REFERENCE

Qualification in Precision Plastics Production:
Fast Competent Support for Healthcare Product Solutions

The Customer

Flex Precision Plastics Solutions (Switzerland) AG is a company of Flex Ltd., one of the Global 500 and 2021 Fortune World's Most Admired Company. With more than 400 employees at its Hägglingen and Küssnacht am Rigi locations, Flex Switzerland is a renowned specialist in plastics solutions for the medical field. This includes medical devices components, laboratory consumables, medical disposables, pharmaceutical packaging and delivery devices.

The Project

During the commissioning of two production lines, resource bottlenecks occurred. Short-term support required expertise in the qualification of systems in GMP-regulated production as well as extensive knowledge of the requirements of 21 CFR 820 and ISO13485.

The Task

First, master plans for qualification and validation of the manufacturing lines had to be developed. Event-related or periodic requalifications were also defined. Internal and external qualification activities were coordinated with a view to efficiency and then carried out in a target-oriented manner. The moderation of risk analyses (FMEA) was also part of the services. The task was completed by the final knowledge transfer to the customer's quality unit.

The Realization

Support was provided both remotely and directly on site at the Hägglingen and Küssnacht am Rigi sites. The support was integrated into the customer's team in a routinely and flexible manner. Close, competent cooperation with internal and external parties was characteristic.

The Result

The resource provided at short notice enabled the production lines to be put into operation compliantly and on schedule. The initial quick deployment developed into longer-term support.

gempex GmbH supports leading companies in the chemical, pharmaceutical and medical technology industries with the implementation of quality requirements according to GMP, DIN ISO 9001, ISO 13485 and comparable quality standards. The professional management of validation and qualification projects, including consulting for the planning and construction of facilities, are its main activities. This includes also permanent support for everything related to the customer's ongoing GMP operations.

Key Performance

- *Masterplanning*
- *Qualification and Validation*
- *Moderation of Risk Analysis FMEA*
- *Remote-Support and directly on site*
- *Internal and external communication*
- *Knowledge transfer*