Mitigating Pharma Equipment Risk through Human Factors

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A profound statistic

"one-third of medical device incidents involve user error and more than half of device recalls for design problems involve the user interface"

FDA spokesperson 2005

Who wants to have a product on the market that is used correctly 60% of the time?

So, what is Human Factors?

A multidisciplinary field including:

- Learning & Behavior
- Cognitive Psychology
- Sensation & Perception
- Statistics
- Experimental Design
- Anthropometrics & Biomechanics
- Industrial Design
- Human Computer Interaction

Ultimate Goal of Human Factors is to understand user interactions with product and systems to optimize the user experience and overall system performance.

How is Human Factors Unique?

Beyond perceptions and attitudes.

Multiple scientific-driven methodologies

Analysis at multiple stages in the design process.

Providing concrete and actionable design inputs.

Where else is Human Factors leveraged?

Government and consumer sectors of industry have been incorporating human factors for many years:

- Aviation
- Transportation
- Telecommunication

Continues to be the trend, in other industries to take a retroactive approach to Human Factors.

- *Validation Testing after Tooling*
- *Focus groups after Tooling*

Risk Mitigation is best accomplished when involved Human Factors early and iteratively.

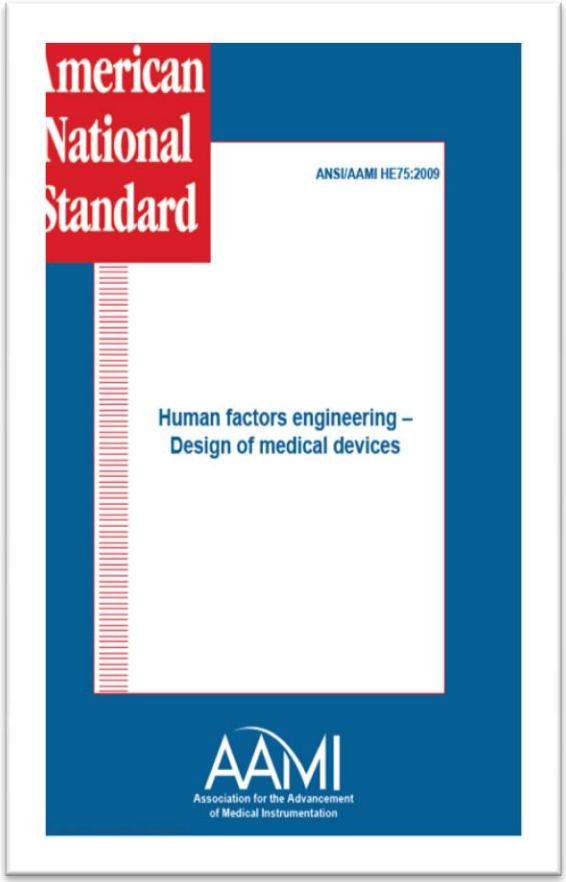
Movement of HF in Medical Devices

Human Factors has received more attention from the medical community with the release of AAMI's standard: **HE75**

Good resource for Pharma Equipment developers.

Key point is the importance of risk mitigation and the involvement of human factors early in the design process.

Many industries can benefit from this standard.



Standards for HF are not completely new

Code of Federal Regulations (Section 820.30)

(c) Design input

•Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the users and patient.

(d)Design output

- Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

(g)Design validation

- …Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

But the product works…

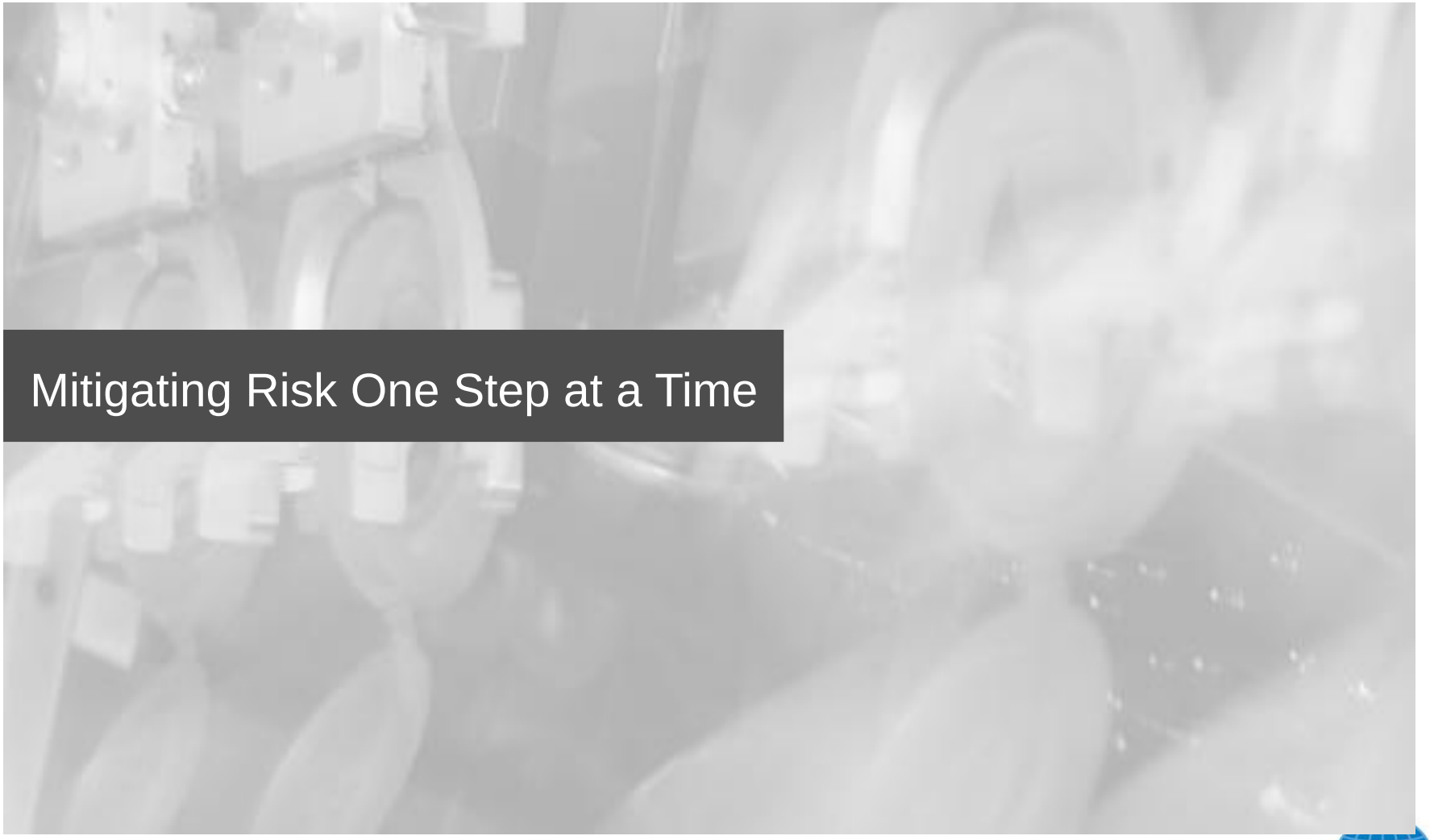
Technical functionality does not guarantee user functionality.

