



MANAGING RISK IN THE LIFE SCIENCE INDUSTRY

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Introduction

- ◆ Risk In Life Science Industry Is Multi Dimensional
- ◆ Tendency To Focus On One Risk, At The Expense Of the Others
- ◆ PMBOK Can Help
- ◆ PMBOK Can't Guarantee Project Success



Terminology

- ◆ Risk
- ◆ Risk Management
- ◆ Mitigation
- ◆ Risk Trigger
- ◆ Qualitative Risk
- ◆ Quantitative Risk



Types of Risk

- ◆ Market Risk
- ◆ Company Reputational Risk
- ◆ Financial Risk
- ◆ Technical Risk
- ◆ Regulatory Risk

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- } Focus of Presentation



Technical Risk

- ◆ Product Efficacy
- ◆ Product Safety
- ◆ Process Risk
- ◆ Schedule Risk
- ◆ Cost Risk



Regulatory Risk

- ◆ Regulatory Changes
- ◆ Product Approval



Risk Management

- ◆ Qualitative Risk Management
- ◆ Quantitative Risk Management
- ◆ Risk Response Planning
- ◆ Risk Monitoring And Control



Qualitative Risk Analysis

- ◆ Objective of Qualitative Risk Analysis Is To Identify And Subsequently Determine Which Risks Warrant A Response
- ◆ Can Be Used To Decide If Project Should Proceed



Probability and Impact

- ◆ Scales
 - ◆ High, Medium, Low
 - ◆ 1 – 10
 - ◆ 1 – 5
- ◆ Risk Prioritization Number
- ◆ Impact Matrix

Impact Matrix

		Impact				
		1	2	3	4	5
Probability	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5

Qualitative Risk Analysis

Project: Install Bio-Reactor Tank And Agitator

Risk	Probability	Impact	Risk Score
Resources Reallocated			
Agitator Delivered Late			
Agitator Costs Less			
Production Impacts Shutdown			
Agitator Does Not Fit			
Installation Simpler			
Weather Delays			

Qualitative Risk Analysis

Project: Install Bio-Reactor Tank And Agitator

Risk	Probability	Impact	Risk Score
Resources Reallocated	2	2	4
Agitator Delivered Late	3	4	12
Agitator Costs Less	2	5	10
Production Impacts Shutdown	1	5	5
Agitator Does Not Fit	3	5	15
Installation Simpler	4	4	16
Weather Delays	1	3	3

Qualitative Risk Analysis

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Qualitative Risk Analysis

- ◆ Define Assumptions
- ◆ Assign Risk Owners
- ◆ Identify Risk Triggers

Identify And Assess Both The Bad
And Good Things That Can Happen



Quantitative Risk Analysis

- ◆ Objective of Quantitative Risk Analysis Is To Numerically Analyze Each Risk And The Potential Impact That Each Risk May Have On The Overall Project
- ◆ Note: Quantitative Risk Analysis Is Not Always Required In Risk Management

Probability and Impact

- ◆ Probability and Impact May Be Estimates
- ◆ Impact May Be To Cost And/Or Schedule
- ◆ Monte Carlo Simulation
 - ◆ Replaces A Deterministic Value for Probability or Impact With A Range Of Values
 - ◆ Third Party Literature And Software Available

Expected Value of Project

Project: Install Bio-Reactor Tank And Agitator

Project Cost: \$500,000

Risk A	10% Probability Of A Delay In Receiving Agitator With A Cost To Project of \$25,000
Risk B	65% Probability Agitator Will Be \$20,000 Cheaper Than Expected
Risk C	40% Probability That Agitator Will Not Fit On Tank, Resulting In An Extra \$150,000 Cost
Risk D	5% Probability That Installation Will Be Simpler Than Expected, Resulting In A \$35,000 Savings



Expected Value of Project

What Is The Expected Value Of These
Risks And Opportunities?

