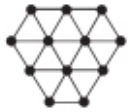
Managing Design Risk

**….how to reduce design risk,
share real world examples**



Product Realization Group™
Bridging the Product Development Gap

Background

Product Realization Group (PRG) is the only one-stop-shop of product lifecycle services tailored for high technology businesses. PRG enables rapid and cost effective introduction of products to the market, regulatory compliance, manufacturing, service, and lifecycle support.

Engagements are tailored to fit business and product profiles. Twenty PRG companies currently deliver services to over 400 high technology clients.

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Services / Partners

Marketing/Bus. | **Product Design** | **Test / Reliability** | **Data Management**

Regulatory | **Supply Chain** | **Manufacturing** | **Logistics / Repair**

ACS Adelph Consulting Services

KENT H. LANDSBERG CO. 60 years 1947-2007

AIRTRONICS Metal Products, Inc.

arena

EXTRON YOUR OPERATIONS PARTNER

FusionDesign

AVNET

OPS A LA CARTE RELIABILITY CONSULTANTS

CAMSTAR SigmaSure

SolutionSources PROGRAMMING, INC.

Voler SYSTEMS Division of Strawberry Tree, Inc.

WRIGHT ENGINEERED PLASTICS

Industries / Clients

Medical	Defense	Telecom	Semiconductor
Networking	Consumer	Industrial	Clean Tech

Upcoming Events

Sept 17 - Summer Symposium & BBQ
(Sunnyvale Sheraton)

Sept 25 – Certificate Program
(Foothill College)

www.productrealizationgroup.com/index.php?/events

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PRG Seminar Series

- Advance the understanding of the Product Realization Process
- Highlight current best practices
- Provide a local networking forum

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Audience Question

What is your role?

- **Product Development**
- **Quality / Regulatory**
- **Operations / Manufacturing**
- **Management**
- **Other**

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Michael Keer
Founder and CEO
Product Realization Group

PRODUCT DEVELOPMENT OVERVIEW

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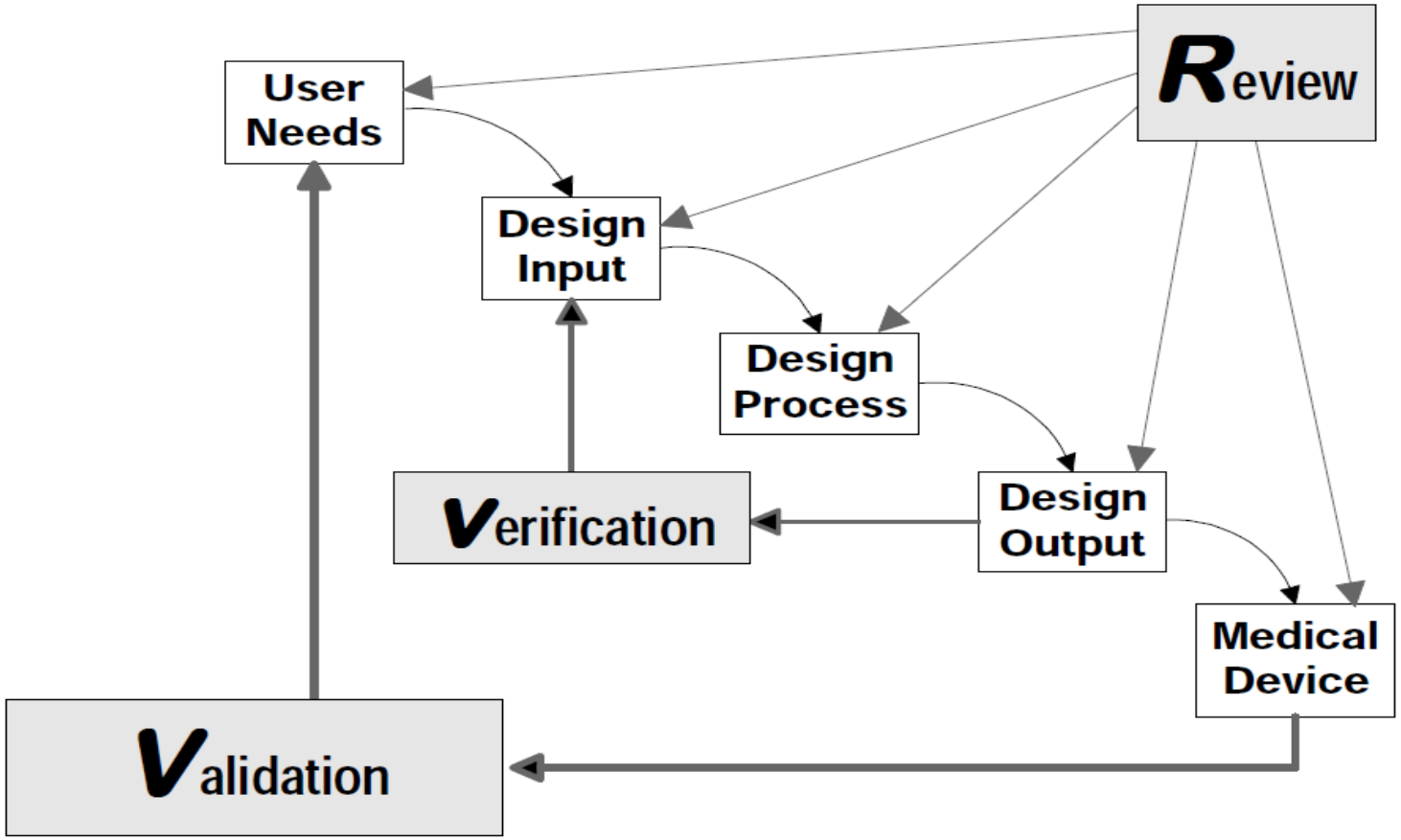
Design Process



