

Technology transfer with stringent time-lines for an NCE in Animal Health Division

Client - US based multinational with markets across globe and among the top four worldwide players in Animal Health Space

Program

- Complete Process Development based on preliminary RoS provided by Client
- Construction of a dedicated facility for the client to deal with Animal Health segregation requirements
- Scale Up and Validations by using process optimized in the laboratory
- Regulatory filing of VMF/CEP/ASMF for all the target markets
- Cost Optimization (Innovations) to meet the cost target so that final Drug Product is commercially viable

Challenge

- First time handling of Animal Health products with all the required segregations and quality levels
- Usage of Simulated Moving Bed (SMB) equipment at commercial scale
- 7 step process including challenging chemistries like Homogeneous Catalyst usage and recoveries, Cyanation, NBL reaction etc
- Manufacturing across multiple manufacturing locations

Solution

- Laurus & Client had multiple meetings to align on overall requirements in terms of quality, cost and regulatory requirements
- Weekly virtual meetings with continuous feedback mechanism
- Extensive support taken from SMB supplier to optimize the SMB parameters for best results
- Close Supply chain coordination to ensure no delay in development, scale up, validations and filing timelines
- Construction of dedicated AH facility before the targeted timeline

Outcome

- Process Optimized meeting all the required quality parameters and within the reasonable cost
- Scale Up and validation completed at 50 KG scale.
- Seven batches of validation/ post validation batches delivered to Drug Product site
- Regulatory filing completed for US and Canada; File preparation for CEP/ ASMF under process
- Client adding more products to the program