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Supplementary Materials

A Generative AI-Based Framework for Proactive Quality Assurance and Auditing

This document provides supplementary information supporting the proof-of-concept (PoC) case study and details about the ChatGPT-5-Thinking (hereafter, ChatGPT) workflow.

Contents:

- S1. PoC case input package
- S2. Full PoC deliverables (expert team vs ChatGPT)
- S3. Evaluation indices and scoring rubric
- S4. Inter-rater reliability and supporting rating tables
- S5. Generative AI prompting sequence and human-in-the-loop verification gate
- S6. Abbreviations and notation

S1. PoC Case Input Package

The PoC case study evaluates an NPI quality-planning task for the ST-200 smart thermostat. Both conditions (expert team and ChatGPT workflow) were conducted within the same fixed 10 business-day window and used the same ST-200 case brief and constraints (product architecture, assembly flow, CTQ requirements, and process constraints). The required outputs were specified upfront and are identical for both conditions: PFMEA, linked Control Plan, supplier PPAP templates/requests, and an Internal Audit Evidence Pack. Acceptance logic follows the framework's three-level gates (Levels 1–2 in Figure 1 and Level 3 in Figure 2) using the KPI bundles θ_{pd}, θ_{pc}, and θ_{op}.

Table S1. Level-specific KPI bundles used as acceptance gates in the PoC.

KPI bundle	Scope	Illustrative acceptance conditions used in the PoC
θ_{pd}	Product-level (CTQ outcomes)	FPY ≥ 95%; DPMO ≤ 500 (CTQ-oriented indicators)
θ_{pc}	Process-level (capability/stability)	Cp/Cpk ≥ 1.33 (where applicable), with defined monitoring and reaction logic
θ_{op}	Operation-level (governance/auditability)	0 major nonconformities; ≤2 minor nonconformities; CAPA on-time closure ≥ 90%; verified traceability and data integrity

Gate-handling logic (aligned with Figures 1–2): if θ_{op} is not satisfied, the workflow triggers a reset of the operation (including rework) or escalates to process design review; if θpc is not satisfied, it triggers a reset of the affected process or escalation; and if θ_{pd} is not satisfied, the case returns for redesign and/or technology improvement at the product level.

S2. Full PoC Deliverables (Expert Team vs ChatGPT)

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This section provides the full PFMEA and Control Plan tables used in the PoC evaluation. Supplier PPAP templates/requests and the Internal Audit Evidence Pack are provided as structured lists.

S2.1. PFMEA (full)

Table S2. PFMEA (expert team, full).

#	Step	Failure mode	Effect	Cause	S	O	D	RPN	Current control	Action
0.0	SMT paste print	Solder bridging	No connection, high draw	Excess paste, stencil wear	8	4	4	128	SPI, AOI	Reduce aperture, retrain operator
1.0	SMT placement	Tombstoning of 0402s	Intermittent RF issues	Offset, thermal stress	7	3	5	105	AOI, placement program verification; feeder/nozzle checks	Adjust design layout, feeder check
2.0	Reflow soldering	Voids under PMIC	Thermal instability	Poor soak profile	9	2	5	90	X-ray, FT	DOE on profile, SPC control
3.0	AOI inspection	False negative	Undetected solder defects	Contrast variation, bad thresholds	8	5	4	160	Golden board validation	MSA study, standardize AOI parameters
4.0	ICT/Boundary-scan test	Open circuit detection failure	Missed defects	Poor fixture contact	6	3	5	90	Fixture validation, periodic check	Improve fixture, pin map validation
5.0	Display bonding	Misalignment > 0.2 mm	Light-bleed	Fixture drift, excess glue	6	4	5	120	Visual check	Add vision inspection, GRR validation
6.0	Sensor + connector sub-assembly	Loose sensor connector	Signal loss, inaccurate reading	Operator handling	7	4	4	112	Visual inspection	Introduce poka-yoke, operator training
7.0	Firmware flashing	Wrong image	Bricked unit	Config control lapse	9	2	6	108	CRC, manual log	Auto flash check, signed build required
8.0	Functional test (BLE/Wi-Fi,	Temp offset >	Inaccurate user	Sensor miscalibratio	8	3	4	96	Calibration,	Cp/Cpk monitoring

