The Risk Management Primer: Getting Started with Risk in ISO 9001:2015

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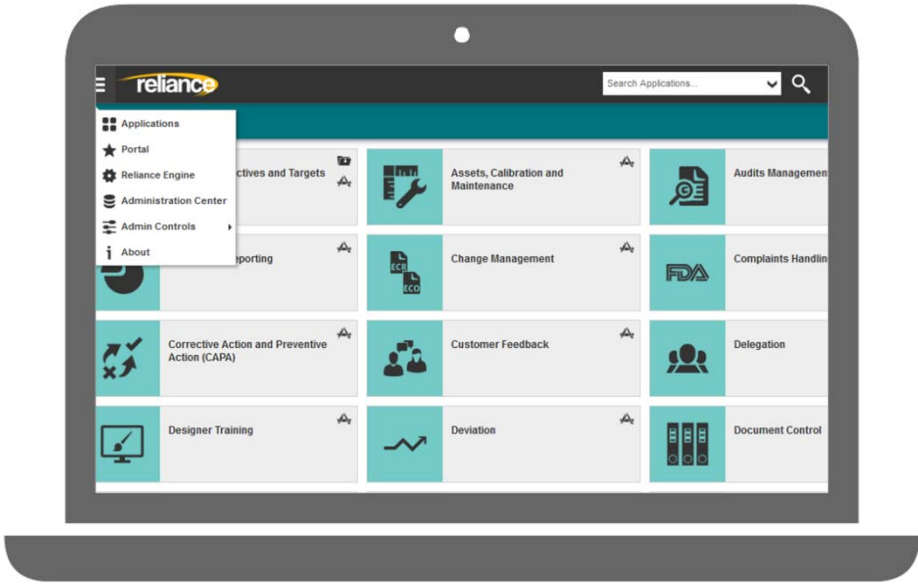
EtQ Reliance

Quality and Compliance Management Solution

Gain Visibility and Control over Compliance.

- Configurable workflow-based business process automation tool
- Web-based workflow ensures consistent processes
- Enterprise Reporting and Analytics
- Quantitative Operational Risk Management methodology and tools



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Agenda

- Understanding Operational Risk Management
- How Risk Management processes drive new ways of looking at compliance in operations
- ISO 9000:2015 and Risk Management
- Common tools for leveraging risk in compliance

Increasing Rate of Change

There is an Increasing Rate of Change

- We are more complex
  - Global Scale of Production, Design, Sourcing
  - More Mergers, Acquisitions
  - Growing Supply-Chain
- There is more competition
  - Competition leads to shorter product lifecycles
  - Increases in product complexity
  - More variety of goods in more areas
- Companies need to maintain compliance AND keep up with the pace of business!

Time to shift our mindset?

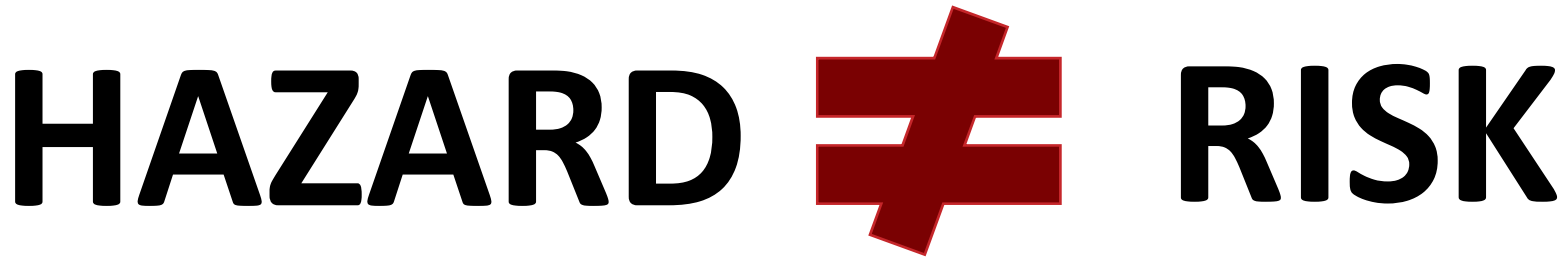
- How compliance keeps up with change
  - Automation of compliance processes
  - Integration with business systems
  - Harmonization of compliance processes

- Cost of compliance is skyrocketing
  - Cost of systems, people and time
  - Cost of holding back operations
  - Cost of holding back inventory

- Quality and Compliance need to expand!
  - We must think beyond Quality silo
  - From audit results to risk assessments
  - Risk is a more efficient measure of compliance

Risk Management Primer: Hazard vs Risk

- The terms "hazard" and "risk" are often used interchangeably. However, in terms of risk assessment, these are two very distinct terms.



Risk Management Primer: Hazard

- ***1.Insurance:*** *Condition or situation that creates or increases chance of loss in an insured risk, separated into two kinds (1) Physical hazard: physical environment which could increase or decrease the probability or severity of a loss. It can be managed through risk-improvement, insurance policy terms, and premium rates. (2) Moral hazard: attitude and ethical conduct of the insured. It cannot be managed but can be avoided by declining to insure the risk.*
- ***2.Workplace safety:*** *Dangerous event or situation that may lead to an emergency or disaster. It could also be a biological, chemical, or physical agent in (or a property of) an environment that may have an adverse health effect, or may cause injury or loss. As such, a hazard is a potential and not an actual possibility.*

Read more:
http://www.businessdictionary.com/definition/hazard.html#ixzz3miUj2jq1

Risk Management Primer: Risk

- Risk is defined as the probability that exposure to a hazard will lead to a negative consequence, or more simply:

Risk = Hazard x Probability of **Exposure**

- Thus, a hazard poses no risk if there is no exposure to that hazard.

Risk Management Primer: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

3 in a boat

Three people crossing the Atlantic in a rowboat face a hazard of drowning...

300 in a ship

Three hundred people crossing the Atlantic in an ocean liner face the same hazard of drowning

Risk Management Primer: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

The risk to each individual per crossing is given by the probability of the occurrence of an accident in which he or she drowns

RISK = probability of accident occurring x hazard

High Probability = equipment, # of people, environment

Low Probability = equipment, # of people, environment

Risk Management Primer: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

The hazard [drowning] is the same for each individual, but the risk [probability of drowning] is greater for the individuals in the rowboat than in the ocean liner

