12 Steps to Six Sigma

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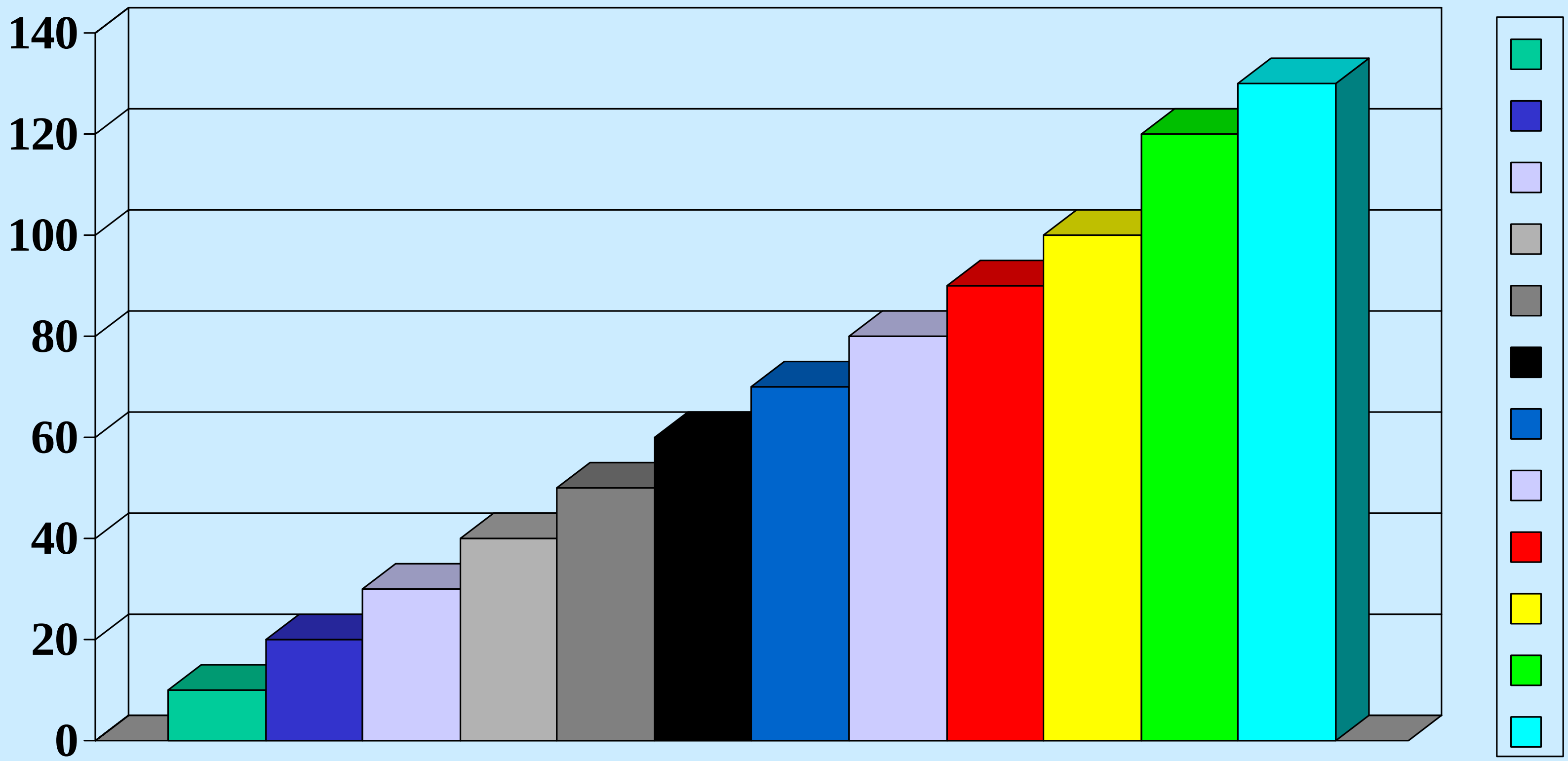
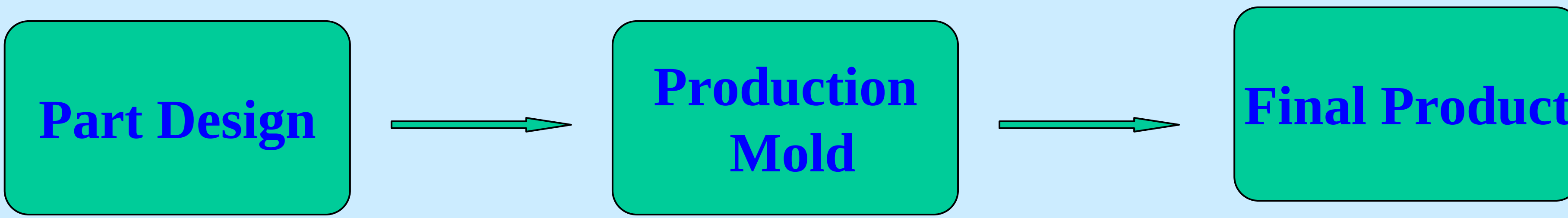


