VELOSITY
Accelerating Innovative Solutions

WHITE PAPER

Program Transfer

In year's past, program transfers referred to moving a mold or two. Today, the scope of program transfers encompasses nearly every aspect of the supply chain. From molds and machining to subassemblies with secondary operations and full assemblies, the opportunities are unlimited. With the right preparation and a capable partner, even complex transfers can achieve desirable outcomes.

This white paper explores the best practices for a successful program transfer process.

Program Transfer: A Proven Process

Overview:

Whether to address supply chain consolidation, performance-related concerns or complacency from a current supplier, companies are looking for alternative sources to make established products.

The more you know about the program transfer process, the better prepared you will be, and the more confidently you can choose a partner with the capabilities to get you over the finish line.

So, what distinguishes successful transfers from unsuccessful ones? In short, a partner that understands the barriers to success; sets realistic expectations; challenges the status quo; prepares mitigation strategies by leveraging the collective experience of the team; and of course, executes to plan.

No one can guarantee a transfer without some challenge, but qualified partners skillfully respond to challenges. The last thing you want to hear is, "Well, we didn't build the mold so <*insert problem here*> is not our issue."

This white paper explores our proven process which relies on a collaborative, comprehensive approach to solving problems. Success is never a one-sided affair.

At Velosity, our step-by-step process provides a simple, effective road map to demystify the process. We request detailed information from our partners, and we ask a lot of questions. Many of the surprises encountered during a transfer are born from faulty assumptions; lack of clear and reasonable expectations; or simply not asking the right questions. Collaboration and communication are key elements in our process. With tight lead times, staying aligned is essential for success.

Before embarking on any program transfer, carefully consider what you are trying to achieve; gather as much information as possible; prepare to set clear expectation; and ensure your partner is capable.

Finally, plan to have fun. Yes, the work can be hard, and the pressure to reach the finish line will grow as the timeline shortens, but don't forget to lighten the mood along the way and celebrate small wins.

Program Transfer: Step by Step

Step 1: Gather information and request a proposal.

Define goals.

It's vital to clarify your reasons and goals for the transfer. The most successfully completed transfers started with open and honest conversations about goals and requirements, not just a quantity of parts required by a certain date. Things to consider: Are there price sensitivity issues, current part quality concerns, or is the mold and/or equipment simply worn out and should be replaced?

STEP 1: KEY TAKEAWAYS

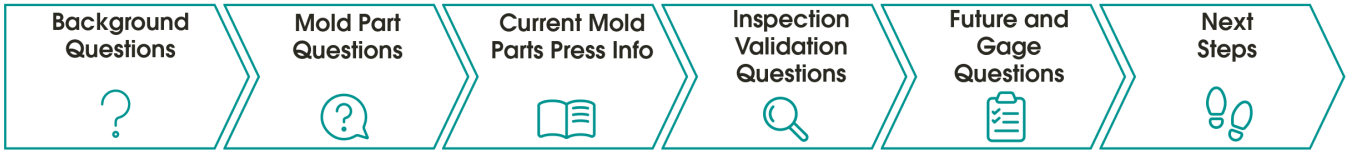
- Know your goal / expectations
- Provide clarity in the request
- More information is better
- If you're not sure...ask

Communicate thoroughly, success is in the details.

Understanding your starting point and your vision of success is critical in defining the appropriate plan. Share current program details and issues, no matter how insignificant they may seem. They will inevitably come up during the sample development or validation activities. All programs have issues, and some continue into production, becoming "accepted" as desensitization occurs with smaller annoyances. Inherited transfers do not mandate the acceptance of inherited problems. At Velosity we prefer to resolve legacy issues through the transfer process whenever possible. Mitigation strategies are more effective when issues are known ahead of time.

Download our questionnaire.

Velosity's easy-to-follow questionnaire helps you compile the details needed to generate an accurate proposal. You'll be guided to provide information in the following categories:



Download the program transfer questionnaire.

Validate Proposal Accuracy.

Complete and detailed information create the foundation for an accurate proposal, one that integrates goals, expectations, and pricing. The proposal should be discussed in detail to address inaccurate assumptions and mitigate risk from the start. Team alignment is imperative. The more accurate the proposal, the more quickly a solid project plan can be developed. Once the proposal is accepted, the real work begins.

Step 2: Project Planning.

Leverage a cross-functional team.

At program kickoff, a cross-functional project team starts the project planning process and determines a cadence for project updates. It is critical at this phase for the team to understand all the moving pieces, known barriers, historical problems, and ability to make print changes. This ensures activities, deliverables, and mitigation strategies are properly accounted for in the project schedule.

