Chapter 5

# Risk Mitigation Strategies in Innovative Projects

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Additional information is available at the end of the chapter

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**Abstract**

This chapter discusses the challenge imposed by the dispersed innovation that shifts toward replicating the positive traits of co-location and coupling it with the unique advantages of the global initiative. Key concepts in this chapter include project risk, risk pertinent to the innovative projects, importance of risk mitigation in innovative projects, different risk categorization involved in mitigating risk in innovative projects, risk mitigation planning, risk mitigation strategies in innovative projects, and risk evaluation and mitigation strategies (REMS) in various types of innovative projects including the lesson learnt from the innovative projects to handle project risk by adopting risk mitigation strategies.

**Keywords:** strategies, risk evaluation, risk mitigation, innovative projects

## 1. Risk and innovative projects

In the current context of market globalization, where the world is emerging with new and more advanced technologies and increasing their competitiveness, companies are trying to offer more and more innovative products. New projects or new ideas always give birth to new challenges, new risks which come across during the development and execution of a project. Different mitigation strategies exist to handle new risks. Moreover, increasing companies are now drifting toward project management tools and techniques to manage innovations, to ensure a better product quality, to meet deadlines, and to reduce the cost. Thus, decision makers along with academicians are trying to minimize risk by applying project management methods.

A risk is "an uncertain event or condition that, if it occurs, it has a positive or negative effect on at least one of the project objectives." A risk is an uncertain event that if it happens, adversely impacts on the project objectives such as scope, schedule, cost, or quality. Project managers should identify risks using different project management approaches that can impede the project's success. Risk identification is carried out through various processes depending

upon the nature of the organization and projects which can be related to operations, technology, organizational procedures, etc. Once risks get identified, then techniques, strategies are observed, and contingency planning is done to lower the impact [1]. According to the ISO 31000:2009, risk analysis is a critical exercise for any project regardless of its size to manage risk. A risk analysis becomes an imperative element in the planning phase of the business development.

The risk, defined as the likelihood of occurrence of a condition or event, may have a positive or adverse effect on project objectives. In projects, there are three categories of risks: (a) project risks; (b) product risks; and (c) business risks. Every organization or project must learn to adapt against the emergence of risk, business changes, and investments in anticipation of its likely futuristic occurrence. However, risk significance is even more important for organizations working on innovative projects because the management must adopt strategies to overcome and mitigate the potential effects of risk which may be negative and alongside its related opportunity. Innovation brings itself with the prospects together with many types of risks such as strategic, technical, delivery, and enterprise [2]. Innovative products are usually ahead of time, strategic risks relate to the lack of investment, different business process understanding, and limited support from management [3].

Innovation is a key to organizational rejuvenation and success. Novelty is central to innovation, but this inevitably implies risk. The risks are inevitable in all projects but are especially important in innovation for which a high failure rate is typical [4]. In some industrialized countries, the success rate of new products is 15%, and for underdeveloped countries like Hong Kong; it is just 2% [5]. It is desirous from innovative management to identify the unacceptable risks as early as possible that often become apparent only in the later stages, at a greater expense. However, a fear of failure would be detrimental to innovation; indeed, accepting the possibility of failure as an everyday reality is one of the defining characteristics of the innovation project. Any model for the process novelty needs to incorporate failure as a likely outcome. In many other projects abandoning the venture is general but remote option, whereas in the innovative project, it is integral for good management. Risk management can help managers in making the critical decision to abandon a project, providing an active sieve of the good and poor prospects and helping direct the continuing research that is fundamental in innovation projects. The risk is central to innovation, but it is often not managed explicitly [6].

Projects regardless of their type and size face risks. Project's characteristics such as innovation level, constraints, a joint venture by multinational and political stakeholders, changing the environment, and such similar traits can increase the project risk level. Hence, the project manager must find a win-win solution to lessen risks besides ensuring that the novelty rate is achievable, and the available resources are adequate to meet the expectations. The risk mitigation strategy plays a vital role to keep the project on track for which identification of potential risks is a must. There are calls for correct risk evaluation and appropriate remedial strategies to gain a realistic and accurate estimation of the project's cost and duration.

Modern innovation requires quality global resources at a rapid pace for which outsourcing—a concept very popular to bring about efficiency, seems a realistic option especially in the context

of risk mitigation. Outsourcing extends the proficiencies to take on complex and pioneering projects, and over the period has proved to be an excellent risk mitigation strategy. However, despite it being the best resource across the globe, outsourcing also has presented with the challenges of managing the means in new turbulent economic scenarios. In recent times, a detailed scrutiny has been carried out to seek the portfolio of the outsourced IT companies [7]. Some of the studies have focused on the level of complexity and cost and time overrun, and the primary emphasis of which has remained on developing a model that can establish a relationship between the complexity, the related risks, and its implication on overall objectives. Its foundation stands not only in identifying risks at commencement but also the mitigation strategies alongside by allowing for the interaction of the three and all that in the framework of Expected Utility Theory [8].

