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Abstract

The Project Management Office (PMO) Regulatory Team, manages regulatory projects that include in the scope all countries globally that can import and distribute their products. The Master Regulatory Schedule (MRS) is prepared with the countries' outcome to provide visibility to the Franchise and Supply Chain (SC) of the projects that are in the process of being implemented. Challenges for Supply Chain to provide accurate data into the Master Regulatory Schedule and for countries to review the data provide and align dates have been evaluated to identify the risks for restricted countries that cannot receive the previous product after submitting or approving the new product. The main goal is to achieve supply continuity in all countries and avoid any disruptions in product supply by implementing a Green Light Signal. The Project Management Office team started gathering feedback to improve the process, reduce workload, identify priorities, and avoid and mitigate risk.

Key Terms – Green Light Signal, PMO, Restricted countries, Supply Continuity

Project Description

Project in scope is the global implementation of the European Union Medical Device Regulation herein called MDR regulation. MDR goal is that products comply the highest level of quality for the safety of the patients for products produced or supplied to European union's countries (EU countries). One of the goals for the business is to avoid and mitigate the product supply gaps in the countries as part of the registration process triggered by MDR. The PMO and SC are experiencing challenges with high inventory build ups due to lack of understanding and tracking of countries transition dates to the new product. It was decided to improve the process by implementing the Green Light Signal.

Problem Statement

The high volume of projects, countries and products makes the identification of risks a complex process. To achieve the goal of properly identifying the risks of supply chain gaps in the countries, PMO and SC provided their feedback as shown in Figure 1.

Challenges	Risks
Supply Chain Team Feedback	
<ol style="list-style-type: none"> Supply Chain questions #1, #2 and #3 have multiple answers that can be interpreted incorrectly. To understand when countries can receive the new products, too many filters are needed. No traceability of changes in documentation dates. No record of alignment with specifically, restricted countries. 	<ol style="list-style-type: none"> No clear visibility of countries aligned can lead to supply issues. Inventory build ups are high due to tardiness in alignments or misalignments. High volume countries and restricted countries end up with supply issues, and product blocks.
PMO Team Feedback	
<ol style="list-style-type: none"> Supply chain feedback need to be interpreted, long sentences, no specific dates provided, and no priorities provided. Date aligned with country and SC has no traceability. Countries responses to SC questions are not harmonized and introduced complexity when data needs to be analyzed. Information for prioritization is needed. 	<ol style="list-style-type: none"> Information provided to the supply chain team can lead to misalignments if it is not harmonized or simplified. Information can be interpreted incorrectly by the countries if no specific dates are provided to them. Date of importation alignments are in risk if there is no clear identification of restricted countries for SC and if no prioritization is defined.

Figure 1: SC and PMO Team Feedback

Methodology

After understanding the challenges and issues that are being faced during the process and outcomes obtained it was decided to start gathering ideas using the Supply Chain Team and PMO team as clients. The process has always been improving, that is why we already know we will have to plan based on ideas, design what is needed, test the file to achieve the outcome desired, deploy for the clients, and finally review if it was successful.

- Plan:** This first step of the project was focused on understanding the requirements from the SC team and PMO team to define the timeline, strategy, goals, and resources.
- Design/Develop:** The MRS will be modified to include information, columns, formulas that will complement the information already in the file to reach the user requirements. In this step of the process, training forms were created to help guide the process to SC and the countries. Planning team and PMO defined the criteria and created the formulas.
- Test:** For the formulas that will be added by the planning team to the MRS, the PMO representative will be checking those formulas using tables with acceptance criteria predefined. PMO is responsible to verify for each iteration if the new columns are added to the MRS.
- Deploy:** Each iteration will be deployed to only one business unit, SC representative, one planning representative, and one PMO representative since the process is the same for all Business Units.
- Review/Results:** After each iteration, a goal must be met as defined in the Plan phase. PMO is responsible to review and document the results. Lastly, determine if the goals were achieved or not.

Results and Discussion

The solutions and ideas to mitigate the risks mentioned in Figure 1 are detailed below.

Plan:

The roadmap of the project is shown in Figure 4. The roadmap was created to define the iterations, their timeline, goals, and iteration description or features included in the MRS.



Figure 2: Project Roadmap

Design/Develop:

In this phase we documented the criteria for each new column to train SC. Also, a table with the Harmonized answers expected from the countries in the questions #1 and #3 in the MRS. All formulas were developed and shown in Table 1.

