



Gap Analysis and Risk Assessment

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Imagine!

- **There were no guidelines/ regulations**
- **There was no training**
- **No Procedures**
- **No Inspectors**



The aftermath

- Inform All staff of the outcome



Most Common Deadly Sins of Non-Compliance

- Inadequate Change Control
- Inadequate Validation
- Inadequate follow-up
- Repeat violations
- Inadequate Training
- Inadequate/Deficient controls



Most Common Deadly Sins of Non-Compliance

- Inadequate Failure Investigations (Non Conformances and CAPA)
- Failure to Follow Procedures
- Inadequate Internal Audits
- Inadequately staffed Quality departments

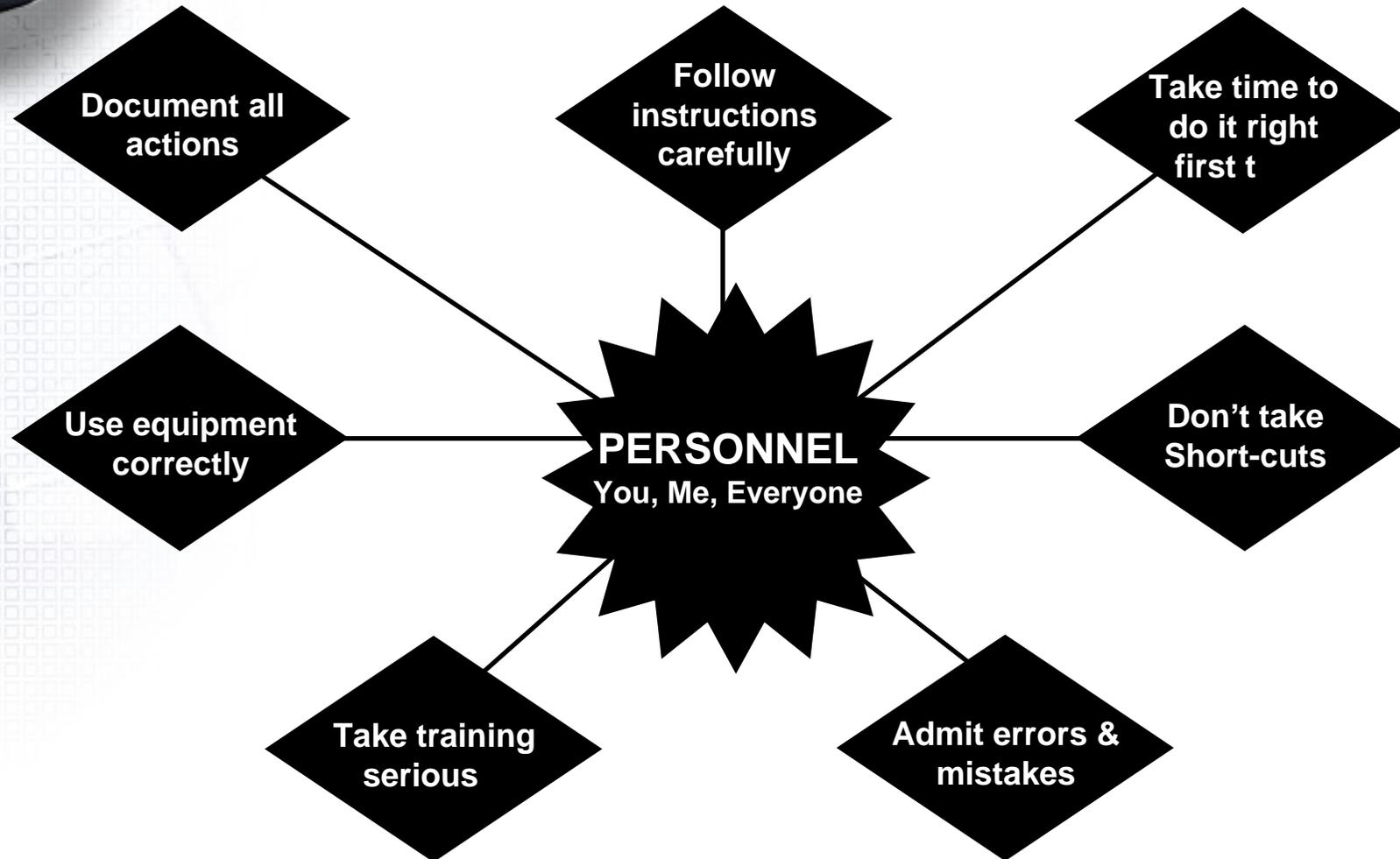


Quality Lessons for All

- Deficiencies occur / mistakes happen
- Key is to have systems in place that:
 - Investigates root causes
 - Assures complete and systematic correction
 - Documents and validates changes



What does all this mean to me?



