RISK BASED DECISION MAKING

Have you ever gone to the circus or seen the lion tamer on television? When the lion tamer goes into the cage with the lion, what three things does he carry? He carries a gun, a whip, and a chair. You might think that the gun and the whip are effective weapons for the lion tamer; however, they are not. The chair is his only weapon. The gun has blanks and the cat only responds to the sound of the whip.

Next time, watch how the lion tamer uses the chair. He puts it right in the lions’ face…jab and turn, jab and turn, jab and turn. As he turns the chair, the lion follows the legs and his head goes in circles. Eventually, the lion becomes dizzy and when a lion becomes dizzy, he becomes passive.

Have you ever felt like that lion while at work? With all of the problems, complaints, customer service calls, etc. you deal with on a daily basis; it is common to feel like you are working in circles. Unfortunately, this is true for entire organizations as well.

Background

Companies deal with overwhelming numbers of events, information, problems, and challenges. This makes it necessary to identify a process by which these activities can be managed. One major area of improvement in this process targets organizational efficiency through the development of a method that assures quick, accurate, and scientifically sound decision-making. This involves taking into consideration the risk associated with making decisions.

Basics

Regulated companies are working diligently to incorporate risk management principles and practices into daily activities. This aids in developing a true Quality Risk Management system, which is an FDA requirement. This holistic system is intended to be responsible for the identification, analysis, and evaluation of individual risks, as well as, control and communication of these risks throughout the organization. This requires risk-based decision-making throughout the organization.

What is risk? Both the ICH Q9 guidance document and ISO 14971:2012 define risk “as the combination of the probability of occurrence of harm and the severity of that harm.” It further
states “achieving a shared understanding of the application of risk management among diverse stakeholders is difficult because each stakeholder might perceive different potential harms, place a different probability on each harm occurring and attribute different severities to each harm.” (ICH Q9, pg 9; ISO 14971:2012, pg1; ISO-IEC Guide 51:2014)

This applies to any decision that involves an actual or potential impact to product user safety, the product or drug manufactured, or to the employees producing the product or drug. Accordingly, both having and using a formal process is required to consider the associated risk of decisions. These decision-making principles may apply to any decision made within the organization. When making decisions, including business decisions, consider the following questions:

- What could go wrong?
- If it does, how will we know it?
- What tool can be used to determine the risk?
- What is the associated risk and is it above an acceptable level?
- What can be done to reduce, control or eliminate the risk?
- What is the appropriate balance among benefits, risks and resources?
- Are any new risks introduced as a result of the identified risks being controlled?

Careful consideration of these questions helps an organization to prioritize activities and direct resources where they are most effective. This must be done within the framework of a formal process with consistent definitions of risk level and acceptability. Further, the documentation of the answers to the above questions provides regulators with greater assurance of a company’s ability to identify and deal with potential risks.

In the case of a specific occurrence of an event, or nonconformance, it is common to conduct a formal Risk Assessment. This involves identifying the hazard and harm associated with the event, analyzing the results, and comparing the results to the pre-determined criteria. Comparing the situation against known criteria allows an objective decision as to where and how to deal with the event.

**Risk Based Decision Making Process**

Risk-based decision-making is not necessarily a complex process. Rather, it allows for the ability to coordinate actions that are commensurate to the risk of the particular situation. This includes both formal and informal activities. In general, this allows stakeholders to obtain the correct information at the correct time.
**Sample Process**

*Step 1*  **Document** the decision to be made  

*Step 2*  **Gather Specifics** regarding the decision  

*Step 3*  Perform a **Risk Assessment** based upon the quantitative or qualitative data available  

*Step 4*  Formal **Disposition** by criteria based decisions and the involvement of appropriate stakeholders  

In the PathWise *Risk Based Decision Making* Webinar, we will delve into the details of this process, its applicability in organizations, and implementation best practices. Join us!  

**Conclusion**  

Dealing with risk is a part of the daily activity in our regulated environment. Regulated companies must strive to improve their knowledge of risk management principles and the risk-based decision-making process to enable more effective and consistent decisions be made across the entire organization.  

**Need additional advice?**  

PathWise offers on-site and webinar training related to Quality Risk Management. Content is also available regarding various risk management tools including Failure Mode & Effects Analysis (FMEA), Fault Tree Analysis (FTA), Hazard & Operability Analysis (HAZOP), Hazard Analysis and Critical Control Points (HACCP).  

If interested, please contact us for more information or to schedule a course.  


Damon Linder, Quality Systems Trainer
Damon Linder is a seasoned quality professional with over 20 years experience in engineering and project management. As the manager in the Global Program Management Office (PMO) at Invacare, he was responsible for the coordination of all project related activities for the Power Mobility Business Category. All aspects of project related activities are included such as: project selection, project prioritization, project planning and finance, resource allocation, approvals and senior management status reporting. Linder holds an MBA from Tiffin University and a B.S. in Mechanical Engineering from GMI Engineering & Management Institute. He is a certified Project Management Professional (PMP) from the Project Management Institute.