

OPxcel LLC

Business Performance Consultants



Operational Excellence Through Process Improvement

Managing Process Risk and Decision Risk

Two types of Risk

- Process Risk- The risk or cost of failures, delays, errors or defects occurring within the process.
- Decision Risk- The risk or cost of making decisions that are not aligned with internal and external Voice of Customer, Company Strategy or lack Leadership support.

Process Risk

- FMEA- Failure Risk
 - Failure Modes Effects Analysis: a tool that helps identify the possible failure modes within a process and the impact of the failures if they were to occur.

Failure Modes Effect Analysis

Process/Product
Failure Modes and Effects Analysis
(FMEA)

Process or Product Name:	
Responsible:	

Prepared by:	Page ___ of ___
FMEA Date (Orig) _____ (Rev) _____	

Process Step/Input	Potential Failure Mode	Potential Failure Effects- Gross Margin	S E V	Potential Causes	O C C	Current Controls	D E T	R P N	Actions Recommended	Resp.	Actions Taken	S E V	O C C	D E T	R P N
What is the process step/ Input under investigation?	In what ways does the process step go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the process step to go wrong?	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode? Should include an SOP number.	How well can you detect cause or FM?		What are the actions for reducing the occurrence of the Cause, or improving detection? Should have actions only on high RPN's or easy fixes.	Whose Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year				
Provide PM	Deliver more than required	Gross Margin is too low	7	Tech error	5	SMS database	10	350	Training on SMS Fast tool usage	FSL	Training provided	7	3	10	210
Provide Emergency Services	Excessive emergency Repairs completed	Gross Margin is too low	7	Improper Cost Allocation	5	Fast Tool/ Dispatch	10	350	Fast tool training	FSL	Eliminate Failure Mode by changing full service contracts to flex. See change process map	7	3	1	21
Provide PM	Deliver more than required	Gross Margin is too low	7	Time Mischarged to contract	7	Fast Tool/ Dispatch	7	343	Fast tool training	FSL	Training provided	7	3	7	147
Provide PM	Deliver more than required	Gross Margin is too low	7	Tech personal preferences	7	Fast Tool/ Dispatch	5	245	Fast tool training	FSL/ Team lead	Training provided	7	3	5	105

Decision Risk Tools

- **Prioritization Matrix- Strategic Risk**
 - A tool that helps prioritize decisions and quantify the potential ROI and customer impact.
- **QFD- Customer Risk**
 - A tool that is designed to mitigate product service and development risk as it correlates with delivering customer CTQs.

Decision Risk- Prioritization Matrix

- Prioritization Matrix – a tool designed to prioritize strategic initiatives or projects.

Quantifies 3 factors:

1. Impact to Internal Customer
2. Impact to External Customer
3. Ease of Implementation

Also takes financial impact into consideration

Decision Prioritization Matrix

Type	Brainstorming Opportunity/Recommendations	Ease of Implementation	Impact on company	Impact on Customer	Action required	Action Owner	Investment Required	OIN	Impact on Company	Financial Impact on Company	Measurement Currently Exist?	Measurement Action
Cust	Lot Release Cycle Time	10	10	10				1000			Y	
Cust	Product Yield %	10	10	10				1000			y	
Cust	Lot Release %	10	10	10				1000			y	
Internal Process	Deviation (unplanned)	10	10	10				1000			y	
Internal Process	OOL	10	10	10				1000			y	Integrate current KPI's
Internal Process	OOS	10	10	10				1000			y	Integrate current KPI's
Internal Process	Time to use for new equipment	10	10	10				1000			n	Develop Measurement and
People & Org	Employee Turnover ratio	10	10	6				600			y	
Innovation & Progress	Implementing LEAN Culture	5	10	10				500			n	Develop Roadmap and action plan
Projects	Batch record Review Process Post Fill	5	10	10	Development of LEAN focused team to identify and correct problems with current batch record review process post fill		Training, team participation outside consultancy expense.	500	Slow batch review process post fill delays the ability to capture revenue. Time spent by QA takes a day for response time and delays process by 2-3 weeks.	60 to 75 day delay in an average of \$130k in revenue recognition per batch. Improving cycle time will have positive impact on Cash Flow, Productivity and revenue. 60 batches per year. Future Desired State is 30 days for customer release.	N	Look at possibility of getting customer involved with team addressing process.