STEP 2: KEY TAKEAWAYS

- Unknowns need to be known
- Align on all expectations
- Challenge the status quo
- Prepare for the unexpected

Get crystal clear on expectations.

Misunderstood expectations typically cause missed milestones, which ultimately drive project delays. The most overlooked factors are the lesser-known problem areas that require special focus during development. Sweating the small stuff early on combats fewer schedule disruptions in the end.

Keep an open mind and communicate hard boundaries.

Velosity excels at challenging the status quo for the betterment of the program, which may be viewed as a hinderance. While the answer may be set in stone, questions still need to be asked to understand and test boundaries. A transfer provides the opportunity to reevaluate issues and consider fresh solutions to existing problems.

What to expect from a project plan and schedule.

While the quote is a summary of deliverables, the timeline is the roadmap on how to get there. The output of this step is a project plan and schedule, which, at a minimum, should address the following:

- √ ***A comprehensive list of all affected components and the timeline to move the program***.
- √ ***The current part or assembly inventory including the usage rate.***
- √ ***All raw materials provided or needed to be procured.***
- √ ***Equipment, mold, and sample development activities.***
- √ ***Validation activities including protocol development and the validation strategy.***
- √ ***Production start and ramp up requirements.***

Avoid lost time.

There must be complete alignment on the schedule within the team. Close any gaps in the schedule. Establish clear lines of communication. Any schedule, no matter how well-planned, requires effective communication. Simply assuming everyone is on the same page results in lost time you can't recover.

Step 3: Assumption verification.

Receive and inspect.

Once the molds, fixtures, raw materials, and relevant documents arrive, the molds are inspected, and all materials (with certs) are put into inventory. Changes identified during the proposal phase are initiated and any new concerns identified will be discussed with the project team to determine next steps.

Conduct initial sample.

The initial sample occurs. For molded parts, Velosity employs a Scientific Molding approach to developing the parameters that strives for a robust process. The "current" process sheet is used as a starting point, but our approach will once again challenge the status quo. Gate freeze, short shot progression, and fill time studies support development of parameters needed for the process characterization step. Part appearance, in addition to quick inspection checks, help determine the assumed nominal process, similar to any new tooling program.

STEP 3: KEY TAKEAWAYS

Robust process is the goal

Change means flexibility

Decisions have consequences

Agreement to move forward

- ❖ Velosity is committed to ensuring long-term process consistency and repeatability, even if that means asking the hard questions and pushing the limit of the expectations.

Perform first full article inspection.

After the sample, normally a full first article inspection (FAI) is completed to base line print conformity to the established process. The level of inspection was determined in the planning phase and documented in the protocol. This verification step provides insight into specification challenges that may lie ahead. The goal of this step is to answer: "Does the equipment work as intended, and is there a process window that aligns with print expectations?" Usually the answer is, "Yes...but," indicating something needs to be addressed. Now what?

Step 3.5: Changes needed...Decision time.

Addressing discrepancies.

This half-step is important because validation cannot commence without a plan to address known discrepancies, versus incurring costly change decisions later. If during the planning phase, the team had an open discussion on handling non-conformances, then this step will be clear. Print changes are always the least costly (in terms of time and dollars). However, the ability to change the print of currently marketed products may be limited. Physical print changes may not need to be made now, but assessing the limits of what can be done is important: it drives what comes next. Saying "no" to print changes leaves two primary options:

- ***Change the tooling.***
- ***Change the process.***

Avoid the expense of indecision.

Experience has shown that drawings finalized from a substandard process or measurement capability come into full view when the "right" process is developed, and good metrology techniques are used. A normal response to a change request is, "We have been running these parts for years with no issues." That is rarely the case, and propagating the same problems into the new process comes with repercussions. Additionally, indecision can

significantly compromise the schedule. Remember that agreement to move forward is key since changes required after validation become much more costly if revalidation activities are required.

Step 4: Validate the process.

Changes have been made and/or agreement on the path forward is complete. The initial nominal process parameters have been determined based on metrology results and feedback on the parts, and process limit starting points have been documented. Now it's time to execute the balance of the approved validation protocol defined during the planning phase.

STEP 4: KEY TAKEAWAYS

All the prior work leads to this moment. If the hard decisions were made prior, this step is simply an execution step with little drama.

Finalize the process window.

Completion of process characterization runs (OQ) are the next steps in finalizing the process window through running at high and low processes and occasionally an additional nominal run. Design of experiments may be suggested based on challenges in meeting the specifications or to address a more concerning issue. Metrology at this stage usually consists of FAI and capability studies at each of the processes to validate the process window. The report details the results. The team discusses any discrepancies between metrology, capability, and the drawing to determine a path forward. Once again, it's decision time, tackling questions in this order:

- ***Can the print be changed?***
- ***Can the tooling be changed?***
- ***Can the process be changed?***

Simulate production.

