



# IS FEAR OF RISK YOUR BIGGEST RISK?

## WHY BECOMING MORE RISK LITERATE IS SO VITAL

by Martin Lush

Let's start with an exercise in risk-based decision making. Imagine I'm standing in front of you with £50. You can take it now (a low risk, sure bet decision) or double your money at the toss of a coin (but stand the chance of losing it all). Heads you win £100, tails you leave empty handed. What would you do? What is your risk threshold? Most would probably take the £50. After all, losses loom larger than gains and most people are risk averse. However, in a volatile and uncertain world, playing safe is the riskier option! Even maintaining the status quo is dangerous.

*"The biggest risk is not taking any risk. In a world that's changing really quickly, the only strategy that is guaranteed to fail is not taking risks."* Mark Zuckerberg

The pharma industry has always been risk averse. After all, mistakes can cost lives. But have we gone too far? I believe we have. Do we need to rethink our relationship with risk? I think we do. Is ICH Q9 (Quality Risk Management) fit for purpose or is it just poorly applied?



A quiz to get you thinking. Answer the following with a simple yes or no:

1. Does your company take a zero-risk approach to most things?
2. Is risk defined as the consequence of severity of harm, probability of occurrence and likelihood of detection?
3. When taking steps to reduce risk, do you habitually add more? It's what I call the "just in case" approach to risk mitigation. More checks, more double signatures, more detailed instructions, more discussions and more measures? More complexity in general... just in case.
4. When faced with risks, are you guilty of paralysis by analysis? Do you overthink?
5. Is failure mode effect analysis your main risk assessment tool?
6. Do you typically err on the safe side when things go wrong?

If you have more yes than no answers, you need to rethink your attitude to risk and its management. I'm not saying take more risks. What I am promoting is being more risk smart. In one sense the urge toward safety can be, and is, good; but if left unchecked can lead to disaster.

But risk aversion is not just natural, it's attractive because it's easy. But, there is a price to pay:

- > Risk aversion creates the dangerous illusion of certainty when there is none. We need to remind ourselves of Franklin's Law:

*"Nothing is certain but death and taxes."*



- > Habitually failing safe kills the creativity and critical thinking skills we need to navigate an uncertain world.
- > Risk aversion adds complexity and confusion at a time when simplicity and clarity are vital.
- > Risk aversion slows innovation and improvements when we need them most. Being risk smart acknowledges uncertainty rather than ignoring it. In times of massive uncertainty, we will have some very tough choices to make. We can only make important decisions if we are risk smart.

## YOUR CALL TO ACTION: FIVE STEPS TO BECOMING RISK SMART

### 1. Stop defining risk in terms of severity of harm and probability of occurrence.

This implies risk is painful, dangerous and something to be avoided. As leaders you must feel safe with risk. View risk as managing and being comfortable with uncertainty (variability).

#### *Is ICH Q9 fit for purpose?*

To recommend deleting severity of harm and probability of occurrence from our risk vocabulary sounds like I'm questioning the value of ICH Q9. I actually like ICH Q9. It's logical and pretty straightforward, but it is far from state-of-the-art. I think we need to revisit it and ask some critical questions with one objective in mind; improvement.

- > Why has ICH Q9 been so poorly applied across our industry?
- > Why is ICH Q9 typically used reactively rather than proactively?
- > How can we use any risk management process without in-depth understanding of our products and process, probability and frequencies?
- > How can the process be improved using all the latest research and best practices relating to the psychology of risk, risk-based decision making and the use of big data for risk profiling?

...so, let's start the discussion!

### 2. Ban the term zero risk and replace it with risk smart.

Zero risk is a dangerous illusion. It doesn't exist. Remember the role intelligent risk management has played in every human advance. Remember, being risk smart doesn't mean gambling with patient safety. It's just a trigger to remind us of reality. Risk is everywhere - in every decision we make and in every problem we solve. Risk smart companies will succeed. Those trapped by institutional risk aversion will not. Leaders at every level must feel safe with risk.

### 3. Recognize that risk-based decision making is a skill that can be taught, practiced and perfected.

Remember that risk management and making risk smart decisions is about making decisions under uncertainty. Don't worry about the decision; just focus on driving down uncertainty. To develop and refine your risk-based decision making skills, visit our resource library or follow these links:

- > NSF's Six to Fix Video: Decision Making Under Pressure, Part 1
- > NSF's Six to Fix Video: Decision Making Under Pressure, Part 2
- > Webinar: Judgement Calls – Making Decisions Under Pressure
- > Webinar: Risk Management – Best Industry Practices

### 4. Create a culture that allows you to fail fast.

An open-loop culture uses problems, errors and mistakes to drive continuous improvement. When the opposite happens and problems and errors are considered bad news, a risk averse, toxic blame culture follows.

### 5. Educate, educate, educate.

To become risk smart, profound knowledge of the psychology of risk aversion, the science of risk-based decision making and (importantly) probabilities is essential. When faced with assessing risk, numbers can help navigate the wash of sentiment that often leads to a risk adverse decision. Numbers, in the form of



probability, can offer a kind of life raft from which to make informed, risk smart decisions. Acquiring some level of statistical literacy is a vital component to risk smart decisions.

Here is your reading list to improve your risk literacy:

- > Risk Strategy: Understanding Risk to Improve Strategic Decisions by Jamie MacAlister
- > Reckoning with Risk: Learning to Live with Uncertainty by Gerd Gigerenzer
- > Risk Savvy: How to Make Good Decisions by Gerd Gigerenzer
- > Risk Intelligence: How to Live with Uncertainty by Dylan Evans

A new acronym has entered the Oxford English Dictionary: VUCA. We all live in a volatile, uncertain, complex and ambiguous world where only the risk smart will prosper. We have limited resources so we have to make tough choices. In the final analysis, success awaits those who have the courage to do only what is right. This means making only risk smart decisions.

## WHAT DOES THE FUTURE HOLD FOR RISK MANAGEMENT IN THE PHARMA INDUSTRY?

We don't need to reinvent the wheel just humbly borrow from those who already have the solutions, such as the financial and insurance sectors. I was speaking with a good friend who works as an actuary for an insurance company that specializes in insuring pharma companies. They feed all of their clients' risk factors into an algorithm to generate a risk profile. Their insurance premium then reflects their risk profile, providing some financial protection following catastrophic failures or losses. We need to do the same, but with a focus on prevention. Repeat deviations, customer complaints, yield losses, reconciliation failures, plant utilization, staff turnover, number of full time employees vs. contractors, supply chain complexity and lots more are all risk factors that can be quantified and used to make better risk smart decisions focussed on prevention, not reaction.

If you want more information, just drop us a line at [pharmamail@nsf.org](mailto:pharmamail@nsf.org). Or visit our resource library [www.nsf.org/info/pblibrary](http://www.nsf.org/info/pblibrary) to access a wide range of useful resources.

### ABOUT THE AUTHOR



Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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