CASE STUDIES

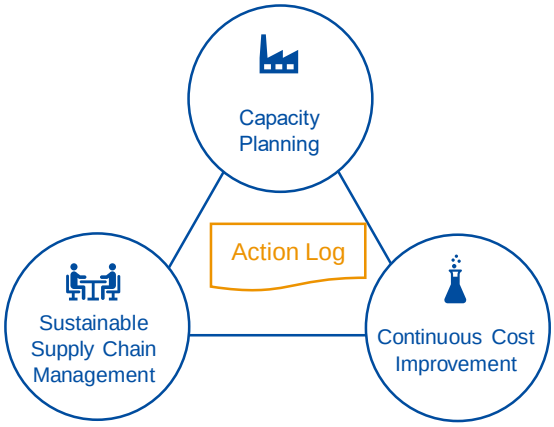
Continuous Improvement of Project Life Cycle Management, Benefiting Customers by Reducing Total Cost

Introduction

The project life cycle is the phases of a project that are necessary for the effective delivery of that project.

Porton's project life cycle management (LCM) involves establishing mid and long-term plans for key projects to ensure the timing and objectives of product supply chain optimization, capacity planning, and cost/process optimizations, meet the long-term requirements from customers and improve the revenue level of products over the life cycle.

Basically, it contains three aspects.



The Porton program manager will evaluate a project to initiate the LCM according to its phase. For early-phase projects, we will focus on the fast delivery, but for late-phase and commercial projects, continuous cost improvement is more important.

For Continuous Cost Improvement

We will evaluate optimizations from the following three aspects:

- For RM cost improvement, we will consider yield improvement, solvent recycling, key raw material process development, and in-house manufacture to reduce the RM costs.
- For conversion cost reduction, we will consider cycle time reduction, batch size enlargement and optimization of operations, such as adding bottleneck equipment, to reduce conversion costs.
- We will also evaluate the possibility of implementing new processes and technologies, such as flow chemistry and enzymatic processes, to reduce costs.

For Sustainable Supply Chain Management

The project manager and the project team will review the existing supply chain situation, conduct a gap analysis, and create a plan for supply chain security management. They will also develop and strengthen supply chain security management through external cooperation, procurement and project support. Normally, we would qualify at least two suppliers for key raw materials. For example, for the customized raw materials that are cost drivers, we will consider developing new suppliers or developing the process to manufacture in-house to ensure supply.

For Capacity Planning

When a product enters the late clinical stage and there is an expected increase in demand, we should understand the potential customer demand in advance and carry out reasonable capacity planning. This preparation is essential to support the increased demand or capacity needs after the product's launch, thereby avoiding supply issues due to limited capacity. Normally, we would plan to meet the entire year's demand within six months.

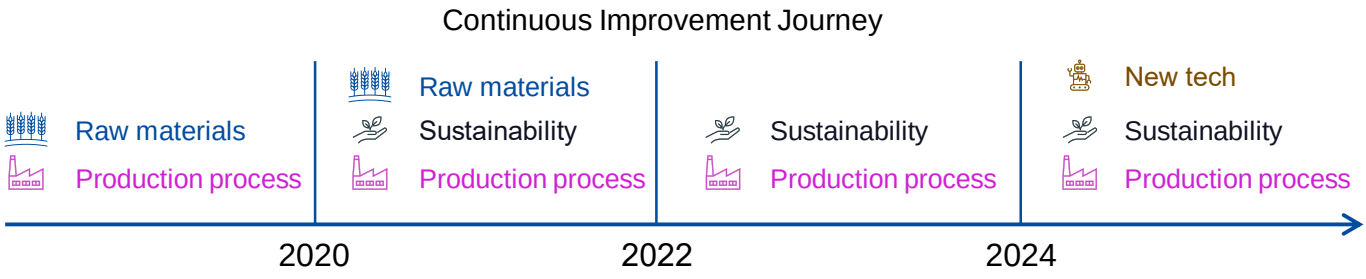
Case Sharing – Project A

Background

Project A, an androgen receptor inhibitor used to treat cancer, was approved by the FDA in February 2018. With the expanded product launch to Europe, Japan, China and other international markets, the market demand is increasing year by year.

Porton was involved in the supply chain of three RSMs. To maintain the competitiveness and ensure the supply position, the Porton team reviewed the long-term market forecast and initiated the LCM for Project A in 2019, focus on raw materials cost reduction, production process optimization, new process development, and improve sustainability.

We have made the detailed plan which involved different departments such as Procurement, Production, Technical, QA, and EHS, among others. Through team efforts, we have achieved a total cost reduction of 20%-50%, with part of the savings shared with our customer and be recognized by them.



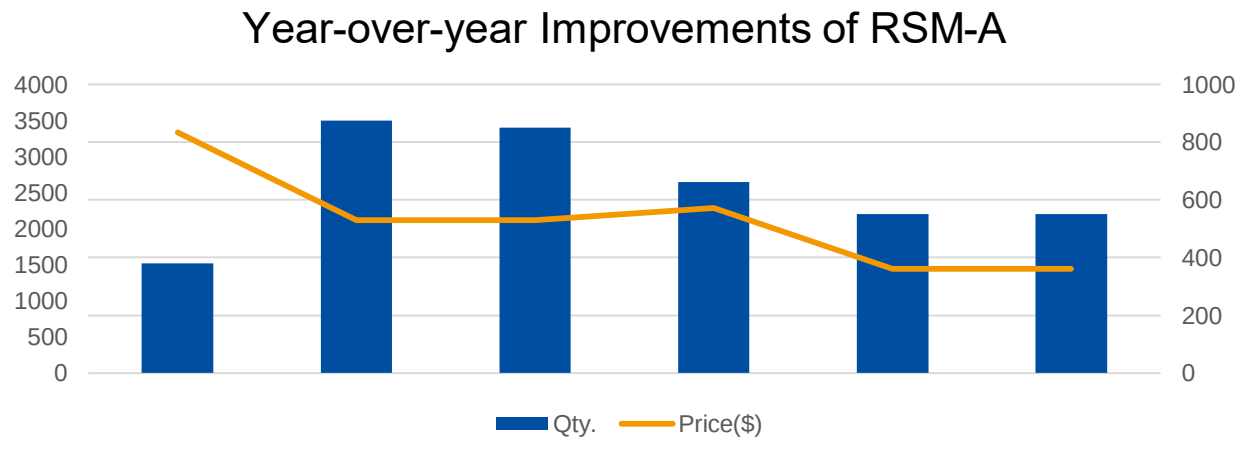
RSM-A

RSM-A is one of the RSMs; it's starting material is customized and has fewer suppliers, and a supply lead time of 2-3 months. After reviewing the original process (as required by the customer) with our technical team, we found another potential route, in which the raw materials are easier to obtain from the market, and the cost of goods is much lower.

Then we conducted a deep dive into the new process and initiated lab work to verify it. After obtaining positive results, we discussed with the customer to check the impact on the filling document and aligned on the scale-up and production verification plan.

After receiving change control approval from the customer, we conducted the scale-up campaign of the new process and obtained a product with comparable quality to the original process. The new process yield is 41% higher, and the starting material cost is 40% lower.

Now we are also evaluating the solvents recovery to reduce the PMI (Process mass intensity) and cost. Optimization will be endless.



From Original Process to New Process

Conclusions

This case demonstrates Poton's ability to implement LCM by establishing medium to long-term plans for projects. This approach effectively ensures that the delivery pace of products meets long-term customer requirements while helping them enhance their product profitability throughout the lifecycle. Poton is committed to delivering tangible benefits to clients through high-quality services.

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