



# Pharma Service

Custom-tailored solution for your product

Packaging Technology



**BOSCH**

Invented for life



# Research and Development

## Outstanding all-inclusive package

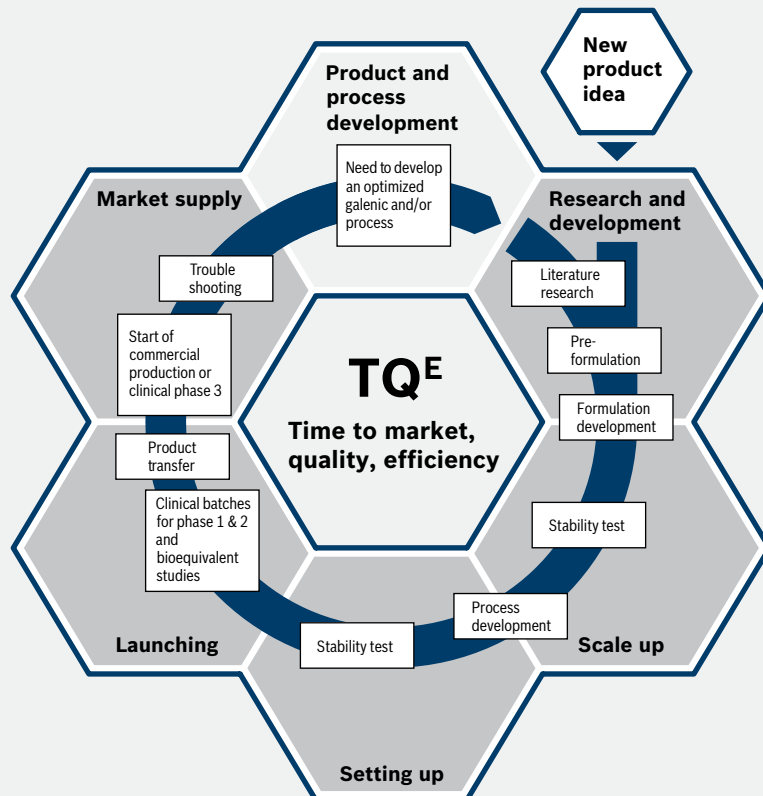
Regardless of project status – Hüttlin has the capability to assist you any time. Hüttlin Pharma Service provides a complete service portfolio for all stages in the life cycle of solid dosage forms production.

The combination of extensive experience and knowledge in all aspects of solid dosage technology and the testing and development possibilities of the Hüttlin Pharma Center enables Pharma Service to provide services with the provision of TQ<sup>E</sup>:

- ▶ Time to market
- ▶ Quality
- ▶ Efficiency

### Key benefits

- ▶ Shorten the time to market with faster development process (TQ<sup>E</sup>)
- ▶ Highest operation efficiency through selection of the right excipients and processes
- ▶ Quality by Design through process understanding and knowledge transfer



## Formulation Development – Make use of our pharmaceutical knowledge



Astute combination  
of excipients turns  
active substance into  
a medicine

Today Time-to-Market is very important for the pharmaceutical industry. In this respect the path of development from R&D via pilot scale up to production scale must occur quickly and sustainably. Hüttlin supports the complete development with its product portfolio, R&D capabilities and pharmaceutical knowledge. Representing a century's worth of knowledge in solid dosage formulations and designing of related equipment Hüttlin is your qualified partner.

### Solid dosage forms

Today powder, granules, tablets, pellets and all its derivatives are the most used dosage forms. New drugs or market driven efficiency programs are forcing our customers to improve the formulation of these dosage forms. Due to the high amount of active substance in the formulation the amount of excipients needs to be minimized.

#### Formulation development (Batch sizes 30 g to 4 kgs)

- ▶ Research articles in publications
- ▶ Formulation strategy
- ▶ Pre-formulation studies
- ▶ Selection of excipients
- ▶ Manufacturing of finished powder, granules, tablets, pellets and analysis



## Process Development – Development and optimization of processes

Once the product and formulation is developed an appropriate process has to be found. Hüttlin Pharma Service with its global reach and strong track records can take pride in being an established partner to the pharmaceutical industry providing this service for many years.

In this phase of the project Pharma Service considers the formulation attributes, together with the possible manufacturing process options, in order to address the selection of manufacturing process and to confirm the appropriateness of the components.

### Processes

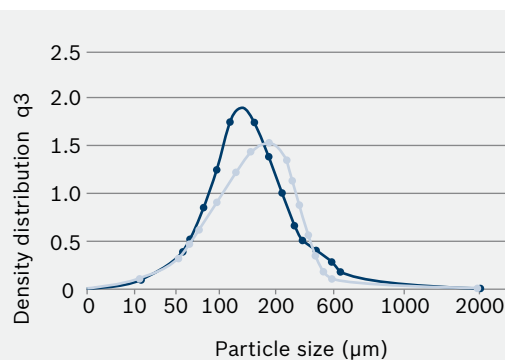
The typical processes in solid dosage manufacturing are:

- ▶ Granulation
- ▶ Coating
- ▶ Layering
- ▶ Taste masking
- ▶ Compression

To improve your production in terms of efficiency and product quality the understanding of above processes is essential. Hüttlin Pharma Service has the expertise to support you.