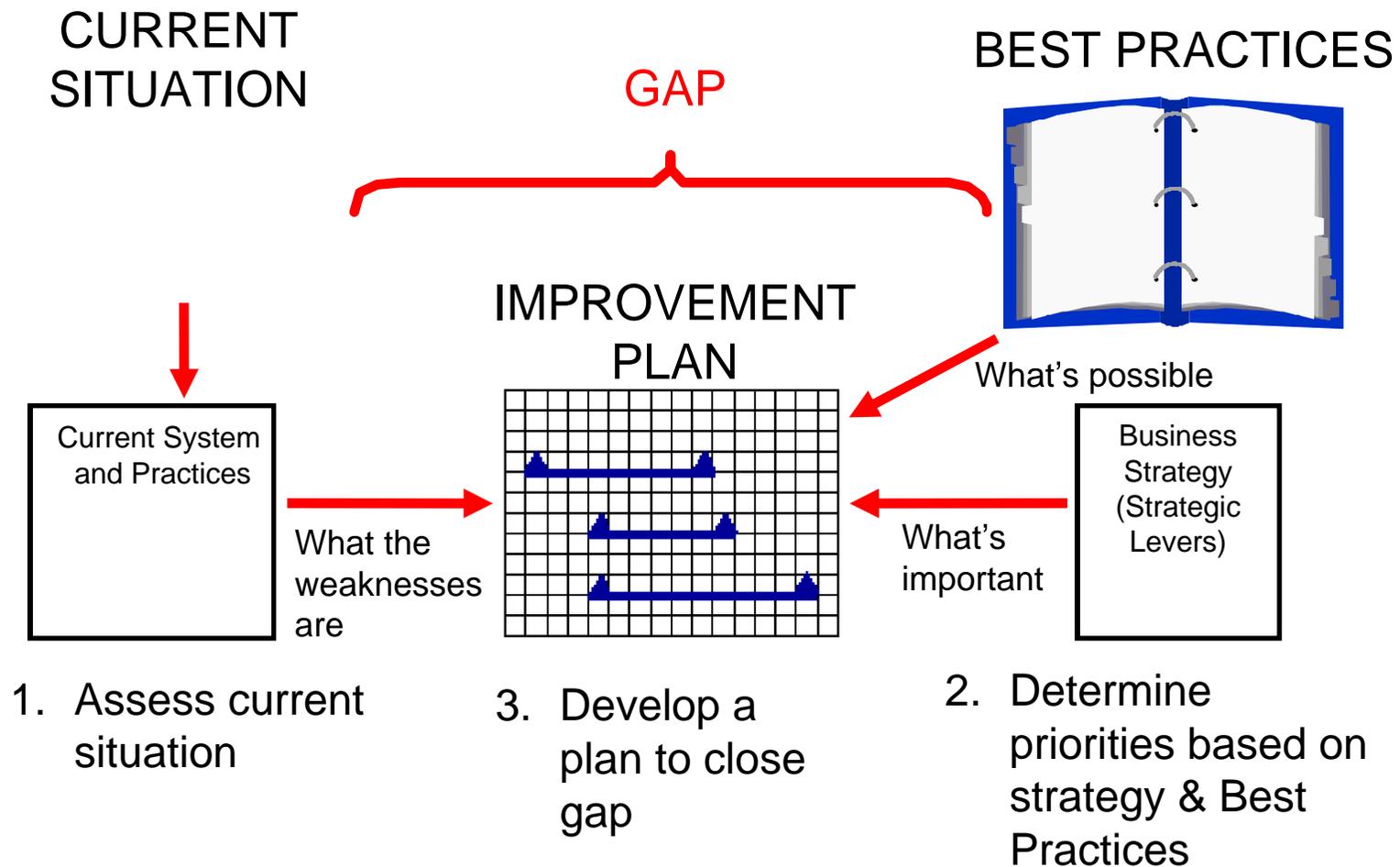


What Is a Gap Analysis?

- A way to compare current conditions and practices in order to identify gaps and areas in need of improvement with regards to compliance to the relevant standards
- Formal means to identify and correct gaps between desired levels and actual levels of performance
- Used by organizations to analyze certain processes of any division of their company



Developing An Improvement Plan





Gap analysis

Methodology

- What type of information?
- Who will collect information?
- Where from?
- How will the information be collated?
- Where will it be stored?
- Who will evaluate and analysed?
- How will information be disseminated?
- Who will disseminate?



