

CLIENT STORY

Building a
Service Solution



We worked with a company that 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 expanding across Europe and the USA.

We came looking for licenses and left with far more than we expected..."

Client

Summary

This is an example of how a client came to IPG requiring four product licenses and progressively entrusted all it's operational functions to IPG. IPG managed the entire supply chain, logistics and end market distribution; Compliance, regulatory affairs as well as the entire quality management including all QP and RP responsibilities. Packaging design, artwork and print control were also included.

By the start of year two an IPG member acted as chief operating officer.

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A company with private equity funding came to IPG seeking specific anti-infective licenses for hospitals, wanting to use factories yet to be GMP approved.

The licenses needed to be given the investor base. After IPG conducted dossier due diligence and gap analysis, the contract to buy four licenses was concluded.

We thought the task was complete however over the next 12 months IPG went from sourcing the licenses to becoming responsible for running and managing the whole Technical and Supply Operations and creating a dedicated team of people. The following year one of the IPG directors became interim chief operating officer for the next five years.



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With the 4 product licences transferred into the name of the client company, IPG were next asked to manage the technical transfer to factories in the Far East (Three of them).

The technical transfers took place all in parallel. The manufacturing sites were all in the Far East and so were the two new API sites. We also changed vial and stopper suppliers too.

The first new supplier was on stream in 10 months, including regulatory approval, and on winning tenders the product was in hospitals on time. The next two sites progressively came on line during the next twelve months.

IPG established parallel workstreams using experienced staff members as well as contractors. We managed and led cross-functional teams across time zones to take four licenses in one country into eleven member states, expanding to ten products in the same time frame.

The well established team were operating at peak performance and all systems were running well until...



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The client, flushed with success, bought a DCP covering licences in 11 European countries.

New factories were again engaged, resources were increased to manage the growth and an EU infrastructure was developed to support the supply base in France, Holland and Germany and Scandanavia.

Meanwhile, the client company had formed a joint venture in the oncology hospital sector. The other partner was in the design and build phase of a new factory in the Far East. They needed new product licenses to gain EU approval for the new factory. IPG sourced, negotiated and closed for the client. Three entire DCPs were purchased covering 10 countries in Europe complementing those in the anti-infective space. Rights for two product DCPs that were still under patent and a few localised licenses were acquired to complete the desired portfolio. Having appointed key people to work in and with the new factory, EU GMP approval was secured in two years later with supply to Europe for the lead product the same year approval was granted.

IPG introduced many procedures, policies, and supplier approval systems during the five-year project relinquishing its role at the end of the five year project plan.

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