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Risk Management

This article discusses how risk management can aid in project success. It looks at the potential gain from good risk management, examines some typical risks that recur regularly on projects, and offers a suggested methodology for managing project risks.

Figure 1. Better levels of project readiness index are correlated with reduced levels of cost overrun.

Risk Management – A Key Requirement for Project Success

by Brett Schroeder, John Alkemade, and Gordon Lawrence

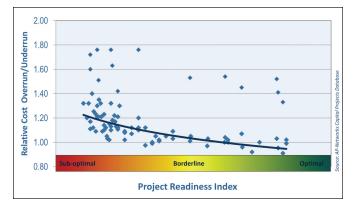
Introduction

ost people involved in capital investment project execution are aware of the link between early design definition and project success. However, the positive role of good risk management is not always as well known. This article discusses how risk management can aid in project success. It looks at the potential gain from good risk management, examines some typical risks that recur regularly on projects, and offers a suggested flow scheme and methodology for managing project risks.

The Next Step after Considering Good Design Definition

Over the course of our work in recent years, we have observed that a high percentage of major capital projects fail to meet their project performance targets.¹ This failure can very often be traced back to poor early design development. Indeed, the link between good early design development and project success has been demonstrated in numerous articles over several years now.

Several organizations provide either qualitative or quantitative measures of early design development. For example, the Association for the Advancement of Cost Engineering-Interna-



tional (AACE-I) provides a qualitative measure² and other, quantitative measures exist, such as the "Project Readiness Index."³ All these sources generally give a similar description of what level of design definition is required in order to achieve a cost estimate of a particular level of accuracy. They generally include an assessment of the level of completeness of such aspects as: scope definition, engineering documents, team alignment, and project control systems.

However, poor design development does not explain everything in relation to the failed projects. Figure 1 shows the Project Readiness Indices of a dataset of capital projects,⁴ mapped against their level of cost overrun/underrun of the approved budget. The graph unsurprisingly illustrates that a better level of Project Readiness Index correlates with lower levels of cost overrun. However, as circled in red in Figure 2, the graph shows a number of outliers which had a significant cost overrun irrespective of their level of Project Readiness.

These outlier projects were examined in order to try to ascertain whether there were common characteristics in this sub-group. The common denominator among all the projects in this sub-group of outliers was that each lacked a clear strategy for documenting potential project risks and mitigating those risks.

> Therefore, it was decided to focus on understanding more about the identification and mitigation of risks with the eventual objective of developing a tool to address "Risk Identification and Management."

The Need for Risk Management

Among the projects in the dataset, significant risks were not being identified and managed. Risk management, if it occurred at all, was an

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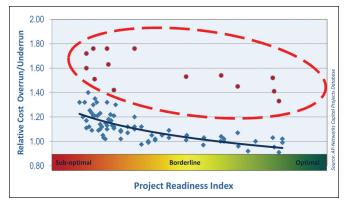


Figure 2. Lack of a risk management strategy correlates with the outliers from the readiness index.

ad-hoc exercise, with spreadsheets littered all over the organization – lacking consistency in categorizing and prioritizing risks. Furthermore, there was no clear assigning of ownership for action/response plans. There tended to be no standardized process for regular management review. This meant that risk occurrences and hence potential lessons learned were not being passed on to other project teams. As a consequence, the organizations were not achieving optimum performance, and were exposing themselves to unnecessary liabilities.

A literature search revealed that other studies had come to similar conclusions. For example, a study by IBM⁵ found a distinct correlation between company success and the presence of formal risk management procedures. Their set of high performing companies had greater return on net assets of (9.3% vs. 7.9%) and a higher compound annual growth rate (18.7% vs. 16%). Thirty-five percent of their outperformers had formal risk identification procedures versus 8% of underperformers and 35% of their outperformers routinely monitored risk factors versus 10% of their underperformers.