#	Step	Failure mode	Effect	Cause	S	O	D	RPN	Current control	Action
	temp, UI)	±0.5°C	comfort	n					FT	, drift alarms, supplier CoC
9.0	Final enclosure assembly	Missing screw	Loose assembly	Manual oversight	5	4	5	100	Torque tool, visual	Torque traceability, poka-yoke
10.0	Burn-in/soak test	Early failure not detected	Customer complaint	Insufficient duration	6	3	5	90	8h cycle	Extend soak time, fault monitoring
11.0	Pack & label	Wrong label	Wrong shipment	Manual labeling	7	3	4	84	Barcode check	Automated scan validation, print log
12.0	Display bonding	Misalignment > 0.2 mm	Light-bleed	Fixture drift, excess glue	6	4	5	120	Visual check	Add vision inspection, GRR validation
13.0	Sensor + connector sub-assembly	Loose sensor connector	Signal loss, inaccurate reading	Operator handling	7	4	4	112	Visual inspection	Introduce poka-yoke, operator training
14.0	Firmware flashing	Wrong image	Bricked unit	Config control lapse	9	2	6	108	CRC, manual log	Auto flash check, signed build required
15.0	Functional test (BLE/Wi-Fi, temp, UI)	Temp offset > ±0.5°C	Inaccurate user comfort	Sensor miscalibration	8	3	4	96	Calibration, FT	Cp/Cpk monitoring, drift alarms, supplier CoC
16.0	Final enclosure assembly	Missing screw	Loose assembly	Manual oversight	5	4	5	100	Torque tool, visual	Torque traceability, poka-yoke
17.0	Burn-in/soak test	Early failure not detected	Customer complaint	Insufficient duration	6	3	5	90	8h cycle	Extend soak time, fault monitoring
18.0	Pack & label	Wrong label	Wrong shipment	Manual labeling	7	3	4	84	Barcode check	Automated scan validation,

#	Step	Failure mode	Effect	Cause	S	O	D	RPN	Current control	Action
										print log

Table S3. PFMEA (ChatGPT, full).

#	Step	Failure mode	Effect	Cause	S	O	D	RPN	Current control	Recommended action	Owner	rRPN
0.0	SMT paste print	Solder bridging	Electrical failure	Overpaste, stencil wear	8	4	4	128	100% SPI, AOI confirmation	Optimize aperture, retrain operator	ME-D3	72
1.0	SMT placement	Tombstoning 0402s	Intermittent RF drop	Thermal stress, offset	7	3	5	105	AOI, placement program verification	Thermal compensation, layout tweak	PE-D4	60
2.0	Reflow soldering	Voids on PMIC pad	Power instability	Inadequate soak profile	9	2	5	90	Profile verification, X-ray sampling, FT correlation	DOE for reflow, add SPC limits	PE-D5	54
3.0	AOI inspection	False negative (fine-pitch)	Latent field failure	Contrast issues, threshold limits	8	6	2	96	Golden board validation, rule-based recheck	MSA/GRR on AOI, rule-based recheck	VisEng-D6	48
4.0	ICT/Boundary-scan test	Incorrect pin detection	Open/short missed	Fixture tolerance	7	3	5	105	Pin-mapping validation	Pin force verification, pin map cross-check	TestEng-D2	60
5.0	Display bonding	Misalignment > 0.2 mm	Light bleed	Fixture wear	6	4	5	120	Vision inspection, bonding confirmation	GRR, fixture maintenance, poka-yoke	VisEng-D7	64
6.0	Sensor + connector sub-assembly	Intermittent sensor signal	Measurement drift	Loose fit, ESD damage	7	4	4	112	Sensor validation, ESD mat compliance	Connector locking feature, ESD audit	QE-D6	52
7.0	Firmware flashing	Wrong image	Bricked device	Version control lapse	9	2	6	108	Release control, hash	Signed firmware, lock	SW-D4	27

#	Step	Failure mode	Effect	Cause	S	O	D	RPN	Current control	Recommended action	Owner	rRPN
									verification	override		
8.0	Functional test (BLE/Wi-Fi, temp, UI)	Temp drift > ±0.5°C	Comfort complaints	Sensor drift	8	3	4	96	Calibration, drift alarms	Cp/Cpk check, recalibration triggers	QE-D7	42
9.0	Final enclosure assembly	Loose mount	Rattle, low durability	Improper screw torque	6	3	5	90	Torque monitoring tool	Torque alarms, torque log review	ME-D6	40
10.0	Burn-in/soak test	Early failure missed	Field returns	Short soak duration	6	3	5	90	Soak cycle time validation	Dynamic soak profiling	QE-D3	45
11.0	Pack & label	Incorrect label	Customer misdelivery	Data mismatch	7	3	4	84	Barcode verification, print logging	Auto-check system with label match	QA-D5	38
12.0	Display bonding	Misalignment > 0.2 mm	Light bleed	Fixture wear	6	4	5	120	Vision inspection, bonding confirmation	GRR, fixture maintenance, poka-yoke	VisEng-D7	64
13.0	Sensor + connector sub-assembly	Intermittent sensor signal	Measurement drift	Loose fit, ESD damage	7	4	4	112	Sensor validation, ESD mat compliance	Connector locking feature, ESD audit	QE-D6	52
14.0	Firmware flashing	Wrong image	Bricked device	Version control lapse	9	2	6	108	Release control, hash verification	Signed firmware, lock override	SW-D4	27
15.0	Functional test (BLE/Wi-Fi, temp, UI)	Temp drift > ±0.5°C	Comfort complaints	Sensor drift	9	2	6	108	Calibration, drift alarms	Cp/Cpk check, recalibration triggers	QE-D7	42
16.0	Final enclosure assembly	Loose mount	Rattle, low durability	Improper screw torque	6	3	5	90	Torque monitoring tool	Torque alarms, torque log review	ME-D6	40
17.0	Burn-in/soak test	Early failure missed	Field returns	Short soak duration	6	3	5	90	Soak cycle time validation	Dynamic soak profiling	QE-D3	45

#	Step	Failure mode	Effect	Cause	S	O	D	RPN	Current control	Recommended action	Owner	rRPN
18.0	Pack & label	Incorrect label	Customer misdelivery	Data mismatch	7	3	4	84	Barcode verification, print logging	Auto-check system with label match	QA-D5	38

S3.2. Linked Control Plan (full)

Table S4. Linked Control Plan (expert team).

