


**Managing Your Risk Has Its Rewards:
Techniques for Automating Risk in a CAPA System**


Presented by **Glenn McCarty**
CEO - EtQ, Inc.

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Agenda



- Aberdeen Risk Mitigation survey
- Implementing Risk Mitigation In a Corrective and Preventive Action (CAPA) system
- Understanding Risk
- Defining a Risk Matrix
- How to streamline the CAPA process
- Techniques to prioritize CAPA using risk assessment
- Benefits of a risk-filtered CAPA system
- Risk assessment beyond CAPA
- Questions



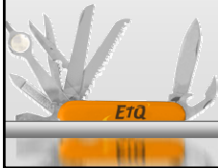
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Background



- **Aberdeen Group Benchmarking Report (2008)**
 - Recognized the need to benchmark quantifying risk in mfg. operations
 - Released a report on risk mitigation in manufacturing operations
 - Over 250 companies responded
 - Designed to benchmark capabilities to assess, quantify, prioritize and mitigate risks against peers and best-in-class companies.
 - Identified best-in-class strategies for mitigating risk
 - 50 question survey that collected data related to risk trends, competitive framework, and technology associated with risk mitigation



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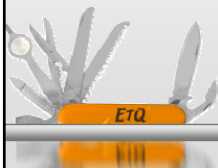


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The Survey - Highlights



The following are key questions posed
by the survey and the results:



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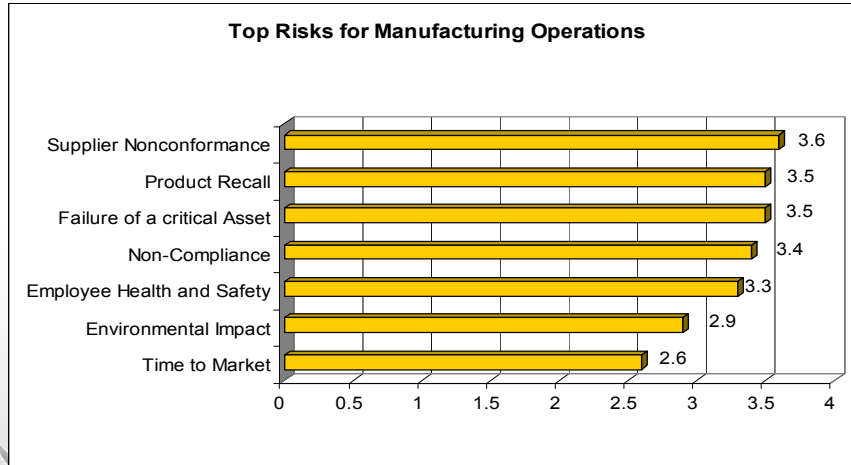


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What keeps you up at night?



What are the Top Risks Facing your Organization?



*Aberdeen Group, 2008



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Market Pressure



What are the top market pressures impacting organizations to mitigate risk in manufacturing operations?

Market Pressures	%
Reduce manufacturing cost	51%
Maximize long term profitability	49%
Compliance to Regulatory Standards	32%
High degree of complexity in global manufacturing operations	29%
Fear of impact in the case of catastrophic event	20%
Protect Brand Equity	18%

*Aberdeen Group, 2008



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Taking Strategic Action



What top strategic actions are companies taking to address the previous stated market pressures?

Strategic Action	Best-in-Class Companies
Provide visibility into global manufacturing operations	37%
Communicate and collaborate across functional departments	37%
<u>Quantify risks across manufacturing operations</u>	<u>37%</u>
Educate employees in regards to managing operational risks	34%
Provide transparency of risks across manufacturing operations	32%
Establish real-time interoperability across product development, manufacturing, and the supply chain	24%

Manufacturers providing transparency of risks and quantifying risks are **2.5 times** more likely to be Best-in-Class

*Aberdeen Group, 2008



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Top Risk-Based Initiatives



Which of the following capabilities does your company possess – or will develop to address the previous strategic actions?

