5 Ways To Stop FDA Recalls

FDA medical device recalls were down 22% in FY2019.

That's good. But don't open the champagne just yet. New device introductions dropped 15% as well. In fact, since FY2003, these two measures have had a 96% correlation. The drop in recalls came from basic economics, not poor risk management. And not from the Wuhan CVD-19 virus. That came after, In FY2020.

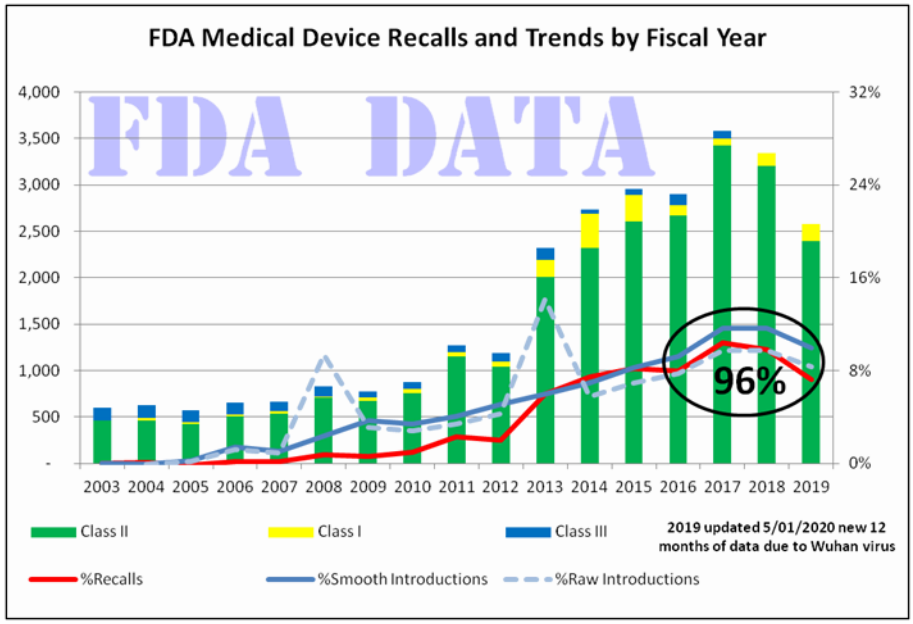


Figure 1 - FY2019 FDA Recalls drop 22% BEFORE Wuhan CVD-19 starts.

Can you follow the blue and red lines on this updated chart below? This is what a 96% correlation looks like. More medical device introductions just mean more devices and many more opportunities for FDA recalls each year.

There was no "Recall Epidemic" raging in the industry these last few years. Maybe nobody looked for the 96% correlation in any of the other FDA databases.

Only one person had to.

<u>Correlation does not always imply causation.</u> But, it does in some cases. It does here.

Every new device introduction brings to market its failure modes, documented and mitigated or not. Hidden faults make hidden device defects. And, going after these faults with resources is important. It is warranted because FDA recalls can hurt people and destroy device manufacturers.

This gives us license to do just about anything to stop them. Including new or updated processes, technology, organization structure and culture. You can choose to break out of the correlation.

Now would be a good time.

The Status Quo

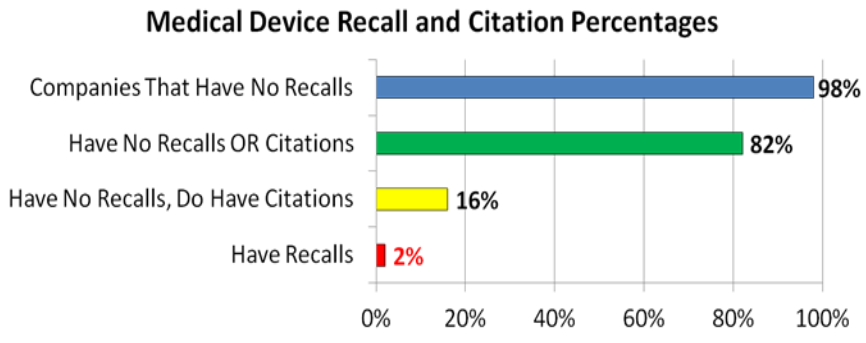


Figure 2 - The Status Quo

Here's the Status Quo. **2%** of firms have recalls. These are represented in Figure 2, at left, by the small **red** bar at bottom. They look small here. But they're associated with a lot of **PAIN**. They are why so much effort and resources are expended to avoid them.

That means **98%** of firms have no recalls. Luckily, that places most of you in the **blue** bar at top.

Most of you are also in the **82%** that are perfect. You have no recalls OR citations. Congratulations! In the chart that puts you in the **green** bar.

