TEGRA MEDICAL

Where medical devices come to life.SM



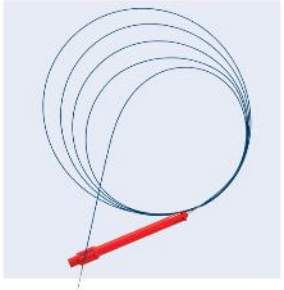
Process Validation - Process

Dan Snell – Quality Manager
Chris Rose – Quality Engineer

An overview of the process Tegra Medical uses to develop Process Validations






Tegra Medical's Process Validation - Process

- Process Validation Overview
  - Process Planning Phase
  - Process Risk Analysis
  - Process Validation
    - IQ Installation Qualification
    - DOE Design of Experiments
    - OQ Operational Qualification
    - PQ Performance
  - Questions

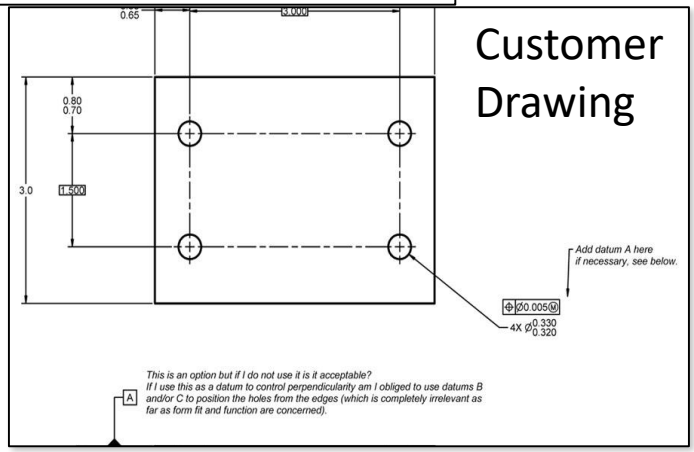
Process Validation Overview

- Process Planning Phase

- Begins with order acceptance at Franklin Facility
- Tegra Qualification Team initiated
  - Project Manager
  - Manufacturing Engineer
  - Quality Engineer

Customer Purchase Order
- Requirements
- Requirements
- Requirements

Customer Drawing



Customer Specifications
- Material
- Testing
- Special Processes
- Packaging

Process Planning - - Macro Process Flow

- Process Planning Phase
- Tegra Engineering begins developing a manufacturing process flow and associated risk analysis and mitigation documents.

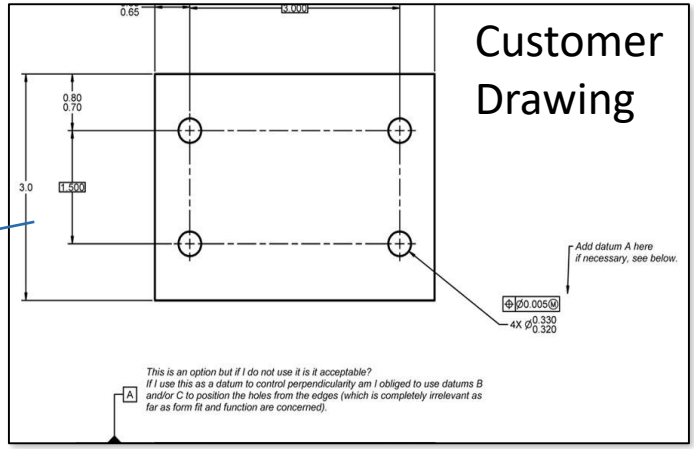
Customer Purchase Order
- Requirements
- Requirements
- Requirements

