



Developing a Tool to Identify At-Risk Tasks and Critical Decisions Points During Product or Process Introduction

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Abstract

Process and product introduction are essential aspects of a company's product list. Many steps are involved in performing a successful introduction or transfer. But some steps include some tasks that can be underestimated. The issue with these tasks is that, even when they are simple tasks, they can affect the whole project. Among the potential effects are budget or timeline impacts, delays, and unnecessary expenses. The tool's use aims to improve planning and readiness and minimize issues by providing clear, organized information for decision-making, requests for additional support, and project tracking. The tool to identify high-risk tasks during process and product introduction was developed using “Excel” by using dropdowns and formulas. The task is identified, and different impacts are evaluated to determine the risk level and suggested action. A real scenario was used to test the tool once implemented. The testing results confirmed that the tool can identify high-risk tasks, assess potential impacts, and suggest actions.

Introduction

Research will be conducted to help minimize delays and failures in executing tasks during transfer. Impact of simple tasks can be underestimated, but the potential effects can be seen in delays, scraps, failures, etc. And this triggered a domino effect. A key challenge in task execution is the inability to identify in advance the additional resources and support required. These situations result in delays and unnecessary expenses. Identifying these risks in advance is critical to ensuring the efficient and successful completion of the task and readiness, a tool will be developed to re-evaluate or escalate the task.

Background

The transfer requires support from many areas. When a transfer is in progress, a strategy and a structured design are developed. Simple tasks can affect the delivery of primary tasks. A digital tool can be developed to support activity planning during a transfer. The tool will support transfer activities through planning, execution, and real-time monitoring. Also, the decision-making process will be conducted with accurate information. These enhances efficiency enabling the use of accurate information to make decisions and coordinate support .

Problem

The main objective is to develop a tool that identifies high-risk tasks and critical decision points during product or process transfer.

Other objectives include:

- Analyze common causes of delays and failures during task execution
- Categorize tasks based on the risk level
- The use of a tool (Smartsheet) for the early identification of tasks with potential impact
- Improve task planning and readiness

Methodology

A series of phases was conducted to develop and implement a tool. The tool is intended for use in a real environment to support task management by identifying risks.

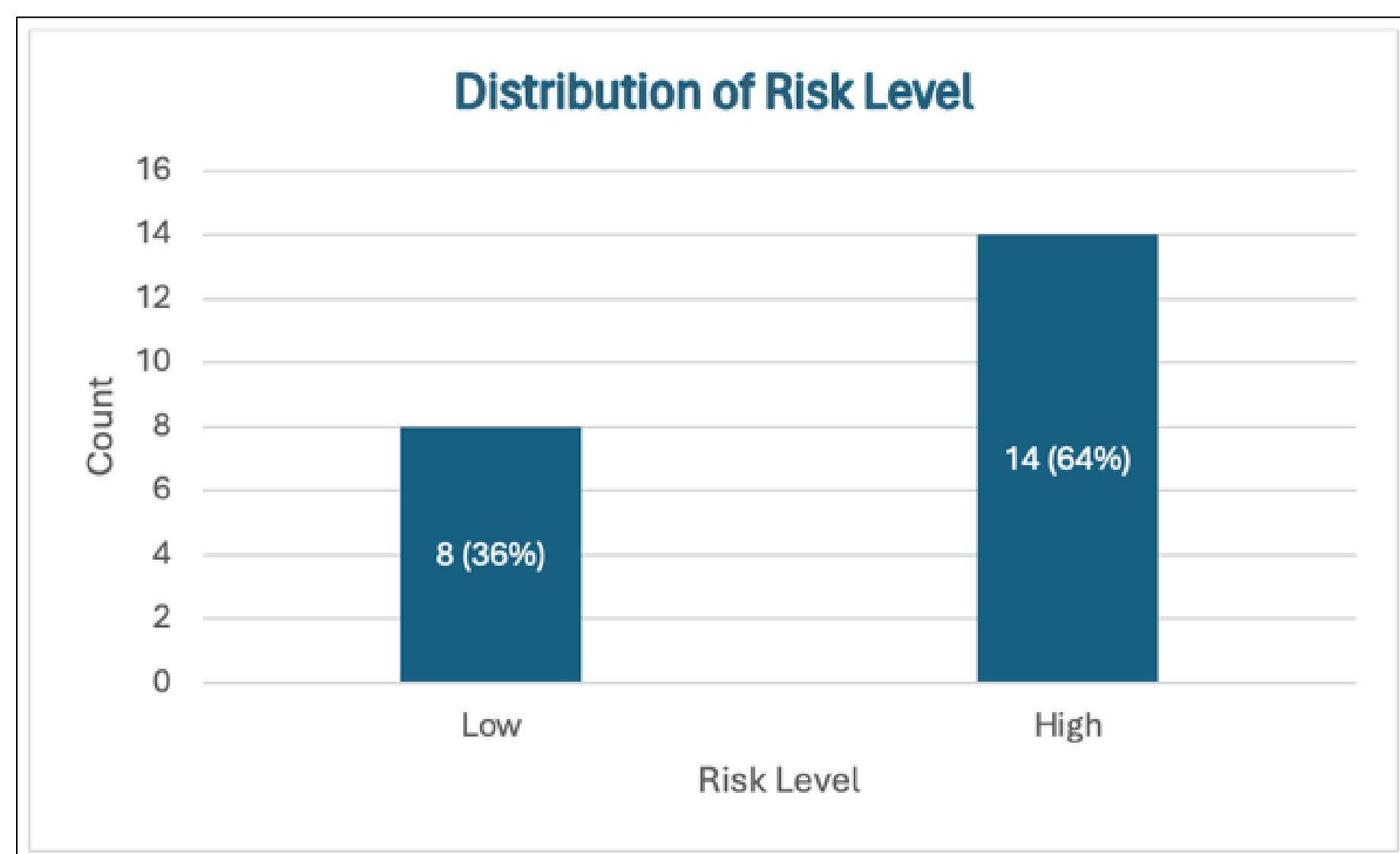
- The first phase in developing the tool is data collection by using historical data, observations during execution, and personnel insights.
- A risk level classification needs to be defined based on the impact on time, budget, quality, or documentation submission.
- The previously identified risks per task will be classified as low or high.
- Using software such as “Excel” to list tasks and risk levels.

