

Shadows Of Missed Opportunities In Learning Excellence



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ABSTRACT

'When failure is not an option, we can forget about learning, creativity and innovation'

- Brene Brown (1)

This quote summarizes an important facet for learning and development within an environment that seeks to encourage mindsets and behaviors such as curiosity and exploring failure as key sources of creativity and innovation. These behaviors are imperative to nurturing and sustaining a transformative, learning organization. However, creating the vision and achieving the organizational alignment to enable a knowledge-led, learning organization remains a challenge for many companies. In this article, the researcher connects the dots from multiple thought leaders and industry experts that have participated in the *Risk Revolution* series of podcasts, which focuses on advancing the maturity of risk management practices across the Biopharmaceutical industry. Using these discussion points the author explores if the quest for a learning culture is one the biopharma industry is truly seeking to achieve. The researcher also leverages foundational work from social science research and practice to identify the key attributes that may be impeding the Biopharma sector's journey towards building healthy learning cultures. The article shows how, even within a hard science sector such as biopharma, the social sciences can be leveraged to improve innovation and develop a culture that is both engaging and inspirational to employees.

INTRODUCTION: DISPELLING THE SHADOWS

Carl Jung once said, *'Everyone carries a shadow, and the less it is embodied in the individual's conscious life, the blacker and denser it is. At all counts, it forms an unconscious snag, thwarting our most well-meant intentions'* (2). In contemplating this concept of "shadows" which can thwart our progress, the idea emerges that these shadows don't just exist in the human psyche or even in small groups or teams, but they can exist within organizations and even in industries as well. Prompting the question do such "shadows" exist within the regulated life science sectors that challenge us from embracing something as seemingly positive as a learning culture?

The researcher, an experienced biopharma industry practitioner, has been examining this question by pursuing a PhD with Technological University Dublin. What began as research into whether the principles of adult learning theory are applied in many of the compliance focused biopharma industry training programs, has developed into finding answers to the question does the biopharma industry have "shadows" regarding its learning culture, stuck deep within the unconscious of the industry, which are preventing the development of adaptive and innovative learning organizations needed to address the 21st Century medical challenges we face?

During the research work, the researcher has published three articles with IVT on this subject:

1. Understanding Adult Learning Principles, CCGMP Training Modalities and the Pharmaceutical Regulatory Landscape (September 2019)
2. Applying Adult Learning Principles in CCGMP Training (November 2019)
3. CGMP Training Models Designed for the Adult Learner (January 2020)

But it was through the Risk Revolution podcast episodes that the hunt for “shadows” in the industry and the research regarding the elusive learning culture really began.

SECTION 1: PODCASTS AS RESEARCH

In his excellent book, *Think Again* (Grant, A. 2021), Adam Grant urges experts to seek feedback and at times rethink their approaches on a topic that they consider within their expertise (3). Grant advises us not to become set in our ways but to constantly seek out new ways or new information that could be used to drive innovation. Seeking out innovative risk management approaches, is what the researcher set out to with *TheRisk Revolution* podcast, which is a monthly series featured on the Voices in Validation platform by the IVT Network. Each podcast episode features one or more experts from the biopharma sector sharing a wealth of knowledge and experience as well as evidence regarding recurring failures within the biopharma industry in addressing critical risks. These podcasts provide an opportunity for evaluating the standard industry approaches and rethink if there are new advancements that might be considered. In assessing the podcast topics, a common thought was, were these recurring failures arising from the “shadows” that may be countering our efforts to build a culture of learning? A listing of the episodes that were used to collect the research data, can be found in Appendix 1.

SECTION 2: DISSECTING THE PODCASTS

This article features nine podcast episodes showcasing biopharma industry experts that among many skills in their toolbox, possessed vast knowledge in learning excellence, facilitation, bias and heuristics, supply chain, risk management and organizational culture. The potential shadows that were researched within the podcast episodes are in Figure 1.



Figure 1. Potential Shadows

The researcher explores these concepts as shadows in the biopharma industry that may be preventing the quest to achieve a learning culture. While these may not be all inclusive, the researcher also provides key learning points to be considered in illuminating the shadows with the idea of bringing the industry closer to a culture of learning excellence. The episodes within the article will be summarized with key themes, potential shadows and learning points.

Adult Learning Theory and its Impact on Training in a cGMP Environment(4).