Hazard = Hazard

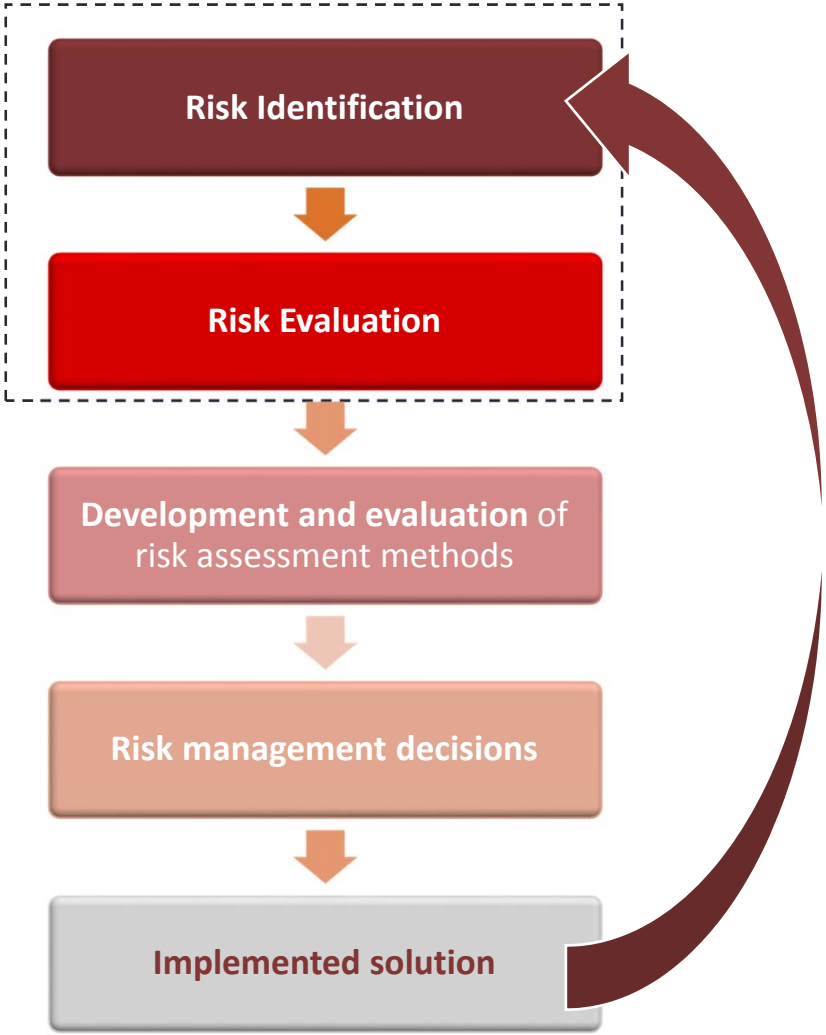
Probability > Probability

MORE RISK

LESS RISK

Risk Management Primer – the Process

- Risk Management is a broad standard (ISO 31000)



Identify all relevant risks (e.g., hazard analysis)

Quantify the risk (e.g., probability and severity)

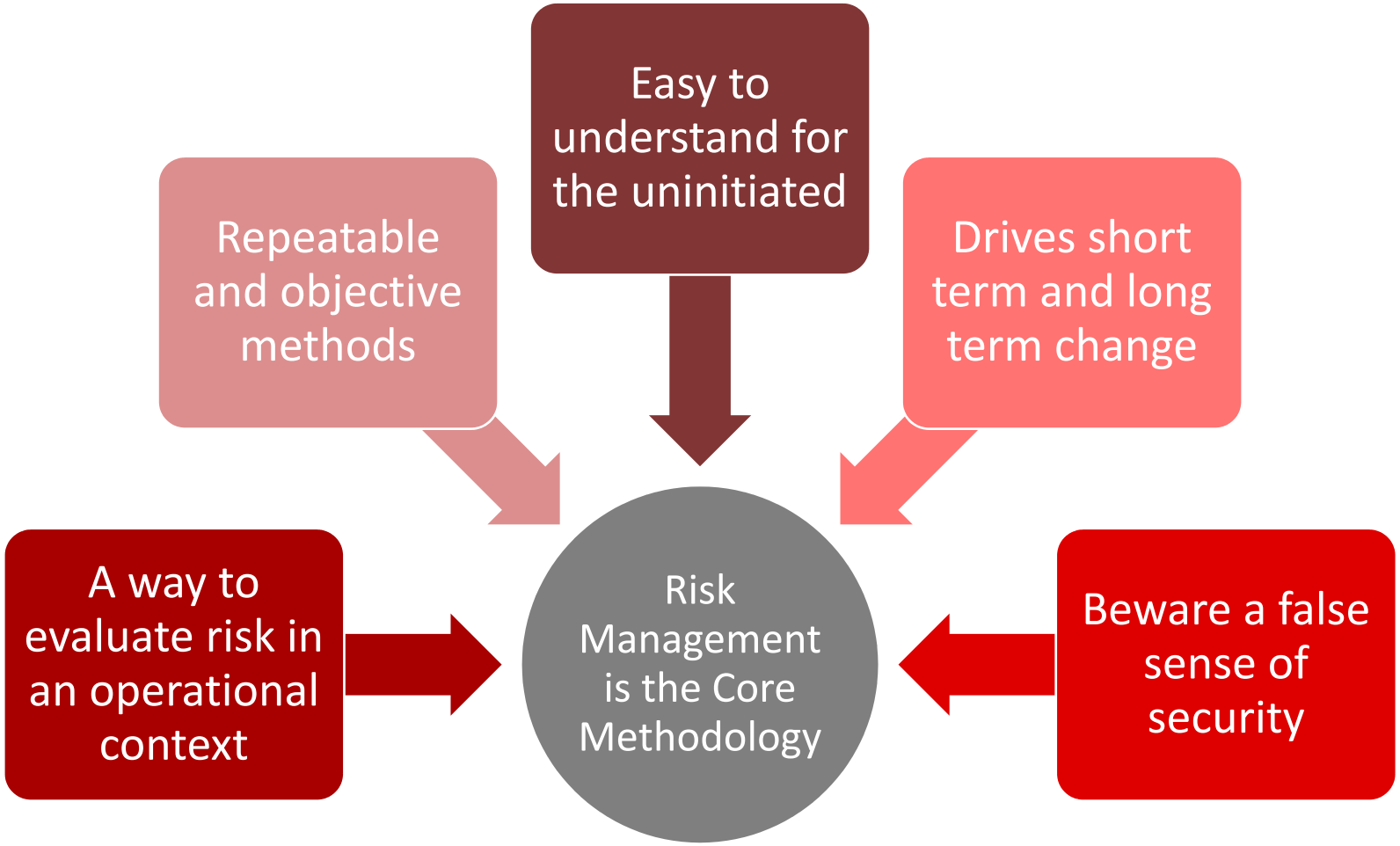
Implement a process
Use objective and proven tools

Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)