Process/Operational and Performance Management Initiatives	Best in Class
Identification and assessment of impacts from adverse events	63%
Historical data is maintained to provide a profile of operational risks	59%
<u>Standardized risk assessment processes across the enterprise</u>	<u>49%</u>
<u>Stake-holders have a clear understanding of the top risks impacting operations</u>	<u>46%</u>
Data collection from manufacturing operations is automated	45%
Cross-functional teams responsible for structuring processes to mitigate operational risk	43%
Non-Conformance alerts are displayed in real time and are role based	41%
Monitoring and prioritization of operational risks across the enterprise	34%
Standardized risk prioritization process across the enterprise	29%
Corporate Risk Team with the responsibility to manage risk across operations	20%

*Aberdeen Group, 2008



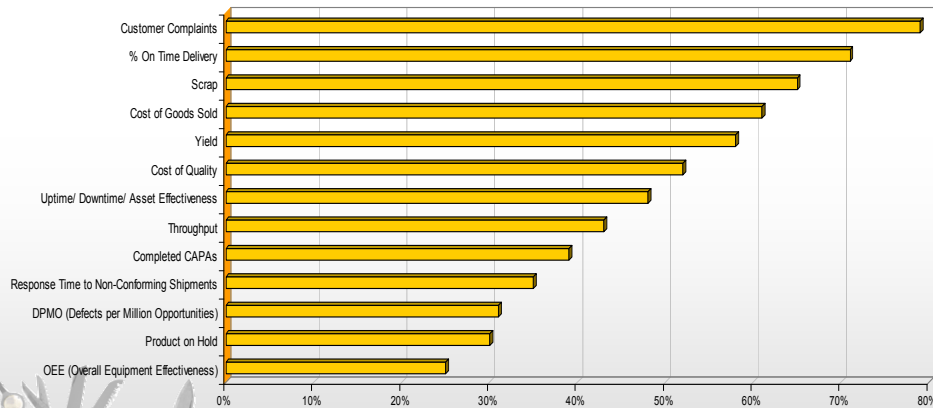
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Key Performance Indicators (KPIs)



Which of the following Key Performance Indicators (KPI) do you track to measure effectiveness of risk mitigation initiatives?



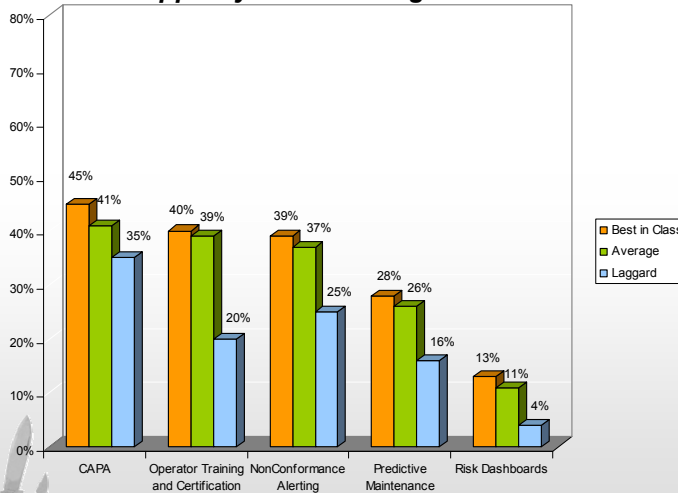
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Technology Enablers



Which of the following capabilities has your company automated or will automate to support your Risk Mitigation initiatives?



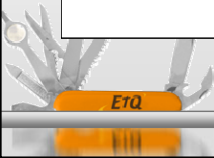
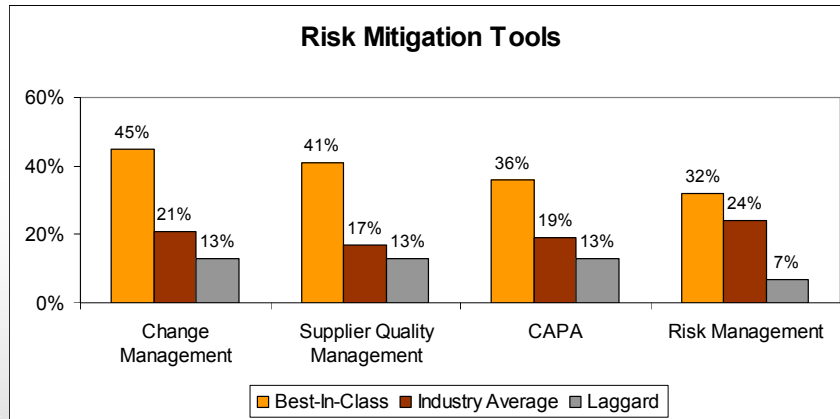
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Risk Mitigation Tools



Which risk mitigation tools are you implementing to address risk in global operations?



