Technology transfer with stringent NCE-1 timelines during COVID pandemic

Client - EU based large generic company with previous relationship with Laurus API Generics known to work on complex generic drug products

Program

Technology transfer of a powder filling process

Challenge

- No previous experience on the technology at Laurus
- Equipment was not available at the kick-off stage
- · OEM was located at Spain
- COVID had made the travel impossible hence the machine design, development, FAT and Qualification had to be all done virtually.

Solution

- Laurus and the vendors relied on virtual tech to video graph and stream the entire qualification process
- Customer's network across EU was used to send a team to the OEM for verification of all parameters
- OEM relied on tech to qualify, install and trouble shoot online
- OEM team in India was used to facilitate with the simple operations/installation while the OEM from Spain was monitoring the entire activity online

Outcome

- Successful installation and qualification of the equipment at Laurus before the agreed schedule
- The product was scale-up and successfully validated on the powder filling line a month before the agreed timeline
- The customer was able to meet the NCE-1 timeline.

Laurus Labs