Change management to introduce or improve controls

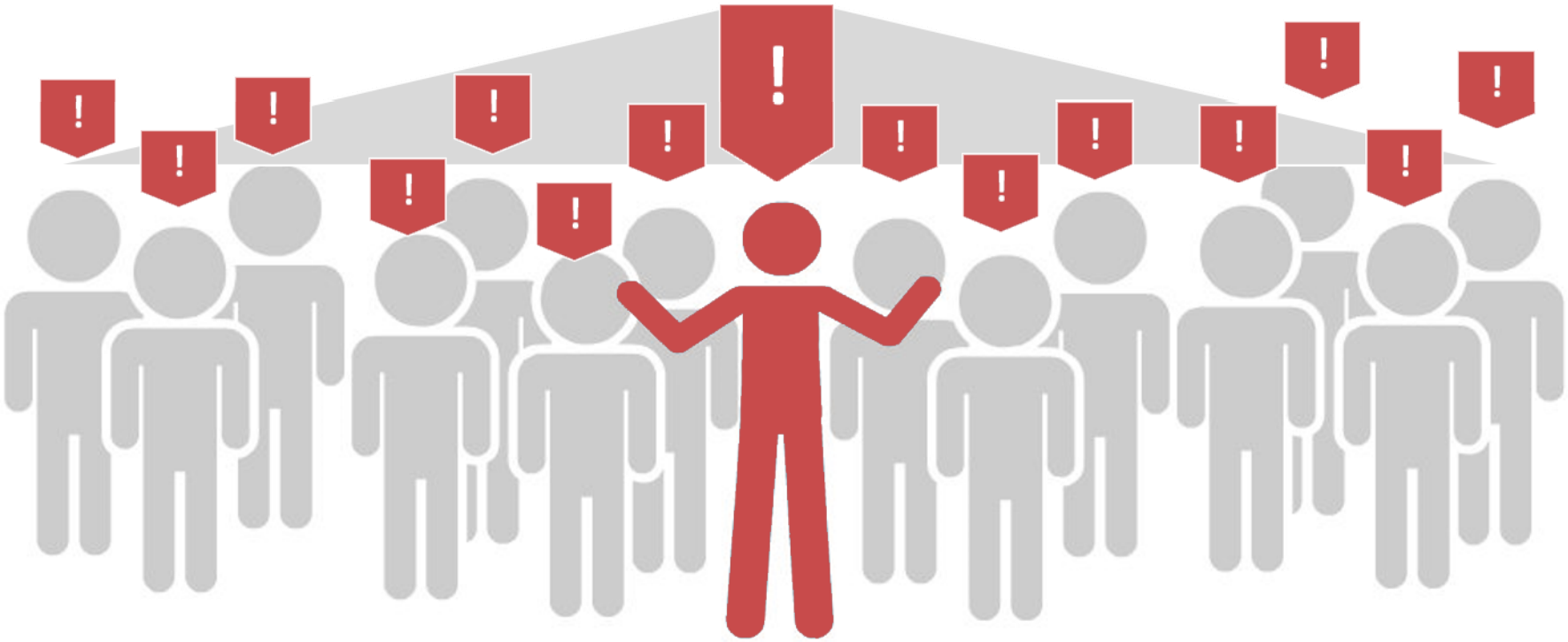
Risk Management Primer: Areas of Coverage

Risk Management Primer: Rationale for Risk



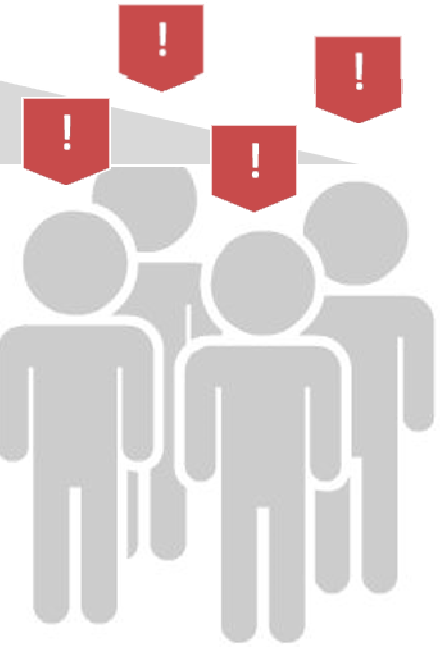
ISO 9000:2015….it's not just requirements,

It's a company mindshare of Quality.



There should be a company-wide commitment/leadership around Quality

ISO 9000:2015 view on risk



Section 5: Leadership

Provide leadership by encouraging a focus on quality

Promote the use of risk-based thinking.

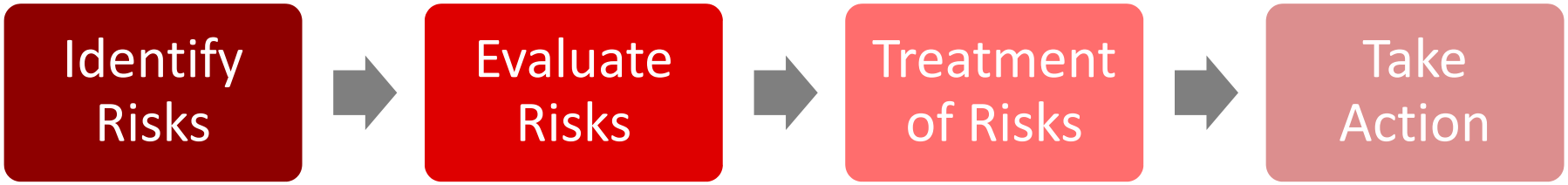
Section 6: Planning

Consider risks and opportunities when you plan your QMS

Plan how you're going to manage risks and opportunities

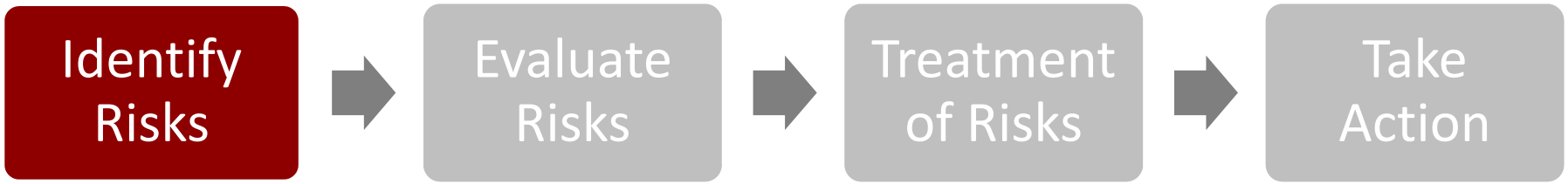
DISCLAIMER: The ISO view on risk is SIMPLY STATED. "Use Risk-based thinking" to manage and plan…. But what does that really mean? Broad, and simple – lots of interpretation!

Planning your QMS with risk in mind

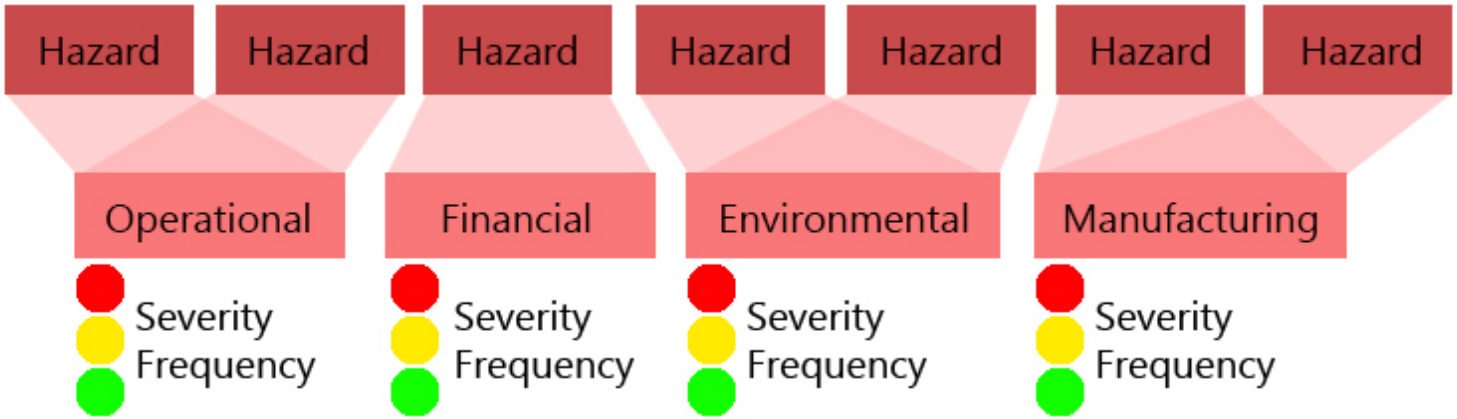


- Identify risks and opportunities to influence QMS performance
- Determine how you're going to measure those risks
- Build risk treatment options
- Define actions to address these risks