Everybody starts off in the green bar.

> So, the question is: will you lose your perfect record to a recall?
> Or, will you fall in with the **16%** that have only citations, in the **yellow** bar?

And, in a larger frame, for everybody in general, do citations result from lapses in QUALITY, or are they more a function of PROBABILITY?

What we NEED are solutions that don't rely on LUCK.

The 5 Ways to Stop FDA Recalls

1. **Detection to the Rescue**
   - Improve your competence in finding faults.
2. **Knowledge Synergy**
   - Go DEEP and make the best of the information and expertise available.
3. **Sharing Synergy**
   - Go WIDE and explore different connections and configurations.
4. **Precise Probabilities**
   - Combine FMEA and FTA and work towards the best in human terms, avoiding Mistakes 1 and 2.
5. **Anchoring Standards**
   - Take risk management ever forward and keep its edge.

5 Ways To Stop FDA Recalls

1. Detection to the Rescue

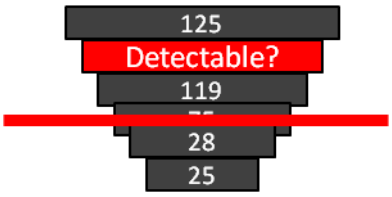


Figure 3 - Detectable Fault?

Figure 3, at left, depicts risk analysis where Detectability is at question. Each black rectangle represents a risk (failure mode or fault). The number is its assigned Risk Priority Number (RPN). A common RPN calculation is to multiply some ordinal integers that rate the risk along three scales for impact, occurrence and detectability.

Notice that the risks are ranked and ordered by RPN. High risks are sorted to the top, low ones to the bottom. The red line represents the dividing line of risk acceptability. Risks above it require mitigation in your estimations. The ones below it are acceptable. In this example there is a large risk in red near the top.

Figure 4, at right, shows the result of mitigating a large risk. The large red risk near the top has become the small green risk at bottom. In practice this would likely reflect the creation of controls that mitigate the dangerous condition.

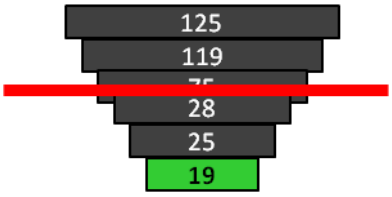


Figure 4 – Mitigated Fault

In reality, high Risk Priority Numbers are not just a paperwork exercise. They call for resources in the form of budgets and effort to find and create tests and design controls.

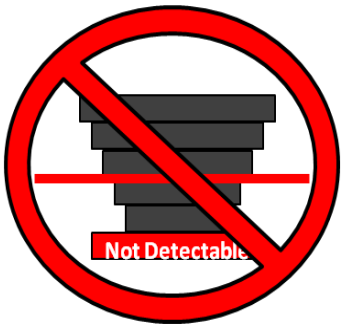


Figure 5 - Undetected Fault

The situation at left in Figure 5 is what we want to avoid: an unmitigated fault / failure mode. It comes from an unappreciated and purposefully undetected fault.

Figure 6 below shows what your real risk matrix looks like when detectability is not considered. Like Ninja's, they are dangerous and hidden.

Detectability is related to the ability to detect a fault, assuming it is present. It is not related to occurrence. Its dimension is orthogonal to that.

Figure 6 - Your Real Risk Matrix?

2. Knowledge Synergy

This method has two synergy flavors. The first is Knowledge Synergy. The idea here is to bring together people with different backgrounds and expertise to create novel solutions from new combinations. For example, bring development team members, with product knowledge, together with specialists having risk management expertise.

This can be accomplished by designing meetings to invite specific people and give its purpose a detailed and specific agenda. The agenda could lead meeting discussions to find deeper problems and more imaginative solutions.

Meetings don't need to be boring or wasteful, either. They could actually become engines of solutions and progress by virtue of heavily engaged participants. Their conversations and collaboration documentation will represent evidence of FDA regulatory compliance.

3. Sharing Synergy

Sharing synergy, the second flavor, lets you go wide and explore different connections and configurations.

The second flavor is Sharing Synergy -- to go WIDE and make the best of the information and expertise available.

Share Cross-Component failure modes and discoveries.