Specifically within the pharmaceutical industry, there are risk management tools available; one example being the "Quality Risk Management" Guideline Q9,⁶ produced by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).⁷ However, many of these tools focus heavily on how to design and operate a facility in order to ensure a quality product.⁸ They tend not to focus on the more general, engineering or construction related risks such as "What is the risk to the schedule if this equipment item is delivered to the site late?" or "Is there a risk of disrupting existing site operations during construction?" or "Have we recognized all the government permits that are required to build this facility?" or "Is there a risk of miscommunication between the design office and the owner engineering office?"

Defining Risks

Kerzner defines risk as "[a] measure of the probability and consequence of not achieving a defined project goal."⁹

Desired project outcomes are inherently under threat of failure or non-compliance due to events that may occur during the project life-cycle. Such events may vary in their degree of probabilistic occurrence, magnitude of impact (severity), and level of manageability.

For our purposes, a risk can be defined as any uncertainty that if it occurs would affect one or more project objectives negatively. We shall discuss the level of risk exposure as being a function of the probability of the risk occurring and the severity of its effect if it does occur.

Risk mitigation will be taken to mean any action taken to reduce either the probability of occurrence or the severity of the effect of a risk. Contingency planning will refer to plans of what to do once the risk has occurred.

The Risks to be Managed

We then looked through a database of projects¹⁰ again, this time looking for projects that did appear to have a good risk management process, rather than those that clearly didn't.

Some projects had focused only on post startup process operational risks (such as those discussed in Annex II of ICH Guideline Q9) and neglected other risks, such as those associated with project execution during engineering and construction, prior to startup. In general, we found that the better risk management processes looked at risks related to aspects of project execution as well as those related to facility operability.

All in all, from our database of projects, we were able to develop a list of more than 110 "generic" risks that cropped up time and again in the projects that we reviewed.¹¹ These generic risks could be grouped, as shown in Table A.

Risk Mitigation

Once the risks had been identified, the project teams that had good risk management plans then proceeded with studies to quantify the risk exposure of their project. This was often

Risk Category	Examples
1. Technology	 Ensuring adequate technical definition prior to detailed engineering Use of new or unproven technology Design flaws
2. Planning/Schedule	 Permitting takes longer than anticipated Long lead times for major equipment
3. Organizational	 Adequate staffing Effective team integration and interface management Joint venture partner alignment
4. Market/Commercial (Economic)	 Ensuring Robust Economic case (ROI) Cost escalation and budget constraints
5. Scope Definition	 Tie-ins with existing facilities (Brownfield modifications) Adequate understanding of OSBL (Outside Battery Limits) interfaces
6. Procurement and Materials	• Availability of staff and supporting equipment
7. Commissioning and Startup	Interference with ongoing operations
8. Health, Safety, and Environmental	Safety incident

Table A. Generic risk areas – rated in order of estimated risk severity.

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done using a Monte Carlo style simulation. For all the individual risks, the Risk Severity was calculated (likelihood of occurrence and the level of impact). The Monte Carlo analysis then simulated "random" occurrence and severity of each of the risks in the risk register.

Once teams were aware of the extent of their risk exposure, the teams then proceeded to assess which risks could be mitigated and using tools such as tornado charts, determined the risks with the highest negative contribution (Cost and Duration), thus deciding on which were the most important risks to mitigate.

This then assisted the project teams in deciding the priority of which risks to focus mitigation efforts on and to develop a mitigation plan with the intent to reduce the risk severity (lower the likelihood of occurrence or lower level of impact).

The Potential Gain – Case Study

To illustrate the beneficial effect of this work, below is a case study example of one particular facility. The study shows the risk exposure before (unmitigated) and after (mitigated) mitigation plans had been implemented.

Unmitigated Risks

The outcome of a Monte Carlo analysis, as shown in Figure 3, was a frequency distribution (or S-curve) of the risk exposure. In this example, the unmitigated risk register (i.e., no mitigation planning done) showed an additional cost impact of 75 percent (Probability 50) on top of the current cost estimate and likewise 122 percent on duration.