Macro Process Flow

Metal Component Dartmouth

Metal Component Franklin

Over-Molding Dartmouth

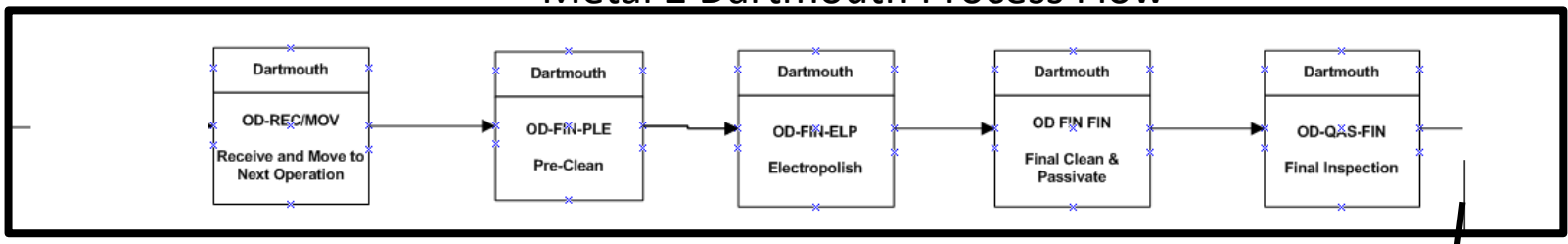


Customer Drawing

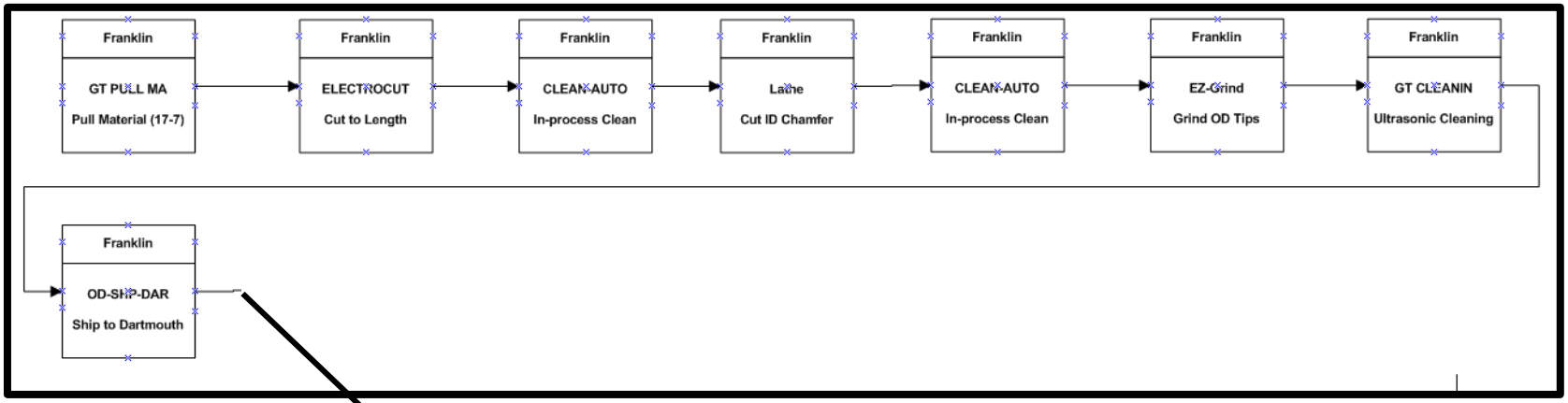
Customer Specifications
- Material
- Testing
- Special Processes
- Packaging