Technical functionality does not prevent use errors.

Users will do things with your product you never expected.

Predicate devices don’t guarantee risk mitigation.

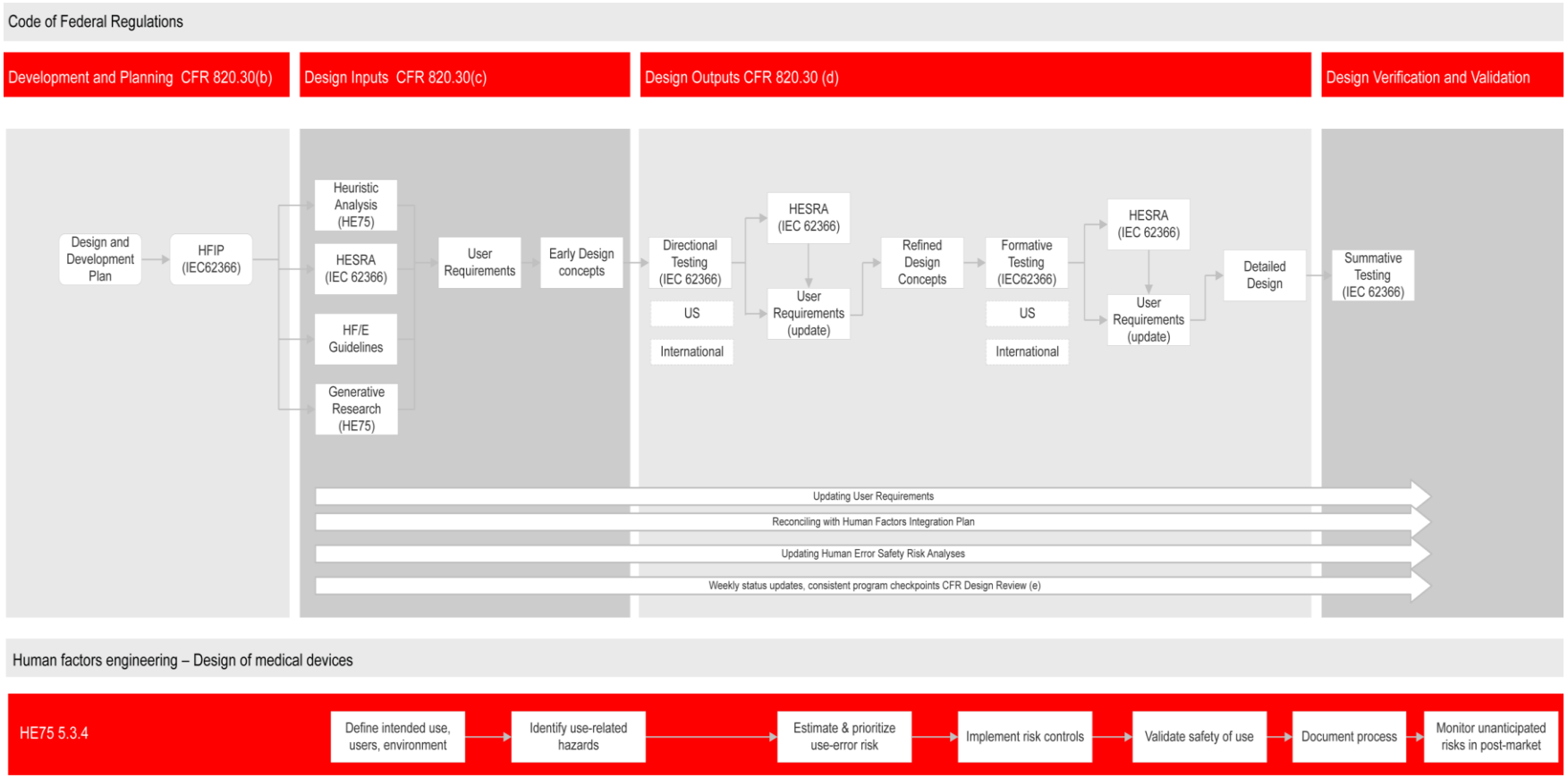
Instructions for use don’t guarantee risk mitigation.


