Johnson Matthey
Pharma Services

CASE STUDY

Development of a commercially viable API process

Summary
Development of a commercially viable, multi-kilogram process suitable for validation with a local client.

Approach

- Utilized Alfa Aesar to obtain difficult-to-source custom starting material at >100kg scale.
- Project management of multi-functional group including process development, pilot plant operations, analytical development and outside contractor for large-scale lyophilization.
- Improved throughput in key large-scale chromatography step by over 50%.
- Identified all critical parameters for process validation.
- Completion of all necessary technical and regulatory activities to support filing of US DMF.

Results

- Over a period of 4 years, the process and analytical methods were suitably developed for process validation and a US DMF filed. This ensured the client's aggressive NDA filing timelines were maintained.