*** A Systematic Approach to developing new products in the shortest possible time**

Intelligent R & D and Manufacturing

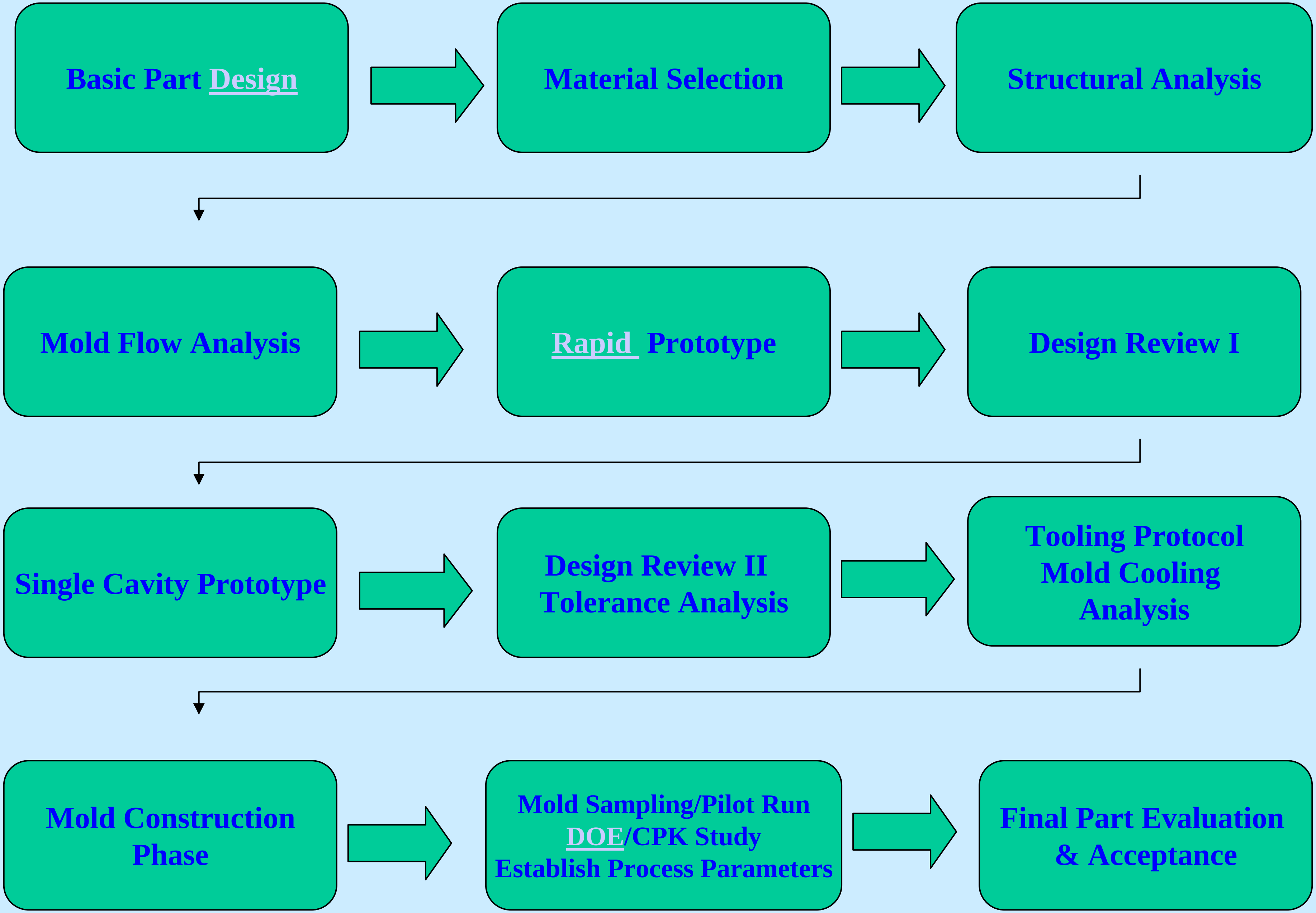
With increasing demands being placed on manufacturers by the market and by regulatory agencies, it is critical to establish a **Robust Product Development Process** that incorporates sound engineering. This can be achieved by incorporating a **Systematic Approach** to developing a new product. This type 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