Mitigating Risk One Step at a Time

User-Centered Risk Mitigation

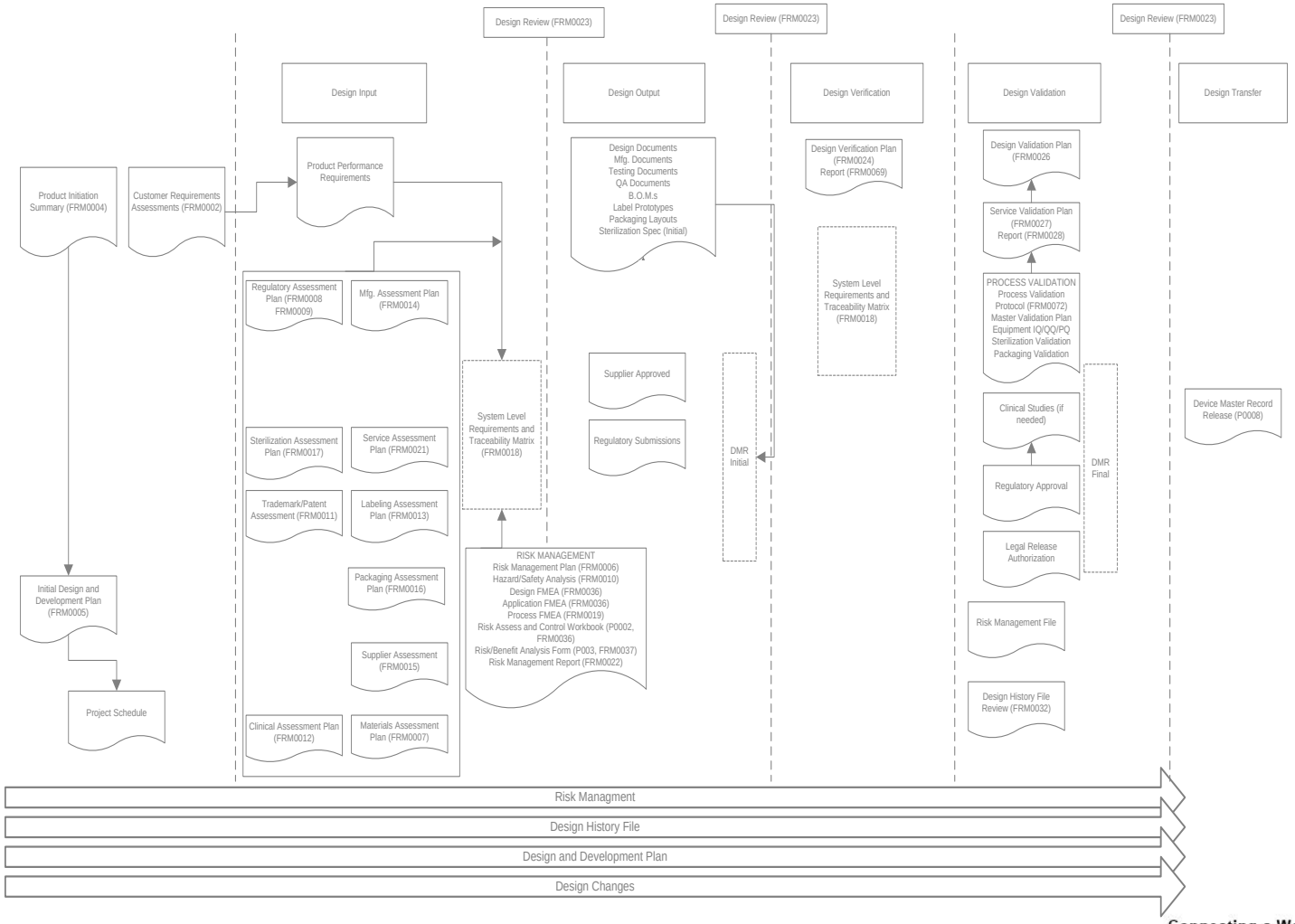
The old way of “mitigating risk.”

