"Part Process" Transferability Using a Machine Independent Variable (MIV) Methodology for Multiple Machines

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ABSTRACT

In the medical device molding industry, manufacturing plastic parts in multiple machines requires expensive and time-consuming validations for each injection molding machine (IMM). Here we employ a Machine Independent Variable (MIV) method to effectively and efficiently transfer a validated "part process" across four distinctly different IMMs. Critical to Quality (CTQ) results for each transfer were required to meet Ppk targets to match the CTQs of the initial validation. Our results show the MIV transfer method, verified with *eDART*® technology, can be used to replicate plastic parts in different IMMs with negligible part variation (dimensional results), using selected capable machines. The data-driven results provided by this lean systematic method are more robust, faster to obtain, and more cost effective than the traditional single machine approach.

INTRODUCTION

Medical device companies require manufacturers demonstrate a clear and in-depth understanding of molding processes, from initial validation through release to manufacturing, and including transferability. Such efforts are extremely important, especially considering the financial expense of current IQ/OQ/PQ validations. If execution and data collection are not precise and accurate and not based on an optimal "part process", then ALL statistics within generated reports become erroneous – wasting valuable time and money, and putting a program behind schedule. A lean systematic method that can replicate the optimized parts/process data will produce a repeatable efficient validation. Along with increased confidence, this will prove more cost effective and increase profitability by speeding products to market.

Currently, manufacturers perform a full validation for each machine whenever a mold is moved to a different IMM. Such full validations are both costly and time intensive – not to mention this approach may or may not utilize scientific injection molding principles. Machine Validations focus on (unchangeable) static input settings, or setpoint processes, that can alter "results" based on variations in variables unassociated with the settings (material viscosity, temp, cooling, etc.). A more efficient scientific method of transferring molds between IMMs offers significant opportunities.

Use of setpoint processes are still not uncommon in the industry with the belief that if machine settings are held constant, the same parts will be produced. However, this focus is on the machine and does not take into consideration other normal variation and environmental influences that can affect machine performance and possibly the part.

The ultimate paradigm shift in molding would be to validate plastic "part process" outputs (plastic conditions and component variables/attributes) using scientific molding principles rather than machine set points. In a "part process" validation, the focus shifts to what is happening to the part inside the mold rather than the machine, and the objective is to achieve more consistent, repeatable results. The standard definition in 21 CFR sec 820.3(1) states: "Process Validation means establishing by Objective Evidence that a process consistently produces a Result or Product meeting it's predetermined specifications." The intent here is to replicate a consistent "part".

During the past two years, a consortium of leading global Medical Device OEM players (see Participants list) have collaborated on a new validation strategy which could reshape industry standards for fundamental mold transfer validation requirements (reference document [1]). The premise of the consortium was to execute a proof-of-concept study based on a white paper written by Rod Groleau entitled "Location Independent PPAP Streamlined for Global Manufacturing" (reference document [2]). In this 2000 article, Groleau suggested the use of a lean systematic "part process" model as an alternative to machine validation.

We define a "Part Process" most simply as a PART-focused process ("from the plastic's point of view"), wherein optimization is applied to the plastic at the part level using design principles, material selection, mold design and construction, and machine capability (i.e. melt prep and delivery).

To develop a validation model for a part process, we employed a machine independent variables (MIV) approach. MIVs are independently measurable variables, such as actual plastic conditions and parameters that characterize a given PART (i.e. - fill time, actual melt temperature, volumetric shot size, hold pressure and time), and are necessary to ensure replication to a specified OUTPUT/RESULT, considering the Four Plastics Variable as guidance. Since these variables are part-specific and not machine-specific, as in the traditional validation approach, they are independent of the specific machine used in the molding process. This is a crucial point, as it makes it possible for the first time to develop a validation scheme which eliminates the need to fully validate each additional IMM prior to manufacturing. Note, this does not eliminate the need for the initial robust full IQ, OQ, PQ validation of the part.

Importantly, there are a large number of benefits that can be realized by implementing a "part process" approach as we are suggesting when compared with machine-based validation strategies (Table 1).

Validation Characteristics	Traditional	Part Process
Time	Weeks/Months for IQ/OQ/PQ	Days for PQ Qualification/Verification
Resources	• Personnel • Equipment • Material, • Inspection allocation for IQ/OQ/PQ requirements	• Reduced labor hours • Reduced equipment disruption • Reduced material quantity • One-time inspection
Costs	• Production disruption • Personnel allocation • OQ Low/Nominal/High runs • Multiple PQ runs • Multiple resin lots • Personnel hours • IQ/OQ scrap • PQ inventory greater than immediate demand • Production hold for results evaluation/approval	• Reduced production disruption • Reduced personnel allocation • Single PQ run • 1 resin lot • Reduced personnel hours • No IQ/OQ scrap • PQ inventory does not exceed immediate demand • Expedited production release
Capacity	Restricted to individual mold/machine combination	Potential to schedule on multiple machines
Flexibility	Mold transfer requires Process Development and Full IQ/OQ/PQ Validation	With detailed Process Development from initial validation, mold transfer with reduced validation on capable machine(s) at any location or Supplier

