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Injection Molding Supplier Audit Checklist

A five-phase qualification framework — from document review to ongoing monitoring. Free engineering resource from JBRplas, Shenzhen. jbrplas.com

How to Use This Checklist

Qualification verifies one supplier against three requirements: **capability** (they can make your part), **capacity** (they can make enough of it, on time), and **control** (they notice process drift before you do). Most failed qualifications fail on control — it is the only requirement a sample cannot demonstrate.

Run the five phases in order. Each item passes only with evidence: a document on file, a measurement on record, or a demonstration on the floor. A checkbox ticked without evidence is a sales claim, not a fact.

Phase 1 — Document Review (Before the Audit)

DOCUMENT	WHAT IT VERIFIES	MINIMUM STANDARD
☐ ISO 9001:2015 certificate	Quality system exists	Scope covers injection molding and mold making; accredited body
☐ ISO 13485:2016 (medical)	Medical device quality system	Required for medical device components
☐ Equipment list	Capacity and toolroom capability	Brands, tonnage, accuracy — not "various machines"
☐ Quality manual & procedures	The system is written down	Incoming inspection, SPC, NC material, calibration
☐ Sample docs from a recent program	The system is actually used	FAI, dimensional report, CoC, material cert — dated within 12 months
☐ Tool ownership & transfer policy	Your asset stays yours	Written policy, exercised in practice
☐ NDA policy	IP protection	Will sign before file review — non-negotiable
☐ Business registration & export license	Legal entity, export capability	Current, names match on all certificates

> **Two signals matter most:** how fast the documents arrive (a supplier slow to collect documents will be slow on CAPA), and whether the documentation is fresh (an FAI from last quarter is evidence; one from 2019 is decoration).

Phase 2 — On-Site Audit

A. Facility and Equipment

- ☐ Machine count matches the equipment list — walk the floor, count the presses
- ☐ Maintenance records exist, current, tied to runtime schedule
- ☐ Material handling: dryers in use, moisture-sensitive resins sealed, lot labels visible
- ☐ Toolroom (CNC, EDM, wire-cut, grinding) exists and runs — no in-house toolroom, no tool maintenance
- ☐ Clean room cell exists if required (ISO 8 / Class 100,000)

  Pass: the floor looks like the equipment list. Red flag: "some machines are in the other workshop."

B. Quality System

- ☐ Calibration certificates for CMM and gauges — current and traceable

- ☐ Incoming material inspection actually happens — ask for today's records
- ☐ SPC charts on the production floor, not just in the quality office
- ☐ Nonconforming material physically segregated and labeled
- ☐ Lot traceability from resin bag to finished carton — ask for a live example
- ☐ AQL sampling follows a stated standard (ANSI/ASQ Z1.4 Level II baseline)

  Pass: the QC inspector shows a live SPC chart and explains the last out-of-control action. Red flag: charts printed for audits only.

C. Engineering

- ☐ DFM report structure: wall thickness, draft, gate position, risk list — ask to see a real one
- ☐ Moldflow simulation used, reports retained
- ☐ Tool design records complete: steel certs, hardness reports, 2D/3D files
- ☐ Change management: documented ECN process for material, process, tool changes

  Pass: engineering explains *why* the gate is where it is on a running tool. Red flag: "the customer specified everything."

D. Process Control

- ☐ Shot-by-shot process monitoring on production presses (pressure, fill time)
- ☐ SPC sampling interval defined (every 50–100 shots is a working standard)
- ☐ Process documentation: setup sheets, locked parameters, deviation records
- ☐ Defect data is real — ask for last month's rate, not the all-time best

  Pass: data flows machine → chart without human transcription. Red flag: parameters live in the operator's memory.

E. Supply Chain

- ☐ Resin inventory depth for your grades — see physical stock, not a purchase order
- ☐ Secondary processes (plating, painting, assembly) defined with named, auditable vendors
- ☐ Packaging and shipping capability matches your destination market

  Pass: the supplier names what happens when the resin supplier is late. Red flag: "that never happens."

Phase 3 — Sample and Tooling Qualification

Samples qualify the part; process data qualifies the supplier. Request both — **and request the data before approving the sample.**

- ☐ DFM report first — identifies risks, proposes fixes, documents decisions before steel is cut
- ☐ T1 dimensional report with measured values, not "all dimensions OK"
- ☐ FAI — full dimensional layout, every drawing dimension measured and recorded
- ☐ Material certificate tied to the actual resin lot used for your samples
- ☐ Tool trial data: cycle time, pressures, temperatures, shot log — your production baseline
- ☐ PPAP Level 3 (automotive): FAI, MSA, Control Plan, PFMEA, capability study — Cpk ≥ 1.33 critical dims (≥ 1.67 precision programs)
- ☐ Steel certificates and hardness reports — paper grade matches measured hardness

Phase 4 — Pilot Production Approval

- ☐ Ramp-up defect target: below 1% within first 90 days, trending down
- ☐ Steady-state target: below 0.3% for established programs
- ☐ Process validation for regulated programs: IQ/OQ/PQ (medical), PPAP (automotive)
- ☐ Documentation set signed off: Control Plan, PFMEA, work instructions, packaging spec, CoC template, inspection plan
- ☐ Logistics path tested: packaging, labeling, export documentation, actual shipping lane

Phase 5 — Ongoing Monitoring and Re-Qualification

MONITOR	FREQUENCY	ACTION THRESHOLD
On-time delivery	Monthly	Below 95% for two consecutive months → review
Defect rate (PPM)	Monthly	Above agreed limit → formal CAPA
CAPA responsiveness	Per event	Unanswered beyond 14 days → escalation
Calibration status	Quarterly	Expired certificate → halt measurement-critical work
Tool maintenance records	Per program review	Missing entries → audit the toolroom
Material/process change notices	Continuous	Any unreported change → immediate review

Re-qualify when: a new material family is added, the tool is transferred or significantly modified, annual volume changes by more than 50%, or production is idle for 12 months.

Master Checklist — One Page

PHASE	KEY ITEM	PASS STANDARD
1. Documents	ISO certs, equipment list, fresh sample docs	Scope covers molding; docs dated within 12 months
2. Audit — facility	Machine count, maintenance, material handling	Floor matches equipment list
2. Audit — quality	Calibration, SPC live on floor, traceability	Inspector demonstrates a live SPC chart
2. Audit — engineering	DFM depth, Moldflow, tool records, ECN	Can explain gate position on a running tool

2. Audit — process	Shot monitoring, sampling interval, setup sheets	Data flows machine → chart without transcription
2. Audit — supply	Resin stock, secondary vendors, packaging	Names the resin-late contingency
3. Samples	FAI, Cpk study, material cert, tool trial data	Cpk ≥ 1.33 (≥ 1.67 precision), data before approval
4. Pilot	Ramp-up defect rate, documentation set	<1% in 90 days trending to <0.3%
5. Ongoing	OTD, PPM, CAPA, calibration, change notice	Defined thresholds, reviewed monthly

> **Every item asks the same question:** is this claim true on the floor, today, with the data to prove it? The supplier that survives is the one whose paperwork, floor, and process data all tell the same story.
