



ISSN (E): 2277- 7695  
ISSN (P): 2349-8242  
NAAS Rating: 5.03  
TPI 2019; 8(1): 258-260  
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www.thepharmajournal.com  
Received: 16-11-2018  
Accepted: 18-12-2018

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## Every project needs careful planning' - quality risk management

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### Abstract

An epitomic treatise to this article which is, to some extent, a comparative study of what we did, what made us change or modify our work module in the area especially in pharmaceutical division. For the years we followed some pattern which did, but not for all time, synchronize with our enhancing requirements in multiple areas like procurement of raw material, planning for production, planning for inventory etc. All such critical issues have always remained tormenting and the same have necessitated to change on-going vision and shift it to a higher version which is capable enough to protect routine problems plus combat with diversified problems of which some are envisaged, and some may be beyond imagination.

**Keywords:** QRM (Quality Risk Management), PERT (Program Evaluation and Review Technique), CPM (Critical Path Method).

### Introduction

The incidence that shall always remain in foundation stone is about the safety of a warship. It is always safe and remains protected on the shore, but the candid fact is that it was designed as a warship and meant to face high tides and sea storms. So far as 'risk management' is related to common business people or new entrepreneur, they do take calculated risk on some known lines or well guided lines. They learn by experience but not by vision.

The phrase 'Quality Risk Management' refers to a wider range and it is by the introduction of the word 'Quality'. Only by approaching to literary meaning its vastness is not unfathomable. Mounting on its saddle, we get a feel of where it leads. Quality refers to achieving the superior state in the area that we have started on hand as a prime objective.

Just to exhibit we can take only one aspect; QRM in procurement of raw material for production. Yes, it refers to the search for the best quality of raw material for the quality production. At the same time, it opens many known and hidden aspects such as,

1. when to buy
2. how much to buy
3. at what price to buy
4. how to design the acquisition schedule
5. planning for storage locations

Stated above are 'Management Factors' which are to some extent can be considered as 'Risk Factors'. If they are planned with some risk of extremes, then we may call it as 'Risk Management'. Risk Management is a systematic process for the technical assessment, partly or complete control, communication and review of risks.

A Risk Management Program starts with identifying the possible risks associated with a product or with the process used to develop, manufacture, and distribute the product. Before designing new strategy, all such impacts, by some statistical rules should be extrapolated to identify its probability of occurrence and possibly intensity of severity. An effective quality risk management process ensures the high quality of drug product to the patient. In addition, quality risk management improves decision making if a quality problem arises. It should include systematic processes designated to co-ordinate, facilitate and improve science-based decision-making with respect to risk.

The industry widely uses two approaches to risk management:

**Proactive:** This approach has been taken at the time when one identifies the threat exposure areas in order to mitigate the potential for loss, before the loss occurs. One who has a sound experience of years in the same area can perceive all such likely events that may obstruct the plans and can shield them with strategically moves.

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**Reactive:** This approach investigates the threat exposure areas to identify the root cause for loss and its impacts, after the loss occurs. Reactive are the measures which one is supposed to implement only after the occurrence of events which were unforeseen or have just skipped from early detection.

Risks: There are two types of risks. One of them is a planned risk and the second one is unplanned-unforeseen.

1. Planned risks and related consequences are merely the outcomes of the decisions which the designer has taken with some anticipation. These are deliberately taken actions which are most likely to materialize in most of the cases and which have shown better results previously. The designers have or are supposed to have provision to assimilate certain losses, if at all they occur. It was already known that the designed plans were susceptible to withstand certain impacts of said losses. These thoughtful plans called proactive and partially reactive.
2. Unplanned risks are those which either have gone out of sight or they were, as said earlier, were unforeseen. To the losses bound to face in the latter cases we have reactive measures to mitigate the consequences.

**An Overview: Quality Risk Management: A matter of Prime Importanc**

If these risk factors are planned according to some strategic short term or long-term goals, then they give rise to what we know as ‘QRM’. It has multiple objectives and the designer has fairly calculated probabilistic risk. In a way it resembles to what is known as ‘goal programming’ in operations research. As what happens in goal programming, the goals or the targets are well known and pre-defined with some bounds-lower bound and upper bound. The next step is to assign priorities for achievements. The goals on the top priorities are to be achieved first and then that which follows in order. Priorities may be maximum profit, maximum sale, incremental production with least wastage, maximum storage with designed dispatch that incurs minimum storage cost and minimizes capital blockage of capital. These points are key points that allows to run the business in a better mode of operations.

**Quality Risk Management - A prime necessity**

Quality Risk Management (QRM) is a team approach. For those who are not truly convinces or have been still unequipped with the notion of QRM, its importance and its applicability, we would strongly recommend to just think for a while about the space project programs carried out by ‘NASA’. Most of the projects that are carried out by aerospace can be considered as first-time projects due to advancing technology and science. Such projects fall under the category of what is known as ‘PERT’. Such projects have been designed with some different or additional features than those of previous ones. Though learnt by past experiences, all the care must be taken to envisage the probable cases of mishaps at any time. This involves different types of losses.

