10 Steps to Medical Device Process Validation

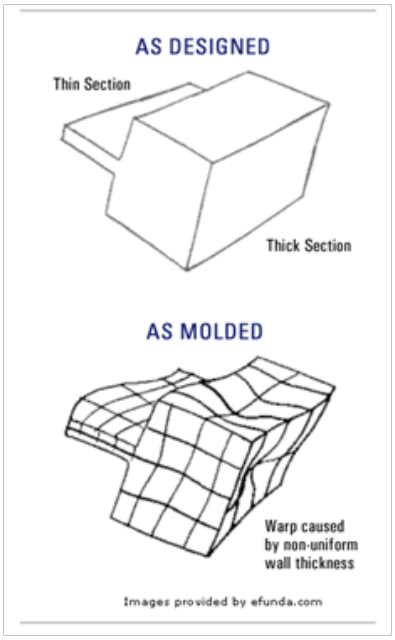
EMPIRE PRECISION

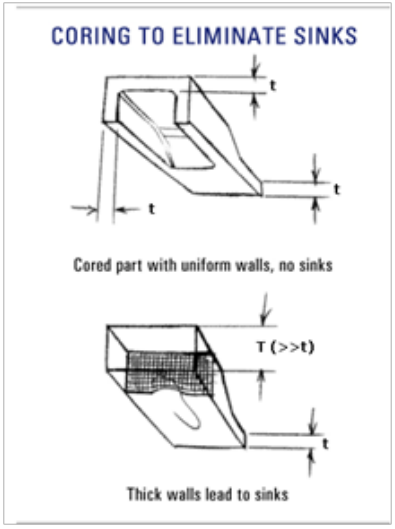
WHERE YOUR IDEAS TAKE SHAPE

Medical Device Process Validation

A robust documented DQ-IQ-OQ-PQ process will minimize wasted time and cost in addressing issues with your part. Empire Precision's medical device process validation establishes guidelines for quality molds and parts, and it can be customized to each customer's specific needs.

At Empire, we use a 10-step process to perform process validation for our medical parts and assemblies. These 10 steps are broken down into checklists to verify that all sub-steps are properly completed. The completed DQ-IQ-OQ-PQ package is then submitted to the customer for evaluation and approval. Some customers have their own validation process, in which case we will submit the package as defined by that customer.





Design optimization

It is important to review part and mold designs to ensure that long-term production is possible.

Design Qualification (DQ)

In the Design Qualification phase, Empire scrutinizes the customer's part design for moldability. There are several common part design issues that must be evaluated, especially in a metal-to-plastic conversion.

Overly tight tolerances

Review tolerances for achievability and best design practices for plastic injection molding.

Non-uniform wall thickness

Non-uniform wall thickness can cause inconsistent shrink rates within the part, which can cause dimensional issues.

Heavy wall thickness

Require extended mold cycle time and can negatively affect part such as sink. This is a common issue in metal-to-plastic conversion.

Robust mold design

Parts are reviewed to ensure that a robust mold design is achievable. It is critical that the mold is capable of achieving long-term production.

Predictive molding using Mold Flow software is the best way to ensure that we identify potential issues in the mold design before mold build. Every mold design at Empire is reviewed using Mold Flow analysis to ensure optimal gate size and location while predicting molded part quality. The Mold Flow software also helps to ensure manufacturability. For example, if a customer is concerned about knit lines in a certain area, or wants to hold to a particular tolerance for flatness, we can predict and rectify the design in advance of molding.

DQ Steps 1-2

1. Part Design

Nominal Wall Thickness, Corner Radii, Proper Draft Angles, Weld Lines, Core Pins, Gate Location, Ejector Style, Parting Lines, CTF Dimensions, etc.

2. Mold Design

3D CAD Design, Mold Flow Analysis, Designing for Scientific Molding, Ejector Style, Parting Lines, Direction of Flash, CTF Dimension Grooming Strategy, etc.

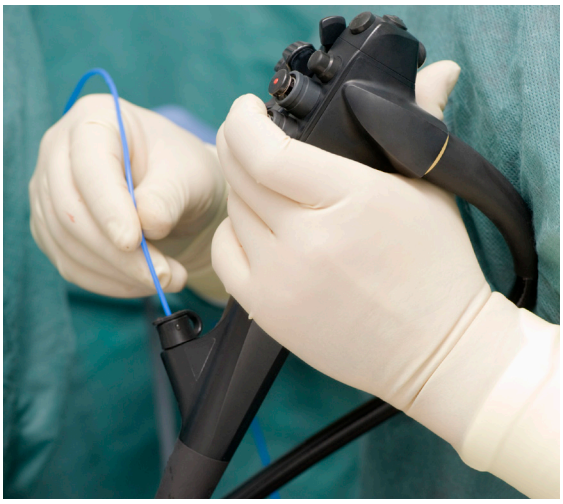
Installation Qualification (IQ)

In the IQ phase, Empire ensures that we have all of the proper tools and equipment necessary to establish the most effective production process for your particular product needs. We inspect and evaluate the mold, the molding press and the supporting auxiliary equipment to confirm they are acceptable and working as planned.

