

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.*

Keywords — *Decision Making, High-Risk Task, Process or Product Introduction, Risk Level.*

PROBLEM STATEMENT

During the program, research will be conducted to help minimize delays and failures in executing tasks during product or process introduction. Sometimes, the impact or purpose of simple tasks is underestimated, but the potential effects can be seen in delays, scraps, and failures. And this triggered a domino effect: once a task is not completed as expected, the upcoming tasks are affected.

A key challenge in task execution is the inability to identify in advance the additional resources and support required. Identifying these

risks in advance is critical to ensuring the efficient and successful completion of the task and readiness.

To address potential delays or failures due to the inability to identify in advance the task that would have an impact, a tool will be developed to re-evaluate or escalate the task. By improving task readiness, the impact on timelines, production schedules, and budgets can be minimized or avoided.

RESEARCH DESCRIPTION

This research aims to develop a tool that helps identify tasks with a high risk of impacting the schedule or budget, or that require decision-making during the product or process introduction.

The study is important because of the frequency of delays, schedule impacts, or material shortages when the area has multiple tasks that often conflict in schedule. The tool will focus on identifying critical tasks, potential high-risk areas, and trigger decision points.

Software such as "Excel" will be used in the research. Where the task information will be documented, and the different formulas will determine the risk level or the need for a decision-making process.

RESEARCH OBJECTIVES

The main objective of this research includes:

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

These objectives are aimed at minimizing potential delays, reducing unnecessary expenses, and improving efficiency.

RESEARCH CONTRIBUTIONS

The research will contribute to improving project management during product or process introduction by:

- Providing a tool to identify and manage high-risk tasks.
- Establish a structured approach to anticipate issues, such as delays.
- Improving coordination among supporting areas.
- Reducing scraps, delays, rework, and unnecessary expenses.
- Informed decision-making process.

This research aims to support more efficient task execution by enhancing effective planning and risk management.

LITERATURE REVIEW

In the biopharma industry, product or process introductions or transfers are common. The introduction or transfer requires support from many areas, including management, validation, and documentation [1]. From the beginning, tasks are designed and conducted accordingly, and, as part of the whole, completion dates must be met to avoid impacts on documentation, upcoming activities, or even the product launch. When a transfer or introduction of a product or process is in progress, a strategy and a structured design are developed. A product or process introduction is a critical phase of maintaining a competitive and innovative company [2]. Once the product or process is introduced, many evaluations and decisions are conducted to ensure that all the resources needed are in place or need to be requested [3] [4]. These evaluations considered the dates established for delivering results and for submitting the corresponding documentation to the agencies. Any failure during

task execution can delay agency documentation or even the product launch [5]. Among the primary tasks identified during planning and resource coordination, a series of simple tasks can affect the delivery of those primary tasks. Those simple tasks have an impact if they are not completed properly [3].

A structured management of tasks needs to be developed to minimize issues by identifying potential risks in advance, improving task planning, and ensuring readiness.

A digital tool can be developed to support activity planning during a process or product introduction. The tool will support introduction activities through planning, execution, and real-time monitoring [2]. Also, the decision-making process will be conducted with accurate information. The tool enhances efficiency in process or product transfer, enabling the use of accurate information to make decisions and coordinate support across departments. Knowing the information and status enables identification of high-risk tasks in advance, avoiding delays and improving communication [4]. When information is shared in a timely manner, processes such as decision-making, support, or resource requests can be initiated to avoid any impact on the process or product introduction [3]. Clear and organized information facilitates identifying any waste and taking appropriate decisions. Lack of materials, waiting for arrival, or rework requests are some of the wastes that can be generated when the information is unclear or out of time.

Using the correct information during a product or process introduction is critical. During the introduction, changes may occur, and it is important to identify any risks to the overall process. Once the risks are identified and the impacts are known, the category can be assigned. The identified and categorized risks in tasks provide opportunities to escalate, make decisions, adjust the schedule, or request any required resources [3].

