

CLIENT STORY

Building a
Service Solution

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CEO

Summary

IPG was approached to source and acquire an MA in the UK or EU for a very old product. The client had a venture with an API producer who had built a new tablet facility seeking EU GMP approval.

IPG manage to acquire the MA The dossier was old and not suitable for fresh application and MRP. IPG undertook a full dossier update and managed validation batches in the new facility using the new API.

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The EP required multiple method changes including a new QC lab appointing and auditing of all new parties. Due diligence had revealed some past quality issues and product recalls.

IPG prepared fresh new designs, completed artwork guidelines and obtained regulatory approval.

The quantity projections were excessively big, so it was agreed with the client that we would use two suppliers for API and Tablets, one in Europe for rapid response, and the other in the Far East for high volume. We also needed supply chain security.

IPG were twelve months or more into the project when the scope changed. The client agreed a distribution deal with a company. This placed pressure on the supply chain because not all variations had been approved, especially the tablet facility which needed GMP regulator inspection and the site in the dossier no longer existed.

It transpired that the distributor company's Far East owner had bought the API supplier (including tablet unit). IPG were told that the MA had been part of the deal and so our services were no longer needed...

Three years later the MA was sold again and IPG was tasked to complete it's project.



IPG tend to treat all our client's products as if they are our own and so for us it is sometimes hard to understand fully when clients change their plans, especially if we would not advise them to. As a service provider it is sometimes tough when all the work undertaken for a client seems wasted, but we try not to become too frustrated, after all the client is in control of their business not us.