Process step	Characteristic (CTQ/CTP)	Spec/Tolerance	Method/Gage (MSA)	Sampling/Frequency	Control method	Reaction plan	Record type
SMT print	Paste height (critical pads)	120 ± 25 μm	SPI (GRR <10%)	1	X-bar–R chart	Clean stencil, reprint, segregate lot	SPI logs
SMT placement	0402 position accuracy	± 0.05 mm	AOI program + camera (MSA)	1	Visual + automated	Adjust pick/place program; feeder check	AOI logs
Reflow soldering	Voids under PMIC	< 20%	X-ray, FT correlation	1 per lot	SPC trending	Adjust soak profile; retest lot	X-ray logs
AOI inspection	Fine-pitch solder quality	IPC-A-610 Class 2	AOI program vX.Y	1	p-chart (DPU)	Stop line; re-inspect; repair	AOI images
ICT/Boundary-scan test	Continuity & shorts	Pass	ICT fixture	1	Binary logic	Debug fixture; repair boards	ICT logs
Display bonding	Alignment offset	≤ 0.2 mm	Vision gauge (GRR <10%)	1	X-bar–R chart	Rework, validate fixture	Vision logs
Sensor + connector sub-assy	Sensor alignment	Nominal ± 0.1 mm	Manual check + vision	1	GO/NO-GO	Rework part; retrain	Inspection sheet
Firmware flashing	Firmware signature	Exact match	Fixture CRC	1	Pass/Fail gate	Reflash, verify image	Flash logs
Functional test	Temperature accuracy	± 0.5 °C	Cal stand vs. golden	1	X-bar–R; Cp/Cpk	Recalibrate, hold lot	FT database

Process step	Characteristic (CTQ/CTP)	Spec/Tolerance	Method/Gage (MSA)	Sampling/Frequency	Control method	Reaction plan	Record type
Final assembly torque	Torque on fasteners	0.45 ± 0.05 N·m	DC torque driver	1	X-bar–R chart	Tool recal, retorque	Torque logs
Burn-in/soak test	Operational duration	24h @ 60°C	Burn-in oven + monitor	1	Run-to-fail	Segregate fails	Burn-in logs
Pack & label	Label correctness	0 errors allowed	Barcode scanner	1	Poka-yoke	Reprint, 100% sort	Label logs

Table S5. Linked Control Plan (ChatGPT).

Process step	Characteristic (CTQ/CTP)	Spec/Tolerance	Method/Gage (MSA)	Sampling/Frequency	Control method	Reaction plan	Record type
SMT print	Paste height (critical pads)	120 ± 25 μm	SPI (GRR <10%)	1	X-bar–R chart + ML-based trend alert	Flag lot, trigger alert; adjust SPI stencil	SPI logs
SMT placement	0402 position accuracy	± 0.05 mm	AOI program + camera (MSA)	1	AOI + anomaly detection model	Auto-recheck flagged anomalies; retrain AOI ML	AOI logs
Reflow soldering	Voids under PMIC	< 20%	X-ray, FT correlation	1 per lot	SPC + predictive reflow analytics	Auto-optimize profile params; trigger DOE	X-ray logs
AOI inspection	Fine-pitch solder quality	IPC-A-610 Class 2	AOI program vX.Y	1	p-chart (DPU) + GPT image eval flags	Auto route flagged units to review; improve AOI	AOI images
ICT/Boundary-scan test	Continuity & shorts	Pass	ICT fixture	1	Digital twin model + logic gates	Isolate pin faults; self-diagnose via log replay	ICT logs
Display bonding	Alignment offset	≤ 0.2 mm	Vision gauge (GRR	1	X-bar–R chart +	Auto-align + alert for	Vision logs