Expected Value of Project

Risk	Calculation	Expected Value (\$)
A	$0.10 \times \$25,000$	2,500
B	$0.65 \times \$20,000$	(13,000)
C	$0.40 \times \$150,000$	60,000
D	$0.05 \times \$35,000$	(1,750)
	Total	47,750

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	Total	47,750

So What?

Expected Value of Project

- ◆ What Is The Best Case (Only Good Things Happen)?
- ◆ What Is The Project Cost (Without Risk Analysis)?
- ◆ What Is The Expected Value Of The Project (With Risk Analysis)?
- ◆ What Is The Worst Case (Only Bad Things Happen)?

Expected Value of Project

Question	Calculation	Result
Best Case	$500,000 - (20,000 + 35,000)$	445,000
Customer Expectations		500,000
Expected Value	$500,000 + 47,750$	547,750
Worst Case	$500,000 + 25,000 + 150,000$	675,000

Expected Value of Project

KEY POINTS

- ◆ Taking Uncertainty Into Account, Project Cost Could Range From \$445,000 to \$675,000
- ◆ Expected Value Is Less Than Worst Case
- ◆ Can Prove That Customer Expectations Are Unrealistic (“Project Must Be Completed For No More Than \$500,000”)
- ◆ Same Calculations Apply To Schedule Risks

Risk Response Planning

- ◆ Objective of Risk Response Planning Is To Determine What Can Be Done To Reduce The Overall Risk Of The Project
- ◆ Levels of Risk Response
 - ◆ Do Something Before It Happens
 - ◆ Do Something If It Happens ⇒ Contingency Plan
 - ◆ Do Something If Contingency Plan Not Effective ⇒ Fallback Plan

Risk Response Planning

- ◆ Options for Risk Response Planning
 - ◆ Mitigate
 - ◆ Accept
 - ◆ Transfer
 - ◆ Avoid
- ◆ Secondary Risks \Rightarrow Risks That Are Generated By A Response To Another Risk

Risk Response Planning

- ◆ Create Schedule and Cost Reserves

Project Schedule = Critical Path Duration
+ Contingency Reserve
+ Management Reserve

Project Budget = Cost of the Tasks
+ Contingency Reserve
+ Management Reserve

Risk Response Planning

Risk	Impact Type	Probability of Occurrence Rating	Impact Rating	Priority Rating	Risk Response		Risk Owner
		1 - None 2 - Low 3 - Medium 4 - High 5 - Certain	1 - None 2 - Little 3 - Moderate 4 - Heavy 5 - Devastating	(Probability x Impact)	Accept Avoid Mitigate (Minimize Probability) Mitigate (Minimize Impact) Mitigate (Deflect)	Identify and Describe Risk Response	
Ensuring compliance with team recommendations across all sites, Metrics to be tracked, How it is reported.	Scope	4	4	16	Mitigate (Minimize Probability)	Leverage engineering and quality stakeholders to support recommendations	George
Quality does not approve of team's recommendations.	Scope	3	4	12	Mitigate (Minimize Impact)	Representative(s) from Q should participate on team.	Tom
Difficulty obtaining agreement from all sites on recommendations.	Scope	3	4	12	Accept	Leverage engineering and quality stakeholders to support recommendations	John
How to document/communicate "Lessons Learned" or process by which the process was streamlined to provide guidance to someone new to the process.	Scope	4	3	12	Mitigate (Minimize Probability)	Implement communication plan before, during, and after Kaizen event	Jim
Implementation dates not met	Time	4	3	12	Mitigate (Minimize Probability)	Use target, and range during implementation planning	Jim