Waterfall Diagram for Design Control (from FDA "Design Control Guidance for Medical Device Manufacturers"

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Scheduling

Create, Revise and Review

- Poor scheduling results in surprises later
- Get buy-in from all team members

Key parts of a schedule

- Specification creation
- Review meetings

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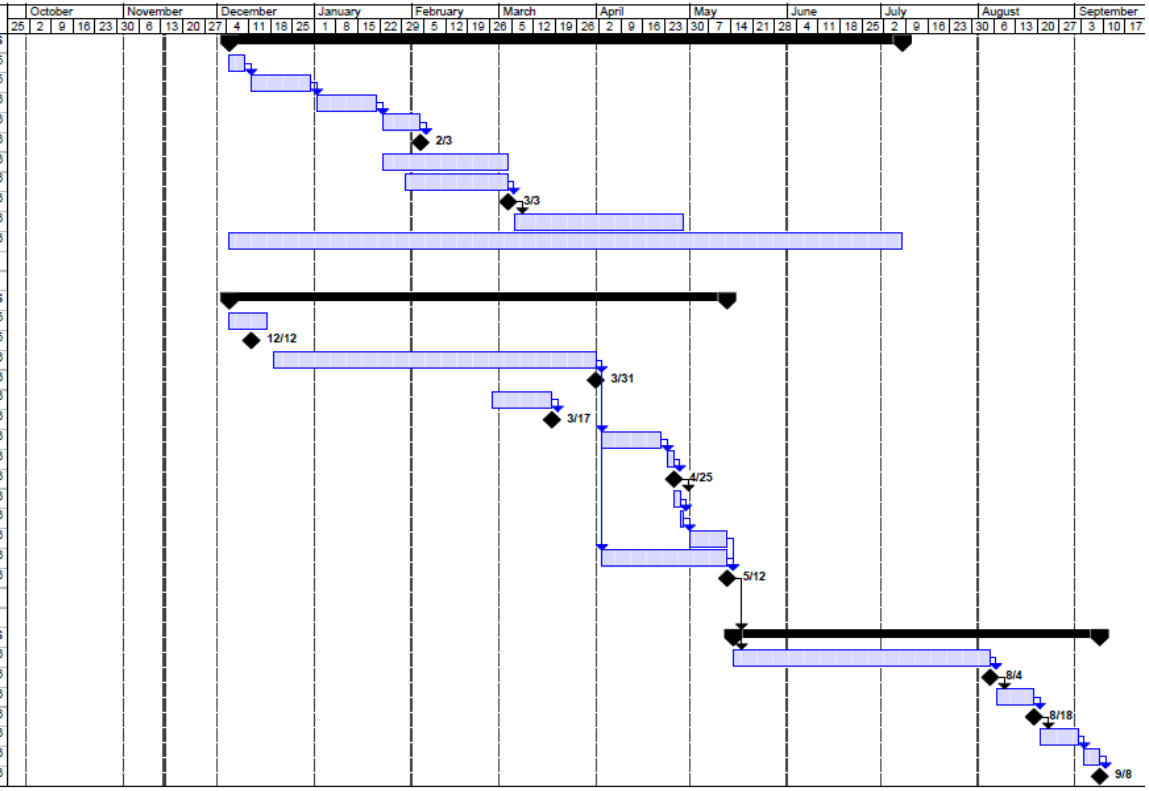
Example Schedule – Gantt Chart