Process Planning - - Detail Process Flow

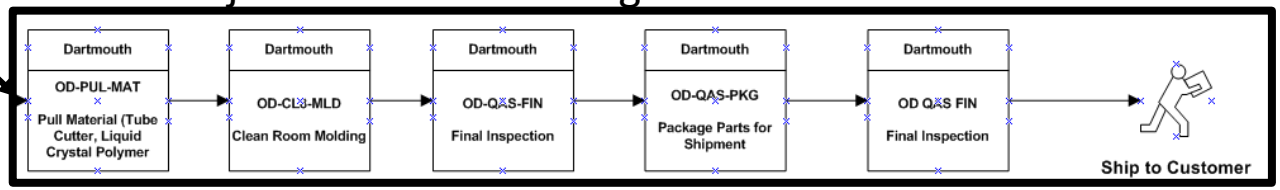
Metal 2 Dartmouth Process Flow



Metal 1 Franklin Process Flow

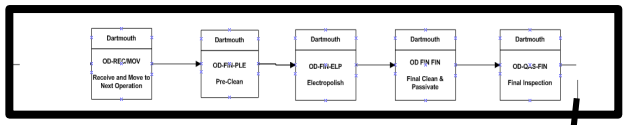


Plastic Injection Over-Molding Dartmouth Process Flow

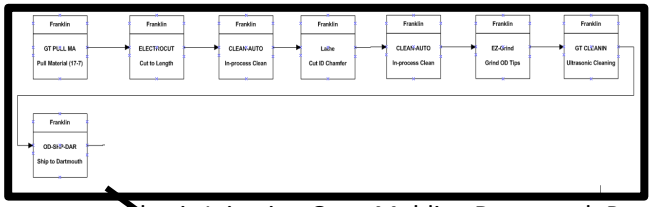


Process Planning – Risk Analysis

Metal 2 Dartmouth Process Flow



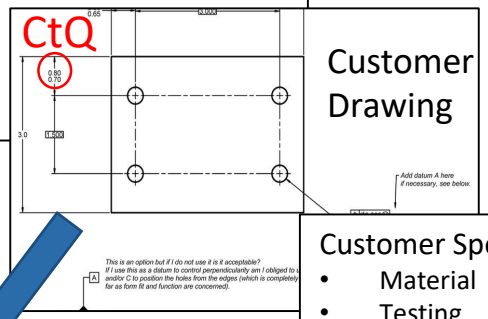
Metal 1 Franklin Process Flow



Plastic Injection Over-Molding Dartmouth Process Flow

Customer Purchase Order

- Requirements
- Requirements
- Requirements



Customer Specifications

- Material
- Testing
- Special Processes
- Packaging

Any RPN Value greater than 100 requires immediate action.

TEGRA MEDICAL

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

Print # Rev. FMEA Number:
Item: Process Responsibility: Prepared by:
Team:
Signatures:

Process Function/ Require-ments	Potential Failure Mode	Potential Effect(s) of Failure	S e v	Potential Cause(s)/ Mechanism(s) of Failure	O c c u r	Cu Pr Co De

TEGRA MEDICAL

Process Control Plan

T-REC-0087 REV 1

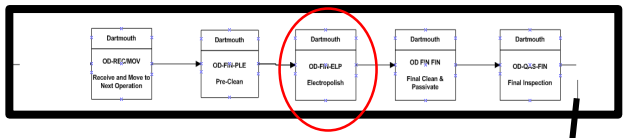
Header -Section 1-

Part/ Process Number	Process Name/ Operation Description	Machine Device, Jig Tools for Mfg.	Characteristics: Number	Product	Process	Special Char. Class	Spec/Work Instruction # / Revision	Methods: Product/Process Specification Tolerance	Evaluation Measurement Technique	Sample Size	Sample Freq.	Control Method	Responsible Party	Reaction Plan

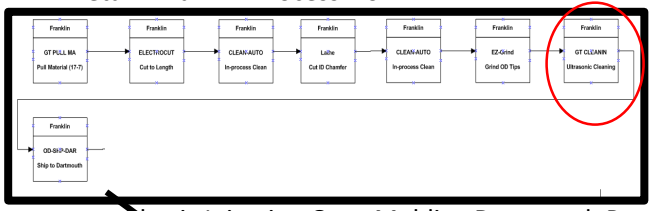
Customer Critical to Quality (CtQ) requirements are mapped against the processes that generate them.

