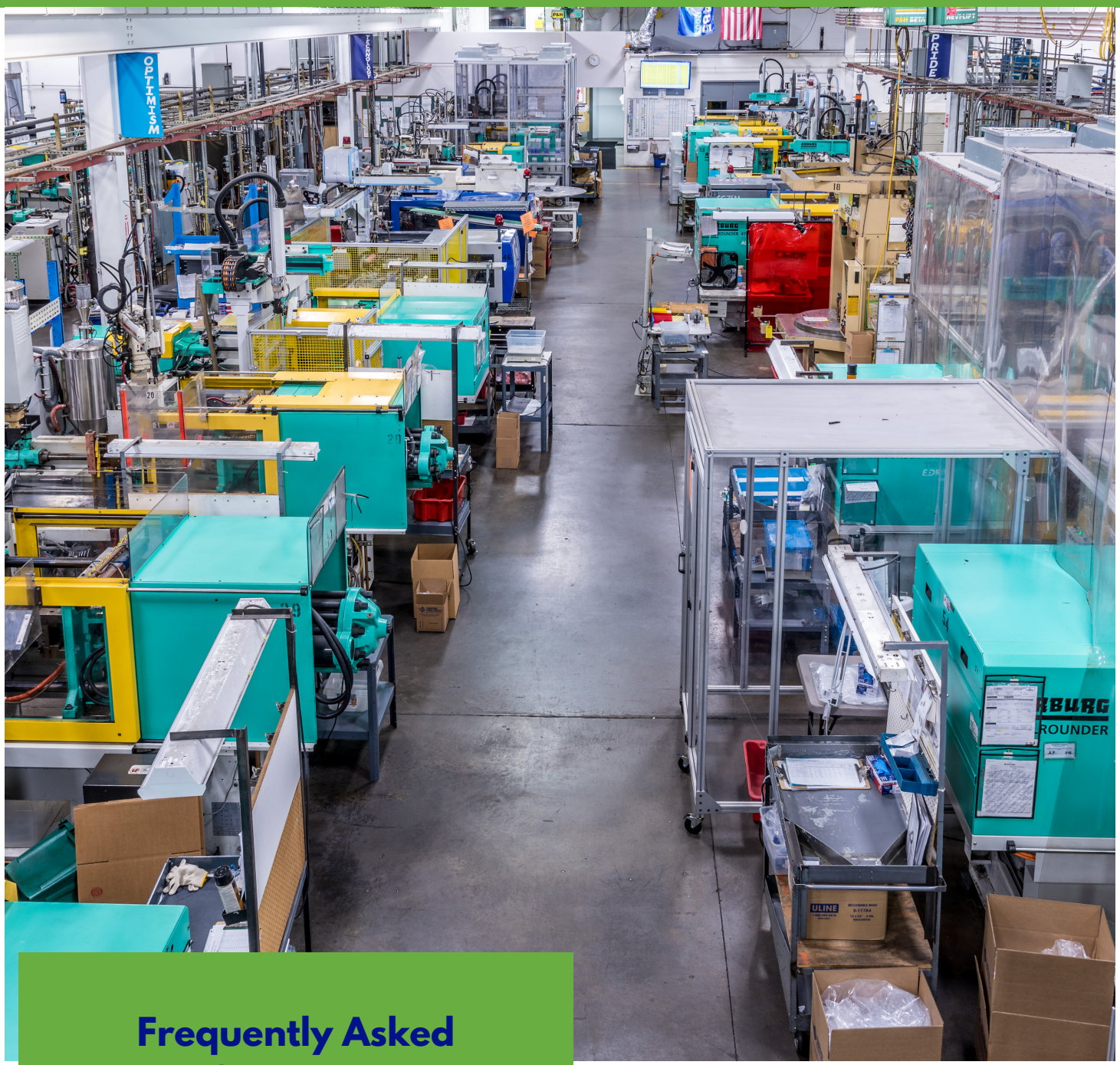
EMPIRE PRECISION

WHERE YOUR IDEAS TAKE SHAPE

Quality Assurance



Frequently Asked Questions

Clarifying Quality Standards

A well-defined, well-enforced quality policy is essential to the development, production, and on-time delivery of products that meet or exceed expectations. At Empire Precision Plastics, we've implemented quality systems that we continually improve to satisfy our customers' evolving needs.

Because many of these systems are similar yet distinct, it can be difficult to keep track of what each means for quality control. The following FAQ should help to address uncertainties that customers might have regarding these standards.

What's the difference between ISO 9001 and ISO 13485?

ISO 9001 is a series of standards that has been developed and controlled by
the International Organization for Standardization (ISO). It defines and establishes an effective quality assurance system for manufacturing and services industries. These standards can apply to manufacturers of products or services worldwide.