ID	Task Name	Duration	Start	Finish
1	**Industrial Design**	**155 days**	**Mon 12/5/05**	**Fri 7/7/06**
2	Research / Strategy	5 days	Mon 12/5/05	Fri 12/9/05
3	Concept	15 days	Mon 12/12/05	Fri 12/30/05
4	Refinement (CAD and Foams	15 days	Mon 1/2/06	Fri 1/20/06
5	Control Files	10 days	Mon 1/23/06	Fri 2/3/06
6	ID Control Files to Engineering	0 days	Fri 2/3/06	Fri 2/3/06
7	Specifications and Artworks	30 days	Mon 1/23/06	Fri 3/3/06
8	Models (Visual)	25 days	Mon 1/30/06	Fri 3/3/06
9	Aesthetic Models for Show	0 days	Fri 3/3/06	Fri 3/3/06
10	Changes	40 days	Mon 3/6/06	Fri 4/28/06
11	Engineering Liaison	155 days	Mon 12/5/05	Fri 7/7/06
12				
13				
14	**Mechanical Engineering**	**115 days**	**Mon 12/5/05**	**Fri 5/12/06**
15	Mechanical Concept	10 days	Mon 12/5/05	Fri 12/16/05
16	Overall Dimensions & Cooling Scheme to Indus	0 days	Mon 12/12/05	Mon 12/12/05
17	3D CAD Development	75 days	Mon 12/19/05	Fri 3/31/06
18	3D CAD Layout & Preliminary BOM	0 days	Fri 3/31/06	Fri 3/31/06
19	Analysis, Thermal	15 days	Mon 2/27/06	Fri 3/17/06
20	Thermal Analysis Report	0 days	Fri 3/17/06	Fri 3/17/06
21	Prototype Fabrication	15 days	Mon 4/3/06	Fri 4/21/06
22	Assembly Coordination	2 days	Mon 4/24/06	Tue 4/25/06
23	Assembled Prototypes (3ea) SLA Tooling	0 days	Tue 4/25/06	Tue 4/25/06
24	Testing	2 days	Wed 4/26/06	Thu 4/27/06
25	Thermal & Acoustical Test Report	1 day	Fri 4/28/06	Fri 4/28/06
26	Design Refinements	10 days	Mon 5/1/06	Fri 5/12/06
27	2D Control Drawings	30 days	Mon 4/3/06	Fri 5/12/06
28	Release to Production Tooling	0 days	Fri 5/12/06	Fri 5/12/06
29				
30				
31	**Manufacture**	**85 days**	**Mon 5/15/06**	**Fri 9/8/06**
32	Production Tooling	60 days	Mon 5/15/06	Fri 8/4/06
33	First Article Review	0 days	Fri 8/4/06	Fri 8/4/06
34	Tooling Revision	10 days	Mon 8/7/06	Fri 8/18/06
35	Production Approval	0 days	Fri 8/18/06	Fri 8/18/06
36	Production Quantity Parts	10 days	Mon 8/21/06	Fri 9/1/06
37	Assemble / Test	5 days	Mon 9/4/06	Fri 9/8/06
38	First Customer Ship	0 days	Fri 9/8/06	Fri 9/8/06



Project: Sample Schedule
Date: Mon 11/14/05

Task
Split
Progress
Milestone
Summary
Rolled Up Task
Rolled Up Split
Rolled Up Milestone
Rolled Up Progress
External Tasks
Project Summary
External Milestone
Deadline

Page 1

Budgeting

Non-Recurring Engineering (NRE)

One time cost for developing and testing a new product.