A similar concept is also given due consideration in the context of the impact of innovation on the environment in the long-term sustainability of nanotechnology argues in the risk governance approaches to mitigation of risks with clear and well-structured risk assessment and management criteria to risk governance [9]. For undergoing any innovative project, as for instance the development of London Heathrow Terminal 5, a lot boils down to the dynamic capabilities of the firms or the organization under consideration to take on the innovative projects. Pioneering projects are often strategic in nature and often made complex owing to the number of stakeholders involved in the project. It therefore requires the whole project to be broken down into phases for better contemplation of fragility of the innovative projects and the list of stakeholders involved in strategic management, ultimately balancing out demands on both ends [10].

Project complexity has direct linkage with the innovative nature of the project. Hence, it is important to assess the prospective level of difficulties that may arise due to the very character of the project. As a result, this could save the delays in project completion and keep in check with the budgets besides keeping repute in a cut-throat competition as in the case of Boeing Dreamliner [11]. Sometimes it comes to sourcing alternative ways of energy from the traditional fossil fuel where the idea itself is innovative and has strong linkages in diversifying the risk regarding risk expansion and decreasing dependencies. Identifying alternative sources of energy is a risk mitigation process other than insurances are very complex and requires work at multidimensional levels of complexity. However, for investment in renewable sources, a major hindrance other than the execution of the project itself is the regulatory requirements prevailing in a given country along with the country's long-term strategic goals which can limit alternative risk mitigation strategies [12].

## 2. Significance of risk mitigation

Risk management can aid good managers in making the critical choice of abandoning a project. It provides an efficient filter of good and poor prospects and helps in continuation of research that is essential for innovative projects. The risk is not often managed explicitly but is crucial to innovation. Encouragement of people in generating ideas is a difficult task, and excessive

use of risk management may discourage radical suggestions and stifle this critical stage. While defining the suitable and profitable method of risk management, every project has to consider the data available, costs and management worth of the outputs of the additional analysis. Likewise, innovative project has to balance the likely effect on creativity. Risk management is inherent in the innovation process, but there may always be significant in making it more unambiguous by incorporating models of innovation and project risk management [6].

The usage of newly acquired information, data, or knowledge for the development of a fresh product of service is referred as innovation [6]. Novelty is vital for innovation but unavoidably involves risk. Risk can occur in any project, but it plays a great role in innovation, and failure rate in such projects is common. Proficient innovation management should be able to ascertain excessive risks as early as possible but time and again risks only become evident in later stages, at a significant cost. Nevertheless, fear of failure can be damaging to innovation; in fact, tolerance to the possibility of failing as reality is one of the essential characteristics of innovation projects. Incorporation of failure, as a likely consequence, is often required in a model designed for change.

Contingency theory in the context of innovative projects is of the view that a project can trail different number and as it is about the state-of-the-art projects, it may not be following the seasoned phases from the generation of an idea to launch. So the biggest challenge lies in identifying a particular configuration that can get employed and resource allocation as per the setup and the reasoning behind it in ensuring the overall success of the pioneering project [13]. In the public sector, the stake is the public, and the success of social sector projects is the resultant outcome regarding its implication on the life of an ordinary man. Social sector projects, in general, do not face funding challenges, while risk mitigation often is assessed on equalities impact assessment (EIA). Added innovative decision-making process of social risk impact assessment (SRIA) must have a preference over EIA which does not take due account of a sector that could face adverse impact due to service cuts [14].

Innovation has a lot to do with the risk management. Exploration of the relationship between the two done with a notion that the whole process of risk management splits into stages with a strong emphasis on when to perform laborious risk management processes and when to go with simpler methods to optimize effectiveness [6]. While considering the risk mitigation policies, the biggest challenge is identifying the root cause of such projects. In this scenario, any system that may get formulated must not only be focusing on the production side of things but must also take into consideration the co-benefits [15]. It is hard to deny the prospective impact of the innovative projects on the intangibles. For example, it is apparent in the case of health, environment safety, and overall sustainability. It is also opined by many that the creators and inventors of technology, more often than not, do not have the skill set and capability to foresee the risks that may get associated with the development of new technologies, especially the impacts on the intangibles. Furthermore, it can be stipulated that incorporating the risk mitigation strategies beforehand and before the launch of new innovative technologies in the market can bring about the much desired competitive advantage to such corporations [16].