Table 1. Benefits of a Simplified Part-Process Transfer Method

METHODS AND MATERIALS

A schematic of the verification model for MIV process transfer can be seen in Figure 1. A complex Drive Clutch component (16 cavity mold) was selected for the purpose of this event. The DII molding process for the Drive Clutch was validated in Trial 1 via IQ, OQ, and PQ testing. Trials 2-4 each exercised a 4-hour qualification run to demonstrate the MIV process transfer of the Validation process from Trial 1. For the individual qualification trials, the MIV Checklist results were compared to that of the Trial 1 validation to confirm repeatability. A formal validation/qualification report was generated to document the results from each trial.

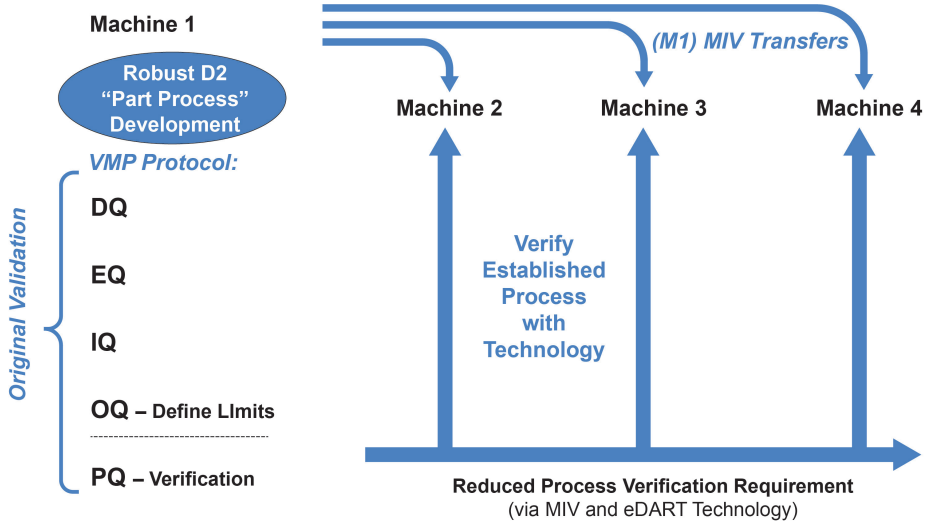

Figure 1. MIV Transfer Verification Process—Conceptual Test Plan for the VMP

Four IMMs were used in our testing of the part process validation approach (Table 2). Initially we had to consider the least capable machine's performance specifications for the given part/mold to perform our validation. The trial was started in the 330T Roboshot machine. The Engel 420T machine had the least capable Volumetric Injection Rate (320cm^3/s) of the four IMMs, so this became the leading constraint across all the machines when developing the validation process.

Trial #	Machine	Volumetric Injection Rate	Machine Tonnage	Facility Location	Type	Barrel Size	% Barrel Size > 20%
1	**Roboshot 330T***	**434 cm^3/s**	**330 T**	**NyproMold - Clinton, MA**	**Electric**	**48 mm**	**7.50%**
2	Engel 420T	320 cm^3/s	420 T	Nypro Devens - Devens, MA	Electric	35 mm	13%
3	Netstal 200T	2375 cm^3/s	200 T	Nymedex - Clinton, MA	Hydraulic	55 mm	3.60%
4	Roboshot 275T	415 cm^3/s	275 T	Nypro Devens - Devens, MA	Electric	40 mm	12.70%

Table 2. Four IMMs Used (Indicates Validation Machine)*

We determined the least capable machine performance specification as follows:

> The team determined the maximum injection speed that can be used in the 330T Roboshot to develop a process that will be capable of running on all four machines. The 420T Engel (35mm) max volumetric injection rate was determined to be 320 cm^3/sec; not to exceed 80% = 256 cm^3/sec. This converted into the max injection speed for the 330T Roboshot (48mm) of 256 cm^3/sec divided by the area of the screw of 1809 mm^2 = 141 mm/s max.

It is important to note that the performance of the machine had to be verified and documented to be within the typically recommended target limits for a given part (i.e. acceptable shot capacity, consistent melt preparation, can hold consistent part tonnage, deliver sufficient volumetric injection rate, and is not pressure limited). It is critical that all selected machines be capable to deliver the MIV part process when employing this methodology; a capable mold to capable machine match must be established and verified with data-driven results, taking the machine performance specifications into consideration.

We define a "Capable" Machine as a MACHINE that can deliver the necessary measurable performance requirements to replicate the specified MIVs to achieve a desired OUTPUT/RESULT for a given "part process".

