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RISK MANAGEMENT FOR PRODUCT DEVELOPMENT

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Introduction

Risk Management (RM) is a topic of growing interest in a variety of business areas. Most organizations already employ some type of RM when making large decisions, as for capital investment or project initiation. But the basic principles can and should be applied to many more business decisions. Among the areas where RM can be crucial to a company is Product Development.

The International Organization for Standardization (ISO) has developed the benchmark process, ISO 31000:2009, *Risk management – Principles and guidelines*. This standard advocates establishing a framework for managing risk within each organization. It also identifies the key steps in a complete RM process. As with other ISO processes, the standard is general and suggests a robust process for the organization, used to assure that strategic plans are comprehensive.

But, more often, we need a scaled-down version of the RM process that we can apply in our own job functions. This smaller RM process needs to have the same basic elements as the larger process, yet be manageable at the team, department or project level. Of special interest is the ability to diagnose areas needing attention early in the design process, even when limited resources are available for a formal design assessment.

RM Definitions

ISO 9004:2009, *Managing for the sustained success of an organization -- A quality management approach* provides a good short definition of risk management in article 9.3.5: "The organization should assess the risks related to planned innovation activities, including giving consideration to the potential impact on the organization of changes, and prepare preventive actions to mitigate those risks, including contingency plans, where necessary."

"Risk Management is the ability to anticipate risks and develop plans to manage them; thus, creating more predictable schedules, improving reliability and customer satisfaction. In many cases, risk management prevents what otherwise might be a catastrophic failure of your development program (1)."

Risk level has also been defined as exposure to the chance of loss or damage. It can be equated to your performance gap: the difference between the protection level you are performing at and the level of protection you should be at. Numerically, it can be expressed as a function of the likelihood of an outcome and the magnitude of that outcome.

Significance of RM to product development

There are a variety of business arenas where formal risk management is mandated: automotive and aerospace being two obvious segments. But these RM tools primarily focus on making sure that the product meets all requirements. Some of these tools are employed during product development to identify process and customer risks, but at this time, there are few requirements for using risk management on the product development process, itself.

There are two main areas of risk that we might consider during product development: those risks associated with not meeting performance requirements, and those risks associated with not being able to deliver the product. There are threads to both of these that we should consider during product design.

Risk Management is applied to help achieve four specific goals in product development:

1. Reduce time-to-market by making obstacles and barriers visible early in the development process.
2. Improve reliability by identifying those failures with high probability of occurring.
3. Reduce waste by diminishing re-design work and other non-value-added activities.
4. Improve customer satisfaction by reducing possible failures, defects, and design flaws

Risk analysis at the time of project inception involves taking the customer's view - what are the risks inherent in the product and its (mis)application? There are tape risks in product initiation, such as not fully knowing customers' requirements or not meeting customers' unstated requirements. Other product design risks in tape/adhesives might include:

- unknown details of adhesion requirements for all significant applications
- possible long-term exposure requirements
- undefined impacts of potential failures at end-users
- adequate resources have not been allocated to meet the required time frame
- higher priority projects emerge before the current project has been completed
- increases in material costs arising after project inception

> An example of design performance related risk might be: "A customer uses a protective tape in an application not included in the product design scope and the tape cannot be removed from expensive finished parts without leaving adhesive residues - the end-user has identified 154 rejected parts so far."

Risk analysis during the development project also focuses on risks in the manufacturing process, risks that can change the planned outcomes of the project. The production risks in the development project could include not being able to find appropriate materials or not having sufficient manufacturing capability to meet design requirements. Other project execution risks in tape/adhesives may include:

- the best raw materials are not available to meet the design intent
- your equipment capability is insufficient to meet quality, cost and/or delivery targets

> An example of a manufacturing risk might be: "A worker in your coating facility sues your company because of a negative physical reaction to the chemicals designed into your adhesive system."

Four Phase process for RM

Most approaches to risk management identify four phases of the RM process. They are

Risk identification - where are my development risks hiding?
Risk [analysis and] evaluation - how important is each risk?
Risk mitigation (treatment) - what do I do about it?
Effectiveness evaluation - how do I know that my actions were effective?

In her 1999 web paper, "Site Server - Risk Management Process for Product Development", Dr. Joyce Statz (2), offers a five step Risk Management process and detailed examples interpreting the important RM tasks.

- Identify project risks
- Analyze risks
- Identify risk handling actions
- Track and control risks
- Improve the RM process

Her process is team-based and targets major projects where the number of risks can be great. She lays out the processes for identifying team roles, required activities and tasks, establishing criteria to determine what will be managed, controlling changes and suggesting deliverables to document the changes. The first four of Statz's five steps are the same as the four phases of risk management. Her addition of a fifth step - improving the RM process itself - echoes best practices defined in the Baldridge criteria (3).

Of the four (or five) steps to the RM process, the first two constitute the diagnostic portion of the process whereas the remaining steps apply the remedy, when needed. Remedies are specific to each risk being mitigated. However, there are some tools that are commonly used during the assessment or diagnostic phase.

<u>Risk Identification</u>

There are several tools, well known in quality circles, for identifying risk. The "house of quality" directly addresses integrating customer needs into design requirements. Technically known as Quality Function Deployment (QFD), it is a graphical representation of the relationships between the characteristics that customers value and the design features and specifications of the product. The house of quality is the first of potentially several deployment matrices that link customer requirements with design criteria, product characteristics and manufacturing specifications.

This first QFD rates the relationships between the customer's requirements and the design features. For example: a customer requires a waterproof tape; R&D interprets that as design requirements for a low permeability backing with a water resistant adhesive system. The use of the house of quality specifically for adhesive and tape development has been addressed in the literature (4, 5); Robin Rawlings-Quinn article can be found in the resources section of the PSTC web site.