The discussion during this episode was regarding the needs of the adult learner to succeed in learning. Key messages included (5):

- Adults have a readiness to learn.
- Adult learners are aware of who they are and what they're seeking from their education.
- Adult learners need to have some autonomy in their learning by having a say in the content of the learning or they will lose interest.
- Adult learners want to play an active role in curriculum development and design of the learning journey.
- Past experiences are critical and if the instructor does not take this into consideration the adult learner may reject a new concept that conflicts with something they already know or practice.
- They must be able to take away a new skill or competency that will help them progress further in their job.
- They want experiences within the learning environment that contain exercises and scenarios which enable them to apply the concepts in real life. This will keep them engaged as a learner and coming back for more.
- Adult learning theory focuses on experiential learning; therefore mistakes, errors and failures are critical learning opportunities that must not be overlooked in the learning journey.

Detailed discussions ensued regarding the failure of the *Read and Understand* modality, which is heavily used throughout the biopharma industry, to transfer knowledge or skills. The industry expert referred to it as the "Read and Pray" culture, insidious within many onboarding programs, which seeks to drown new hire trainees in a sea of SOP reading with little to no contact with the equipment, processes, or even a trainer or peer group to discuss these concepts with. It was also discussed that some trainers may pair actual work or current ongoing projects with the training to build an opportunity to complete training on a subject and get actual work done at the same time. In theory this may be undertaken to encourage participation and engagement in on-the-job training, but if the practice and reinforcement opportunities or learning outcomes are poorly planned it can be less than satisfactory for all concerned.

Potential Shadow. One key quote from Adam Grant that resonates as a potential shadow, addresses the underlying issue of cognitive laziness that can pervade. 'Part of the problem is cognitive laziness. Some psychologists point out that we're mental misers: we often prefer the ease of hanging on to old views over the difficulty of grappling with new ones. Yet there are also deeper forces behind our resistance to rethinking. Questioning ourselves makes the world more unpredictable. It requires us to admit that the facts may have changed, that what was once right may now be wrong. Reconsidering something we believe deeply can threaten our identities, making it feel as if we're losing a part of ourselves' (6). This ability to unlearn what we think to be true and rethink our position or understanding of the world around us can be truly challenging for individuals. This requires learning leaders to create the environment for this to happen, safely. As Grant points out in "Think Again," the capability to listen to new ideas and being vulnerable when you don't know what you don't know, may not only make you a stronger leader ..., but also may unlock a culture that embraces asking questions and seeking to understand when we don't have all the answers (6).

Learning Point. The biopharmaceutical industry needs to embrace this ability of *unlearning to relearn*. This can be achieved by building in systematic processes that enable peer-to-peer reflection, after action reviews, near miss exploration, best practice sharing as a key element of building a learning culture. One significant way to debunk old paradigms is to get specific with hard facts and good data. Prepare actual statistics on outcomes based on the current methodology and seek to empower teams to look for new ways to make targeted improvements.

Risk Revolution: Quality Risk Management Basics as Part of the QMS(7)

This was the first episode of the new Risk Revolution monthly feature through IVT Voices in Validation. In this episode the co-hosts discussed the basics of the pharma industry guidance was discussed, examining the regulations within the FDA, EMA and HPRA that require QRM principles, the expectations of the various health authorities and how Quality Risk Management fits within the lifecycle management of a product. Challenges that have been experienced with respect to risk-based decisions, use of formal tools and processes within companies, the need for more pre-work when planning for a risk assessment and subject matter expertise QRM training requirements and more robust risk review and evaluation of outcomes were all covered in this episode.

Potential Shadow. What was evident in this podcast, was that the strategies for ICH Q9 implementation are still proving to be challenging to the biopharma industry more than 15 years post publication. Despite the widespread availability of a wealth of learning resources, e.g., conference topics, articles, publications and many expert consulting experiences, companies remain challenged to identify and adequately document their risk-based decisions.

If the tools, processes, and expertise are available, then it is not so much an accessibility or knowledge issue but a case of not accepting change. Is this the potential shadow that the industry is best by; being change averse? The work of Pema Chodron on uncertainty and change is helpful in framing this issue. Chodron states that the world is constantly changing, with everything in a constant state of motion. The idea of staying strongly attached to what has been deemed secure falsely leads people to believe they are in a state of control (8). Our compliance focus seeks a state of control. Chodron encourages us to learn to stay within the chaos of change, to relax and not panic but to use this as a source of inspiration.

Learning Point. To overcome its obsession with change aversion, the biopharma industry must build resilience in leaders, teams, and individuals where change is accepted as a constant, and a necessary capability for a learning culture. This must be a behavior that is included in not only the job description, but in the continuous learning and development within the leadership structure.

Risk Revolution: Back to Basics – Let's Get Some Facts Straight (9).