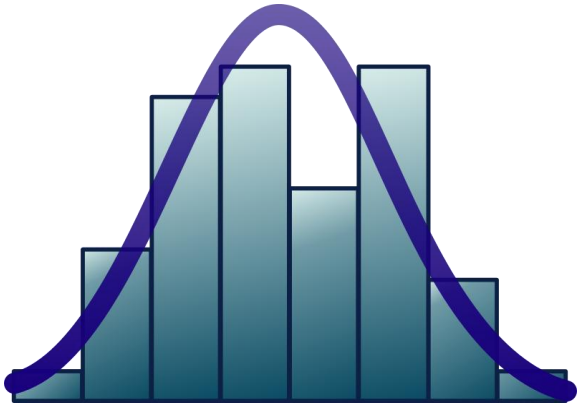
And, find risks and mitigations in Component Interfaces and Interactions.

Conversations should find plenty of synergy in the shared viewing.

Establish periodic risk management meetings with all hands, and in special groups, to make presentations and reap the synergy of sharing analogs of risks and mitigations between components; sharing cross-component failure modes and discoveries; and finding risks and mitigations in component interfaces and interactions.

Larger meetings can show the collective risks to be examined. And, permit new risks and changes to be recorded on the spot and in the minutes of the meeting.

4. Precise Probabilities



In this section learn to combine FMEA and FTA and work towards the best in human terms.

- Add FTA to FMEA.
- Use FTA to calculate quantifiable probabilities.
- Use in Benefit-Risk Assessments.
- Compare risks on human terms.
- Get higher quality and precision results.
- Improve safety and reliability with exanimation of whole structures and possible configurations.

Combine FMEA and FTA. Then make it iterative so it can attack faults and incrementally reduce their probabilities with each cycle. These are steps taken from process improvement. Not included are the formal planning, piloting and study of results.

But, implicitly still included are selection and identification of risks and actions to taken.

Dr.'s Walter A. Shewhart and W. Edwards Deming[1] would have you avoid making two kinds of mistakes: 1) assuming a problem (or medical device failure mode) comes from a special cause when in fact it is a product of a common cause shared system wide, or 2) assuming a problem is system-wide when in reality it has some special cause.

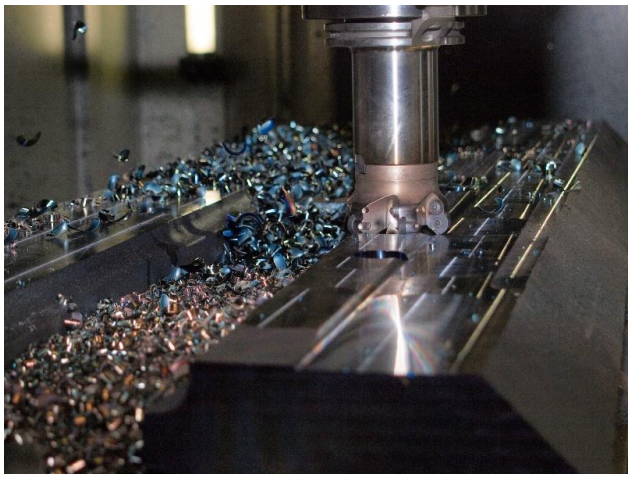


Figure 7 - Iterative and Incremental Reduction

Special causes each need a special fix. Common causes need system-wide solutions, which will often call for cycles of Plan-Do-Study-Act (PDSA), or Six Sigma DMAIC.

This method will give you the processes and the cycles within which to do PDSA, etc., and whittle down failure mode probabilities. If your process becomes stuck in any iteration, then you have the choice to institute a formal problem or process improvement project.

In this risk management framework you could also just accept the risk as-is, find some way to avoid it, abandon it, transfer it, or mitigate it in some other fashion.

5 Ways To Stop FDA Recalls

Add FTA to FMEA. Make your risk management aggressive.

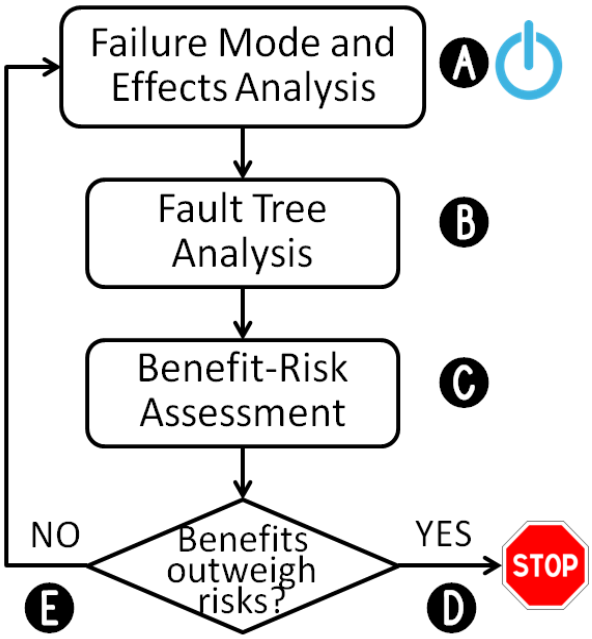


Figure 8 - Combine FTA and FMEA

FMEA is a discovery and bottom-up process. It iteratively works to better understand each fault/failure mode in isolation to control its severity, likelihood and detectability. Also, to understand its causes and probabilities, and find new faults/failure modes and causes. It deals with ordinal or qualitative quantities. This is appropriate to manage the attention and resources applied to individual risks, improving depth of understanding and applying it towards more accurate mathematical probabilities. Which is why FMEA is used in this method.