- Project Management
- Design
- Prototyping
- Testing
- Certifications/Approvals

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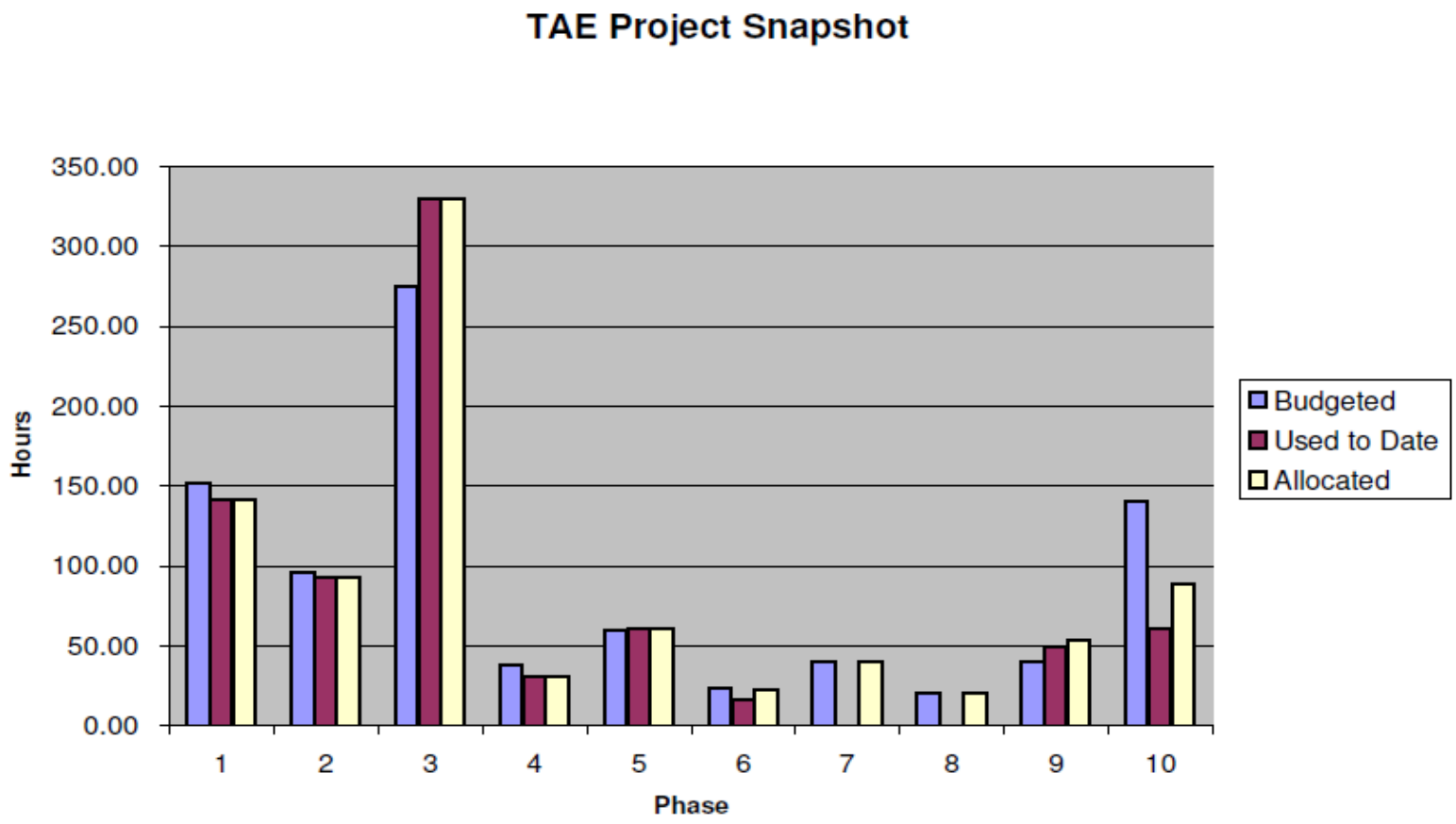
Development Tracking - Example



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Design Outputs

Design Outputs should correspond to Design Inputs – item by item to verify design is complete

All product documentation

- Sufficient information to build and maintain the product
- All information generated during the design

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Types of Output

- Schematics
- Layouts
- Bills of Materials (BOM)
- Mechanical drawings
- Software
- Manufacturing Procedures
- Review meeting notes
- Test Results

