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