

Whether to address supply chain consolidation, performance-related concerns or complacency from a current supplier, medical device companies are looking for alternative sources to manufacture established products. The more you understand the components of an effective program transfer process, the more confidently you can choose a partner with the expertise and capabilities to get you to the finish line.

No one can guarantee a transfer without some challenge, but qualified partners skillfully respond to challenges. At Velocity, our step-by-step process provides a simple, effective road map to demystify the process. The following outline is an excerpt from our recent program transfer process white paper, accessible via the QR code at the end.

PROGRAM TRANSFER: STEP BY STEP



1. Customer gathers information; requests proposal

Define Goals — start with open conversations about goals and requirements, not just a quantity of parts required by a certain date.

Communicate Thoroughly, Success is in the Details — understanding your vision of success is critical in defining the appropriate plan.

Validate Proposal Accuracy — the more accurate the proposal, the more quickly a solid project plan can be developed.



2. Project planning

Leverage a Cross-Functional Team — a cross-functional project team starts the project planning process and determines a cadence for project updates.

Get Crystal Clear on Expectations — misunderstood expectations typically cause missed milestones, which ultimately drive project delays.

Keep an Open Mind and Communicate Hard 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

At a minimum, a project plan and schedule, should address the following:

- 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 starts and ramp up requirements.

Avoid Lost Time — any schedule requires effective communication. Assuming everyone is on the same page can result in lost time.



3. Plan and assumption verification

Receive and Inspect — customer supplied equipment, molds, fixtures, and raw materials.

Conduct Initial Sample — initial sample occurs, part appearance, in addition to quick inspection checks, help determine the assumed nominal process.

Perform First Full Article Inspection — this verification step provides insight into specification challenges that may lie ahead.

Address Discrepancies — validation cannot commence without a plan to address known discrepancies.

Avoid the Expense of Indecision — indecision can compromise the schedule and agreement to move forward is key as changes after validation become more costly if revalidation activities are required.



4. Validate the process

Finalize the Process Window — completion of process characterization runs (OQ) are the next steps, running at high and low processes and occasionally an additional nominal run.

Simulate Production — once the OQ passes, assess process performance (PQ) over several runs, simulating volume manufacturing running under production controls.

Discuss Lessons Learned — identify areas of improvement to accelerate future programs.

NEXT STEPS

Discover valuable insights on program transfer—download the full white paper by scanning the QR code. Have questions? Visit us at velocity.com for more information and support.



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