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Why Implement Risk-Based Software?



Importance of Software Components for Visibility of Risk

2007 Survey of 100 companies, VP level

These drivers have moved Quality Management from an **afterthought** to a **strategic initiative**



Factors Driving Strategic Importance

- Highly publicized recalls
- Ever-increasing regulatory oversight
- Customer demand for quality products



Source: AMR Research 2007

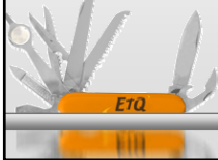
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Required Actions



- **Collaborate: Leverage a risk team** to increase enterprise focus and employee education regarding various risks that exist across manufacturing operations and ways to effectively manage those risks.
- **Integrate: Integrate risk solutions with manufacturing solutions.** This eliminates the silo-ed approach of investing in technology and provides a common platform to share best practices for mitigating risks.
- **Automate: Invest in technology to automate controls for mitigating risk** arising from key areas. This will include adopting modules such as **Corrective and Preventative action (CAPA)**, Non-conformance alerting, predictive maintenance, risk dashboards and operator training and certification. Best-In-Class manufacturers are more likely to adopt all of the above modules.



*Aberdeen Group, 2008



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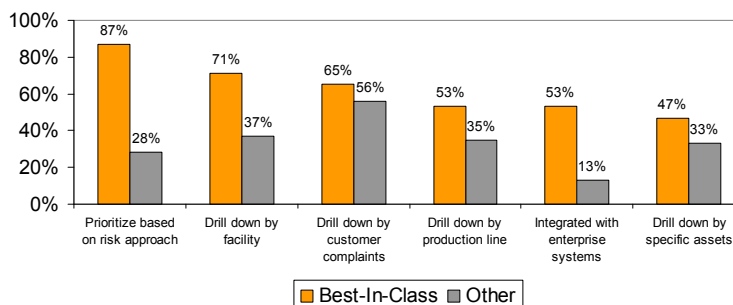
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Implementing Risk Mitigation In a CAPA system



- **Aberdeen Report - Required Action:**
 - **Automate:** Invest in technology to automate controls for mitigating risk arising from key areas. This will include adopting modules such as **Corrective and Preventative action (CAPA)**, Non-conformance alerting, predictive maintenance, risk dashboards and operator training and certification. Best-In-Class manufacturers are more likely to adopt all of the above modules.

Managing CAPAs



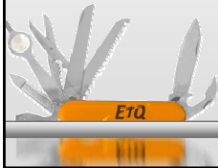
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Implementing a CAPA system is not necessarily best-in-class

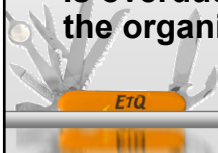
Without the ability to prioritize CAPAs, you end up with significant challenges

creating visibility into top risks.



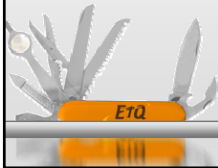
Trouble with CAPA...

- CAPA has become a catchall, even a suggestion box!
- Hundreds of CAPAs/duplication of CAPAs
- How to discern “minor” from “critical” CAPAs
- Unable to focus on CAPAs that produce the most value
- CAPA process is a bottleneck in a Quality Management System (QMS)
- Continuous improvement suffers as a result of keeping up with CAPAs
- Is overdue CAPAs the right measure versus the risk to the organization?



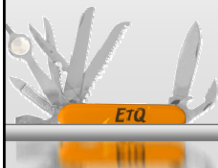
How can we ensure CAPA is handled efficiently,
and identify the critical from the non-critical?

The answer is **Risk Assessment**



Understanding Risk

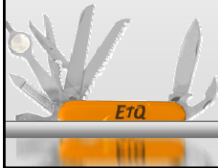
- **Risk Management:**
 - *Systematic* application of policies, procedures, and practices to the tasks of analyzing, evaluating, and controlling risk*
 - Analyze: Look for risk
 - Evaluate: Assess the risk
 - Control: Take action to do something about high-risks
- **Broad Focus:**
 - Risk Management applies to more than quality
 - Design, production, post-production and beyond
 - We will focus on **evaluate** and **control**, in **production** and **post-production** environments