Risk management strategies are critical as they contribute to the success of the projects in following ways:

- Indent and priority of risks enable the project managers and staff to focus on the most essential aspects which have the most impact on the project.
- Risk mitigation actions reduce overall project risk thus accelerating project completion.
- Due to an earlier completion of projects, the projects cost less, besides the risk reduction actions may further reduce project costs.
- Projects which enforce risk mitigation strategies have more predictable completion schedules and experiences few surprises.
- The risk extenuation strategy helps PM set contingency budgets and thus review the adequacy of the budget as the delivery progresses.
- Risk identification allows all personnel to record their perception of what could go wrong and offer ideas on how to avoid or reduce the impact of such problems.
- It provides an audit record of risk handling effort in a project.
- Risk mitigation also helps in achieving business objects and maximizing shareholder value.
- It promotes job and financial security.

## 3. Risk categorizations and mitigation

Risk mitigation strategies are the conceptualized action plans, and it is the process of developing options to enhance opportunities. It performs a thorough evaluation to reduce the likely threats, vulnerabilities, or impairments that can distress a business operation, a project, or any form of the undertaking. A suitable response to each risk should be specified and recorded in a risk register. Studies have indicated several project risk management actions identified, and these may be summarized into categories reflecting the particular characteristics of innovative projects [17, 18]. Risk management is a major component in project success. It is an important activity that should get applied to all projects as fundamental part of every facet of managing the project, in every phase as well as a process group.

### 3.1. Increase responsiveness

Another strategy of mitigating the risk in projects is the increasing responsiveness related to faster deliveries, which accounts for a 20% increase in production rates. The faster one gets the item into consumers' hands the better. Fast-track project implementation can also help mitigate three significant threats to risks associated with costs, scheduling, and safety and quality renewable energy parks.

### 3.2. Reducing cost risks

Some of the most common cost risks that are faced when needing to expedite a project include the accuracy of cost estimates, delayed or miss appropriate funding, complications from schedule compression, and the dearth of vendor competition. Through the fast-track project delivery, risks in cost estimates get minimized through adequate preliminary engineering and scheduling. When the team can identify budget issues early in the design process, cost estimates are more thorough, eliminating threats from potential, costly surprises.

### 3.3. Mitigating schedule risks

When modularizing equipment, it is vigorous for the project team to involve merchants early and to launch an equipment expediting plan to avoid potential scheduling barricades caused by equipment deliveries or damage during transportation.

### 3.4. Mitigating safety and quality risks

Fast-track projects also alleviate issues caused by work area congestion by developing an hour-by-hour roster that ascertains areas of trade overlap and enables the project team to make alternate plans to eliminate this overlap.

### 3.5. Rapid prototyping and test feedback

Rapid prototyping is an essential part since suitable comparisons might not be available in the market or within the organization. However, it can be a part of the quality assurance process of the organization/project. The feedback from the prototyping/experimentation should be thoroughly analyzed and tested, and suitable recommendations for changes adhered to throughout the project duration. The risk like grid connection, delays in start-up, or maintenance issues can be sorted out after critical analysis of these prototypes.

### 3.6. Political, policy, and regulatory risks

Relevant political, policy, and regulatory risks for wind parks include:

- The risk of ex-post facto adjustment of support.
- Continuous inconclusiveness on prospective policy support or regulatory requirements concerning solvency capital requirements.
- The risk of expropriation or war like developing countries. Risk management instruments or mitigation strategies for political, strategic, and regulatory risks are:
- Due persistent practices including an assessment of potential future changes in the legislation such as by identifying political risk indicators.
- Geographical and regulatory diversification is a primary risk mitigation tool. Divergence appears to be a single risk management tool for policy and regulatory risks in general.

### 3.7. Efficient communication

Effective and efficient communication among all key stakeholders throughout the project lifetime is the lifeblood of a project. Without effective and efficient communication mechanism across the channel, no project is bound to be successful. Its importance intensifies even more in such like innovative projects because the lack of proper and timely communication between the project team and all the stakeholders (in this case it is public) can create confusions/conflicts which can act as benchmarks for serious setbacks to the project.

### 3.8. Staff training

This strategy includes developing and supporting organization-wide edification and drill for soft skills in communication, partnership, enablement, servant leadership, critical thinking techniques, and strategic thinking as well as technical expertise. Proper training of staff is of fundamental importance once the team hired might not have experience working in the particular environment and handling the specific equipment/machinery. Training employees can lead to fewer costly mistakes which mean there are less recalls less rework and reduced chances of failure. Therefore, it is essential to devise a suitable comprehensive training program for the project team members to develop proficiency in specific areas of the project.