Planning your QMS with risk mind



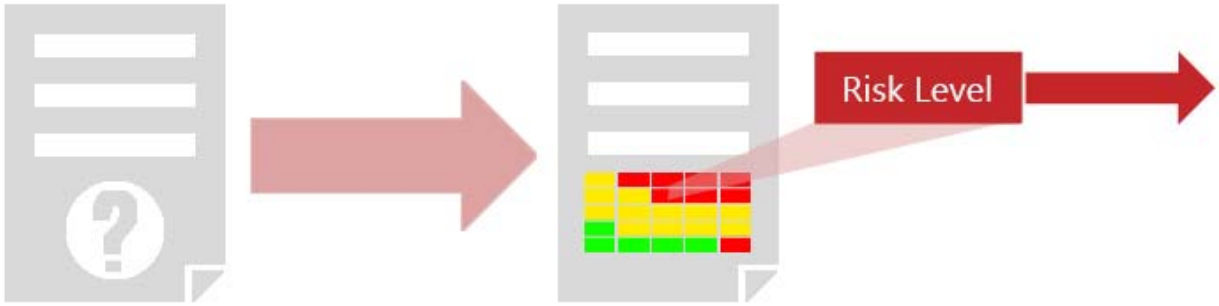
- How to start Identifying risks?
  - Survey your operations
  - Audit, Survey, collect, analyze



Planning your QMS with risk in mind

Identify Risks → **Evaluate Risks** → Treatment of Risks → Take Action

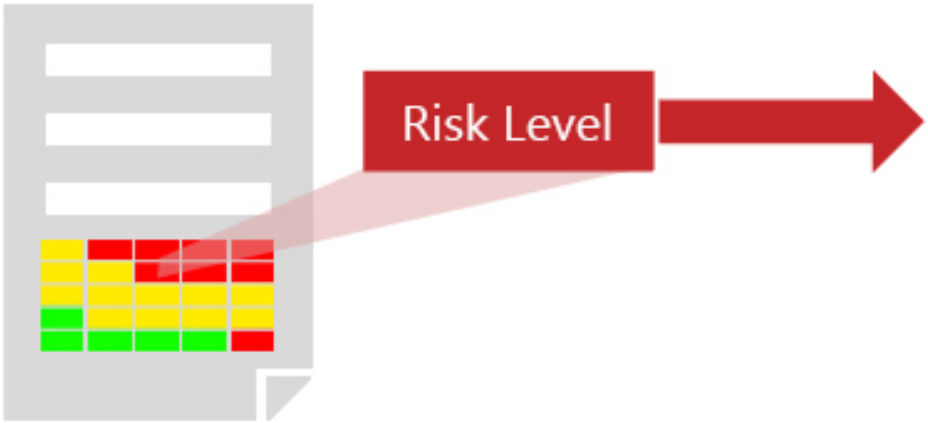
- Evaluate How to handle the risk
- Risk Assessment
  - Should be repeatable, objective
  - Should be backed by REAL-WORLD DATA
- Quantitative means to build a risk assessment



Planning your QMS with risk in mind

Identify Risks → Evaluate Risks → **Treatment of Risks** → Take Action

- We know the risk….how do we handle it?

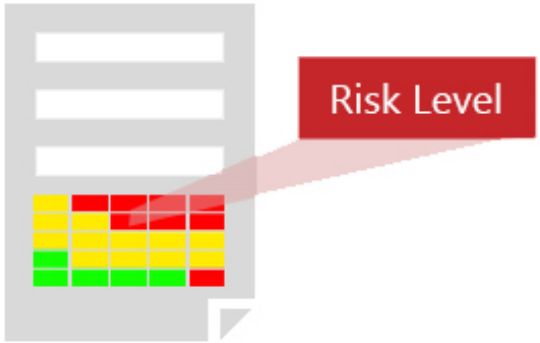


Acceptance: “Worth it”
Reduction: “Mitigation”
Compensation: “Insurance”
Transference: “Move it”
Avoidance: “Stop it”

