

Mastering risks and opportunities: tips, tools & techniques

With some inspiration from Star Wars!

“

Understanding the true scope, nature and impact of risks may be the greatest challenge organizations face today.

Consolidating, monitoring and analyzing vast amounts of risk data... is an overwhelming and costly task that often falls short.

— OCEG

”

Risk is everywhere!

<input type="checkbox"/> Select All	Actions	Facebook Engagement	Twitter Shares	Pinterest Shares	Reddit Engagement	Number of Links	Evergreen Score ¹	Total Engagement	
<input type="checkbox"/>	The 5-Minute Fix: Are we at risk of nuclear war? By Laura Reiley Feb 28, 2022 washingtonpost.com	507.7K	1	0	0	-	0	507.7K	👤 ⏪ 👥 🔗
<input type="checkbox"/>	The Checkup With Dr. Wen: How to think about the risk of long covid By Amy Goldstein Mar 31, 2022 washingtonpost.com	507.7K	0	0	0	-	0	507.7K	👤 ⏪ 👥 🔗
<input type="checkbox"/>	Today's WorldView: Amid Russian aggression, NATO nonalignment creates risk for Finland and Sweden By David Von Mar 14, 2022 washingtonpost.com	507.7K	1	0	0	-	0	507.7K	👤 ⏪ 👥 🔗
<input type="checkbox"/>	Coronavirus Updates: N95 and KN95 masks slash infection risk , study shows By Hannah Sampson Feb 5, 2022 washingtonpost.com	507.4K	1	0	0	-	5	507.4K	👤 ⏪ 👥 🔗
<input type="checkbox"/>	ACS San Diego: The Prosecution of Julian Assange: Is the First Amendment at Risk ? Feb 14, 2022 zoom.us	366.7K	7	0	0	-	0	366.7K	👤 ⏪ 👥 🔗
<input type="checkbox"/>	Know your risk profile - Advice for Investors By The Moneyletter Oct 31, 2021 adviceforinvestors.com	341.7K	6	0	0	-	0	341.7K	👤 ⏪ 👥 🔗

Source: Trending mentions of risk, BuzzSumo

What is risk? Why do we care?

- Risk is *uncertainty*
- Risk can be both negative and positive (opportunity!)
- Risk management involves understanding, analyzing and addressing risk
- Risk management must be *proportionate* to the complexity and size of your organization (otherwise you'll go insane!)

ISO 31000
definition of risk:
'the effect of
uncertainty on
objectives'

The case for better risk management

U.S. FOOD & DRUG ADMINISTRATION

Home / Medical Devices / Medical Device Safety / Medical Device Recalls / Medtronic Recalls MiniMed Insulin Pumps For Incorrect Insulin Dosing

Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

October 5, 2021 UPDATE: Medtronic updated this recall with information that Medtronic will replace any MiniMed™ 600 series insulin pump that has a clear retainer ring with one that has the updated black retainer ring at no charge. A replacement insulin pump will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump. If you have questions about this recall, call Medtronic's 24-hour Technical Support line 1-877-585-0166.

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- MiniMed™ 600 Series Insulin Pumps
- Lot codes: Refer to the Medical Device Recalls database entry for each product.
- Distribution Dates:
 - Model 630G - September 2016 to February 2020
 - Model 670G - May 2015 to December 2020

Content current as of: 10/05/2021

Regulated Product(s): Medical Devices

U.S. FOOD & DRUG ADMINISTRATION

Home / Medical Devices / Medical Device Safety / Medical Device Recalls / Arrow International, LLC (Subsidiary of Teleflex, Inc.) Recalls the Arrow-Trerotola Percutaneous Thrombolytic Device Due to Risk of Tip Damage During Use

Arrow International, LLC (Subsidiary of Teleflex Inc.) Recalls the Arrow-Trerotola Percutaneous Thrombolytic Device Due to Risk of Tip Damage During Use

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Product Names: Arrow-Trerotola Percutaneous Thrombolytic Device (PTD)
- Model Number: [See Recall Database Entry](#)
- Manufacturing Dates: January 1, 2020 to December 31, 2021
- Distribution Dates: February 1, 2020 to December 31, 2021
- Devices Recalled in the U.S.: 24,895