Mitigation of Risks

Figure 4 shows the results of the risk exposure calculation after the major risks had been mitigated. In this example, the mitigated risk register (i.e., mitigation planning developed and implemented) shows a residual cost impact of 13 percent (Probability 50) on top of the current cost estimate and likewise 19 percent on duration. (Note: These percentages do not reflect additional contingency requirements in the cost estimate for "unknown unknowns" or duration float requirements in the schedule, but represent the quantified risk exposure, which could be translated as management reserves and will only be utilized if one of the risks occurs).

Figure 5 summarizes, by showing a comparison of the risk range, pre and post mitigation. In this particular example,

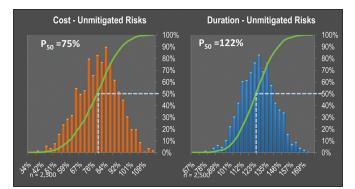


Figure 3. Risk exposure - unmitigated.

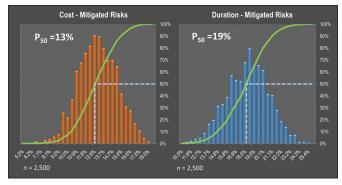


Figure 4. Risk exposure - mitigated.

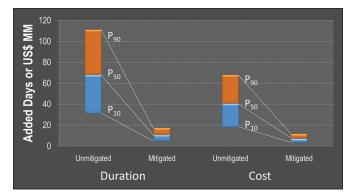


Figure 5. Benefits of quantification.

the reduction in risk around both the cost and the schedule duration is dramatic.

The Prescription for Success

Once we had established the importance of Risk Management, the next step was to develop a "process" of risk management, based on the "good practice" that we observed. The process that we developed is based upon the following key activities.

1. Establish a Common Risk Breakdown Structure (RBS)

Develop a logical structure for grouping risks. A standardized Risk Breakdown Structure (RBS) provides a logical method to group risks. The consistent structure can, in turn help teams analyze risks across a portfolio and facilitate the sharing of risks across different functional areas. When reviewing risks from previous projects, use of a RBS allows teams to learn from experience and better understand the systematic threats that need to be addressed during the (following) risk identification stage. Moreover, teams should be able to identify from the previous projects what action plans were implemented and their level of effectiveness. The structure that we settled on and have now successfully used with a number of capital project teams is shown in Table B.

2. Identify the Risks (Through Cross-Functional Risk Identification Brainstorming Workshops)

Identifying the risks should (at least initially) be done in a large, multidiscipline, "brainstorming" group. In our view, risk identification and assessment workshops have proven

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RBS	Examples		
Project Location	e.g. availability of local infrastructure, etc.		
Market and Commercial Business Issues	e.g. speed to bring to market, etc.		
Process Technology	e.g. new technology, etc.		
Scope Definition	e.g. availability of site data, etc.		
Contracts and Contracting Strategy	e.g. incentive schemes, etc.		
Communication Interfaces	e.g. joint venture partners, etc.		
Health, Safety, and Environmental	e.g. contractor safety record, etc.		
Execution Complexity	e.g. site access constraints, etc.		
Validation, Commissioning, and Startup	e.g. handover sequencing, etc.		
Operational	e.g. operator training, etc.		

Table B. Example RBS.

to be one of the single most important steps within the risk management process. In planning for such workshops specific attention is given to the attendee list, which should reflect the broad spectrum of all project stakeholders. These workshops provide a unique opportunity for team members to not only identify potentially adverse issues arising from their area of responsibility, but also allow these team members to develop and crystallize essential interdependencies among various threats. Hence, risk workshops will add to the connectivity of the individual disciplines and reveal possible misalignment among team members on certain risk expectations. The brainstorming sessions should ask such questions as:

- What can go wrong?
- How can it go wrong?
- What is the potential harm?
- What can be done about it?
- What problems have we experienced in the past?
- How did we manage it when it happened?
- How can we stop it from happening again?
- What losses have our competitors experienced?