Planning your QMS with risk in mind

Identify Risks → Evaluate Risks → Treatment of Risks → Take Action

- Take Action: Create Visibility and Control the Risk

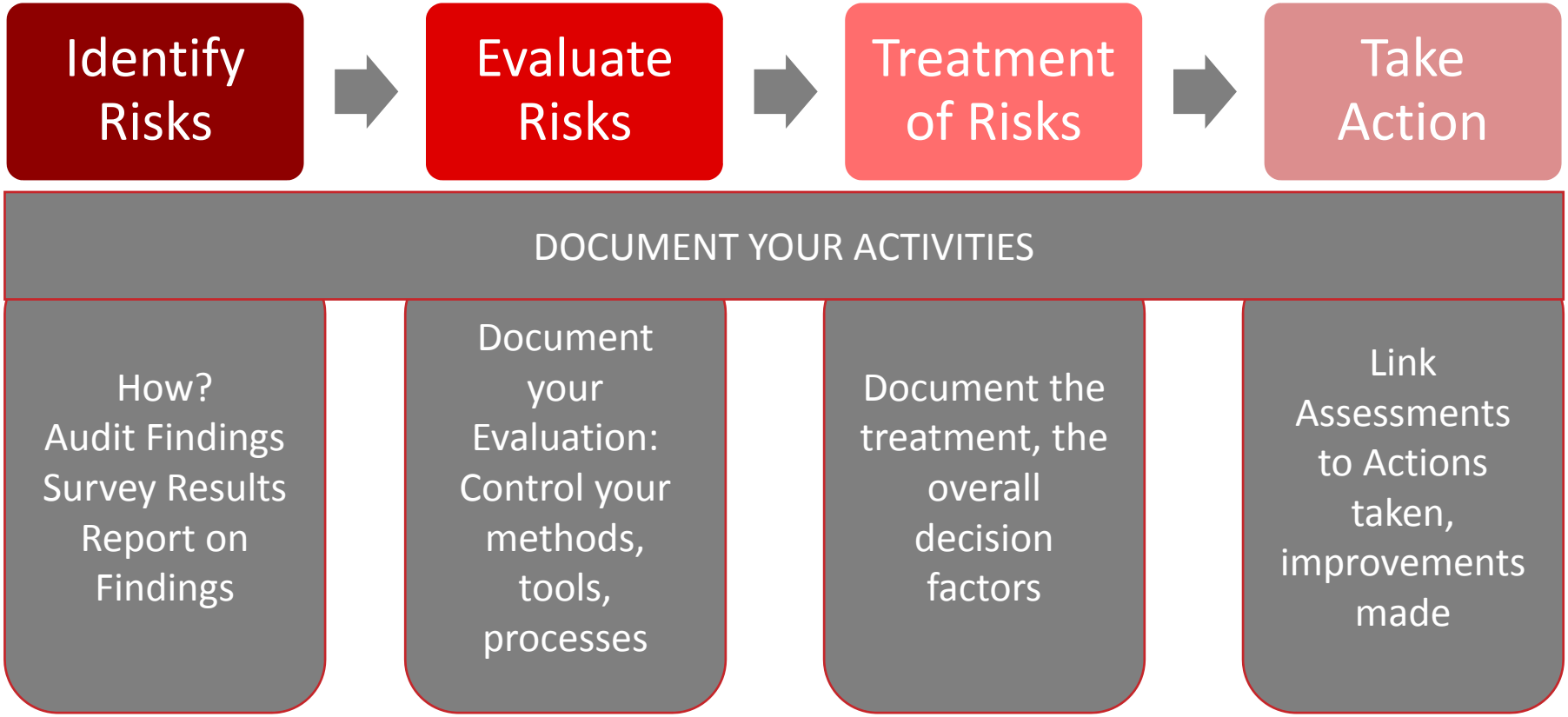


Corrective/Preventive Action

Controls/Action Plans

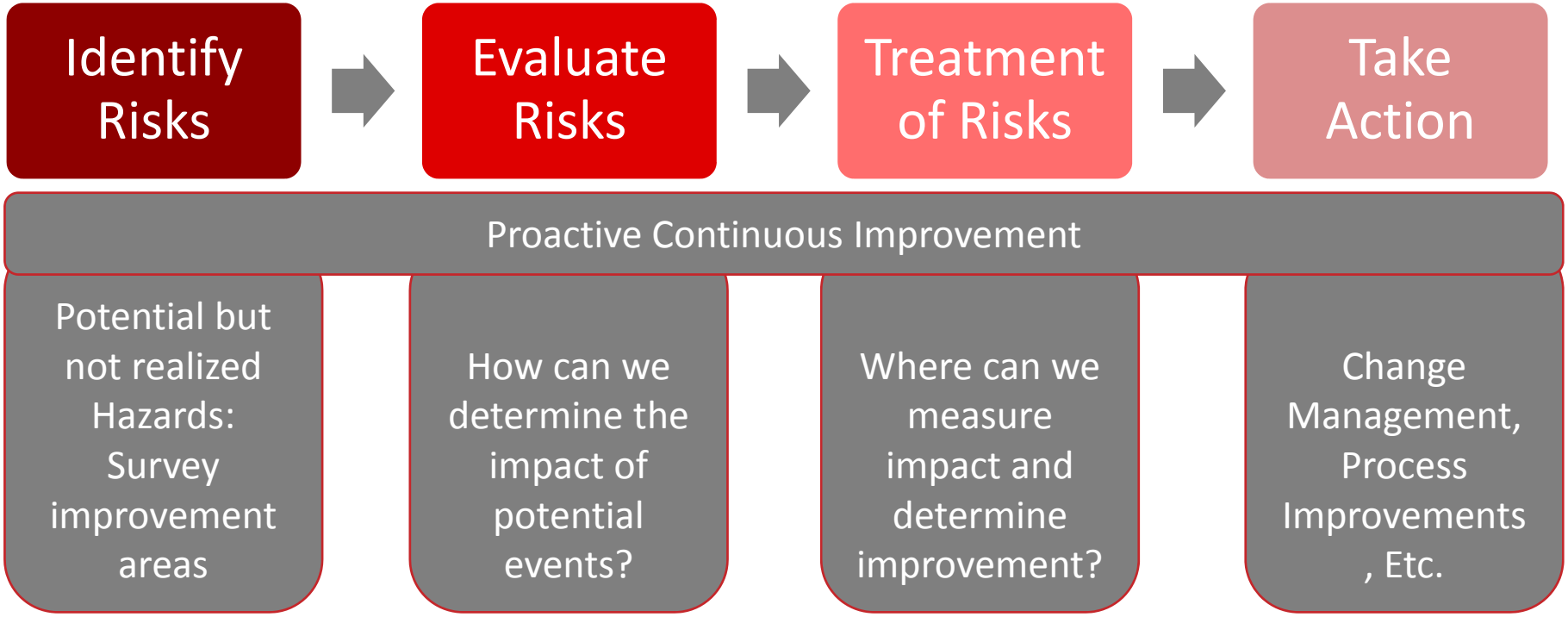
Reporting/Trending

Planning your QMS with risk in mind



Document the process in order to have traceability.

Planning your QMS with risk in mind

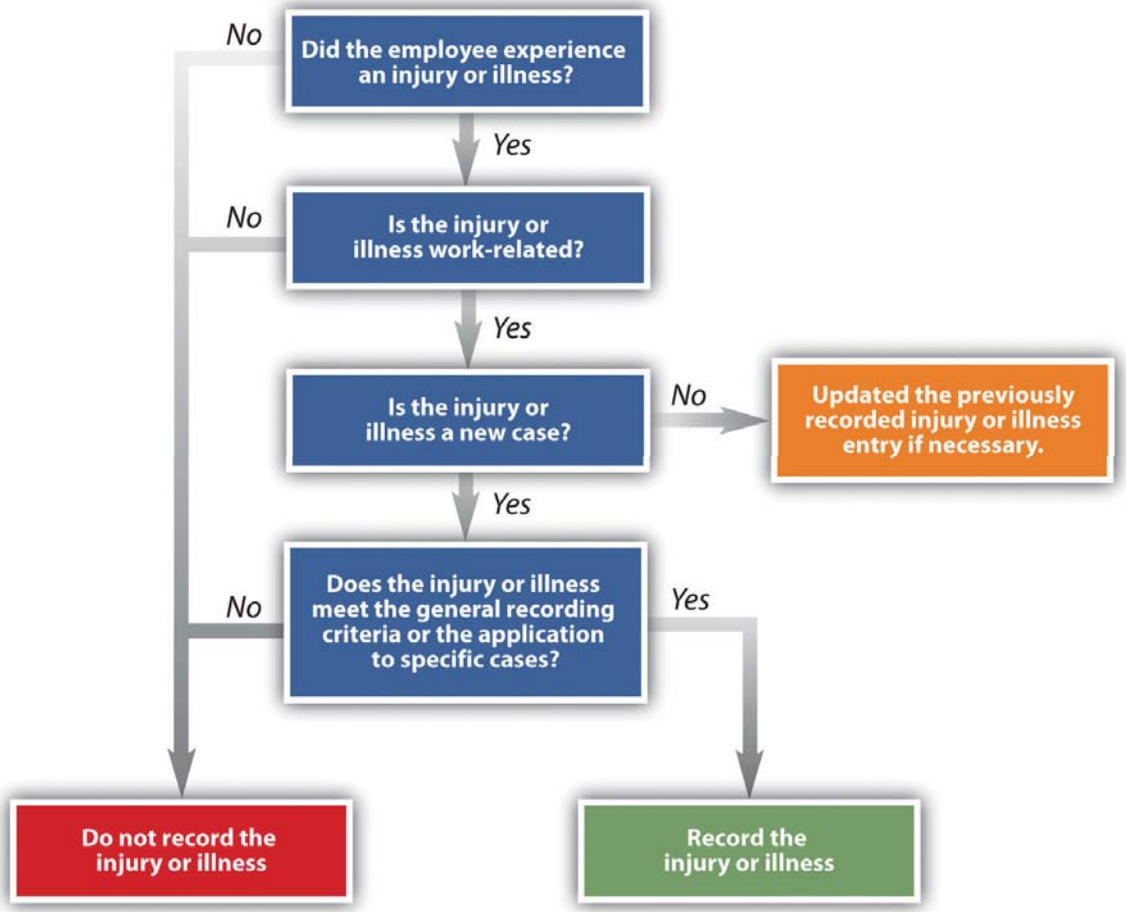


It's not all for just the Risks! Identify Opportunities too!