METHODOLOGY

To identify high-risk tasks and support decision-making during the product or process introduction, a series of phases was conducted to develop and implement a tool. During this phase, qualitative and quantitative approaches were taken to collect data, establish a risk classification, and apply the 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. During this phase, a workflow will be established to identify the tasks associated with each introduction step. The introduction process needs a breakdown into simple tasks to identify common issues or risks.
- A low or high-risk level classification needs to be defined based on the impact on time, budget, quality, or documentation submission. Being the high-risk tasks that need to be identified in advance to adjust or make decisions.
- Once the tasks and possible risks are identified, the tool will be developed. Using software such as “Excel” to list tasks and risk levels. Also, decision points will be included in tasks that are not high-risk but still require evaluation.
- Once the tool is completed, it will be implemented and tested. The testing process will use a simulated or real product or process introduction.

The following phases will be completed to have a completed development of a structured tool for improved planning and task readiness, where the decision-making process is with real-time data to minimize delays, unnecessary costs, or rework.

Table 1
Tool Development Phases

Phase	Activity	Estimated Duration
Data Collection	Introduction tasks identification	1 week
Development	Use “Excel”	1 week
Implementation and Testing	Use a simulation or real introduction	5 days

Results obtained during the testing phase will be analyzed to identify issues in the decision-making process, execution planning, and task impacts. The results will demonstrate the efficiency of task management, effective coordination with other departments, and enhanced decision-making.

RESULTS AND DISCUSSION

The process or product introduction consists of many stages with different activities that, if not completed, may affect the status or progress of the introduction. These simple activities should be monitored to request resources, accordingly, avoid delays, and make decisions. A tool was developed using software such as Excel to visually identify high-risk tasks. Using Excel offers greater reach, as it is easier to access and manage. With Excel, the tool can be kept up to date without requiring additional privileged access. Furthermore, the tool can be used by other groups or departments.

The tool includes columns for manually entering information or dates, dropdowns, and automatic formulas to determine risk levels and actions (see **Figure 1**).

The initial step was to create a process breakdown, as shown in **Figure 2**, to define the process or product introduction stages: Initial, Confirmation, and Validation.

Project: High-risk Task Identification Tool													
Dashboard		Total Tasks:		22	Request Support:		11						
		High-risk:		14	Evaluate:		1						
		Low-risk:		8	Action Required:		0						
Stage	Phase	Task	Description	Quality/Regulatory Impact	Operational Impact	Official Content	Project Timeline Impact	Budget Impact	Not Routine	Additional Department	Impact	Risk Level	Action
Initial	Pre Execution	Test Documentation	Generate Test Material	NO	NO	YES	YES	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	Not Required	NO	NO	NO	NO	NO	NO	NO	0	Low	
Initial	Execution	Readiness	Make a Schedule	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Initial	Post Execution	Final Documentation	Approve Test Material	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Confirmation	Pre Execution	Test Documentation	Generate Test Material	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	NO	YES	2	Low	Request Support
Confirmation	Execution	Equipment	Cleaning	NO	NO	NO	YES	YES	YES	YES	3	High	Request Support
Confirmation	Pre Execution	Readiness	Coordinate Shifts	NO	YES	NO	NO	NO	NO	NO	1	Low	
Confirmation	Execution	Readiness	Make a Schedule	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Confirmation	Post Execution	Final Documentation	Approve Test Material	YES	NO	YES	YES	NO	NO	NO	3	High	Action Required
Validation	Pre Execution	Test Documentation	Generate Test Material	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	Request Support
Validation	Execution	Readiness	Make a Schedule	NO	YES	NO	YES	NO	NO	YES	3	High	Request Support
Validation	Execution	Equipment	Delegate Readiness	NO	YES	NO	YES	NO	YES	YES	4	High	Request Support
Validation	Execution	Materials	Delegate Material Transfer	NO	YES	NO	YES	YES	YES	YES	4	High	Request Support
Validation	Post Execution	Final Documentation	Submit for Agencies	YES	NO	NO	YES	NO	NO	YES	3	High	Request Support
Validation	Post Execution	Test Documentation	Approve Test Material	YES	NO	YES	YES	NO	NO	NO	3	High	Action Required
Validation	Submission	Revision	Validation Revision	YES	NO	YES	YES	NO	NO	NO	3	High	Action Required

Figure 1
High-risk Tasks Identification Tool

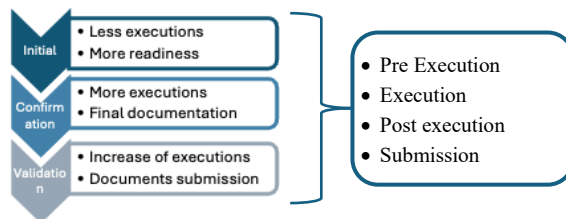


Figure 2
Process or Product Introduction Process Flow

Each stage has different phases where the activities take place: Pre-execution, Execution, Post-Execution, and Submission. During each phase, tasks are established with a short description.