Result: Cost Overruns & Significant Increase in Time to Market

Systematic Approach



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?

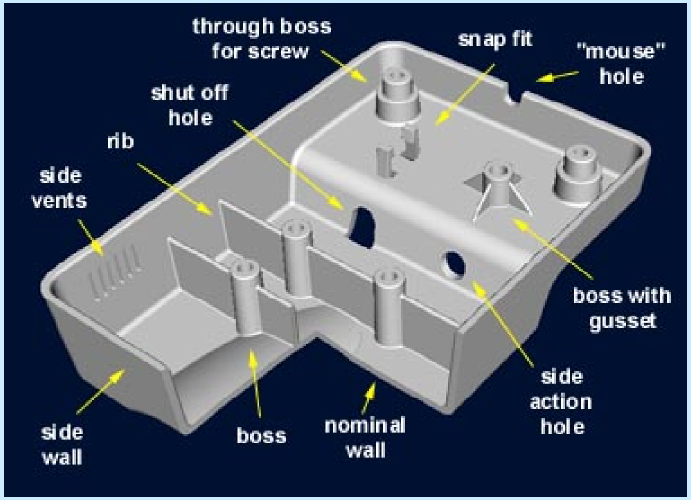
Carry out all the steps as mentioned in the **Systematic approach***

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

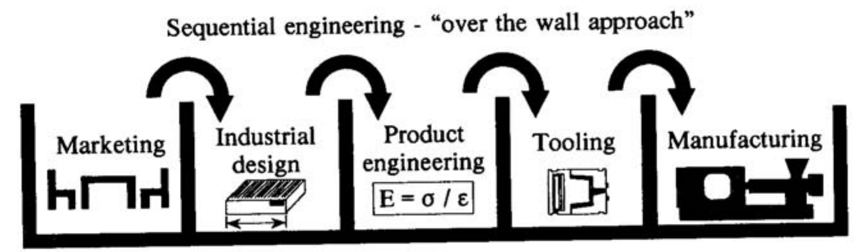
Predictive analysis or simulation of medical devices or other products is a product development tool that can significantly accelerate the time to market and help manufacturers avoid costly mistakes early in the design process.