Table 1: Formulas Developed for New Columns

New Column	Formula
Importation Date	=IF([@Question #1] When the new version can be imported?)="Immediately after Changes Implementation",[@Expected technical documentation date],IF([@Question #1] When the new version can be imported?)="After Regulatory Action completion",[@Estimated Submission Due date],IF([@Question #1] When the new version can be imported?)="After HA approval",[@Estimated Health Authority Approval due date],"")
Importation date within SC proposed dates?	=IF([@Importation Date]<[@Importation date not before],"Before SC proposed dates",IF([@Importation Date]>=[@Importation date not after],"After SC proposed dates","Within SC proposed dates")
Priority	=IF([@Forecast]=0,"Yes","No")
PMO Quick Check	=IF([@Question #2] After Regulatory Action, can countries receive both versions?)"="No",IF([@Importation date within SC proposed dates?]="Before SC propose dates","Country to propose new dates",IF([@Importation date within SC proposed dates?]="After SC propose dates","Country to propose new dates","Change Green Light to YES"),IF([@Question #2] After Regulatory Action, can countries receive both versions?)"="Yes","No actions","")

Test

Testing of formulas was performed using defined acceptance criteria and known values to confirm if formula was correct or not. PMO representative reviewed all information input by countries or SC as established by iteration.

Deploy:

Each iteration was deployed as defined and columns and formulas added as described in the description in Figure 2.

Review/Results:

Columns and formulas were added and tested. All information was input correctly in the columns and formulas worked as intended. With the new information and formulas, PMO was able to assign Green Light Signal to countries and record the Signal Date.

PMO was able to identify that 42 strategy/country combination were at risk being a 4% of the total strategy/country combination, see Figure 3. From those 42 strategy/country combinations, 38 strategy/country combination have not started the submission process, see Figure 4. The remaining 4/strategy/country combinations, were escalated to raise the risk to be appropriately managed. From the 91 strategy/country combination, 54 strategy/country combination are submissions that can be completed as scheduled without any risks identified, see Figure 4.