### 3.9. Relying on proven technologies

Innovation always scatters around uncertainty. In an innovative project like this, there is a need to build on the already proven technologies/strategies for building/manufacturing the products to control the uncertainty factor. Moreover, proven techniques/strategies are more likely to have been tested and verified already and information regarding their effectiveness/efficiency might be available in the market. It would naturally reduce the uncertainty factor of the overall project to some extent.

### 3.10. Multiple sourcing

Multiple source approach relies on the options such as never to keep all of the eggs in the same basket. A good project manager should always have multiple concurrent options available at any point of reference. A single option can quickly turn into chaos due to any unforeseen circumstances. The importance of various sources becomes even more important in this innovative project due to the unpredictable/uncertain availability of resources/parts which require replacement. The idea of multiple source strategy can be extended to various disciplines, for instance, technological options, HR options, vendor/seller options, etc. However, holding various resources can get very costly. The reason is simple: Because cost holdings incurred continually, the optional resources would be used only in the rare event of a disruption. As a consequence, the company pays (and continues to pay) for reserves that may never get tapped.

### 3.11. What-if scenario

It is imperative to understand the complexity and nature of issues/problems that could arise throughout the project life. The reason is that there might not be sufficient time or resources

to act on the time when the issue occurs. Therefore, all the issues need to pre-assessed and analyzed in advance. Relevant what-if scenarios require formulation, and contingency plans should be proposed accordingly in advance to avoid the future disturbance or failure due to damage to physical assets or non-availability of certain items.

### 3.12. Counterparty risk

The supplier or contractor's financial stability of operation and maintenance (O&M) services is critical. The counterparty risk of major suppliers or contractors considerable issue for offshore wind parks, where financial strength concerns contract fulfillment, as well as guarantees or warranties. All parties see skilled developers and reputable contractors with current credit evaluation and performance track record, particularly pertinent for offshore wind parks, as well as long-term contracting.

## 4. Planning risk mitigation

The risk mitigation step involves the development of mitigation plans designed to manage, eliminate, or reduce risk to an acceptable level. Once implemented that plan is continually monitored to assess its efficacy with the intent of revising the course-of-action if needed. The risk reduction plan includes evolving options and actions to enhance opportunities and reduce threats to project objectives. Reducing risks is the process of executing risk mitigation actions. Risk mitigation progress monitoring includes tracking identified risks, identifying new risks, and evaluating risk process effectiveness throughout the project. Risk mitigation handling options is (a) assume/accept—acknowledge the existence of a particular risk and make a deliberate decision to take it without engaging in extraordinary labors to control it. However, approval of a project or program leaders is a priori in such cases; (b) avoid—adjust project necessities or constraints to eliminate or reduce the risk. This adjustment could be to accommodate a change in capital, technical requirements, or timetable; (c) control—compliance with planned actions to minimize the effect or probability of the risk occurrence; (d) transfer—making others responsible for causing or handling risks; (e) watch/monitor—monitor an event for a change that may yield an effect on nature and the impact of the risk.

Best management practices require that the known and perceived risks need to be analyzed on merit based on the gradation and probability of the anticipated adverse results. After that, all such risks examined gets preserved according to their priority levels in accordance with the risk mitigation plan followed by the development and integration of the corresponding risk reduction strategies and get referenced in the previously qualified risk management plan. A risk mitigation plan shall serve as the checklist of the anticipated risks, explaining by the degree of probability, like high, medium, or low. Some project managers, however, deem it more appropriate to categorize the risks as most likely, likely, or unlikely. The project manager must take complete authority of reducing the probability of occurrence of risks while executing a project.

## 5. Risk mitigations strategies in innovative projects

Risk mitigation in innovative projects means taking steps to reduce adverse effects or a systematic reduction in the extent of exposure to a risk and the likelihood of its occurrence. The risk response must revolve around following response strategies to ensure minimization of the paraphernalia of uncertain events. Doing this will facilitate innovative project continuity and ensure disaster recovery. These risk responses include:

### 5.1. Attending to the uncertainty level

If a project is destined to have a small degree of risk, then the optimal policy is to proceed expediently to upsurge the present-day value of the project by finishing it as soon as possible and thereby earning its benefits faster. Fixed-price contracts, conceivably with schedule enactment incentives, are suitable for this type of project. The whole enchilada otherwise being similar, projects that take longer generally cost more and deliver less value to the owner. However, when a project has some ambiguity, a full-speed-ahead approach may not be optimal. In such projects, scope changes and iterative recycling of the design are the norms not the exception. For projects with an extraordinary degree of uncertainty, fixed-price contracts may be inappropriate, but performance-based incentive contracts appear convincing.