Organizations that are already registered to ISO 9001 often elect to expand into specific industry versions of the standard. ISO 13485, for example, is an international standard that specifies requirements for the medical device manufacturing industry. Meeting this standard proves that a company 1) has a quality manufacturing process for medical devices and 2) has the
management standards in place to maintain that quality. Other specialty standards are TS16949 (for the automotive industry), and AS9100 (for the aerospace industry).

A principal difference between the general and industry-specific standards is that ISO 9001 requires the organization to demonstrate continual improvement, whereas ISO 13485 requires only that the certified organization demonstrate that the quality system is effectively implemented and maintained. Additionally, the ISO 9001 requirements regarding customer satisfaction are absent from the medical device standard.

Empire Precision Plastics holds both ISO 9001:2015 for general quality management and ISO 13485:2016 for quality control in medical device manufacturing

How do I make sure my quality requirements are met?

There are several strategies for making sure that requirements are met. Many of them were developed based on the automotive industry's Advanced Product Quality Planning (APQP), a framework of procedures and techniques used help ensure that product objectives are achieved.

The APQP addresses project issues quickly when they are relatively easy and inexpensive to resolve. It provides a defined pathway for project stakeholders to follow throughout the project life cycle. This tool has been modified and adopted in quality planning methods in many industries. One of the key strategies, particularly in the molding industry, is process validation.

What is process validation?

Process validation is the collection and evaluation of data, from the process design stage through commercial production, which establishes scientific evidence that a process is capable of consistently delivering quality product.

A series of activities takes place over the lifecycle of the product:

- **Stage 1 – Process Design**: The commercial process is defined based on knowledge gained through development and scale-up activities.
- **Stage 2 – Process Qualification**: Process Design is evaluated to determine if the process is capable of reproducible commercial manufacturing.
- **Stage 3 – Continued Process Verification**: Ongoing assurance is gained during routine production that the process remains in a state of control.

The purpose of process validation in injection molding is to identify a capable mold-process combination that will achieve required part dimensions and tolerances consistently and repeatedly.

In both optical and opaque injection molding, the production process begins with the plastic pellets coming into the shop and ends with the finished product, either a single molded part or an assembly. Every procedure and piece of equipment that is involved in this process is evaluated to see if it is capable of contributing to the molding of the product.

Different industries have different names and protocols for the validation process. The automotive industry calls it PPAP (Production Part Approval Process) whereas the medical industry calls it IQ-OQ-PQ (Installation Qualification, Operational Qualification, Process Qualification).

Process validation is a critical component of a quality management system. It ensures that every procedure and piece of equipment can effectively contribute to the development of a quality end product.

What is PPAP?

The PPAP (Production Part Approval Process) is an industry guide that details the specific reports and documentation required to gain part approval. It was initiated by the automotive industry but has gained wider adoption in the medical and industrial markets. The PPAP is governed by the AIAG (Automotive Industry Action Group), which publishes the PPAP manual.

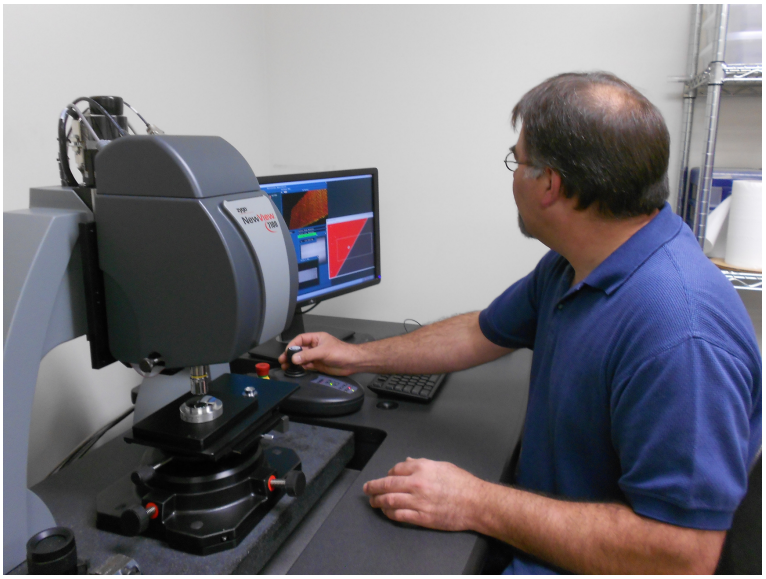
The objective of a PPAP is to demonstrate the ability of the supplier's production process to consistently meet customers' requirements.

What is the AIAG?

The Automotive Industry Action Group, or AIAG, is an organization that was founded in 1982 to develop a structure for improving quality in the North American automotive industry. It originated the PPAP requirement in its QS-9000 (now ISO/TS 16949), the automotive version of the ISO 9000 quality system. The AIAG publishes the PPAP manual and outlines the steps necessary to obtain PPAP process approvals.