Once the tasks were established, different impacts were identified using historical data. 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. Tasks were manually entered, with the respective impacts selected as “yes” or “no”. The impact and risk level are established using different formulas listed in **Table 2**; conditional formatting was applied to both columns. The impact column is calculated by counting the number of impacts answered “yes”. If the impact result is three (3) or higher, the risk level column is considered high.

Table 2
Formulas to Determine Impact and Risk Level

Name	Formula
Impact	=COUNTIF(Table1[@[Quality/Regulatory Impact]:[Additional Department]],"YES")
Risk-Level	=IF(L2>=3, "High", "Low")

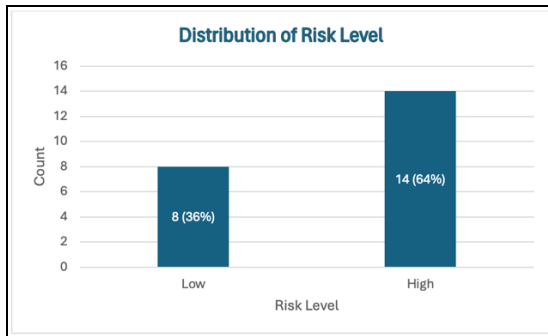
Once the tool was completed, it was implemented and used to conduct a test using information from the *Product 1* introduction. Refer to **Table 3** for a summary of the tool’s implementation and testing.

Table 3
Formulas to Determine Impact and Risk Level

Process Stage					
Process Stage Initial (6 Tasks)					
Phase		Low-risk Tasks	Suggested Action	High-risk Tasks	Suggested Action
Pre Execution	3	Test Documentation Readiness Equipment	None	-	None
Execution		-	None	2 Materials Readiness	Request Support
Post Execution		-	None	1 Final Documentation	Request Support
Submission		-	None	-	
Process Stage Confirmation (7 Tasks)					
Pre execution	1	Readiness	None	1 Test Documentation	Action Required
Execution	2	Material Equipment	Evaluate Request Support	2 Material Readiness	Request Support
Post Execution		-	None	1 Final Documentation	Action Required
Submission		-	None	-	None
Process Stage Validation (9 Tasks)					
Pre Execution	2	Test Documentation Readiness	Action Required	-	None
Execution		-	None	4 Readiness (2) Equipment Materials	Request Support
Post Execution		-	None	2 Test Documentation Final Documentation	Request Support
Submission		-	None	1 Revision	Action Required

According to the data obtained with the tool, a total of twenty-two (22) tasks were identified:

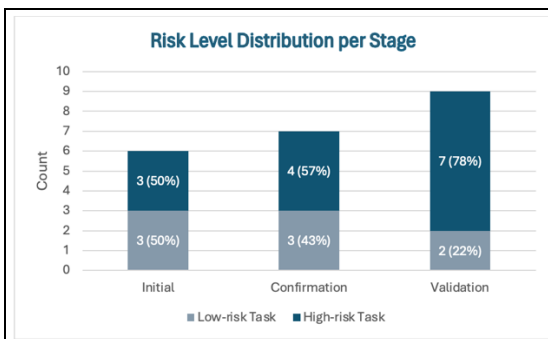
- Fourteen (14) tasks, or 64% of tasks, were classified as high-risk (see **Graph 1**).



Graph 1
Distribution of Risk Levels

Nine (9) of the identified tasks are from the validation stage, which is the stage with the most tasks:

- 78% of the validation tasks were classified as high-risk in **Graph 2**.

