

PRODUCT LOCALIZATION AND TECHNOLOGY TRANSFER

Client: Janssen S.p.a – Johnson & Johnson

Industry: Pharmaceutical industry

Objective: Implement a robust technology transfer process of oral solid forms from a Janssen site located in Puerto Rico to one of Janssen External Manufacturer in Russia

Offered Solution: Consulting Services

1. The Company

Janssen-Cilag SpA, a member of the Johnson & Johnson group, is a leader in the pharmaceutical sector with more than 30 specialty products on the market. Born out of the merger of two major pharmaceutical companies in the J&J Group, Janssen Pharmaceutica and Cilag, the company has been operating in Italy since 1995, with locations in Cologno Monzese and Borgo San Michele (Latina).

Technology transfer and localization of drug product manufacturing play a key role for Janssen Pharmaceutical in developing a competitive market access strategy into emerging markets.

SBT4 technology transfer team has a vast experience in leading and supporting multinational teams during the technology transfer implementation stage.

Based on the extensive global knowledge gained over the last years managing global transfers, we helped Janssen client to ensure the successful technology transfer of production to new supply sites globally.

2. Phases of the Project



Based on best practice established, our team managed the following activities:

- Identifying the risks associated with the transfer and developing mitigation plans

- Originating in Trackwise system the control of change related to the product transfer and tracking the impact of the change
- Working closely and getting alignment with global and local regulatory teams, with receiving and sending QA and QC accountable
- Establishing a culture of open communication and effective collaboration between international teams
- Gathering information & product knowledge to use it as the basis for the Manufacturing Control Strategy and Process Validation
- Establishing Transfer plan and issuing the Technology Transfer Strategy
- Coordinating the product/process/analytical method transition between sites;
- Providing onsite technical support in order to meet project timelines:
 - preparing, reviewing and approving development, validation protocols and reports
 - reviewing process parameters and product attributes gaining information on potential sources of variability;
 - supervising manufacturing activities
- Once assured comparability of product, process and analytical parameters between sending and receiving sites, issuing the Technology Transfer Report

3. Results

All deliverables listed above have been successfully achieved meeting project timelines.

Thanks to our experience and in-house skills, product localization to Russia was completed with no disruption to supply.