Gap Analysis Tool

- Phase 1: Identify Gaps
- Phase 2: Fill Gaps



Gap Analysis Tool

Identify Gaps:

- Make a list of requirements, this is usually in the form of questions.
- Review of all current practices, written or otherwise
- Review for
 1. Adequacy
 2. Suitability
 3. Effectiveness
 4. Compliance



Gap Analysis Tool

Identify Gaps:

- Three answers are possible for each question:
 - **Yes** – organization has met one of requirements
 - **No** – points to a gap
 - **N/A** – question is not applicable to situation



Gap Analysis Tool

Identify Gaps:

- Each time “NO” is answered, there is a column to help organization identify which processes need to be fixed
 - Quality Management Process
 - Internal Communications Process
 - Document Control Process
 - Record Keeping Process
 - Training Process
 - Internal Audit Process
 - Management Review Process
 - Measuring and Monitoring Process
 - Nonconformance Management Process
 - Continual Improvement Process



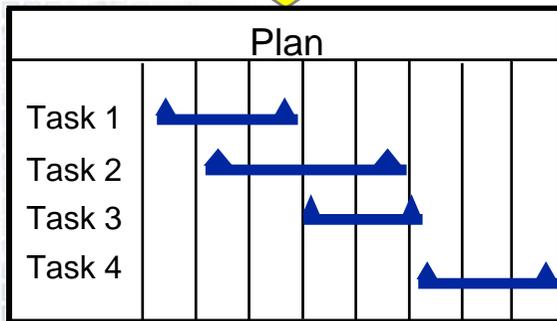
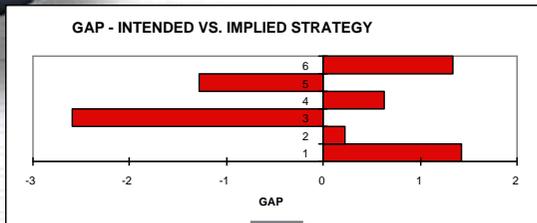
Gap Analysis Tool

Fill Gaps:

- The Gap Analysis questions are turned into action statements
- These action statements formulate remedial actions which will fill in the gaps
- Develop plans to address the gaps
- These remedial actions are used to fill the gaps that are found
- All remedial actions must be assigned a Remedial Action Number
- Job responsibilities are then given out to make sure that the remedial actions are carried out



Developing The Action Plan



Assessment Category	Assessment Weight	Company Weight	Effectiveness
Business & Product Strategy	0.5	1	3.2
Product & Pipeline Management	1	1	3.7
Technology Management	0.75	1	2.8
Management Leadership	1	1	4.5
Early Involvement	1	1	5.1
Product Development Teams	1.5	1	5.3
Organizational Environment	1	1	6.4
Process Management	1	1	3.4
Process Improvement	0.75	1	3.3
Understanding the Customer	1	1	3.9
Requirements & Specifications Mgt.	1.5	1	3.4
Development Process Integration	1	1	5.0
Supplier/Subcontractor Integration	1	1	4.7
Product Launch	1	1	5.1
Configuration Management	1	1	6.8
Design Assurance	0.75	1	6.6
Project & Resource Management	1.25	1	3.5
Design for Manufacturability	1	1	4.4
Product Cost Management	1	1	4.2
Robust Design	1	1	5.7
Integrated Test Design & Program	0.75	1	6.1
Design for Operation & Support	0.75	1	4.7
Product Data	1.25	1	3.5
Design Automation	1.25	1	5.2
Simulation and Analysis	1	1	3.8
Computer-Aided Manufacturing	0.75	1	4.6
Collaborative Tools & Technology	0.75	1	2.9
Knowledge Management	0.5	1	4.2
Weighted Total			4.5



1. Identify performance gaps relative to categories
2. Identify strategy gaps and associated practices
3. Examine individual practices with low performance & high importance in large gap categories & strategies
4. Look for logical relationships & precedence among practices
5. Develop the action plan & gain consensus to the plan



How to effectively approach the project?

- Steering committee and task force
- Diagnosis of an existing system
- Execution plan
- Training
- Planning, Documenting
- Implementation
- Audits and review
- Possible changes



Planning

- Prioritize development projects
- Don't overload resources
- Rapidly staff the project according to plan
- Capture and document requirements and specifications completely
- Tightly manage requirements
- Plan concurrent development
- Learn to work with partial information
- Plan and coordinate requirements
- Resolve problems quickly
- Create a comprehensive, realistic project plan



Planning

- Obtain personnel's commitment to the project plan
- Communicate project plans and responsibilities
- Identify project staffing requirements
- Plan development resource requirements
- Allocate and manage resources
- Standardize where possible
- All review the plan on a regular basis



Summary of Gap Analysis

- Gaps can be found in any process of an organization's operations
- Gap Analysis is one of the best procedures to help lead an organization to not only improve their processes, but recognize which processes are in need of improvement.



What is Risk?

**The danger or probability of
loss/error.**



What is Risk Management?

“The culture, processes and structures that are directed towards the realization of potential opportunities and the effective management of adverse effects”



What is risk?