What is included in the PPAP?

As defined by the AIAG, the PPAP contains a checklist that details all the requirements for its completion, which are called elements. The PPAP Checklist includes Levels (from Level 1 to Level 5), which determine the requirements for each element. Many companies will modify the AIAG model to suit their specific needs.



What elements are found in a PPAP Checklist?

As defined in the AIAG's PPAP manual, there are 18 required PPAP elements (documents):

1. PSW (Part Submission Warrant)
2. Design Records & Bubbled Part Print
3. Engineering Change Documentation
4. Customer Engineering Approval
5. Design Failure Mode Effect Analysis (FMEA)
6. Process Flow Diagrams
7. Process FMEA (PFMEA)
8. Control Plan
9. Measurement System Analysis Studies (MSA)
10. Dimensional Analysis
11. Material, Performance Results
12. Initial Process Studies (Cpk) Capability Studies
13. Qualified Laboratory Documentation
14. Appearance Approval Report (ARR)
15. Sample Product Parts
16. Master Sample
17. Checking Aids
18. Customer Specific Requirements

What do PPAP Levels mean?

Each PPAP Level determines how each element listed in the PPAP Checklist is to be handled by the supplier. The PPAP Checklist details 5 PPAP Levels. The PPAP Level indicates which elements will be submitted to the customer. The amount of time required to develop a PPAP submission differs by Level; a Level 1 may only take an hour, a Level 3 could take three days. The differentiating factors is the amount of supporting data that is required.

PPAP Submission Levels:

Level 1: Part Submission Warrant (PSW) only submitted to the customer.
Level 2: PSW with product samples and limited supporting data.
Level 3: PSW with product samples and complete supporting data.
Level 4: PSW and other requirements as defined by the customer.
Level 5: PSW with product samples and complete supporting data available for review at the supplier's manufacturing location.

How do I get my supplier to submit a PPAP?

Ideally the PPAP, along with the part drawing and the PPAP Checklist, will be included in the request for quotation. This will make sure that all of your requirements are accounted for in the supplier's manufacturing proposal.

Having a PPAP can, in some instances, increase the time it takes to complete a project.

How long does a PPAP take to complete?

There are many factors that govern PPAP approval time. The biggest driver is the length of time needed for the PPAP negations. The time needed to complete all PPAP elements and the time needed by your company to review, approve and return the signed Part Submission Warrant (PSW) will contribute to the total time required.

What does IQ-OQ-PQ involve?

IQ - Installation Qualification

During the first stage, the process equipment, supporting systems, and sub-systems are inspected to ensure that they conform to the requirements of the manufacturer and are installed appropriately. The molds are validated for their ability to create parts that adhere to strict dimensional, economical and performance necessities.

A few factors that are considered during IQ include the installation conditions, design features of the equipment, environmental conditions, and any documents, illustrations or manuals provided by the supplier.

Once installation and design specifications are met, guaranteeing the ability to repeatedly produce parts that will perform up to standard, the process validation can continue to OQ.

OQ - Operational Qualification

This stage tests the newly installed equipment to ensure that it operates as expected, and gauges the conditions under which it will continue to do so. Test runs will determine the highest, lowest and optimal operating processes by varying the pressures, temperatures, velocities and other factors from the initial process arrived at during IQ.

Factors considered during OQ include the process control limits, the raw material specifications, requirements for handling the materials, training, and short-term stability and capability.

If Operational Qualification is successful, it will validate that all aspects of the equipment perform as expected under various conditions.

PQ - Performance Qualification

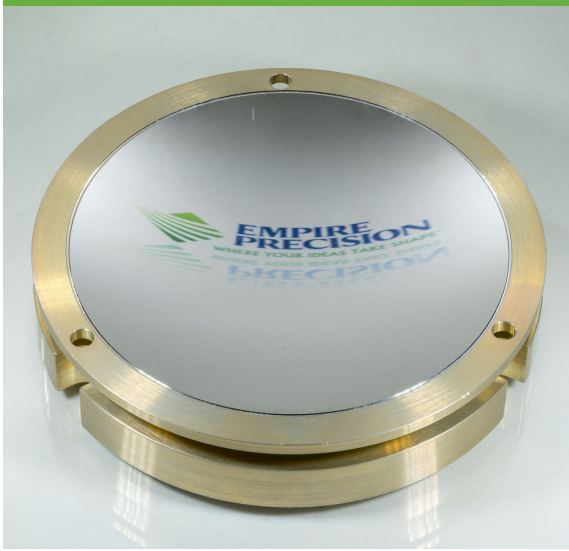
During Performance Qualification, the equipment will be run several times. Real manufacturing materials will be used, and the equipment will be allowed to cool between each run to verify that the injection molding process is capable of consistently producing quality products in a range of operating conditions, as established during the OQ part of the process.