IQ Steps 3-5

3. Mold Inspection

The mold is assessed for markings (asset tagging, engraving, cavity numbering, etc), cavity/core surface and component quality (free of undercuts, pitting, blemishes, nicks, chipped edges, slides have positive locks, stops, grease, function easily, clear part, etc.), mold base (fits in press,



Plastic conversion

Switching from metal or glass to a plastic material presents a tremendous opportunity to drive out cost for your medical product.

KO rods, pry bar slots, mold plate chamfer, correct wiring & functionality for hot runners/sprues, etc.) as defined in our mold inspection checklist.

4. Molding Machine and Auxiliary Equipment

Assess for the appropriate molding machine, auxiliary equipment (blenders, dryers, water units, process monitoring, etc), analyze/establish preventative maintenance requirements, establish process monitoring parameters (times, temperatures, pressures, cushion, etc.)

5. Mold Installation and Dry Cycle

Documented production folder (process setup sheet, water diagram, temperature and flow rates, hot runner connections, etc.), mold installation (location, level, ejector rods, etc.), mold dry cycle (verify mechanical actions and slides), check for fundamental flaws (mold build, design, cooling channels etc.) In this step, the mold is dry cycled in the specified press, ensuring that the mold functions as designed with its support equipment.

Operational Qualification (OQ)

Our initial scientific process development ensures repeatable manufacturing output. Scientific molding determines the optimal process parameters for a particular mold by defining the following conditions:

- Rheology curve
- Mold cavity balance
- Gate seal
- Pack pressure latitude study
- Cooling time optimization

Empire may also perform Design of Experiments (DOE) for establishing process limits, which would include high-low process studies, in order to establish process limits for key characteristics. The results of the DOE will ensure that all outputs (KPI or Key Process Indicators) of a molding press are defined to produce parts at the optimal process with controlled limits.

Contact Empire Precision at 1.800.541.7135 or info@empireprecision.com to speak with an expert who can who can guide you through multiple considerations for improved program cost and performance.

OQ Steps 6-8

6. Scientific Molding Principles

Initial process determination, establish first shots, rheology study, mold cavity balance, pack pressure latitude, gate seal, cool time optimization, designed experiments, etc.

7. Steel Safe Adjustments

Optimal process setup, achieve steady state, run parts for quality submission, submit to quality for 100% FAIR and capability study, evaluate inspection reports, make steel modifications from inspection analysis, etc.

8. Verification Run

Set back to optimized process, achieve steady state, run parts for quality submission, submit to quality for 100% FAIR and capability study, and evaluate inspection reports (Are parts good? If yes, continue; otherwise back to tool room). Run OQ to test limits of the process to in turn test the limits of the part specification, send OQ parts to customer for approval of all parts, etc.

Production Qualification (PQ)

In the PQ phase, or run at rate, we verify that everything leading to this point is a capable process for long-term production. This phase verifies that parts are good in large quantities in an extended engineering run.

A drift in quality over a long run can indicate issues with the mold such as venting. PQ establishes that the mold and molding process are stable when running at the established molding process.

While every stage of the DQ-IQ-OQ-PQ process can be customized to the customer's standards and needs, the PQ process may include capabilities studies to validate that parts achieve a customer's Cpk levels. .

PQ Steps 9-10

9. Extended Acceptance Run

Determine (with help of customer) the required length of run (in hours) needed for PQ (typically 4 to 24 hours), set to optimal process, and start the production run. This is treated as a standard production run. The idea is to run this as a production order allowing the production floor do their thing. It should not be treated as a special run. All inspection is done according to production in-process inspection procedures.

10. Approvals

Parts pass first article inspection, parts pass visual and functional testing, mold achieves a minimum Cpk or better on all CTF dimensions, mold is running at or faster than the quoted cycle time, steel inspection dimensions are received and in specification, spare component steel is within range of steel measurements in the mold, production folder is complete, customer approval is received.

Medical Device Process Validation Checklists

Empire Precision uses process validation checklists for medical molding, new build tooling, and transfer tooling. There are more than 200 check boxes on our DQ/IQ/OQ/PQ checklist. The completed checklist is part of APQP (Advance Product Quality Planning).

Customized Validations Available

At Empire Precision, we know that many companies have their own process validation checklists, and we are more than equipped to work within your validation process. Our team will work with you to ensure that your process is complete and delivers the desired results.

Have Questions?

Please contact our team members.

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