



Production Part Approval Process (PPAP) for Additive Manufacturing

We specialize in additive manufacturing of high-performance components for production programs. Our process is designed to ensure dimensional stability, functional performance, and repeatable surface finish/color, all while reducing risk and accelerating time to market. We work closely with our clients every step of the way to refine designs and establish a robust production-ready process.

LEVEL 1: Get the Baseline - Define Regulatory & Performance Requirements

1. Define material requirements, tolerances, mechanical performance, and surface finish expectations.
2. Identify regulatory requirements (FDA, ISO 13485, AS9100, IATF 16949, etc.).
3. Document initial process parameters, key control factors, and risk considerations (DFMEA/PFMEA).

LEVEL 2: Design & Process Feasibility

1. Produce a small batch (typically 1-5 parts) based on the existing design for initial evaluation.
2. Validate fit, function, and surface finish, identifying potential failure modes.
3. Document initial process settings, print orientation, and post-processing methods.
4. Conduct preliminary risk assessment for production scalability.

LEVEL 3: Process Optimization & Validation

1. Produce revised design samples focused on dimensional accuracy, consistency, and repeatability under real-world conditions.
2. Perform first article inspection (FAI) and document Cpk/Ppk (process capability indices).
3. Validate mechanical properties and post-processing impact (color, surface finish consistency, structural integrity).
4. Conduct process capability study (5-100 parts) to establish statistical process control limits.
5. Implement design refinements for manufacturability & scalability.

LEVEL 4: Pre-Production Validation & Scalability Testing

1. Document key process parameters to ensure repeatability & traceability.
2. Run pre-production validation with a pilot batch (10-25% of full production volume).
3. Confirm consistent performance under scaled conditions.
4. Identify and document any adjustments before transitioning to full production.

LEVEL 5: Release for Series or Batch Production

1. Components are manufactured at the required production volumes with verified repeatability.
2. Full PPAP documentation package (Control Plan, FAI, Process Flow, Capability Studies, etc.) is completed and submitted.
3. Any design or process changes require re-validation per established change control processes.