Understanding Risk



- **How do you define risk?**
 - Not an easy task
 - Companies spend a lot time and effort to define risk for their company
- **Typical risk measures: Probability & Severity**
 - Probability – the likelihood that the hazard/harm will manifest itself
 - Severity – the degree of harm incurred
- **Additional measure: Detectability**
 - Detectibility of hazards - pre-harm



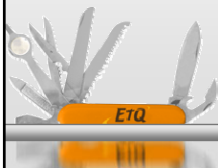
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Understanding Risk



- **How do you define Hazards/Harms?**
 - Hazard: is the source of the harm* (cause)
 - Harm: physical injury or damage to health, property, or the environment* (the end result)
- **What is Safety?**
 - Freedom from unacceptable risk*
 - What is *unacceptable*?
 - A subjective measure based in part on vague society standards, system benefits, and the potential for mitigation



*ISO 14971



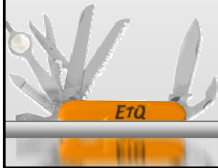
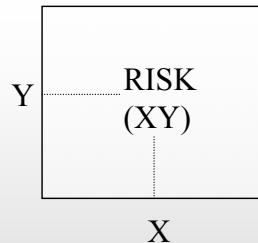
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Defining a Risk Matrix



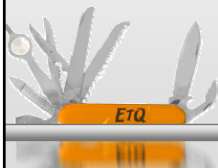
- **The Risk Matrix:** tool used in the Risk Assessment process, it allows the severity of the risk of an event occurring to be determined.
- Graphically displays the total of each of the hazards/harms that contribute to the risk
 - Severity = X
 - Probability = Y
 - Risk Score = XY



Example of a Risk Matrix



How did we get to this?



Defining a Risk Matrix - Verbal Scale

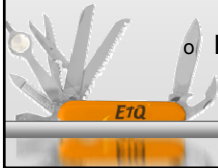


- **Severity Verbal Scale**

- Catastrophic Likely to result in death
- Critical Potential for severe injury
- Moderate Potential for moderate injury
- Minor Potential for minor injury
- Negligible No significant risk of injury

- **Probability Verbal Scale**

- Frequent Hazard likely to occur
- Probable Hazard will be experienced
- Occasional Some manifestations of the hazard are likely to occur
- Remote Manifestations of the hazard are possible, but unlikely
- Improbable Manifestations of the hazard are very unlikely



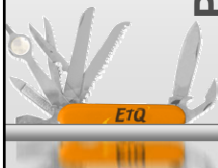
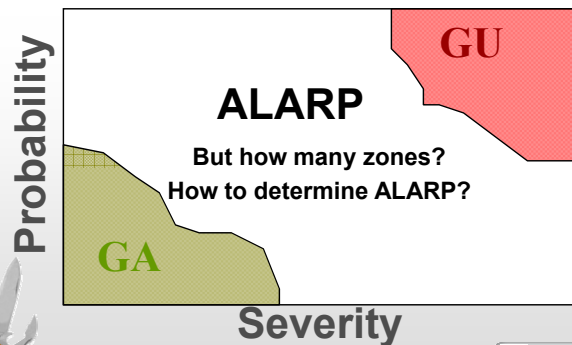
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Defining a Risk Matrix



- When defining risk management, some organizations find it convenient to categorize risks into the following three regions:
 - The broadly acceptable region (**Generally Acceptable - GA**)
 - The ALARP (As Low As Reasonably Practicable) region; and
 - The intolerable region (**Generally Unacceptable - GU**)



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Defining a Risk Matrix



- **CBA (Cost-Benefit Analysis)**
 - Determines low level of risk responsibility
 - CBA: convert both risk & sacrifice to a common set of units – **money** – so that we can compare them.
- **ALARP**
 - Determines the higher level of risk
 - Rule is this measure must be adopted unless the **sacrifice is grossly disproportionate** to the risk.
 - Spend \$1M to prevent five customers suffering blisters from turning a dial is obviously grossly disproportionate, but;
 - To spend \$1M to prevent a fatality is obviously proportionate.
 - So, the costs can outweigh benefits and the measure could still be reasonably practicable to introduce.
- **How much cost outweighs the benefit before being judged grossly disproportionate?**
 - Depends on how big the risk is to begin with
 - The larger the risk, the greater the disproportion between cost & risk

