

Over 350 m² of laboratory area for tests under controlled climatic conditions.

The original counts:

The final proof of perfect functioning of machines and installations (FAT, qualification) can only be performed with the original product (verum). As a rule placebo material will never be able to be a substitute for the original material. Thus, for example, the flow and dosing behavior of powders with numerous parameters such as particle size, particle density and form, moisture content, hygroscopicity and tendency to tribo-electrical charging are determined.

The ambient conditions, above all the relative humidity, are further important influencing variables. Whenever possible, dosing attempts should therefore take place with original product and under the ambient conditions envisaged later.

Strategy as a recipe for success:

Innovative companies nowadays use strategic alliances to minimize development costs and the time to market. Harro Höfliger is recommended as a development partner for product lines and process-specific lines. As an introduction to a joint powder project Harro Höfliger offers, for example, a comprehensive analysis of the products, on which a preselection of the dosing system can be based. A further optimization of the selected system with original product can then be performed in our own laboratory facility under controlled conditions together with the customer. At the end of the multi-stage development of the pilot line through to the finished production line there is the possibility of already manufacturing time-saving stability samples using the qualified machine at Harro Höfliger's plant and operating the complete line with verum under production conditions.



Individual benefits of Pharma Service.



The customer advantages of a comprehensive service:

- High efficiency through the direct availability of development and manufacturing
- Time gained, e.g. by production of the first stability samples on-site
- An experienced team with pharmaceutical technological know-how:
 - A pharmacist with many years of industrial experience
 - Engineers from the internal development department
 - Specialists from the qualification development
 - Experienced assembly and service staff
- Availability of machine modules and test rigs for:
 - micro-volume dosing of powder
 - thermoforming / sealing of innovative films
 - feeding / dosing of solid and liquid components
 - laminating and delaminating
 - die-cutting and separating
 - forming

Service & Consulting:

- Analysis and classification of powder preparations
- Process development and optimization
- Support with recipe and package development
- Qualification and GMP training

Tests under controlled atmosphere conditions:

- Testing of customer-specific rigs („POPs“)
- Line commissioning with “real” product (verum) instead of placebos
- Optimizing process parameters and machine settings
- FAT and qualification runs under future production conditions

Technical data

Surface:	approx. 300 m ² 4 GMP rooms 1 laboratory
Environmental conditions:	18 - 22°C 20 - 50% rel. humidity
Ventilation/ Air condition	- approx. 10-fold air exchange - final make-up air filters (H14) - control of differential pressure



Process optimization through product analysis.

Powder at the center of consideration:

The behavior of powders is determined by numerous parameters such as the grain size distribution, particle shape, particle density, melting temperature, hygroscopicity, the tendency to become electrostatically charged etc. This explains the very varying behavior of different powders, for example during feeding and dosing, and requires knowledge as precise as possible of the materials to be handled.

As an introduction to a joint project Harro Hoefliger therefore initially offers its customers a powder analysis of the material, which is then referred to as a basis for selection of the most suitable dosing system. At the same time this analysis provides valuable indications as to what ambient conditions, e.g. temperature and relative humidity, have to be ensured during the later processing of the powder in the machine or in the production rooms. The adhesive behavior on various materials can also already be investigated at this stage. This has a decisive influence on the selection of the materials of all parts that come into contact with the product.

POWDER PROJECT