Use FTA to calculate quantifiable probabilities.

FTA is a top-down analysis process. Iteratively parsing the structure of a product and its faults/failure modes, it derives quantifiable probabilities of failure and harm. It seeks to understand the vulnerabilities of the structure overall and find new configurations that improve safety and reliability. And, find new faults/failure modes that fit into the structure.

Figure 8 shows the two techniques combined. The method starts with A FMEA because it can be done while design is just beginning and risks are not all known. No tree or partial fault tree is needed for analysis. It is done bottom-up on each new and current failure mode with a fresh understanding of structures and probabilities from the last FTA and device sensitivities to complex failures. Each iteration looks more deeply for detections, controls and mitigations that would make a risk more acceptable.

B Fault Tree Analysis is done next. It's a top-down process to create and maintain the device fault tree. Its purpose is to understand the overall structure of the product and calculate the mathematical failure probabilities needed for the next step. . Each iteration starts at a top-level fault and can reduce risk with structural changes as well as controls

C Benefit-Risk Assessment is performed at [C] to keep the overall goal in mind. It applies the probabilities to the harms and balances outcomes against absolute safety and reliability goals.

D Next at [D] the outcomes of benefit risk assessment are checked. Specifically, that all the risks have been accepted and considered, that there will be no more risks to be assessed, and that all outcomes are outweighed by the benefits with an acceptable margin. If so, then the process can stop.

E If not, then at [E] the loop returns to the top and FMEA is done again to get a deeper look at each failure mode for further mitigation. It can go around many times to ensure that all manner of detection and mitigation has been applied to current controls, thus driving down absolute probabilities of device failures.

The method has TRIGGER EVENTS and INPUTS that add to the risk data they own.

Design, functional and process documentation is always available and up to date.

Design Verification will be a common trigger…CAPA…Non-conformance…Internal Audits

Remember, it's not NAKED risks that are accepted. Faults are usually accepted with all their controls and other mitigations. And, these must be documented, traced, and audited.

Use in Benefit-Risk Assessments.

It can be to your benefit to follow non-binding recommendations. They often point in new and useful directions. Note that the assessment risk factors are all mathematical probabilities. This is necessary to express the uncertainly, precision and risk in human terms for comparison to the benefits. The good news is that this method uses FTA to calculate fault/failure mode mathematical probabilities which can be used directly in these human impact calculations.

Compare risks on human terms.

"Likelihood of risk considers risk factors related to the potential number of patients at risk of experiencing harm: the likelihood that a medical device will have problems, the likelihood of a patient experiencing harm, and the total number of patients exposed.[2]"

Get higher quality and precision results.

Automation in the transfer of failure modes for FMEA or FTA calculations will speed up iterations and reduce clerical errors. Also, software that can increase risk management collaboration between risk specialists and development team members will produce synergy in the understanding of failure modes and discovery of new ones. Especially, if meetings can be designed to bring people together that are remote or part of outsourced solutions.

Internet facilitated meetings can remove the requirement that attendees need to be in the same room. This can reduce the cost of outsourcing and travel, or the need for any altogether.

A great number of companies like yours are running process improvement programs. If yours has one, you might think of recruiting it to your needs.

5 Ways To Stop FDA Recalls

Improve safety and reliability with exanimation of whole structures and possible configurations.

This method iteratively invokes FMEA and FTA to understand vulnerabilities, prioritize efforts, and work to optimize safety and reliability. It was inspired by a very complex technical article.[3] Their method was a mash up of FTA and FMEA. It did not include Benefit-Risk Assessment.

This method can also establish confidence that recalls are being proactively prevented and that lack of recalls is not just by good fortune. The goal of risk management here is to improve device safety and reliability by moving all risks into the 'Accepted' category until marginal returns set in. The method works by making risks incrementally smaller and less likely by changes in design (or manufacture, etc.), or application of controls, in each iteration. (This can be seen in Figure 9 below). The trail of analysis, changes, and risk acceptance will provide such confidence.