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



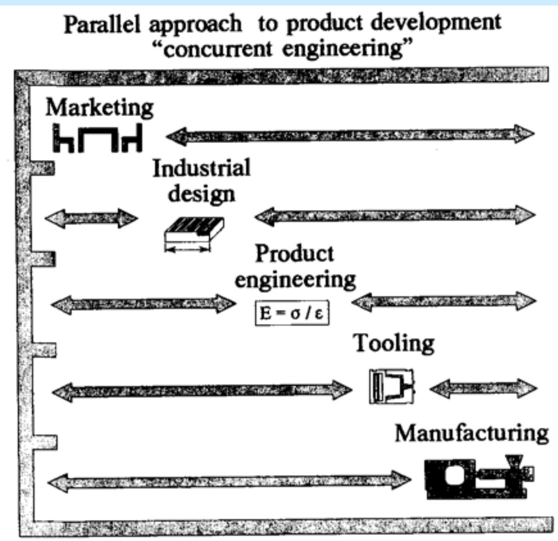


Figure 3.4. "Parallel" or "Concurrent Engineering" approaches to product design reduce development time, improves quality, and minimizes the potential for unanticipated production or performance problems.

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**

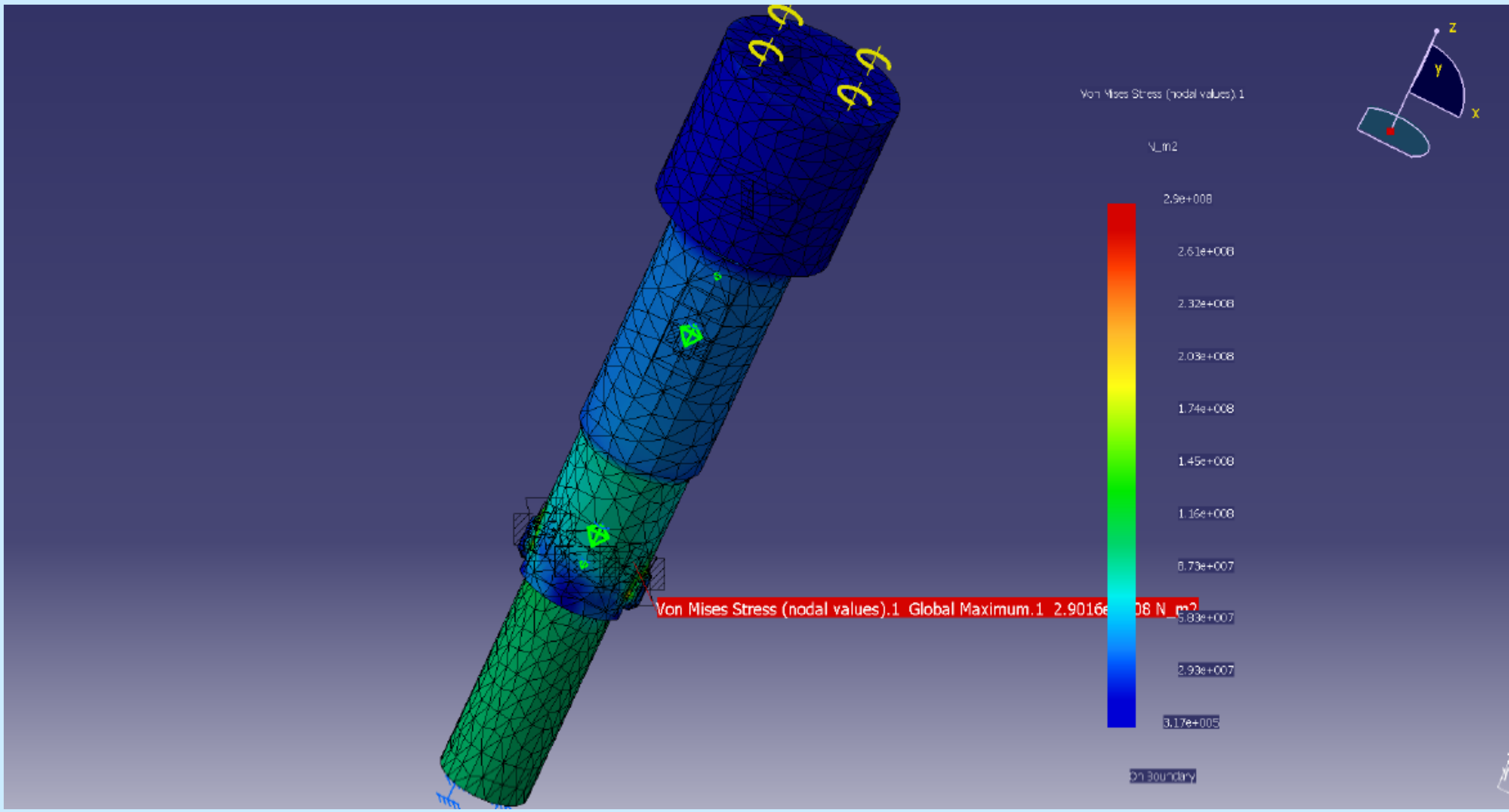
Resistance of Thermoplastics to various chemicals is dependent on:

