existing product without checking whether the new SKU's risk category matches. A cosmetic product and a food product may both be produced at the same facility, but AQL 4.0 on the food product is likely insufficient and may not survive a BPOM inspection.
- Setting row 7 (operator training) to 'completed verbally.' Verbal-only training produces verbal-only compliance — inconsistent and unverifiable. The minimum for a new IPQC point is a demonstrated simulation with at least one passing and one failing unit.
- Skipping row 10 (disposition for rejected units) on the grounds that 'we'll figure it out if it happens.' The worst time to decide whether a batch goes to rework or scrap is when a batch is sitting on hold and the customer is waiting for a delivery. Decide before the first run.
- Treating the 10-run review as optional if the first few runs seem fine. Initial runs often run fine because the team is paying extra attention. The review is most valuable at run 8–10, when attention has normalized and real process behavior is visible.

SECTION 8

Appendixes

Appendix A — IQC Spec Derivation Methods (in priority order)

```
Method 1 — Supplier datasheet
  Use the parameter and tolerance from the supplier's published spec.
  Record: supplier name, document title, date accessed.
  Limitation: supplier spec reflects what they can produce, not
  necessarily what your process requires.

Method 2 — Sample measurement from known-good material
  Measure 10 samples of material that has produced acceptable output
  in an analogous product. Set tolerance to the measured range.
  Record: date measured, person who measured, instrument used,
  calibration status of instrument.
  Limitation: sample may not capture full supplier variation.

Method 3 — Back-calculation from end-use requirement
  Identify the minimum acceptable output parameter (e.g., seal
  integrity under pressure). Work backwards: what input parameter
  range produces outputs that always pass?
  Record: the derivation logic in writing. This is the weakest
  basis for an IQC spec — acceptable only when Methods 1 and 2
  are unavailable before launch. Must be replaced after first
  10 runs with real measurement data.
```

Appendix B — 10-Run Review Checklist

```
Run this review after exactly 10 production runs of the new SKU.

IQC review:
[ ] How many lots were rejected at IQC? ___/10
[ ] Was the IQC parameter the one that mattered, or were there
    other incoming parameters that caused problems?
[ ] Is the tolerance range still accurate given actual material variability?

IPQC review:
[ ] How many units were held at the IPQC point? _____ total
[ ] Was the binary question consistently answered without ambiguity?
[ ] Did any IPQC failure lead to a customer complaint? Yes / No

Final inspection review:
[ ] How many lots were rejected at final inspection? ___/10
[ ] Were rejection rates above or below AQL acceptance threshold?
[ ] Should AQL level be tightened or relaxed based on actual data?

Sign-off: QC lead _______________ Owner _______________ Date ___
```

CONFIRMATION

WHERE THIS WORKSHEET COMES FROM

Quality Control Systems

Consistent Quality Is the Result of a System, Not Inspection

by Ibrahim Anwar

This worksheet is one of nine in the *Quality Control Systems* companion worksheet pack. The full pack is grouped into three categories: high-volume worksheets you can run weekly, niche-search worksheets for rare but high-value situations, and specific-case worksheets that walk you through a single concrete scenario.

Every framework, decision filter, and figure used in these worksheets is drawn from the chapters of the source book. The book sets the diagnosis, the worksheets give you the form to act on it.

Available on Google Play Books

play.google.com/store/books

PT Hibrkraft Kreasi Indonesia · Cileungsi, Bogor · hibranwar.com