User-Centered Risk Mitigation

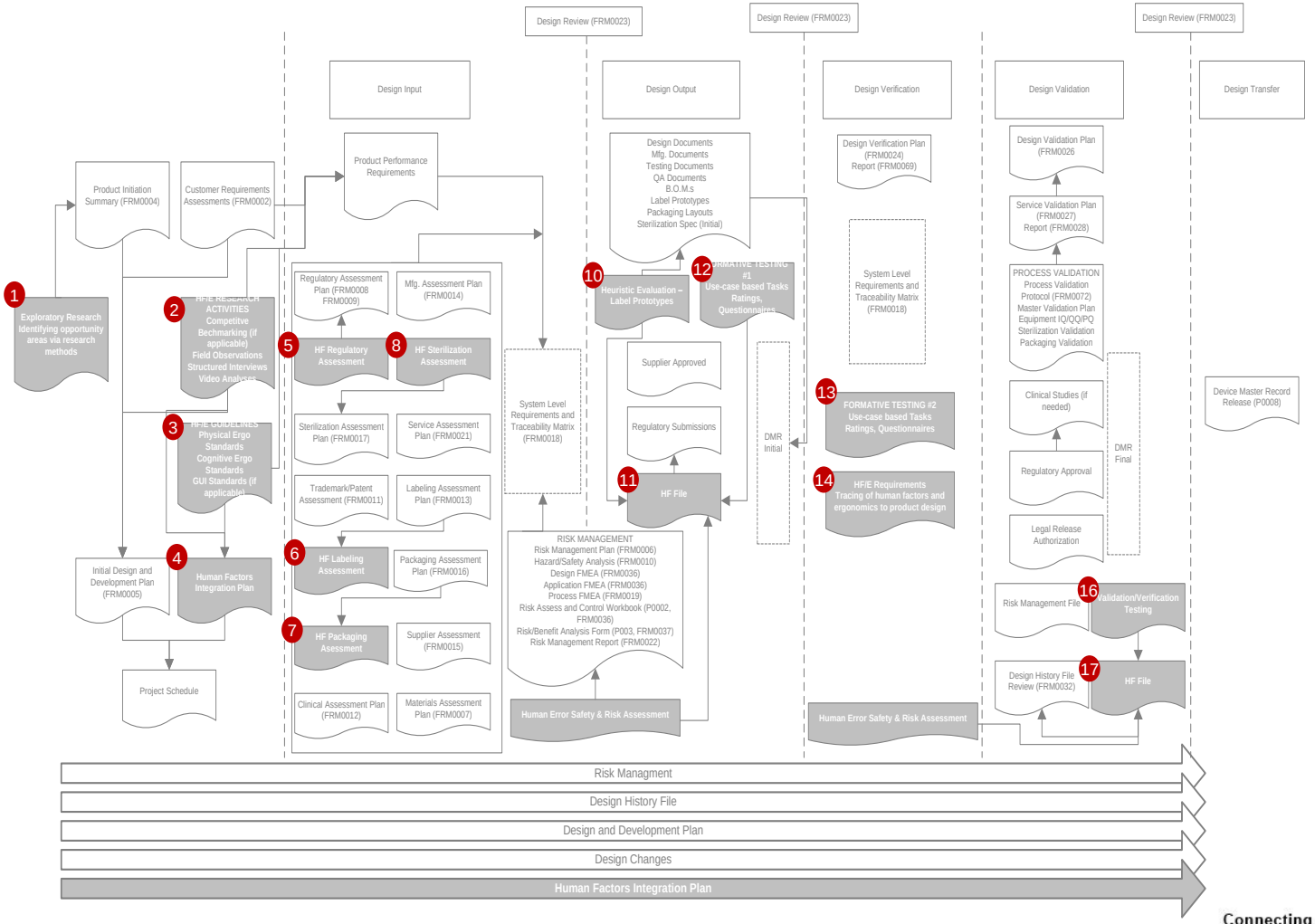


The user-centered way of mitigating risk.

Design Controls (no HF integration)



Design Controls with HF integration



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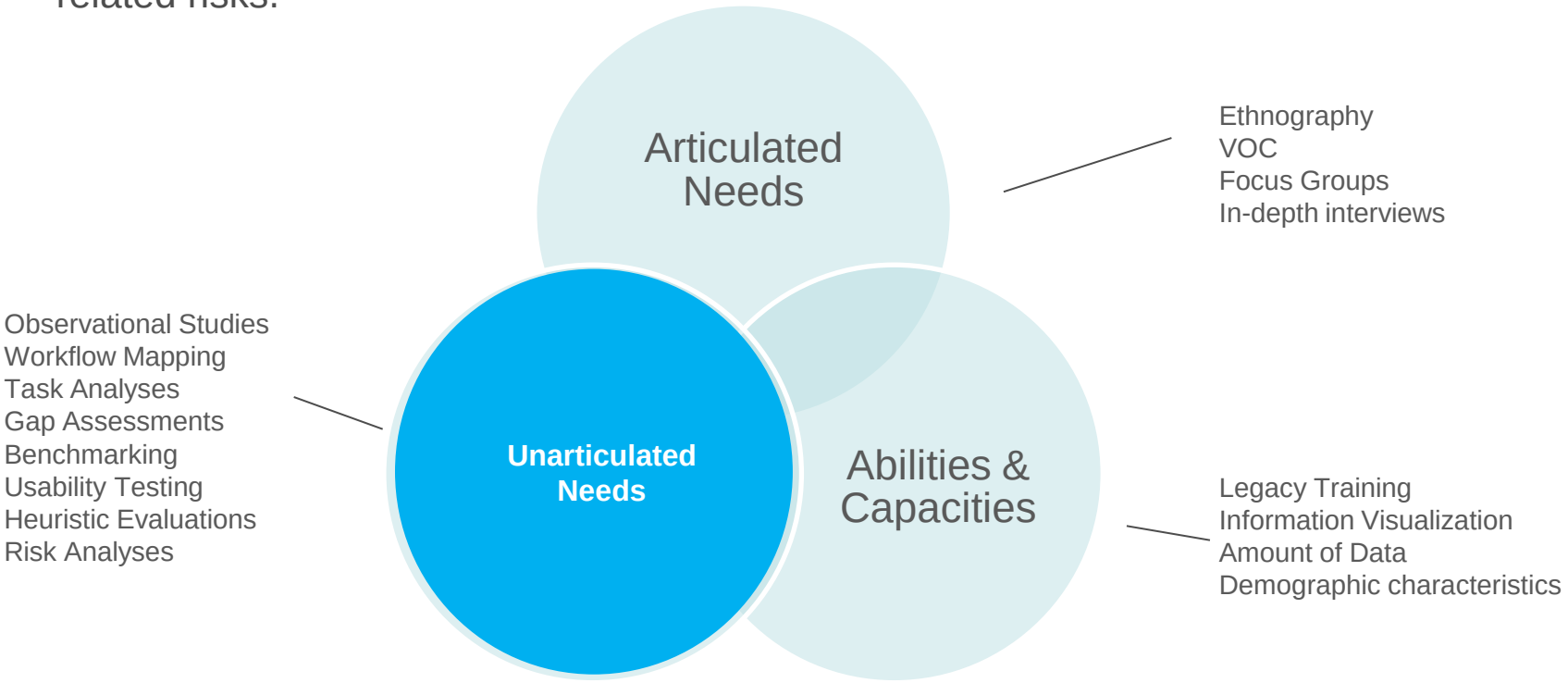
Putting this into Action

How does Human Factors mitigate risk early?