### 5.2. Risk transfer and contracting

There is a common perception about risk management, namely that the owner should allocate risks to the parties best able to manage them. Even if this sounds right, it is far as easy to say in place of performing. It is hard, for example, to allocate risks when there is no quantitative extent of them. Risk apportionment without quantitative risk assessment can lead to attempts by all project participants to shift the responsibility for risks on others, instead of searching for an optimal allocation based on mutually recognized risks. Contractors in general agree to take risks only in exchange for adequate rewards. It is necessary to quantify the risks so as to come to an understanding in a fair and just price that the owner should pay a contractor to accept the risks associated with particular uncertainties. Risk transferal can be entirely appropriate when both sides fully understand the risks compared to the rewards. This strategy seems applicable to contractors, indemnities, or indemnification firms. The party that assumes the risk does so because it has an acquaintance, expertise, or other characteristics that will lessen the risk. It then is justifiable and economically proficient to hand over the risks, as each party considers itself to be better off after the altercation than earlier and the net project value increases with risk transference.

### 5.3. Risk hedging

Risk hedging (or risk buffering) is to keep some reserve that can engross the effects of several risks without endangering the project. A contingency is an example of a buffer where a

large exigence decreases the risk of the project running out of money before its completion. Buffering can also include the allocation of additional time or other resources used by the project. It can mean increasing supplies to cater for the uncertainties in futuristic requirements. Risk buffering is often applied by project contractors as well as by owners. Misjudging the number of hours worked, or other costs such as buffering used by project contributors. If jobs get awarded by lump-sum, fixed-price bids, then too much budget cushioning can be detrimental to contractors' competing abilities. Contractors and sub-contractors may succeed in winning compensation by overestimating project or activity durations. Schedule buffers allow contractors to adjust their workforce and resource allocations within projects and across multiple projects.

### 5.4. Risk evasion

Risk avoidance is the exclusion or evasion of the class of risks or by altering the bounds of the project. It strives for reconfiguring the project such that the risk in question disappears or gets abridged to some bearable value. The flora of the solution may be engineering, technical, financial, political, or whatever else addresses the cause of the risk. However, care is needed so that circumventing one known risk does not lead to taking on unknown risks of even greater significance. Risk averting is perhaps underutilized as a stratagem for risk extenuation, whereas risk transference is overused. It is because those owners are likely to first think of how to transfer risk to someone else rather than restructuring the project to avoid the danger. Risk averting is a plan that the stakeholders can turn to their benefit.

### 5.5. Risk controlling

Risk control prohibits the unlikely events from occurring in a project. It minimizes risks by barring their freely spread in the project through planned mitigation. Risk control can employ data gathering for analysis purposes or an advanced cushioning system that is capable of providing accurate and on time information about a risk. Managing risk is expensive. For example, in the case of a new product development (NPD) where competition may cause risks, then one of the solutions is to accelerate the proceedings even at a substantial cost, to come out as a leader. This technique is a standard norm in high-tech industries. The associated risk, however, is that the scientific development as promised may not occur and may require abandoning of the project.

### 5.6. Risk acceptance

Accepting risk is the last resort in developing a risk encountering strategy. It means that if a risk remains unavoidable, cannot be controlled, indemnified, eradicated, transferred, or mitigated; then it must just be accepted so as to continue with the project. Ostensibly, this implies that the risks associated with going ahead are less than, or more acceptable than, the risks of not going forward.

## 6. Risk evaluation and mitigation strategies (REMS) in innovative projects

The purpose and importance of risk evaluation mitigation strategies (REMS) are to lessen or reduce if not eliminated but at least are being reduced to some lower level that the adverse impacts of the known or perceived risks are inherited in a particular undertaking or even before any damage or disaster takes place. The quicker the risks get identified and avoided, the smaller the chances of having to face that particular risk's consequence. Known risks must get analyzed according to their anticipated impact. All the risks should be first prioritized and then documented.

### 6.1. Research and development (R&D) projects

The risks and uncertainties are mostly high in research and development projects, especially new product development projects. To handle such challenges one of the most shared and efficient risk mitigation strategy used in R&D projects is FMEA model, that is, failure mode and effect analysis. The extended version of this model is a project risk failure mode, and impact analysis abbreviated as RFMEA which is now evolving as an emerging technique rigorously used in R&D and new product development (NPD) projects efficiently. RFMEA model can benefit the project managers to classify operational contingency plans for effectively mitigating high-priority risks in R&D projects. While FMEA reduces the risks linked with the project's technical facets such as design and planning progressions of the product development, RFMEA is used to quantify and analyze risks, specifically in the project environment.