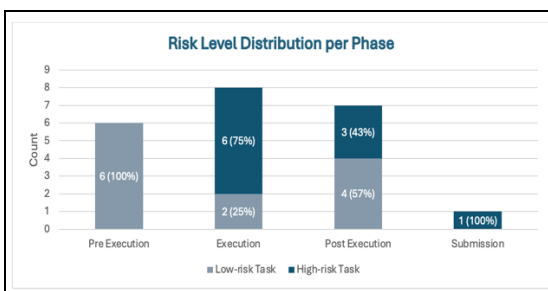


Graph 2
Risk Level Distribution (per stage)

The phase with more tasks during the product introduction is execution. A total of eight (8) tasks were identified, refer to **Graph 3**.

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

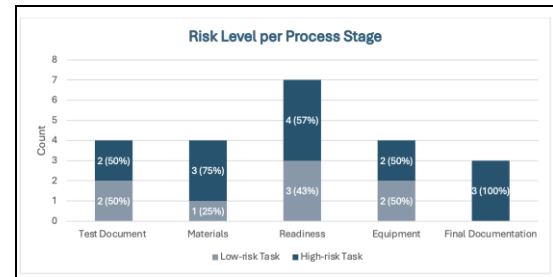
Pre-execution and submission tasks are 100% low-risk and 100% high-risk, respectively.



Graph 3
Risk Level Distribution (per phase)

Readiness activities occur during the initial, confirmation, or validation stage. A total of seven (7) readiness tasks are identified as the primary contributors to the high-risk distribution (see **Graph 4**).

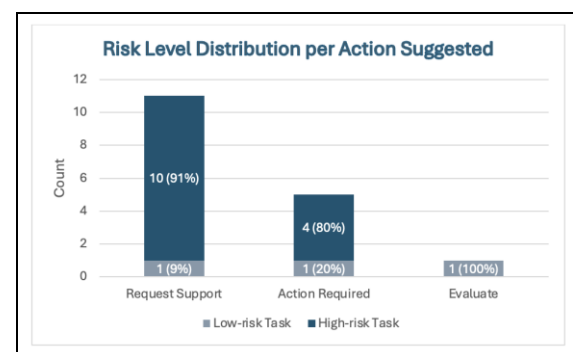
- 100% of the final documentation tasks are classified as high-risk.
- Test documentation and equipment tasks has 50% classified as low-risk and high-risk.



Graph 4
Risk Level Distribution (per process stage)

In addition to classifying tasks by risk, an action is suggested based on potential risks and their levels: request support, action required, and evaluate. Refer to **Graph 5**. These actions will alert when other departments need to collaborate, when a task needs to be evaluated, or when an action related to regulatory compliance is required. Of the seventeen (17) tasks that required action, eleven (11) required collaboration with other departments:

- 91% was classified as high-risk tasks.



Graph 5
Risk Level Distribution (per action suggested)

Even with a low-risk classification, the impact on the additional department triggered a suggested action to request the required support. An “action required” suggestion is triggered by an impact on

quality or regulatory compliance, regardless of the impact level. A task with a suggestion to evaluate is due to impact on budget and timeline, even though it is a low-risk task.

This use of the tool provides visual support for identifying potential impacts on quality/regulatory, operations, project timeline, and budget, evaluating decisions, and requesting the required support. Tasks with an impact on quality/regulatory compliance and that required support were easier to identify and address in advance.

CONCLUSION

The process or product introduction high-risk tasks identification tool was developed. Also, the tool supports decision-making during product and process introduction. The use of task management and evaluation provides an effective approach to improve planning, coordination, and execution, thereby avoiding potential impacts on the timeline, scrap, or budget. 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 highest 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.

The visual identification of potential risks and their levels improves communication among groups, provides real-time data to the decision-making process, and enhances efficient execution. Risk identification helps mitigate issues such as delays, unnecessary expenses, and impacts to the production timeline.

An environment with a high workload tends to have many tasks conducted in parallel. It is important to maintain task tracking to avoid missed due dates. But some simple tasks are underestimated, and if they are not completed, they could affect a project's results. 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.

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. Also, delays could be more easily identified, and the appropriate decision could be made.

The tool provides an easy visual way to identify high-risk tasks, better-organized projects, effective planning, and enhanced decision-making. Communication and resource requests can be conducted in real time and in advance. An efficient execution, minimized delays, and reduced unnecessary costs demonstrate enhanced risk management.

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