Results and Discussion

A tool was developed using software such as Excel to visually identify high-risk tasks. The tool includes columns for manually entering information or dates, dropdowns, and automatic formulas to determine risk levels and actions. The process or product introduction stages are Initial, Confirmation, and Validation. Each stage has different phases where the activities take place: Pre-execution, Execution, Post-Execution, and Submission. The impacts to evaluate per task are quality/regulatory, operations, project timeline, and budget. Also, issues such as managing official content, collaborating with additional departments, and handling non-routine tasks were identified.

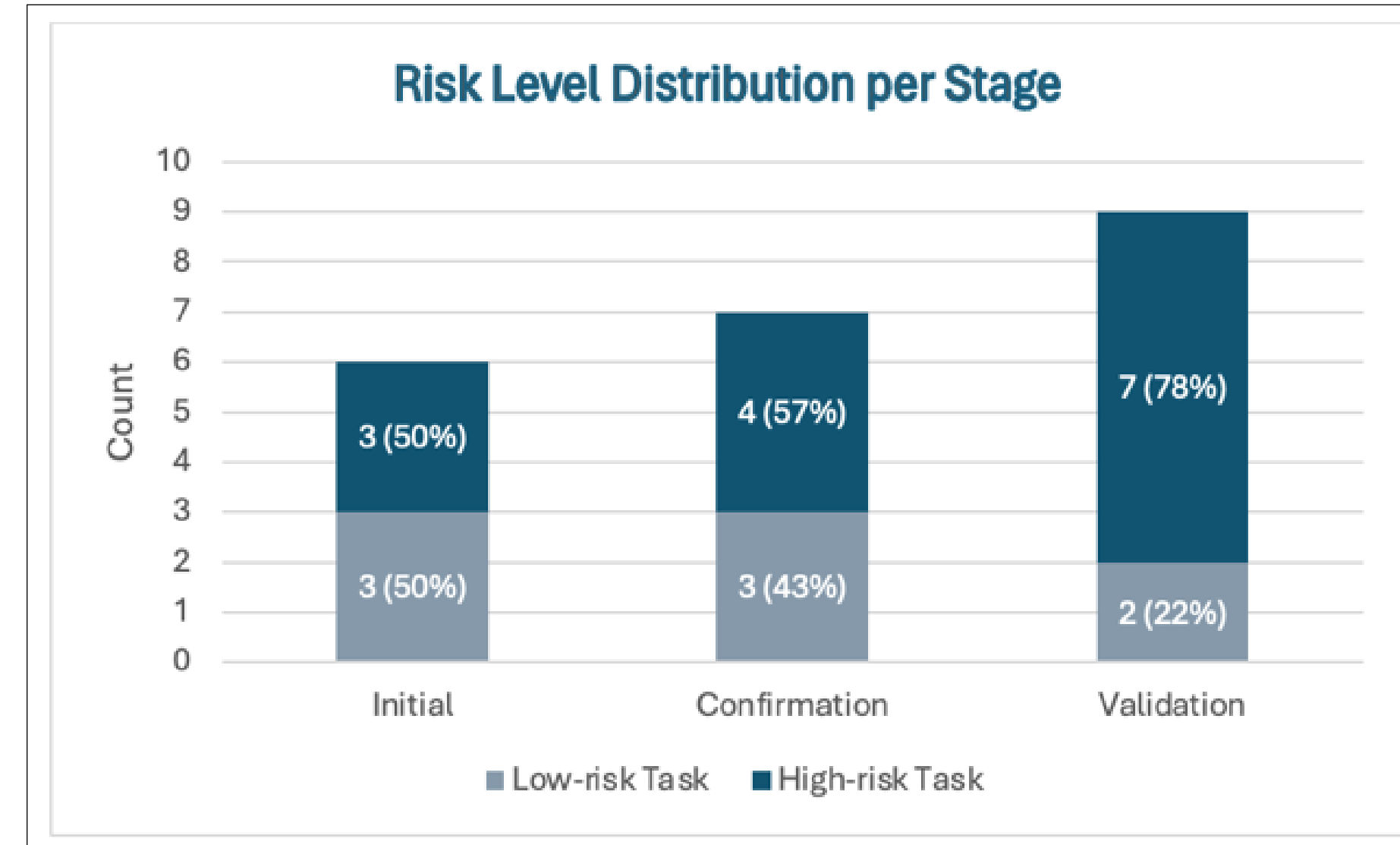
Project: High-risk Task Identification Tool													
Dashboard		Total Tasks	22	Request Support	11	High-risk	14	Low-risk	8	Action Required	5		
Item	Phase	Task	Description	Quality/Regulatory	Operations	Project Timeline	Budget	Official Content	Collaboration	Handling Non-routine	Risk Level	Action	Notes
Initial	Pre-Execution	Test Documentation	Generate Test Manual	NO	YES	YES	NO	NO	NO	NO	2	Low	
Initial	Execution	Materials	Request Materials	NO	NO	NO	YES	YES	NO	YES	3	High	Request Support
Initial	Pre-Execution	Readiness	Coordinate Shifts	NO	YES	NO	NO	NO	NO	NO	1	Low	
Initial	Pre-Execution	Equipment	Set Request	NO	NO	NO	NO	NO	NO	NO	0	Low	
Initial	Execution	Readiness	Make Schedule	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Initial	Post-Execution	Post Documentation	Approve Test Manual	NO	YES	NO	YES	NO	NO	YES	3	High	Action Required
Confirmation	Pre-Execution	Test Documentation	Generate Test Manual	YES	NO	YES	YES	NO	YES	NO	4	High	Action Required