We developed a pro-forma for participants to write down their potential risks on. This improves the capture of ideas during the brainstorming. The pro-forma includes space to write: a description of the risk, a check box for affected outcome, a check box for risk severity, and a check box for risk manageability.

It is recommended that several team workshops are held prior to the execution phase. These team workshops may have at times various foci other than risk depending on the project area or discipline under discussion (e.g., planning status, team alignment, etc.), but should at a minimum feature a review or discussion of the current status of risk assessments and risk-related action plans.

3. Quantify Impact Values and Probabilities

Once the risks are identified, the affected outcome needs to be specified. The following are outcome categories that are most commonly used:

- CAPEX cost
- Project Schedule
- Construction Safety
- Facility Operability
- Environmental
- Company Reputation

Next, the level of risk exposure needs to be assessed, by quantifying probability of occurrence and severity if it occurs. To classify severity of occurrence, we use the criteria in Table C. Plotting the risks on a matrix such as the one shown in Figure 6 helps to visualize where the highest risk exposure lies.

4. Document the Risks in a Risk Register

Next, the risks need to be documented in a register that ideally can be accessed by all team members and includes fields for:

- Risk ID and Text Description
- Affected Outcome
- Probability and Severity Ratings
- Level of Manageability
- Risk Owner
- Mitigation Action(s) and Owner
- Contingency Plan(s) and Owner

Among those project teams that are addressing risk management, many teams have adopted spreadsheets to maintain risk registers. There is nothing inherently wrong with the use of spreadsheets, but their use tends to concentrate the risk management process to a single individual and preclude the cross-functional dialogue that should be a key part of the risk process. The use of specialized risk management software systems avoids this problem since the register can be accessed and reviewed by various team members.

5. Develop Mitigation and Contingency Response Plans

Many teams do a good job at identifying and quantifying risks and capturing them in a risk register. However, in our experience many teams fail to complete the risk management cycle by developing the appropriate mitigation and contingency response plans. For large registers the task may appear overwhelming to develop response plans for each risk. If this is the case, the team needs to prioritize on the high-impact and high-probability risks and ensure that at a minimum these are addressed. The team also needs to communicate the low probability risks that have high impact on project objectives. These are the threats that often result in catastrophic failure.

All of this work in developing mitigation and contingency plans does take time and effort. However, this needs to be weighed against the potential loss in terms of cost and schedule if a particular risk is not mitigated and comes to pass.

6. Assigning Responsibilities

The next step in the process requires responsibilities to be

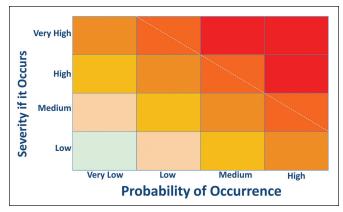


Figure 6. Risk exposure matrix.

assigned in order to ensure that the mitigation plans are implemented and the contingency plans fully prepared. The following are recommended:

- Assigning a Risk Champion/Coordinator with adequate authority to police the activities of those developing mitigation and contingency plans.
- Assigning specific responsibilities for each mitigation and contingency plan preparation.
- Including the development of those plans in the project schedule.
- The mitigation and contingency plan preparations are monitored and reviewed at each project progress meeting.

7. Review the Risk Register as Part of Regular Team Meetings

We recommend making the review of the risk register a regular part of the weekly or monthly team meetings. This ensures that the risk process remains central to the management and communication processes.

8. Re-Evaluate Risks Periodically

Even after the project is well under way, teams still need to hold-periodic cross-functional risk events to update the register with new threats and opportunities and re-assess existing risks.

