12 Steps to Six Sigma

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* A Systematic Approach to developing new products in the shortest possible time
Intelligent R & D and Manufacturing

With increasing demands being placed on manufacturers by the market and by regulatory agencies, it is critical to establish a Robust Product Development Process that incorporates sound engineering. This can be achieved by incorporating a Systematic Approach to developing a new product. This type of logical and scientific approach has always produced tangible benefits in terms of cost reduction, Reduced Time to Market, premature failures, and minimal rework loops.
Traditional Approach to Product Design and Development

Part Design -> Production Mold -> Final Product

Result: Cost Overruns & Significant Increase in Time to Market
Systematic Approach

Basic Part Design → Material Selection → Structural Analysis

Mold Flow Analysis → Rapid Prototype → Design Review I

Single Cavity Prototype → Design Review II Tolerance Analysis → Tooling Protocol Mold Cooling Analysis

Mold Construction Phase → Mold Sampling/Pilot Run DOE/CPK Study Establish Process Parameters → Final Part Evaluation & Acceptance
Why Cost Overruns and project delays?

- Hasty material selection
- Plastics part design missteps
  Creep & stress relaxation, Temperature dependence of properties, Chemical resistance, synergistic effects, Margin of safety calculation errors
- No structural analysis
- Skip prototyping
- Skip process simulation analysis
- Lack of Design for Manufacturing (DFM) and Design for Assembly (DFA) considerations
- No detailed tooling requirement spelled out
- Numerous design changes in production mold
- No formal process and part qualification procedures specified
How do you avoid these problems?

Carry out all the steps as mentioned in the **Systematic approach**

* A logical approach to launching a successful product to market in the shortest possible time

**Predictive analysis or simulation of medical devices or other products is a product development tool that can significantly accelerate the time to market and help manufacturers avoid costly mistakes early in the design process.**
Plastics Part Design Process

- Defining end-use requirements
- Create preliminary concepts sketch
- Initial material selection
- Design part in accordance with material properties
- Final materials selection
- Modify design for manufacturing
- Prototyping
- Tooling
- Production
CONCURRENT ENGINEERING

Sequential engineering - "over the wall approach"

Parallel approach to product development
"concurrent engineering"

Figure 3.4. “Parallel” or “Concurrent Engineering” approaches to product design reduce development time, improves quality, and minimizes the potential for unanticipated production or performance problems.
Material selection criteria

• Define requirements
• Narrow down choices...process of elimination...clear vs. opaque
• Rigid, flexible, elastomeric?
• Specific application? Medical?
• Material selection guidelines
• Specific property requirement...
Material selection criteria (continued)

• **Identify application requirements**
  Mechanical (Load, Stiffness, Impact etc.)
  Thermal (temperature range, Maximum use temperature, etc)
  Environmental considerations (Weather, UV, Moisture)

• **Identify the chemical environment**
  Define the chemical stress, temperature, contact time, type of chemical

• **Identify special needs**
  Regulatory (UL, FDA, NSF, etc.)
  Outdoor or UV exposure
  Light transmission, Fatigue and creep requirements

• **Define Economics**

• **Define Processing Considerations**
  Type of Process (Injection Molding, Extrusion, Blow Molding, Thermoforming, etc.)

• **Define Assembly requirements**
  Painting/Plating
  Shielding

• **Search history for similar commercial applications**
Material selection criteria (continued)

- Environmental Considerations

  Exposure to UV, IR, X-Ray
  High humidity
  Weather Extremes
  Pollution: Industrial chemicals
  Microorganisms, bacteria, fungus, mold

  The combined effect of the factors may be much more severe than any single factor, and the degradation processes are accelerated many times.

  Published test results do not include synergistic effects...always existent in real-life situations.
Material selection criteria (continued)

- **Chemical Behavior/Chemical resistance**

  Resistance of Thermoplastics to various chemicals is dependent on:

  - Time (of contact with chemical)
  - Temperature
  - Stress (Molded-in or External)
  - Concentration of the chemical

  **Chemical Exposure may result in:**

  - Physical Degradation - Stress cracking, Crazing, Softening, Swelling, Discoloration
  - Chemical Attack – Reaction of chemical with polymer and loss of properties
Structural Analysis (FEA)
Mold Filling Simulation to Optimize Designs

- Optimize gate locations and number of gates
- Confidence of fill
- Knit line and gas entrapment locations
- Fill time
- Pressure distribution
- Temperature distribution
Rapid Prototyping

Thermal printing

SLS

SLA

FDM
Design Review I

- Review part design based on rapid prototype results
- Verify theoretical analysis results from design viewpoint
- Modify design (radius, sharp corners, thick walls etc.) for manufacturability and performance
- Review preliminary material selection
Single Cavity Prototype

- Aluminum or P-20 steel?
- Hand loads or automatic?
- MUD insert or stand alone mold?
- Keltool process
- SLS rapid tooling
- Quick turn-around prototype tooling
Design Review II
Tolerance Analysis

- Review part design based on molded prototype
- Verify engineering functions and manufacturability
- Conduct end product testing
- Test for assembly
- Conduct tolerance analysis
- Modify design to improve knit line, warpage, sink marks etc.
- Residual (Molded-in) Stress Analysis
Tooling Protocol

• Detailed Production mold standards

A well defined Production Mold Standards address two major issues. First it allows tool makers to quote the tooling on equal basis reducing the possibilities of huge discrepancies in quoted prices. Second, it spells out every single important tool criteria in detail so that there is no confusion between the buyer and tool maker.

• Cooling Analysis if deemed necessary
Mold Construction

- Review of detailed tooling layout prior to construction. 3D Mold Design
- Tooling progress using Microsoft Project Software
- Visit tool maker to review the progress and construction
Mold Sampling, Doe/CPK Study
Establish Process Parameters

• 24 Hour pilot run

• DOE study to determine Predictor Dimension using Algorithm

The new algorithms are based on the fact that although the relationships between causes (process settings) and effects (part characteristics) may be difficult or impossible to determine, the relationships between effects for many processes are consistent and predictable irrespective of changes in the process settings.

• Visual Standards

• Scientific Molding Techniques
  • Universal Set-Up sheet
  • Controlling four key process variables
  • Decoupled Molding
Why Finalize Process Parameters?

Most Common Process Induced Failures can be prevented

- Drying of material
- Molded-in stresses
- Knit lines
- Overpacking
- Degradation
- Shrinkage voids
- Re grind level
- Contamination
Final Part Evaluation, approval and Acceptance