<http://www.hse.gov.uk/risk/theory/alarpglance.htm>
<http://www.hse.gov.uk/risk/theory/alarpcheck.htm>

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Defining a Risk Matrix



- **You must vet the matrix**
 - Risk score is a mathematical measure
 - Use “real world” examples to ensure validity of the matrix
 - Example: False symmetry in risk matrix – needs to be validated with real world situations

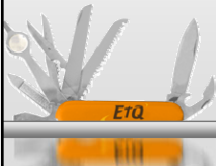
PROBABILITY ↑	5	10	15	20	25
	4	8	12	16	20
	3	6	9	12	15
	2	4	6	8	10
	1	2	3	4	5
		SEVERITY →			

Risk Assessment



We will discuss the concept of how to automate and **control** high-risk events in the Quality System

Using the risk matrix as the driving factor in the process...



Techniques to Identify Risk



The screenshot displays the EtQ Reliance software interface. A central window titled "Probability of Harm (P)" shows a risk matrix with the following data:

	Minor 1	Negligible 2	Marginal 3	Critical 4	Catastrophic 5
Frequent 5	Acceptable	Acceptable	ALARP-Evaluate	Intolerable	Intolerable
Probable 4	Acceptable	Acceptable	ALARP-Evaluate	Intolerable	Intolerable
Occasional 3	Acceptable	Acceptable	Acceptable	ALARP-Evaluate	ALARP-Evaluate
Remote 2	Acceptable	Acceptable	Acceptable	Acceptable	ALARP-Evaluate
Improbable 1	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

Legend:
Intolerable (Red)
ALARP-Evaluate (Yellow)
Acceptable (Green)

The interface also includes a "Hazard Analysis" section with fields for "Initiation", "Last Comment", "Analysis Number", "Subject", and "Severity Level". A "Calculate Risk" button is visible, and a "Corrective Action Guidance" section provides instructions for Class I recall.

How to Apply Risk to CAPA



- **Use Risk Assessment to filter events**
 - Aids in decision making process
 - Risk Matrix aids in determining next steps
 - Severity, Probability, etc.
 - Create risk outcomes that specify related actions
 - Build knowledgebase of similar events and actions
 - Creates a history of events with similar risk – further aids the decision
 - Automate the knowledgebase to assign next steps based on risk outcome
 - Helps to refine guidance on future decisions
- **Resolve low-priority events at the source where they are found**
 - Minor Complaints/Nonconformances/Audit findings
 - Events with little impact can be immediately resolved



Techniques to Identify Risk



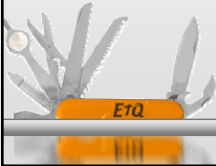
- **Risk Views**
 - Display all risk within the QMS, and their corresponding levels
 - Spreadsheets, Software, Business Intelligence (BI) tools, etc.
 - Show risk levels in a Dashboard view
 - Roll-up reporting – what are my current risks across business processes and the enterprise?

Event Type	Event Number	Subject	Meeting Date	Current Phase	Results
Document Control	DC-0001	Documents not released	Jun 18, 2007	Draft	ALARP-Undesirable
NonConformance	NC-0001	Functional	Jun 21, 2007	Assigned	Intolerable
Audit	AUD-0001	Functional	Jun 21, 2007	Approval	ALARP-Tolerable
Audit	AUD-0002	This is the problem...	Jul 10, 2007	Assigned	ALARP-Undesirable
Complaint	COMP-0001	Functional	Jun 21, 2007	Approval	Intolerable
Complaint	COMP-0002	Functional	Jun 21, 2007	Assigned	ALARP-Tolerable
Complaint	COMP-0003	Functional	Jun 23, 2007	Approval	Intolerable
Complaint	COMP-0003	Functional	Jun 23, 2007	Approval	Intolerable

Additional Uses of Risk



- **Risk Mitigation: Applies risk assessment to CAPA verification and effectiveness**
 - Does the corrective action taken reduce the risk to the specified parameters?
 - Ensures that actions taken not only correct the problem, but reduce the risk within compliance levels
- **Risk Portfolios**
 - Builds a history of risk events
 - Can show risk by product, process, complaint type, plant, or any criteria associated with the risk
 - Can determine which elements in the business have the highest risk



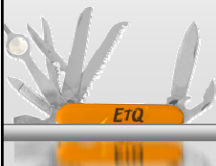
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Close the Loop on Risk