Content current as of: 02/23/2022

Regulated Product(s): Medical Devices

Ireland's thalidomide survivors: 'The State is only waiting for us to die'

People affected by drug linked to birth defects have called for 'an apology and a fair deal'

Mon, Dec 6, 2021, 06:01

June Shannon



Thalidomide survivor Maggie Woods lays a white rose outside the Dáil to mark the 60th anniversary of the withdrawal of the drug from international markets in November 1961. Photograph: Fran Veale/Julien Behal Photography

"We are now 60 years of age. As the years go on we are left with the impression that the State is only waiting for us to die, without any intention of meeting with us or coming up with a fair and just settlement." – Jacqui Browne, Irish thalidomide survivor.

FINANCIAL TIMES

US opioid epidemic + Add to myFT

Sackler owners offer up to \$6bn to settle Purdue Pharma bankruptcy

Proposal revealed by court mediator comes after a judge rejected earlier deal

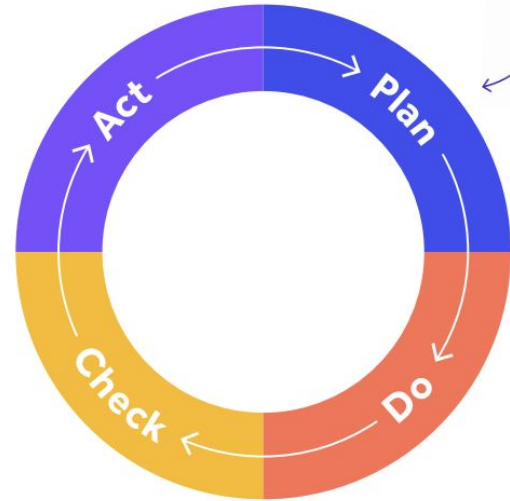
Portrait, maker of the painkiller OxyContin, filed for bankruptcy in New York in 2019 © REUTERS

Risk-based thinking



Risk-based thinking means...

1. Actively determining risks and opportunities
2. Planning actions to address them
3. Implementing them in your QMS
4. Evaluating their effectiveness



Proactive, not reactive



Reactive

Proactive



"Difficult to see.
Always in motion is the future."

— Yoda

How can we physically document risk-based thinking?

- Management review meeting minutes
- SWOT analysis
- Customer feedback reports
- Process planning/mapping

Strengths

- Expertise
- Reputation
- Culture of excellence, engaged teams
- Quality management system

Weaknesses

- Outdated/inaccurate documented info
- Risk training
- Innovation
- Silos
- Poor IT infrastructure
- Internal actions

Opportunities

- Diversification
- Market penetration
- Standards
- Outsource risk
- Business continuity management
- Physical security
- Malware protection

Threats

- Competitors
- Regulations
- Supply chain buying power
- Value of dollar
- Substitute products
- Bargaining power of buyers

Risk vs. opportunity: two sides of the same coin

Risk

- Potential for loss/damage
- Detect, treat and mitigate
- Eliminate

- Uncertain event or condition
- Requires a set of plans and executed processes

Opportunity

- Potential for gain/improvement
- Detect, nurture and exploit
- Enable

- Uncertain event or condition
- Requires a set of plans and executed processes

5 tips for finding risks

1. Create a systematic process including a risk register
2. Gather information from various sources (make each department responsible for sourcing risks and applying risk-based thinking)
3. Document the risks
4. Document the risk identification process
5. Assess the process effectiveness



Leadership



The role of leadership

ISO 9001 prescribes two key responsibilities for business leaders:

1. General oversight

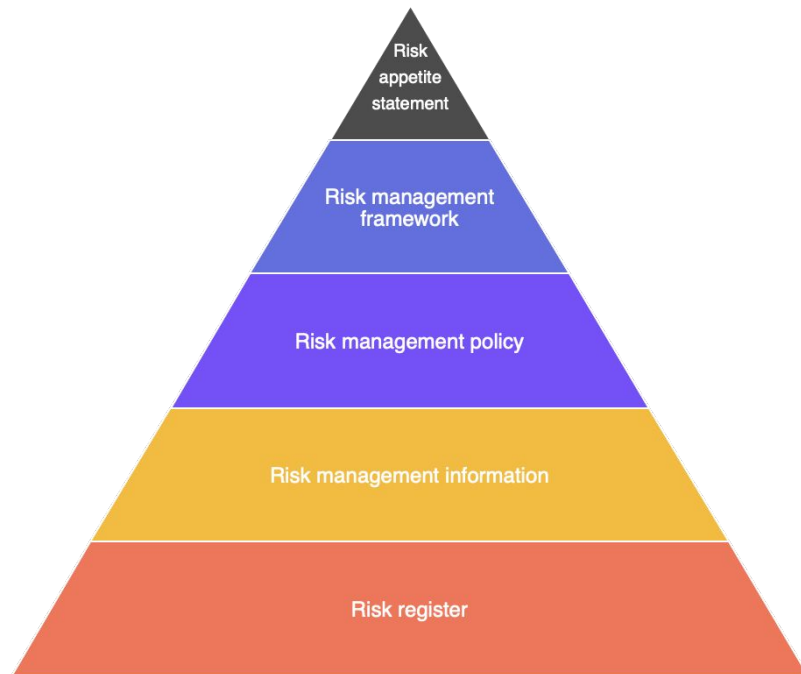
- A. Determining the risk appetite
- B. Ensuring the effectiveness of the QMS
- C. Ensuring intended results are achieved
- D. Monitoring external and internal threats
- E. Being mindful of opportunities which will support/accelerate/ease the realization of intended results

2. Promote risk-based thinking

- A. Explicitly promote risk-based thinking through the QMS
- B. Give documented, evidenced and active day-to-day support for a risk-based approach

Setting your risk appetite

1. Establish direct links to organizational objectives
2. Take all objectives and projects into account
3. Align people, processes and infrastructure
4. Ensure clarity and precision to enable business-wide communication
5. Set acceptable tolerances and parameters for risk
6. Recognise the need to regularly review and update the statement as risks change
7. Establish monitoring and assurance to ensure application



Make your business leaders active risk-based advocates



"You may dispense with the pleasantries, Commander.

I'm here to put you back on schedule."

— **Darth Vader**

ISO best practice

True or false?

Leadership are required to undertake a formal risk assessment

Leadership must determine the risk appetite

Leadership must be mindful of opportunities which will help the business

Leadership can delegate their risk management responsibilities to a well-trained management representative

Leadership can demonstrate commitment to managing risk by investing in risk/quality management systems which are available for the entire business

Leadership must promote risk-based thinking

Leadership must determine the review and reporting requirements of the accountable individuals involved in delivering and monitoring risk processes

ISO best practice

True or false?

Leadership are required to undertake a formal risk assessment

False

Leadership must determine the risk appetite

True

Leadership must be mindful of opportunities which will help the business

True

Leadership can delegate their risk management responsibilities to a well-trained management representative

False

Leadership can demonstrate commitment to managing risk by investing in risk/quality management systems which are available for the entire business

True

Leadership must promote risk-based thinking

True

Leadership must determine the review and reporting requirements of the accountable individuals involved in delivering and monitoring risk processes