Process step	Characteristic (CTQ/CTP)	Spec/Tolerance	Method/Gage (MSA)	Sampling/Frequency	Control method	Reaction plan	Record type
			<10%)		OCR vision overlay	bonding shift	
Sensor + connector sub-assy	Sensor alignment	Nominal ± 0.1 mm	Manual check + vision	1	GO/NO-GO + embedded sensors	Trigger rebuild if sensor deviation > threshold	Inspection sheet
Firmware flashing	Firmware signature	Exact match	Fixture CRC	1	Pass/Fail + signed firmware validator	Block override; hash-verify firmware trace	Flash logs
Functional test	Temperature accuracy	± 0.5 °C	Cal stand vs. golden	1	X-bar–R; Cp/Cpk + drift monitor	Predictive drift compensation; notify QE	FT database
Final assembly torque	Torque on fasteners	0.45 ± 0.05 N·m	DC torque driver	1	X-bar–R chart + auto retorque if deviant	Tool triggers auto-cal routine if Cpk drops	Torque logs
Burn-in/soak test	Operational duration	24h @ 60°C	Burn-in oven + monitor	1	Run-to-fail + predictive failure log	Preemptively replace units with error codes	Burn-in logs
Pack & label	Label correctness	0 errors allowed	Barcode scanner	1	Poka-yoke + traceable label hash	Hash mismatch triggers 100% review	Label logs

S2.3. Supplier PPAP templates/requests

To ensure supplier quality, the QA team uses Production Part Approval Process (PPAP) documentation. For our critical suppliers (e.g. PCB assembly house and plastic enclosure molder), the expert request would include all standard PPAP elements: design records/drawings, engineering change notes, process flow diagram, PFMEA, control plan, measurement system analysis (MSA) studies, capability studies (Cp/Cpk) for key features, initial sample inspection reports, material/test certifications, and a signed Part Submission Warrant. This thorough set of documents "proves" that the supplier can consistently meet specifications before full production. For example, the electronics

supplier might be asked to submit a Level 3 PPAP (including 100% dimensional data and initial test results), whereas the plastics supplier might provide a Level 2 submission (first-article dimensional report and material spec sheet).

Expert Team: We would prepare PPAP templates/checklists for each supplier type. The electronics PPAP would emphasize electrical testing (e.g. ICT/GTS reports), solder joint reliability data (if applicable), and IPC-A-610 conformance records. The plastics PPAP would focus on polymer grade certificates, mold trial reports, and dimensional accuracy records. All PPAP work follows the AIAG/APQP framework.

ChatGPT: The AI can draft PPAP checklists via a prompt such as "List the PPAP submission requirements for a PCB assembly supplier and a plastic housing supplier in electronics manufacturing". Its output might enumerate items like "Design Drawings, Engineering Change Summary, PFMEA, Control Plan, Process Flow Diagram, MSA results, Dimensional Inspection Reports, Material Certifications, Functional Test Data, Part Submission Warrant", customized by supplier. This mirrors PPAP guides which stress comprehensive documentation for supplier readiness.

Expert team

A. EMS (PCBA) Supplier – PPAP Level 3 (Consumer Electronics Adaptation)

- The expert QA team defines a comprehensive Level 3 PPAP request, tailored to high-reliability consumer electronics:
- Design Documentation: Approved design record with revision history; Bill of Materials (BOM); Gerber and stencil designs.
- Change Control: Documented engineering change orders (ECOs) with traceability to layout changes, firmware revisions, or component substitutions.
- Risk & Quality Planning: Complete DFMEA, PFMEA, and Control Plan aligned with IPC-6012 and IPC-A-610 class requirements.
- Process Flow Diagram: Detailed flow from solder-paste printing through final testing and packing.
- MSA Studies: Gage R&R and bias for SPI, AOI, ICT fixtures (GRR < 10% preferred).
- Dimensional Inspection Reports: Key features including solder paste height, connector fit, and pad alignment.
- Initial Process Capability Studies: Cp/Cpk ≥ 1.33 for:
- SPI paste height (critical pads)
- AOI defect rate (false calls and escapes)
- ICT pass/fail yields
- Compliance & Materials: RoHS and REACH declarations, solder paste Certificates of Conformance (CoC), ESD program documentation.
- Functional Test Plan: Final test routines (BLE/Wi-Fi, UI, sensor calibration) with acceptance criteria.
- First-Article Samples: Fully tested units from pilot build with traceable serials.
- Packaging Plan: ESD-safe, shock-resistant packaging validated for drop/transport tests.
- Part Submission Warrant (PSW) Equivalent: Signed approval form referencing all supporting evidence.

B. Plastics Supplier – Modified Level 2/3 PPAP

- For enclosure and structural plastic parts:
- Material Certification: Resin CoC; flammability certification (e.g., UL94 V-0).
- Process Flow & Controls: From molding through trimming and inspection.

- PFMEA & Control Plan: Addressing voids, warping, shrinkage at key dimensional and cosmetic CTQs.
- MSA: GRR studies on visual inspection gauges, vision systems.
- Dimensional Layouts: Measurements on all "critical to fit/function" and "critical to appearance" features.
- Appearance Standards: Color swatches and finish specs (e.g., matte/gloss, grain).
- Initial Capability: Cp/Cpk ≥ 1.33 for:
- Warp (PCB seating surface)
- Shrinkage (mounting bosses)
- Color Matching & Control: Spectrophotometric verification against master sample.
- Packaging Instructions: Fit, orientation, protection from surface damage.
- Sample Parts: Labeled with lot/date and dimensional inspection tags.

