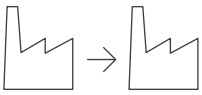
LEGACY PHARMACEUTICALS SWITZERLAND

Pharma Services Portfolio

Product Transfer

Benefit from our experienced project management team in each phase of a product transfer



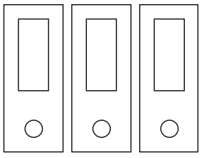
Site closures, modified business models, and competitive strategies of pharmaceutical companies often necessitate outsourcing of drug manufacturing as well as the associated transfer of process responsibilities in nearly every phase of a product life-cycle.

We support you with process development, process validation and validation of analytical methods, commercial production, and sales of your products. Our extremely well-trained transfer teams stand by your side with deep specialized knowledge, experience and dedication in each process phase.

Whatever transfer project you would like to tackle – with us it is in the best of hands and will of course be documented in all transfer phases in a GMP-compliant manner. We know that compliance with regulatory requirements is not all that is necessary. Perfect planning and sustainable documentation are the key factors for a successful product transfer.

Drug Registration

Drug registration: we know what we're doing



Even tiny errors on forms can render years of research and development work on pharmaceutical products useless in a short time. Therefore a registration strategy that anticipates even the most stringent tests is indispensable for successful product marketing. We ensure that registration documentation and actual manufacturing processes (incl. analytical methods) match. Our experts support you with preparation of the appropriate documents (Module 3).

Contact

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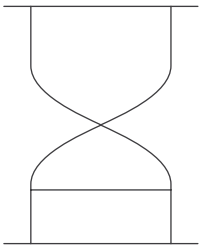
ICH Stability Testing

ICH stability. An important contribution to patient safety, and a significant contribution to your success

Specification-compliant product quality around the globe and under the widest range of climate and storage conditions is an important quality characteristic of pharmaceutical products. It is a matter of nothing less than the trust and safety of the patients who use the products we make. We inspect and test for all standard climate zones according to the guidelines of the International Conference on Harmonisation (ICH). Our quality assurance laboratory offers all conventional analytical methods for testing the quality of your product over the course of your stability study. ICH guidelines give recommendations for stability test protocols, in particular temperature, humidity, and duration for various climate zones, in order to simulate a wide variety of warehouse conditions and obtain data and information such as how the quality of a product is influenced over time.

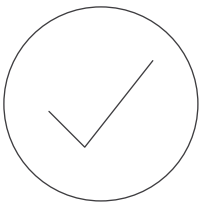


- **Long-term testing: 25°C and 60% relative humidity**
- **Long-term testing / intermediate conditions: 30°C and 65% relative humidity**
- **Stresstest / accelerated conditions: 40°C and 75% relative humidity**

Qualification and Validation

A GMP-compliant QMS is more than inspections of facilities, devices, processes and materials

Of central importance in a GMP-compliant product transfer is validation of the manufacturing process, validation of analytical methods, and qualification of all relevant process facilities. Our experts support you with defining the manufacturing process, determining suitable research-based specifications, production of technical batches, and successful production of validation batches. For this purpose there are a variety of approaches that can be taken as needed for process validation, for example "bracketing," which can greatly reduce validation work and remain compliant with applicable guidelines.



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Pharma Services Portfolio

Procurement Services

Rapid commercialization also means: from active ingredient to pharmaceutical end product from a single source...

Along with quality, time and availability are crucial factors for being able to rapidly and safely provide the market with products. This is a good reason to trust Legacy Pharmaceuticals and its proven experience to handle not only your manufacturing processes, but also to optimize your upstream procurement stages through concentration.

Our purchasing specialists accelerate your „speed-to-market" and reduce your process costs with their deep knowledge of global sourcing markets, and they negotiate the best purchase conditions with sustainable quality. We constantly analyze and optimize our ordering processes, thereby ensuring short and reliable delivery times while meeting your individual needs.

A sample overview of our procurement services:

- **Independent procurement analyses and price comparisons**
- **Procurement and supply scenarios that are adapted to quality and product requirements set by the customer and that are guaranteed by general as well as specific service and delivery agreements.**
- **Secure supply chains with respect to product availability, qualified suppliers, and product quality.**
- **Cold chains for logistics and storage**

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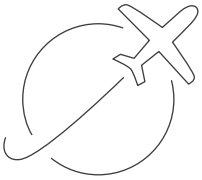
LEGACY PHARMACEUTICALS SWITZERLAND

Pharma Services Portfolio

Distribution Support / Services

Continuous logistics and distribution throughout all of your markets.
Successful pharmaceuticals marketing takes strong partnerships

We work closely with our customers' distributors to reliably ensure that patients have quick access to the products we have manufactured. According to GDP (Good Distribution Practice), we offer monitored storage and shipment. Transport validation can be performed and documented by Legacy Pharmaceuticals. Our mission is to find the best solutions and best value for your specific needs.



We strive for the highest quality standards at Legacy Pharmaceuticals. Our process workflows, storage concepts, and operational processes are continually optimized and our employees are regularly trained in order to ensure that they can keep with global best practice solutions.

An overview of our sales services at a glance:

TRANSPORT

We transport and manage product distribution in all markets, including products requiring cold chains. Validation also performed by request.

PICK & PACK

Our robust packaging and distribution management system focuses on your individual needs and can be tailored to your administrative and organizational requirements.

STORAGE

Our warehouse and infrastructure in Birsfelden enable us to work with even the shortest order times in order to meet all of your product delivery requirements on schedule.

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