Many Definitions:

- It is widely accepted that the concept of risk has two components – Chance & Consequences:
 - How likely is the scenario to happen?
 - If it does happen, what are the consequences?

Key Considerations:

- The probability of occurrence of harm, (chance, possibility, uncertainty, etc.)
- The consequences or severity of that harm, (injury, cost, supply issues, etc.)

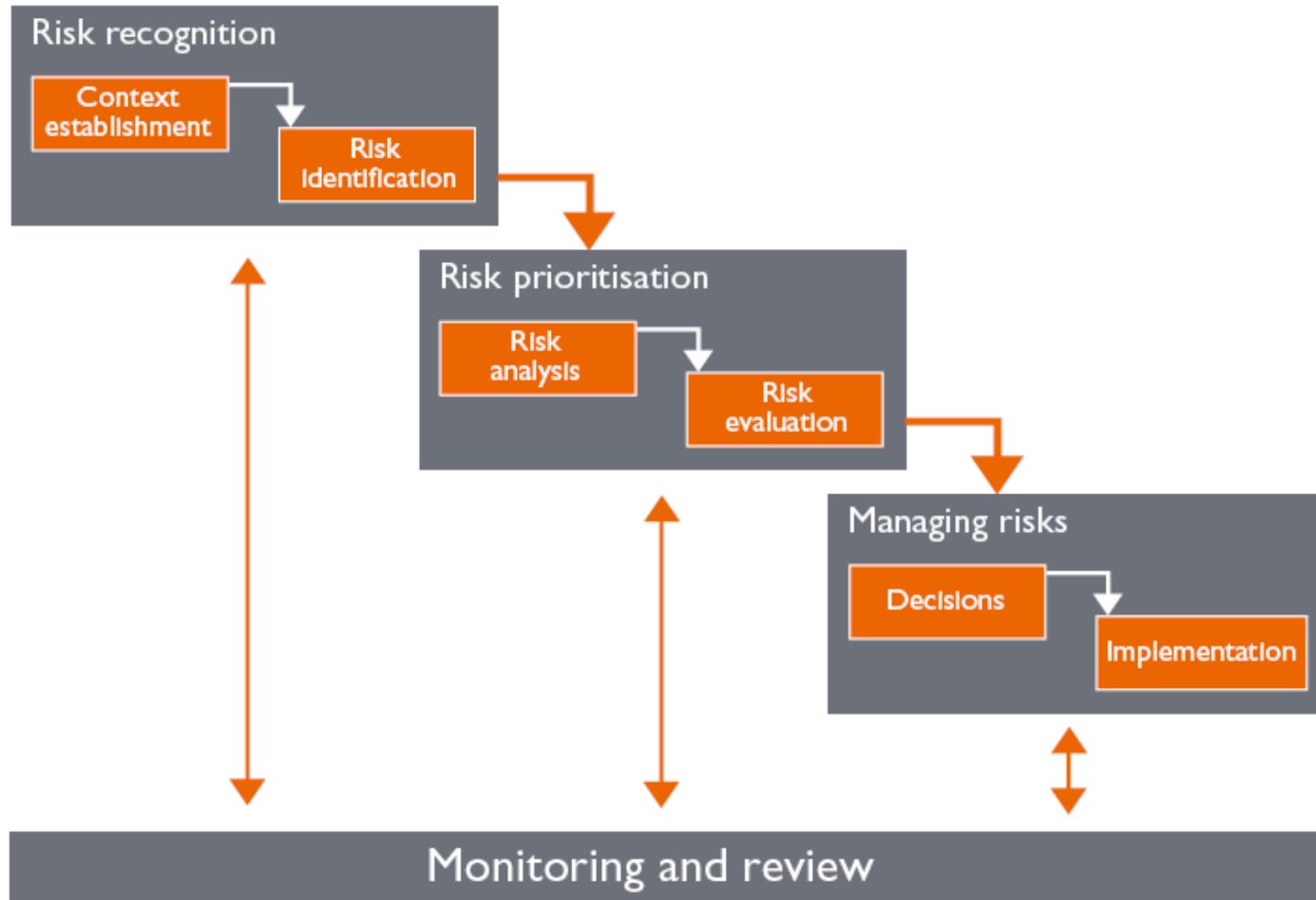


Risk Assessment.....