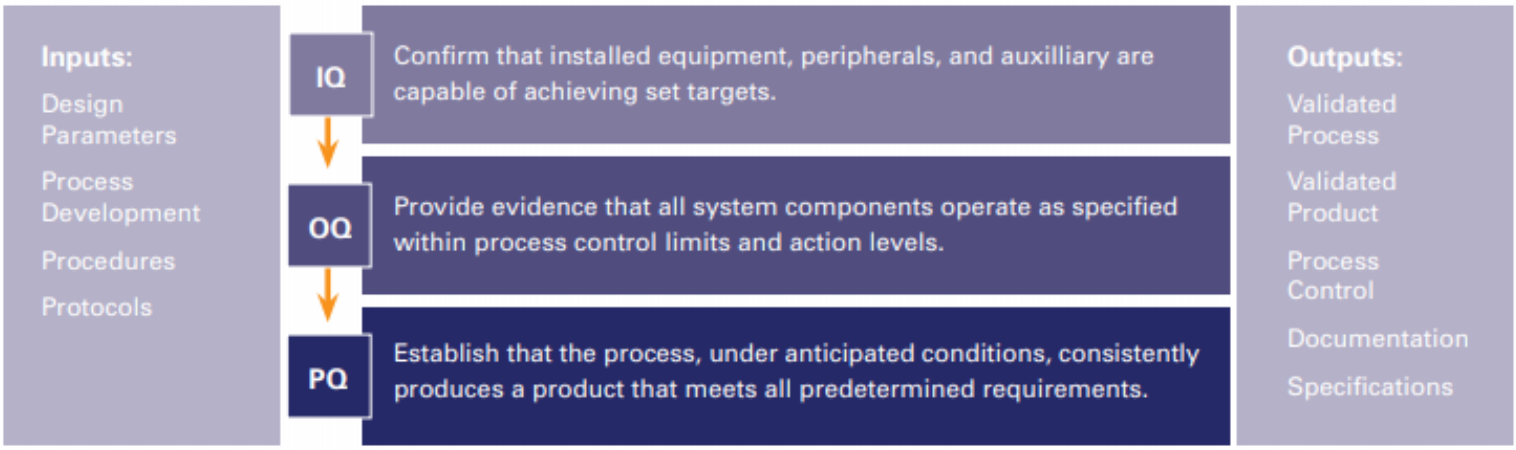
Considerations during PQ include long-term stability, and whether the products produced under the expected levels of operating conditions consistently perform to standards.

At each phase of the validation process, documents must be drawn up that detail inspection results, parameters settings, and any deviations from the expected performance and the reasons for them. Only after IQ, OQ and PQ have been successfully completed, and documents are produced that verify the acceptability of every phase of the injection molding validation process, can production begin. This detailed process has proven to be the ideal way to guarantee the best quality parts, time after time.

Tooling Tradeoffs

Learn the pros and cons of various tooling methods on the Empire blog.





How is process validation applied in Scientific Molding?

Molding for medical devices, especially, involves critical processes that must offer repeatability, accuracy, and a high degree of quality. Scientific injection molding is a highly technical, scientific approach to develop and optimize an injection molding process. It follows a standardized, data-driven methodology to plan and collect important, exact data from the molding process.

Scientific injection molding is a strong tool supporting the process validation objectives. The main steps of process validation are:

1. Process stability experiment
2. Mold viscosity assessment
3. Balance of fill analysis
4. Gate seal study
5. Multi-cavity evaluation
6. Process centering

ABOUT EMPIRE PRECISION PLASTICS

Empire Precision (http://www.empireprecision.com) When your mission-critical program needs an extra edge, come to Empire Precision Plastics “Where Your Ideas Take Shape”.

Empire excels at precision molding of intricate components – the more complex the better.

Our Idea Factory guides our customers from new product development, prototyping, through mold construction, to close tolerance injection molding and component assembly – Empire is large enough to consistently service your needs, yet small enough to provide the personal attention that you deserve.

We have built this company to meet the needs of our customers’ programs, growing from an injection molder to a full-service systems manufacturer. When the demand for faster delivery of quality optics became clear, we acquired and integrated precision polymer optics design, prototyping and production services.

We listened when our customers needed white room capability for medical device subassembly to better meet compliance standards.

We continue to grow and invest in the automation and other manufacturing methods that your programs demand. We offer dedicated custom centers for volume manufacturing and continue to pursue the enhanced capabilities to serve you better.

Empire Precision Plastics is ISO 9001:2015 and ISO 13485:2016 Certified

To learn more about how Empire’s advanced technology and disciplined approach can benefit your next program, contact us at info@empireprecision.com.