The multidisciplinary approach focuses on understanding human capacities as they relate to product design and user needs. Designing the “right” product, leveraging the “appropriate” capacities, and supporting user “needs” mitigate use- and market-related risks.



Understanding the Environment & Users

What are the inherent risks associated with the environment?

What is the user responsible for? What are the risks associated?

Where does the product live? What are the risks associated?

What are their days like?

How much information are they processing at time?

What are their qualifications?

What are they doing now and why?

Understanding the Challenges

Expensive product

Difficult to conduct “re-dos”

Shear size of the units

Scaling up but supporting a platform

Setup

Breakdown

Transportation

Cold environments

Lab space

Early Concepting and Evaluation

Human Factors allows us to look at a concept with a different lens.

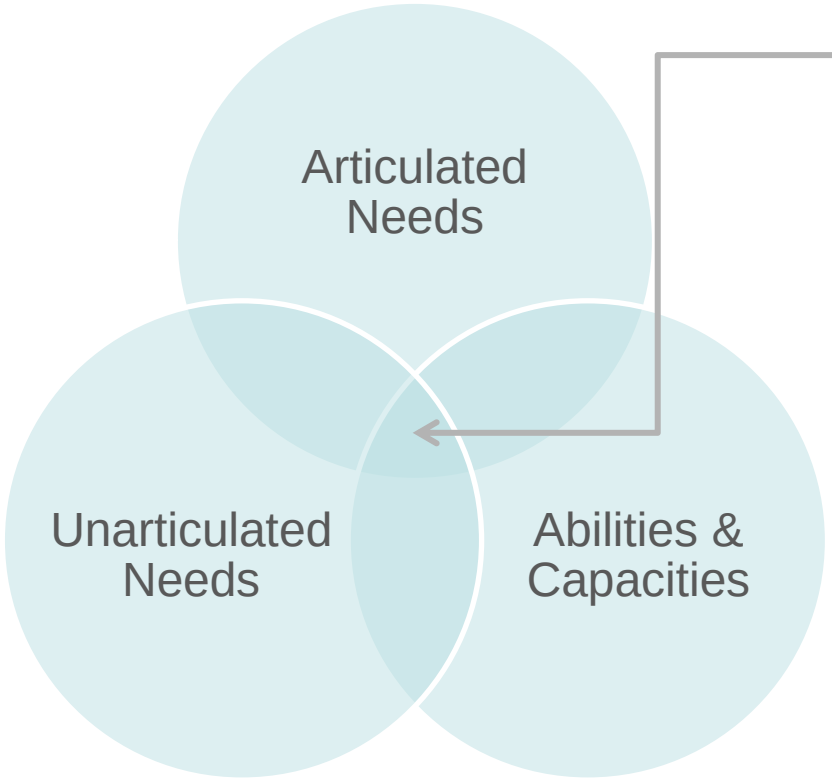
Using an HF lens provides the opportunity to highlight potential risk to the user, equipment, and product.

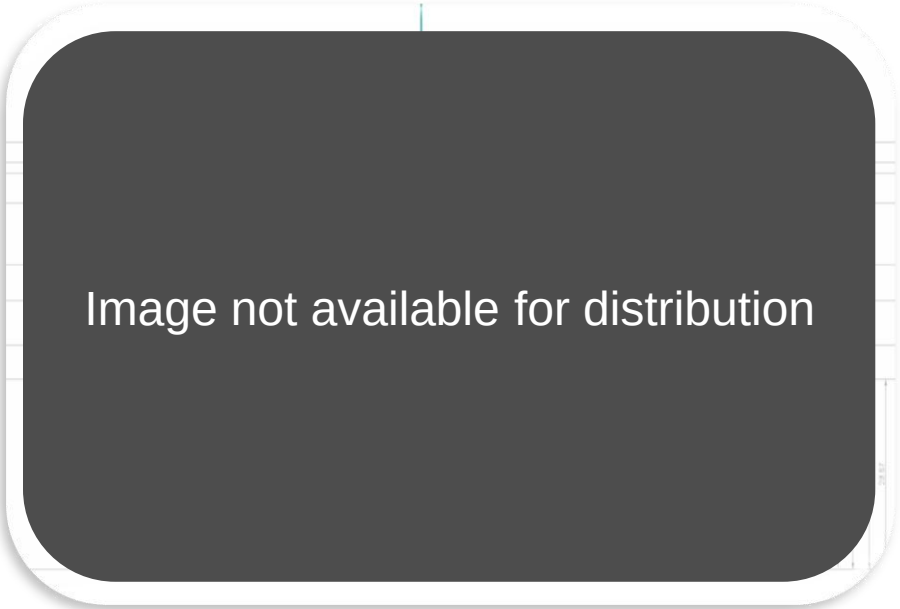
The concept to the right posed a number of potential risks that needed to be mitigated in design updates:

- Inadequate spacing from floor to critical feature
- Inadequate access to critical feature
- Inadequate access to emergency stop button
- Inadequate access (height) to critical feature
- Less than optimal door hinging and handle placement

Mapping the Risk Intersections

Not meeting the HF intersection can pose a number of risks to product, user, compliance, and user experience.





The system above mitigated a number of risks such as:

- Improved cable management
- Appropriate reach and access to controls
- Appropriate placement of monitor and keyboard
- Improved access to critical controls
- Improved maneuverability

Delivering the Successful Product

Human Factors provides us with a multitude of tools to be proactive about identifying risks.

The instrument to the right is one which had the benefit of a rigorous human factors program.

