



Johnson Matthey Pharma Services

CASE STUDY

Production of a commercially approved API

Summary

Process validation and commercial production of a complex multi-step potent API with Big Pharma client.

Approach

- Developed process scaling fold and improved overall yield from 10 fold (24 steps).
- Developed crystalline advanced intermediate for improved purification.
- Completed process and analytical validation activities including filing of DMFs globally.
- Managed the sourcing of regulatory starting materials from overseas partners to reduce long term API costs.

Results

Customer has filed DMFs globally and is supplying product commercially. API costs were reduced from \$416/g to \$69/g through yield, cycle time and scale improvements allowing customer to be competitive with other products in the market place.