Risk Monitoring and Control

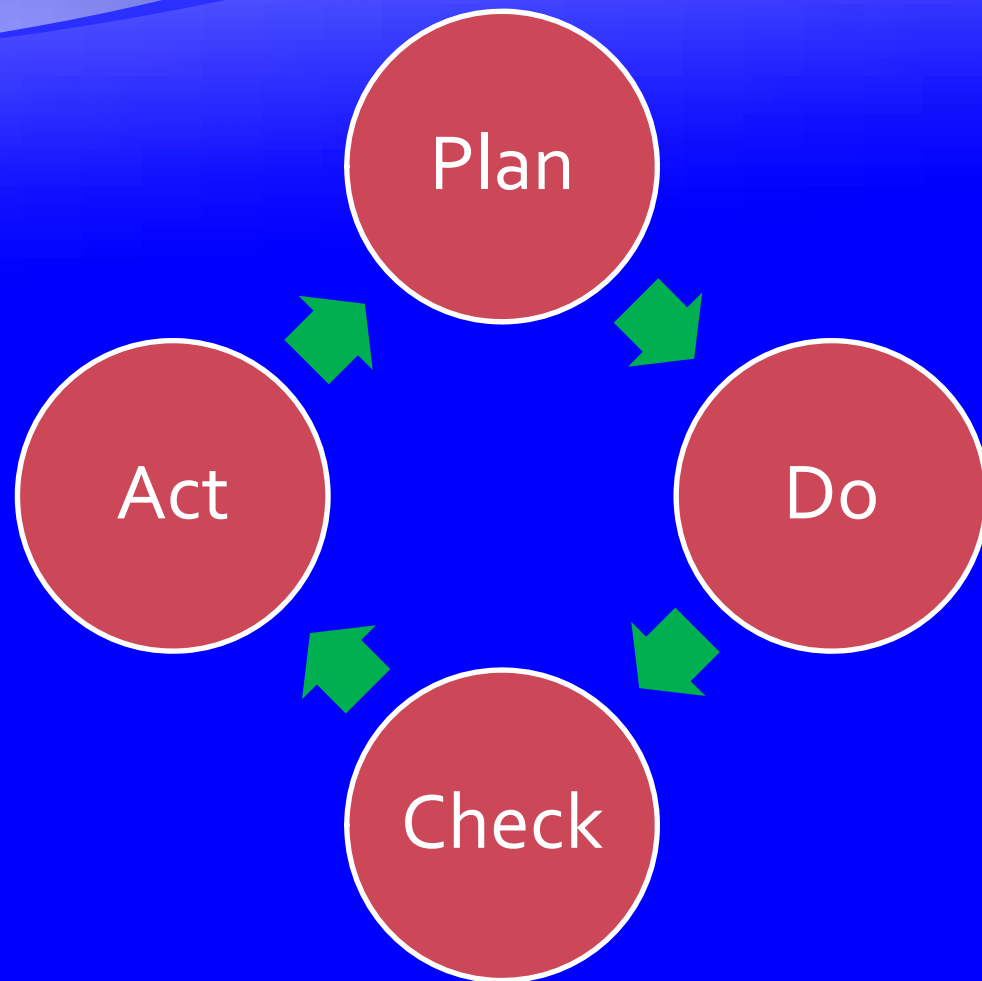
- ◆ Tasks: Implement the Risk Response Plan, Ensure Compliance, and Manage Progress
- ◆ Manage The Contingency and Management Reserves
- ◆ Communicate The Risk
 - ◆ Earned Value Analysis
 - ◆ Risk Reserve Report



Risk Monitoring and Control

Manage The Highest Risk Path,
Not Just The Critical Path

Risk Monitoring and Control



Risk Monitoring and Control

Monthly Project Status Report

Project Name: Install Board Test Station	PM: Moore	Report Date:04Feb2000
Project No. 1776	Sponsor: Franklin	Completion Date: 10Oct2002

Status	Comment
Cost	Committed spending is ahead of schedule
Schedule	
Scope	
Quality	
Risk	

Accomplishments	Successfully conducted specification review
Tasks Scheduled for Next Reporting Period	Procurement review Design review
Risks	Processor is currently on back order, contingency plan implemented



Summary

- ◆ Managing Risk In Life Sciences Industry Is Challenging
- ◆ PMBOK Tools Are Important and Useful
- ◆ Identify Risks And Opportunities
- ◆ Be Proactive
- ◆ Communicate



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