

CASE STUDY

Program & Project Management: Technical Transfers



Challenge

- ProPharma was engaged in the Project and Program Management of multiple Tech Transfers (TT), i.e.: API supplier changes, Bulk production site changes, and Packaging site changes
- Scope: More than 40 individual projects with multiple dosage forms/ strengths
- Involvement at an early stage in the TT, creating challenges and chances for setting up the right organizational structure for the multidisciplinary Teams, incl. documentation
- Creation of Transfer Master Plans and Risk Assessments; clear planning overviews, action trackers, flow charts, etc.
- Time pressure on phasing out drug products from Originator (Sending Unit (SU)) to CMO (Receiving Unit (RU)) within agreed timelines with our Customer, maintaining a strong Supply Chain position
- "Like for like" transfers to enable a smooth Regulatory process within acceptable timelines; matching equipment trains between SUs and RUs

Solution

- Created a PM structure to oversee and execute the project involving all stakeholders: the client, SU/RU staffing, and ProPharma personnel
- Brought more focus to the initiation or preparation phase, setting up Transfer Master Plans and Risk Assessments involving the CMO
- Created clarity on Roles and Responsibilities (RACI model)
- Staffed this with Technical PM directly noticing Technical gaps and thus being able to quickly fill these
- Staffed this with experienced people in PM, QA, and Reg. Affairs
- Strict in following the plan but flexible in executing the activities, meaning that erratic workload can be absorbed properly; one TT Team can handle multiple projects

Results

- Having a clear and transparent overview for all contributors to the programs and projects
- Avoidance missing out on key activities and create the right and detailed order of needed deliverables
- Reduced lead times on activities; increased clarity and commitment
- Positive impact on timelines, doing things the first time right and delivering to promise; multiple complex projects closed within reasonable timelines
- Quick mutual and individual understanding of tasks; higher success rate in closing/completing projects
- Efficiency, meaning work can be divided evenly, and teams dedicated to the projects, programs, and organizational structure set-up for this client can be maintained

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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