Decision Risk- QFD

■ Quality Functional Deployment-

1. **Capture Customer Priorities. Have customers rank and weigh**
2. **Evaluate competitive position and establish development priorities**
3. **Customer prioritizes, ranks and weights functional requirements**
4. **Establish targets, timing and measurement systems and validate with customer**

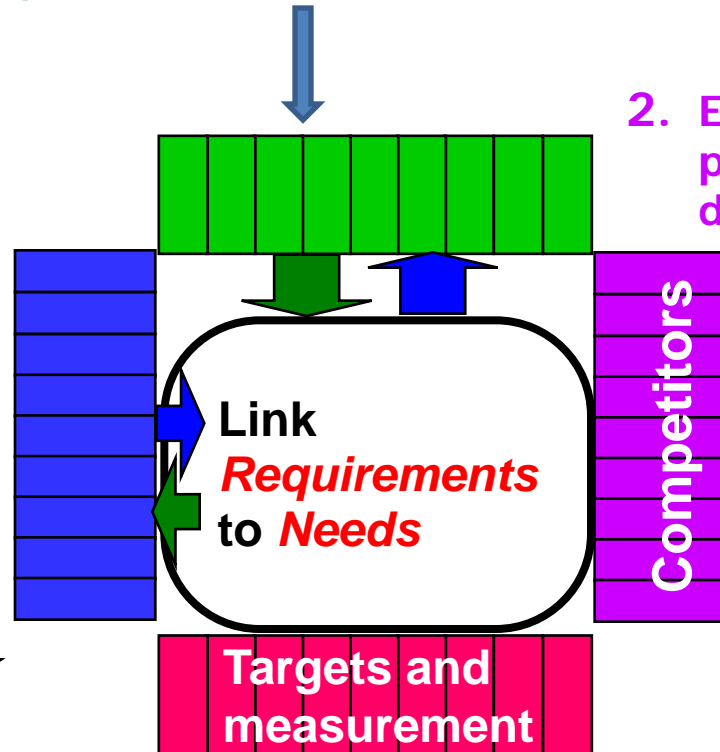
What ?

How?

3. Customer prioritizes, ranks and weights functional requirements

1. Capture Customer Priorities
 - Have customers rank and weight
 - Capture differentiators
 - Design for differentiators & not the minimum to compete

2. Evaluate competitive position and establish development priorities



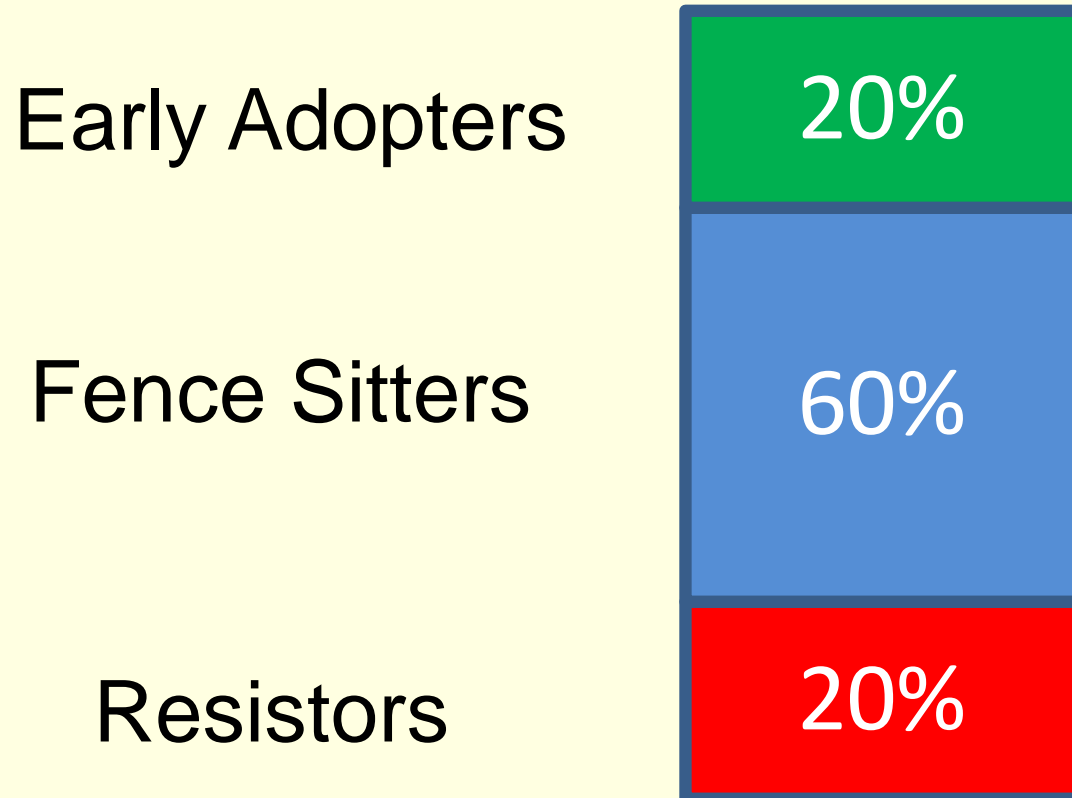
4. Define your design target and validate with customer
Establish targets, timing and measurement systems

Never Do This
Without
Multiple Customers Inputs
Within Target Segment

The Greatest Risk is Change

- Human Risk- Resistance from People

Understanding the 20/60/20 Rule



The Bottom line on Risk

- We must determine the business impact and human impact of the priorities, choices and decisions that we select to address.