ChatGPT

Using generative AI, a prompt can be constructed to replicate and customize the expert team's PPAP strategy. Example prompt:

Prompt:

"Generate a PPAP checklist for an EMS supplier and plastics molder supporting a smart thermostat assembly. Include design records, DFMEA/PFMEA, MSA, capability studies, material certifications, inspection criteria, packaging, and signed acceptance documentation".

AI-Generated Output

A. EMS Supplier – Digital PPAP Request (Level 3 Equivalent)

- Design package: PCB layout (Gerber), BOM, assembly drawings, stencil data.
- Change tracking: Engineering change log with revision notes.
- Risk tools: AI-formatted PFMEA and Control Plan files with digital version control.
- Workflow map: AI-generated process flow from SMT through final packaging.
- MSA reports: SPI/AOI/ICT fixture calibration data and GRR reports.
- Key features:
- Solder paste height (paste: 120 ± 25 μm)
- Placement accuracy (X/Y offset ≤50 μm)
- ICT open/short coverage ≥98%
- Capability studies:
- SPI defect rate Cp ≥ 1.33
- AOI false call DPMO <1500
- Compliance docs: RoHS 3.0 declaration, solder paste shelf-life and storage logs.
- Test programs: BLE, Wi-Fi, thermal response mapped to FT protocols.
- Serialization: Sample unit traceability with firmware version hash.
- Packaging: Barcode label template, drop test reports.
- PSW form: Auto-filled GPT-reviewed PDF submission.

B. Plastics Supplier – PPAP Summary

- Material: Polycarbonate ABS UL94 V-0 resin with CoC and MSDS.
- Flow: AI-drafted molding process flow with control loops.
- Risk tools: GPT-generated PFMEA/Control Plan templates with color-coded risks.
- Visual gage studies: Digital camera-based inspection calibration.
- Dimensional layout: Key features (snap fit, boss location) plotted vs. nominal.
- Cosmetic control: Surface finish standards (e.g., MT-11010) + tolerances.
- Color: ΔE ≤ 1.0 versus golden sample.
- Packaging: Molded tray layout; anti-scuff film specs.

- Sample parts: QR-coded and logged.

Both expert- and AI-based PPAP packages fulfill ISO 9001 and IATF 16949 principles of supplier qualification, verification of fit/form/function, and assurance of traceable, repeatable manufacturing. The ChatGPT version enables fast drafting and dynamic formatting, but must be validated and approved by qualified quality engineers prior to use.

S2.4. Internal Audit Evidence Pack

To ensure audit readiness and regulatory compliance under the proposed QA framework, both the expert-led and generative AI-driven planning workflows generated structured evidence packages aligned with ISO 9001 and industry best practices for electronics manufacturing. Each evidence pack documents the foundational quality planning artifacts, the intended record types and monitoring logic for pilot deployment, and formal mappings between identified risks, applied controls, and quality system requirements. This documentation serves as the basis for internal readiness reviews, pre-production gate approvals, and potential external audits. Below, we present the evidence contents prepared by the expert QA team and the ChatGPT–enabled workflow, respectively.

Expert team – evidence pack structure

- Documented Information
- PFMEA & Control Plan: Manually prepared, reviewed under ISO 9001 QMS; covers critical operations such as SMT, placement, reflow, display bonding, flashing, and final testing.
- Process Flow Diagram: Sequential map for ST-200 covering electronics assembly through packaging.
- Work Instructions / SOPs: Available for SMT printing, bonding, firmware flashing, and test stations; version-controlled via internal document system.
- Engineering Change Orders (ECO): Two formal ECOs logged – one affecting solder stencil aperture, another updating firmware signing procedure.
- Training Matrix: Operator competency records verified for key stations; visual inspection and reflow profile review required retraining in week 3.
- Calibration & MSA: GRR results available for vision inspection tools (bonding and display); torque tools passed 6-month calibration window.
- Test Programs & Backups: AOI, ICT, FT routines stored in secure local directory; verified checksums.
- Firmware Releases: CRC-confirmed images; manual checklist used to approve version flashing.
- Traceability System: Lot-based; board ID to torque log, paste print, and test record linkages stored in MES.
- Supplier PPAPs: Collected for PCBA and plastics; partial dimensional layout still pending from plastics molder.
- Risk Register: Qualitative register updated quarterly; top risks reflected in PFMEA and control response.
- Records (illustrative examples for pilot deployment)
- Pilot SPC Snapshots: X-R charts for paste height, reflow peak temp; p-chart for AOI false-call rate.
- Yield Metrics: FPY = 94.8% (slightly under θ_{pd}); DPMO = 520; Cp/Cpk = 1.32 average.