In this episode, the idea of removing the “Q” from Quality Risk Management was explored. The principle idea discussed was that the industry needs to evaluate risk holistically, end-to-end across the product lifecycle encompassing more than just the quality and compliance risks in order to make the best decisions for the patient. The current modus operandi tends to separate quality and business risks, however within a regulated patient-focused environment, business and quality are one in the same. Pharmaceutical companies have a responsibility to provide safe and effective products to the patients, otherwise the business could be negatively impacted. Understanding the supply chain risks and the various nuances and levers that could impact the success of that supply chain, really requires a holistic risk management process is in place to ensure all sources of disruption are considered, e.g., quality of supplies, potential transportation problems, weather disruptions, globalization impacts.

Potential Shadow. In recent years, the issue of drug shortages has been in the spotlight, this has brought about many publications and enhanced awareness on how each company can assess potential shortcomings within their complex supply chains. Expectations amongst health authorities have helped to focus efforts on business continuity capability and supply chain control strategies. This raises the opportunity to apply systems thinking as part of the risk management planning.

Systems thinking is a set of synergistic analytic skills used to improve the capability of identifying and understanding systems, predicting their behaviors, and devising modifications to them in order to produce desired effects. These skills work together as a system (10).

Events rarely occur in linear fashion, by defining the system in terms of both the intrinsic and extrinsic factors, can help to identify root causes when failures present themselves and better enables the ability to predict potential issues within the system (10).

Learning Point. Systems thinking should be a required skill for building a learning culture. Risks in meeting patient demand could be greatly reduced if a more holistic, systems thinking approach was an integral part of the biopharma culture. Rewarding mapping exercises of various systems in the organization to drive continuous improvement activities and action plans is just one way to reinforce this necessary way of thinking.

Risk Revolution: Developing a Risk Culture Part 1 and 2(11)

This episode asked a key question; What is a proactive risk culture and what are the behaviors and attitudes that we need to embed and reward to assure that issues and opportunities are surfaced and solved robustly?

Possible risks were discussed based on the organizational roles and reporting structures. Risk assessment team member roles and functional silos can present their own challenges when encouraging open dialogue. There can also be an aversion to exploring ‘red’ risks, where high risks can be viewed with fear instead of an opportunity for increased product or process knowledge. This raised the concept of risk curiosity and how a change of perception or reframing can help to change how risk is viewed. Implementing a proactive risk culture as well as the sustaining behaviors needed continues to be a challenge across the industry.

Potential Shadow. Transforming organizational culture is difficult and the biopharma sector struggles with transforming their organizational culture from one focused on compliance toward one focused on excellence (12). Traditionally, much of the emphasis has been on the operation of the quality management system and business processes that support the commercial operations. The issue of “Quality Culture” has only been discussed in more recent years by both regulators and the industry.

Learning Point. One interesting risk culture model the biopharma industry should consider is the ABC model for embedding and sustaining a healthy risk culture which is based on the following definitions (13):

- Attitude is the chosen position adopted by an individual or group in relation to a given situation, influenced by perception
- Behavior comprises external observable actions, including decisions, processes, communications etc.
- Culture is the values, beliefs, knowledge and understanding, shared by a group of people with a common purpose

This ABC model provides an approach to enhancing performance through people and not just through systems by managing attitudes and behaviors with respect to proactive risk prevention. By implementing tools such as the ABC model to develop a risk culture, this would be a progressive step of moving the biopharma industry out of the

compliance driven mindset to a focus on learning excellence.

Risk Revolution: Bias, Heuristics and Risk Part 1 and 2(14)

Following the insights gained from the expert opinions on risk culture, the next episode focused on how human bias and heuristics can impact risk-based decision-making. Biases and heuristics are by their nature developed to protect the human by providing a reference point or data set to assist or shortcut the decision-making process. However, there are many places where bias and heuristic can prove to be flawed and even dangerous due to a lack of actual scientific data. Potential approaches to managing bias and heuristics within a team involve activities such as enhancing awareness about bias and how this can impact decision making, creating an environment where team members can feel safe to discuss potential biases about the topic being discussed, and how these influences can be counteracted.

Potential Shadow. It is not clear that the Biopharma industry currently embraces the environment needed to openly discuss how human behaviors can and do impact decision. Without an understanding of how bias and heuristics may be interfering with routine application of critical thinking in our decision making, it is possible the biopharma industry may be hindered in truly embracing a learning culture. Is this lack of honest dialog or even awareness impacting our individual thought processes or impacting the thinking of others during a team meeting such as a risk management activity or significant investigation?