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Electrical Output - Examples

- **Schematics**
  - System block diagrams
  - Subsystem schematics
- **PCB layouts**
  - Gerber files for manufacturing
  - Layout source files
- **Bill of Materials (BOM)**
  - System level
  - Subsystem level

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Mechanical Output - Examples

- **Mechanical Drawings**
  - 3D CAD files
  - 2D CAD fabrication drawings
- **Bill of Materials (BOM)**
  - Top level, and sub-assemblies
- **Manufacturing Procedures / Test**
  - Assembly method sheets
  - Operational Standards and testing
  - Test results

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Experienced
Risk Management
Panelists

PANEL DISCUSSION

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Barbara Roberts

President & CEO

Wright Engineered Plastics

- Precision Injection Molding
- Cleanroom assembly
- Insert and overmolding
- ISO 13485

Collaborate ◦ Innovate ◦ Realize

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Mark Brinkerhoff

President, Fusion Design

Mechanical Development

- Products
- Equipment
- Prototypes
- Turnkey Systems

Accelerating Concepts to Creation

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Mike Silverman

Managing Partner

Ops A La Carte

- Reliability Solutions
- Reliability Training
- Reliability Testing / HALT and HASS Labs

We provide Confidence in Reliability

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Walt Maclay

President, Voler Systems

Electronic Circuit Design

- Sensors
- Analog

System Design

- Test Systems

Software & Firmware

We are the “Sensitive Engineers”

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Moderator: Mike Keer

Founder and CEO

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- Reduce Time-to-Market
- Minimize Investment
- Lower Cost and Risk
- Improve ROI

"Bridging the Product Development Gap"

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Engineering Is About Tradeoffs

We Make Decisions or Tradeoffs on

- Time
- Appearance
- Performance
- Cost

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Yet, We Want To Avoid

Undesirable Outcomes!

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Manage Risks

What are some techniques you use to manage risks?

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Barbara's Tips for Managing Risks

- Eliminate manufacturing steps
- Simplify and test all processes
- Obtain feedback from suppliers
- Fixture assembly for repeatability
- Design in-process testing to reflect real conditions for use

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Barbara's Tips for Managing Risks

- Test product design using min/max tolerances for all manufactured components

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Mark's Tips for Managing Risks

- Find the best fabricator for that tough part
- Plan for the worst and shoot for the best!
- Lead the target

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Mike's Tips for Managing Risks

- Develop and monitor the goal

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Mike's Tips for Managing Risks

- Write a reliability plan

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Mike's Tips for Managing Risks

- Start your failure identification process (FMEA) early and do often

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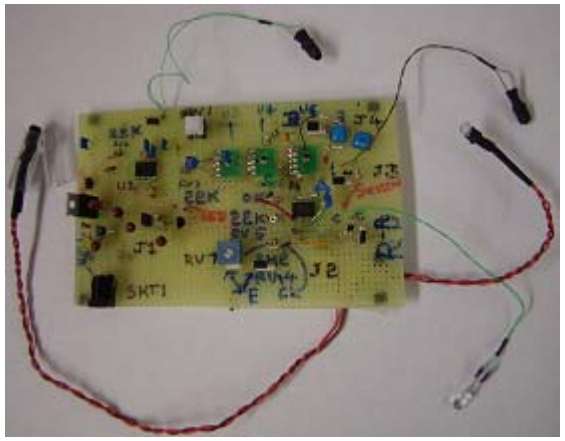
Walt's Tips for Managing Risks

- Select components that are in stock at a top tier distributor
- Evaluate risky technology first



- Don't combine: short schedule, tight specs, small budget

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Communicating Risks

What are a couple techniques you use for communicating risk at the design team level?