All individual trial requirements were executed as defined in the approved Drive Clutch Validation Master Plan (VMP) protocol without deviation. Systematic Molding principles were executed to develop the part process, and there was no additional technology utilized to develop the initial validation process. The machine independent variables where documented in an MIV Checklist utilizing the Four Plastics Variable as guidance.

The MIV method was exercised in a manner to demonstrate the overall effectiveness at various stages of process refinement. We used a good, better, best categorization to minimize "part process" variation, and exercised this through each trial. We defined good, better, best as:

Good - Standard DII process (No instrumentation technology)

- Replicate machine Independent Variable (MIV) only.
- The DII process is in terms of the plastic and part variables – melt temp, plastic flow, plastic pressure, cooling, as well as, how to use fill time together with fill only and full shot gram weights as sound scientific molding methodology.

Better* - Standard DII process (*machine* fully instrumented with technology)

- Ability to monitor and match *machine* performance with the ability of matching injection pressure via template/pressure curves.

Best* - Standard DII process (*mold* (cavity pressure) and *machine* fully instrumented with technology—cavity pressure was ONLY used as a visual aid for the consortium event)

- Ability to monitor and match both machine performance and cavity pressure via template/pressure curves.

** Increased Levels of Confidence: Establish statistical assurance with instrumentation (replication and record of shot to shot performance data)*

The MIVs for Trial 1 were duplicated in Trials 2 through 4. For each subsequent individual trial, the process was allowed to stabilize, and sample parts were measured to confirm in-process dimensional acceptance. This was completed by utilizing the Process Development and Transfer conversion table, an example screen shot of which is shown in Figure 2. Here, the Validation machine is defined in the first column, and the target machine in the second column is selected from a machine database. The machine database contains specifications for all available molding machines. The MIV data from the validation trial is entered into the "Optimized Process" column. The process transfer method uses the machine specifications and documented part process information to provide suggested starting process parameters for the target machine. Once these settings are established for the targeted transfer machine, the team optimized the MIV plastic measurements to match those of the Validation. Using technology, the machine pressure curves of the respective individual qualification trial molding machines were compared and verified to the Trial 1 validated molding machine before the PQ qualification run was executed.

	from machine	to machine
machine number	ATC	Devens 2
machine manufacturer	Milacron	Engel
type	electric	electric
tonnage	330 ton	420 ton
screw diameter	48.00 mm	35.00 mm
intensification ratio	1.0	1.0
max plastic pressure	34136 psi	34809 psi
max fill speed	240 mm/s	333 mm/s
max shot size	176 mm	200 mm
max volume flow rate	434.290 cm3/s	320.380 cm3/s
max shot volume	313.000 cm3	192.400 cm3
screw type	GP	GP
screw compression ratio	?	?
screw L/D	20.0	20.0
max hydraulic pressure	na	na
max back pressure	2845 psi	5800 psi
max screw rpm	400 rpm	300 rpm
min mold height	15.7 in	11.81 in
max clamp open	29.5 in	29.53 in
tiebar space - horizontal	31.9 in	30.7 in
tiebar space - vertical	28 in	30.7 in

☐ *Machine Specifications*

	optimized process from machine ATC		calculated starting setpoints for machine Devens 2		
clamp force	140	ton	140	ton	33.3%
back pressure	1000	psi (plastic)	1000	psi (plastic)	17.2%
screw rpm	40	rpm	55	rpm	18.3%
shot size	27.00	mm	50.78	mm	25.4%
transfer position	10.00	mm	18.81	mm	
decompression	3.00	mm	5.64	mm	
fill speed	80.00	mm/s	150.47	mm/s	45.2%
fill time	0.27	sec	0.27	sec	
transfer pressure	22,398	psi (plastic)	22,398	psi (plastic)	64.3%
short shot weight	1.27	g	1.27	g	
hold pressure	10,000	psi (plastic)	10,000	psi (plastic)	
hold time	1.0	sec	1.0	sec	
A side cooling temp	200	F	200	F	
B side cooling temp	200	F	200	F	
cooling time	5.5	sec	5.5	sec	
cycle time	15.8	sec	15.8	sec	

☐ *"Part Process" MIVs*

Figure 2. Recommended starting point for machine to machine transfer: "Part Process" transfer using Machine Independent Variables (MIV) that are repeatable based on machine capability

RESULTS AND DISCUSSION

MIV-Replication Only

The MIV transfer method demonstrated capability for replicating parts with dimensional stability. By matching the MIVs and using the fill-only retains and parts weights, along with the final part weights, the in-process dimensional results were documented to be within the print specifications and passed the VMP requirements. Using the MIV method, the validated part process executed on Machine 1 could be replicated on Machines 2, 3, and 4. During a transfer, one can run an effective streamlined validation with more assurance of the end results.

