



Medical Molding Validation & Process Development

Seminar Outline

1) Introduction; The Strategy

- a) Purpose
- b) Perspectives on the plastics' industry, Manufacturing
- c) Staying Competitive
- d) Components of a successful plastic's application
- e) Concurrent engineering and its benefits
- f) Organizing the hundreds of variables in processing/parts; four categories
- g) Machine conditions vs. Plastic conditions
- h) Validation Strategy
- i) Case History

2) Piece Part Design Overview, You cannot violate laws of nature!

- a) Components of Design
- b) The "Golden Rule" for nominal wall
- c) Shrinkage, Amorphous vs. Semi-Crystalline
- d) Cooling and Warp
- e) Draft
- f) Venting
- g) Gating with respect to weldlines

3) Resin Selection

- a) Polymer Basics, making and breaking polymer chains
- b) Questions that must be answered
- c) Properties to watch during the selection process
- d) What data sheets tell you
- e) Single point data

4) IQ (Installation Qualification, Does the equipment work correctly?)

- a) Procedures and Records Available
 - a.i) Quality
 - a.ii) Training
 - a.iii) Maintenance
 - a.iv) Control Plans
 - a.v) Gage R/R on Metrology
 - a.vi) Calibration documentation
 - a.vii) Software validations
 - a.viii) Process Failure Mode Effects Analysis (PFMEA's) analysis
 - a.viii.1) Recognize and evaluate potential failure

- a.viii.2) Identify actions to reduce or eliminate failure
 - a.viii.3) Document the process
 - a.viii.4) Track changes to the process made to eliminate potential failures
 - a.ix) Machine Specifications
- b) Establish room/building requirements
- c) Machine placement
- d) Auxiliary/Secondary Equipment
 - d.i) Dryer
 - d.ii) Cooling/heating tool GPM
- e) Machine Calibrations
 - e.i) Pressure
 - e.ii) Stroke
 - e.iii) Timers?
 - e.iv) Temperatures ...set points???
- f) Machine Function (Machine Audit)
 - f.i) Velocity control, Delta P
 - f.ii) Load compensation
 - f.iii) 1st to 2nd stage switch over response
 - f.iv) Velocity linearity
 - f.v) Pack Velocity function
- g) Mold/Tooling Requirements
 - g.i) Mold drawing available
 - g.ii) Spare parts available
 - g.iii) Mold steel measurements available
 - g.iv) Water flow diagrams with GPM demand available
 - g.v) Water flow per channel verified
 - g.vi) Water channels labeled on tool
 - g.vii) Mold filling analysis

5) OQ (Operational Qualification; Establish a Process, Document and Define Ranges/Window); Starting with a Pre-run or Baseline Process

- a) Step 1: Optimizing First Stage; Plastic Flow Rate
 - a.i) How plastic flows, viscosity
 - a.ii) Viscosity curve
 - a.iii) Viscosity vs. temperature, lot variations and injection rate
 - a.iv) Flow balance
 - a.v) Cruise Control on injection molding machines
 - a.vi) Two stage molding
 - a.vii) Case history
 - a.viii) Non-return valve (check ring) & nozzles
 - a.ix) Nozzle tips
- b) Step 2: Optimizing Second Stage, Plastic Pressure
 - b.i) Basic hydraulics
 - b.ii) Hydraulic Pressure vs. Melt Pressure
 - b.iii) Back Pressure

- b.iv) Intensification Ratio
- b.v) Pressure Loss
- b.vi) Gate seal vs. unseal
- b.vii) Pressure vs. time graphs
- b.viii) Clamp force
- b.ix) Platen wrap
- b.x) Pressure Loss Documentation
- c) Step 3: Cooling Rate and Time
 - c.i) Percent of Cycle
 - c.ii) Turbulent Flow
 - c.iii) Series vs. parallel circuits
 - c.iv) Cooling issues
 - c.v) Infrared Thermography
 - c.vi) Cycle time optimization studies
- d) Step 4: Plastic Temperature
 - d.i) The hopper
 - d.ii) Drying
 - d.iii) The feed throat
 - d.iv) Barrel vs. melt temperatures
 - d.v) Screw components and design
 - d.vi) How plastics melt
 - d.vii) Back pressure
 - d.viii) Screw problems
 - d.ix) How to measure temperature
- e) Step 5: Challenge the Process
 - e.i) When to start saving parts
 - e.ii) Force viscosity variations
 - e.iii) Different resins?
 - e.iv) Capability studies
- f) Step 6: Test the part; expect issues to develop
 - f.i) Test Conditions
 - f.ii) Thermocycle
 - f.iii) Environment
 - f.iv) Metrology
 - f.v) First article inspections (FAI's)
 - f.vi) Visual inspections
- g) Do the DOE's Necessary/Correctly
 - g.i) What are the issues, problem(s) clearly defined?
 - g.ii) List factors
 - g.ii.1) Possible factors
 - g.ii.2) Recommendations
 - g.iii) Factors with respect to four plastic categories
 - g.iv) Do we know the response for any of these factors
 - g.v) Select Factors (variables)
 - g.vi) Machine "Set Points" vs. "Plastic Conditions"
 - g.vii) DOE check list

- g.viii) Screening DOE's to establish process window
- h) Documentation
 - h.i) Set up sheet per machine
 - h.ii) Universal Set-up sheet, mold specific
 - h.iii) Process Monitoring Recommendations
 - h.iii.1) First tier
 - h.iii.2) Second tier.

6) PQ (Process Performance Qualification; Test production performance of the process under "production" conditions)

- a) Run established process for production, time 4 – 24 hours
 - a.i) Lot variations
 - a.ii) Different Processors
 - a.iii) Shift changes
- b) Run on different machine
- c) Verify output, Dimensions, function, capability, scrap etc.
- d) Document corrective action and confirm
- e) Evaluate entire system, molding, secondary operations, labels, and document results
- f) Implement corrective actions
- g) Document process/equipment changes
- h) Process monitoring variables
- i) Obtain customer approval

7) Miscellaneous

- a) Universal Setup Sheet
- b) Optimization Guidelines
- c) Recommended resources and web sites
- d) Background
- e) Evaluation