Once the OQ passes, the final step is to assess the production performance (PQ) over several runs, simulating production running under production controls. Final metrology and reports are complete, and normally, with a well-executed plan, there is usually little to see here, other than saleable parts.

For assemblies that depend on molded parts, there are many different pathways to validate the assembly, and the execution will be based on the protocol defined earlier. Assemblies that rely on molded parts should use samples from the molding OQ process challenge to ensure variation in the molded parts are represented in the assembly.

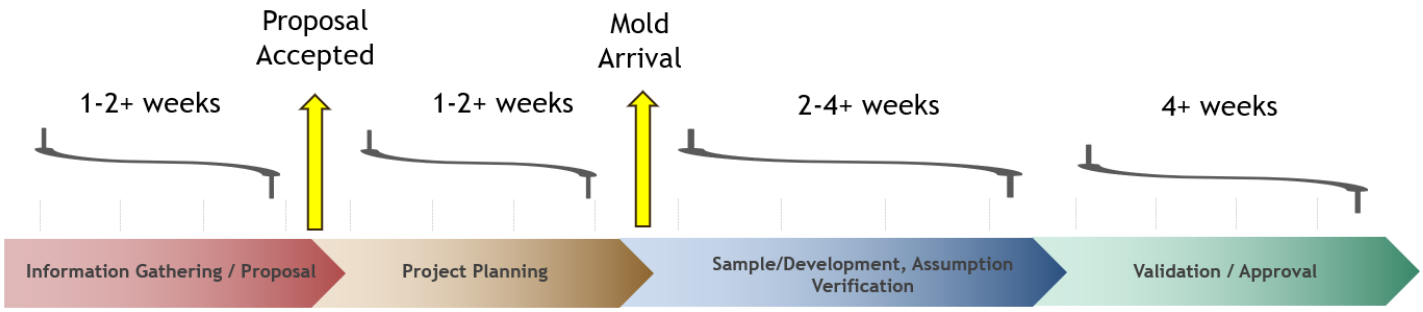
Finally, all that is left is to approve the process and start running production. The hard work is done, materials are in house, the mold and any assemblies are fully validated, and production can begin. Time to celebrate**.**

Discuss lessons learned.

Before the team disbands to work on other projects, we encourage a quick wrap-up and discussion of lessons learned. We have found that after the first transfer, the next opportunity is not far away. Identifying areas of improvement positions the team for speedier turnarounds in the future.

How long will it take?

There is no standard timeline since each program presents different tasks, opportunities, and complexities. Many times, situations are out of our control, such as mold availability, mold functionality or raw material issues. We have completed simple transfers with no issues and minimal qualification requirements in as little as two weeks, while more complex transfers with significant validation have taken over three months. Unique exceptions aside, a basic starting point follows the chart below and is extended or compressed during the project planning phase. Defining expectations, unknowns, and deliverables early makes the schedule more accurate and predictable.



Here's what sets Velosity apart.

This white paper provides a comprehensive guide for companies seeking to navigate program transfers successfully. It emphasizes the importance of thorough planning, collaboration, and adaptability throughout the process, and demonstrates the mission-critical role of a capable partner. To understand what sets Velosity apart, consider our points of difference.

- Our people and their deep level of experience. From our engineering, tooling, and process expertise all under one roof to our solution-based decision-making hard-wired into our DNA, we know how to take risk out of the program, and we are not afraid to ask the hard questions to drive the right solution, not just a solution.
- We invite our partners to spend time on the floor, talking to those who are making it happen, asking questions, collaborating, and learning. The more interaction there is on a project, the more successful the outcome. Our customers routinely express their appreciation for the ways we encourage participation. You won't sit in a conference room, while parts are brought to you. Where's the fun in that?
- Our highly skilled technical resources have encountered and solved most of the issues these programs present, making successful risk mitigation a staple in our process.
- Our best-in-class molding equipment and facilities with on-site tooling resources covering all three shifts keep your molds in top working order. If you have not been to one of our facilities, we encourage you to schedule a visit.
- Vertically integrated, best-in-class mold manufacturing is available to support and provide continuity for any future production tooling needs.

- ❖ Other vertically integrated resources, such as precision machining, are available to reduce supply chain bottlenecks. Reach out to discuss how other services can help with your transfer.
- ❖ We are ISO13485, AS9100, FDA registered, along with other certifications. View certificates on our website at www.velosity.com.

Ready to get started? Reach out to your Velosity Business Development Manager for an initial conversation. Then, answer our questionnaire and plan to get involved as much as your schedule allows, we'll handle the rest. We look forward to hearing from you soon!