Additionally, we used process-monitoring technology to visually verify and confirm that the process was normalized between the qualification and validation machines. Machine(s) were instrumented with pressure sensors and linear transducers to monitor plastic pressure and linear displacement in the screw. The mold had flow meters and temperature sensors to monitor the water cooling circuits and temperature of the cavity and core steel. Each cavity was equipped with force sensors positioned after the gate and at the end of fill to read plastic pressure. The result can be shown as a graphical representation of the molding process. Figure 3b shows the graphical output of three shots made during the validation run. Overlaid on this graph are shots made on the Roboshot 330T using the high, nominal, and low values of the tested hold pressure range window. The corresponding internal cavity pressure is graphically documented for each respective hold pressure setting that was tested, and this can be directly compared to the dimensional results for reference (Figure 3a).

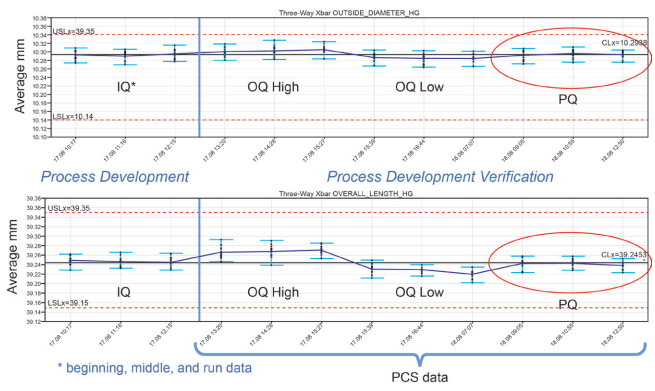

Figure 3a

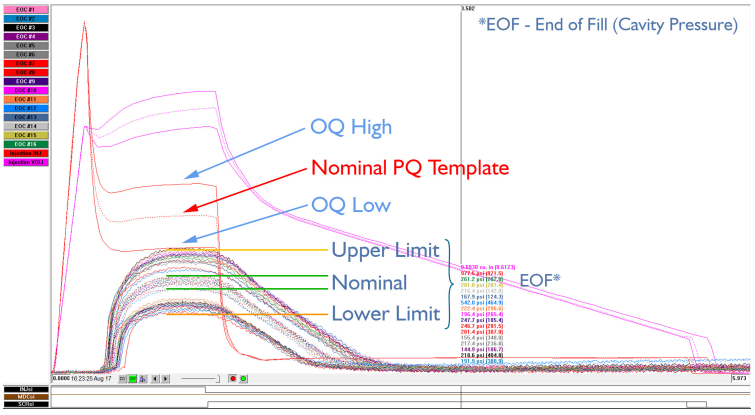

Figure 3b

Figure 3. Process Development results for validated DII part process development in Machine #1 – dimensional results (fig 3a) for the specific parts inspected shown within the specification limits (dotted red lines) along with the corresponding graphical representation of the actual process output overlay of the OQ High, OQ Low, and PQ Nominal (fig 3b) that generated the parts.

Technology provides additional process verification to show that repeatable parts are being made by the transferred process. This also provides a full shot-to-shot graphical record of process outputs representing the "fingerprint" of the "part process" that replicates the dimensional results. Using a combination of the defined MIV Checklist and available process-monitoring technology, users can easily reproduce the process on any machine, allowing for mold transfer and increased flexibility in capacity management. Figure 4a shows the MIV-matched process transferred to the Engel 420T machine compared to the nominal PQ run performed on the Roboshot 330T machine. Figure 4b shows the same comparison, but with adjustments to normalize the machine performance so that the transferred process visually matches the original validated process template for the resultant injection pressure (the dotted red template curve).

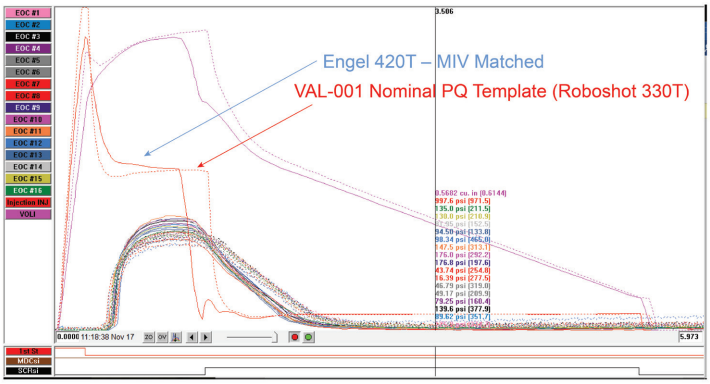

Figure 4a.