- Nonconformance Logs: Five solder bridging events; one firmware mismatch; documented via NCRs.
- Hold & Sort Actions: 100% sort initiated after AOI false-pass spike; fixture realignment completed.
- CAPA Actions: Action plans implemented for solder aperture issue and firmware validation failure.
- Effectiveness Checks: AOI retraining confirmed via reduced DPU trend.
- Torque Trace Data: Available for all units; one low-outlier flagged and retorqued.
- AOI Image Samples: Stored for audit; flagged and resolved image contrast inconsistency.
- Compliance Docs: Supplier declarations for RoHS and REACH; ESD compliance audit passed (no major findings).
- Mappings
- Clause-to-Evidence Index: Basic index linking ISO 9001 clause to doc type; mapping handled manually in audit file.
- Risk-to-Control Map: PFMEA rows linked to risks (e.g., solder bridging → aperture change → SPI monitoring).
- Change Control Log: Excel-based tracker logging updates to work instructions, control limits, and firmware protocols.

ChatGPT – evidence pack structure

- Documented Information
- PFMEA & Control Plan: Auto-generated, version-tagged; governance metadata embedded (owners, rRPN, links to thresholds).
- Process Flow Diagram: Generated via prompt; exported in .svg with embedded QR codes linking to SOPs.
- Work Instructions / SOPs: Drafts generated in a standard SOP format; approval workflows captured in document history.
- ECO Log: Full log of PFMEA-triggered changes, timestamped; includes auto-generated diff between revs.
- Training Matrix: Auto-filled operator matrix cross-checked with role assignments and SOP access history.
- Calibration & MSA: GRR data visualizations embedded in reports; alerts triggered if GRR > 10%.
- Test Programs & Backups: Stored in Git-based version control with access audit logs.
- Firmware Releases: Only signed binaries allowed; hash + device ID matched in build logs.
- Traceability Schema: Serial-level tracking; unit-level linkage from SPI through FT and torque logs.
- Supplier PPAPs: Status dashboards for electronics and plastics; each field auto-validated against checklist.
- Risk Register: Structured risk taxonomy auto-linked to PFMEA cells with dynamic updates on control changes.
- Records (illustrative examples for pilot deployment)
- SPC Snapshots: Cp/Cpk, *X*-R charts embedded in HTML reports with auto-flagging of out-of-control points.
- Yield Metrics: FPY = 96.4%; DPMO = 430; Cp/Cpk = 1.35 with trend indicators.
- Nonconformance Logs: Auto-tagged incidents with timestamps; integrated with MES alerts and audit trail.

- Hold & Sort Actions: Triggered via exceedance of θ_{pd}; documentation auto-bundled into evidence pack.
- CAPA Actions: AI-suggested plans (e.g., for PMIC voids and firmware errors); routed through approval flow.
- Effectiveness Checks: Drift metrics and event recurrence tracked; rRPN drops confirm impact.
- Torque Data Traces: Securely logged via DC tool integration; alerts for deviations > 0.05 N·m.
- AOI Image Samples: Stored with pass/fail tags; sample set auto-selected for audits.
- Compliance Docs: Supplier attestations signed digitally; RoHS/REACH/UL flags monitored continuously.
- Mappings
- Clause-to-Evidence Index: Auto-generated ISO 9001 matrix with hyperlinks to documents.
- Risk-to-Control Linkage: PFMEA structured with embedded control references; rRPN calculated post-control.
- Change Control Log: System-generated changelog with rollback ability and embedded reviewer signoffs.

S3. Evaluation Indices and Scoring Rubric

The PoC evaluation uses five indices (DQ, DC, PCS, GP, TE). Table S6 summarizes the index definitions and the scoring rubric used by the expert raters (0–4 scale).

Table S6. Evaluation indices and rubric (0–4 scale).

Index	Definition (summary)	Score anchors (0–4, brief)
DQ	Documentation completeness, internal consistency, and audit readiness (e.g., clause-to-evidence links, metadata).	0: missing/fragmented; 1: incomplete; 2: usable with gaps; 3: complete and coherent; 4: audit-ready with explicit trace links
DC	Coverage of nonconformities, containment logic, and hold/stop triggers (including rare scenarios).	0: absent; 1: generic; 2: basic rules; 3: explicit triggers and actions; 4: comprehensive + edge-case coverage
PCS	Capability and stability controls (e.g., Cp/Cpk targets) with monitoring and reaction logic for drift.	0: absent; 1: stated only; 2: monitored; 3: monitored with reaction rules; 4: early-warning + robust reactions
GP	Governance/provenance: accountability, approvals, version control, and change traceability.	0: none; 1: minimal; 2: partial; 3: consistent governance fields; 4: fully traceable and audit-defensible
TE	Effort/time efficiency to produce the integrated deliverables under the fixed time window.	0: unacceptable delay; 1: slow; 2: baseline; 3: faster with quality maintained; 4: substantially faster with governance preserved

S4. Inter-Rater Reliability and Supporting Rating Tables

Three independent experts rated both solutions on the five indices. Table S7 reports the individual rater scores and means. Table S8 summarizes the inter-rater reliability statistics reported in the manuscript.

Table S7. Expert ratings (three raters) and mean scores for both conditions.