Learning Point. As Daniel Kahneman points out, we need to learn to identify opportunities to slow our thinking down for complex problems by recognizing situations where it may be very harmful if a quick decision is made or that it is a decision where a mistake may be likely. Then we can call upon our deeper thinking system to assist (15). Critical thinking skills and understanding of bias and heuristics must be required as a key attribute or a training opportunity within decision making roles in the organization.

Risk Revolution: Facilitator - Friend or Foe(16)

Facilitator – Friend or Foe provided the basis for a lively conversation on the challenging world of risk facilitation. The skills and attributes that are crucial to the successful facilitation of any cross-functional team session discussed during this session included:

- Managing brainstorming with an open mindset to ensure that various voices are heard at the table
- Preparing the team by performing offline prework that captures risks and controls that will be a good starter before the team meets together for the holistic discussion
- Basic understanding of the topic being covered in the risk assessment
- Teaching capability to ensure the team of Subject Matter Experts (SMEs) can understand the basics of the tool and provide the knowledge that is critical to the assessment
- Strong leadership of cross functional experts in various levels within the organization that may contain difficult personalities to manage
- Managing bias and heuristics to ensure where available, data drives the conversation
- Set the expectation that the facilitator is going to ask challenging questions and has an open mindset, will be looking for places of disagreement
- Drive mitigation discussions to seek the point of disagreement during discussion and seek to understand to cease group think

Insights were shared regarding opportunities and challenges posed with virtual risk facilitation in the pandemic environment. The pivotal position of the facilitator role in leading a team of SME, asking the right questions to extract key information while simultaneously scribing the outputs highlights just how demanding (and undervalued) this role can be. An innovative concept of positioning SMEs as *Knowledge Stewards* can help to enable a mindset of knowledge curation and sharing and dispel actions that result in knowledge hoarding. This perspective also recognizes the importance of engaging a diverse group in the risk identification and assessment process to broaden the potential information input and positions the facilitator as the guide of the overall process.

Virtual Facilitation Tips

- keep the team engaged with cameras on if it's a remote facilitation
- ice breakers for fun breaks and engagement
- don't fear probing into areas where tough questions need to be asked,
- keep sessions reasonably timed for 2-3 hours
- encourage micro-learning sessions to teach the tool usage that is directed with a narrow scope and instant use to encourage learning with the team
- provide the documents, in advance, needed for the team to review the process being assessed or maps, data, etc.
- use breakout functions in virtual platforms where small groups can assess risks and bring back their findings to the large discussion

Potential Shadow. The biopharma industry rewards a behavior of “being in the know,” where it is the expectation that everyone is an expert in their individual own right. Rewarding this behavior drives a culture that fears the vulnerability of saying, “I’m not aware of this topic... Tell me more about that process.... I don’t understand the acronyms you’re using.... I’m not sure of the answer to that question, but I can find out and come back to the team.... I don’t know....” Removing the negative stigma in asking these questions may open a wealth of opportunities to sharing information and learning key differences between processes and functions. It is important for a facilitator to express vulnerability to adequately guide SMEs in a meeting. Without vulnerability, learning is not possible. When we practice vulnerability, we are open to thinking about creative solutions and listening to many ideas which directly correlates (17).

Learning Point. When we are vulnerable and open to asking questions, we are seeking to understand. To be a good facilitator you need to check your ego at the door and to be vulnerable to asking the “dumb” questions about the system or process under evaluation. Asking questions that come from a place of seeking to understand encourages the SMEs to explain in detail how or why something is designed to do what it does. It is during these forced explanations by an expert to a layperson that the difficulties, gaps, and risks in the design can be discovered. It is this behavior which encourages vulnerability which must be embraced.

In her groundbreaking work on courage, vulnerability, shame, and worthiness, Brene Brown describes vulnerability as the willingness to show up and be seen with no guarantee of outcome and as the birthplace of innovation, creativity, and change (17). In looking back at the role of the facilitator, vulnerability is a key characteristic of an effective facilitator and an environment needs to be cultivated to encourage this.

Risk Revolution: From Dreading the Risk Process to Living the Risk Life(18)

The episode kicked off with sharing anecdotal stories and comments heard from participants in risk assessment sessions. These sessions are often approached with a bit of dread as comments come up by SMEs, “why are we doing this,” “I already know all the risks,” “something must have gone wrong for us to be talking about risk.” It was explored why the teams see risk assessment sessions with a negative lens rather than sessions of exploration and learning. Why is there shame associated with risk discussions or even avoidance? The topic of psychological safety being woven into the environment to cultivate these discussions was brought to the forefront as an area to explore further.