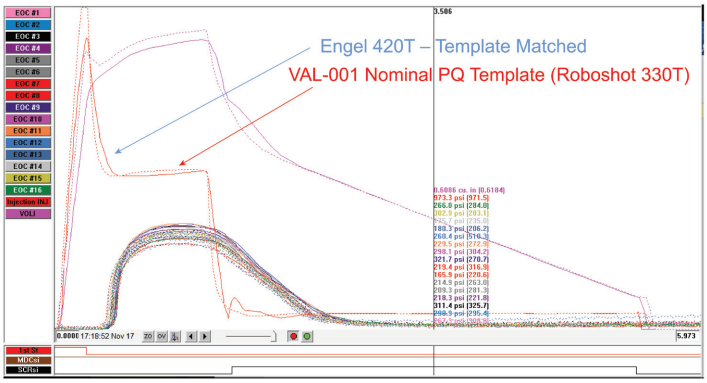

Figure 4b.

Figure 4. "Part Process" MIV transfer and eDART template match: Engel 420T MIV-Transferred Process (fig 4a) compared to the normalized eDART Template Match (fig 4b) of the validated "part process" in the 330T Roboshot. Technology helps identify and verify the normalized performance differences of the IMMs.

This study demonstrated that during a transfer, one can now run an effective streamlined PQ trial with assurance of the end results. Once the formal PQ dimensional report is generated and the parts pass the VMP criteria, parts can be approved and released into the product stream with increased confidence (Figure 4c).

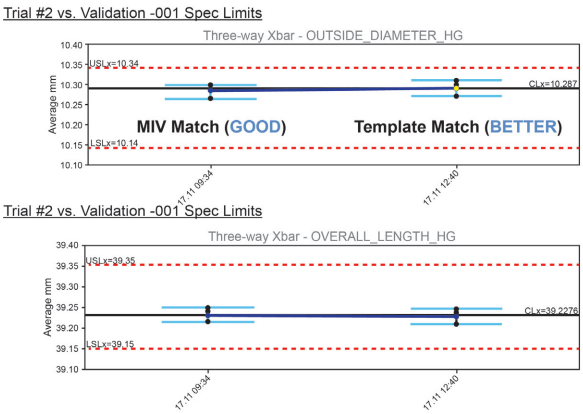

Figure 4c. Comparison of MIV-transferred vs. template match dimensional results

Use of process-monitoring technology also made it possible to quickly identify and manage performance differences among machine interface/controllers which can result in a slightly different molding process even though the molding input parameters were the same across each machine. If necessary to normalize the target machine's performance, process-monitoring technology provides that ability.

The *eDART*® was utilized for Trials 2 through 4 to help define and visualize the "part process" as a measurable output of machine input settings, or the resultant graphical representation of the process – called a process Cycle Graph. After the MIV results were confirmed and optimized, the technology was turned on to verify how close the transferred "part process" machine and cavity pressure curves/outputs were to the validation cycle graphs. If there were differences in the results, the machine inputs/settings were adjusted (normalized) to match the Validation cycle graph. With technology, one can graphically measure the differences in machine performance established from the input settings, and have the ability to adjust them to normalize the output to reproduce the desired results.

MIV-Replication Assisted by Process-Monitoring Technology

When the technology was used to monitor the process, there were differences observed in the actual machine outputs. Specifically, machines 1 and 2 had a different pressure response and measured injection forward times differently, resulting in cavity pressure response differences (Figure 4a). To address these differences, technology was utilized to further optimze and better replicate the Validated process. As seen in the Figure 4b, when the *eDART*® is utilized, the injection pressure curve shifts to align with validated process, causing the cavity pressure curves to also align. We used this technology based approach to achieve the final part process match. The end result was achievable without technology; while, the advantage of using technology was immediate identification and response to IMM variation.

Dimensional Comparisons Between MIV and Template Matched Inspected Parts

Manufactured parts were evaluated to verify the in-process CTQs, which were overall length and diameter, process performance (Ppk), and visual criteria. Figure 4c reveals that the corresponding dimensional results of the Template Match improved over the straight match of MIV established during the validation run – demonstrating the Good and Better results, with the added benefit of utilizing the technology for verification of machine process performance.

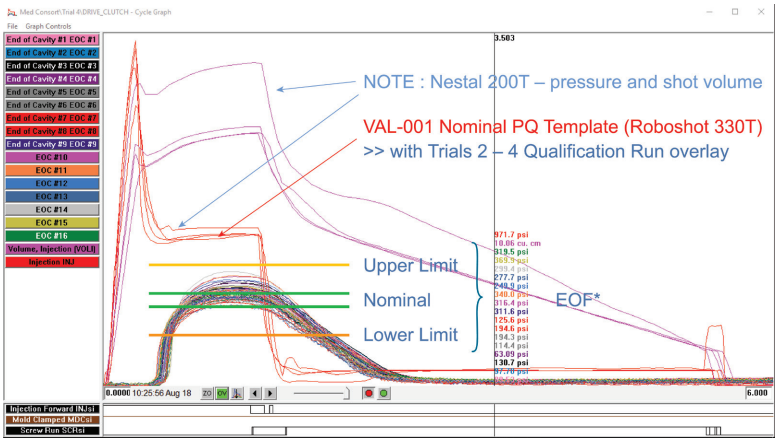

Figure 5a.

