De-risking large-scale supplies by back-integrating manufacture of starting material

Client - UK based Biotech developing oncology drugs using a proprietary delivery platform. 10+ years of association with Laurus for clinical API development & supply across 3 clinical candidates in Phase III, IIb and I respectively

Program

- Built on an approved oncology drug (drug-2), this candidate was designed to enhance to improve cellular concentration of active metabolite at high doses & still minimize the side-effects & long-term drug resistance
- Two indications in clinical phase II

Challenge

- The active component of this drug (drug-2) being very old drug, there were no reliable vendors for clinical &/or commercial-scale GMP supply with requisite CMC support capability
- The detection of an unknown impurity at levels above 0.03

Solution

- Laurus developed a chemical process for the active moiety (drug-2) , scale-up & validated the same. This was done without any additional expense to client & in the spirit of insourcing critical SMs, where possible
- The unknown impurity was identified, root-cause defined & controlled at scale
- In view of the 3 programs client docked with Laurus, a containment suite was dedicated and clinical—2-commercial scale equipment was installed

Outcome

- The client could take a pivot & initiate another phase-I using enantiopure API which then showed highly improved safety & bioavailability
- The program could be seamlessly advanced to PII & PIII owing to early optimization of the pure diastereoisomer chemical process
- Client decided to place rest of his clinical programs with Laurus
- MULTIPLE KILOS OF CLINICAL QUANTITIES DELIVERED