



**PIRAMAL-PHARM  
A END-TO-END  
PARTNERSHIP**

## CHALLENGES



A big pharma customer was seeking opportunities to identify and implement cost optimization of a multi-ton API manufacture. Continuous Cost Reduction was the key to improve their competitiveness and profitability.

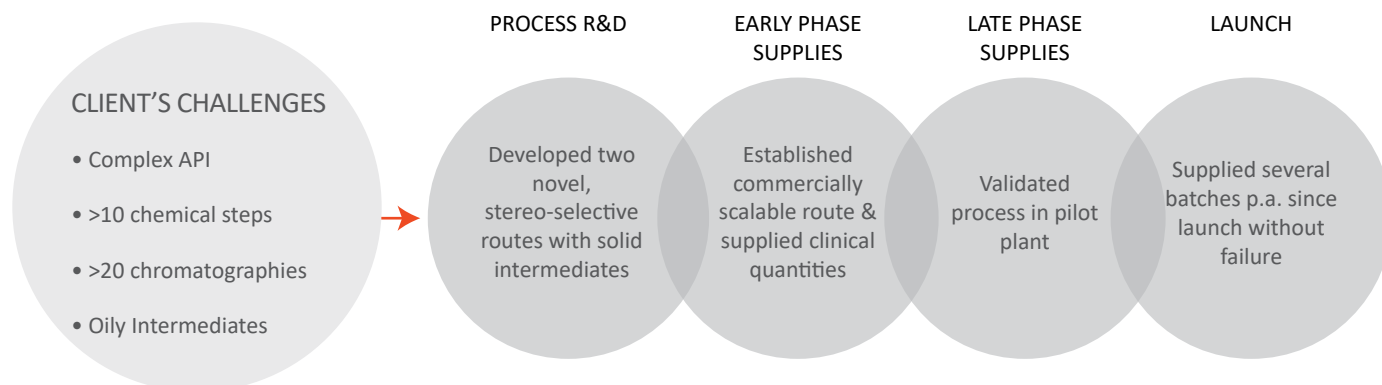
## HOW PIRAMAL HELPED?

- Resolved the challenges by
  - ◆ Complete elimination of chromatography (original route required >20 chromatographies to generate 20 g lab sample)
  - ◆ Conversion of a non-selective chemistry based route into two novel, stereo-selective routes
  - ◆ Conversion of oily intermediates into solid intermediates
- After developing a commercially scalable route and supplying GMP clinical quantities (@ ca. 0.5 kg scale), the route was further validated on economics, robustness & quality
- In the late phase the process was validated (@ 3 kg scale) in pilot plant, post which several batches were supplied every year with consistent quality

## KEY OUTCOMES

- Reduced the number of isolation steps from 11 to 4
- Developed a robust route with significant cost benefits & security in supply
- The product was filed in US & Worldwide

## DRIVING PRODUCT FROM EARLY STAGE THROUGH LAUNCH



Successfully executed client program from early stage chemistry through launch

### KEY OUTCOMES



Complete elimination of chromatography



Streamlined process to four isolation steps



Filed in US & Worldwide



Robust route; significant cost benefits & security in supply



Piramal Pharma Solutions is a contract development and manufacturing organization (CDMO), offering end-to-end development and manufacturing solutions across the drug life cycle. We serve our clients through a globally integrated network of facilities in North America, Europe and Asia. This enables us to offer a comprehensive range of services including Drug Discovery Solutions, Process & Pharmaceutical Development services, Clinical Trial Supplies and Commercial supply of APIs and Finished dosage forms. We also offer specialized services like development and manufacture of Highly Potent APIs, Antibody Drug Conjugation and are well versed in technologies such as Bio-catalysis, Route Scouting etc. Our capability as an integrated service provider & experience with various technologies enables us to serve Innovator and Generic companies worldwide.



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