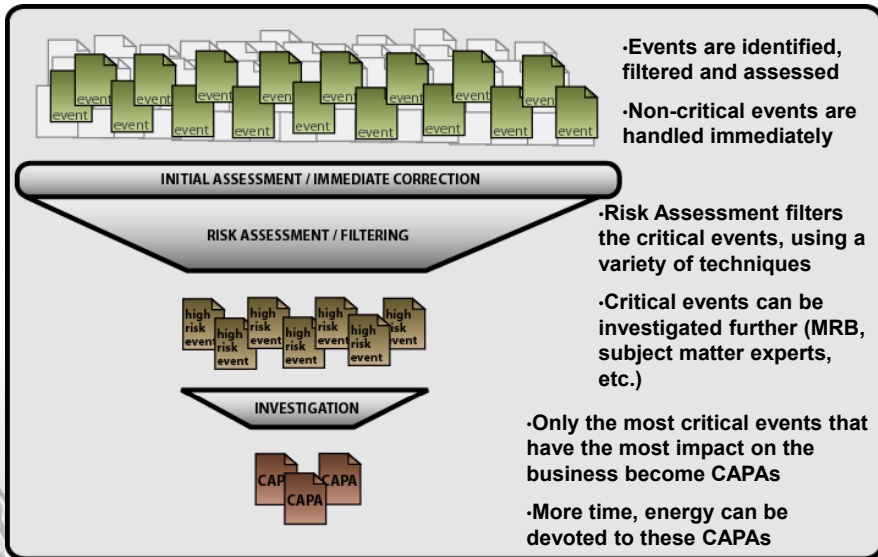
- **Go back and review**
 - DFMEA, PFMEA, based on risks assessed in post-production events
- **How do high-risk events affect:**
 - Product Design
 - Production Processes
 - Product Development / Related Products
- **Change management resulting from high-risk events in post-production**



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Result of a filtered CAPA system



•Events are identified, filtered and assessed

•Non-critical events are handled immediately

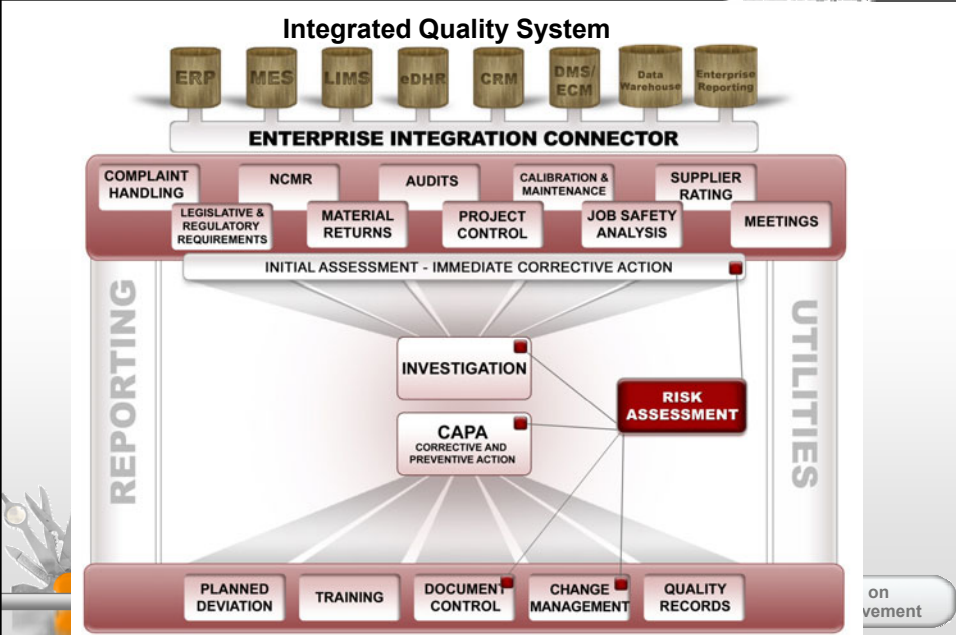
•Risk Assessment filters the critical events, using a variety of techniques

•Critical events can be investigated further (MRB, subject matter experts, etc.)