1. Designing and manufacturing cost of space crafts
2. Cost towards money, manpower, and time spent
3. Life threats to astronauts and its impact on future projects
4. National and International loss of reputation
5. Slim chances of approval on the future projects
6. Blocking of technology and hence competition with other countries

Thinking on such losses that can happen, we can conclude

that QRM is highly essential for:

1. Safety
2. Security
3. Reliability and
4. Consistency

In addition to the above area, techniques of QRM are critically employed in the fields like

1. To design war strategy in Military
2. To coordinate combined operation of Air force, Naval force, and militants of Ground force
3. In addition to regular operation of drug manufacturing, the different phases that the bio-scientists pass through till the new prescription drug is successfully introduced in the market with proven results
4. Designing financial policy for each fiscal year

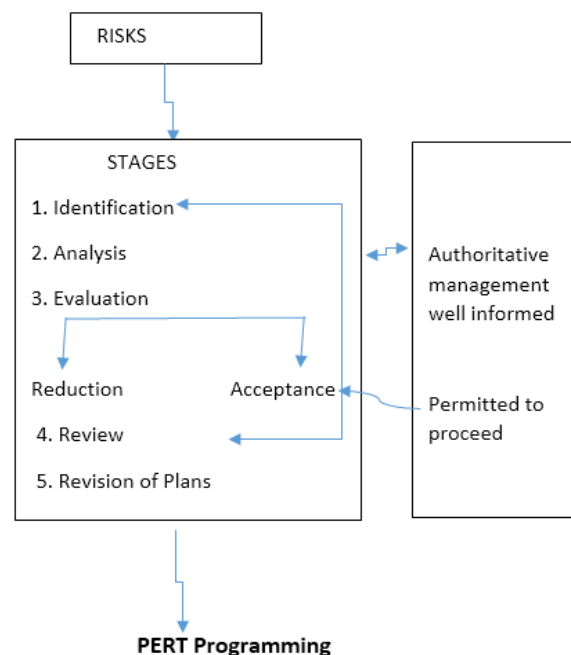
These are few areas where it is utmost essential to purview the different risks based on some past experience and making an extrapolation of the past record for the near future.

Hence, it is essential to inter-mingle necessary features of QRM in every project that fall in the category of PERT. These are first time projects that has no exhaustive list of activities and has unplanned cost and time. It has uncertainty but a firm determination towards completion of the project. Some events are initially critical and severe but along with time asymptotically diminishing while there are some others with reverse impact of occurrence.

Designers should have clear objectives and goals and exhaustive list of future events that can create obstacles in fulfilling the goals on a stipulated time with estimated cost. In some cases, goals are liable to cancellation or some to be restructured under new situation.

Whatever the cases are decision making targets should be safe drive with justifiable and answerable compromises. Extrapolation of the risks and their impacts which have already occurred during the previous cycle will help to mitigate the risks in future. To add to these the most important criteria is authoritative management must be or must be kept well informed at every stage of development.

**Following stages are used during a basic risk assessment process as shown in above chart**



### **Risk Identification Stage**

What might go wrong is the basic question used at this stage. It helps in identifying the hazards based on the data and experience.

### **Risk Analysis Stage**

This stage will analyze the risks that have been identified in the previous stage. Following question can be used to get the information. What is the likelihood of this event going wrong? What are the consequences or severity it will go wrong? And what is the likelihood it will be detected if it goes wrong?

### **Risk Evaluation**

What is the risk level and which are the different effective stages to be adopted all these will be decided according to RPN. This is risk probability number. It suggests that higher the RP number, higher the risk. Most attention must be focused on it. The types of removal of such risks or mitigating them or accepting them as they are can be decided by the designer of the policy. The prime objective is to minimize the impacts in terms of project cost and completion time.

### **Risk Review**

This stage will address whether there is need to revisit the risk assessment at a point in the future.

### **Revision of Plans**

Any change that needs to be done in the processes because of the adverse effects of identified risk factors may be adopted at this stage.

### **Vision**

In this direction we are able to open the study and impacts of QRM in different important areas. Critically speaking every project, may be of manufacturing line or that of military science and development or one that concerns economic policy and future plan need to be revised by treating them with QRM technique.

### **Conclusion**

A profound study in this area (QRM) has provided a clear vision that once can employ in any plan or strategy which are designed for better production run. Clear identification of risk factors along with proactive and reactive plans are sure to succeed with minimum cost and minimum time.

### **Acknowledgements**

We are highly thankful to some important suggestions provided by Dr. Pradeep J. Jha.

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