The five risk prioritization parameters of RFMEA technique depend on: (1) the likelihood that a risk will occur; (2) the severity of the effect on the project should it occur; (3) the risk score (RS) for a risk (RS = likelihood × severity); (4) the risk detection factor, that is, the ability to foresee its occurrence; and (5) the risk priority number (RPN) for a risk (RPN = RS × detection factor). This technique not only helps to prioritize risks and mitigate them accordingly but also to reduce the risk management efforts exercised on the projects. The efforts become streamlined as there are fewer risks to focus on, and hence the ability of the team to work on the project efficiently, by focusing on other areas, significantly increases which in turn results in higher productivity [19].

### 6.2. Operational hedging in innovative technological projects

Every technologically savvy project is exposed to uncertainties some of which are technology specific whereas others are organization specific. Organizations going through the deployment of highly innovative technologies have to tolerate significant operational and financial risks. Invariably it becomes tough to assess the risk profiles. Investigation of the operation management literature shows that organizations can, in fact, manage and mitigate risks using services, that is, through operational hedging.

In literature, operational hedging appears as "the ability of an organization to anticipate and respond to uncertainty and change in development and market conditions flexibly

using structuring of resources and processes with the product, production and supply chain options". The operational activities include activities like flexibility, postponement, capacity, which is akin to real options like "prospects to delay and adjust investments and operating decisions over time in response to a resolution of uncertainty" and are termed "operational hedging mechanisms".

Operations design is integral to operational hedging by adding to the evaluation of the project risk profile through the structuring of operational activities. The operation design brings about tradeoffs linked to structural investments and infrastructural decisions to mitigate risks and value degradation due to uncertainties. Its basic aim is to maximize net organizational value by acquiring resources and configuring processes. For example, with smart structural and production volume decisions, an institution lacking in financial resources can effectively manage supply uncertainties for better future growth. Hence, the project managers involved in highly innovative and risky projects can use such operation design to improve the project valuation and efficiently manage risks by engaging risk mitigation levers.

### 6.3. Drug manufacturing projects

Risk evaluation and mitigation strategies are conceived as essential in drugs manufacturing projects for protecting public health by ensuring the safety of drug use. In new drug development projects, there are a lot of questions hindering the success factor in such projects. For instance, the efficacious of the drug or the disease/syndrome/symptom it is intended to treat? Is the drug safe for use in the intended patient population? Do the benefits of the product outweigh the risks? [20].

REMS has emerged as one such technique to tackle such uncertainties. REMS approach is being used to manage and mitigate risks effectively. Not all drugs require REMS; this method is being used for those drugs that are of high-risk bearing associated with the treatment of fatal diseases. REMS apply to any new drug application. Therefore, this risk management approach has raised the thoroughness that the manufacturers must meet [20]. Depending on the magnitude of the risk to be mitigated, risk evaluation and mitigation strategies differ in scope and complexity. Standard REMS elements are Medication Guides (MedGuides), Communication Plans, and Elements to Assure Safe Use (ETASU). The REMS is here to mitigate risk to its full potential to get the full benefit from the drug. The primary stakeholders are very much required to be involved in the developing and implementation of a REMS program to enhance the benefits to the public.

### 6.4. Global software development projects

Global software development projects encounter a lot of risks having different dimensions. One of the most common risks in such projects is language and cultural barrier problems between client and the vendor. This risk usually occurs because of the different foreign languages. In global projects, people from ethnically diverse backgrounds group together to work resulting in high risks of failure in coordination and collaboration. Product failure occurs because of lack of common language and mode of communication as a result of which the product requirements and specifications fail to get comprehended.

To mitigate these types of risks, strategies are formulated such as selecting a vendor who has the knowledge of the client's language and culture. Merit should get ahead of any other selection criteria while choosing a supplier. For example, a vendor should have a reliable supply and delivery record for a large number of projects. The vendor should possess a know-how of the client's language and culture which should act as an enabler for understanding the product requirements and for the customer to give away full specifications and information resulting in a successful project with minimal risk impacts.

### 6.5. New IT software projects

Software projects are always prone to high-level risks especially the innovative IT projects. When working on an innovative software development project, one of the major hurdles which come across is the incorrect specifications or requirements of a software project. This, however, is tough to manage in innovative projects as no previous data can be used or consulted in that matter. One has to be very vigilant in gathering requirements of the customers and end users.