Potential Shadow. Amy C. Edmondson is the Novartis Professor of Leadership and Management at the Harvard Business School, a chair established to support the study of human interactions that lead to the creation of successful enterprises that contribute to the betterment of society (19). Her work is focused on creating environments of psychological safety that lead to innovation, critical thinking, problem solving and learning environments. When a culture of psychological safety does not exist, then employees will hold back their feedback and not provide new ideas if they fear offending management. This will not result in innovation and could cause more mayhem. Is psychological safety an element within the biopharma culture that is valued for a learning environment?

Learning Point. Important ideas for moving participants from a dreadful feeling of the assessment to one that encourages participation to meet the needs of the patient:

- remove silos within the organizations so that information can be shared transparently in sessions

- drive encouragement in participation by having leadership reward participation, embracing the vulnerability that comes with failure identification in a risk assessment and encouraging a safe environment to share these thoughts by ensuring strong facilitation.
- vulnerability is a key factor in opening minds to learning new things and discussing provocative topics
- Always connect the assessment to the patient driving the importance that the work is providing to the company and to ensuring treatment for the patient.

In Adam Grant’s podcast Work Life, Amy Edmondson provided several key benefits to encouraging a culture of psychological safety which is imperative to explore vulnerability in a learning culture (20).

- Accidents are prevented as teams report mistakes openly and participate in identifying causes and repeat issues. They will also openly report near misses that can help in the future.
- Innovation thrives as “out of the box ideas” are openly shared. Diversity allows open thinking and more ideas.
- When ideas fail, because not all will work out, there must be a culture of acceptance and lessons learned.
- You must be able to bring your full self to work.

CONCLUSION

While learning management systems and procedures and policies that govern learning programs are necessary to meet compliance requirements, these are all for not if the culture of the company does not encourage the importance of learning culture in transforming the business. Researching podcast episodes that did a deep dive into risk management topics plaguing the biopharma industry, allowed the researcher to link similar elements to developing a learning culture. The researcher took the biopharma issues and mirrored them with foundational work from social science research to identify attributes that may be shadows in the Biopharma sector’s journey towards learning excellence (Table 1).

Although the biopharma industry continues to hyper focus on a culture of compliance, the hope is that research articles such as this one, will bring to light the imperative need for not just robust compliance but also learning excellence within the biopharma industry. A culture of learning excellence propels the industry toward better serving the patient with diversity of thought, lessons learned, systems thinking and an open mindset that welcomes continuous improvement. It is the researchers hope that this conglomeration of research from podcasts combined with critical work in the social sciences field will provide a new direction for the industry to focus a continued effort to better serve the patient by shining the light to dispel the shadows. As Peter Senge noted in The Fifth Discipline, ‘Through learning we re-create ourselves. Through learning, we become able to do something we never were able to do. Through learning, we re-perceive the world and our relationship to it. Through learning, we extend our capacity to create, to be part of the generative process of life’ (21).

Researcher	Theory
Adam Grant	Unlearning to Relearn
Pema Chodron	Uncertainty and Change
Albert Rutherford	Systems Thinking
David Hillson	Risk Culture
David Khaneman	Bias in Thinking
Brene Brown	Vulnerability
Amy Edmondson	Psychological Safety

Table 1. Learning Culture Capabilities

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Appendix 1. List of Risk Revolution Podcast Episodes

Title	Theme	Experts Panel	Date
Adult Learning Theory and its Impact on Training in a cGMP Environment	Learning theories and models that have impact and relevance to adult learners in the pharmaceutical industry	James Vesper	July 2021
Quality Risk Management Basics as Part of the QMS	Basics of QRM principles in context of ICH Q9	No Panel	September 2021
Back to Basics – Let’s Get Some Facts Straight	A look at risk management in the broader context defining the roles of quality professionals, supply chain, supply chain mapping and crisis planning	Chris Flask	November 2020
Developing a Risk Culture Part 1 & 2	Defining Risk Culture, highlighting a need for risk identification, covering some risk communication tools, and broadening the understanding around risk-based decision-making processes	Ghada Haddad and Vivian Rowland	December 2020 and January 2021
Bias, Heuristics and Risk Part 1 & 2	Exploring how bias and heuristic traits can impact our ability to identify and assess how we address risk in this regulated industry	Randy Friedman	March and April 2021
Facilitator – Friend or Foe	Discussing the importance of facilitation in the risk management process and how it leads to the success of a risk assessment	Tiff Baker	May 2021
From Dreading the Risk Process to Living the Risk Life	Taking our colleagues on a journey from dreading their participation in the risk process to actually living a work-life. How can we build a culture that embraces risk management?	Amanda McFarland	July 2021

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