- How do we reduce the chance of errors occurring?
- Examination of process and develop safety barriers to minimise chance of error.
- Understand why risk needs to be managed and what the risk is.
- Understand where risk comes from and how people process information



Risk Management Process

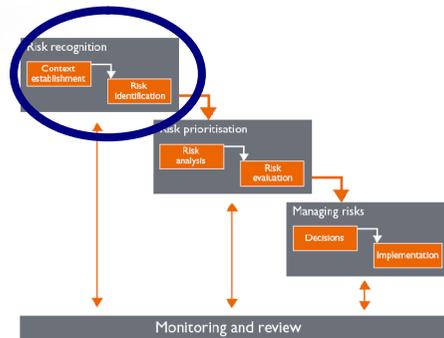




Recognition in Risk

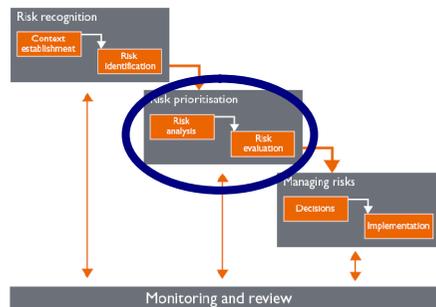
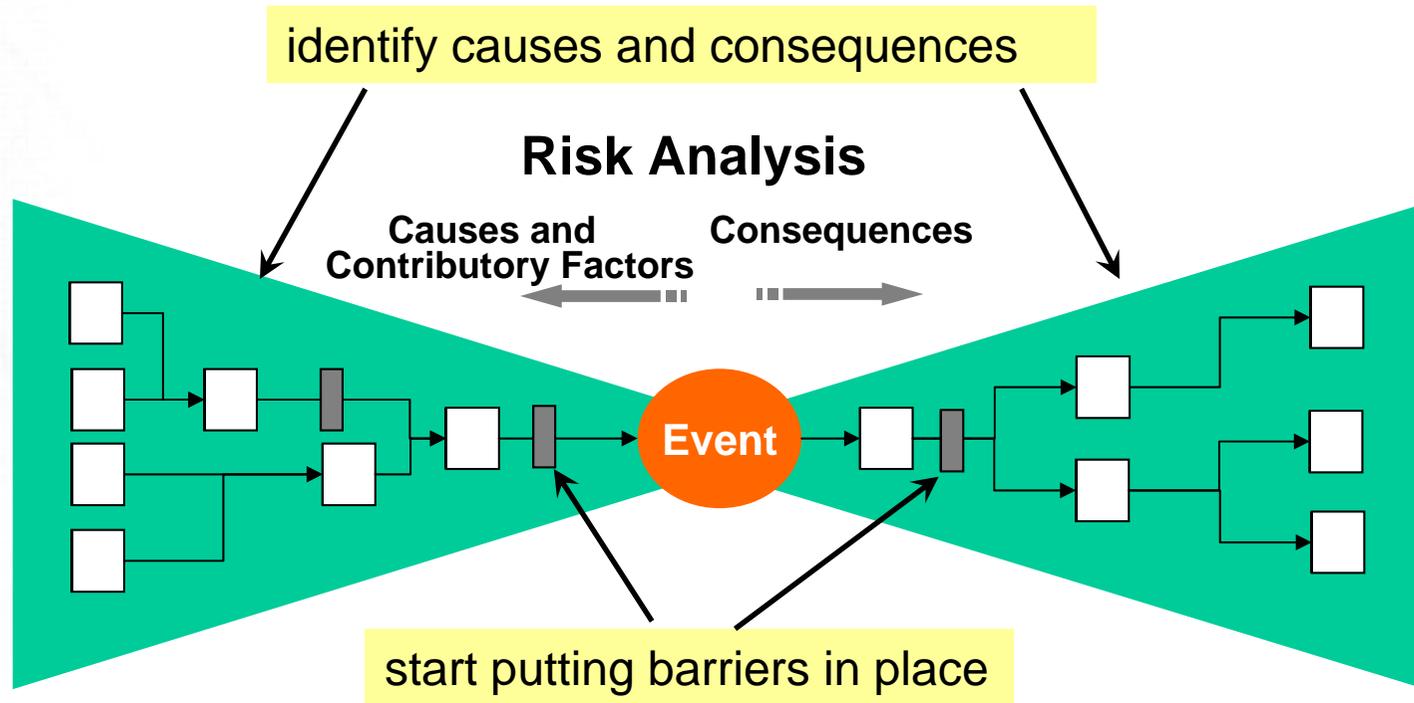
start by identifying what may happen