9. Lessons Learned

In addition, it is helpful to conduct project closeout assessments of the efficacy of specific risk mitigation actions taken during the project. The results of such feedback measures strengthen the use of "lessons learned" in future projects.

A Risk Management Tool

Based on the process described above, a Web-based tool was developed for Risk Analysis and Management. This tool has been used successfully on a wide range and large number of projects in the last four years. The tool allows teams to: identify, evaluate, and register risks and key information; assess risk severity/manageability; track risks and mitigation plans; access to datasets of most common industry risks; and share risk information

The tool can be used by all team members with minimal training. It provides a framework for carrying out the activities discussed in the previous section and it offers the team a number of visual reporting formats (such as spider charts) to illustrate risk severity, track risk mitigation and contingency actions, and so forth.

Conclusion

Achieving project success requires not just good front end definition and a well integrated project team. Project success also hinges on good management of project risks. This requires teams to:

- identify, evaluate, and register risks and key information
- assess risk severity/manageability
- develop mitigation and contingency plans
- actively track the risks and mitigation plans

Holding a risk identification session early in a project, as part of the front end development process will improve the project teams chances of having a successful project.

Definitions		nitions	Affected Outcome							
			CAPE X	Schedule	Safety	Operability	Environmental	Reputation		
		Very High	Increase more than 8%	Delay more than 10%	Fatality and/or Permanent Disability	More than 7% reduction in operability performance	Major Spill (Full Response)	Worldwide negative news coverage (Governmental Obstruction)		
		High	Increase between 4% to 8%	Delay between 5% to 10%	Major Injury (LTI's)	Between 3% to 7% reduction in operability performance	Serious Spill (Significant Response)	Negative local news coverage (Permitting Delays)		
Counsitu		Medium	Increase between 1% to 4%	Delay between 1% to 5%	Medical Treatment (Recordables)	Between 0.5% to 3% reduction in operability performance	Moderate Spill (Limited Response)	Negative exposure at facility (Emotional Unrest)		
		Low	Increase less than <1%	Delay less than <1%	No or Minor Injury (First Aid)	Less than 0.5% reduction in operability performance	Minor Spill (No Response)	No concern		

Table C. Example severity quantification.

Endnotes

- 1. Where performance targets are taken as predictability of Capital Cost, predictability of Project Schedule and level of facility operability after startup.
- 2. AACE-I Recommended Practice No. 18R-97 (2005) Cost Estimate Classification System – As Applied in Engineering, Procurement, and Construction for the Process Industries.
- 3. The "Project Readiness Index" is provided by Asset Performance Networks as part of the "Project Pyramid", web-based self-assessment tool for measuring project readiness and project team alignment. See http://www. project-pyramid.com/index.html for further details.
- 4. Internal Asset Performance Networks database.
- Steven Edwards, Stephen Williamson, Jacquie Glass, Michel Anderson and Penny Koppinger; "Where There's Smoke... – Achieving Safe and Reliable Operations with Enterprise Risk Management", IBM Global Business Services, July 2008.
- 6. The guideline can be downloaded here: http://www.ich. org/cache/compo/363-272-1.html.
- This is a link to the ICH Web site: http://www.ich.org/ cache/compo/276-254-1.html.
- 8. Refer to Annex II of ICH Q9 for examples.
- 9. Kerzner, Project Management, A Systems Approach to Planning, Scheduling, and Controlling, 8th ed., 2003, Chapter 17.1.
- 10. Note that this database covers a wide range of process industries. It does not focus exclusively on pharmaceutical projects.
- 11. Some of these risks, (specifically, those related to oil & gas projects) were discussed in Schroeder, Brett & Jansen, Jan A., "Why Traditional Risk Management Fails in the Oil and Gas Sector: Empirical Front-Line Evidence and Effective Solutions,"2007 AACE International Transactions, RISK.01, AACE International, Morgantown, WV, 2007. The risks related specifically to other process industries than pharmaceuticals have been omitted from this list.

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