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Barbara's Tips for Communicating Risk

- Monitor risk during development team meetings
- Prepare a communication plan for transfer to high volume manufacturing
- Uncover undocumented but necessary specifications

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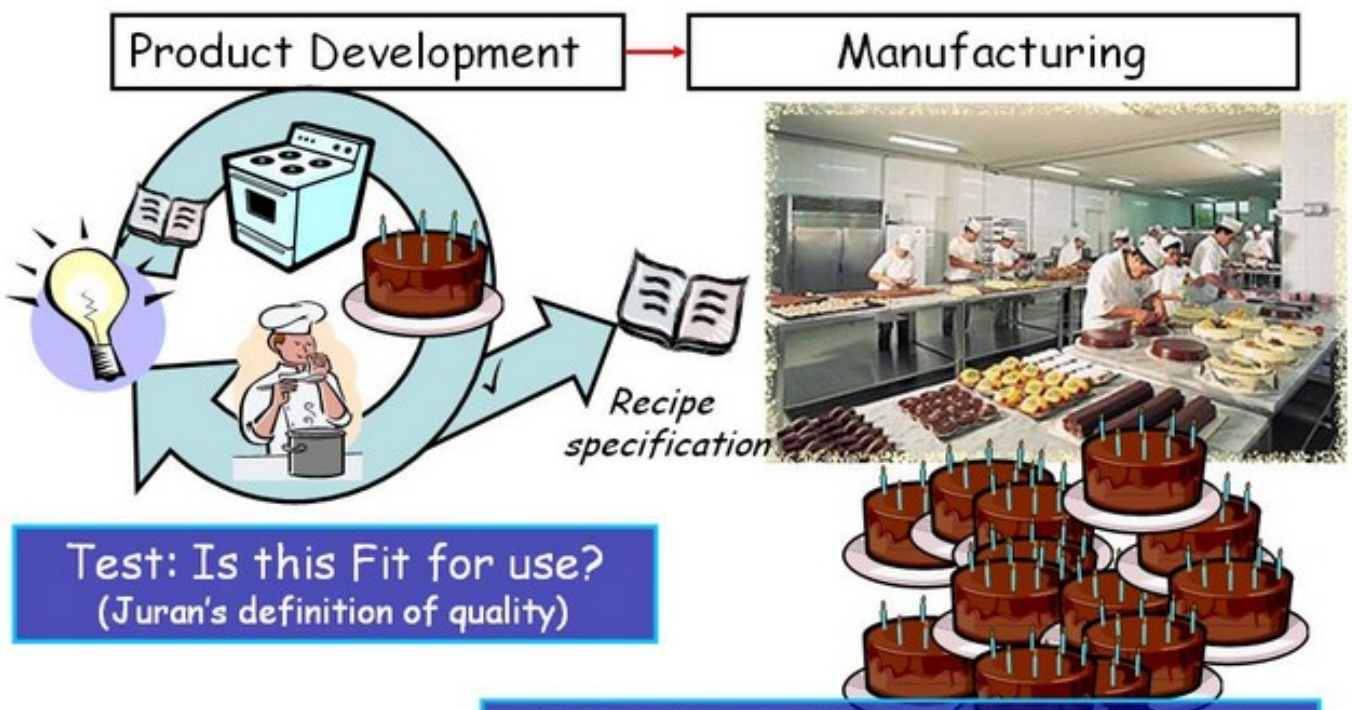
Barbara's Tips for Communicating Risk

Product Development vs. Manufacturing



Clarke.ching@gmail.com

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Mark's Tips for Communicating Risk

- Focus and brainstorm solutions weekly
- Define, track and post the target
- Strategically Leverage 3rd party unbiased experience

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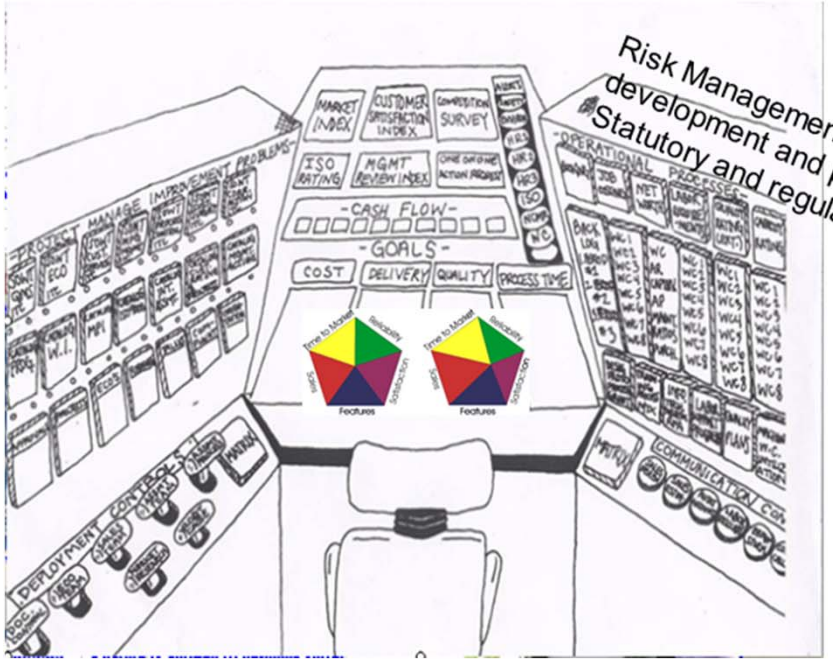
Mike's Tips for Communicating Risk