Event





Risk Prioritisation

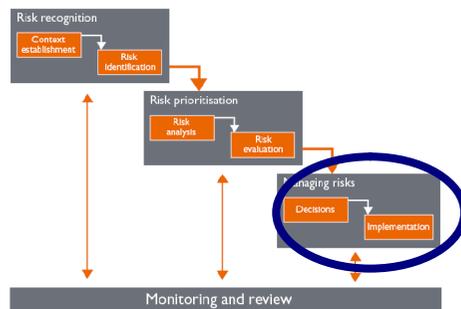
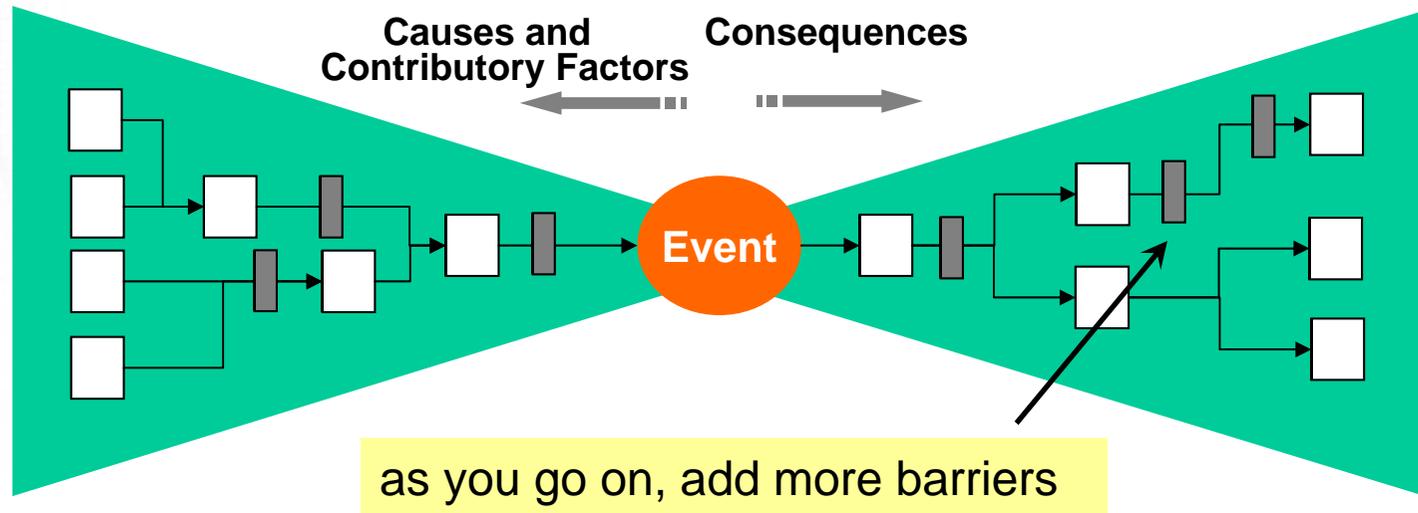


- = Risk Measures (Barriers)**
- Safety Related Systems: IT ,
 - Safety Systems: Other Technologies
 - External Risk Reduction Measures