#	Likelihood	%
10	Very Likely	20
9	Very High	10
8	High+	5
7	High-	2
6	Moderate+	1
5	Moderate	0.2

Figure 9 - Likelihood/Probability Table

Often risks can be attributable to root causes. FMEA does this formally and often handles each risk individually. FTA can do this but it is more complex. All root causes become new risks that expand and reconfigure the tree to calculate the total effect.

FTA does not really 'iterate' over risks. The methodology typically 'solves' for top-level risk probabilities based on causal risks lower in the tree. Like a harbor tide, as water recedes, new features are revealed that were hidden just below the surface of the water. The good news is that computer tools designed for this analysis are available that make it much easier to perform. So, a deep tutorial on FTA will not be found in this document.

Upon exit of a Fault Tree Analysis, risk probabilities can be translated into, or reconciled with, likelihood values using a mapping table like in Figure 9. This data, with its book values, should be established beforehand and maintained as a very valuable organization asset. It can be used to translate initial verbal and ordinal scale likelihood rankings into probability approximations. Later, when more accurate probabilities have been calculated, the situation reverses. Risk probabilities can be translated to ordinal numbers and verbal characterizations, and thus participate in RPN calculations and discussions.

A FAILURE MODE AND EFFECTS ANALYSIS

Figure 10 shows the steps in an FMEA. Its purpose is to evaluate and mitigate risks in a continual loop until marginal returns set in. To begin 1 review or update all risks (faults, failure modes), checking 2 that each has been mitigated, controlled, and/or accepted in turn with fresh understanding of structures and probabilities from the last FTA and newfound device sensitivities to complex failures. If so, then EXIT. If not, 3 update each risk's residual severity description, quantification, and ranking after mitigations or controls or detections are applied. With this information, 4 identify new or update old root causes and new risks for new iterations. Also, 5 update each risk's residual occurrence description, quantification, and ranking. Then 6 review, identify or update current controls that are in place. Knowing this, 7 update the residual detection descriptions, quantifications, and rankings, 8 recalculate the RPN values, and 1 review that all risks are 2 mitigated, controlled by doing everything we can with everything we know so far, and/or accepted with mitigations and controls.

