



Facility Start-up & Tech Transfer Program Management

CASE STUDY



Welcome to KPC International

EXCELLENCE FROM CONCEPT TO COMPLETION

KPC International is a key supplier of specialist technical services and solutions to the Pharmaceutical and Bio-pharmaceutical industries. Since 2001, our team has worked on some of the largest projects throughout Ireland, Europe, the US and Asia, helping our clients to deliver their life changing products to patients.

At KPC International, our mission is to facilitate our clients in achieving their project goals through innovative solutions that focus on delivering exceptional technical expertise and on building strong relationships between project teams and stakeholders. To date, our expert team has an excellent track record in achieving Schedule Certainty while reducing costs and increasing efficiency for our clients.

Our Tech Transfer Program Management and Operational Readiness expertise are among the most in-demand services here at KPC. Our team are highly experienced in Tech Transfer Program Management, Quality and Compliance and other specialist technical areas which ensure an integrated approach and a holistic view across the program of deliverables required to start-up a facility, bring a new product on line, or make it operationally ready.

Case Study

API MANUFACTURING FACILITY, CARRIBBEAN



In 2017, KPC International was contracted by a multinational client to provide holistic services for the start-up of a new large API facility. The existing manufacturing plant had significant challenges and a project had been started to build a new bulk API manufacturing facility. Among the range of services provided were our Tech Transfer Program Management and Operational Readiness expertise.

The specific services provided by our Tech Transfer and Operational Readiness team on this project are as follows:

- Site Evaluation for an existing and new facility with respect to all functional areas
- Gap Assessment and Risk Mitigation Plan
- Delivery of Strategic Start-up Plan for new facility
- Development and implementation of Site Capital and Tech Transfer Program Management Process
- Guidance and support for Tech Transfer Program Master Planning
- Provision of resources in the following disciplines
 - Automation
 - QA
 - Documentation
 - Tech Transfer Specialists
 - Engineers
- Leading meetings, Risk Management Progress Reporting
- Provision of mentoring and guidance with respect to technical requirements

At KPC, we are used to working with people from different cultures, different levels of expertise and different organizations. We understand the pride that clients take in their project or site and the unease outsiders can bring. That is why on all KPC projects we invest heavily in building strong relationships with our clients and stakeholders from the very beginning. First, we listen. We take time to understand the people and what has worked well for them. We then share our experiences openly; we offer advice and guidance with an open mind and then we build and implement the solutions needed to achieve success. This is the KPC proven approach of: **Discover, Define, Develop & Deliver.**

In this project, the Site Evaluation and Strategic Start-up Plan identified the key areas of risk and their mitigations. The implementation of a solid Project Management philosophy for both Capital and Tech Transfer Projects gave the Engineers and Scientists a framework and process to enable effective planning, execution, monitoring and communication for these projects. A Project Management manual was delivered, and staff were trained and mentored. As a result of the above services, KPC enabled the development of a cohesive and integrated project team, developed clear and efficient team structures and stimulated relationship growth between Sending and Receiving units. The success was the ability of the team to deliver PPQ batches, having dealt with significant engineering and scope changes as a result of environmental impacts

Case Study

MULTINATIONAL BIOTECH
CLIENT

In 2015, KPC International was contracted by a large multinational client for the provision of Tech Transfer expertise and Tech Transfer Portfolio Management. Under this project, the specific services provided by the KPC International team included:

- Development of a standardized approach to monitoring / controlling and de-risking Tech Transfer Programs for the global client organisation
- Guidance, mentoring and support for project colleagues, external project stakeholders (CMO) and management.
- Establishment of a Tech Transfer Project Portfolio and Reporting structures
- Support and mentoring on specific technical elements: Gap Analysis, Quality Risk Management, Validation, Raw Material & Supplier Qualification, Tech Transfer Strategy and Regulatory Filling Strategy

As a result of the above services, a significant Tech Transfer project was recovered and delivered, several international Tech Transfer projects were planned and implemented and the team of Tech Transfer specialists were better equipped to support further projects.

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Case Study

MULTINATIONAL BIOTECH CLIENT

In 2019, KPC International was contracted by a multinational biotech client to provide Tech Transfer and Program Management expertise to their global technical operations organisation. In the provision of these services, our KPC consultant has and continues to work with the client's project teams to ensure a holistic, integrated and standardized approach to Tech Transfer Program Management.

Some of the specific Tech Transfer activities undertaken on this project are as follows:

- Optimization and standardization of the Tech Transfer Program Management Process for Clinical Phase I, II and III and commercial biological drug substances and drug products
- Provision of guidance on de-risking Tech Transfer Programs
- Provision of comprehensive training to Technical Operations, Technical Services, Quality, Analytical and Process Development staff as well as mentoring of Tech Transfer Leaders

This is an ongoing project where KPC's key achievements to date include:

- The delivery of training to and mentoring to Leaders in the execution of multiple drug substance and drug product transfers in a global organization
- Multiple project kick-offs using a standardized approach with a strong focus on leadership and fostering a unified team approach from the project outset

Case Study

LARGE-SCALE BIOTECH DRUG SUBSTANCE FACILITY

In 2017 KPC International was contracted by a multinational client to provide holistic services for the start-up of a new large API facility. This project was approaching completion of detailed design, and construction was well underway. Detailed planning was required for the facility start-up.

On this project, the KPC International team provided assessment and developed a Start-up Strategy utilizing a best-practice and risk-based approach. KPC also delivered a Schedule and Execution Plan to support successful delivery of a PPQ campaign. The unique approach taken by KPC on this project was a proven 4-step process of:

- **Discover**
- **Define**
- **Develop**
- **Deliver**

This unique approach resulted in a successful project outcome and led to the following client feedback:

"On behalf of the Leadership Team, I just want to thank you both for your excellent work, engagement, drive, cooperation and delivery of the Start-Up Strategy and Schedule. The level of resilience, enthusiasm & professionalism to continue to engage with all of our functional leads and departments in a very proactive and supportive way was great to experience and you leave us with a Strategy & Execution Plan that we not only own but feel responsible for. This has been a very successful collaboration."



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WHY WORK WITH KPC INTERNATIONAL?

The KPC International team brings an unrivaled breadth and depth of knowledge to plant facility start-up projects and is highly experienced in the areas of Tech Transfer & Operational Readiness. Our focus on integrating with client project teams to facilitate knowledge sharing and communication ensures a unified team approach in meeting project goals and sets them up for sustainable success.

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