



## A performance-oriented risk management framework for innovative R&D projects

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### ARTICLE INFO

#### Keywords:

R&D management  
Risk management  
Project management  
Balanced scorecard  
Quality function deployment

### ABSTRACT

Uncertainty is one of the major inherent difficulties in developing innovative products, due to their highly dynamic markets and technologies. The presence of a large degree of uncertainty leads to high R&D risks, resulting in many R&D failures. Therefore, it is important to manage R&D risks through all R&D stages to improve R&D project success rates. This paper proposes a new risk management framework that aligns project risk management with corporate strategy and a performance measurement system to increase success rates of R&D projects and to accomplish corporate strategic goals. The balanced scorecard is used to identify major performance measures of an R&D organization based on the firm vision and strategy. Quality function deployment is adapted to transform organizational performance measures into project performance measures and a systematic procedure is developed for risk identification, assessment, response planning, and control. The proposed risk management framework enables an R&D project to be focused on achieving the corporate goals and provides a more effective way to identify, assess, analyze, and monitor R&D risks along the project cycle. The proposed methodology is illustrated with a drug development project.

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### 1. Introduction

In the increasingly competitive and globalized marketplace, technological innovation is one of the important key strategies for high technology firms to survive and achieve corporate growth (Teece, 1986; Freeman and Soete, 1997). However, various types of innovation (Dewar and Dutton, 1986; Henderson and Clark, 1990) involve different degrees of uncertainty in technologies and markets that may cause failures of R&D projects (Doctor et al., 2001; Raz et al., 2002; Lee et al., 2010). For example, in the pharmaceutical industry, the success rate of a drug development project from the first study in humans to launch is less than 10% (CMR, 2006). Therefore, it is important to manage risks for innovative R&D projects through all the development stages to improve their success rates (Smith and Merritt, 2002; Keizer et al., 2002; Bush et al., 2005; Pisano 2006).

Risk management is a structured approach for the identification, assessment, and prioritization of risks followed by planning of resources to minimize, monitor, and control the probability and impact of undesirable events (Smith and Merritt, 2002). It has

been widely applied in many disciplines, such as management, engineering, insurance, finance, environment, politics, etc. In R&D management, the major purpose of risk management is to increase success rate of an R&D project, which will lead to corporate success. Most literature in the R&D risk management literature is more focused on an individual project level, and so the ways to identify, assess, and prioritize risks are limited within a single project scope (Smith, 1999; Browning et al., 2002; Keizer et al., 2002; Raz et al., 2002; Saari, 2004; Keizer et al., 2005). The main problem is that if the identified risks are improperly identified and prioritized, then time and cost can be wasted in dealing with risk of losses. Therefore, there is a need to link individual project risk management with the corporate strategic management to ensure that managed risks are coped with by the corporate strategy and corporate objectives can be eventually achieved.

This research considers risk to be an event having a negative impact on project outcomes (Browning et al., 2002; Raz et al., 2002; Smith and Merritt, 2002; Keizer et al., 2002, 2005; Perminova et al., 2008) and develops a new risk management framework that aligns project risk management with corporate strategy and a performance measurement system to increase success rates of R&D projects and to accomplish the corporate strategic objectives. The proposed framework, which follows the risk management process that have been widely used in industry,

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integrates the balanced scorecard (BSC) (Kaplan and Norton, 1992) and quality function deployment (QFD) (Hauser and Clausing, 1988) to help project managers organize risk management activities in a top-down manner. The BSC is used to identify major performance measures of an R&D organization based on the firm vision and strategy. Furthermore, QFD is adapted to transform organizational performance measures into project performance measures and a step-by-step procedure is developed for risk identification, assessment, response planning, and control. The proposed risk management framework enables an R&D project to be focused on achieving the corporate goals and provides a more effective way to identify, assess, analyze, and monitor R&D risks along the project cycle. To our best knowledge, there has been no research study that provides an integrated risk management framework based on the BSC and QFD to link R&D risk management with corporate strategy and a performance measurement system.

This paper is organized as follows. Section 2 reviews the related literature. The proposed risk management framework is developed in Section 3. In Section 4, the proposed methodology is illustrated with a hypothetical drug development project. Section 5 concludes the paper.