Process Planning – Risk Analysis

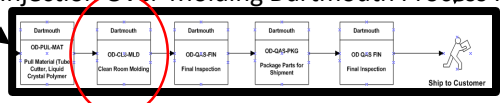
Metal 2 Dartmouth Process Flow



Metal 1 Franklin Process Flow

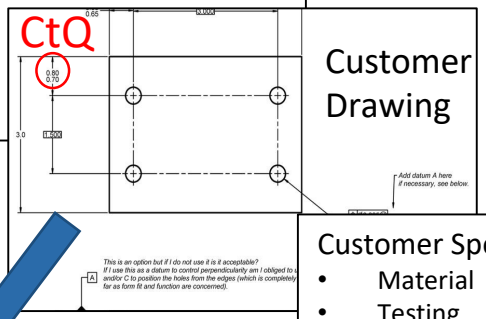


Plastic Injection Over-Molding Dartmouth Process Flow



Customer Purchase Order

- Requirements
- Requirements
- Requirements



Customer Specifications

- Material
- Testing
- Special Processes
- Packaging

Any RPN Value greater than 100 requires immediate action.

TEGRA MEDICAL

POTENTIAL
FAILURE MODE AND EFFECTS ANALYSIS
(PROCESS FMEA)

Print # Rev. FMEA Number:
Item: Process Responsibility: Prepared by:
Team:
Signatures:

Process Function/ Require-ments	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential Cause(s)/ Mechanism(s) of Failure	Occur	