•Only the most critical events that have the most impact on the business become CAPAs

•More time, energy can be devoted to these CAPAs

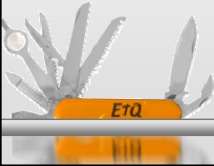
Risk in the QMS, Beyond CAPA



Case in Point



- **Fortune 1000 Medical Device Manufacturer**
 - Makers of equipment and supplies for treatment of cancer
- **The Challenge**
 - Receives over 10,000 complaints per month – not all are critical
 - Every complaint became a CAPA
 - “Needles in a Haystack”
 - Asked, “How can we find the most critical events out of the complaints and devote our resources to them?”



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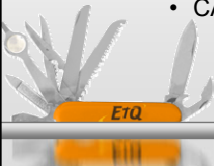


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Case in Point



- **The Solution**
 - Risk-based approach to Complaint Handling
 - Risk Matrix applied to each investigated complaint
 - Risk Matrix determines the Severity and Probability of each complaint
 - High-risk complaints are handled differently
 - Low-risk complaints are corrected immediately
 - High-risk events are investigated, initiates a CAPA
 - Investigation and CAPA workflow
 - Dedicated group put in place to handle high-risk complaints
 - Material Review Board (MRB), Subject matter experts review and manage data
 - CAPA process becomes streamlined



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Case in Point



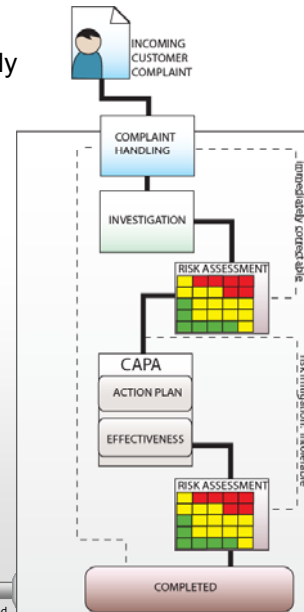
Excellence Through Quality

- **The Result**

- Majority of complaints are corrected immediately
- High-risk complaints receive the most attention
- CAPAs will have direct impact on the business
- Overall Quality is improved

- **Going Forward**

- Risk Mitigation: Effectiveness of CAPA resolution is assessed to determine if risk was reduced
- Risk Assessment History: Knowledgebase of previous complaints' risk levels is kept
 - Ensures future complaints with similar risks are handled properly
 - Builds a Risk Portfolio – by Product, Complaint Type, etc. Risk is determined for various levels within the system



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Case in Point



Excellence Through Quality

- **Major Airline Carrier**

- 23,500 employees , 207 aircraft
- Over 32 million passengers / year
- 161 destinations on 5 continents with 165+ stations
- Diverse fleet types

- **The Challenge**

- Regulatory and code share requirements
- Insurance costs
- Passenger safety
- Security pressures

- **Integration of Safety, Quality, Security , Enterprise Risk, Environmental and Occupational Safety & Health into the 'Airline Management System' (AMS) = Integrated AMS**



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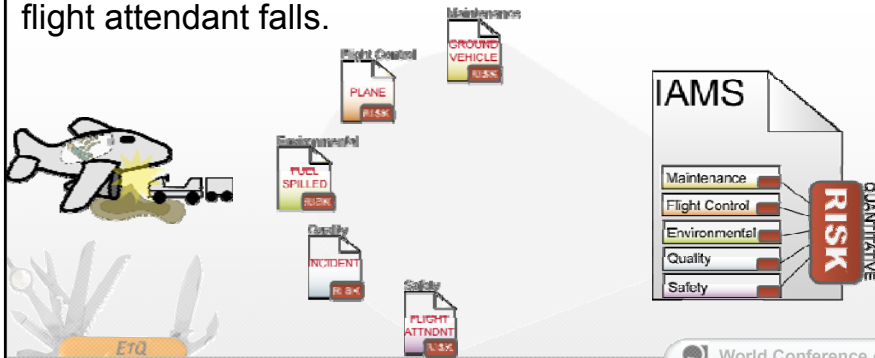
Case in Point



• Applying Risk Beyond Quality

- o Risk can be applied to Safety, Environment, Maintenance, etc.
- o Example: Integrated Airline Management Systems (IAMS)
 - Holistic Approach to Risk – One risk Matrix for all departments
 - Consolidates events into one enterprise view

Incident: A ground vehicle hits a plane, fuel is spilled, and flight attendant falls.