Confirmation	Execution	Materials	Request Materials	NO	NO	NO	YES	YES	NO	NO	2	Low	Evaluate
Confirmation	Execution	Equipment	Preparation	NO	YES	NO	NO	NO	YES	2	Low	Request Support	
Confirmation	Execution	Equipment	Cleaning	NO	NO	NO	YES	NO	YES	3	High	Request Support	
Confirmation	Pre-Execution	Readiness	Coordinate Shifts	NO	YES	NO	NO	NO	NO	NO	1	Low	
Confirmation	Execution	Readiness	Make Schedule	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Confirmation	Post-Execution	Post Documentation	Approve Test Manual	YES	NO	YES	YES	NO	NO	NO	3	High	Action Required
Validation	Pre-Execution	Test Documentation	Generate Test Manual	YES	NO	NO	YES	NO	NO	NO	2	Low	Action Required
Validation	Execution	Readiness	Coordinate Shifts	NO	NO	YES	NO	NO	YES	YES	3	High	Request Support
Validation	Pre-Execution	Readiness	Coordinate Shifts	NO	YES	NO	NO	NO	NO	NO	1	Low	
Validation	Execution	Readiness	Make Schedule	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Validation	Execution	Equipment	Design/Preparation	NO	YES	NO	YES	NO	YES	YES	4	High	Request Support
Validation	Execution	Materials	Design/Manual Transfer	NO	YES	NO	YES	NO	YES	YES	4	High	Request Support
Validation	Post-Execution	Post Documentation	Submit to Agency	YES	NO	YES	NO	NO	YES	3	High	Request Support	
Validation	Post-Execution	Test Documentation	Approve Test Manual	YES	NO	YES	YES	NO	NO	NO	3	High	Action Required
Validation	Submission	Review	Validation Review	YES	NO	YES	YES	NO	NO	NO	3	High	Action Required

Once the tool was completed, it was implemented and used to conduct a test using information from the Product 1 introduction.