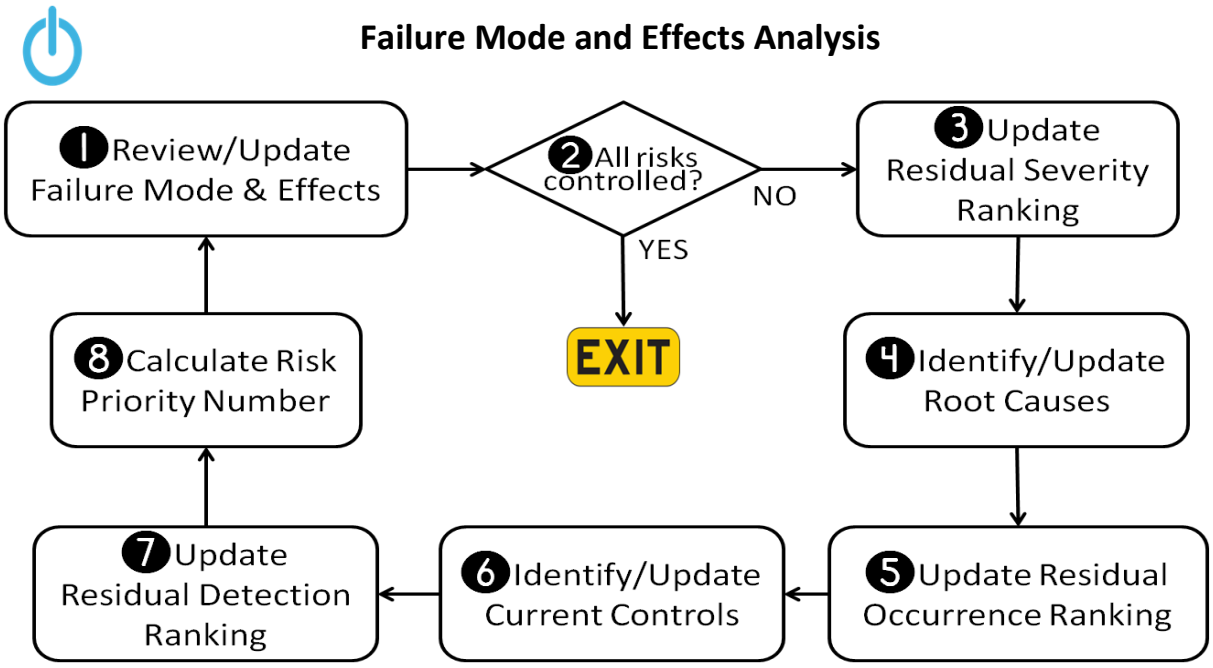


Figure 10 - Failure Mode and Effects Analysis

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B FAULT TREE ANALYSIS

Fault Tree Analysis starts with the tree 1. The first iteration will begin construction of the risk tree of events and gates, etc., and the estimation, structure and assignment of probabilities. Subsequent iterations will update and manage it. 2 The goal here (Figure 11) is to evaluate the probabilities of all risk(s) and determine if they have all been controlled or their effects limited given the tree risk structure and mitigations. If so, we EXIT. If not, 3 top level faults are evaluated. Following that, 4 COMMON, system-wide structural mitigations, restructuring, reformulations are then investigated. FTA can see and make changes that FMEA cannot because it can see new perspectives, view fresh angles, and exercise new freedoms to maneuver and innovate that FMEA does not have. From there, 5 identify new risks and specify more mitigations for all the changes.

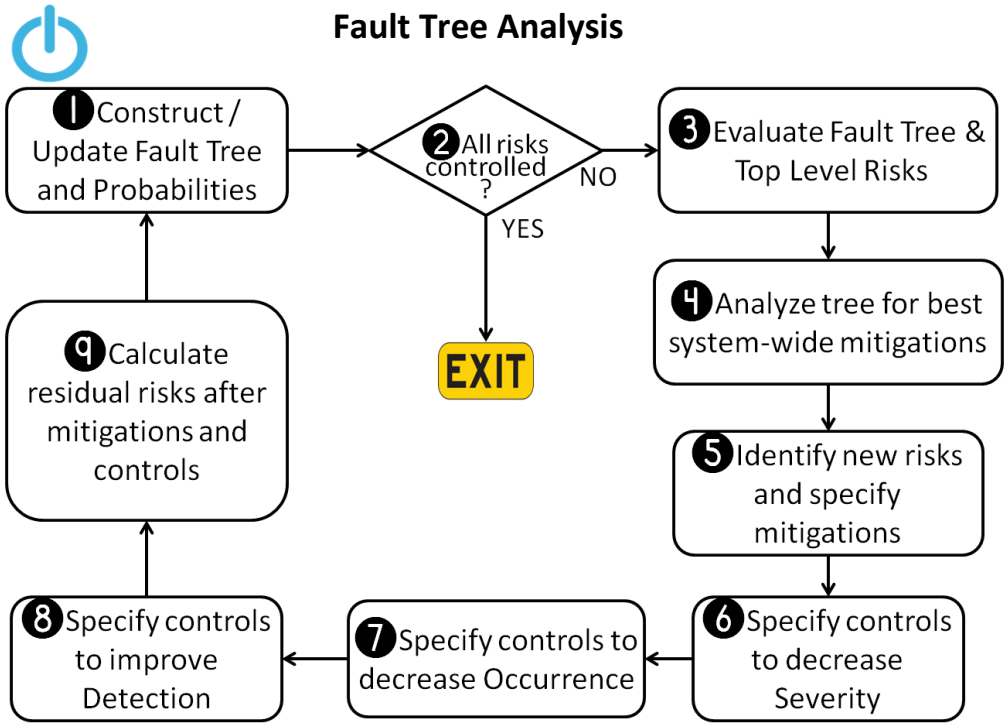


Figure 11 - Fault Tree Analysis with Detection

Continuing with this new information, then 6 review and update controls with which to decrease severity of risks. Next 7 review and update controls with which to decrease occurrence of risks. And, 8 review and update controls with which to improve the detection of risks. When done updating control specifications, 9 calculate the residual risk occurrences and severities after application of all controls and mitigations. Then 1 update the fault tree again with the new data and recalculate risk probabilities. When we have done everything we can with everything we know so far, all risks have been accepted with their residual values after controls have been applied, and all failure paths have been investigated 2 then exit.