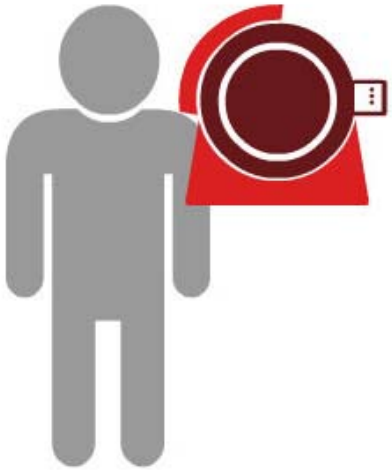
Common Tools for Risk Management Treatment (a sample)

Decision Tree Analysis

Easy to integrate with everyday processes



Decision Tree Example

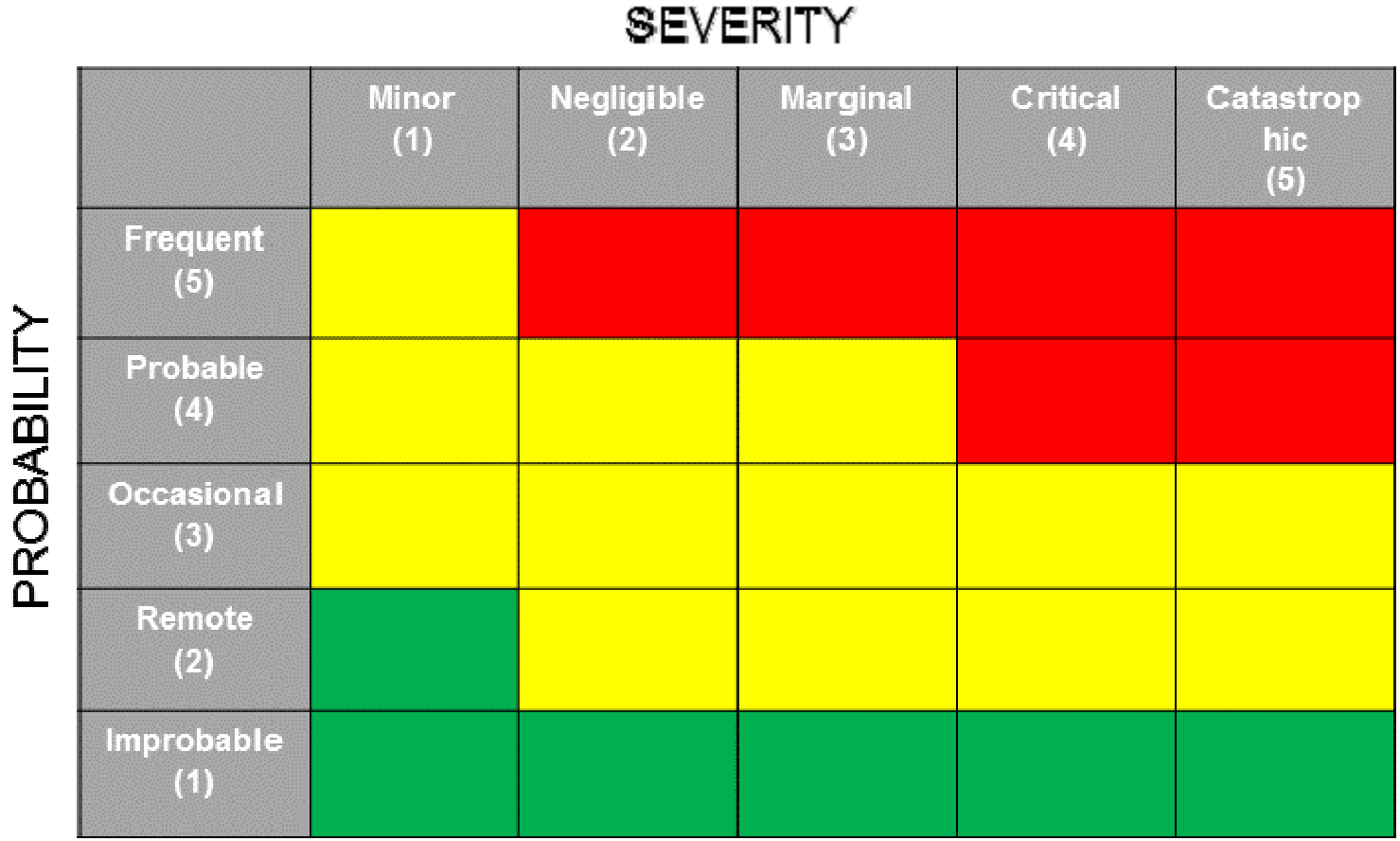


- When to report to the FDA
  - Medical device manufacturer
  - Reporting decision embedded in complaint handling process
  - Filled out by analysts for every potential adverse event
  - Drives decision to report (Yes/No) and acceptable delay (when?)
- Prioritize internal notification
  - Global Utilities company
  - Automated determination of who needs to be notified of incidents based on risk level
  - Immediate initial risk assessment determines risk level
  - Risk level determines email distribution list, including SMS (text) alerts for highest level
  - Follow up risk assessment performed after investigation is completed (for long term trend analysis)
  - Take immediate action on critical issues, and implement long term improvements on unacceptable trends

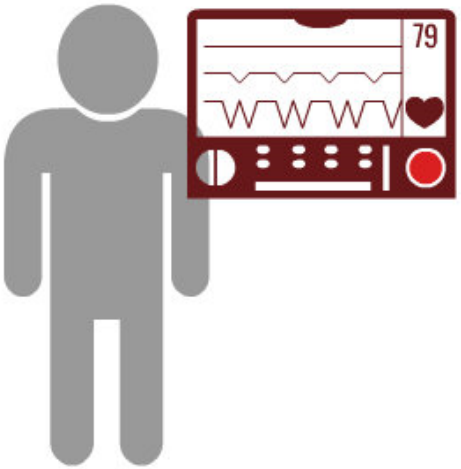
Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

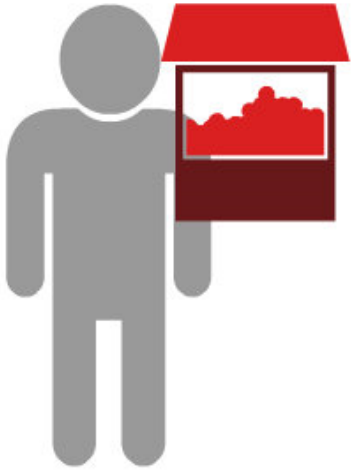


Risk Matrix Example



Identify potential adverse events

- Medical device manufacturer(a different one)
- Customer complaints routed for investigation
- Subject matter experts perform risk assessment (meeting)
- Risk levels drive decisions for recalls, notifications, CAPA