### Process development (Batch sizes 2 kgs to 7 kgs)

- ▶ Definition of process parameter
- ▶ Adoption of formulation
- ▶ Quality control
- ▶ Selection of adapted formulation



## Scale-Up and Product Transfer – From R&D to production within the shortest time

A new product has been developed or an existing product has been improved in the laboratory. The transfer to the production scale in most cases requires a lot of time and investment. Hüttlin Pharma Service is able to provide you with the knowledge which will help you to reduce the time to market significantly. Using the Hüttlin capabilities offers you the advantage of greater flexibility and efficiency.

### Scale-Up – Precise, efficient and reproducible

Developed by Hüttlin experts NexStep scale-up software is an excellent tool to calculate the required process conditions and to save time. Based on thousands of trials NexStep is verified to provide precise information enabling R&D scientists to transfer 3 kgs batch trial results to a e.g. 200 kgs production machine. No investments are necessary for the pilot size equipment required for the intermediate step towards the planned production batch size.

#### Scale-Up (Batch sizes 10 kgs up to 200 kgs)

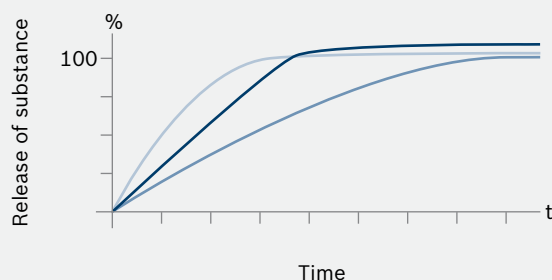
- ▶ Definition of process parameters using NexStep software
- ▶ Manufacturing of products
- ▶ Quality control

### Product Transfer – Fast, reliable and resources saving

A process is perfectly working in one production site, but it takes weeks, months if not even years to have a transfer to another production site or to different equipment. Specialists experienced in hundreds of product transfers and having recourse to the Hüttlin Pharma Center can solve cases like this.

#### Product Transfer (Batch sizes 100 kgs to 900 kgs)

- ▶ Definition of process parameters using NexStep software
- ▶ Manufacturing of products
- ▶ Quality control



Quality first, independence of technology and location



The quality of the product must match the requirements for the next phase





## Trouble shooting – Example

The customer's product is out of specification.  
In this case the pellets are not gastric resistant.

If you find yourself in such a scenario why  
not involve Hüttlin Pharma Service?  
We have a proven track record for fast and  
sustained solutions to cut down time.

### Improving by understanding

- ▶ Analysis of the ongoing process and each process step
- ▶ Risk analysis of each process step
- ▶ Search for deviation
- ▶ Identification of variance
- ▶ Action plan for consistency

## Hüttlin Pharma Center – harmonious coordination for your process

The Hüttlin Pharma Center offering harmonized range of equipment for the development and production of solid dosage forms, starting with batch sizes of 30 g for feasibility studies up to 200 kgs for process optimization on production scale in state-of-the-art environment. All installed equipment is designed to process aqueous based as well as organic solvents based products.

To provide the complete range of development we invested in the latest state-of-the-art off-line, at-line and in-line analysing tools.





## Customer trials and rental machines – Custom-tailored solution for your product

Using the extended capabilities of the Hüttlin Pharma Center we provide our customers hands on assistance at any step of its product life cycle state. These could be complete solutions as well as the improvement of special part aspects. Our customers appreciate the freedom to choose whether the trials are processed by Hüttlin pharmacists or by themselves using the entire infrastructure of the Hüttlin Pharma Center.

### **Formulation and process development**

Robust formulation or process development in laboratory scale from 30 g to 7 kgs supported by the state-of-the-art inline measurements.

### **Analytics – in-process control**

To assess the quality of the product we are equipped with a extensive range of analytical tools. In cooperation with our partners we can deliver the full range of analytical support.

### **Production scale**

The scales perfectly match each other. Process optimization in real production equipment from a batch size of 10 kgs up to 200 kgs is possible.

### **Your solid dosage**

Complete production equipment of solid dosage forms are offered in the Hüttlin Pharma Center.



