

Providing phase-appropriate but scale-ready solutions for tapping global markets

Client - A global pharmaceutical company based in a G7 country and focused on developing and commercializing small molecule & biological therapeutics primarily in Cardiology, Oncology, Pain segments. Associated with Laurus for the past 10 years

Program

- RSM & Intermediate of a Calcium Channel modulator drug which has been approved in one major G7 country (*the intermediate is built on the RSM)

Challenge

- The compound was in PIIb-PIII across multiple years in multiple geographies. Given the complexity of the chemistry & the different regulatory expectations, the purity/impurity profile of the RSM & Intermediate were continually evolving (~more stringent)
- The Intermediate synthesis involved a chiral resolution agent is classified as a substance of abuse in many countries & highly regulated and hence the supply assurance was limited
- Given the multiple clinical trials (one still underway), it meant the demand can be sudden & hence need for production quick ramp-up at a short notice is likely

Solution

- Laurus worked on the chemistry and established process controls that enabled consistent supply of RSM the quality & impurity profile of which was almost akin to an API
- Given the high quality development & delivery of the SM, client chose Laurus to manufacture the intermediate. In order to overcome the risk of supply for chiral resolution agent, Laurus developed a process & back integrated the manufacture in its own facilities
- While production of the Intermediate is managed in a multi-product block, multiple upgrades were made including installation of a HMI for the high vacuum distillation apparatus

Outcome

- The client launched the product successfully & Laurus has been supporting the commercial supplies seamlessly
- Given the scale-capability of Laurus for the intermediate, client could comfortably take a decision to target the Chinese market & completed the PIII there very recently
- Client earmarked Laurus as a potential CDMO for some other key programs in their pipeline
- 8000KG OF RSM & 12000KG OF INTERMEDIATE DELIVERED AS ON DATE.