- Survey of known and unknown threats
  - Services organization
  - Periodic survey to all business functions
  - Managers re-calculate risk levels for known threats and suggest new threats
  - Prioritization of compiled risk levels drives strategic risk mitigation initiatives (managed through CAPA process)

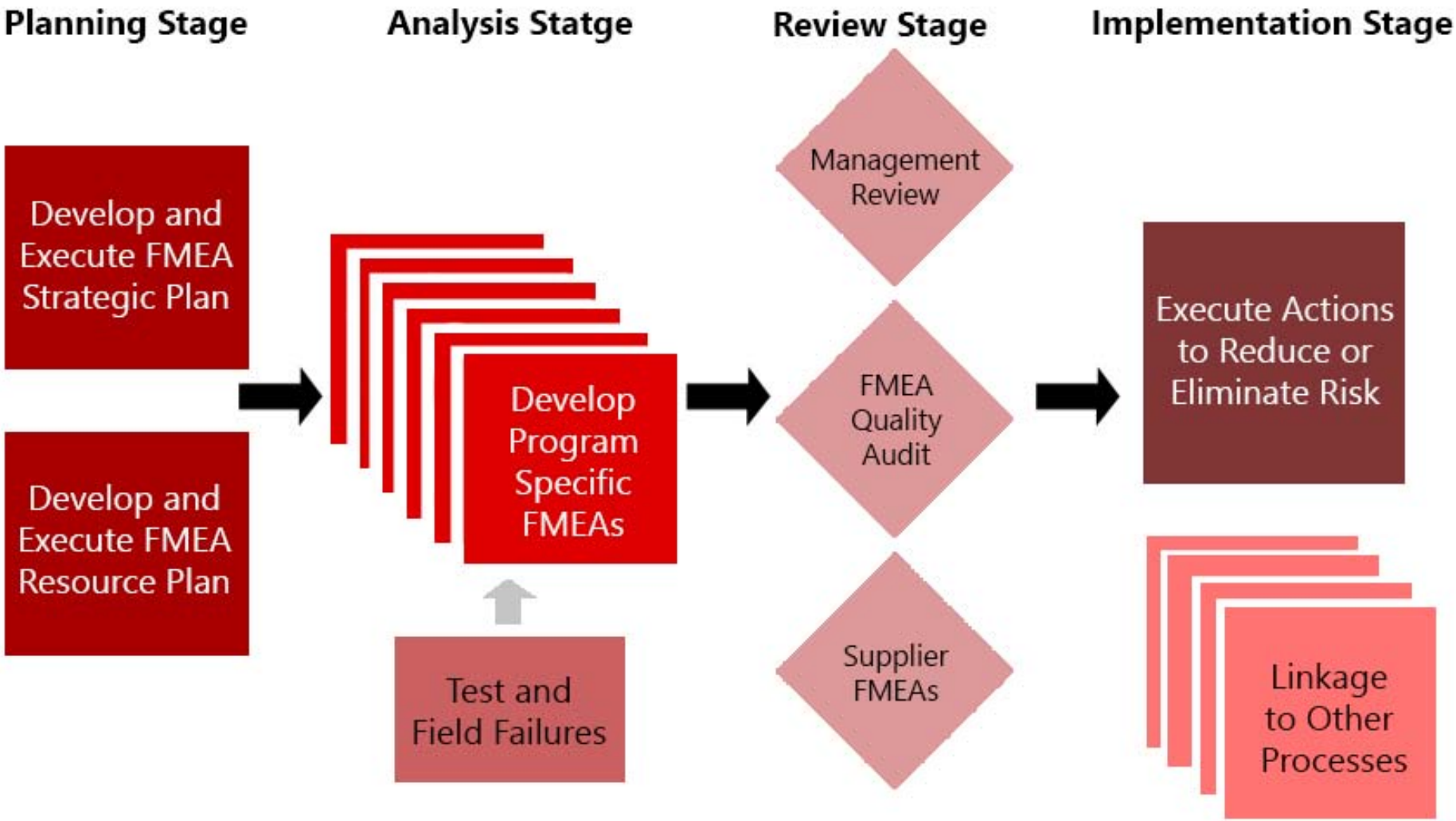
Failure Modes and Effect Analysis

For design of products and processes

☐ Subsystem ☑ Component	Chrysler Motors Corporation		DC-77323-XYZ	Org. Date 2/11/98	Page 1 of 2
	Supplier Any Company, Inc.	Code ACI-001	Supplier Part No. A-9514	Dwg. Rev. 8	Key Date 2/11/98	FMEA No. DFMEA-001
Part Name Filter			Design Responsibility Brad Anderson	Application/Model Year Sedan / 1998		
Core Team Brad Anderson,Jerry Benware,Lisa Brown,Ken Caracci,Bill Cox,Fred Jordan,Ken Kratz			Prepared By Brad A. Anderson		Date 2/11/98	

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Class	Potential Cause(s) / Mechanisms of Failure	Occur	Current Design Controls	Detec	R.P.N.	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken	Sev	Occ	Det	R.P.N.
Filter for assembly with B44 to firewall	Insufficient wax coverage over specified surface	Deteriorated life of door leading to: Unsatisfactory appearance due to rust through paint over time, Impaired function of interior door hardware	4	◇	Insufficient wax thickness specified	4	Supplier certification	1	16	None	N/A 2/11/98					
					Inappropriate wax specified	5	set up set up	4	80							
							Five piece setup, in-process, end of run study	2	40	None	N/A 2/11/98					
	Corroded interior lower door panels	Improper oxide coating	6	⛉	Entrapped air prevents wax from entering corner/edge access	6	Test spray pattern at startup and after idle periods, and ...	5	180	Add team evaluation using production spray equipment and specified wax	Engineering and Assembly Operations 2/18/98	Based on test reults (Test #9989) spray head modified to ...	6	2	5	60
				⛉	Spray heads clogged: Viscosity too high, Temperature too low, Pressure too low	4	Incomming audit per 200-16 certification, SPC Lot/Qtr	2	48							
							Laboratory test using "worst case" wax and application hole size	3	72	Add laboratory accelerated corrosion testing	ABC Labs 2/27/98	Test results show specified ...	6	3	3	54
										Conduct DOE on wax thickness	Engineering Associates 2/18/98	DOE shows 25% variation in specified thickness is acceptable	6	2	2	24
					Feeder not properly or	3										

