

Super-accelerated scale-up & commercialization of complex processes

Client - US based big-pharma company with a unique track-record of rapidly designing, developing & launching biopharmaceutical & small-molecule interventions with high focus on safety, quality & access. Associated with Laurus on multiple smaller projects across past 15 years before this mega program

Program

- Two of the three key building blocks (RSMs) of a peptide-mimetic small molecule NCE with an accelerated pathway to development & launch.

Challenge

- The RSM1 which is a 3-azabicyclocompound involved enzyme catalysed reaction that has not been studied at the scale required & with multiple complications with respect sourcing the Starting material, the enzyme & one other critical reagent
- The RSM2 synthesis was complex involving LiHMDS mediated nitrile introduction at cryogenic conditions & also hydrogenation at scale
- Scaling-up and delivering multi-tonne quantities within 3-4 months

Solution

- Laurus created a dedicated group of R&D scientists for executing the project with minimal lag
- Laurus de-risked RSM1 SM supply by back-integrating the manufacture in-house & the RSM process was scaled-up from 180kg 500kg. Towards RSM2, Laurus installed high volume hydrogenator to support large-scale production
- Despite time-pressure, Laurus evaluated the nitrosamine risk & ensured there are no unknown knowns in the commercial material
- Laurus installed & dedicated capacities to support >20MT of each of the RSMs in <4months from project initiation

Outcome

- The scale-up was successfully concluded for both the RSMs within 3-4 months and commenced commercial-scale supplies
- Client significantly increased the purchase volume from Laurus from earlier projected numbers.
- 3500KG DELIVERED TILL DATE WITH ANOTHER 20000KG SCHEDULED IN CURENT FISCAL