- Use an "organic dashboard" to show management where risks are and how they will be mitigated.



Risk Management Approach to product development and product realization

Statutory and regulatory requirements

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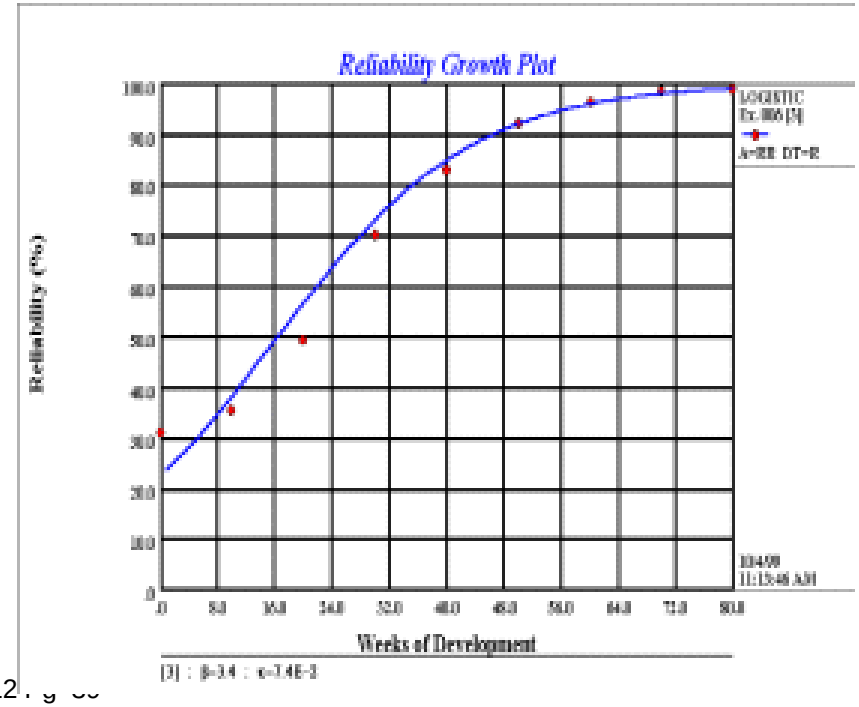
Mike's Tips for Communicating Risk

- Integrate reliability testing schedule in with development schedule to make sure tests hit targets before release.



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Walt's Tips for Communicating Risk

- Over communicate
- Write good specifications
- Include all stakeholders in planning

  (Engineering, Marketing, Manufacturing, Customer Service, Finance)

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For Your Area of Expertise

What is no longer a risk?

What is an emerging risk?

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Plastic Molding

No longer a risk:

- Unexpected part fill problems

Emerging risk:

- Tool construction and sampling in remote locations
- Condensing timelines by skipping verification steps

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Mechanical

No longer a risk:

- Rapid Mock ups to align development path with customer needs

Emerging risk:

- Global single sourcing

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Reliability

No longer a risk:

- Using Design for Reliability reduces risk
- RoHS

Emerging risk:

- REACH
- New standard to comply with
  - IEC60601-1, 3rd Edition

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Electronic Design & Software

No longer a risk:

- Wireless modules

Emerging risk:

- Increase in regulations

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Submitted Questions

Share an example where

technological risks were involved

What did you do to mitigate?

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Submitted Questions

Share an example where **transfer from design to manufacturing** risks were involved

What did you do to mitigate?

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Audience Questions

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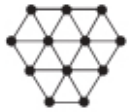
Managing Design Risk

**….how to reduce design risk,
share real world examples**



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