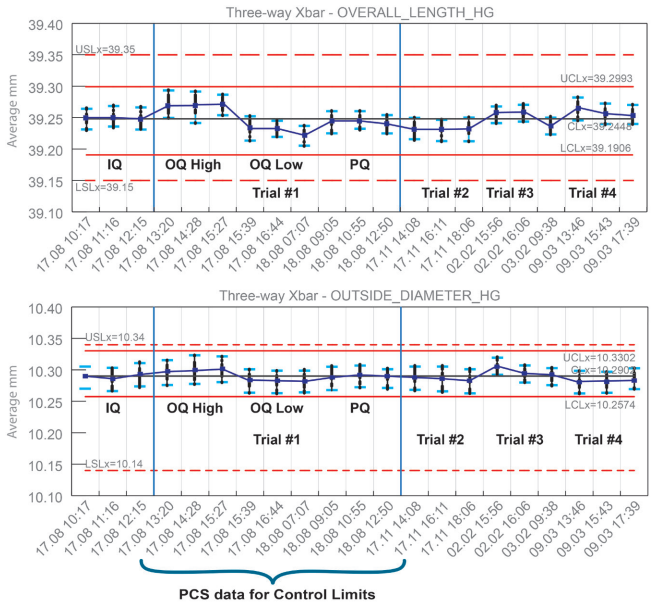

Figure 5b.

Figure 5. PQ Template Matched "Part Process" Transfer and Verification: Overlay of the graphical representation for trials 1-4 after process template matching (fig 5a) with dimensional results (fig 5b) within in-process control limits (solid red lines) established from the original validation trial.

With the process replicated across all four machines, parts were evaluated to verify the in-process CTQs. VMP requirements were met in Trial 1 and following verification trials. Trials 2, 3, and 4 also were within the control limits established in Trial 1. Figure 5 shows all four machine part processes overlayed vs. the template when using process-monitoring technology to replicate the original nominal PQ validation process. The corresponding dimensional results are within the dimensional control limits established during the validation run.

Capability

All VMP requirements for capability were met and Figure 6 shows the results of the in-process control dimension for the overall length. A minimum Ppk of 1.5 was required for this CTQ. It is very process sensitive since the part is manufactured out of a high shrinkage semi-crystalline material, Acetal. While the specification 39.15 +/- 0.10mm has a range of 0.2mm, these samples have differences in the order of thousandths; 0.0105 mm between the shortest and longest mean length. The dimensional results were achieved across all four molding machines, based on the successful transfer of the MIVs and verification with technology.

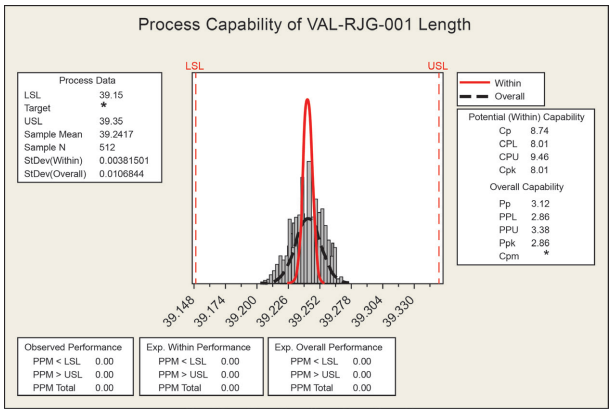

Figure 6a.

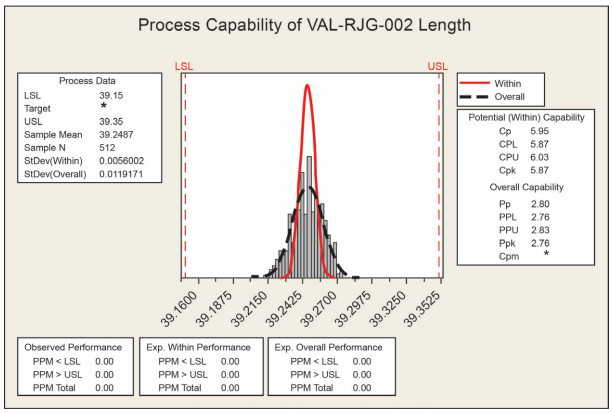

Figure 6b.

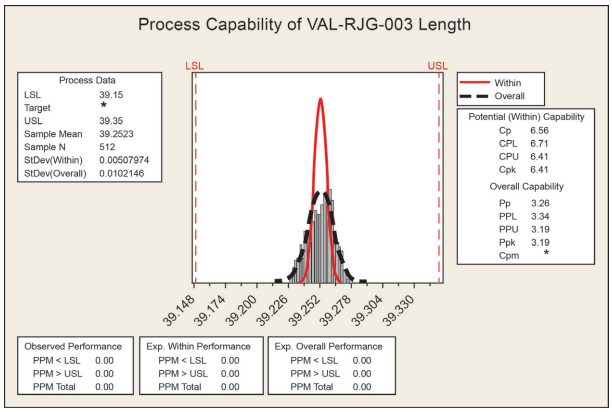

Figure 6c.

