Collaborating across continents to let drugs for unmet-needs reach market faster

Client - US based publicly listed biopharmaceutical company focused on developing treatments in the under-met space of blood disorders. Associated with Laurus for the past 6 years.

Program

- Antineoplastic and immunomodulating agent that rode on a fast-track designation & got monotherapy approvals from FDA for two different indications within 2020

Challenge

- As a supplier of an Intermediate & an RSM Laurus required to align with the UK based API manufacturer both with respect to timelines & quality needs as determined by the down-stream needs
- The quickly evolving clinical & later commercial demand owing to the drug candidates fast-track status meant being the material demands can shift between zero to multi-hundred kilos within 2-3 months
- Providing a commercial-scale readiness despite the uncertainty of a clinical evaluation

Solution

- For both moieties, Laurus developed multiple sources for the critical SMs & RMs so as to eliminate this as a bottleneck
- While the intermediate was validated at a lower-scale in one of its manufacturing sites, post commercialization, Laurus transferred and validated a much larger batch-size in another site where capacities could be dedicated, thereby seamlessly supporting the launch and initial commercialization material demands
- Assured seamless supply by way of maintaining a safety stock of both the RSM & Intermediate

Outcome

- The client successfully launched his drug in the market very quickly after the approval and managed to maintain supplies for both the indications without any hassle.
- Given the support provided by Laurus (& the API manufacture), the client is evaluating this drug in 5 clinical trials mostly as combination therapy
- Client earmarked Laurus as a potential API site when the volumes justify
- A TOTAL OF 6000KG (RSM+INT) DELIVERED AS ON DATE