**Rental machines High Shear Mixer**

	<b>M</b>	<b>G</b>	<b>D</b>	<b>C</b>
<b>Mycromix</b> 0.5 l to 10 l	●	●		
<b>SinglePot 10</b> 9 l	●	●	●	

**Rental machines Fluid Bed Systems**

	<b>M</b>	<b>G</b>	<b>D</b>	<b>C</b>
<b>Solidlab 1 - Fluid bed</b> 3.8 l to 5.2 l	●	●	●	●
<b>Solidlab 1 - Coating</b> 3.5 l to 7 l				●

**M** = Mixing**G** = Granulation**D** = Drying**C** = Coating**Key processes in the Hüttlin Pharma Center**

- ▶ Fluid Bed drying, granulation, coating (30 g to 200 kgs)
- ▶ High-Shear Mixer (50 g to 200 kgs)
- ▶ High-Shear Mixer Single Pot (1.5 kgs to 200 kgs)
- ▶ Blending
- ▶ Compression



## Seminars and Training – Leadership through knowledge

To keep a leadership position in the pharmaceutical industry requires the design of efficient and economic processes. For this reason Hüttlin supports you with a multi disciplinary knowledge transfer in a team or individual company approach. Using the synergy effects of Hüttlin Pharma Center and the knowledge of Hüttlin a series of seminars and tailored trainings are offered. Depending on the requirements the main focus of such training sessions could be on theoretical subjects or operator based hands on lectures.

### Seminar range

The “Expert of Solids” (four seminars, certificated by Hüttlin) is the preliminary stage of the “Master of Solids” (additional two seminars, certificated by Hüttlin). All aspects of development and production of solid dosage forms

are highlighted from the basis of granulation, via the experimental design to the compression of the tablets. A “Master of Solids” will gains detailed knowledge in manufacturing solid dosage forms. Individual courses on “Expert of Solids” can be taken.

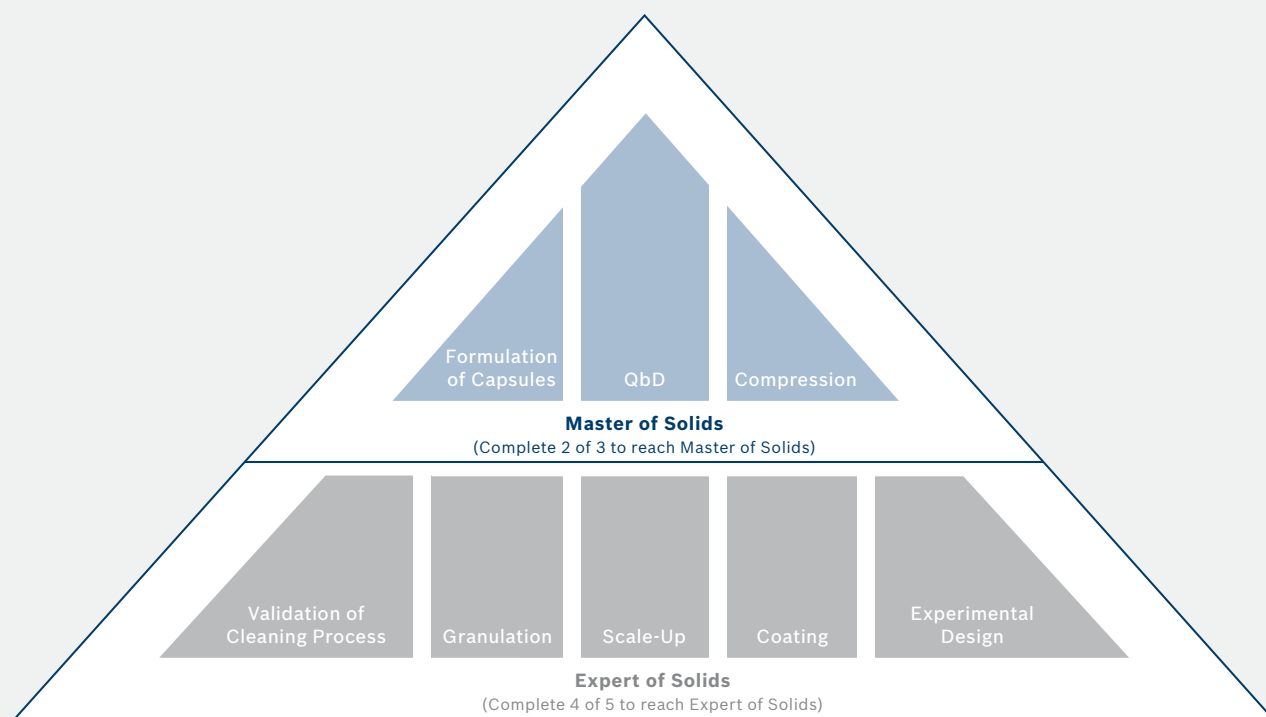


### Tailor made seminars onsite to your requirements

In the individual approach you can select different topics and combine them to tailor made seminars. The topics are diversifying from the basics of the fluid bed system and high-shear mixer up to topics of quality by design and design of experiment. In hands on courses the knowledge can be focused on your own formulation and processes.

### Training

Productivity, efficiency, reproducibility are not academic phrases only. In customized training sessions machine operators, validation scientists, research and development scientists and quality assurance manager become trained on the machines involved in the solid dosage forms production. Trainings are proven to improve the productivity, the efficiency and the reproducibility of production as well as in the R&D environment. Training sessions are tailored to the specific requirements of the participant's background. How to operate the machine and how to increase the efficiency will be more important for the machine operator, where reproducibility is of higher importance to the validation managers.



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