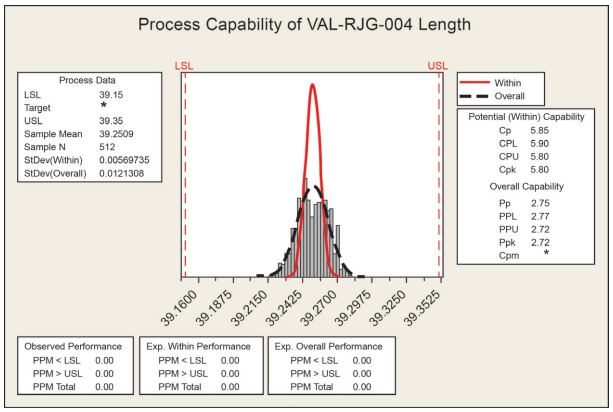

Figure 6d.

Figure 6. Statistical Results for Overall Length: Verification of the statistical analysis that the in-process control dimensional results are within the predetermined control limits of the approved validation. RJG-001 is the original Validation, RJG-002 through RJG-004 are the Transfer and Qualification Trials in three additional machines: (fig 6a) 330T Roboshot, (fig 6b) 420T Engel, (fig 6c) 200T Netstal, (Fig 6d) 275T Roboshot

CONCLUSIONS

Here we have challenged the traditional single machine validation model to advance the standardization, practicality, and acceptance of a lean systematic "Part Process Development and Validation" method/protocol for multiple machines. This facilitates a strategy for mold transferability that requires limited process development and a reduced PQ for verification.

The results of our data-driven testing clearly show that transferring a process from a validated machine to a targeted capable machine using MIV values alone results in parts that are dimensionally replicated comparative to those made using the validated process in the original validated machine. Dimensional analysis demonstrated that the parts made in each of the transfer machines satisfied dimensional and Ppk requirements, and were visually acceptable. Using these methods for evaluation, the parts made during the four separate trials were consistent with the normal variation that would be seen over four runs using the same machine and process. Table 3 provides evidence of the effort to impart as much variation (location, material, machine, people, inspection, peripheral equipment) to stress the proof of concept trials, reinforcing the strength of the end results—dimensionally stable parts replicated in different machines.

	8/18/2016	11/17/2016	2/3/2017	3/9/2017	
Trial Variation	**RoboShot 330T DCII Process Development**	**Engel 420T Process Transfer**	**Netstal 200T Process Transfer**	**RoboShot 275T Process Transfer**	**Comments**
Validation	**VAL-RJG-001**	**VAL-RJG-002***	**VAL-RJG-003***	**VAL-RJG-004***	***Match PQ Cycle Graph Template from VAL-RJG-001 (Process Results)**
Location/Facility	**NyproMold**	**Nypro Devens**	**Nymedex**	**Nypro Devens**	Different Divisions
	Clinton, MA	Devens, MA	Clinton, MA	Devens, MA	Different Towns
Material					
Type/Grade	Acetal (POM)	Acetal (POM)	Acetal (POM)	Acetal (POM)	
Lot #	Lot #1	Lot #2	Lot #3	Lot #4	Different Lot # for ea. trial documented
Machine	Milicron	Engel	Netstal	Milacron	
Machine Tonnage	330T	420T	200T	275T	Different Tonnage
Type: Hydraulic/Electric	Electric	Electric	Hydraulic	Electric	Different Make and Type
Screw Diameter	48 mm	35 mm	55 mm	40 mm	Different Screw Diameter
MAX Volumetric Flow Rate	434 cm^3 /s	320 cm^3 /s	2375 cm^3 /s	415 cm^3 /s	Different Vol. Flow Rates
Mold (Set Up)	**2x**	**2x**	**2x**	**2x**	Disassembled/Assembled 2x each Trial
Flow Meters (with Temp)	B&B 4B-40-B	B&B 4B-40-B	B&B 4B-40-B	B&B 4B-40-B	Disassembled/Assembled for each Trial
Process					
Process Engineer	Processor #1	Processor #2	Processor #3	Processor #4	Different for each Trial
OEM Support Team	Process Dev	Quality Team	STATs Team	Final Team	See Attendees Tab
Inspection	Clinton	Devens	Clinton	Devens	Approval to start PQ
Validation Inspection	NyproMold	NyproMold	NyproMold	NyproMold	Metrology / CT Scanner
Peripheral Equipment	Different	Different	Different	Different	See Equipment List
Thermolators					
Robot					
Hot Run Controller					

Table 3. Introduced Environmental and Equipment Variation for Machine to Machine Transfer: the team executed a plan that imparted the most variability to stress the resultant "part process" output.