Index	Expert team (R1)	Expert team (R2)	Expert team (R3)	Expert team (Mean)	ChatGPT (R1)	ChatGPT (R2)	ChatGPT (R3)	ChatGPT (Mean)
DQ	3.12	3.23	2.77	3	3.89	3.67	3.83	3.8
DC	2.53	2.76	2.64	2.6	3.13	3.02	2.94	3
PCS	3.15	3.07	2.91	3	3.36	3.45	3.49	3.4
GP	2.72	3.04	2.85	2.9	3.95	3.9	3.88	3.9
TE	2.98	3.38	3.16	3.2	3.81	3.74	3.62	3.7

Table S8. Inter-rater reliability statistics.

Workflow	Percent agreement (PA)	Kendall's W	Cronbach's α	ICC(3,1)
Expert team (conventional)	0.773	0.773	0.851	0.655
ChatGPT (AI-augmented)	1.000	0.956	0.981	0.946

Note: Detailed calculation worksheets (including ANOVA summaries) are provided in the accompanying data tables.

S5. Generative AI Prompting Sequence and Human-in-the-Loop Verification Gate

The AI-augmented PoC condition used ChatGPT as a controlled decision-support and documentation-assistance tool to generate four interrelated NPI planning deliverables: (1) PFMEA, (2) linked Control Plan, (3) supplier PPAP templates/requests, and (4) Internal Audit Evidence Pack. The workflow followed a structured prompting sequence comprising four stages aligned with these deliverables. The model received the same ST-200 technical specification used by the expert team, including product architecture, assembly flow, CTQ requirements, and process constraints. No pre-existing corporate templates were supplied to the model; instead, it was instructed to generate the required structures from the prompted engineering requirements. The AI-augmented PoC was executed within the same 10-business-day window as the baseline condition, and ChatGPT was accessed via a secure enterprise interface.

After each stage, the generated outputs were reviewed through a human-in-the-loop verification gate before acceptance into the integrated PoC package. The verification checks covered: (i) technical accuracy and feasibility; (ii) internal consistency across artifacts; (iii) traceability and provenance; (iv) completeness and specificity; and (v) conformance to the framework acceptance logic defined by θ_{pd}, θ_{pc}, and θ_{op}. Where deficiencies were identified, a targeted refinement prompt was issued, and the artifact was re-checked before acceptance. The detailed core prompts for each stage, together with the refinement prompt template, are reported below.

The AI-assisted condition was implemented using ChatGPT as a controlled documentation-assistance tool. We report the following descriptors to support reproducibility: access mode (web UI / enterprise workspace / API), model identifier as

displayed by the platform at time of execution, date range of runs, whether retrieval/grounding to provided source documents was enabled (and if so, which document set), and any fixed generation parameters exposed to the user (e.g., temperature or equivalent). Where a parameter was not user-exposed or not controlled, this is explicitly stated.

S5.1. Stage 1 — PFMEA Generation (Risk Identification)

Core prompt:

"Generate a comprehensive PFMEA table for the ST-200 smart thermostat assembly process, covering all major electronic assembly and final test steps (from SMT through Final Test). Include columns for: Process Step, Failure Mode, Failure Effect, Potential Cause, Severity/Occurrence/Detection (S/O/D), RPN, Current Control, Recommended Action, Owner, and Residual RPN (rRPN). Ensure CTQ-related failure modes are explicitly included and that recommended actions are specific and verifiable".

Intended output: PFMEA draft suitable for NPI planning, including governance metadata (ownership and residual risk notation).

S5.2. Stage 2 — Control Plan Generation (Control Strategy Linked to PFMEA)

Core prompt:

"Generate a Control Plan linked to the PFMEA. For each high-risk PFMEA item and each CTQ, specify: control characteristic, control method/measurement system, sampling or monitoring approach, acceptance criteria, reaction plan, and escalation rule if process capability/stability conditions (θ_{pc}) are not met. Include explicit pass/fail rules and define what evidence/record type is produced for each control".

Intended output: A Control Plan that operationalizes PFMEA risks into measurable controls, reaction logic, and traceable records.

S5.3. Stage 3 — Supplier Readiness (PPAP Templates/Requests)

Core prompt:

"Generate PPAP checklist templates/requests for the EMS supplier and the plastics supplier supporting the ST-200 assembly. Include requirements for design records, PFMEA and Control Plan alignment, MSA/GRR evidence, capability studies (e.g., Cpk ≥ 1.33 where applicable), material certifications, change-control records, and signed approval documentation. Specify the expected evidence artifact for each PPAP element".

Intended output: Supplier-oriented PPAP templates/requests aligned with the NPI deliverables and evidence requirements.

S5.4. Stage 4 — Internal Audit Evidence Pack (Traceability and clause-to-evidence mapping)

Core prompt:

"Compile the generated PFMEA, Control Plan, and PPAP outputs into an Internal Audit Evidence Pack. Add a clause-to-evidence index aligned with ISO 9001 and IATF 16949 requirements. For each clause, list the relevant artifact(s), the specific evidence record type, ownership, and how traceability is maintained (version, approval status, and linkage). Ensure the package supports auditability and governance conditions (θ_{op})".