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Unified Risk Assessment



AIRCRAFT DAMAGE	2 Occasional	3 High	B
EQUIPMENT / FACILITY DAMAGE			
SAFETY OF FLIGHT			
ENVIRONMENTAL	1 Low	2 Medium	D
REGULATORY			
SECURITY			

OVERALL SAFETY REPORT IRAM RATING: B

Action / Investigation: Medium level investigation: require safety callout; usually requires Branch resources and coordination; a qualified investigator is assigned; approx. 30 days; usually internal to the company may require full Risk Assessment; usually results in corrective actions. I Type: Class II. Report Composition: Includes a Branch Executive Summary; Forami Investigative Report format approx. 2 - 25 pages; may include Assess.

View Category Search Advanced Search

View Options

Description

1. Low: Activation of a safety system or safety procedure with correct crew response; an avoidance maneuver that is deemed not to have been required; loss of single primary system with redundant system available; smoke, smell, or fire that was brief, identifiable, and extinguished. (v7.0)

2. Medium: Activation of a safety system or safety procedure followed by an incorrect crew response, which however did not result in an increased safety threat; an avoidance maneuver that is deemed to have been required; loss of multiple primary systems with redundant systems available; an un-commanded flight control input that is easily counter controlled; smoke, smell, or fire that was prolonged and identifiable, but contained or extinguished. (v7.0)

3. High: Activation of a safety system of safety procedure with incorrect response which did result in an increased safety threat; an avoidance maneuver that is deemed to have been aggressive or prolonged; loss of primary system with no redundant system available; an un-commanded flight control input that is difficult to counter control; smoke, smell, or fire that was prolonged and not identifiable, or not contained, or not extinguished. (v7.0)

4. Critical: Hull loss. (v7.0)

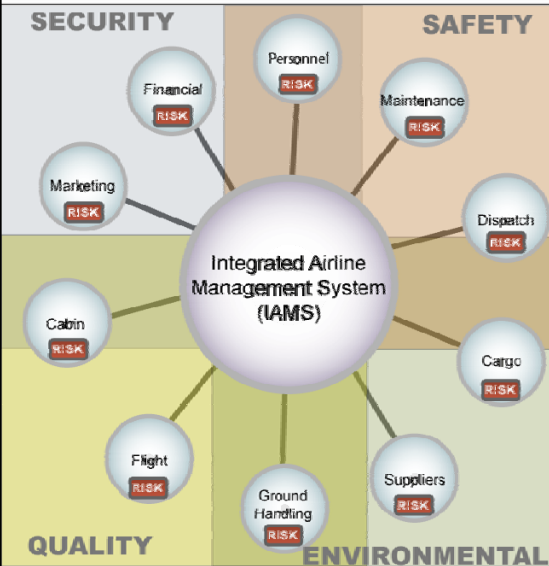
The overall risk for an incident is the highest risk for any one outcome

The employee is also provided with direction

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Case in Point

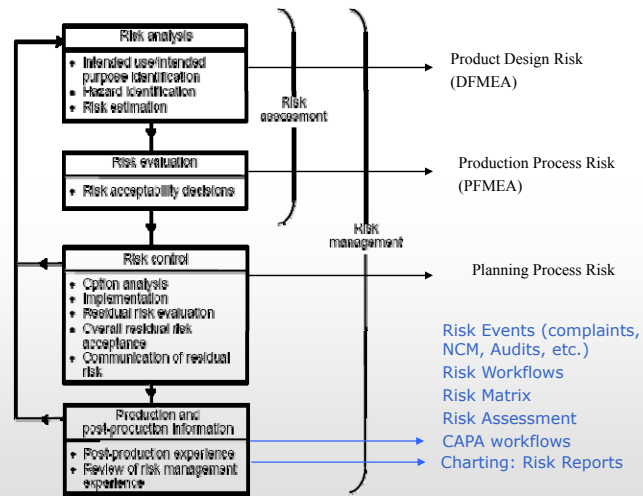


- Multi-Departmental Risk
- One event might impact multiple areas
- Single, Holistic Risk Assessment identifies:
 - Risk at each Department
 - Total Risk of Event
 - Total Impact
 - Resulting Actions taken

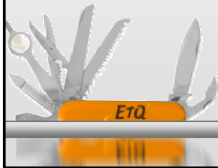
Risk Management Explained



- **ISO 14971** Application of risk management.



Questions?



Thank You!



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