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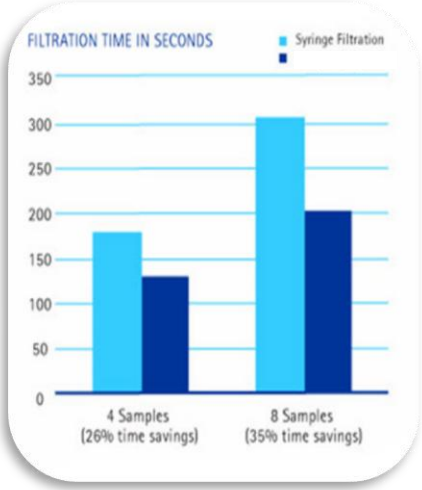

Through human factors research the following marketing claims were validated:

- Faster filtration time
- Marked reduction in waste
- Decreased amount of force requirements yielding less risk for injury

			% Reduction in Waste
Weight (g)	2827.5	4232.9	33.2%
Volume (in^3)	1000	3000	66%

Risk Mitigation through Human Factors

Human Factors is best when leveraged proactively.

1. Identify your risk and opportunities early on.
2. Make informed decisions throughout and be accountable for them.
3. Validate your product/systems and decisions.

Mitigating risk one step at a time!

Thank you

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Boston Area Chapter

September 2011

Use of Risk Management in CAPA Root Cause Analysis

Presented by:
Susan C. Reilly
Reilly & Associates, LLC

Agenda

- General overview
- Risk and prioritization
- Defining the scope (problem statement)
- Identification of root cause
- Root cause toolbox

General Overview

Definitions - Correction

- Action to eliminate a detected nonconformity
  - Does not address cause
  - Repair, rework, re-grading, scrap
  - Retrain, rewrite

Definitions - Corrective Action

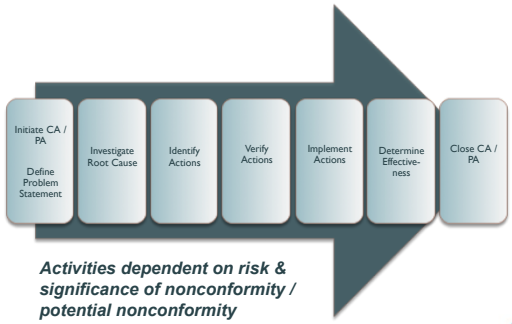
- Action to eliminate the cause of a detected nonconformity or other undesirable situation
  - Taken to prevent recurrence
  - Can be more than one cause for nonconformity
  - Correction may be taken in conjunction with a corrective action

Definitions - Preventive Action

- Action to eliminate the cause of a potential nonconformity or other undesirable situation
  - Can be more than one cause for nonconformity
  - Taken to prevent occurrence

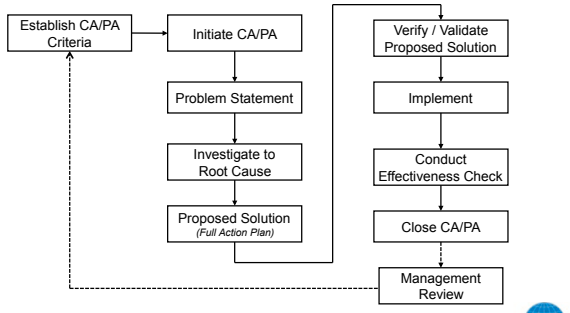
Risk and Prioritization

CA / PA Simplified



Activities dependent on risk & significance of nonconformity / potential nonconformity

CA / PA Simplified



Expectations

- Manufacturers will determine significance, risk, and (if applicable) potential for recurrence
  - No action
  - Collect more data
  - Correction
  - Corrective Action (with or without correction)
  - Preventive Action

Integrating risk management

- Classify by severity / seriousness
- Classify by likelihood
- Significance of consequences
  - Is risk acceptable? Intolerable? Easily remediated?
  - Link to product / process risk files

Prioritize at initiation … re-evaluate at all phases

Risk & prioritization

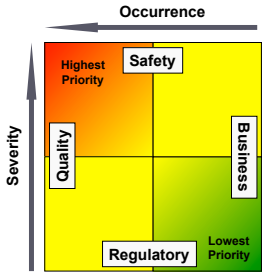
- Establish a risk assignment & prioritization method
- Use the method *consistently* across the quality management system

⇨

- *Complaint Handling*
- *Nonconforming Product, OOS*
- *Supplier Performance*
- *Change / Document Control*
- *Environmental Monitoring*
- *Process Controls*
- *Servicing*
- *Audits*
- *Etc.*

Risk & prioritization

- Prioritize when problem is identified
  - Re-assess priority when cause is identified
  - Re-assess priority when solution is identified
  - Re-assess while action plan being implemented



Defining the Problem Statement

Problem Statement

- Necessary for the investigation
- Clearly identifies and describes the problem you are trying to solve
  - Avoids guesswork
  - Avoids "shooting from the hip"
- Assists in further identifying risk

Problem Statement

- What is a "problem"?
  - A deviation from the expected
  - When what ***happened*** is different from what ***should have happened***

Problem Statement

Does

- Contain the what, who, when, where, how much, and how many
- Focuses on the difference between expected and actual
- Includes measurable and objective evidence

Does not

- Offer a solution
- Assign a cause
- Address more than one problem
- Assign blame

Details

- Nature of the nonconformance
- Specific product or process involved
- Extent of the nonconformance
  - Number of problems
  - Percentage of product affected
  - Impact on patient, user, process
  - Is the problem still occurring

Example

- On 8/3, NCR 080306-02 scrapped 1/2 of tubing produced on 1st and 2nd shift in room #8 (extruders #s 1-3) due to visual contaminants in the tubing. NCR 080306-03 scrapped 1/5 of the production from 3rd shift for visual contaminants (same extruders). On 9/5 NCR #090506-03 scrapped 100% of tubing extruded during 1st shift on the same extruders.
- The three extruders in this room have been shut-down until the cause can be identified. The decrease in production will cause backorders in at least two of our IV product lines, resulting in a potential $xx sales loss.