Intended output: Audit-ready evidence package with explicit clause-to-evidence linkage and record-type traceability.

S5.5. Human-in-the-Loop Verification Gate (applied after each stage)

After each generation stage, the outputs were reviewed and refined under a human-in-the-loop gate before acceptance into the integrated PoC package. The verification checks covered:

- Technical accuracy and feasibility (manufacturing realism, correct control logic, credible failure modes/controls).
- Internal consistency across artifacts (PFMEA ↔ Control Plan ↔ PPAP ↔ evidence pack alignment).
- Traceability and provenance (ownership tags, clear record types, version/approval readiness).
- Completeness and specificity (no vague reaction plans; measurable acceptance criteria where applicable).
- Conformance to framework acceptance logic (explicit linkage to θ_{pd}, θ_{pc}, and θ_{op} conditions).
- If deficiencies were identified (e.g., missing owners, incomplete control-to-evidence linkage, ambiguous reaction logic, or weak escalation/reset triggers), a targeted refinement prompt was issued and the artifact was re-checked before being accepted into the final evidence package.

Refinement prompt template used when the verification gate identified gaps:

"Revise the previous artifact to address the following gaps: [list gaps]. Add missing owner tags, make reaction rules measurable (trigger/threshold/action), and ensure each control is linked to a traceable record type. Do not remove valid content; only correct and complete it".

This staged prompting and verification protocol was used to standardize iteration structure, artifact generation, and acceptance checks in the AI-assisted condition, thereby improving comparability with the expert-only workflow.

S6. Abbreviations

The following abbreviations are used throughout this manuscript.

Abbreviation	Definition
8D	Eight Disciplines Problem Solving
ABS	Acrylonitrile Butadiene Styrene
AI	Artificial Intelligence
AOI	Automated Optical Inspection
APQP	Advanced Product Quality Planning
BLE	Bluetooth Low Energy
BOM	Bill of Materials
CAD	Computer-Aided Design
CAPA	Corrective and Preventive Action(s)
CoC	Certificate of Conformity
CoPQ	Cost of Poor Quality
Cp	Process potential capability index
Cpk	Process capability index
CRC	Cyclic Redundancy Check
CTQ	Critical-to-Quality
DC	Direct Current
DDD-GenDT	Dynamic Data-Driven Generative Digital Twin

DFMEA	Design Failure Mode and Effects Analysis
DMAIC	Define–Measure–Analyse–Improve–Control
DMS	Document Management System
DOE	Design of Experiments
DPMO	Defects per Million Opportunities
DPU	Defects per Unit
DQ	Documentation Quality
DT	Digital Twin
ECO	Engineering Change Order
EMS	Electronics Manufacturing Services
eQMS	electronic Quality Management System
ERP	Enterprise Resource Planning
ESD	Electrostatic Discharge
FPY	First Pass Yield
FT	Functional Test
GAN	Generative Adversarial Network
Gage R&R	Gage Repeatability and Reproducibility
GP	Governance and Provenance
GRR	Gauge Repeatability and Reproducibility
GTS	Go/No-Go Test System or General Test System
ICT	In-Circuit Test
IATF	International Automotive Task Force
IoT	Internet of Things
IPC	Acceptability Standard for Electronic Devices
KG	Knowledge Graph
KPI	Key Performance Indicator
KPIs	Key Performance Indicators
LIMS	Laboratory Information Management System
LLM	Large Language Model
LLMs	Large Language Models
LQC	Lean Quality Control
LSS	Lean Six Sigma
LVLMs	Large Vision-Language Models
MES	Manufacturing Execution System
ML	Machine Learning
MSA	Measurement System Analysis
MSDS	Material Safety Data Sheet
NCR	Non-Conformance Report
NPI	New Product Introduction
OEE	Overall Equipment Effectiveness
OEM	Original Equipment Manufacturer
PCB	Printed Circuit Board
PCBA	Printed Circuit Board Assembly
PCS	Process Capability Stability
PDCA	Plan–Do–Check–Act
PFMEA	Process Failure Mode and Effects Analysis

PLM	Product Lifecycle Management
PMIC	Power Management Integrated Circuit
PoC	Proof of Concept
PPAP	Production Part Approval Process
PPM	Parts Per Million
PSW	Part Submission Warrant
QA	Quality Assurance
QMS	Quality Management System
QM	Quality Management
RAG	Retrieval-Augmented Generation
RCA	Root Cause Analysis
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RF	Radio Frequency
RoHS	Restriction of Hazardous Substances
RPN	Risk Priority Number
rRPN	residual Risk Priority Number
S/O/D/RPN	Severity / Occurrence / Detection / Risk Priority Number
SMT	Surface-Mount Technology
SOPs	Standard Operating Procedures
SPC	Statistical Process Control
SPI	Solder Paste Inspection
SQE	Supplier Quality Engineer
SQM	Supplier Quality Management
TE	Time Efficiency
TQM	Total Quality Management
UI	User Interface
V&V	Verification and Validation
VAE	Variational Autoencoder
XAI	Explainable AI

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