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

- **Chemical Exposure may result in:**

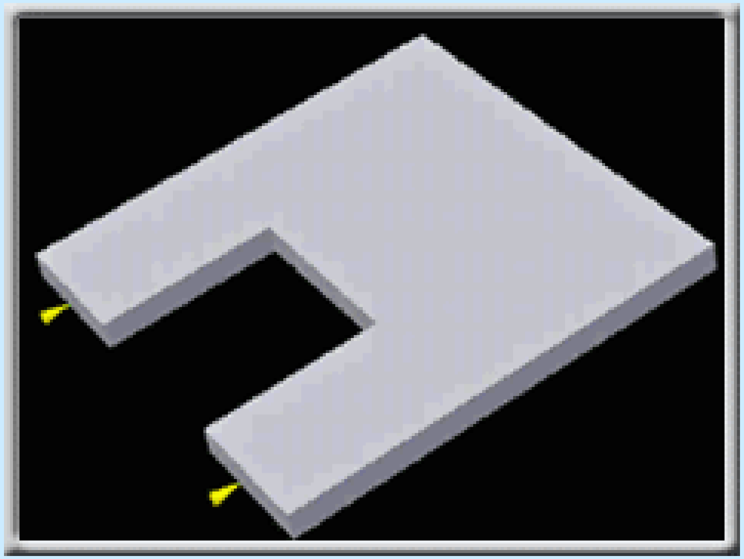
- Physical Degradation - Stress cracking, Crazing, Softening, Swelling, Discoloration
- Chemical Attack – Reaction of chemical with polymer and loss of properties

Structural Analysis (FEA)



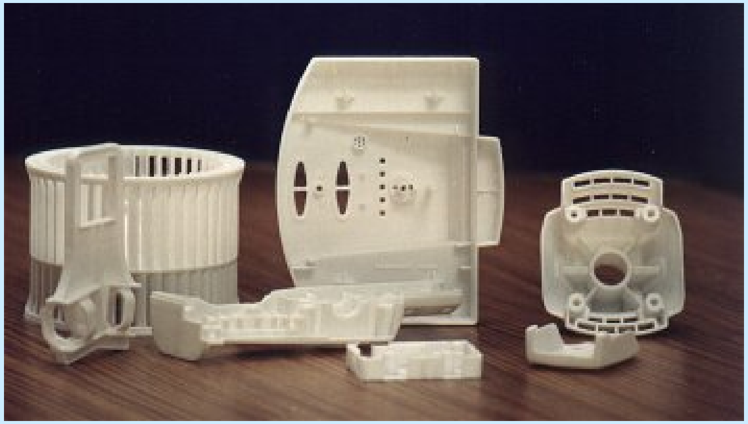
Mold Filling Simulation to Optimize Designs

- 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

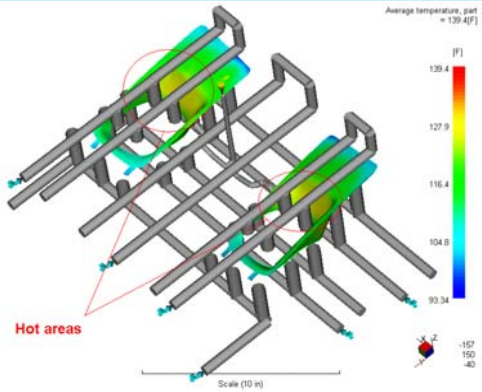
- Review part design based on molded prototype
- Verify engineering functions and manufacturability
- Conduct end product testing
- Test for assembly
- Conduct tolerance analysis
- Modify design to improve knit line, warpage, sink marks etc.
- Residual (Molded-in) Stress Analysis