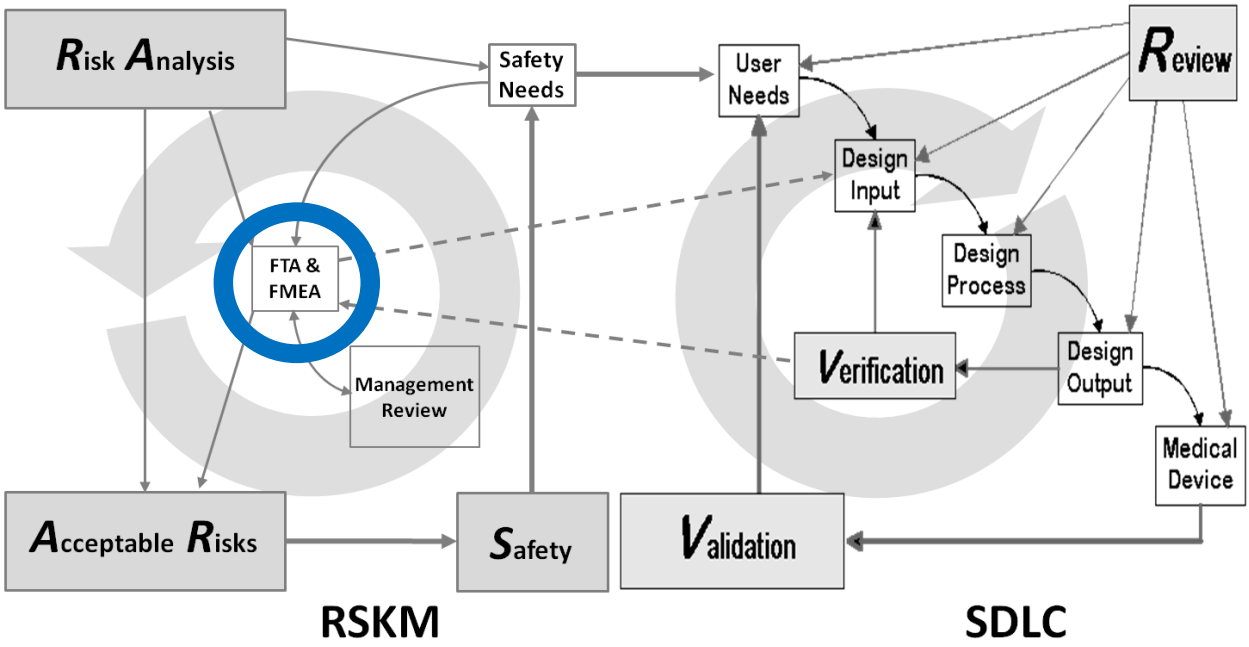


Figure 12 - Integrated Risk Management and Development

The curious may want to know just where this method would fit into your processes. How exactly should everything be integrated?

Aggressive risk management uses the simplified model above for integrating risk management, quality management and performance management. You can use it to improve your results by embedding it in your own proprietary processes. The method is used in the blue circle in the middle of the RSKM loop on the left: FTA & FMEA.

The model of integration in this method (Figure 12) might be familiar. At least the right half. It was on the FDA website on a page about Software Development Life Cycle (SDLC) for medical devices.

Use this new method to break out of the status quo. Use the SDLC model to also stand in for non-software related System Development Life Cycle as a guide to tie Risk Management into your medical device development cycles. There should be analog processes for development of devices with no software at all; devices with embedded software; and devices that are all software. And, for traditional software development and all flavors of Agile.

Your challenge is to understand the theory of this method, make the connections in your current processes, and make it all operational in the context of your system of development.

How it works.

There are two loops operating in Figure 12. The one on the right half, labeled SDLC, goes clockwise. It starts at **User Needs** and goes around to **Validation**. The one on the left, labeled RSKM for Risk Management runs counterclockwise. It starts at **Safety Needs** and goes around to **Safety**. The SDLC loop terminates at **Validation** when its criteria are reached. RSKM terminates when all risks are acceptable and Safety is achieved.

The RSKM loop begins by contributing **Safety Needs** to **User Needs** ❶. This is the first connection from RSKM to SDLC. These 'needs' are expressed within SDLC design and development.

Risk Analysis monitors all risks (i.e. faults, failure modes) and acts by moving them into **Acceptable Risks**. Also, if needed, it updates **Safety Needs** and **FTA & FMEA**.

To start, **Risk Analysis** triggers **FTA & FMEA** so that the initial Fault Tree is built. After that, **Verification** triggers **FTA & FMEA** ❸ so the impact of design and development changes can be assessed on risks. This is another connection between RSKM and SDLC.

Changes from **Risk Analysis** and **FTA & FMEA** can trigger changes to **Design Input** ❷ to contribute requirements design and features that mitigate risks.

FTA & FMEA is monitored and controlled by **Management Review**. **Risk Analysis** depends on **FTA & FMEA** to analyze all risks from top to bottom, and mitigate all risks so they individually meet acceptance criteria to the greatest extent possible at the moment.

