Catalent – galenics experts from Schorndorf

Pharmaceutical and biotechnology companies are working intensively on the discovery and development of new drugs for the efficient and safe treatment of diseases. However, before drugs are authorised for treating humans and animals, they have to be made into a form that is acceptable. That is where a company called Catalent Pharma Solutions, with a facility in Schorndorf in the south of Germany, comes in.

Galenics, the process of turning a chemical compound into a medicinal product that is effective and appropriately dosed and packaged, is an important step in the drug development process. This is precisely where the expertise of Catalent's drug development team lies. The company's developers are experts in solid dosage forms, i.e. tablets, filled capsules, and all kinds of powders. Catalent, whose facility is in the Baden-Württemberg city of Schorndorf, close to Stuttgart, specialises in the development, manufacturing, and packaging of a variety of solid dosage forms on behalf of pharmaceutical companies, researchers, and biotechnology companies. Investigational medicinal products for small-scale clinical trials can also be produced in Catalent's Schorndorf facility.

Investigational products for clinical studies also available in small batches

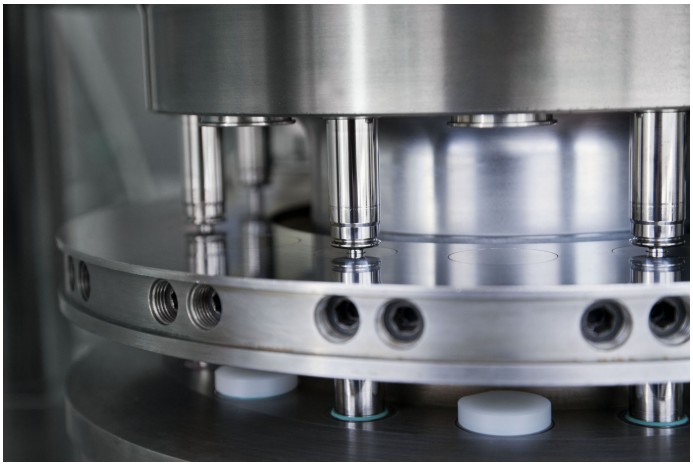
It may take years before a new drug reaches a development stage where it can be tested in human clinical trials. Pharmaceutical companies can only embark on clinical drug trials if they have conducted preclinical studies in animal models to assess a drug's efficacy and safety. From this stage, the compound has to be processed in conformance with good manufacturing practices (GMP) and in the same form as it will later be sold to patients. Catalent can assist in this process: the company produces Investigational Medicinal Products that satisfy the demanding requirements of global regulatory authorities.

Schorndorf-based Catalent turns active compounds into dosage units for oral administration.

Catalent Schorndorf, along with complementary capabilities available

throughout the Catalent network, can produce drugs in very small batches of a few tablets for use in early clinical testing. This requires just a small amount of active ingredient in solid form. All batches, however small, must be produced according to GMP and be suitable for oral ingestion, i.e. absorption of the drug via the oral mucosa or the gastrointestinal tract. Involving Catalent's experts in these early phases of drug testing can facilitate the upscaling and comparability of the drug form throughout all clinical trial phases. This in turn may facilitate regulatory approval of the drug under investigation. Catalent can also produce almost any placebos required for clinical trials, organise commercial products for comparative testing, repackage them for clinical studies (e.g. double blind trials), and help to ensure that the results are transparent and reproducible.

Bioavailability is decisive



Highly innovative technologies enable Catalent to create almost any formulation type.

The dosage of drugs tested in clinical trials is determined by the sponsoring company, which is also responsible for the clinical trials it carries out. Although Catalent does not replace a traditional contract research organisation, it makes sense to include the galenics experts at a very early stage in the drug development process for specialist advice. An orally administered drug needs to be dissolved in the gastrointestinal tract and then absorbed by the body in order to exert its effect. Current drugs are often very poorly soluble and thus fall into Biopharmaceutical Classification System (BCS) category II or IV. The physico-chemical characteristics of a drug, e.g. its solubility in the gastric juice or its absorption in the gastrointestinal tract, are the keys to success. Catalent experts will recommend a suitable development strategy based on a drug's many characteristics. Due to their long-standing experience, experts from Schorndorf are usually able to quickly assess a drug's physico-chemical characteristics and propose a formulation that best supports bioavailability. Start-up companies can also use this service and seek advice. Catalent's services are modular so that start-ups can put together a project according to their specific requirements.

Innovative technologies for drugs that are poorly soluble

Catalent specialises in the development of BCS category II and IV drugs into suitable oral formulations. Using innovative technologies such as Hot Melt Extrusion, highly innovative R P Scherer softgel (capsule) technologies, or micronisation, the company can offer a variety of strategies for making an orally delivered drug systemically available in sufficient quantities. The optimisation of bioavailability is one of the most common reasons for developing new formulations of already approved drugs.

About Catalent
Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 80 years serving the

industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply.

Catalent employs approximately 9,200 people, including over 1,400 scientists, at 33 facilities across 5 continents. In the fiscal year 2015, the company generated more than $1.8 billion in annual revenue. Catalent is headquartered in Somerset, NJ, USA. Catalent Germany Schorndorf GmbH employs more than 600 staff at its facility in Schorndorf, near Stuttgart.

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The article is part of the following dossiers

Chemical tools for biological applications

No new drugs to be placed on the market without clinical trials

pharma | services | biocompatibility | galenics | active pharmaceutical ingredient | drug application