Tooling Protocol

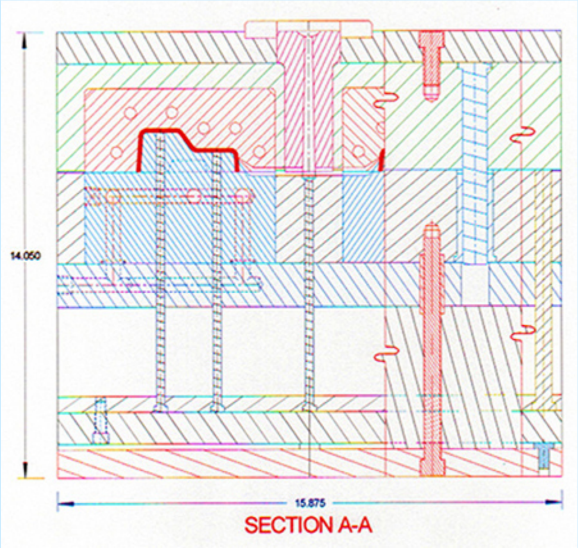
• **Detailed Production mold standards**

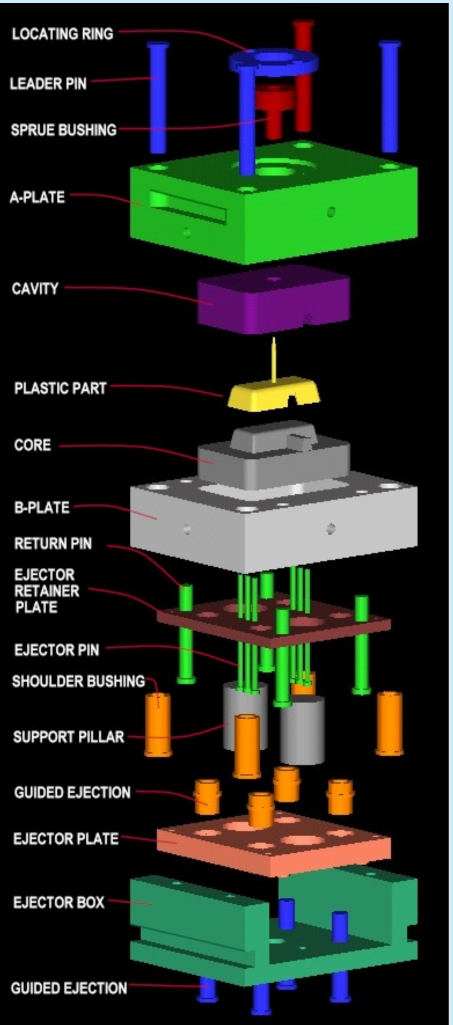
A well defined Production Mold Standards address two major issues. First it allows tool makers to quote the tooling on equal basis reducing the possibilities of huge discrepancies in quoted prices. Second, it spells out every single important tool criteria in detain so that there is no confusion between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

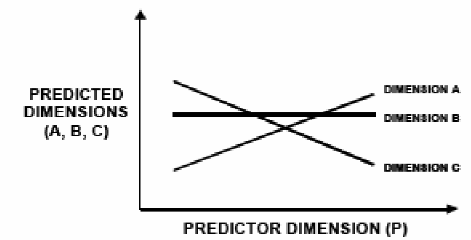


Figure 1

Why Finalize Process Parameters?

Most Common Process Induced Failures can be prevented

- Drying of material
- Molded-in stresses
- Knit lines
- Overpacking
- Degradation
- Shrinkage voids
- Regrind level
- Contamination

Final Part Evaluation, approval and Acceptance