

First Article Inspection (FAI) Process: Bridging the Gap Between Prototype Approval and Mass Production Run

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1. Executive Summary: The False Security of Prototype Sign-Off

In B2B contract manufacturing, successfully approving a prototype component is a major milestone, but it does not guarantee readiness for full-scale mass production. Prototypes are typically manufactured using short-run, single-cavity RTV or soft steel tooling configurations. These processes are run under heavily monitored, slow-speed conditions that do not replicate the intense thermal, mechanical, and physical dynamics of continuous multi-cavity production machinery.

When migrating production to multi-cavity, high-tonnage liquid injection molding (LSR) systems or high-volume extrusion lines, new processing variables appear. Variations in cavity thermal distribution, high shear rates, and material shrinkage can introduce dimensional drift, localized warp defects, and out-of-spec parting line flash. The ****First Article Inspection (FAI)**** process acts as a mandatory verification gate, confirming that the mass production tools, machinery, and inspection methods can reliably yield parts that match engineering drawings before volume capital is unlocked.

Quality Directive: A prototype proves a design concept works; a formal First Article Inspection Report (FAIR) proves that the industrial process, machinery, and hard tooling can consistently manufacture the component within print tolerances.

2. Anatomy of a First Article Inspection Report (FAIR)

A compliant FAI evaluation is structured around a rigorous technical data packet, universally organized to trace every functional attribute of the component layout. Following established aerospace and medical standards (such as ****AS9102**** or ISO 13485 protocols), the final packet consists of three primary verification sheets:

- **Form 1 - Part Number Accountability:** This sheet establishes structural traceability by logging the part number, engineering revision level, active manufacturing equipment, assembly bill of materials (BOM), and associated raw material lot codes.
- **Form 2 - Product Accountability:** This document tracks chemical compliance. It logs specific material datasets, raw material specifications, compound lot numbers, material data sheets (MDS), and post-curing thermal logs to verify absolute purity.
- **Form 3 - Characteristic Accountability (The Dimensional Layout):** This matrix maps out the core dimensional verification. Every dimension, radius, material thickness callout, and geometric dimensioning

and tolerancing (GD&T) characteristic on the print is assigned a distinct bubble number. The physical measurements taken from the first sample run are then paired against these target parameters to calculate exact variation values.

3. Silicone Metrology Challenges: Non-Contact Measurement of Flexible Media

Executing an FAI protocol on high-precision silicone rubber parts introduces complex metrology challenges not found when testing rigid metals or hard plastics. Because silicone is inherently flexible, traditional contact instruments like mechanical calipers, micrometers, or touch-trigger coordinate measuring machine (CMM) probes apply small physical forces that deflect the elastomer during contact. This deflection introduces measurement drift and yields false out-of-spec readings.

To eliminate these measurement errors, Reemane utilizes non-contact metrology systems within our quality control units. Dimensions are verified using high-resolution **2D Optical Profile Projectors** and automated multi-sensor **Vision CMM Systems**. These instruments project structured light or capture high-definition edges, allowing quality engineers to measure flexible lip seals, O-ring cross-sections, and fine internal draft angles with micro-level precision ($\pm 0.002 \text{ mm}$) without distorting the part profile.

4. Performance Matrix: Prototype vs. FAI vs. Mass Production Control Gates

The transition from initial product development to sustained mass production requires distinct quality controls at each gate. The FAI process serves as the bridge that validates the production environment before scaling up volume runs.

Quality Control Gate Characteristics

Operational Metric	Prototype Approval Stage	First Article Inspection (FAI)	Mass Production Run (OQC)
Tooling Setup	Single-cavity soft prototype tools	Production multi-cavity hard tools	Production hard tools (with wear tracking)
Measurement Depth	Fit-and-function critical characteristics	100% of ballooned print characteristics	AQL-based statistical sampling arrays
Sample Lot Requirements	1 to 5 prototype pieces	Typically 1st part per cavity	Continuous lots (tracked via SPC graphs)
Statistical Metrics	None (Dimensional verification only)	Baseline process capability data	Sustained $\sigma_{pk} \geq 1.33$ validation tracking

5. Sourcing Strategy: Mitigating Risk through Formal FAI Sign-Off

For B2B procurement professionals and supply chain managers, implementing a mandatory FAI sign-off step within the manufacturing contract is a highly effective tool for financial risk mitigation. Sourcing custom silicone parts globally involves substantial capital outlays for custom injection or extrusion tooling. Authorizing a supplier to initiate a high-volume production run based solely on prototype performance can lead to significant scrap risks if the final multi-cavity tool develops cavity imbalance issues.

By mandating a formal First Article Inspection Report (FAIR) review, procurement teams gain a documented, multi-point verification trail confirming that the production line is completely dialed in. This process checks tool alignment, material mixing accuracy, post-cure processing stability, and inspection measurement methods. Reviewing and signing off on this data package establishes a clear quality baseline, protecting your capital investments and ensuring defect-free delivery across the entire product lifecycle.

Secure Your Production Scaling with Robust FAI Validation

Eliminate dimensional drift, validate multi-cavity tool balancing parameters, and secure a certified, multi-point quality trail before launching high-volume production runs. To review our standard FAI documentation templates, coordinate an engineering print ballooning alignment session, or request process capability analyses, contact our quality division directly at sales@siliconefactories.com or explore our precision metrology infrastructure at www.siliconefactories.com.