TEGRA MEDICAL

Process Control Plan

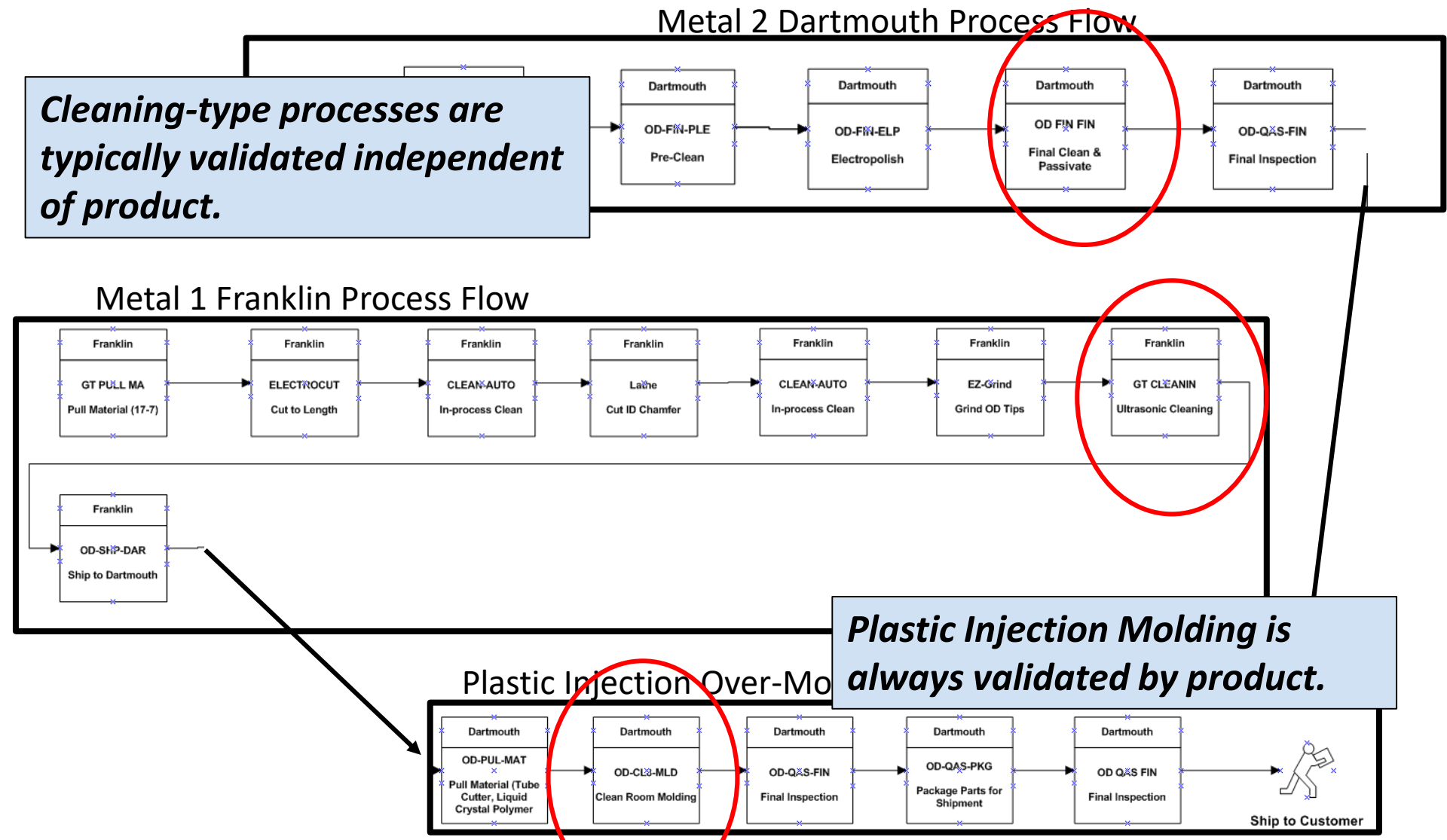
T-REC-0087 REV 1

Header -Section 1-

Special Processes are identified for validation.

- ***Cleaning***
- ***Electropolish***
- ***Welding***
- ***Plastic Injection Molding***

