

Technology Transfer – Case Studies



- As part of a multi-site, transcontinental organization, we offer our customers the opportunity to obtain a comprehensive range of chemical and manufacturing solutions from a single supplier. This extends from rapid supply of intermediates and Active Pharmaceutical Ingredients (APIs) for preclinical use, to large-scale commercial manufacturing. An efficient and effective technology transfer process is the key to the successful transfer of processes either from the customer to CARBOGEN AMCIS or between two CARBOGEN AMCIS sites.

Our technology transfer expertise is a key element in our ability to take advantage of the economies of scale and lower cost base associated with the CARBOGEN AMCIS high potency plants in India and China.

Technology Transfer Process

Complex, multi-step processes under both current Good Manufacturing Practice (cGMP) and non-GMP have been successfully transferred. For transfer outside of Switzerland, a specialist team follows an established three-stage procedure:

- 1 Initiation:** the scope and goals are agreed upon by all parties – preparation of technology transfer master plan, definition of responsibilities, as well as preparation and transfer of technical information package;
- 2 Piloting:** the process is trialled in the lab, analytical method transfer is completed, along with the key change review and pre-manufacturing review processes to ensure compliance with regulatory and quality standards. Finally trial batches are produced;

- 3 Sign-off:** the trial campaign is reviewed in detail, any further learning implemented, and the transfer signed off. Routine production follows against established batch instructions.

A crucial element in successfully transferring technology across linguistic and cultural barriers is the quality of the communication between our experienced personnel, alongside clear definition of roles and responsibilities.

Where it provides benefits, team members from the transferring site are present at the receiving site, for example for project kick-off, and during production start-up.

Case Study 1:

Reduced lead time and cost with continuous local project management

The first four steps of an eight stage registered process, previously run in Switzerland on 1,600 L scale, were successfully transferred to operations in India within a timeframe of five months. The transfer was mainly driven by growth in product volume coupled to the need to reduce overall lead times. The process is now executed in India at 4 times the previous scale, allowing us to make significant reductions in both cost and lead time. The intermediate is sent to Switzerland for conversion to the final API with no measurable difference in quality. This approach offers the customer flexibility in managing cost and quality demands without draining his own resources.

Case Study 2:

Product lifecycle management

A three-stage process to manufacture a launched API for a US customer had been successfully running in Switzerland for over 10 years. To support the customer in the generic market with lower costs, the exact process was transferred to India. Following regulatory approval of the change of site, the customer will benefit from a more economic source of the API with identical quality, while the supply chain is maintained with ongoing manufacture in Switzerland.

Case Study 3:

Cost and feasibility aspects

A multistage production process for a non-GMP intermediate was performed at CARBOGEN AMCIS' Manchester site for a Japanese customer. Subsequent transfer to India was successfully accomplished, and the process was subsequently scaled up to 300 kg batches in a multi-ton campaign within 6 months. A chemist from Manchester supported the transfer on-site. In this case the transfer was driven mainly by the scale of production, but the customer also obtained a cost advantage from the increased scale at the new site.