Risk Management

Risk Analysis

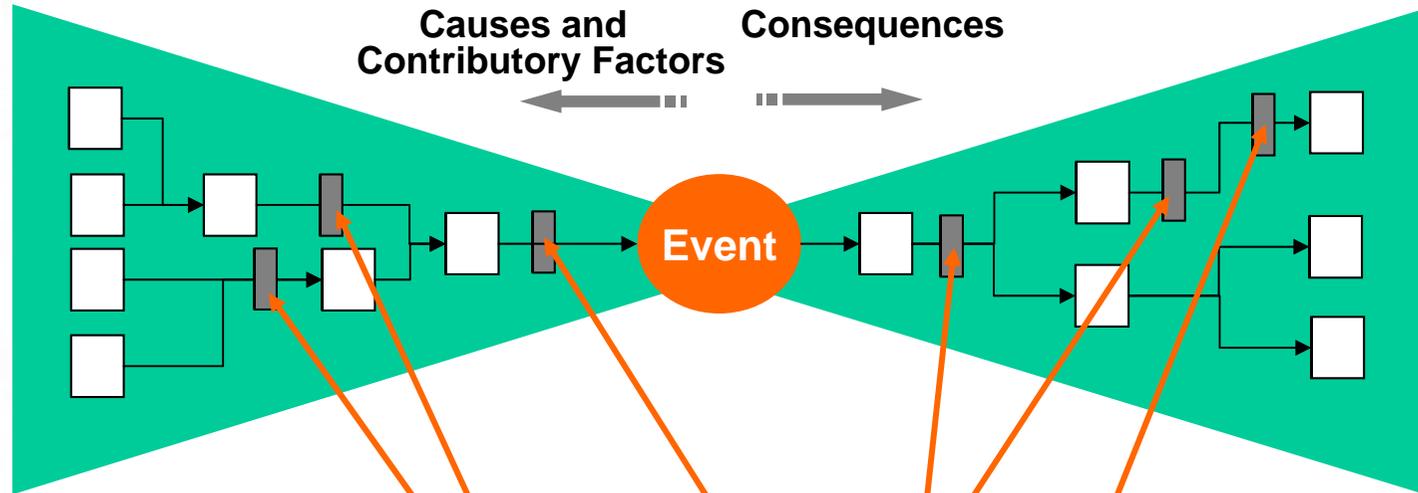


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Risk Management Activities

Risk Analysis



Risk Management Activities

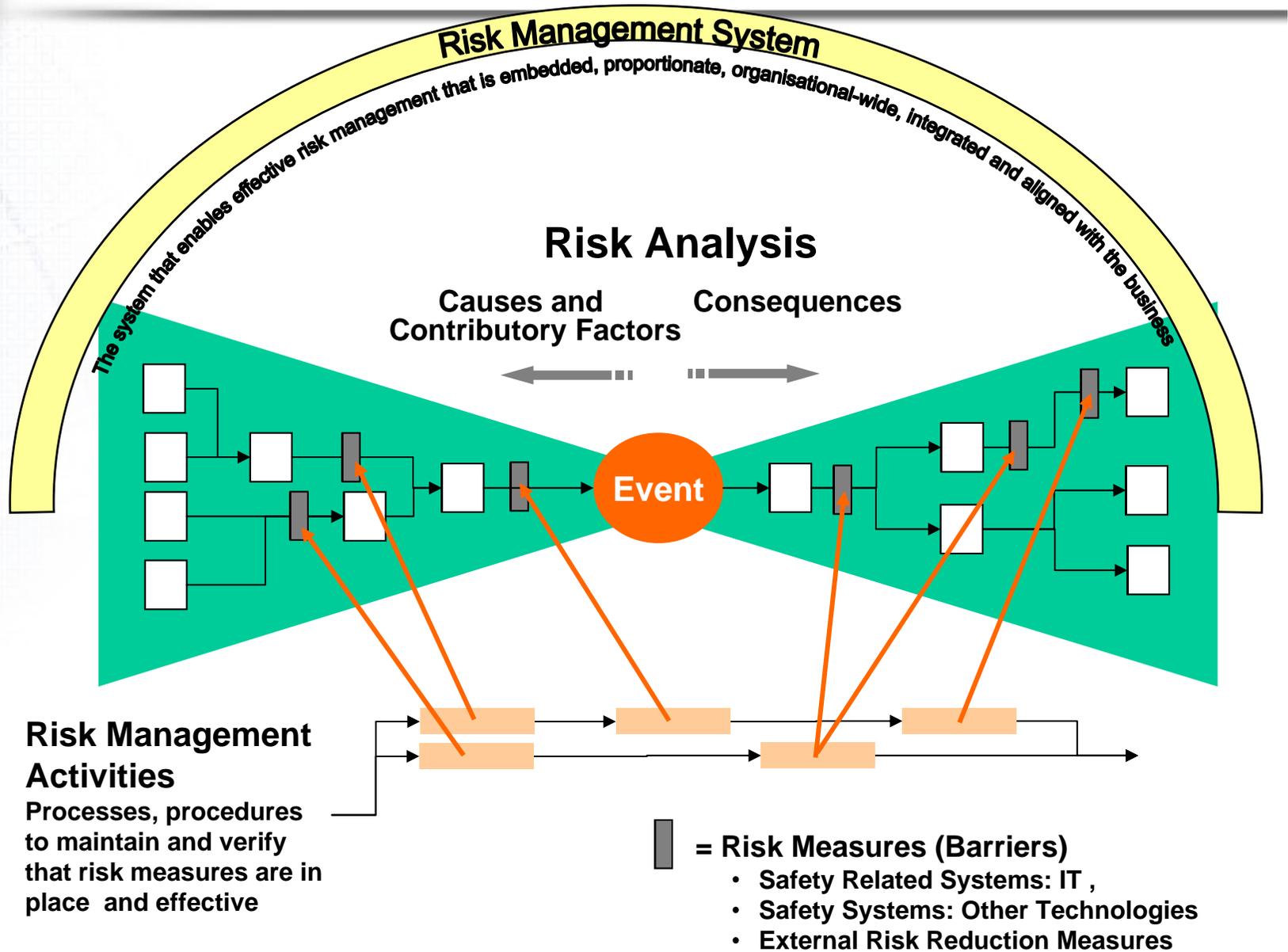
Processes, procedures to maintain and verify that risk measures are in place and effective

- = Risk Measures (Barriers)**
 - Safety Related Systems: IT ,
 - Safety Systems: Other Technologies
 - External Risk Reduction Measures

constantly ensure barriers are maintained



Risk Management Activities





A Risk Definition

- Risk is the combination of the probability of occurrence of harm and the severity of that harm
 - Risk = Probability x Severity
 - Risk = (P x S)
- Risk can be Quantified or Qualified
 - Risk = (4 x 3) = 12
 - Risk = (Moderate x Major) = Unacceptable



What about Detection?

