Making hazardous processes scale-safe while coordinating knowledge transfer

Client - EU based large multinational biopharmaceutical organization developing mostly biologicals & some small molecule therapeutics

Program

- The program started out as a NCE asset for PI from a drug Boston based development company & the program got sold to the EU biopharma.
- The drug candidate is a small molecule capable of crossing BBB & treating neurodegenerative diseases – this is currently in clinical phase IIb

Challenge

- The chemistry involved undesirable cost & process safety aspects that could potentially make this product costlier & the process scale-unfriendly
- The primary challenge started when the PI asset moved from Boston developer to the EU big pharma

Solution

- Laurus optimized process to replace hazardous NaH with NaOH; replace costlier Propanephosphonic acid anhydride(T3P) with cheaper ethyl chloroformate; making it scale-ready
- On the manufacturing front, Laurus optimized the Hydrogenation stage to a larger input batch-size so as bring down overall cycle-time. Derisked SM & critical reagent supply by finding and qualifying commercial-ready alternate vendors & by maintaining certain levels of safety stock
- Laurus, value-added to the dossier by identifying an controlling potential mutagenic impurities at clinical stage itself
- Closely coordinated project transfer between two client organizations and ensured the EU biopharma had no knowledge, data gaps

Outcome

- The EU Biopharma despite it having a CDMO division themselves continued with Laurus & Laurus is supplying clinical API quantities regularly
- With the positive experience during the project, knowledge transfer, the EU Biopharma qualified Laurus as a vendor in their system and considering placing few more programs with Laurus
- 350KG CLINICAL API DELIVERED AS ON DATE ACROSS MULTIPLE CAMPAIGNS.