FMEA Process



Sample FMEA Form

Design FMEA

Revision 6.0 2/11/98

☐ System ☐ Subsystem ☑ Component	**Customer** Chrysler Motors Corporation	**Customer Part No.** DC-77323-XYZ	**Org. Date** 2/11/98	**Page** 1 of 2
	Supplier Any Company, Inc. **Code** ACI-001	**Supplier Part No.** A-9514	**Dwg. Rev.** 8 / **Key Date** 2/11/98	**FMEA No.** DFMEA-001
Part Name Filter		**Design Responsibility** Brad Anderson	**Application/Model Year** Sedan / 1998	
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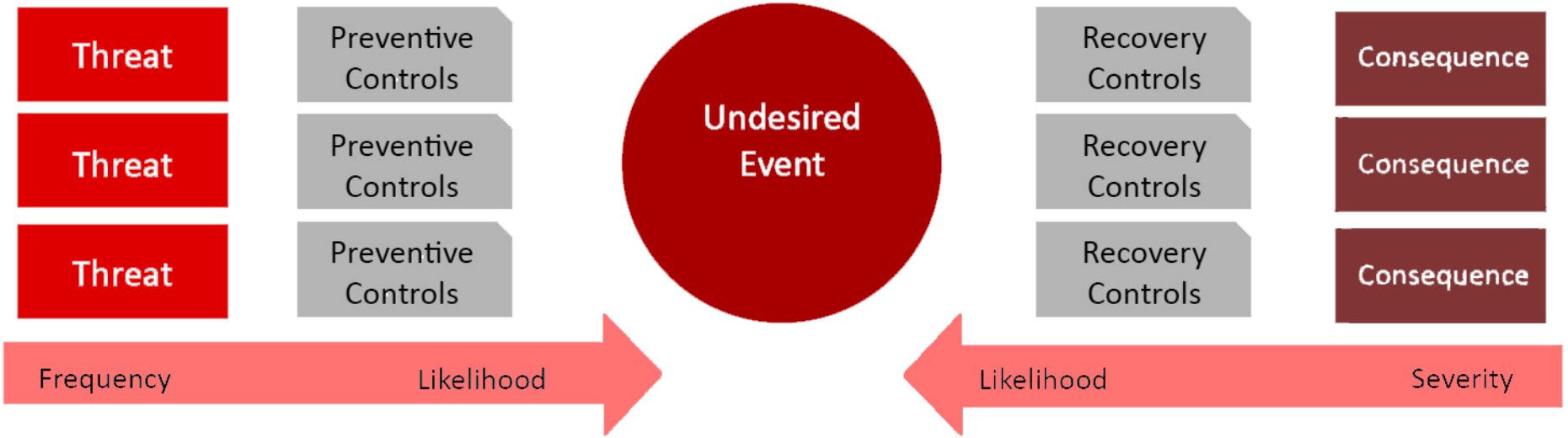
					Feeder not properly or	3										

FMEA Example

- Demonstrate acceptable quality to customer
  - Global engineering company
  - Uses PPAP to coordinate design changes with parts suppliers
  - FMEA submitted by supplier and evaluated by engineers
  - Risk Priority Number (RPN) drives remedial actions and general acceptability

Bowtie Model

For low-occurrence events that are catastrophic

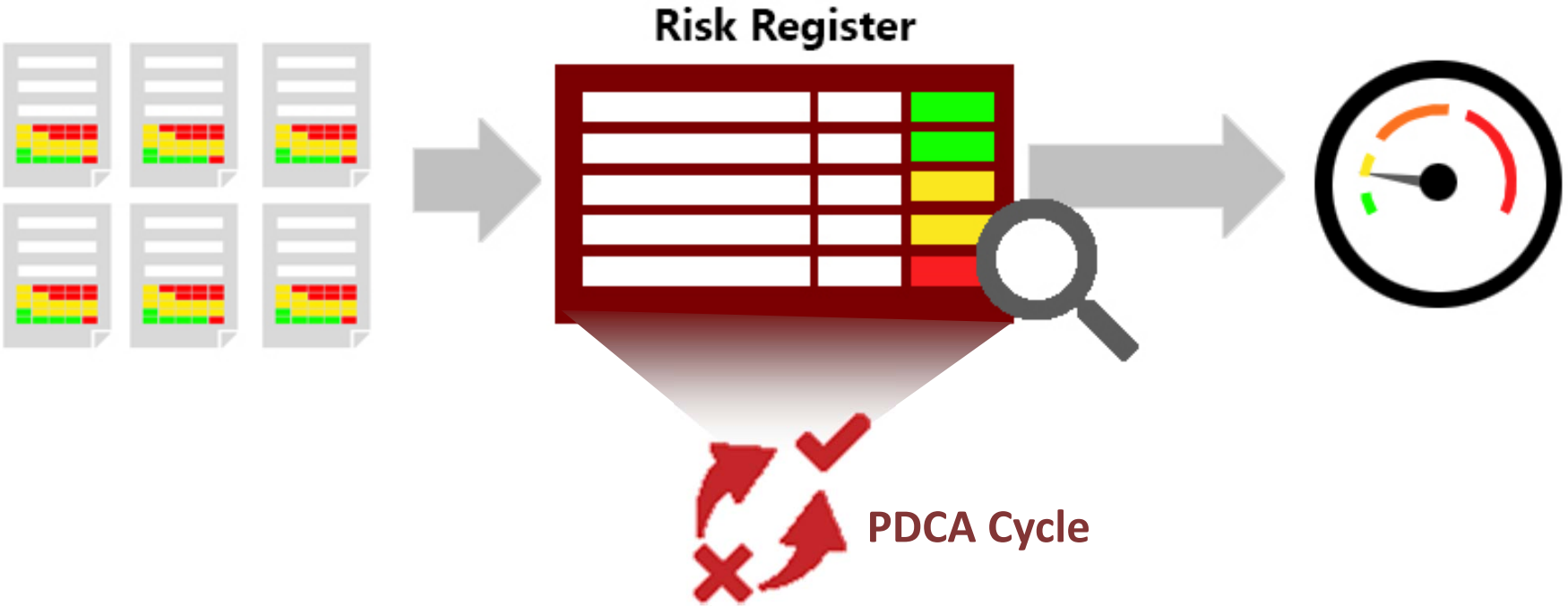


Bowtie Example

For low-occurrence events that are catastrophic

Risk Register

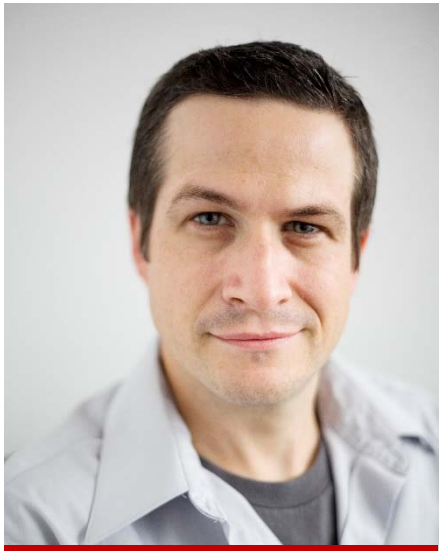
- Monitors risk levels over time
  - Library of hazards (typically known for each industry)
  - Collects risk assessment data from many processes
  - Provides visibility into critical events and data for trend reporting



Summary

- Complexity and scale breeds the need for change
- Risk is a universal compliance constant
- ISO 9000:2015 is about enrolling everyone in Quality
- Risk in ISO 9000:2015 is simply stated, but maps well to the risk methodology
- Figure out your path to risk, and leverage tools to expand to a risk-based QMS
- There are tools to help ease this transition!

Thank you! Questions?



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