Scope Creep

- Keep the problem statement boundaries defined throughout the investigation
  - Don't start working on other issues
- Statement *can* be further defined as the investigation evolves, but should not "creep" into another problem
  - Handle as separate issues
  - Makes risk difficult, if not impossible, to assess

Root Cause

Data Collection

- Focus on the problem statement at hand
  - Different than data analysis
- Information to address the "what, who, where, when, how much, how many questions"
  - Helps lead to the "why"
- Collected throughout the evaluation process
- Most useful when from various data sources
  - Across processes, systems, product lines, and quality systems

Considerations

- Is this a recurring problem?
  - Has the severity changed?
  - Has the frequency changed?
- Is this a new problem?
  - What is the overall risk?
- Is the situation likely to get worse?
- Is there a potential for other problems to develop during the investigation

Root Cause

- An effective CAPA process should have an established system for identifying and investigating root cause
  - The fundamental, underlying reason for a problem, which, if corrected, will prevent recurrence of that problem
  - An identified reason for the presence of a defect or problem
  - ***This*** is what we want to find!

Investigate Cause

- Contain nonconformity
- Investigate to the level necessary
  - To determine cause
  - Relative to the significance and risk of problem
- Re-assess risk throughout investigation

Useful Tools

- 5 Whys
- Cause and Effect Diagram
- Fault Tree Analysis
- Pareto Chart
  - Used singularly or in combination
  - Brainstorming key input for all tools

What is Brainstorming?

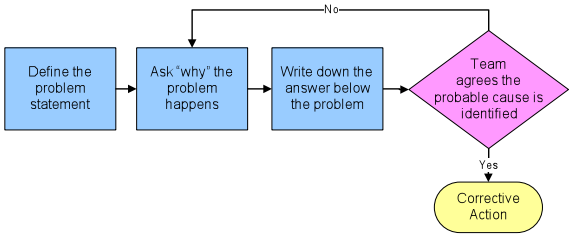
- A tool used by teams for creative exploration of options in an environment free of criticism
- Benefits of Brainstorming
  - Creativity
  - Large number of ideas
  - All team members involved
  - Sense of ownership in decisions

Root Cause Analysis Toolbox

5 Whys

- The practice of asking, five times, "why" the failure has occurred in order to get to the root cause(s) of the problem
- Generally carried out by a team utilizing brainstorming
- No special technique or statistical analysis is required
- A technique used to get beyond the symptom

5 Whys



Cause and Effect Diagram

- Visual tool used to logically organize possible causes for a specific problem or effect by graphically displaying them in increasing detail
  - Help identify root causes and
  - Ensure common understanding of the causes
- Also known as the Fish Bone or Ishikawa diagram

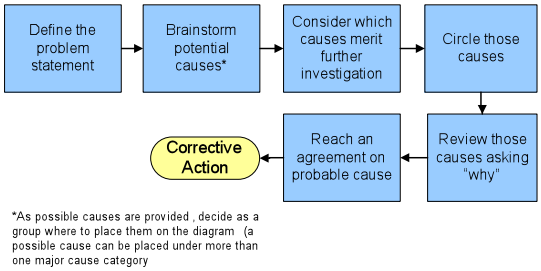
Cause and Effect Diagram

- Causes are arranged according to their level of importance or detail
  - Search for root causes
  - Identify areas where there may be problems
  - Compare the relative importance of different causes

Cause and Effect Diagram

- Related causes in a cause & effect diagram are frequently arranged into major categories
  - People, material, machine, environment, methods, measurement
  - Policies, procedures, plant, people

Cause and Effect Diagram



*As possible causes are provided , decide as a group where to place them on the diagram (a possible cause can be placed under more than one major cause category

Fault Tree Analysis

- FTA is an analysis technique that visually models how logical relationships between equipment failures, human errors, and external events can combine to cause specific accidents
  - More sophisticated form of 5 Whys

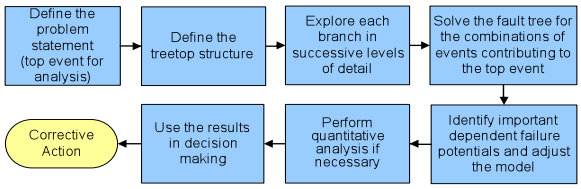
Fault Tree Analysis

- Qualitative descriptions of potential problems and combinations of events causing specific problems of interest
- Quantitative estimates of failure frequencies and likelihoods, and relative importance of various failure sequences and contributing events

Fault Tree Analysis

- Lists of recommendations for reducing risks
- Quantitative evaluations of recommendation effectiveness

Fault Tree Analysis

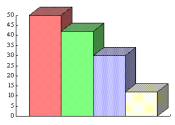


Pareto Chart

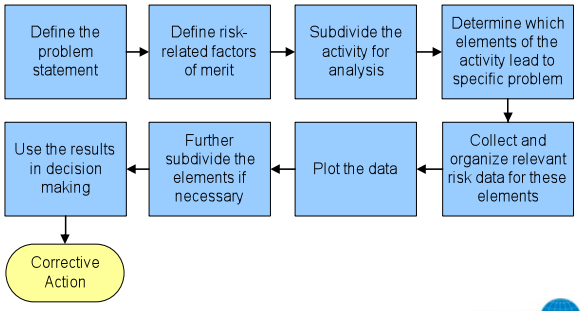
- Employs the 80-20 rule, which states that about 80% of the problems or effects are produced by about 20% of the causes
- Classifies items, events, or activities according to their relative importance or priority
- Typically used in combination with other tools