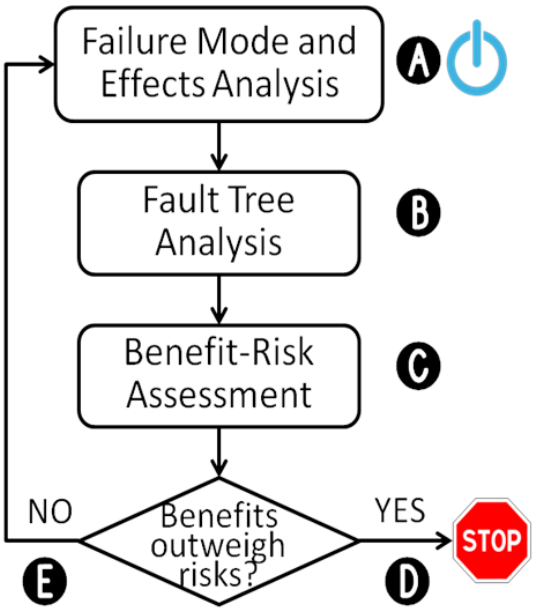
Make Benefit-Risk Assessment a permanent part of risk management. Keep safety-related behaviors from fading, and preventing other motivating factors to come to the fore.

Implement the RSKM loop and links to your SDLC into your Standard Operating Procedures.

So, this is how FEMA and FTA are combined and implemented. However, as soon as it is built, then it will start to degrade. Start to lose its edge. The last component is how to keep it sharp. How to keep the quality up and actually keep improving it.

5. Anchoring Standards

Take risk management ever forward and keep its edge.



- **Make benefit-risk assessment a permanent part of risk management.**
- **Keep safety-related behaviors from fading. Don't take quality for granted.**
- **Prevent other motivating factors from coming to the fore.**
- **Do assessments using fixed global standards for safety and reliability.**
- **Anchor risk management in your culture and prevent it from being eroded by time or expediency.**
- **Create and maintain a Risk Vault.**

Figure 13 - Anchoring Standards

Make benefit-risk assessment a permanent part of risk management.

… BY embedding it into your processes and improving it over time.

Keep safety-related behaviors from fading. Don't take quality for granted.

… BY maintaining practices like special meetings in plans and processes to keep their edge.

In addition, this method will prevent the fade of safety-related behaviors by anchoring them to global standards and absolute risk management goals used in each Benefit-Risk Assessment (BRA). Create a Risk Vault to store memories in their culture and stop learning/forgetting cycles that cause many disasters.

Prevent other motivating factors from coming to the fore.

… LIKE cost cutting, or temporarily eliminating factors that don't contribute.

Do assessments using fixed global standards for safety and reliability.

… BY documenting standards and reviewing them regularly.

Anchor risk management in your culture and prevent it from being eroded by time or expediency.

… DON'T cut corners or take short cuts that pay off short term, but may stick around as a bad practice.

5 Ways To Stop FDA Recalls

Create and maintain a Risk Vault.

Manufacturers that have been in business a while should have a proprietary risk vault of past risks detected and, better yet, not detected before reaching a user. This is a learning process. It creates a precious resource for future risk management, and future detection.

Your risk vault should drive planning and process design and product design. Any past problem is a potential future problem. This resource should gradually improve the safety and quality of your products. Every project should have a post-mortem where its history is mined for project risks, product faults, and lessons learned.

PROBLEMS WITH SCORING METHODS AND ORDINAL SCALES IN RISK ASSESSMENT

Douglas Hubbard and Dylan Evans, both of IBM, are not fond of scoring methods based on ordinal scales in common use. They argue conclusively in the IBM Journal of Research & Development [4] that the "perceived benefit is probably illusory in most cases." And, explain why "risk assessment approaches should describe risk in terms of mathematical probabilities." Note that Fault Tree Analysis operates on, and delivers results, in terms of mathematical probabilities.

There is a companion article, 'Detection to the Rescue', that shows how avoiding use of Detectability rankings can be dangerous. It explains how hidden faults make hidden device defects. That is why this method recommends its use. And, especially recommends using FTA with mapping tables and dealing with mathematical probabilities whenever possible.

Ordinal scales are also useful to look at relative priorities and exposures. These can show where attention and resources should be budgeted. And, using different combinations, like simple RPN, weighted RPN, or just Severity alone, provides different looks at the data. Thus making it harder for a risk to hide from scrutiny and mitigation.

REFERENCES

[1] The New Economics, Dr. W. Edwards Deming, pp 174-189.
[2] Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions
(https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm506679.pdf)
[3] Safety Analysis of Combined FMEA and FTA with Computer Software Assistance ± Take Photovoltaic Plant for Example
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[4] Hubbard, D. and Evans, D.; (2010, MAY/JUNE). Problems with scoring methods and ordinal scales in risk assessment. *IBM J. RES. & DEV. VOL. 54 NO. 3*, PAPER 2.