

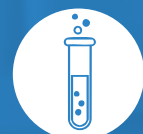
Enabling Product Transfer for Procurement Optimization

INDUSTRY:



Life Sciences

PRODUCTS AND SERVICES:



Ophthalmic consumables,
equipment, interocular
lenses, and surgical fluids

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

This client is a medical manufacturer and distributor of ophthalmic products. The company's principal products include ophthalmic consumables, equipment, interocular lenses, and surgical fluids.

The client was involved in the relocation of kit components from multiple suppliers to a single third-party supplier and was in the final elements of Phase 1 of the transfer. The client was facing ongoing challenges while closing out the project. Having worked with Clarkston on a previous project, they reached out to us again for project management support as they entered Phase 2 of the final product transfer to the new supplier.

Additional support was required to address remediation activities associated with findings from Phase 1. In moving products to new suppliers, the client had not been verifying the replacement product met the same form, fit, and function as the currently procured product, leading to customer dissatisfaction. Clarkston's role was to provide support to develop and oversee the activities to resolve these issues.

PRIMARY OBJECTIVES:

- Complete final transfer of 25 kit components to supplier
- Oversee eight kit components not accepted by customers from initial transfer in Phase 1
- Manage the supplier transfer of 24 finished products to support client's distribution network
- Develop a project transfer process for purchased "commodity" product, i.e., gauze, swabs, towels, eye pads
- Oversee the identification from Phase 1 of the inaccuracies to establish the root cause and short-term and long-term corrective actions to remediate the findings



SOLUTION:

- Provided project management oversight for the final 69 SKUs at two international manufacturing sites, ensuring continuity of implementation and addressing emerging issues
- Designed and executed the strategic approach for remaining project phases, establishing a detailed project plan, communication routines, workstreams, and interdependencies
- Ensured successful material stabilization and reduction at previous suppliers and supported development of First Article Inspection (FAI) and dock-to-stock plans
- Oversaw CAPA and gap closure plans stemming from initial product transfers, mitigating risks and ensuring compliance
- Facilitated lessons learned session, capturing key insights and challenges to guide future project phases
- Delivered Phase 2 project management under the original SOW, identifying improvement areas and coaching the client's internal team for ongoing success

KEY BENEFITS:

- Stabilized inventory and safety stocks for Phase 1 products, with a defined phase-out plan to mitigate excess and obsolescence (E&O) risk from the previous supplier
- Closely controlled Phase 2 components and finished goods, minimizing shortages and E&O while ensuring readiness of Artwork, Labels, Tech Data Sheets, and compliance with EU Article 120 Significant Equivalency requirements
- Implemented robust monitoring processes for purchase specifications, inspection methods, and manufacturing integration dates to reduce customer stockouts and support regulatory alignment
- Established a documented cross-functional procurement process for “equivalent” products, clearly defining roles across engineering, quality, regulatory, procurement, finance, and IT
- Delivered a documented “lessons learned” summary and CAPA cost analysis to inform future project prioritization and marketing decision-making
- Clarified internal responsibilities for customer communication during product changes, enhancing transparency and compliance with change control requirements



KPIs

- Project was stabilized with 100% of product transitioned to supplier under a controlled manner
- SKUs begun and/or in production with supplier in an approved and controlled manner
- Project successfully transitioned back to client for close-out