Pareto Chart

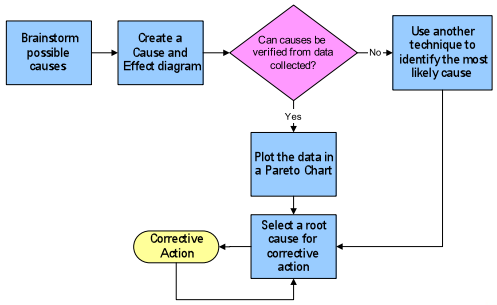
- Breaks big problem into smaller pieces
- Identifies most significant factors
- Shows where to focus efforts
- Allows better use of limited resources



Pareto Chart



Sample Process



Summary

Questions?

Thank You !

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Take Away Example

Flat Tire Example

- Situation – prior to leaving for work in the morning one of the car's tires was found to be deflated.
  - Is a single occurrence of a flat tire "CA worthy"?

Flat Tire – Problem Statement

- What – rear passenger tire appears deflated
- When – discovered before leaving for work
- Where – unsure of location of occurrence
- Where – mom's car
- How many – one tire
- Risk – possible safety issue if car is driven, possible damage to car

Flat Tire – Investigation

- Brainstorming, testing (physical examination), interview
- 5 Whys
- Why is tire deflated?
  - Wasn't properly inflated when installed
  - Someone intentionally let air out of tire
  - Tire is leaking

Tire is leaking

- Why is tire leaking?
  - Valve stem is leaking
  - Aluminum wheel is leaking
  - Interface between wheel and tire is leaking
  - Tire has a puncture

Tire has a puncture

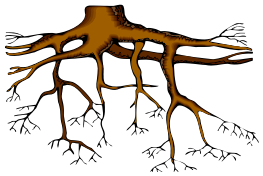
- Physical cause
  - Correction – plug the hole or replace the tire
- Why did it occur?
  - Someone intentionally punctured it
  - Driver ran over something hazardous

Driver ran over something

- Why?
  - Didn't see a hazard in the road
  - Tried to avoid rear-ending another vehicle and swerved off the road hitting a hazard
  - Habit of driving through the median to avoid heavy traffic

Root Cause

- Habit of driving through the median to avoid heavy traffic



Possible Solutions

- Change driving habits
- Change driving route to avoid heavy traffic
- Change driving times to avoid heavy traffic
- No action and risk recurrence

Toolbox

Examples and Additional Information

Brainstorming Ground Rules

- Active participation by everyone
- No discussion
- Build on others' ideas
- Display ideas as presented
- Set a time limit
- Clarify and combine

Brainstorming Sequence

- Review the rules
- State the question
- Collect ideas
  - Structured
  - Unstructured
- Record and display ideas
- Clarify the meaning
- Eliminate duplications

5 Whys - Example

- Problem Statement *(simplified version!)*
  - Complaints have been received from 5 customers in the past 2 months on custom critical care kits. Customers indicate that the product is not per their specifications. Two long-term customers have stopped placing orders for custom kits.

5 Whys - Example

- Why are customers being shipped bad products?
  - Because manufacturing built the products to a specification that is different from what the customer and the sales person agreed to.

5 Whys - Example

- Why did manufacturing build the products to a different specification than that of sales?
  - Because the sales person expedites work on the shop floor by calling the Manufacturing Manager directly to begin work and an errors have been happening when the specifications were being verbally communicated.

5 Whys - Example

- Why does the sales person call the Manufacturing Manager directly to start work instead of following the established process?
  - Because the "start work" form requires the Sales Director's approval before work can begin and this slows the manufacturing process (or stops it when the Director is out of the office).

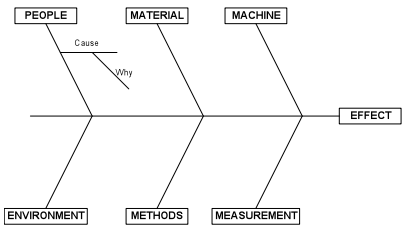
5 Whys - Example

- Why does the form contain an approval for the Sales Director?
  - Because the sales director needs to be continually updated on sales for discussions with the CEO.

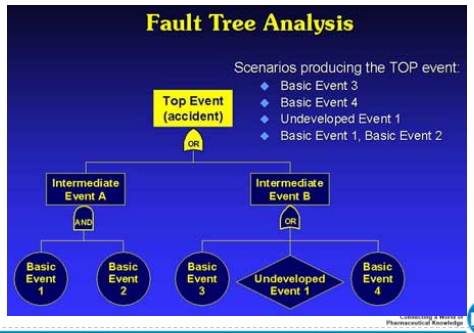
5 Whys - Example

- In this case only four Whys were required to find out that a non-value added signature is helping to cause a process breakdown

Cause and Effect Diagram



Fault Tree Analysis Diagram



Other Tools: "Is" – "Is Not"

	IS	IS NOT
WHAT		
WHEN		
WHERE		
EXTENT		

Is / Is Not Diagram

Other Tools: Contradiction Matrix

Facts From Step 1

Causes From Step 2

	Fact 1	Fact 2	Fact 3	Fact 4						
Cause 1	O	A	O	O						
Cause 2	O		X							
Cause 3		O	A	O						
Cause 4	O		O	O						
Cause 5	O	X								

X – Fact contradicts cause
A – Assumption Made (Need to verify w/data)
O – Fact supports cause
Blank – need more data

Other Tools: Event and Causal Factor Charting