# Planning Lifecycle Management Activities During Design and Development

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## Abstract

Combination product development can be incredibly challenging. An effective and efficient development timeline is a delicate balance of concept development, clinical testing, verification and validation activities, and submission timelines. What is often overlooked in this balance is design maintenance post launch and learnings from life cycle management (LCM) experience.

The combination product design must adhere to design controls, which must be maintained through its life cycle. A typical combination product spends only a fraction of its total lifespan in development, with the majority of its life devoted LCM.

Considering, it's crucial to strategize LCM activities during the development phase to ensure successful development and management throughout the product's life cycle. However, the drive to meet accelerated timelines often poses a significant risk to consider LCM. As development schedules become increasingly demanding, teams may resort to time saving measures, leading to decisions that may be beneficial in the short term but unsustainable in the long run..

An effective and efficient development strategy should aim not only to prepare a product for regulatory submission but also to ensure its sustainability once it hits the market. Therefore, certain activities should be prioritized during the development phase to guarantee successful LCM.

## Problem Statement

As the medical device industry becomes increasingly competitive, there's a growing pressure to streamline product development activities and expedite market launch. To achieve this, development teams are evaluating which stages are crucial to ensure a successful product launch.

The DMAIC (Define, Measure, Analyze, Improve, Control) methodology serves as a guiding framework for teams when executing tasks and projects. By nature, engineers emphasize phases that yield high numbers of concrete deliverables, and overlook the power of the planning or Define phases.

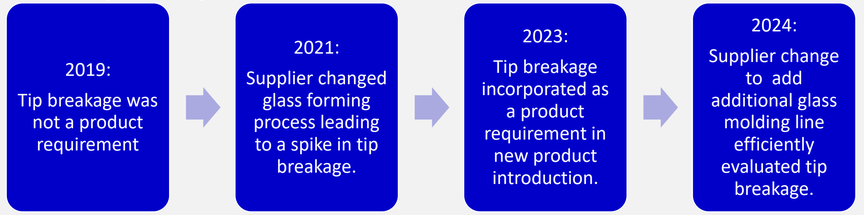
In the realm of product development, the Define phase involves identifying user needs and translating these needs into product requirements. If teams overlook the importance of the Define phase the translation of these needs into product requirements is also impacted. Consequently, impacting the quality of the verification and validation package.

To ensure the product's success as it transitions from the development phase to life cycle management, it is crucial to encourage teams to devote more time to the Define phase. This involves thoroughly identifying user needs and defining design input requirements. Learnings and feedback from LCM should also be utilized as inputs for this phase to ensure product quality is maintained. Prioritizing the Define stage can ensure a successful product launch and reduce the time required for LCM activities, ultimately ensuring a consistent quality supply to benefit patients.

## Case Studies

### Incorporating LCM feedback into the Define phase:

**In 2021, Pfizer experienced an increase in tip breakage complaints on the 10-piece packaging configuration for a pre-filled syringe product due to a change in the glass molding process at the syringe barrel supplier. The original product issue was remediated and learnings put toward new products. The users experienced the failure mode as the impact of the updated molding process on tip breakage was not evaluated since tip breakage was not included as a product requirement.**




**When the next new product was developed, the feedback from the LCM space was incorporated and tip breakage was included as a product requirement. When a supplier change to add an additional glass molding line was introduced, this requirement was evaluated and product quality maintained.**

### Define Phase Benefits:

**During the development of a new prefilled syringe combination product, the evaluation for finger flange breakage was defined as a variable test. To verify a requirement with a variable test, the data set must be normally distributed and meet the pre-determined acceptance criteria at a specific confidence and reliability level. During the initial phases of evaluating this requirement, it became clear that glass breakage does not follow a normal distribution. On further evaluation and consideration, the finger flange breakage test was redefined as an attribute test. As time was given to appropriate attribute characterization, the appropriate verification method was chosen.**


## Key Activities: Planning

### Define Clear User Needs

**Important Questions to ask:**

1. What must the product provide for the user to successfully utilize the product?
2. What about the user interface is crucial to the user's ability to utilize the product?
3. How can LCM feedback be incorporated?

### Define Clear Product Requirements

**Important Questions to ask:**

1. Which attributes/functions of the device are crucial to the user effectively using the product and having a positive experience with the product?
2. Which attributes and/or components are subject to design changes?
3. For components sourced from a supplier, clearly define requirements that reflect why these components were chosen. What made them stand out from a design or functional perspective?
4. How can LCM feedback be incorporated?

## Conclusions

As development timelines become shorter, teams can benefit greatly from spending more time in the define phase. Teams should focus on:

- Defining user needs
- Translating user needs into product requirements.
- Incorporation of LCM learnings

Effectively defining user needs and translating them into product requirements leads to robust design verification and design validation. When the product transfers from the development team to the LCM team, clear product requirements and a robust verification and validation allow LCM teams to easily evaluate design and supplier changes. Feedback from LCM teams should be incorporated from the Define phase, as this allows for maintenance of product quality.

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