How do we find potential areas of risk? Some risks are obvious: inadequate moisture resistance in a product designed for outdoor application or the use of toxic chemicals in our production process. But many possible risks do not readily come to mind. Brainstorming with others in your organization is a traditional method for eliciting new ideas. But much can be done on your own using published references like ISO standards or the PSTC RTM criteria. Looking at our PSTC RTM criteria might suggest considering:

- Hazardous materials: When scaling up to production, do we determine what trace chemicals are contained in the commercial chemicals we purchase?
- Air Pollution: Production adhesive solvents are captured and handled in the coating process. How are emissions from laboratory tests measured and do they comply with all requirements?

Other techniques for identifying potential risks include

- Working groups and brainstorming
- Surveys and interviews
- Experiential or documented knowledge
- Outputs from "what if" scenario analyses
- Historical information - lessons learned
- Templates: critical path, engineering

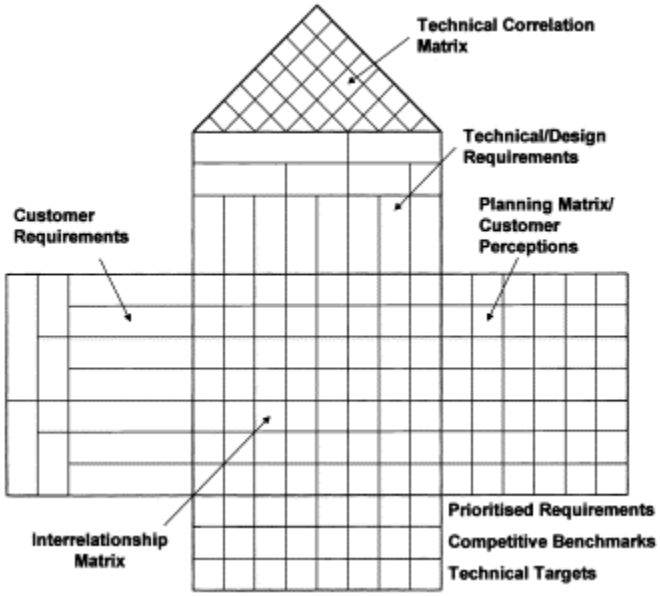

Figure 1. House of Quality, the initial QFD analysis

Risk Analysis and Evaluation

Many companies have formal risk management processes in place for organization-level decisions such as large capital investments. Typically, assessments of costs vs. benefits use financial ratios such as Return on Investment (ROI), Net B/C ratio = (PV of benefits – PV of operating costs)/PV of capital costs or Internal Rate of Return (IRR). Some of these may be applicable to evaluating the presence (or absence) of product characteristic. However, often, it is difficult to put a dollar figure on the value of a product characteristic.

Other approaches for risk quantification include:

- Weighted probabilities
- Extended cost
- Future Value or Net Present Value
- Capability analysis
- Value stream mapping
- Cost of poor quality
- Discounted Cash Flow

Again, some of these require an estimate of costs or projections of future production levels that may not be available at the time of product development.

Using your company's financial evaluations for determining project performance will speak directly to management. But, when dollar estimates are not available, Failure Mode and Effects Analysis (FMEA) provides a method to develop potential root causes of failure and to prioritize them for action. When used as a design tool, FMEA asks how the product can fail:

- What are the consequences of failure (severity)?
- How often would this failure be expected (frequency)? and
- Can we see failure coming (detectability)?

A typical section of an FMEA analysis is shown in Figure 2.

Item-Part / Function: Enter a system function using verb/noun format	Potential Failure Mode: Failure mode = loss of function or negative of function	Potential Effect(s) of Failure: Consequences on other systems, parts, or people	Severity	Potential Cause(s) / Mechanism(s) of Failure: From block diagram, determine if/how each element can cause system failure	Frequency	Current Design Controls: Method, test or technique used to detect cause of failure	Detect	RPN
Anti-Multilation Tape to Protect Surface	Adhesive Transfer to Substrate	Surface must be cleaned	7	Poor Film Anchorage	2	QC test face-to-face test	6	84
			7	Laminated Product Stored Under Extreme Conditions	4	Customer controlled evaluation	2	56

Figure 2. Section of an FMEA risk analysis

In this approach, Severity, Frequency and Detectability are separately rated from 1 to 10. The rating criteria for each can be customized for our application; various examples are given in the literature (6, 7). Generally, each characteristic is rated from 1 to 10. The Rating Priority Number (RPN) is the product of the three values.

$$RPN = Severity \times Frequency \times Detectability$$

Note that this technique for prioritization is based on the risk level (the product of the likelihood and the magnitude of an outcome) modified by our ability to detect and intercept the defect or problem. Where the RPN is greater than 100, the potential defect requires remedial action (mitigation). For those issues with initial RPNs lower than 100, the RPN suggests the priority with which each should be addressed. Some issues may have such a low RPN that they can be accepted without change.

Summary

Risk Management (RM) is the formalization of change management processes for rapid response to a shifting business climate. It can address issues both at tactical and the strategic levels and may be particularly important in the development of new products.

"… many critical risks will be cross-functional …"

"… focus on risks that are likely to disrupt the schedule (8). "

When tasked with a product development assignment, identification of potential risks through analysis of potential impact is the key phase. "... the greatest risks are never the ones you can see and measure, but the ones you can't see and therefore can never measure (9)." The QFD house of quality is a straightforward method for determining which customer requirements may need specific design consideration. Failure Modes Effect Analysis (FMEA) allows you to prioritize potential issues and track improvements as they are addressed.

These two tools can be instrumental in assuring that the products we design will meet the requirements of our customers, our companies and our communities.

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