Process Planning - - Detail Process Flow

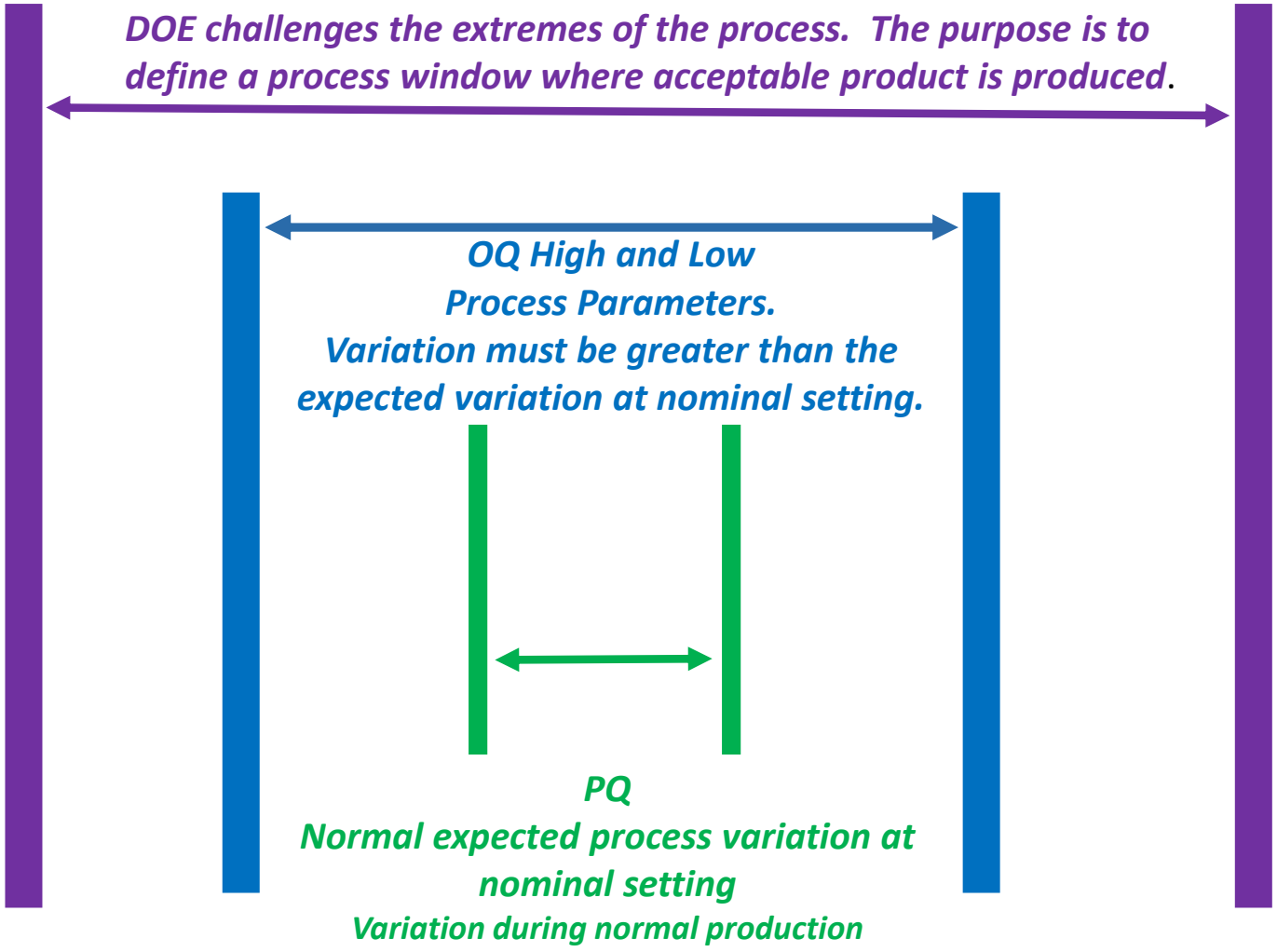


Process Validation – Plastic Injection Molding

Installation Qualification - IQ

- ***Ensure equipment operates as intended***
- ***Ensure proper utilities are available and functioning (air / water / electricity)***
- ***Validate Software***
- ***Determine PPE and Ergonomic requirements***
- ***Develop Calibration Plan / Schedule***
- ***Develop Preventative Maintenance Plan including required chemicals (hydraulic fluid, lubricants, etc)***

Process Validation – Plastic Injection Molding



Operational Qualification - OQ

- ***Simulates actual production but forces parameter extremes***
- ***Challenge high and low settings to allow for a process "window" to simulate normal expected variation.***
- ***Develop / Validate Inspection methods (MSA, GR&R, TMV)***
- ***Measure output –***
  - ***Variable - CTQs, required to pass specification requirements to Ppk of 1.33***
  - ***Attribute - 95/95% Confidence / Reliability***
- ***Lockdown Nominal Parameter Settings***

Performance Qualification - PQ

- ***3 Production runs with nominal parameter settings***
- ***Run Production equivalent lot sizes***
- ***Break down machine between runs (cool down, remove mold) to simulate normal operation***
- ***Measure output –***
  - ***Variable - CTQs, required to pass specification requirements to Ppk of 1.33***
  - ***Attribute - 95/95% Confidence / Reliability***
- ***Perform First Article Inspection***
  - ***all features and drawing notes measured/verified***
- ***Develop detailed process work instruction***
  - ***setup, operation, inspection, shutdown.***

Process Validation – Plastic Injection Molding

Process Validation Plan - PVP

- *Verify all aspects of initial qualification plan were completed*
  - *Planning Documents (Flow Map, Control Plan, PFMEA, MSA)*
  - *Qualification Documents (IQ, OQ, PQ, FAI)*
- *Lock down process*
  - *Part Master Template (PMT)*
  - *Inspection Documents (In-Process, Final)*
  - *Supplier Inspection /Qualification*
- *Train all applicable associates to work instructions*
- *Ready for Production*
- *Monitor & Improve*

TEGRA MEDICAL

Where medical devices come to life.SM

Questions????

Two Content with Header

HEADER TEXT HERE

- Bullet text
- Bullet text

HEADER TEXT HERE

- Bullet text
- Bullet text

Intro with 2 Content Headers slide

Introductory sentences here

HEADER TEXT HERE

- Bullet text
- Bullet text

HEADER TEXT HERE

- Bullet text
- Bullet text

Title Only slide

TEGRA MEDICAL

Where medical devices come to life.SM

www.tegramedical.com ▪ 508.541.4200 ▪ *A member of SFS*

THANK YOU