We have effectively proven the methods that any molder needs to demonstrate, with objective evidence, that the best process for the PART has been achieved – any deviation from this has to be documented as a concession/ exception, or fixed. There is an optimal HOW and WHY associated with every documented "part process" that will correlate to the best dimensional outputs (and statistical measurements).

Fully documented dimensional and MIV part process related results will satisfy the criteria typically outlined in any master validation plan (MVP) and allow streamlined PQ validations in other capable machines vs. the machine setpoint process approach. By documenting the MIV data in the original validation report, you now have the record of origin as to what needs to be replicated across multiple machines. Using a combination of the MIV Checklist and available technology (in this case, the *eDART*® System), one can easily and quickly reproduce the process in any machine that is defined as capable. The technology provides additional measurable trend data and full traceability of the shot to shot record of the respective parts produced - this can be incorporated into the device history record (DHR). These results can be plugged into any standard validation/qualification report to satisfy the regulatory documentation requirements. A Medical Device OEM could also add any specific documentation they believe is needed for their particular FDA submission as well.

Effective "Part Process" development and validation with data-driven results (with MIV or MIV verified with technology) will enable the industry to mitigate risk and increase manufacturing flexibility to optimize a sustainable product stream and profitability. Adding the use of technology takes advantage of lead indicators, providing immediate feedback that drive measurable outcomes and provides actionable and manageable information. Suppliers that practice these methods and use available technology will experience higher success rates, minimizing resource allocations and reducing overall costs.

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MEDICAL OEM CONSORTIUM PARTICIPANT LIST

The team employed the benefits of collaboration. This was executed at a high level within the medical OEM Consortium (MOEMC); the leaders of this initiative consisted of employees from six medical OEMs—Becton Dickinson, Eli Lilly, Johnson & Johnson, Unnamed, Teleflex Vascular Division, and Terumo Cardiovascular Systems—along with the medical molder (Nypro, a Jabil Company), and the mold maker (NyproMold), all facilitated by RJG. Each company was required to have Quality Management representation present.

2016 Medical OEM Consortium

Attendees

Team Leaders

Name	Company	Title
Rod Brown	Eli Lilly	Consultant Engineer - TS/ MS
David Shore	Eli Lilly	Quality Manager
Kevin Walsh	Eli Lilly	Senior Molding Engineer
Mike Wolf	Eli Lilly	Quality Engineer
DJ Brown	Teleflex Medical Vascular Division	Staff Plastics Engineer - Global Operations, Vascular
Mark Martin	Teleflex Medical Vascular Division	Staff Quality Engineer
Warren Rohde	Teleflex Medical Vascular Division	Process Development/ Validation Manager
Brad Smith	J&J Medical Devices	Principal Plastics Engineer Johnson & Johnson Supplier Excellence
Sue Tucker	J&J Medical Devices	Global Sub-Category Lead, Plastics
Jay Newman	J&J Medical Devices	Senior Engineer FOD & COE
Greg Lusardi	Becton Dickinson	Worldwide Leader Molding
Sean Tucker	Becton Dickinson	Quality Engineering, Manager
Gary Francom	Becton Dickinson	Quality Engineering, Supervisor
Scott Scully	Terumo Cardiovascular Systems	Director, Corporate Molding/Tooling
Nick McDonald	Terumo Cardiovascular Systems	Molding Engineer
Mary Ann LaFontaine	Terumo Cardiovascular Systems	Senior Engineer I
Dustin Koob	Terumo Cardiovascular Systems	Senior Engineer - Program management
Joe Butler	Terumo Cardiovascular Systems	Corporate Molding Engineer II
Mark Harrington	Unnamed	Senior Process Engineer
Steven Lazarz	Unnamed	Plastics Engineer
Dave Marchand	Unnamed	Senior Supplier Quality Engineer
Chris Lillyman	Nypro, a Jabil Company	Manufacturing Engineering Manager
Paul Leonesio	Nypro, a Jabil Company	Director of Quality Operations - North America
Ed Valley	Nypro, a Jabil Company	Senior Engineering Manager - Tooling
Guthrie Gordon	Nypro, a Jabil Company	Project Engineering Manager
Steve Marquart	Nypro, a Jabil Company	Project Engineer
Dave Newby	Nypro, a Jabil Company	Quality Engineer IV
Brian Gavin	NyproMold	PDC Manager
Rob Irwin	NyproMold	Director Business Development
Dave Butler	NyproMold	Account Manager
Matt Therrien	RJG, Inc.	Northeast Regional Manager
Mike Coyle	RJG, Inc.	Quality Manager
Bob Reese	RJG, Inc.	Sr. Consultant/ Trainer
Thom Smith	RJG, Inc.	Sr. Consultant/ Trainer
Scott Molnar	RJG, Inc.	Strategic Account Manager
Rod Groleau	RJG, Inc.	Chairman
Paul Robinson	QSCS	Lead Regulatory Advisor

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