ICE Pharma Group (IPG) is a generic pharmaceutical company with its own Marketing Authorisations (MAs) and experienced operational teams who can manage manufacturing through to final product release into European markets, as well as supply chain logistics all over the globe.

CASE STUDY

Summary

In total Company A ended up with 120 MAs at the end of IPGs tenure (and supply chain operations from 5 factories in the Far East) released into Europe through to hospitals. We were at the helm from the first 11 Mas through to the final 120. IPG implemented many SOPS, procedures, polices and supplier approval systems. As the client grew, the IPG role grew, providing services which included artwork, sales, order processing, administration, supply chain and logistics, regulatory management, PV management, dossier management and storage, QP release to market, quality management, GMP auditing, commercial and integrated project management, managing outsourcing providers and the role of interim Chief Operating Officer.

The challenges of rapid growth shouldn't be underestimated, especially when budgets are constrained by equity holders, and the tight profit margins and changing regulatory landscape of the generic industry are considered.

Overview

Companies often come to us seeking one service and over time, our business relationship expands as their requirements grow or develop. Typically, our services are provided as an extension of one business function, and thus a client enters the IPG world through a focused need. Others come to us seeking outsourcing solutions or turn key solutions across multiple business functions, building value prior to disposal.

Company A was a one year old start up with private equity funding. Their business model was bringing generic injectable products from vertically integrated facilities in the Far East through to the UK market and then spreading across Europe and the USA. They developed several manufacturing partnerships that met their objectives and needed licenses that could have their manufacturing freely moved to these partners without any restrictions. In mid-2012 they came to IPG seeking certain hospital anti-infective licenses without a supply commitment. These needed to be UK licenses by preference. They were needed to trigger approval of a new factory in the Far East and then they wanted commercial supply. The objective of no supply commitment was not the norm in the industry. After 3 months IPG offered a series of options for four products. One option was chosen where IPG progressed through to contract closure with the client managing the deal closure. After IPG conducted dossier due diligence and gap analysis, by the close of 2012 the contract to buy these four licenses was concluded. The contracted task for IPG was completed.

ICE PHARMA GROUP HAS BEEN A PREFERRED SERVICE PARTNER SINCE 1999

Having successfully acquired the license Company A explored what other services and expertise they could tap into to get the products to market.

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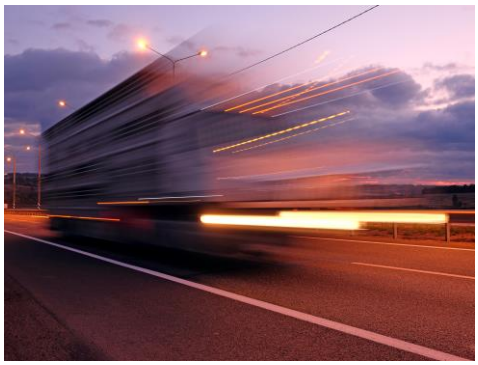

Key Learning

The key learning experiences have served to strengthen the IPG service offerings as well as broaden its scope. The challenges of rapid growth are not to be underestimated especially when budget constrained by equity holders and the tight profit margins of the generics industry and the changing landscape of the regulators. The ability to understand the client's growth objectives earlier would have meant a more strategic approach to resources development and enable more effective project management. However, it is recognised that as a service provider it is not always appropriate to be party to detailed business plans.

Contact Us

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Phased in over the following 3 to 6 months, ICE Pharma Group became responsible for managing the entire Technical and Supply Chain Operations.

This covered regulatory, technical transfer, supply chain and logistics from the Far East through to the end customers along with order and invoice processing. By 2013 one the IPG directors became an integral part of the Company A team as interim chief operating officer through to 2017. With the 4 products (and their 11 licenses for each strength) transferred in to Company A's name, IPG were next charged to manage the technical transfer to two factories including changing site, active ingredients and primary packaging, regulatory management, appointing pharmacovigilance providers as well as establishing supply chain and logistics through to UK hospitals, then through into some key EU countries.

The first technical transfer was achieved in 10 months and first supply commenced in autumn 2013. IPG used its own quality management system and imported the products under its MIA and distributed under its WDA including release of the product. Auditing under EU GMP was managed and undertaken by IPG.

In 2013 another 3 products were sourced and bought. These covered licenses in 11 countries across Europe. IPG were charged with absorbing this into the operations it was managing. New factories were again involved and GMP approval gained. Resources were increased to manage the growth; certain staff were employed by Company A but reported to IPG heads of function. EU infrastructure was developed to support the supply base in France, Holland and Germany.

In 2014 the original 4 products were successfully processed through the MRP procedure into the 11 EU markets and supply commenced. This meant further resources across the technical operations group.

Why Outsource?

Generic Pharma companies are aware of the need to be flexible, forward-thinking and have access to new skill sets. As such, there are many benefits to using outsourcing solutions for a range of operations.