- Are Detection Controls not taken into account?
- Is Risk Not (Probability x Severity x Detection)?
 - Risk Priority Number (P x S x D) often used, especially in FMEA, FMECA
 - Advantage – simple concept, easy to use and understand

Comment

- There is much confusion about where to consider detection controls during Risk Assessment....



Probability of Occurrence Levels

<i>Probability</i>	<i>This Means The Failure Mode...</i>
<i>Frequent</i>	... is Very Likely to Occur, > 20%
<i>Probable</i>	... will Probably Occur, 5 – 20%
<i>Occasional</i>	... should Occur at Some Time, Infrequently, 0.1 – 5%
<i>Remote</i>	... Unlikely to Occur in Most Circumstances < 0.1%

Note: These levels are arbitrary and for illustrative purposes only



Severity Levels

<i>Severity</i>	<i>This Means the Failure Mode May Result in....</i>
<i>Critical</i>	Very Significant Non-Compliance with GMP or Patient Injury
<i>Major</i>	Significant Non-Compliance with GMP or Patient Impact
<i>Minor</i>	Minor Infringement of GMP No expected Patient Impact

Note: These levels are arbitrary and for illustrative purposes only



Risk Table – Acceptance Criteria

<i>Failure Mode</i>	<i>Minor Severity</i>	<i>Major Severity</i>	<i>Critical Severity</i>
<i>Frequent</i>	Orange	Red	Red
<i>Probable</i>	Orange	Orange	Red
<i>Occasional</i>	Green	Orange	Orange
<i>Remote</i>	Green	Green	Orange

Note: These criteria are arbitrary and for illustrative purposes only



Risk Table – Acceptance Criteria

<i>Failure Mode</i>	<i>Minor Severity</i>	<i>Major Severity</i>	<i>Critical Severity</i>
<i>Frequent</i>	Unacceptable	Intolerable	Intolerable
<i>Probable</i>	Unacceptable	Unacceptable	Intolerable
<i>Occasional</i>	Acceptable	Unacceptable	Unacceptable
<i>Remote</i>	Acceptable	Acceptable	Unacceptable



Acceptance Criteria Notes

- **Red Means...**
 - The Risk is Intolerable. Eliminate the Hazard or build in systems/controls to ensure the effects of the hazard are not realised (e.g. redundant systems)
- **Amber Means...**
 - The Risk is Unacceptable. The Risk must be Reduced or Controlled to an acceptable level
- **Green Means...**
 - The Risk is Acceptable. No Reduction or New Controls are Required



Detection Levels

<i>Detection</i>	<i>This Means....</i>
High	High Likelihood that Controls will Detect the Failure Mode or its Effects
Medium	Medium Likelihood that Controls will Detect the Failure Mode or its Effects
Low	Low Likelihood that Controls will Detect the Failure Mode or its Effects
None	Detection Controls are Absent

Note: These levels are arbitrary and for illustrative purposes only



What is FMECA?

Failure Mode, Effects & Criticality Analysis

- A Risk Assessment tool based around *Failure Modes*
- (A Failure Mode is a way in which a process can fail to provide the anticipated result)

FMECA...

- Identifies potential Failure Modes in a system, facility, process or product
- Prioritises the Failure Modes in accordance with their risk
- Puts controls in place to address the most serious concerns



Human Factors

- However, around 80% of accidents are attributable to human factors
- What are the contributing factors in the images in the next two slides?



What Caused the Problem

- Is it the donkey's fault?
- Is there something wrong with the design of the cart?





What Caused the Problem

- Is this a problem caused by the design of the plane?
- Why did this happen when this is something these people do many times everyday?





Some General Considerations for Risk Assessment and Risk Management

Start Early!

- It is more difficult and more costly to make changes to a process, facility, system or product after the fact than early on

Map the Process.... and do this well.

- A well mapped process is usually a major advantage when doing Risk Assessment work
- This is also a prerequisite of most Risk Assessment tools, eg FMEA,



On-going?

- Risk Management should be viewed as an on-going Quality Management process



What's in a Name?

Many of us do Risk Assessment & Risk Management without calling it this...

- Warehouse Temperature Mapping is a form of Risk Assessment
- Change Control is a Risk Management tool to a degree
- A Company Validation Master Plan is a form of Risk Management
- Self-Inspection Programme is a component of Risk Assessment



What to expect during Inspections

- Inspectors may ask to see evidence of how Risk Assessment was used when determining what qualification & validation work was carried out on a certain process, piece of equipment, etc
- Inspectors may ask to see evidence of how Risk Assessment was used when designing qualification & validation protocols, and in Change Controls
- Inspectors will not require any specific Risk Assessment tool to have been used
- We will look for evidence that hazards were adequately identified and that risks were adequately assessed & managed
- We will ask to see how risk acceptability criteria were chosen



In Summary.....