### 6.6. Clear scope specifications

To mitigate such risk effectively, the scope of the project and the specification of the product should be clearly defined and sign off. Moreover, to mitigate such risks, stakeholder involvement is of paramount importance. Stakeholders should be involved in the whole process so as to clear the requirements and specifications of the product or software. Stakeholder engagement is a sure way to a successful project and mitigates most of the risks. This strategy not only helps to eliminate the risks but also to control any future uncertainties as well. The functional people in the client's organization should actively participate to gather complete requirements and precise specification for a particular scope. If the end user of the product is an organization, then functional people are important to be engaged in the process as they are the ones who would be using the product and their satisfaction is necessary, and only they can help in mitigating the risk of incomplete requirements and specifications.

### 6.7. Effective communication plan

While undergoing innovative software projects, one of the biggest challenges that come across is to communicate the scope of the project and the progress to its stakeholders and team members. This risk can create havoc if not treated properly at every level of the course of the project. If the pertinent information fails to get conveyed to the team member and the principal stakeholders, the project can lead to failure. Hence, it follows that mitigation of this risk is essential for developing an effective communication plan and implementing it. Effective and efficient communication strategy is imperative for delivering the right kind of information at the right time to the right audience through right kind of channel. Ease of access and availability of information to the general public can reduce many of the uncertainties and ambiguities surrounding the project. The strategy should also include face-to-face meetings and social events

to enhance communication and collaboration. Improved communication and cooperation increase trust and mutual understanding which is of utmost importance in innovative projects.

This risk can majorly arise in software projects where teams are located at different geographical area and cannot communicate face to face. Visits and exchanges between sites are a must to overcome the communication gap and interaction limitations. A delegation of responsibilities among team members and relocation of team members to support each other can also be the risk mitigation actions in this strategy [21]. There must be infrastructure compatibility among geographic locations to remove any confusion and frustration causing hurdles [22].

### 6.8. Resource planning

In innovative projects, one risk that came across to be very evident was the improper project plan. As innovation comes with no prior experience, hence, it usually faces planning failures such as an inadequate resource allocation. Risk planning strategies are preferred means to mitigate risks. Planning is the backbone of any project and its successful completion. Therefore, project execution requires adequate time and effort in the devising a plan. The mitigation actions include clear roles and responsibilities of the team members so that they know their job and how to make them active. The project manager can play a significant role in such case. The project manager should explicitly relate the purpose of the project to organization's overall strategy, mission, and vision to communicate the purpose of the task. The project manager should establish and compel the members to a shared project goal to cultivate a collective identity [22].

Clearly planned and communicated project's mission and scope statement are important to plan resources accordingly. During innovative projects, resource constraints occur at the crucial point of the project which has a very negative impact on the project. This risk, however, should be mitigated by proper planning of resources and taking members on board by making them aware of all aspects of the project.

### 6.9. Autonomous vehicles (AVs) technological innovation projects

Today development of autonomous vehicles (AVs) is under way. There are various uncertainties and risks exists while utilization of this AV technology which varies from the danger of technological failure to uncertainty concerning the impact of AVs on society, etc. However, these risks and developer's understanding of them will change and evolve as the technology and its implementation progress.

### 6.10. Liability attribution

The existing system of attributing vehicular accident liability is well established however with the development of AVs will threaten to disrupt standard conventions. For example, individuals while operating vehicles assume the responsibility for accidents since they voluntarily take control of their vehicles and the responsibilities associated with such control (personal/tort/criminal liability). This risk exists both for the user and manufacturers. To mitigate this

risk, manufacturers need to come up with vehicles that meet given standards and performance expectations. Thus, they can be liable for accidents in case a defect or failure in their manufactured vehicle contributes to an accident (product liability).

Formulations of strict liability seem reasonable for accidents occurring under fully driverless conditions, the situation becomes less clear when considering accident scenarios involving vehicles using semi-autonomous technology. Any mode that is not driverless necessarily infers some degree of human control and interaction which introduces the possibility of human error and consequentially liability. Therefore, precise rules/regulation regarding the liabilities of AVs with fully automated and semi-automated needs to be developed and finalized prior to formal utilization of AVs at the government level.