## 2. Literature review

### 2.1. R&D risk management

There are many definitions of risk that vary by different application domains. In economic theory, risk refers to situations where the decision maker can assign probabilities to different possible outcomes (Knight, 1921). Similarly, in decision theory, risk is the fact that the decision is made under the condition of known probability over the states of nature (Luce and Raiffa, 1957). In project management, there is no consistent definition for risk (Ward and Chapman, 2003; Perminova et al., 2008). In the project management body of knowledge (Project Management Institute, 2004), risk is considered as “an uncertain event or condition that, if it occurs, has a positive (opportunity) or negative (threat) impact on project objectives.” However, many practitioners and researchers in project management still consider risk to be more related to adverse effects on project performance (Williams, 1995; Boehm and DeMarco, 1997; Smith and Merritt, 2002; Ward and Chapman, 2003). From this perspective, project risk management seems to be about identifying and managing threats to the project.

Furthermore, in the literature of R&D management, uncertainty is defined as unpredictability of the environment, inability to predict the impacts of environmental change, and inability to predict the consequences of a response choice (Milliken, 1987; Doctor et al., 2001; Sicotte and Bourgault, 2008). Risk is often defined as undesired project outcomes, exposure to uncertainty (Smith, 1999; Browning et al., 2002; Raz et al., 2002; Smith and Merritt, 2002; Keizer et al. 2002, 2005). This research follows the definition that is mostly used in the literature of R&D risk management and defines the risk as an event having a negative impact on project outcomes.

Managing R&D uncertainty to enhance project success rates has been studied for many years (Doctor et al., 2001; Loch et al., 2006). Risk management is one of the approaches that have been widely applied in practice (Williams, 1995; Smith, 1999; Keizer et al., 2002; Raz et al., 2002; Cooper, 2003; Smith and Merritt, 2002). In the literature of R&D risk management, several studies have found that applying risk management techniques to innovative R&D projects can improve their success rates (Raz et al., 2002; Salomo et al., 2007; O'Connor et al., 2008). Smith

(1999) described principles and guidelines for effective risk management and emphasized the importance of active risk management for accelerating projects and improving their success rates. Raz et al. (2002) performed an empirical study and reported that risk management practice is more applicable for higher-risk projects and appears to be related to project success. Salomo et al. (2007) investigated the effects of business planning and control on the performance of new product development projects and found that project risk planning and goal stability throughout the development process are found to enhance performance significantly. O'Connor et al. (2008) defined three learning oriented risk management practices, including option mentality, use of experimental and learning processes, and use of harvest strategy, and found that using the first two practices has a significant positive effect on the success of radical innovative project. Mu et al. (2009) conducted an empirical study and showed that risk management strategies targeting technological, organizational, and marketing risk factors influence the performance of new product development.

Several researchers have developed risk management methodologies to improve success rates of R&D projects. Browning et al. (2002) proposed a risk value methodology that quantifies technical performance risks to identify, assess, monitor, and control the identified risks throughout the project. However, their research is only focused on technical risks. Keizer et al. (2002) presented a case study of the risk diagnosing methodology (RDM) developed by Philips Electronics Co. to identify and evaluate technological, organizational, and business risks in product innovation. Since R&D is people and knowledge intensive, Cooper (2003) suggested using knowledge management systems and collaboration tools that capture practitioner experience for reducing R&D risks. Keizer et al. (2005) proposed a risk reference framework for diagnosing risks in technological breakthrough projects and concluded that the success of breakthrough innovation projects could be improved through formal risk assessment. Gidel et al. (2005) developed a decision making framework for risk management from the cognitive science viewpoint. Ogawa and Piller (2006) suggested integrating customers into the innovation process and proposed a new market research concept called “collective customer commitment” to reduce the risk of unmet customer needs. In addition, several studies have been published on determinants of new products success and failure (Maidique and Zirger, 1984; Cooper et al., 2004). The key success factors identified in these studies can be used for identifying potential risks.

Due to the long development lead-time, rising development cost, and high failure rate for drug development projects, effective management of R&D risks is important to the pharmaceutical industry. Most of the pharmaceutical risk management has been focused on managing drug safety issues including detection, assessment, understanding and prevention of long-term and short-term adverse effects of medicines (Bush et al., 2005). Some researches have studied the pharmaceutical risk management at the drug development project level. For example, Saari (2004) applied the project risk management framework to the drug development project. Vanderbyl and Kobelak (2008) identified growth and risk factors for Canadian biotechnology industry and suggested that a risk mitigation plan is required to manage those risk factors for project success. Some studies have developed portfolio/pipeline management approaches to select appropriate projects for increasing success rates of product launch and to capture the business opportunity and keep the constant revenue for the company (Blau et al., 2000, 2004; Rajapakse et al., 2005). There is a lack of research on providing an integrated framework that links operational risk management with corporate strategies and provide a systematic approach for risk identification, assessment, response planning, and control.

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