

Is Risk Management Valuable for Me?



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Questions to Answer

- **Is it enough to just comply?**
 - **And if I do not need to comply, should I do it at all?**
- **Can I get the promoted benefits without taking up a ton of time?**
- **As a small company in the early stages of development, do I need this for my team?**
- **As an established company, with an existing product line, do I need it?**

Agenda

- **Risk as compliance**
- **Risk types**
- **Tools for risk**
- **Tips for success**

Risk as Compliance

- **Industries requiring compliance with risk management expectations**
 - **Medical device**
 - **Defense**
 - **Aerospace**
 - **Automotive industry suppliers**

Typical Application of Risk Management

- Painful, useless, required deliverable
- Extra paperwork when we are already too busy
- File goes into cabinet, never to be seen again
 - Change title and you are done

Sound familiar?

Intended Value of Risk Management

- **Avoid surprises (prevention)**
- **Prioritize efforts**
- **Document thought process**
- **Training**
- **Problem solving**
- **Enables you to take risk!**

Would you benefit from this?

Are We Seeing the Benefits

- **Medical device recalls**
- **Delays in major defense programs, including cancellation**
- **Planes landing various places, like the Hudson**
- **Concerns of quality in US auto industry**
- **Overall, most organizations fail to accomplish goals on schedule**
 - **Only 20-30% success rate on major milestones**

Should We Do It?

- **Realize that you are either doing risk management formally or informally**
- **Sharing the vision builds trust and credibility**
- **Fear (uncertainty) produces apprehension, thus project delays**

So What is Risk?

- **Safety?**
- **A project deliverable?**
- **Issues?**
- **Uncertainty?**
- **OR**
- **“We do not have any risk”**
 - **“We are smart people”**
 - **“We already took care of it”**

**If you have no risk, you are not changing enough
and will not be in business very long.**

How can Risk be Used?

- **Decisions on requirements**
- **Test scope**
- **Project tasks**
- **Level of project tracking**

High Level Types of Risk

- **Project risk**
- **Product risk**
 - **Process risk – a subset that directly relates to the above**

Often – too narrow of a view is taken

Project Risk

- **Project risk**
 - **Performance**
 - **Cost**
 - **Schedule**
 - **Business results**
 - **Market**

Product Risk

■ Product risk

- Final customer
- User/ operator
- Concept
- Detailed design/ bill of materials

■ Process risk

- Manufacturing
- Component/ vendor
- Equipment
- Service/ installation
- Business

Typical Risk Tools

- **Preliminary hazard analysis**
- **Fault tree analysis (FTA)**
- **Failure modes and effects analysis (FMEA)**
- **Hazard and operability study**
 - **Key words – at nodes - no, more, less, as well as, reverse, other than**
 - **Parameters – flow, temp, pressure, composition, phase, level, relief, instrumentation, sampling, corrosion/ erosion, services/ utilities, maintenance, addition, safety, reaction, inserting/ purging, contamination**
- **Hazard analysis and critical control point**

Advanced Risk Approaches

- **Risk scoring systems (project risk)**
- **Software risk systems**
- **Monte Carlo analysis for statistical risk calculation**
- **Design Of Experiments to develop understanding of the uncertainty or unknowns**
 - **Can simulations really reduce risk? Does it just reflect your current understanding?**

Keys for Success

- **List all potential issues, even ones you have addressed**
 - Take credit for the work you have done
- **Recognize if recommended solution will reduce risk to acceptable level**
- **Unless it is a prediction, it is most likely a relative measure**
 - If you have all low risks at the start of a project, then why is the project not already done?

Monitoring and Tracking Risks

- **How deep do you need to go?**
 - **Further depth in areas of higher risk**
 - **Do not treat all areas equally**
- **Monitor high risks to ensure they are tracking toward success, but at a lower level of detail (not with a high level measure)**
- **Review remaining risks periodically to record additional learning and find shifts in assumptions**
 - **Moderate risks kill projects more so than high risks**

Use of Time

- **Clean sheet versus leverage existing documents**
- **Use of idea triggers**
- **Part number versus family approach**
- **Using the results**

Risk and Planning

- **What about during the “fuzzy front end”?**
- **“We do not know enough yet”**
- **Plan, even if you can not do it**
- **There is much less creativity during a crisis**

Summary

- **Identify risks and do something before you “hit the wall”**
 - Then it IS an issue
- **Recognize risk measurement is relative**
- **Recognize your desired benefit and then develop a time efficient approach to obtain it**