



SUCCESS STORIES



API intermediate: Successfully delivering 600 kgs of a custom synthesized intermediate for a critical API employing a new RoS

BACKGROUND

Based on a recommendation, ExSyn was approached by a new customer, a large multinational pharmaceutical company in the EU. Their purchasing team was facing a highly challenging situation: they were working on a critical project which required a complex API intermediate and one of their approved suppliers dropped out of the project. This resulted in production coming to a halt.

THE CHALLENGE

1. Given the situation, we had a narrow time window for the source development with a commitment to deliver 600 Kgs within 30 days
2. The customer required full regulatory support as the end product was an API

THE APPROACH

ExSyn reached out to a key partner who had handled a similar chemistry for a previous project. They confirmed their ability to synthesize the requested compound and submitted the RoS.

THE SOLUTION

- Y RoS was shared with the customer, who was unaware of this route and surprised it was even an option
- Y Since the customer was concerned about the impurity profile, they requested a pre-shipment sample
- Y The customer also requested the development of an HPLC method for the intermediate (so far they had been testing purity by GC)
- Y ExSyn's regulatory team carved out an HPLC test method together with our manufacturing partner to better monitor the purity profile

FURTHER RESULTS

ExSyn firstly delivered the pre-shipment sample, which was approved, and the complete order was successfully delivered on schedule. The customer was highly satisfied with ExSyn's performance and decided to order additional 200 kgs as they were likely to fall short.



WHAT OUR CLIENT SAID...

"Thanks again for your support on the product. Despite my concerns about the isomers, the raw material supplied is in use and everything seems to be OK. There are only 2 sources which supplied in full and in-time - and you are one of them. For a development - with different RoS to competition - an impressive performance"