True

Some risk management tools and frameworks

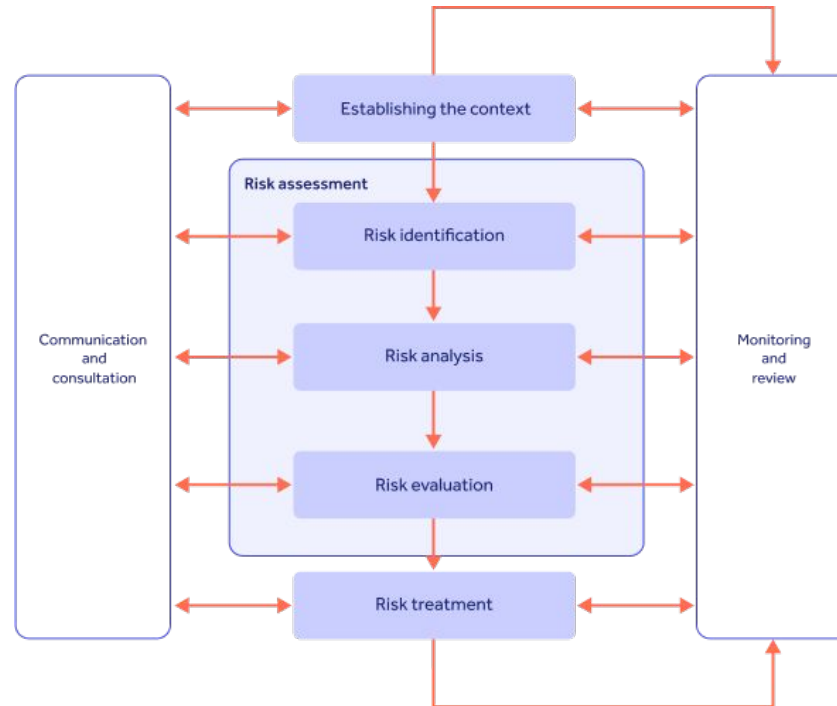


Risk management frameworks to try

- ISO 31010 (general supporting standard to ISO 31000)
- ISO 14971 (medical devices)
- ICH Q9 (pharmaceutical)
- Failure mode and effect analysis (FMEA)
- HAZOP
- Cause and effect analysis
- Delphi technique: structured, interactive forecasting
- Scenario analysis
- Root cause analysis
- Risk indices
- Cost/benefit analysis

ISO 14971 FMEA Create risk									
Risk	Hazard	Hazardous situation	Harm	Initial	Final	Last updated	Status	Design Control	
RK-14	Mechanical, Interfacing Components	Crack in the tubing causing loss of damage	Underdose: ineffective therapy	High	Medium	Dec 17 2021	Assessment	In Review	Edit Copy
RSK-1	Mechanical, Interfacing Components	Crack in the tubing causing loss of dosage	Underdose: ineffective therapy	Medium	Low	Mar 29 2021	Approved	Approved	Edit Copy
RSK-2	Mechanical, Electrical	Over-administration >5% over target	Overdose: serious injury or death	Low		Apr 28 2021	Assessment	Approved	Edit Copy
RSK-3	Mechanical, Electrical	Under-administration >5% under target	Underdose: ineffective therapy	Low		May 5 2021	Approved	Approved	Edit Copy
RSK-4	Mechanical	Patient may not be able to receive therapy	Delay in therapy	Low		Apr 28 2021	Assessment	Approved	Edit Copy

Make a repeatable, business-wide framework for managing risk



Building blocks for a risk-based quality culture

Do you have...



Leadership sending consistent and clear messages on acceptable levels of risk?



A system of accountability with sanctions for those taking inappropriate levels of risk?



Risk and risk appetite discussions as part of key strategic decisions?



Appropriate levels of resource to address risks?



Considerations of what might go wrong, and deciding upon appropriate tolerance levels when considering targets and performance?



A central, business-accessible area to document, record and treat risks?



Adequate risk reporting, monitoring and incident reporting based upon clearly defined risk appetite?

Common mistakes to avoid

1. Relying on historical data
2. Focusing on narrow measures
3. Overlooking risks
4. Failing to communicate
5. Not managing risks in real time
6. Offloading risk responsibilities onto quality and compliance
7. Listing risks then doing nothing about them

Sources:

<https://hbr.org/2009/03/six-ways-companies-mismanage-risk>

<https://www.aicpa-cima.com/news/5-risk-management-mistakes-and-ways-to-address-them.html>



"Your overconfidence
is your weakness."

— Luke Skywalker

Start the risk conversation!

Formal structures

- A. Suggestions process
- B. Get every single employee engaged

Meetings with employees

- A. Audits
- B. Monthly drop in-sessions and 'quality council'

'Voice of the business' survey

- A. Values & organizational culture
- B. Training and development
- C. Leadership, gaps & issues
- D. Systems & structure
- E. Ask for ideas

Conclusion: top tips for risk mastery



Quantitatively measure your current cultural values



Align culture, strategy and structure: create shareholder value from risk management by linking risk to business performance



Incentivize staff and stakeholder participation



Communicate and demonstrate the change



Get guidance and oversight from the top down

Thanks for reading!