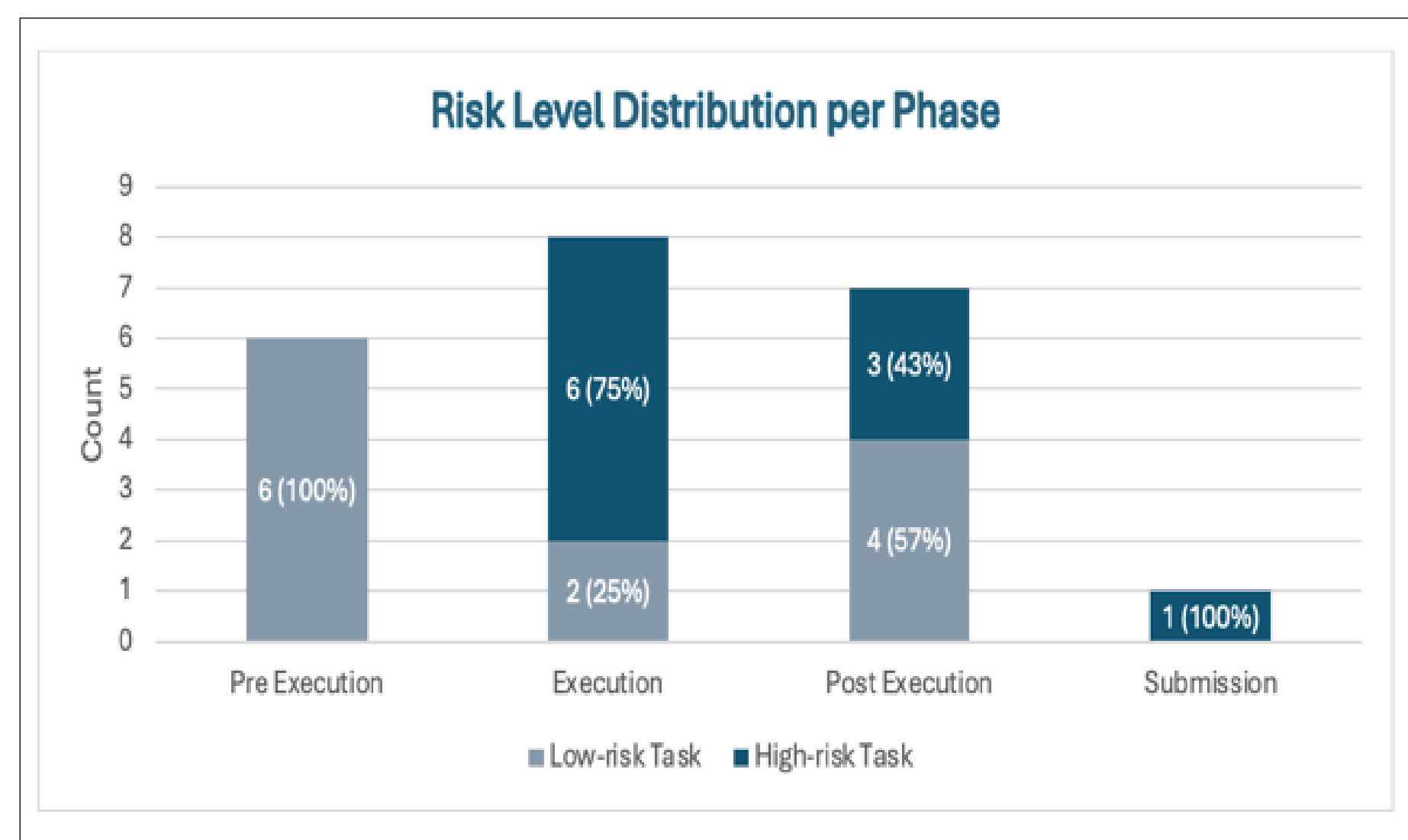


- Fourteen (14) tasks, or 64% of tasks, were classified as high-risk

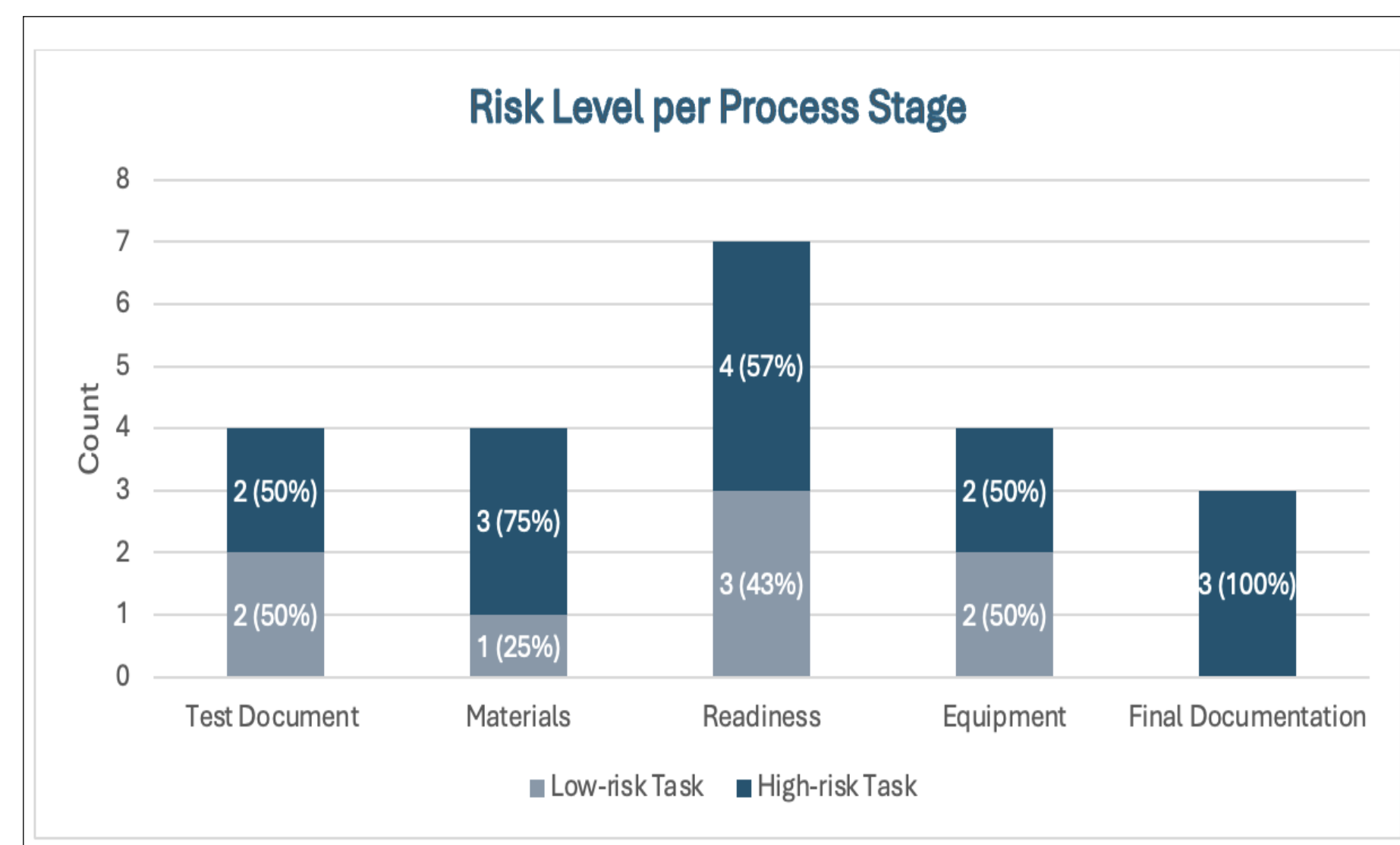
Results and Discussion



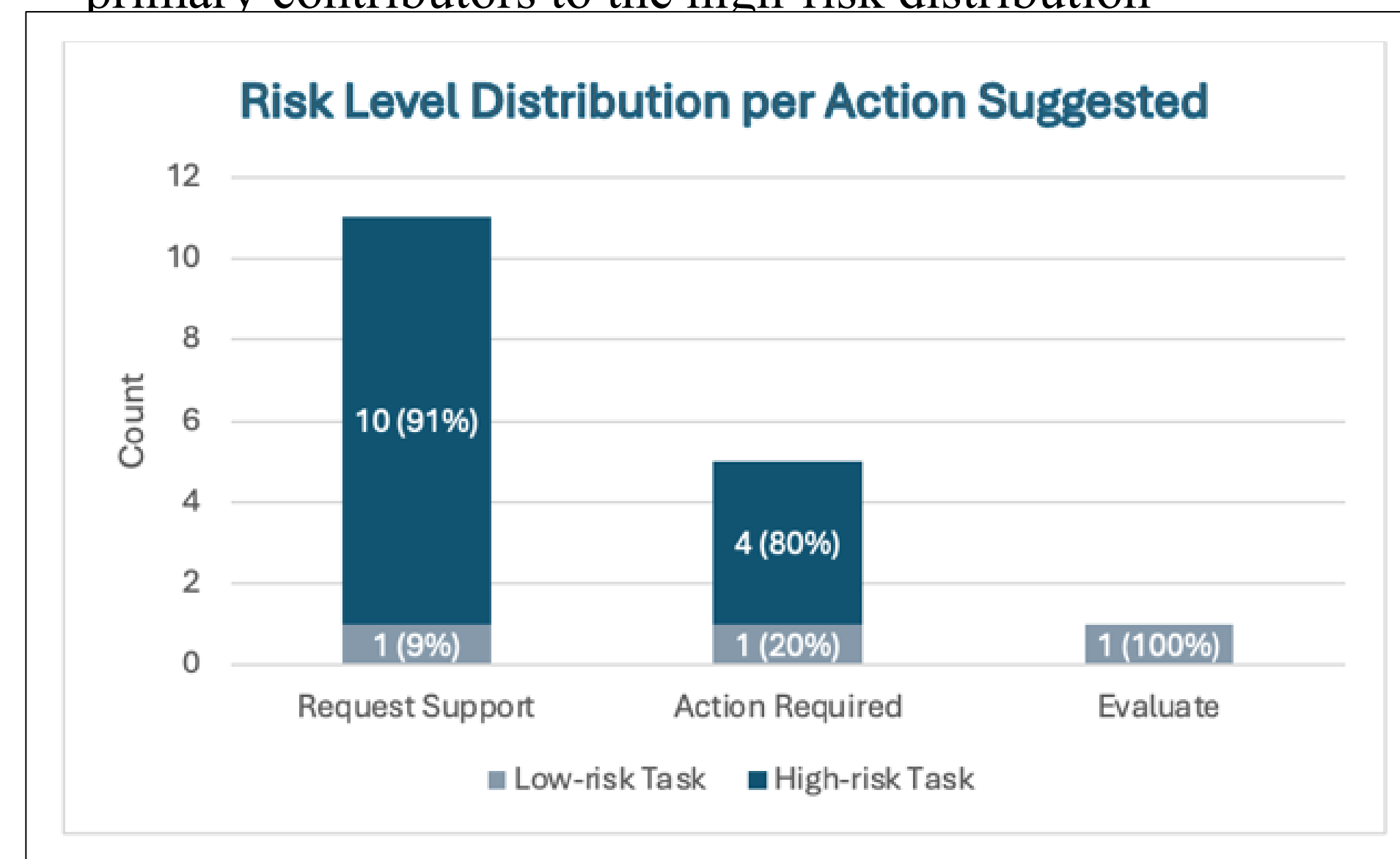
- 78% of the validation tasks were classified as high-risk



- 75% of the execution tasks were classified as high-risk



- A total of seven (7) readiness tasks are identified as the primary contributors to the high-risk distribution



- 91% of collaboration with another department was classified as high-risk tasks.

Conclusions

The tool's analysis helps identify potential risks in advance, enhancing planning, resource requests, and decision-making. The tool was developed in Excel, an accessible, easy-to-use software, using automated calculations and formulas to enable early identification of high-risk tasks. Also, a dashboard was included to visualize the total number of tasks and the suggested actions.

The introduction to Product 1 lists all high-risk tasks. This testing shows a greater quantity of high-risk tasks during the validation stage. Execution is the phase with the most high-risk tasks. Furthermore, the readiness activity is the primary contributor to the high risk. The actions suggested for most of the high-risk tasks were to request collaboration.

Risk identification helps mitigate issues such as delays, unnecessary expenses, and impacts to the production timeline. It is important to maintain task tracking to avoid missed due dates. The use of the tool provides the opportunity to track these tasks, not just in a regulated environment; it could be used in environments that provide customer services, among others.

Future Work

In the future, the tool could include due dates and status to provide a better picture of task progress. Also, high-risk tasks that have not been stated could be identified, and a follow-up could be provided.

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