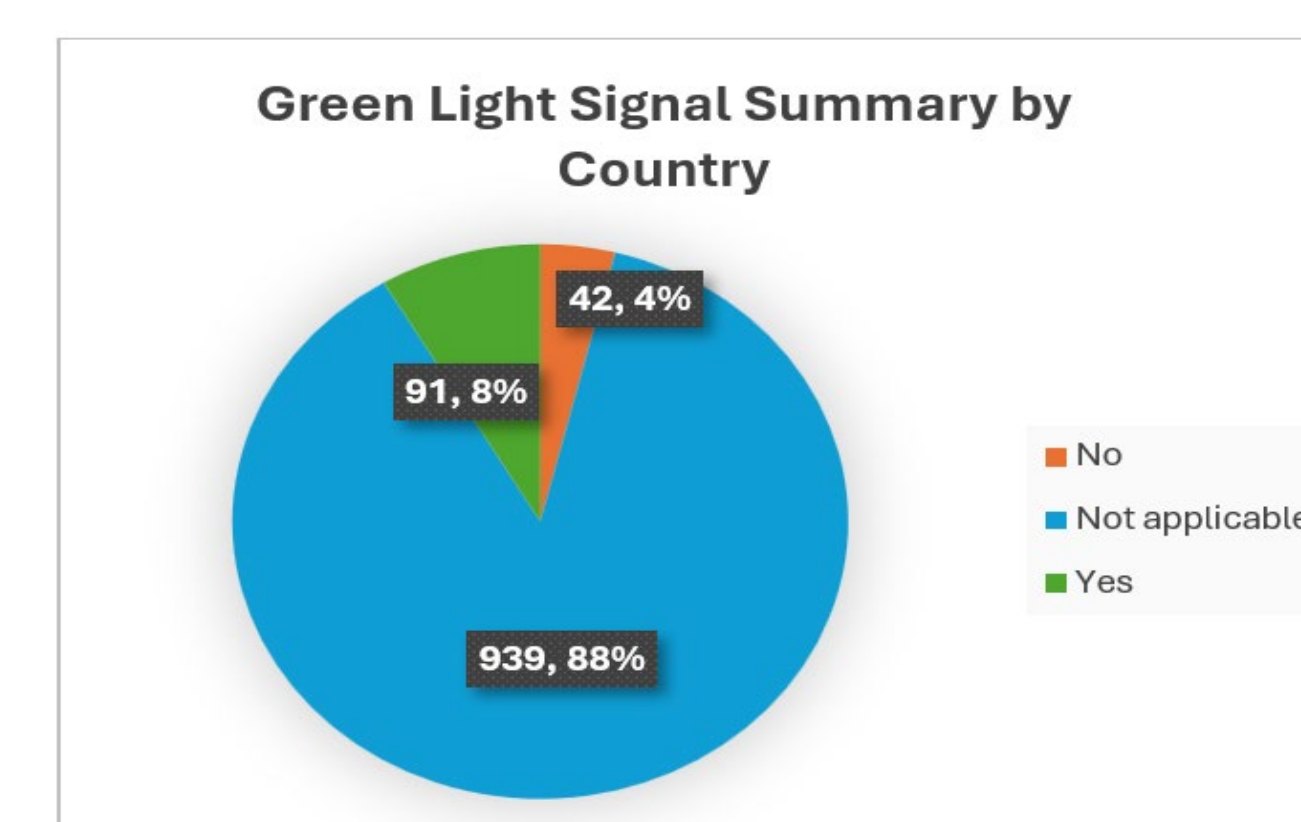


Figure 3: Green Light Summary by Country

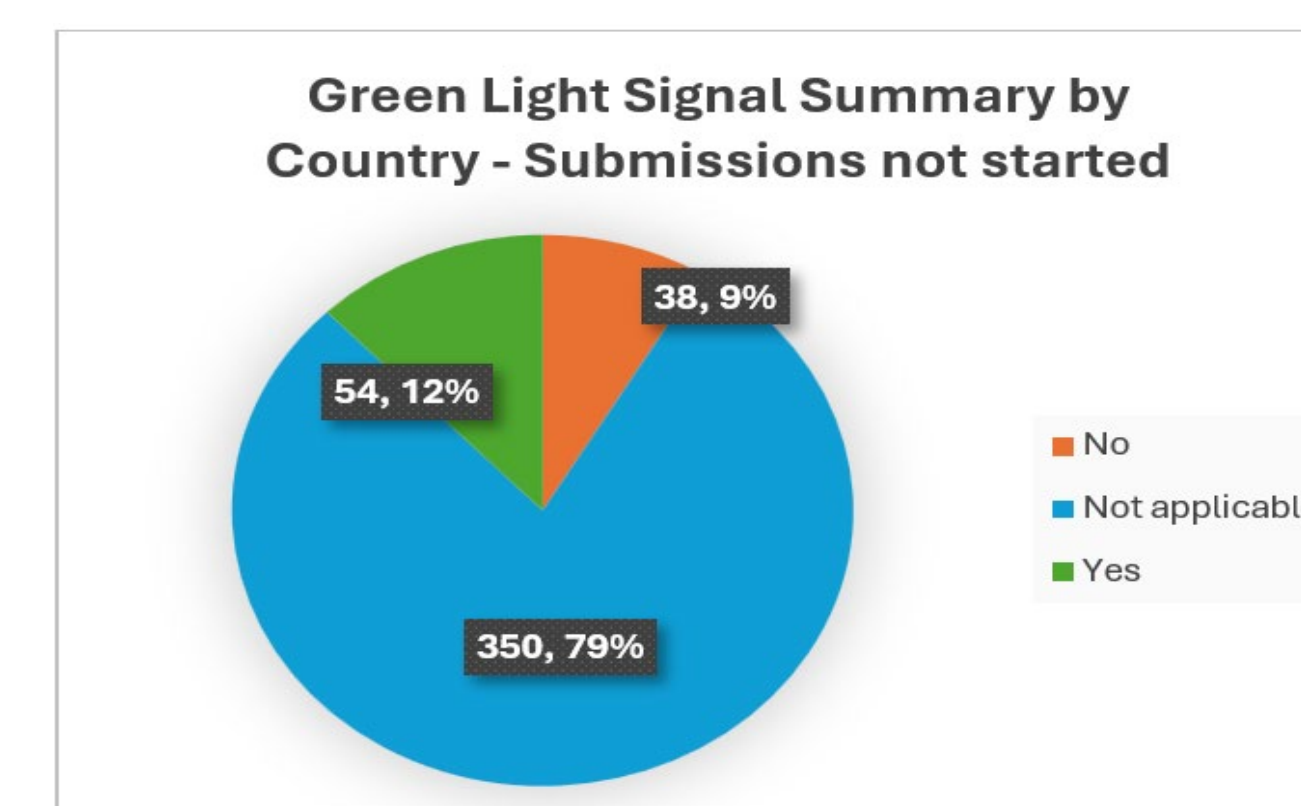


Figure 4: Green Light Summary by Country – Submissions Not Started

Conclusions

In summary, all goals established by iteration, as per Figure 2, were achieved. PMO was able to assign country Green Lights "Yes" and to identify which are "No" so the risks are clearly identified. The priorities were identified successfully with the forecast information, and countries can focus on reviewing and aligning by priorities.

The Green Light Signal Process Project Implementation it is beneficial to the Business to prevent risks of product supply continuity to countries. By reducing the product build ups and product gaps, helped the Business to substantially save costs. Not only was beneficial for the Business and SC but also for PMO team by reducing the filtering time and errors caused by wrong filters. The process demonstrated benefits and efficiency, and will be implemented to all Business Units.

Future Work

- Create a cycle of one month for this process to provide more time for inputs.
- To reduce workload, include forecast value (\$) to prioritize between Business Units and teams.
- Work towards the alignment of the 100% of submissions.
- Create forums for risk management with Global SC and Stakeholders to provide visibility of risks to receive the support.

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