### 6.11. Check and balance

While "to err is human," machines are not excluded from the capacity to err as well. Sensor suites and algorithmic capabilities of AV are not immune to failure, creating the potential for significant known and unknown safety risks. Risks identified to affect AVs include environmental factors such as snow and heavy rain, potentially hindering the ability of AVs to perceive their environment accurately. Even detecting primary obstacles, for example, potholes and uncovered utility holes, and differentiating between individual objects, like a rock and a potholed piece of paper, proves to be challenging for AV technology. Furthermore, while detecting a pedestrian is possible, however, it can become a problem in winter, or when the person is moving or quickly emerging from behind an object. Employing reliable technology and more learning from tests and pilot studies can alleviate these challenges/risks. However, the improvements may not be immediate or linear.

The mitigation of risks is crucial if companies producing AVs want to remain in business. Almost every vehicle production company installs automation technology in vehicles. Some use series of sensors and cameras to make sure that car drives smoothly with the help of automation technology, adaptive cruise control or simple cruise control, lane departure warning and front collision assist are a very typical example of this system in which automation system works with the support of human driver. Tesla on the other side has taken automation to a new level and built the full automatic self-driven vehicle. Here, the risks above are very likely to happen. However, they also have come up with a new strategy in which headquarter of Tesla always remains in touch with the onboard car computer. Every moment of a vehicle gets recorded even in different conditions such as weather, road condition wise, and also, the self-driving feature's ability to drive in rush hours. Through such techniques, Tesla, improve the software of the car and give software updates regularly and Tesla's study shows that their self-driving cars got a less ratio of accidents on human being driving. At the start, Tesla was only using sensors, but now with the improved technology, they are putting cameras, in car side pillars to avoid different risks. This, obviously, is to ensure that automated systems will solve many risks on its own, which a man never think off during driving because they are getting data, from across the world and from that they are improving technology so that AVs can work anywhere without any hazards. Therefore, by Tesla's example, making improvements in technology, these risks will never get solved companies must keep a check on their vehicles like the Tesla and keep on improving the software and hardware as well.

### 6.12. One step at a time

The main risk involved in AVs technology to develop is investment risks as the technology may not work out as hoped, resulting in a loss of profit. Conversely, failure to invest in new and potentially transformative technology can make businesses irrelevant, or at best, set them behind their competitors. The uncertainty surrounding AV technology and its applications requires businesses within the automotive industry to take risks that align with their best predictions of how the technology will develop and used. However, this risk is manageable by employing features of autonomous driving commercially attractive and viable, as these AVs can be accepted quickly and easily considering inherent advantages. Additionally, for an industry that typically operates from traditional car ownership-based models, the new capabilities promised by AV suggest a gradual shift to a more service-centric business models. Also to mitigate the risks of going out of business because of lack of interest of people can be overcome by different ways but one step at a time can be a good strategy to solve such issue. The automotive company must not offer the full AV vehicle at once, they must offer some automatic feature at the start and get feedback from the customer about the mechanical features installed in the vehicle. Results based on those surveys will suggest whether launching a fully automated vehicle is a good idea or not. The step-by-step policy will also show that which areas of the world or country are suitable for AVs and when will be the appropriate time to launch such vehicle and slowly company transfers their vehicles to AVs. Through this, company's chances of going out of business will be less. Also, this transaction is anticipated as well received by the market.

## 7. Conclusion

Projects are used as a mean of innovation in organizations. Uncertainty is the foremost impediment in developing innovative merchandise in today's exceedingly vibrant business and technologies which lead to a high degree of risks resulting in significant project failures. Hence, it is imperative to manage risks through all stages of product development to improve project success rates. This chapter proposes a framework to manage risk throughout the product and project management phases and its alignment with business strategy and performance, gauging system to increase project success rates and to attain business strategic goals. Quality function enticement transforms business measures into project enactment measures and an organized procedure helps to identify risks, its assessment, mitigation planning, and control. The risk mitigation strategies discussed in this chapter enable the projects to remain focused on accomplishing the business goals and objectives while delivering in a more effective way to detect, gauge, scrutinize, and perceive risks across the project phases.

Today, it is domineering to develop knowledge and technology based innovation to drive the economy for establishing strong collaborations within the business community. Innovation for technological development requires an entwined system of business interactions with public and private sector alike. Such interactions increase the likelihood of

innovative development within the innovation systems framework. Adhering to strategies is of paramount importance and a significant necessity in industries such as autonomous vehicles (AVs) with its intricate physiognomies, inflated, and laborious procedures. Embracing innovative stratagems and plan for technology development requires a clear understanding of the business environment and subsequent identification of the success factors. This chapter aimed to highlight critical success factors in high-tech innovative development of autonomous vehicle (AV) industry. Liability, check and balance, and one step at a time are the techniques emphasized in this chapter as the most prominent and effective methods for such innovative programs.

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