



# Packaging Cold Chain Program Improvement

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## Abstract

With the growing trend of biologic medicines coming to the market, a packaging engineering group needed to create an internal cold chain process to meet market demand in this area of cold shipments; although there is a process in place from a compliance quality perspective, there wasn't one from the packing side. This resulted in different ways to execute projects, and in order to address this issue, the team met and defined roles and responsibilities, determined process steps using best practices and research found and, most importantly, established the requirements needed for each project moving forward.

## Introduction

In recent years there has been a shift in the pharma industry into more of a bio-pharmaceutical industry; the Packaging Engineering groups in each company are responsible for developing packaging solutions and making sure the product is packaged in a shipper box that keeps the correct temperature.

Cold chain is defined as the process of designing shipping containers that keep products at a specified temperature range during storage and shipment. This is not a new field of work, however in recent years it has seen a significant increase in importance, particularly as more and more biologic medicines reach the market. Currently, as this field develops, some bio-pharmaceutical companies don't have internal packaging group process in place for performing cold chain projects leading to differences in project execution. In route to address the gap, the quality group cold chain guide ensured compliance as the new process was developed and aligned which created a packaging process that allows the team to reach the project objective of reducing rework caused by missing requirements.

## Problem Statement

There is no standard packaging process in place for cold chain and this has allowed folks to execute cold chain projects in their own style showing a gap.

## Objective

Reduce rework caused by missing requirements.

## Methodology

- Define Packaging Eng. role
- Identify all requirements
- Establish a process
- Create rework metric
- Execute process
- Collect & analyze metric data
- Report out results

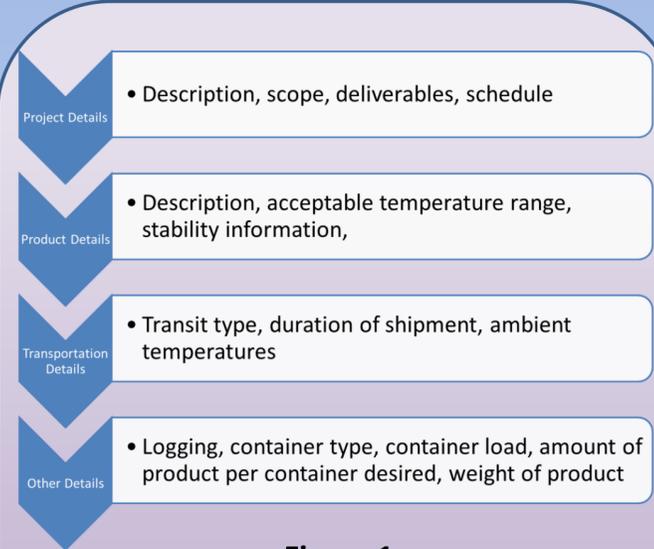
## Results

As part of the results of this project, the roles and responsibilities for each group were identified and are shown in Table 1.

**Table 1**  
Roles and Responsibilities

Item	Group Responsible
Passive Shippers – US	Packaging Group
Passive Shippers – Ex-US	Quality Supply Chain
Active Shippers – Global	Supply Chain & Distribution
Temperature Monitors - Global	Supply Chain & Distribution

Figure 1 shows the identified requirements needed for the project to be successful in the real world application and globally. The last section in Figure 1, Other Details, contains some information required internally for a better project experience and is not requirements found in research.



**Figure 1**  
Information Required for Cold Chain Projects

As for the structure for the cold chain projects and steps to follow for successful implementation, the process was established as per research found and incorporating some best practices while also taking into account suggested steps from internal team who have executed cold chain projects; the steps can be found in Table 2.

**Table 2**  
Process Steps

#	Description
1	Obtain project information as described in Table 1.
2	Establish project team and define roles per person
3	Agree on defined project description, scope, deliverables, and schedule
4	Produce draft design and verify if vendor pre-qualified shippers are a solution to the project
5	Team meeting to confirm design draft (return to "drawing board" if team not satisfied)
6	If using a vendor pre-qualified solution go to step 8, if not continue to step 7
7	Perform design verification as per company policy
8	Perform operational qualification per company policy
9	Perform performance qualification per company policy (if required)
10	Document all steps and provide report signed to Quality for approval
11	Implement packaging shipper solution

For sustainability, during step 4 of the process, engineers will consider eco-friendly solutions and reusable containers as opposed to one time use containers; engineers will also receive feedback from patients that will enable better future designs.

Taking into account all the results discussed, the team focused around one metric titled Rework Metric, which is measured by the amount of iterations performed in step 8. The target for the Rework metric is that the number of times step 8 is executed is only one time.

## Pilot Run

During the pilot run of a cold chain project for the purpose of this project, the team found the process to work very well and the definition of roles and responsibilities helped ensure each team member knew what their expected contributions were. There were 2 iterations of step 5 which increased value as all information brought forward was value adding and furthermore helped identify a missing requirement from the process that has now been incorporated which was "amount of product desired per container" as this was the missing link which triggered the second iteration of step 5. The team moved forward and executed steps 7 through 9 per company policy and only one iteration of step 8 was performed. The team is currently in step 10; documenting in our internal policy documents the design specifications.

## Conclusion

In conclusion, this project has been successful in completing its objective of reducing rework caused by missing requirements. The team successfully defined the roles and responsibilities, established the requirements of information needed for each project, produced a process, and created a metric to measure rework.